White Paper

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

Ecuador

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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), Ecuador (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 Ecuador, 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

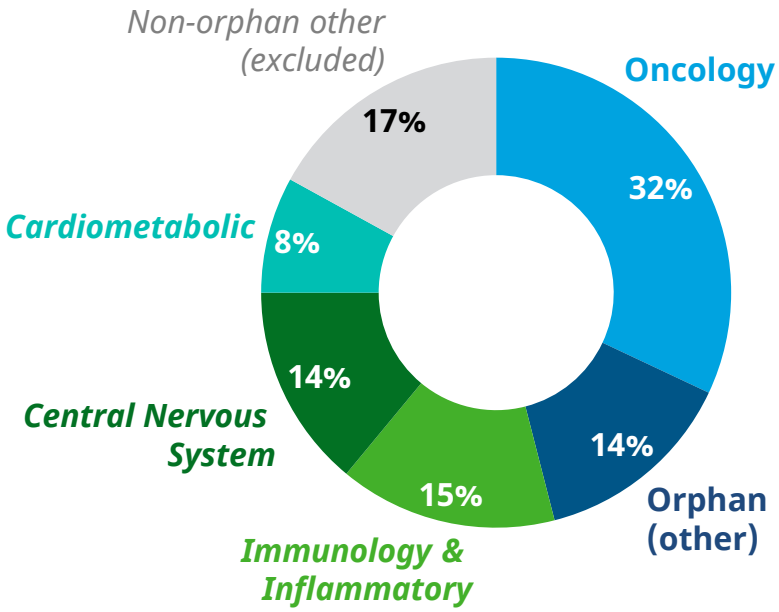


*See appendix for definitions, exchange rates, and indicators
Acronyms: NRC: Non-retail Channels; USD: US dollars; WHO: World Health Organization

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

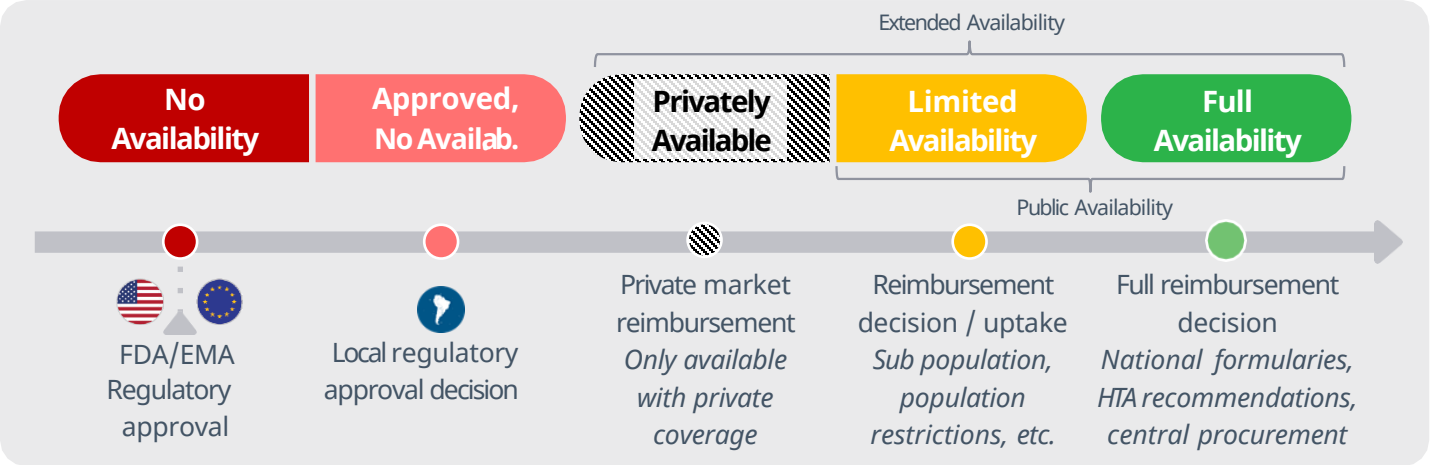
Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

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 Ecuador 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 Ecuador involved inclusion to public health formularies like MSP and IESS

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	

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 - Ecuador

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

- Ecuador's time to approval is higher than the regional average (44 vs 36 months), but local time to availability is 6 months under the regional average (26 vs 32 months)
- Time to availability varies substantially in Ecuador across therapeutic areas, with CNS showing the longest delays taking ~64 months to become locally available and ~18 months to become publicly available (~ 82 months for the whole process). Orphan and CM become available faster (~ 51 and ~ 59 months respectively)

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, 26% are approved in Ecuador
- 30% of molecules with regional public availability (limited or full availability) have public availability in Ecuador
- 24% of molecules approved in Ecuador have some level of availability; out of this extended availability, only 19% have reached full availability status
- Accesss is concentrated in limited channels for all of the TAs, particularly for oncology (58%) and CNS (56%)

Availability Over Time

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

- Between 13% and 42% of molecules that received global approval from 2014 to 2018 are approved in Ecuador; however, availability remains below 40%
- For therapies approved globally after 2018, approval and availability rates decline sharply, both reaching 0% by 2025

Improvement Index

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

- 1% of the molecules in Ecuador have improved their availability status over the past year, significantly lower than the regional average
- Ecuador had 0 newly approved molecules this year

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

Summary of Regional Root Causes and Opportunity

Innovation is outpacing system capacity, driving saturation and delays

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

Low investment constrains institutions, fragments processes, and reduces competitiveness

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

Access improves when clinical value and system readiness are mutually reinforcing

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

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

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

Key regional takeaways



Innovation is accelerating as disease burden evolves

A growing and complex disease burden in Ecuador 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, Ecuador'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 Ecuador's ability to absorb innovation efficiently, leading to delays, operational misalignment, and uneven access outcomes



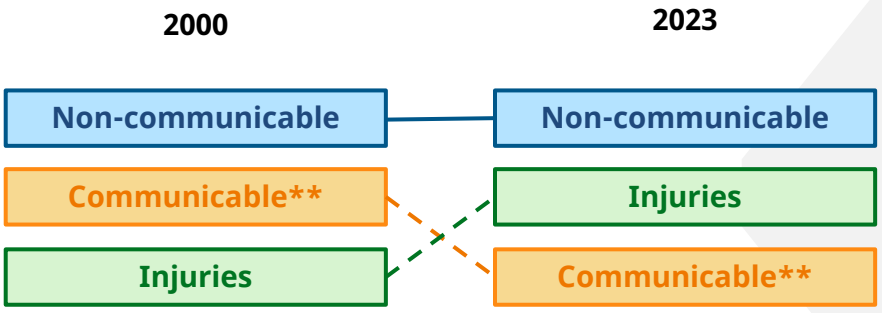
A window for transformation is emerging

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 Ecuador's health burden

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

Evolution of Disease Burden in Ecuador - 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	Other non-communicable
5	Maternal and neonatal
6	Self-harm & violence
7	Respiratory infections & TB
9	Diabetes & CKD
10	Musculoskeletal disorders
12	Neurological disorders

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

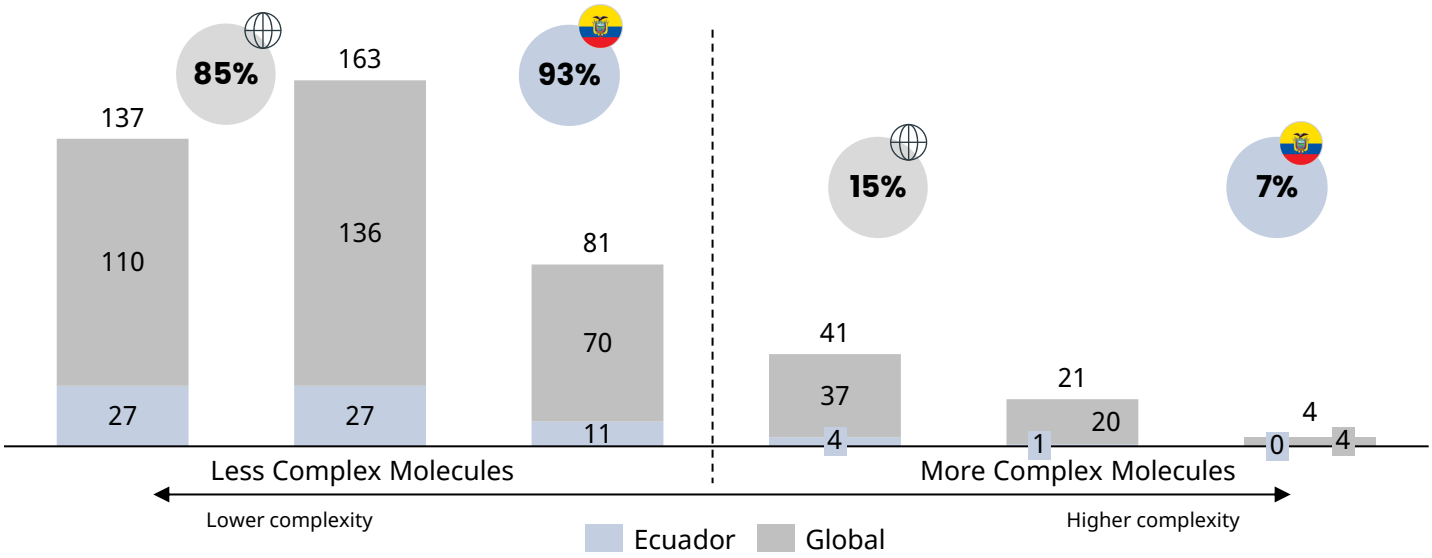
Ecuador's disease profile justifies the focus on innovative medicines for NCDs, while the rising burden underscores the importance of timely access to novel therapies

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

Complexity introduces additional considerations for systems

Ecuador changes compared to LATAM complexity distribution, with ~93% of molecules approved concentrated in lower-complexity segments

Complexity of Global and Local Approved Molecules – WAIT Dataset



- The complexity levels shown reflect a set of factors that place additional strain on health systems and require capabilities or expertise beyond standard regulatory, , and implementation processes.
    - Biologic or next generation therapies (e.g., nucleotide, RNAi, gene, cell, tissue, immunotherapy): Require specialized manufacturing, handling, and regulatory expertise beyond small-molecule drugs
    - Innovative / first-in-class therapies: Novel mechanisms may lack precedent, requiring deeper reviews and raising uncertainty around long-term safety and real-world efficacy
    - Precision medicine (i.e., diagnostic required): Companion diagnostics require parallel validation and infrastructure deployment before therapies can be administered effectively
    - Orphan population: Often target smaller populations, making large-scale trials difficult and limiting the availability of robust comparators
    - Route of administration: Complex routes (e.g., infusion, intrathecal, one-time delivery) demand specialized infrastructure, trained staff, and coordinated care pathways
- From a system-facing perspective, complexity magnifies capacity constraints. From a technical perspective, complex molecules pose greater challenges in evidence generation and interpretation.
- Ecuador's complexity index is higher than LATAM's average, with ~93% of molecules concentrated in the lower-complexity side versus ~7% in higher complexity, indicating a stronger skew toward less complex treatments

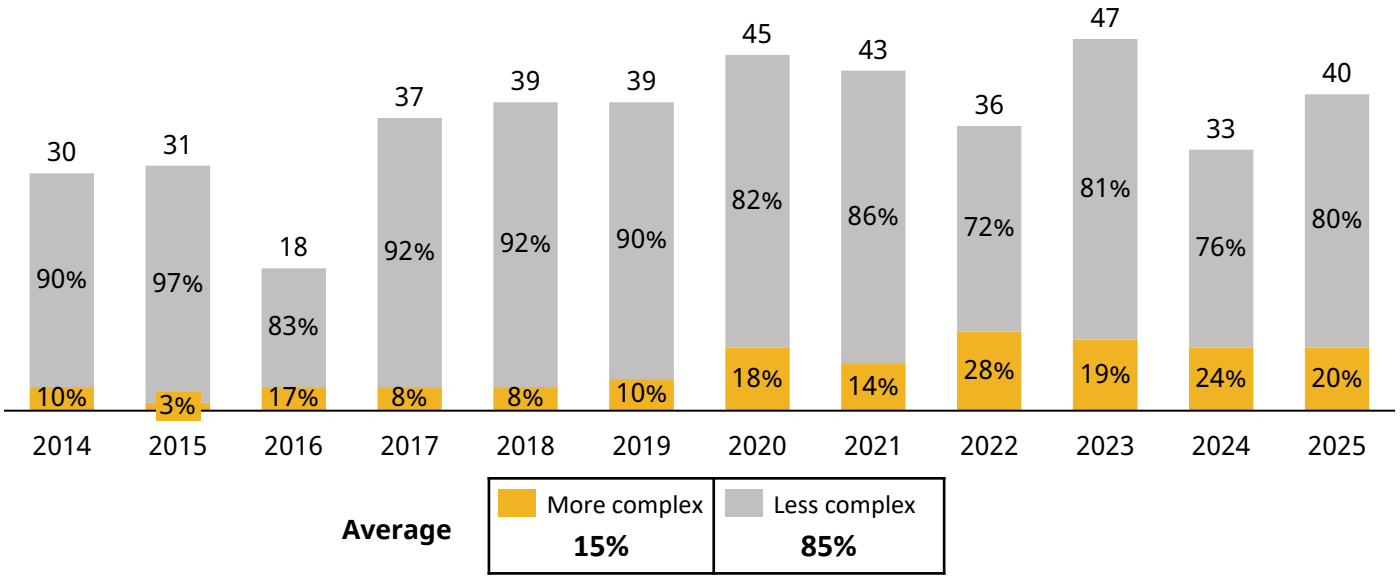
Innovation often introduces technical challenges during evaluation and creates downstream system constraints for regulators, payers, and providers in resource-limited settings

Acronyms: RNAi, RNA interference

Innovation is also becoming more complex

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

Complexity of Global Approvals - WAIT Dataset



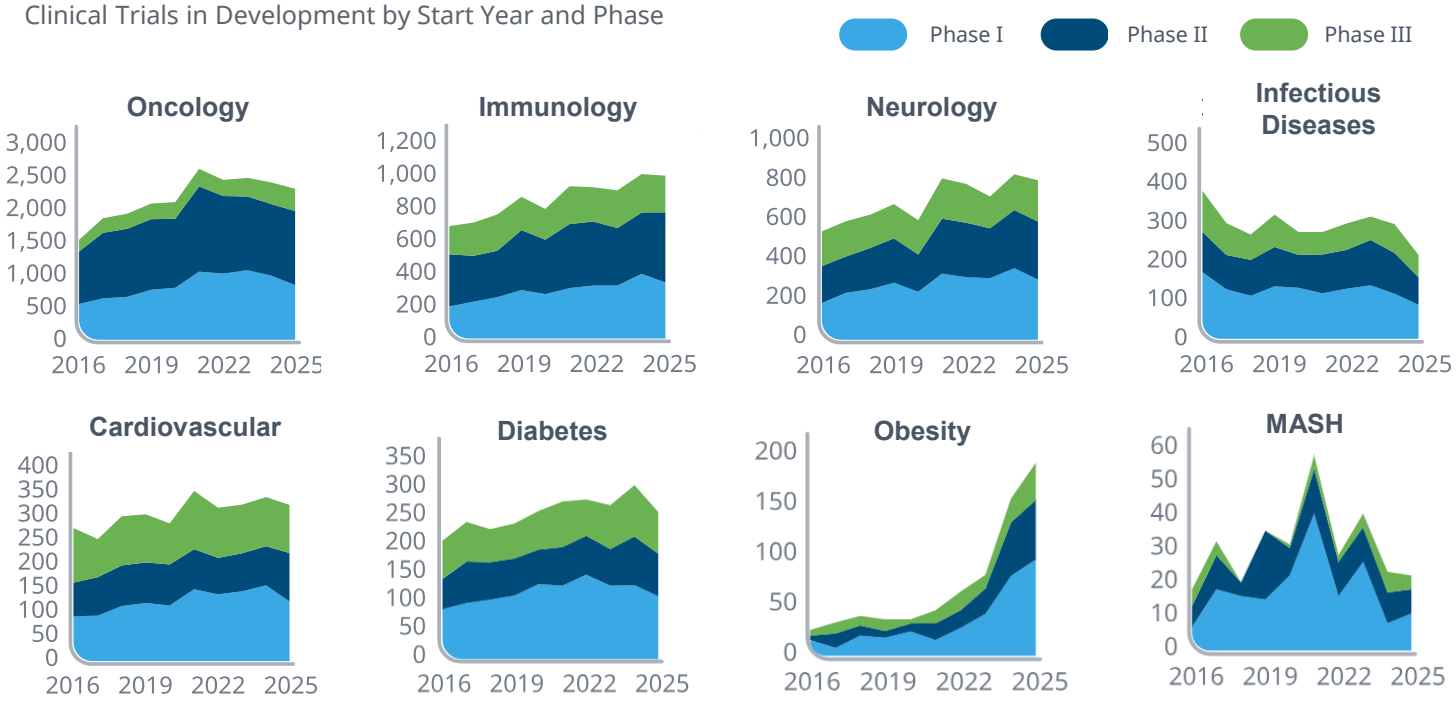
- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)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

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

A robust global pipeline signals sustained innovation and mounting system pressure

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

Clinical Trials in Development by Start Year and Phase



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

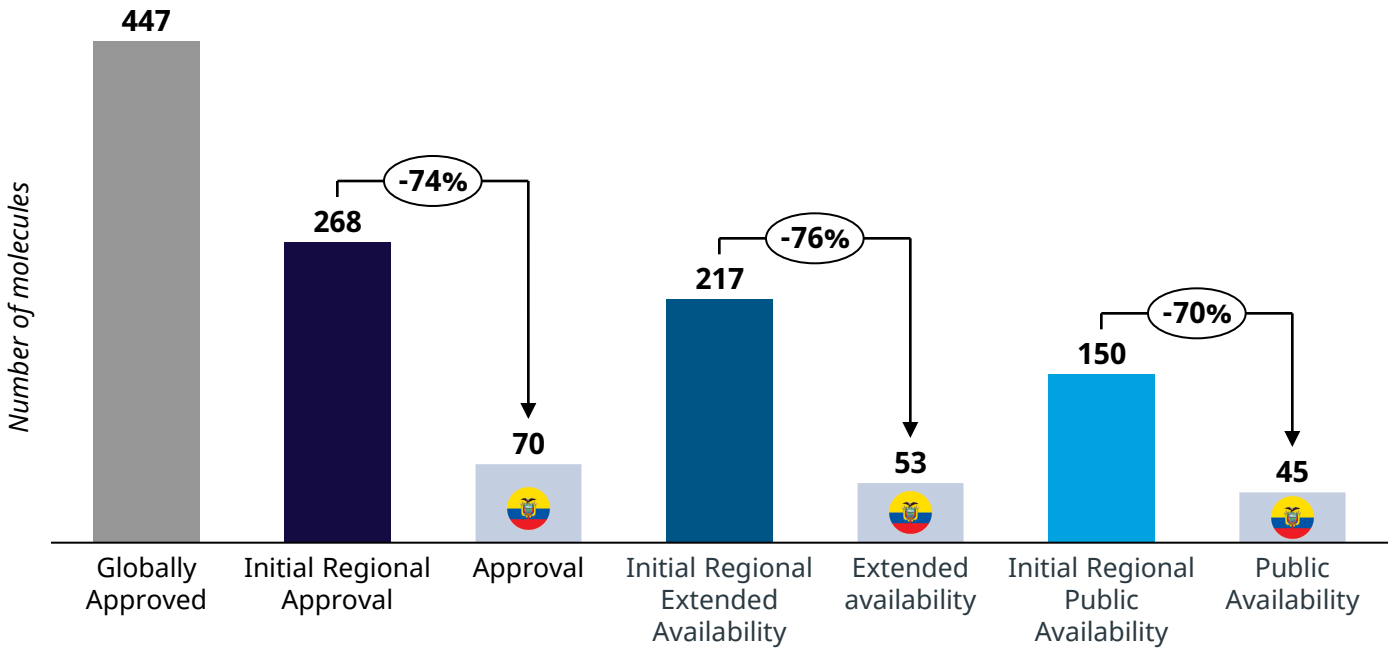
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

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

Ecuador captures only a fraction of regional innovation

Access in Ecuador is constrained at both the approval and post-approval stages, with severe attrition compounding from regional entry through to public availability

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



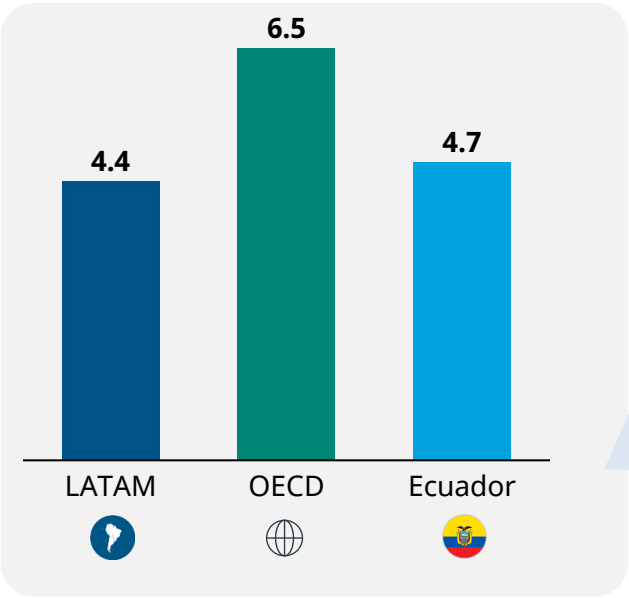
- Initial regional approval and availability represents where a molecule is approved or is available in at least one country in the region, the comparative graph represents Ecuador's status
- There is a substantial gap between regional and local approvals, with only ~26% of LATAM's regional approvals translating into the Ecuadorian market (70 vs. 268 molecules), reflecting a –74% drop-off that indicates the country is not effectively capturing regional innovation at the regulatory entry point
- Public system uptake remains highly constrained, with only 45 reaching full availability in Ecuador out of 150 molecules with regional public availability, demonstrating that broad patient access through public channels is structurally limited by funding, prioritization, and procurement capacity
- This dynamic results in systematic desynchronization between innovation entry and general patient access. Ecuador's regulatory pathway captures a narrow share of regional approvals, and the system fails to scale public availability at meaningful levels, leaving most therapies inaccessible to the broader population
- Extended and public availability gaps mirror the approval gap, with all three stages losing ~70–76% of molecules between regional and local levels, suggesting that the access challenge is structural and consistent across the entire pathway

In Ecuador, a narrow regulatory throughput combined with consistent attrition across the access pathway results in restricted availability at every stage, with public availability reaching only a small fraction of globally approved molecules;

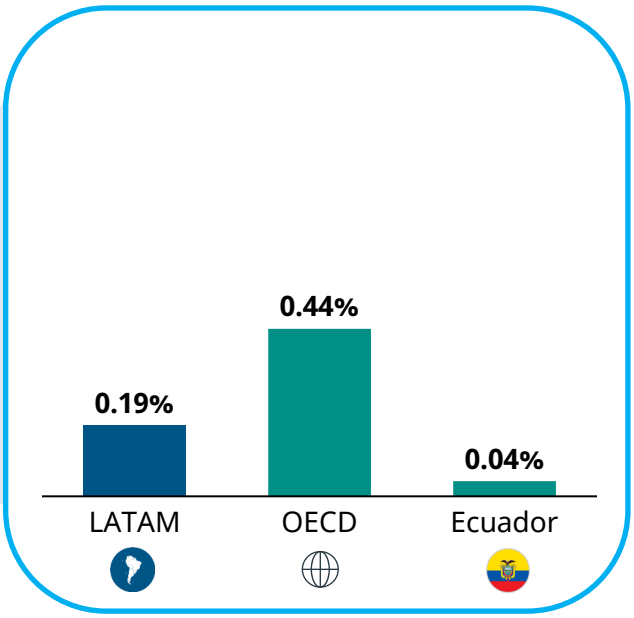
Ecuador’s health spending is below the OECD target

While overall healthcare spending is closer to LATAM levels, limited funding for innovative treatments constrains access to advanced therapies

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



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



- Public health spending in Ecuador reaches 4.7% of GDP, slightly above the LATAM average (4.4%), but still well below the OECD benchmark (6.5%), indicating moderate but insufficient system funding; however, investment in innovative treatments is significantly lower at 0.04% of GDP, far below both LATAM (0.19%) and OECD (0.44%) levels
- This disparity highlights a structural imbalance, where baseline healthcare funding is relatively aligned with the region, but innovation remains underprioritized, due to focus on essential services and limited funding for high-cost therapies
- The relatively stronger overall health spending suggests better system capacity compared to lower-spending markets, supporting broader service coverage and infrastructure

- The relatively stronger overall health spending suggests better system capacity compared to lower-spending markets, supporting broader service coverage and infrastructure

- However, the very low allocation to innovative treatments limits the system’s ability to adopt and scale access to new therapies, restricting the availability of high-value medicines despite moderate overall spending

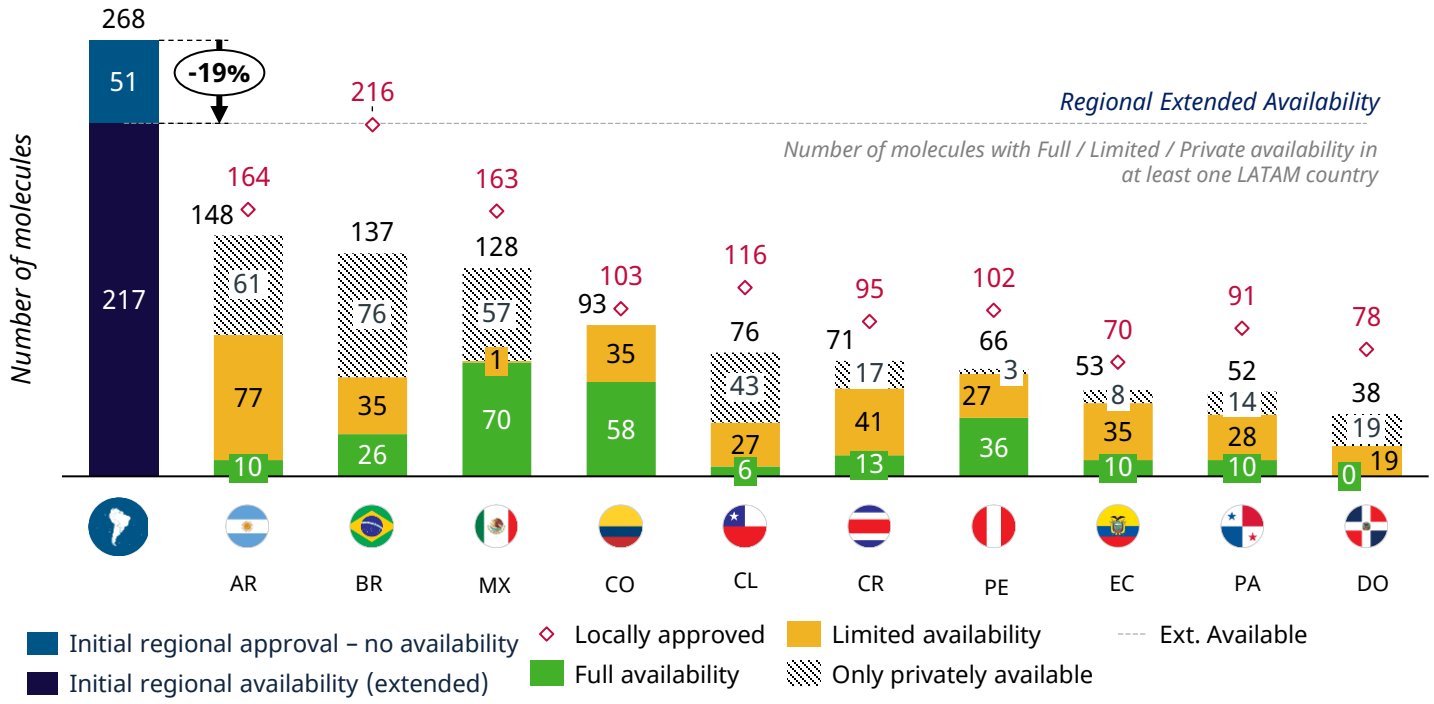
In Ecuador, moderate healthcare spending is not matched by investment in innovation, limiting the system’s ability to translate funding into access to advanced therapies

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

Ecuador 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; Ecuador, Chile, Dominican Republic and Panama show a more pronounced gap between approvals and availability
- Argentina and Ecuador 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 Ecuador 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

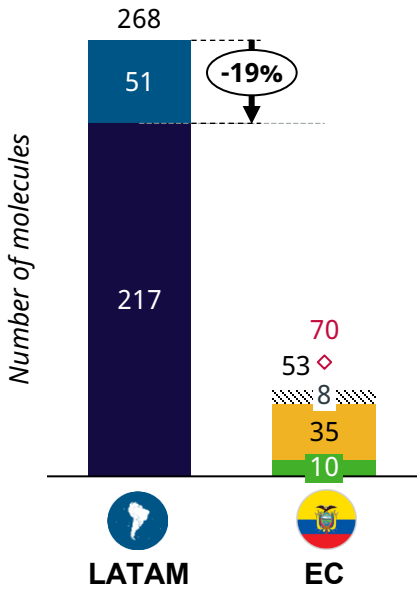
*See appendix for further detail

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

Ecuador’s availability lags compared to the approval

Ecuador faces challenges in both market entry and conversion into access, clearly reflected in the smaller approval base compared to regional levels

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



Regional Extended Availability

Number of molecules with Full / Limited / Private availability in at least one LATAM country

Initial regional approval – no availability
Initial regional availability (extended)
Locally approved
Full availability
Limited availability
Only privately available
Ext. Available

- A large share of approved therapies progresses to extended availability (53 out of 70) in Ecuador, indicating that once therapies enter the market, there is a relatively consistent pathway toward some level of patient access
- However, the total number of approved molecules remains limited compared to LATAM, constraining the overall scope of innovation reaching the country from the outset
- The distribution of availability is skewed toward limited access (35 limited vs. 10 full), suggesting that while therapies are present in the system, breadth and depth of access remain uneven
- The relatively higher share of therapies reaching extended availability compared to the total approved base suggests that bottlenecks are more pronounced at the entry stage than in downstream access pathways
- The limited presence of therapies in private channels (8 molecules) indicates that access is not heavily supplemented by out-of-pocket or alternative routes, placing greater pressure on formal system pathways to drive availability

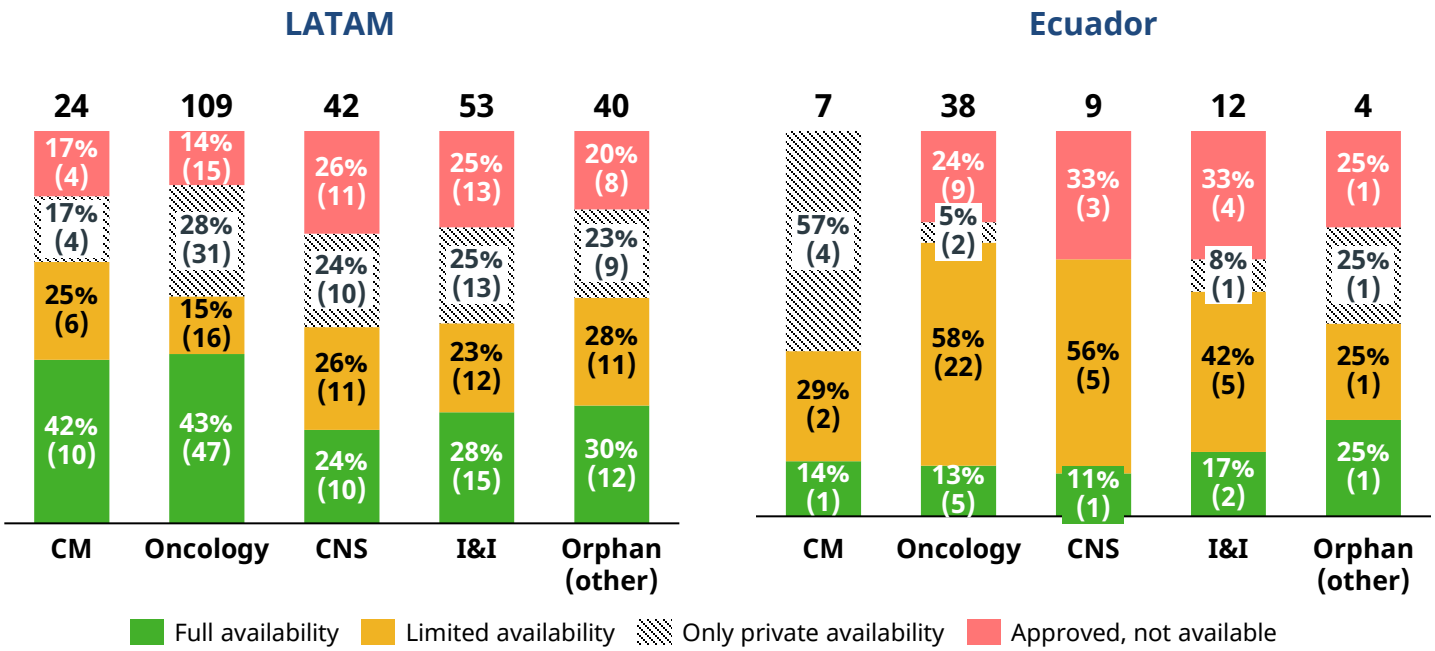
In Ecuador, while a limited approval base continues to constrain overall access, existing pathways enable a subset of therapies to reach patients, primarily through partial availability channels

Acronyms: EC: Ecuador

Significant differences also exist by therapeutic area

While some therapies reach patients across TAs, access in Ecuador is largely driven by limited availability and constrained by "approved but not available" in key areas

Regional and Local Availability Status by Therapeutic Area



- Access across therapeutic areas is primarily driven by limited availability (e.g., Oncology 58%, CNS 56%, I&I 42%), reflecting constrained funding and prioritization mechanisms that restrict therapies to partial or controlled use rather than broad uptake
- High "approved but not available" shares in key areas such as CNS and I&I (both 33%) indicate bottlenecks in reimbursement and implementation, where therapies enter the market but face delays or barriers to being incorporated into routine care
- The reliance on private availability in CM (57%) suggests that gaps in public access are partially offset by out-of-pocket pathways, likely due to differences in disease management structures and funding priorities
- The predominance of limited availability across therapeutic areas suggests that funding and reimbursement mechanisms are structured to control costs, favoring restricted access models rather than broad, system-wide uptake
- Variability across therapeutic areas reflects differentiated prioritization and care pathways, where certain disease areas rely more on private funding or alternative channels to complement gaps in public access

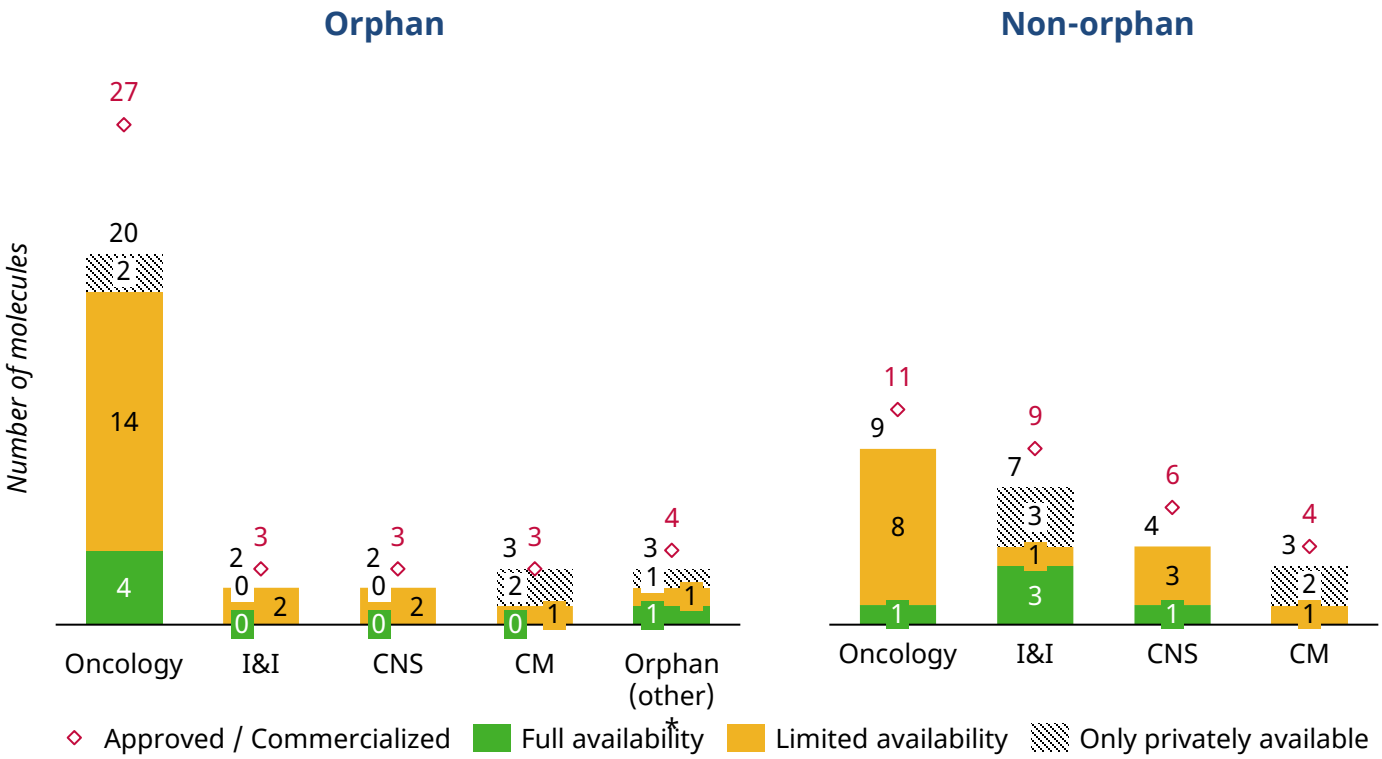
In Ecuador, access is present across therapeutic areas but largely shaped by constrained funding and reimbursement mechanisms, resulting in uneven availability and reliance on partial access pathways

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

Availability for non-orphan and orphan therapies varies

In Ecuador, access in both segments is primarily driven by limited availability, with modest differentiation across therapeutic areas

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



- Orphan therapies show limited full availability across TAs (e.g., Oncology: 4 molecules), with access largely concentrated in limited channels (14 in Oncology), reflecting restricted but present access pathways for high-cost therapies
- In smaller TAs (I&I, CNS, CM), availability remains minimal (2 or less than 2 molecules), suggesting lower prioritization and challenges in scaling access for rarer conditions outside oncology
- The presence of privately available therapies in oncology, CM and orphan TAs indicates that access is partially supplemented by out-of-pocket channels, likely due to funding constraints for orphan drugs in the public system

- Non-orphan therapies follow a similar pattern, with access primarily driven by limited availability (oncology: 8 therapies; CNS: 3 therapies), suggesting system-wide reliance on restricted access models rather than broad coverage
- The similarity in access patterns between orphan and non-orphan therapies suggests that constraints are driven more by system capacity and funding structure than by therapy type

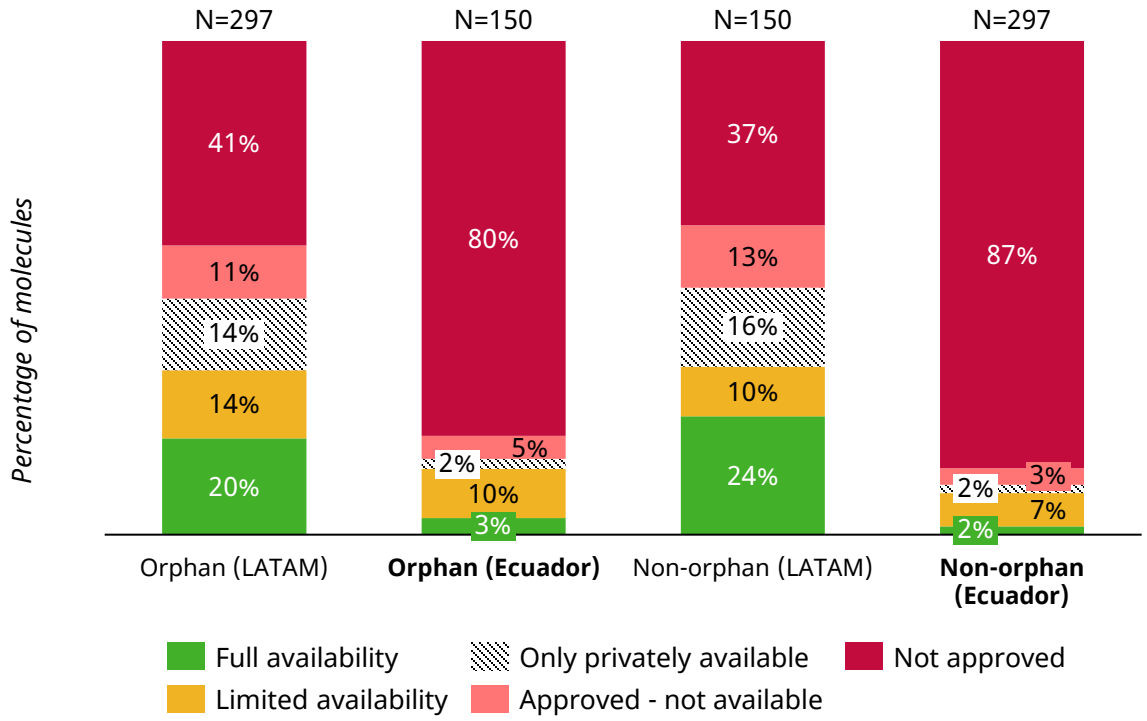
In Ecuador, both orphan and non-orphan therapies rely on similar, primarily limited access pathways, indicating system-wide constraints in expanding broad availability, with only modest differentiation across therapeutic areas

* 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

High "not approved" shares limit availability across both segments in Ecuador, with only a small portion of therapies progressing into access pathways

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



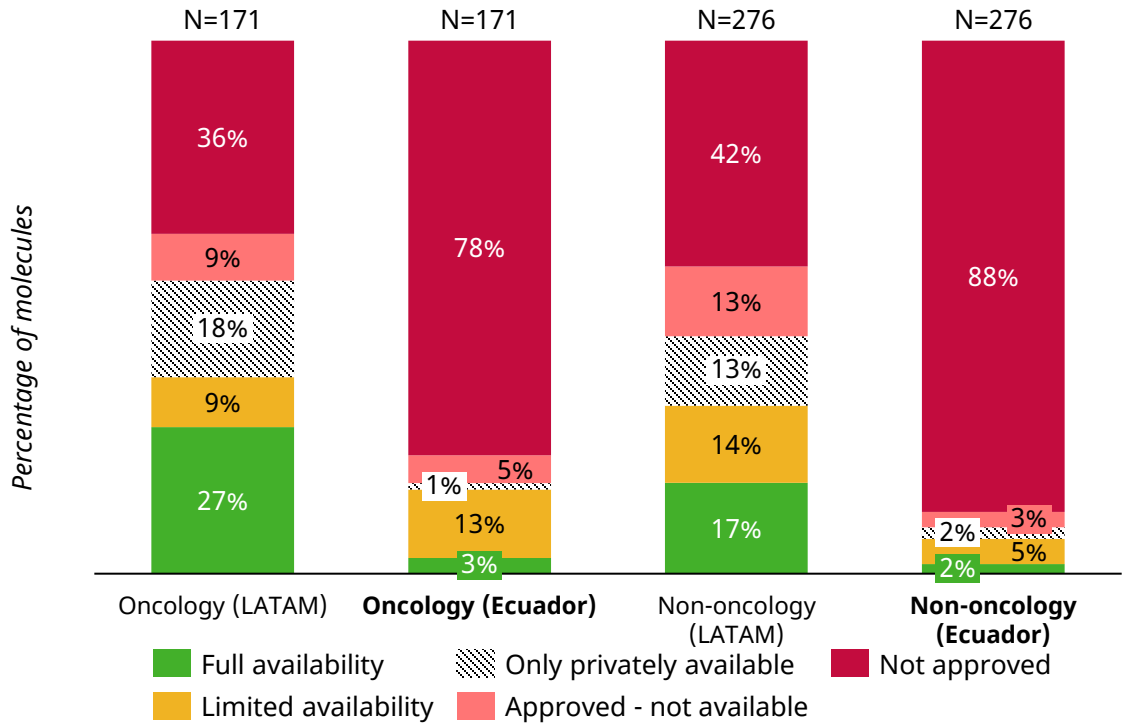
- Not approved therapies dominate in Ecuador across both segments, reaching 80% in orphan and 87% in non-orphan therapies, significantly above LATAM levels (41% and 37%, respectively), highlighting pronounced entry barriers
- Full availability remains minimal in Ecuador (3% orphan; 2% non-orphan), compared to 20% and 24% in LATAM, indicating limited conversion into broad access
- Among available therapies, access is primarily driven by limited availability (10% orphan; 7% non-orphan) and private channels (2% in both), suggesting that therapies reaching the market are mostly restricted in scope
- The predominance of non-approval suggests that access constraints in Ecuador originate primarily at the regulatory and market entry stage, rather than downstream reimbursement alone
- The small share of therapies progressing beyond approval into availability reflects constrained system capacity to absorb innovation, even after initial entry is achieved

In Ecuador, access is primarily constrained at the entry stage, with high non-approval rates limiting the number of therapies that can progress into availability, regardless of therapy type

Non-oncology lags behind oncology in Ecuador

Non-oncology lags slightly behind oncology; however, both segments show limited availability driven by high "not approved" shares

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



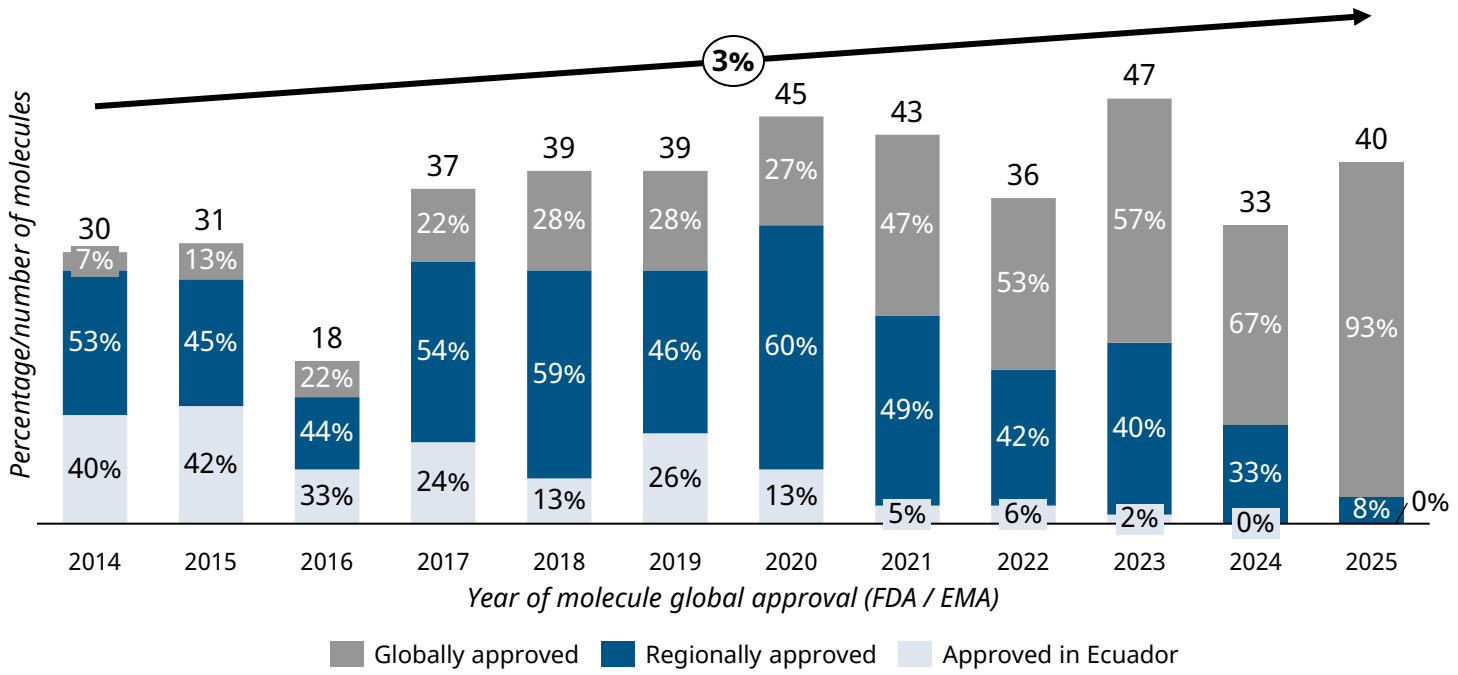
- Oncology shows a slightly broader mix of access pathways than non-oncology, with a higher share of therapies progressing into limited availability (13% vs. 5%), indicating relatively more developed channels for higher-priority diseases
- Non-oncology access is highly compressed, with minimal distribution across availability categories and a strong concentration in "not approved" (88%), suggesting fewer entry points across the system
- Private availability plays a negligible role across both segments (1–2%), indicating limited reliance on alternative access routes and a stronger dependence on formal system inclusion
- The more diversified access profile in oncology suggests that existing pathways are better defined and more consistently utilized, likely due to clearer clinical prioritization and treatment frameworks
- In contrast, the compressed distribution in non-oncology reflects weaker pathway development, where fewer therapies progress beyond initial entry stages into structured access routes
- The limited presence of private channels reinforces that access expansion depends primarily on public system mechanisms, restricting flexibility in how therapies reach patients

In Ecuador, oncology benefits from relatively more structured access pathways, while non-oncology remains highly constrained, with limited progression beyond entry and strong dependence on formal system uptake

New medicines increase, approvals are lagging behind

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

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



- Global approvals have grown steadily at ~3% CAGR between 2014 and 2025, reflecting a sustained acceleration of pharmaceutical innovation worldwide; however, Ecuador has failed to keep pace, with local approvals showing a sharp downward trend over the past four years
- Ecuador's local approval share has collapsed in recent years, dropping to single digits since 2021, and reaching 0% in both 2024 and 2025, indicating a near-complete disconnection between global innovation entry and local regulatory uptake
- 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 Ecuador, reaching 93% regional and 40% Ecuador availability for 2014 cohorts, whereas more recent approvals show substantially lower penetration due to shorter time since launch
- Furthermore, over time the “ceiling”, that is the peak level of approvals in the region for globally approved medicines, is lowering with a very clear downward trend over time, even for the medicines in mid-late lifecycle, indicating compounding challenges to launching in the region

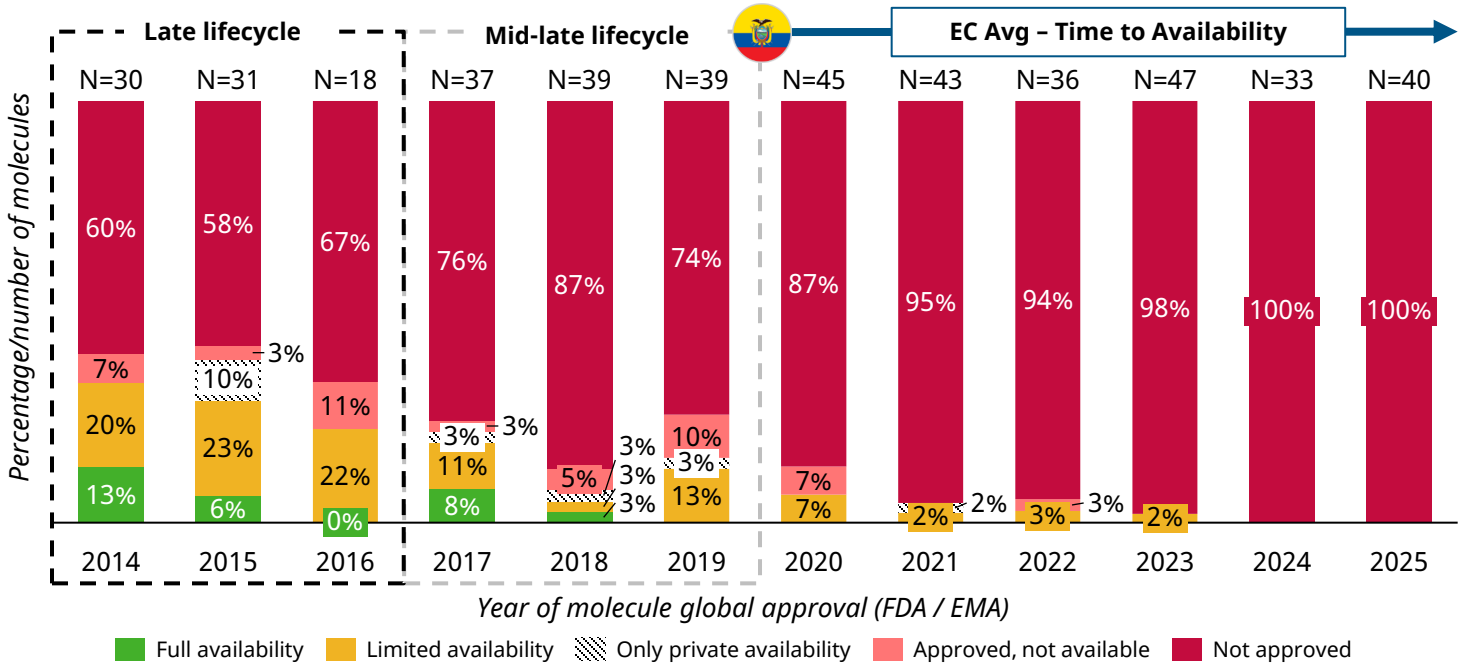
Approval rates are declining in the region, whilst global approvals are increasing; the gap will continue to widen without concerted action

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

Even for older technologies, public access is highly challenging

Earlier cohorts achieved partial access through limited and private channels, but recent years show a near-total disconnection

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



- Full availability remains consistently low across all cohorts and declines in recent years, dropping from 13% in 2014 and 8% in 2017 to 0% from 2019 onwards, indicating persistent challenges in achieving broad access
- The share of not approved molecules increases sharply for newer cohorts, rising from 60–58% in 2014–2015 to 95% in 2023, 100% in 2024 and 2025, highlighting the challenges in reaching consensus on both submission and approval
- Approved but not available molecules represent a small but persistent share in earlier cohorts, peaking at 11% in 2016 and 7% in 2014 and 2020, suggesting that even when regulatory approval was achieved, post-approval bottlenecks delayed real-world availability, a pattern that has since been overtaken by the broader collapse in approvals
- Limited and only-private availability together provided a partial access pathway in early cohorts, accounting for ~20–30% of molecules in 2014–2015, but have eroded sharply since 2020, with most recent cohorts showing zero or near-zero contribution from these channels
- The overall distribution shifts toward lower access over time, with recent cohorts increasingly concentrated in not approved and unavailable categories, pointing to a growing backlog and widening access gap despite ongoing innovation

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

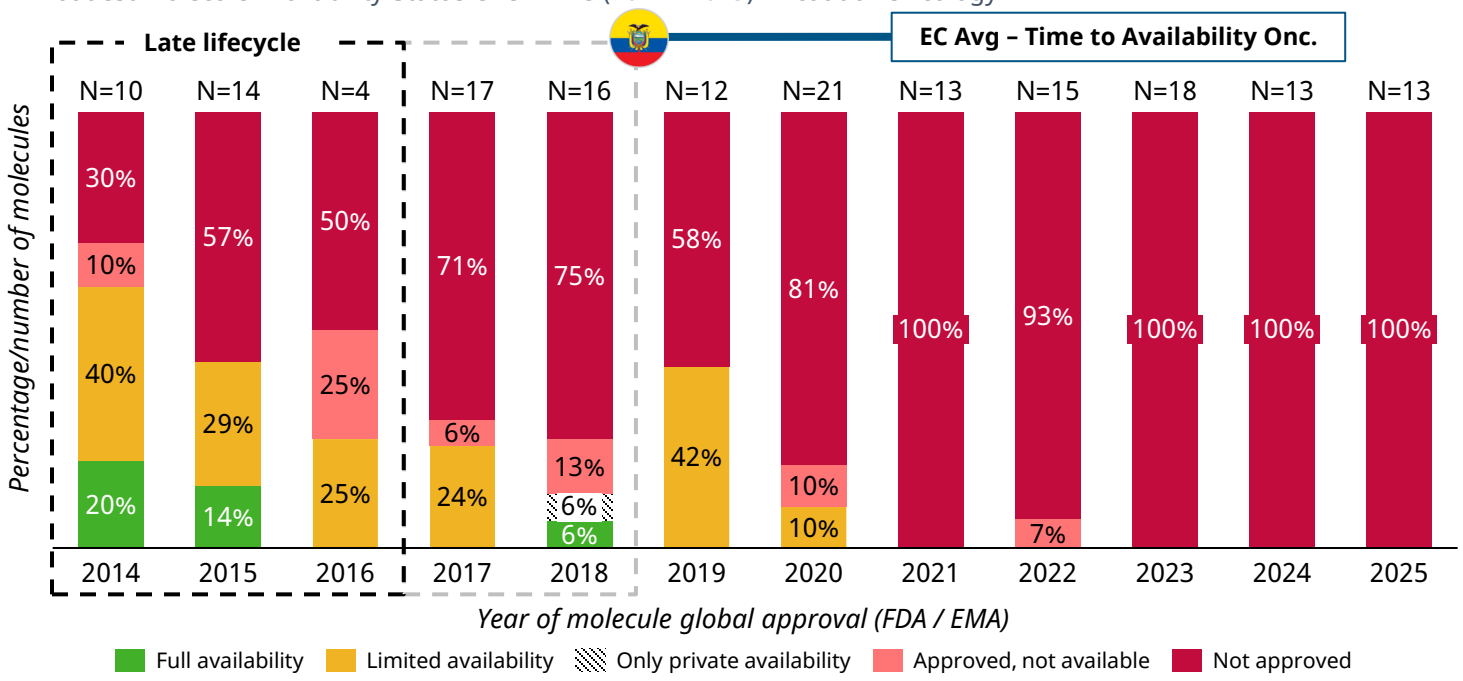
- ex-Minister of Health

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

Oncology access in Ecuador has decreased over time

Earlier oncology cohorts achieved meaningful access through limited and full availability channels, but recent years show a lower availability

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



- Full availability in oncology has historically been marginal and is now absent, peaking at 25% in 2016 and 20% in 2014, but dropping to 0% from 2019 onwards, confirming that recent oncology innovation has not reached the public system at all
- The share of oncology molecules that are not approved rises sharply in recent years, increasing from 30% in 2014 to 50% in 2016, 81% in 2020, and 100% from 2023 onwards, highlighting major barriers for newer oncology therapies
- Limited availability represents an important access pathway, accounting for 40% in 2014, and 42% in 2019, suggesting that many products reach patients only through private channels rather than broad public availability
- Approved-but-not-available molecules represent a small and inconsistent share across cohorts, appearing only sporadically (10% in 2015, 13% in 2018, 10% in 2020, and so on) and absent in most other years, indicating that post-approval bottlenecks are not the main driver of access gaps in Ecuador Oncology
- Access to oncology innovation in Ecuador has shifted away from broad availability toward restricted or absent access, with recent years showing minimal progression to full availability and a growing concentration of molecules that have not yet reached patients through the healthcare system

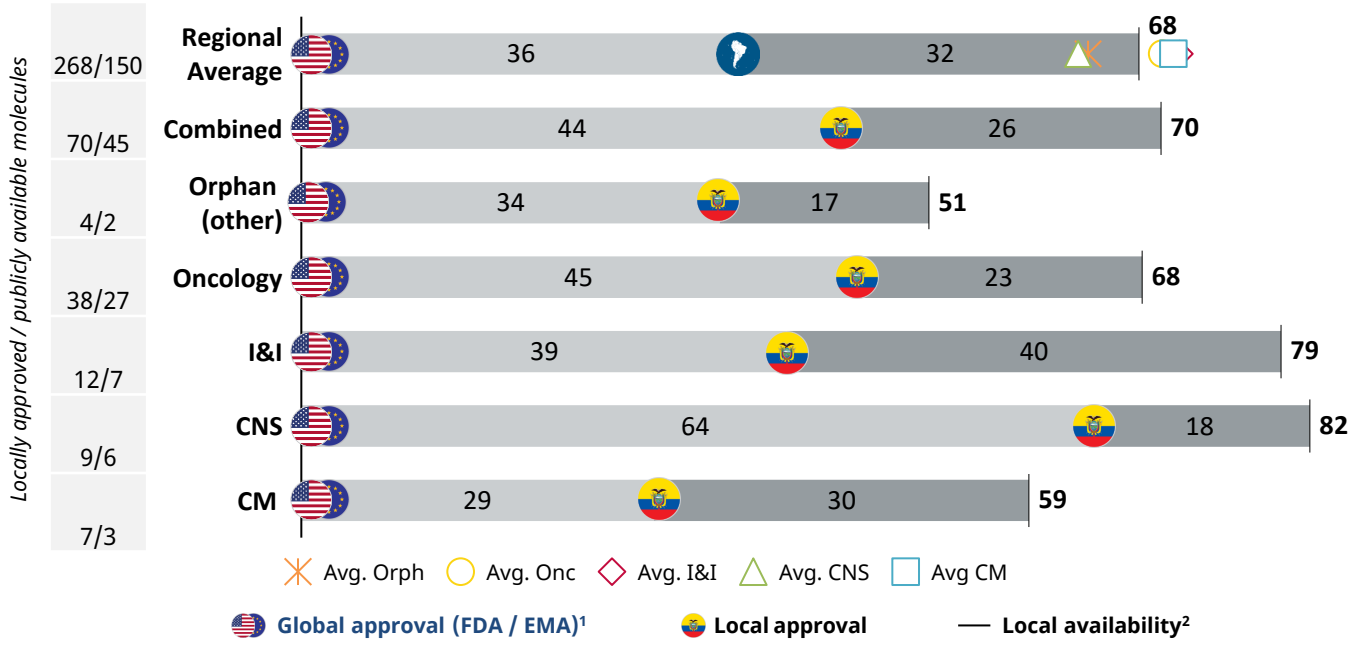
Access to oncology molecules in Ecuador has worsened over time, with newer cohorts increasingly concentrated in not approved or restricted-access categories

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

Access is a long and fragmented process

The time to availability in Ecuador averages 5.8 years, with a time to approval of 3.6 years and a time to availability of 2.1 years

Time to Availability from Global Approval (2014 - 2025) – Ecuador 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 Ecuador reaches ~70 months (~5.8 years), closely aligned with the regional average (68 months), confirming that patient access remains significantly delayed despite earlier innovation approvals in Ecuador
- Ecuador benefits from relatively faster regulatory availability timelines (26 months vs. 32 months regional), which indicates that downstream funding, reimbursement, and procurement processes operate more efficiently
- However, local approval times lengthen the process, taking 8 months longer in Ecuador than the regional average (44 months vs. 36 months regional), indicating that most access delays occur when getting approval
- The most significant delays post approval correspond to the CNS medicines, mainly because of the time to local approval (~64 months). The total time to availability exceeds the local average by ~1.2 years
- In contrast other therapeutic areas, Orphan (49 months) and CNS (50 months), are strikingly quicker to availability

Ecuador's access process is broadly aligned with the regional benchmark in total duration but remains long and fragmented, with delays accumulating across regulatory approval mainly

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

Timelines lengthened in 2026, driven by post-approval delays

Ecuador's overall time to availability lengthened modestly vs. 2025, with availability delays as the main driver; however, I&I and CM show meaningful improvement across both stages

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

	Approved	Available	Total
Regional average	-5.6%	+9.4%	+1.5%
Combined	-	+7.7%	+2.9%
Orphan (other)	+52.9%	-123.5%	-5.9%
Oncology	-	+8.7%	+2.9%
I&I	-7.7%	-45.0%	-26.6%
CNS	-	+16.7%	+3.7%
CM	-6.9%	-6.7%	-6.8%

- Ecuador shows a +7.7% increase in time to availability vs. 2025, resulting in a +2.9% overall delay, which equates to approx. 3 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 (+18.6%) showing the largest increase in time to availability and Oncology (+8.7%) also experiencing deterioration, evidencing chronically evolving systemic strain
- In contrast, Orphan therapies (-38.1%), I&I (26.6%) and CM (-6.8%) show improvements, suggesting targeted prioritization or lower budget impact enabling faster access in select segments
- There are isolated improvements, but the overall trend indicates that system capacity is not keeping pace with innovation inflow, resulting in slower transitions from approval to availability

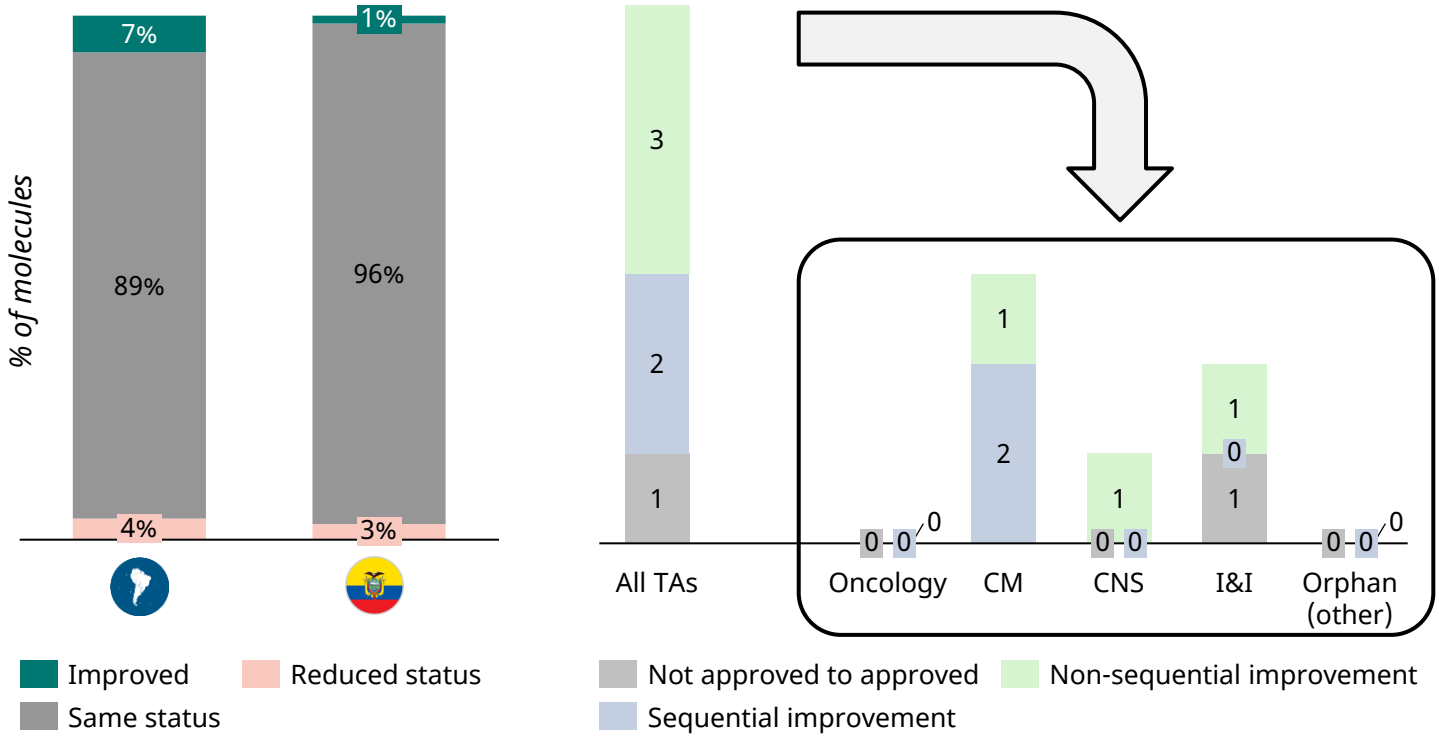
Ecuador's access dynamics in 2026 vs. 2025 reflect a mixed picture, with overall timelines lengthening modestly but meaningful improvement concentrated in I&I and CM; downstream availability delays remain the dominant driver of deterioration across most TAs

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

Ecuador’s improvement lags significantly beyond LATAM’s

Ecuador's access landscape remains largely static vs. 2025, with limited progress concentrated in CM and I&I and minimal movement across other therapeutic areas

Improvement Index Ecuador (2026 vs 2025)



- Ecuador's improvement rate (1%) is seven times lower than the regional average (7%), while reductions in status are broadly aligned (3% vs. 4%), confirming that the country is not only progressing far more slowly than the region but also shows minimal upward dynamism across the access landscape
- Most molecules (96%) remained in the same status year-over-year, exceeding LATAM's 89% inertia, indicating that Ecuador's access landscape is highly static, with virtually no movement in either approval transitions or availability conversions across most therapeutic areas
- Of the molecules that did improve, progress was skewed toward transformative rather than gradual shifts, with 3 non-sequential improvements outweighing 2 sequential transitions
- Across the therapeutic areas, more improvements are made in CM and I&I, followed by CNS. The least improvements are in Oncology and Orphan

Ecuador's improvement dynamics are significantly narrower and slower than the regional benchmark, with CM and I&I absorbing nearly all the limited progress while Oncology, CNS, and Orphan therapies remain entirely static

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

Key system updates are strengthening access pathways

Recent reforms to the national medicines list, procurement coordination, and regulatory processes are improving system structure

Recent Health Reforms in Ecuador



Ecuador is implementing structured updates through formulary expansion and regulatory modernization

- 12th revision of the Cuadro Nacional de Medicamentos Básicos
- Evidence-based prioritization of medicines through CONASA/CONAMEI evaluation processes
- Strengthening of regulatory oversight and pharmacovigilance through ARCSA
- Expansion of regulatory pathways for special access

- Ecuador has advanced the 12th revision of the CNMNB, incorporating new treatments across priority therapeutic areas, including oncology and chronic diseases. This process is based on structured evaluation criteria: efficacy, safety, and economic impact; ensuring that additions are evidence-based
- Through CONASA and the CONAMEI, Ecuador applies a structured evaluation model to prioritize medicines for inclusion; this introduces a more formal, Ecuador approach to decision-making, strengthening the rigor of access decisions; however, the process is highly selective, with only a small proportion of submitted medicines progressing through evaluation, limiting the number of therapies that reach inclusion
- ARCSA has reinforced monitoring systems, including ongoing pharmacovigilance and safety reporting frameworks, improving post-market surveillance of medicines
- Ecuador allows exceptional importation and authorization mechanisms for medicines not available in the country, particularly for rare, catastrophic, or specialized treatments. These pathways provide an alternative route to access, especially for innovative therapies, but they are typically case-specific and do not scale to system-wide availability

Ecuador is building a more structured and evidence-based access framework, but the translation of policy into availability remains constrained by system capacity

Sources: Global Health Expenditure Database, International Trade Administration, OECD
Acronyms: CONASA: Consejo Nacional de Salud; CONAMEI: Comisión Nacional de Medicamentos e Insumos; CNMNB: Cuadro Nacional de Medicamentos Básicos; ARCSA: Agencia Nacional de Regulación Control y Vigilancia Sanitaria; Ecuador: Health Technology Assessment

Ecuador’s regulatory system is strengthening

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

Global Reliance of Ecuador’s Health Agencies





Agencia Nacional de Regulación, Control y Vigilancia Sanitaria

Global Reliance

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

- Ecuador has reinforced post-market surveillance through structured pharmacovigilance systems, including regular safety alerts and updates to product information for medicines in use. These mechanisms enhance patient safety and regulatory confidence, but add complexity to ongoing product monitoring and compliance requirements
- Ecuador has a strong reliance framework whereby it can accelerate approvals by reducing duplicative work realized by Equivalent Foreign Regulatory Authorities (AREEs), primarily US-FDA, EU-EMA, UK-MHRA and Health Canada
- Furthermore, Ecuador is active in its global collaboration via International Council for Harmonization (ICH), and Project Orbis (for oncology medicines)whereby it is a contributor in assessments as well as a participant benefiting from parallel reviews and other mechanisms
- Ecuador (ARCSA) is also recognized by PAHO/WHO as a National Regulatory Agency of Regional Reference (NRAr), indicating the consensus in the international community on the advanced level of maturity of the agency, and enabling other countries in the region to fast-track approvals by relying on the evaluation of ARCSA

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

Acronyms: ARCSA: Agencia Nacional de Regulación, Control y Vigilancia Sanitaria; NRAr: National Regulatory Authorities of Regional Reference; FDA: Food and Drug Administration: EMA: Eurpoean Medicines Agency, MHRA: Medicines and Healthcare products Regulatory Agency; PAHO: Pan American Health Organizaton; WHO: World Health Organizaton

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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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