White Paper

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

## *Costa Rica*

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# Overview of the study

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

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

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

# Additional scope and validation

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

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













**Added in 2026**




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

*- ex-Minister of Health*

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

# Drug usage and spend analysis

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

Full scope of the FIFARMA 2026 WAIT report

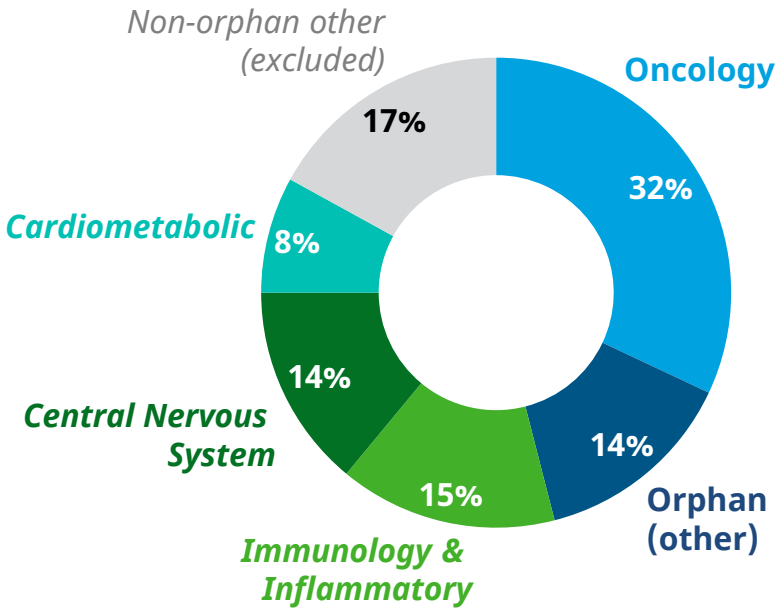



*See appendix for definitions, exchange rates, and indicators
Acronyms: NRC: Non-retail Channels; USD: US dollars; WHO: World Health Organization

# Methodological considerations

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

Molecule selection by therapeutic area 2026




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

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

Additional detail is outlined in the appendix

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

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

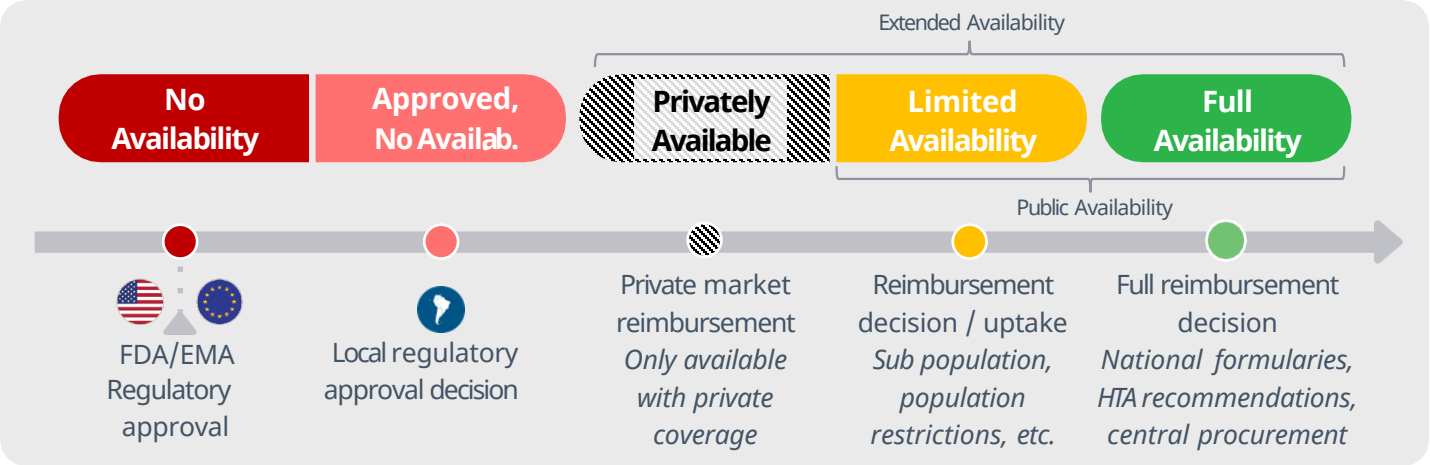
Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; NAS: New Active Substance; JP: Japan; US: United States; EU: European Union; UK: United Kingdom; PDL1: programmed death-ligand 1: 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; SoC: Standard of care; HTA: Health Technology Assessment

# Methodological considerations

## The detailed definitions for molecules' availability status in Costa Rica involved inclusion to public health formularies like the CCSS LOM

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

# 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 – Costa Rica

## 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

- Costa Rica's time to approval is higher than the regional average (57 vs 36 months), but local time to availability is 2 months under the regional average (30 vs 32 months)
- Time to availability varies substantially in Costa Rica across therapeutic areas, with CM showing the longest delays taking ~57 months to become locally available compared to ~32 months of the regional availability and ~50 months to get public availability. CNS therapies become available the fastest

*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, only 35% are approved in Costa Rica
- 36% of molecules with regional public availability (limited or full availability) have public availability in Costa Rica
- 32% of molecules approved in Costa Rica have some level of availability; out of this extended availability, only18% have reached full availability status
- The TA with highest extended availability is oncology (70%), while CM and orphan don't have any therapy with full availability

## Availability Over Time

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

- Over 23% of molecules that received global approval from 2014 to 2018 are approved in Costa Rica; less than half of these are also available
- 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***

- 7% of the molecules in Costa Rica have improved their availability status over the past year, same as the regional average
- Costa Rica had 19 newly approved molecules this year

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

# Summary of Regional Root Causes and Opportunity

***Innovation is outpacing system capacity, driving saturation and delays***

The volume and complexity of globally approved medicines continue to rise, creating mounting challenges for Costa Rica'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 Costa Rica'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 Costa Rica. 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 Costa Rica 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 Costa Rica 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.

*Costa Rica'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 Costa Rica 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, Costa Rica'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 Costa Rica's ability to absorb innovation efficiently, leading to delays, operational misalignment, and uneven access outcomes



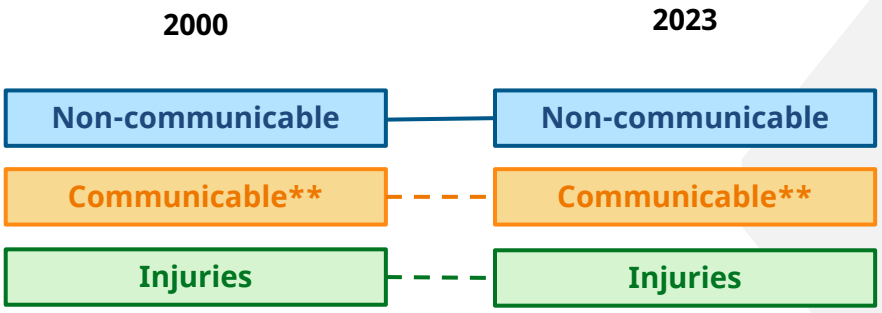
### A window for transformation is emerging

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 Costa Rica's health burden

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

Evolution of Disease Burden in Costa Rica - DALYs per 100,000




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

| | |
|---|---|
| 1 | Neoplasms |
| 2 | Cardiovascular disease |
| 3 | Diabetes & CKD |
| 4 | Musculoskeletal disorders |
| 5 | Mental disorders |
| 7 | Other non-communicable |
| 8 | Neurological disorders |
| 9 | Digestive disorders |
| 14 | Respiratory infections TB |
| 15 | Maternal and neonatal |

- Costa Rica's disease burden is driven by non-communicable diseases. However, Costa Rica'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.
- 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.

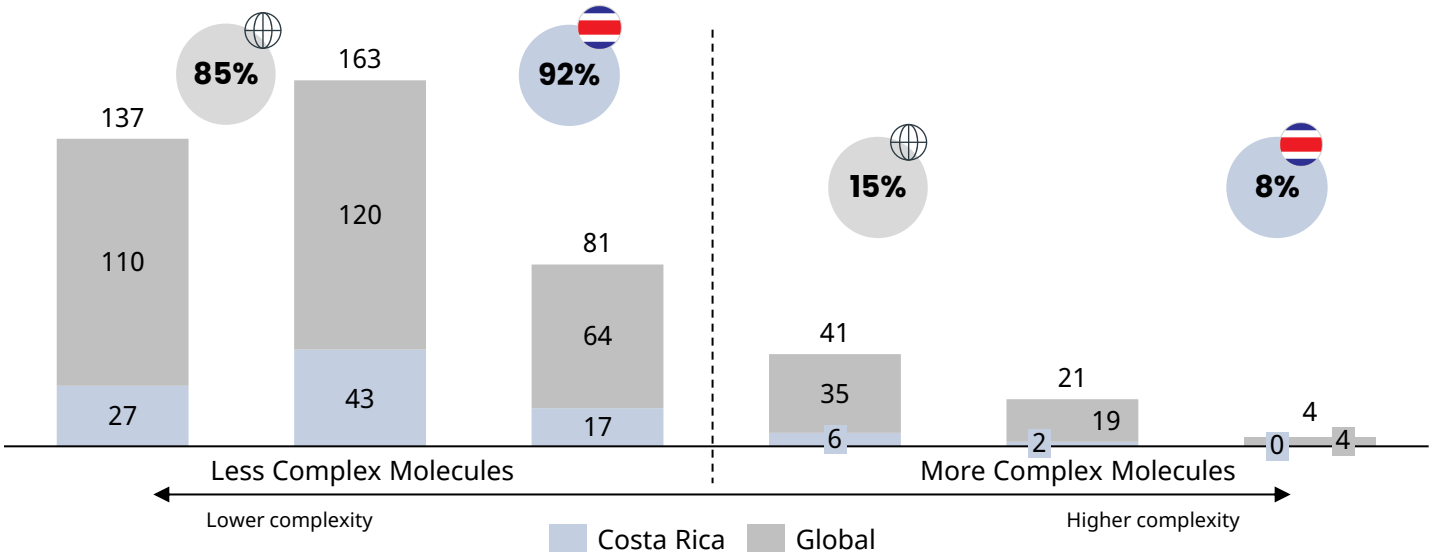
*Costa Rica's disease burden is strongly driven by non-communicable diseases, but the persistence of communicable conditions creates a dual burden that increases system complexity and demand for both innovation and sustained care.*

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

# Complexity introduces additional considerations for systems

## Costa Rica closely follows 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 magnifies capacity constraints. From a technical perspective, complex molecules pose greater challenges in evidence generation and interpretation.
- Costa Rica's complexity index closely mirrors LATAM, with ~92% of molecules concentrated in the lower-complexity side versus ~8% in higher complexity, indicating a consistent regional distribution pattern

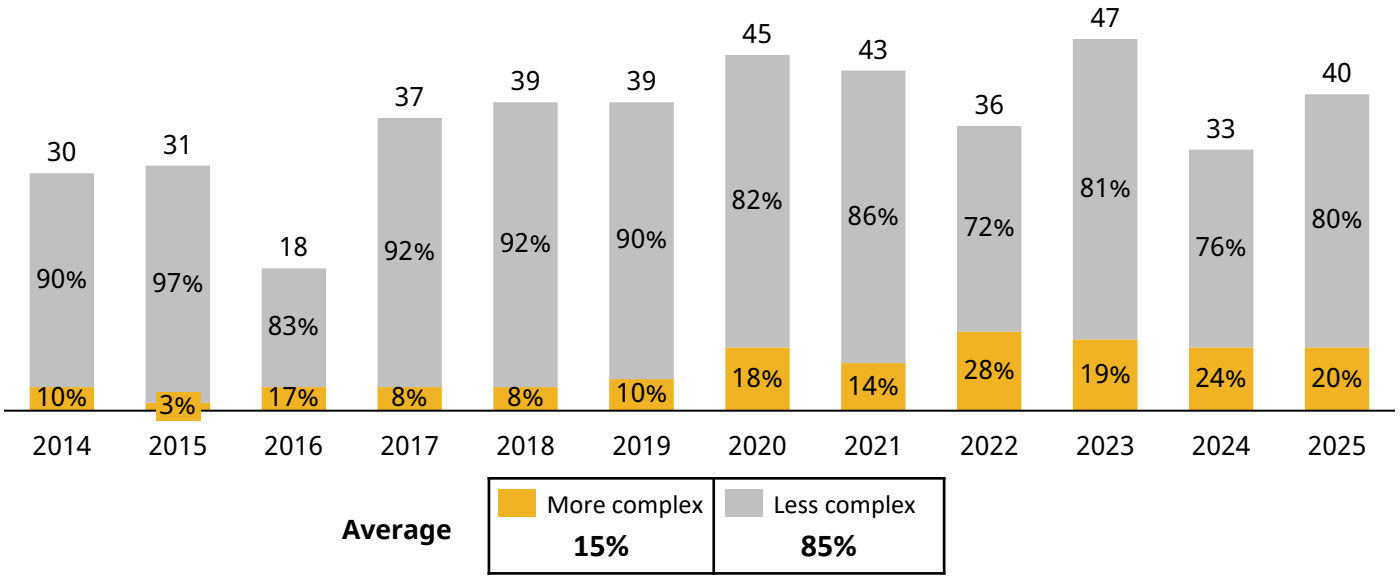
*Innovation often introduces technical challenges during evaluation and creates downstream system constraints for regulators, payers, and providers in resource-limited settings*

Acronyms: RNAi, RNA interference

# Innovation is also becoming more complex

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

Complexity of Global Approvals - WAIT Dataset



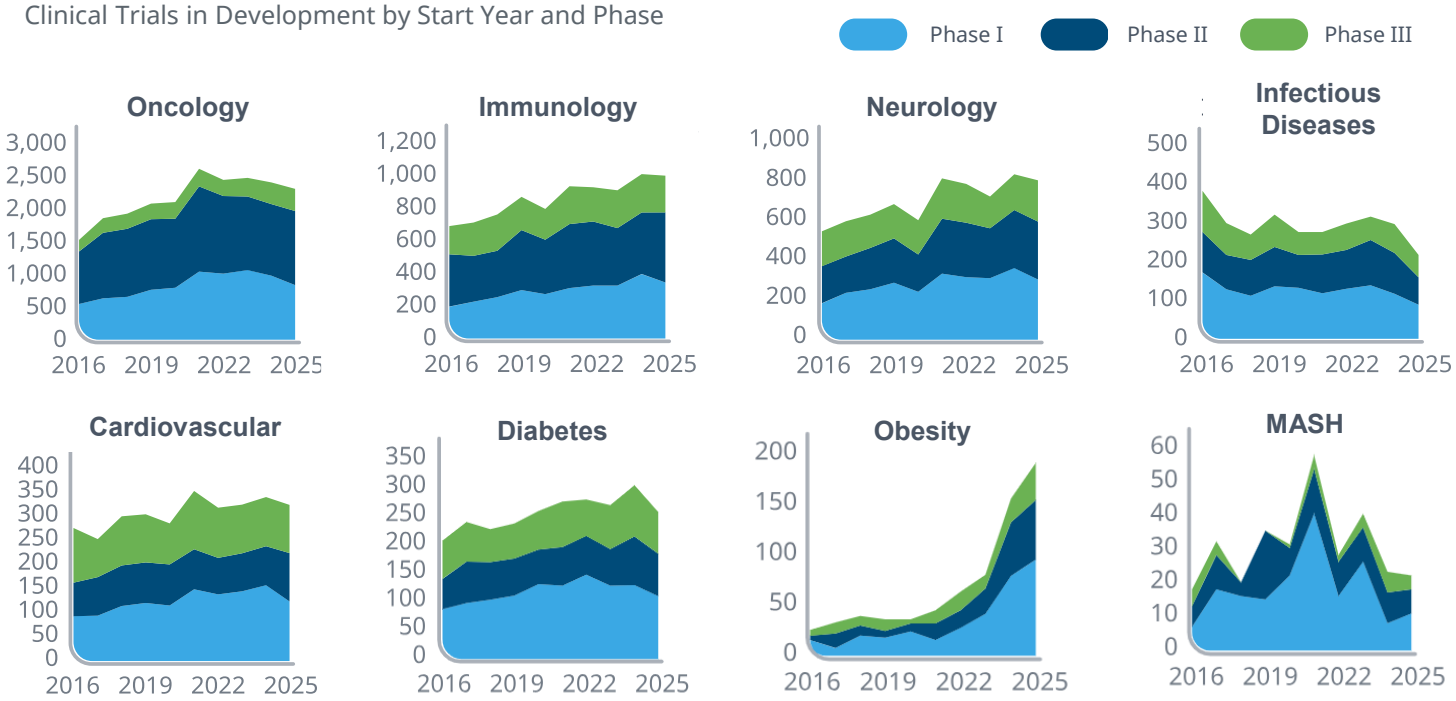

- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)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

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

# A robust global pipeline signals sustained innovation and mounting system pressure

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

Clinical Trials in Development by Start Year and Phase




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

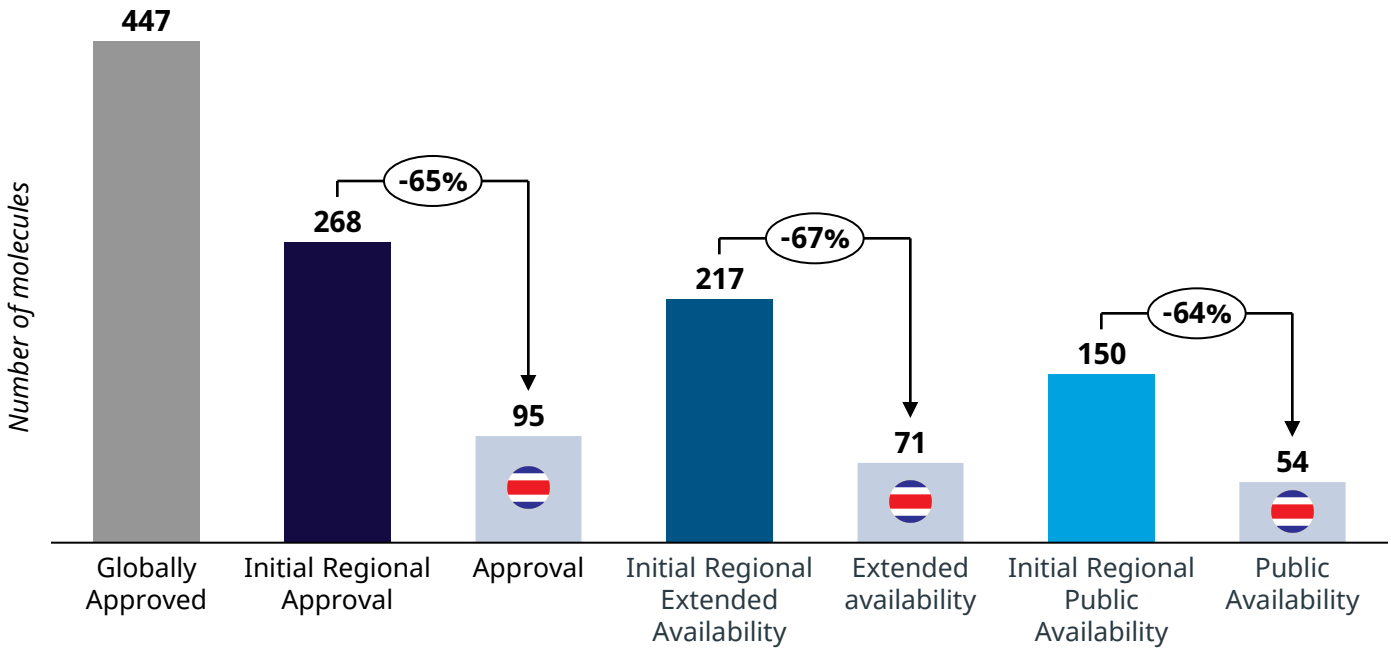
*A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed*

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

# Access challenges are present across all stages of the pathway

## 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



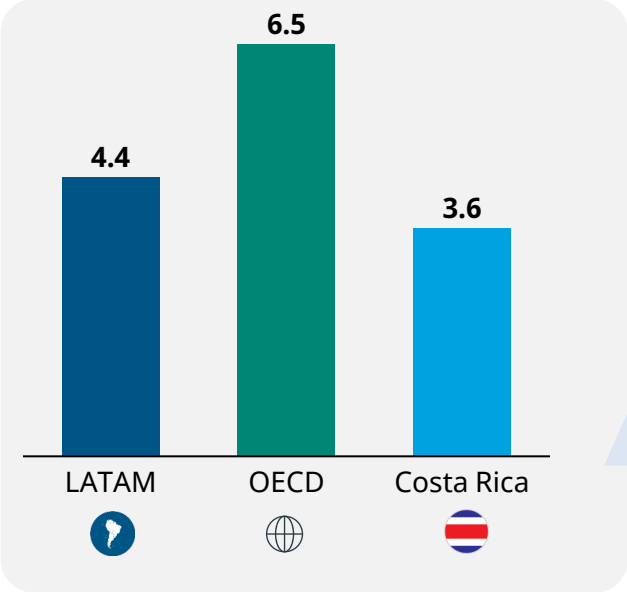

- Initial regional approval and availability represents where a molecule is approved or is available in at least one country in the region, the comparative graph represents Costa Rica's status
- Costa Rica shows a significant gap at the approval stage, with only 95 molecules approved vs. 268 regionally (–65%), indicating limited conversion of global innovation into local regulatory approvals
- This gap persists through the access pathway, with extended availability reaching 71 molecules (–67% vs. regional), highlighting constraints in progressing therapies beyond approval into broader system use
- The most pronounced gap is shown when considering public availability. Where only ~36% of the molecules are available compared to the regional benchmark
- Losses remain consistent across all stages (–65% to –67%), indicating that constraints are not concentrated at a single point, but rather reflect system-wide limitations across approval, incorporation, and access
- Unlike markets where post-approval performance improves, Costa Rica shows no meaningful recovery after approval, suggesting structural barriers affecting both entry and downstream integration

*Costa Rica's challenge lies in limited system capacity, where consistent constraints restrict the overall ability to absorb and scale innovation*

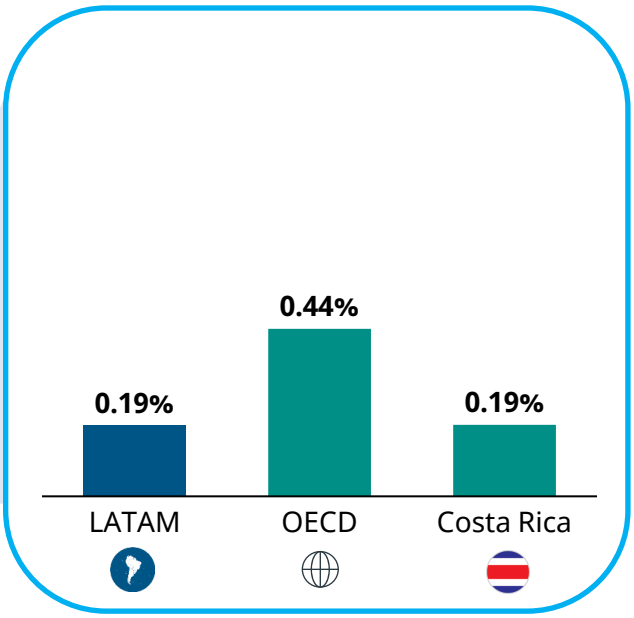
# Costa Rica's health spending is below the OECD target

## Public health spending in Costa Rica is below LATAM and OECD benchmarks, while innovation spending aligns with LATAM but remains below OECD levels

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 Costa Rica remains lower than the recommended 6.5% GDP share by WHO and the OECD average, indicating a comparatively tighter funding base for the health system
- Costa Rica allocates the same share of GDP to innovative treatments as the regional benchmark (~0.19%); however, the country remains below the OECD benchmark, limiting the system capacity to grant access to innovation
- The wide gap vs OECD highlights structural underinvestment in health, which may reduce the system's flexibility to respond to growing demand and incorporate innovation at scale
- As a result, Costa Rica may face stronger prioritization pressures, with available resources focused on essential coverage rather than broader adoption of newer therapies
- The alignment with LATAM indicates that Costa Rica's challenge is less about regional underinvestment in innovation specifically, and more about the broader health funding ceiling that limits expansion capacity

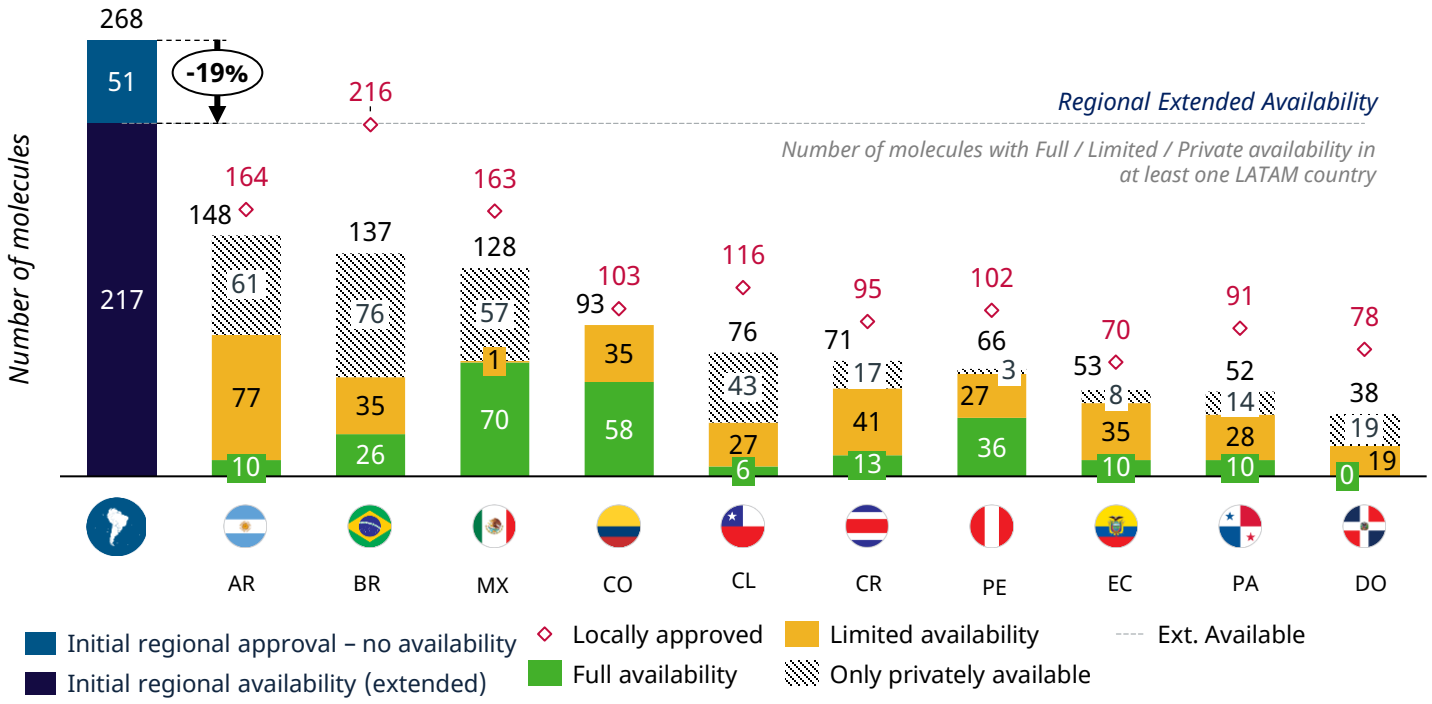
*Costa Rica's innovation spending keeps pace with LATAM, but lower overall health expenditure and a significant gap vs OECD benchmarks suggest that broader system funding constraints continue to limit the scale and sustainability of access to innovative therapies*

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

## 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*

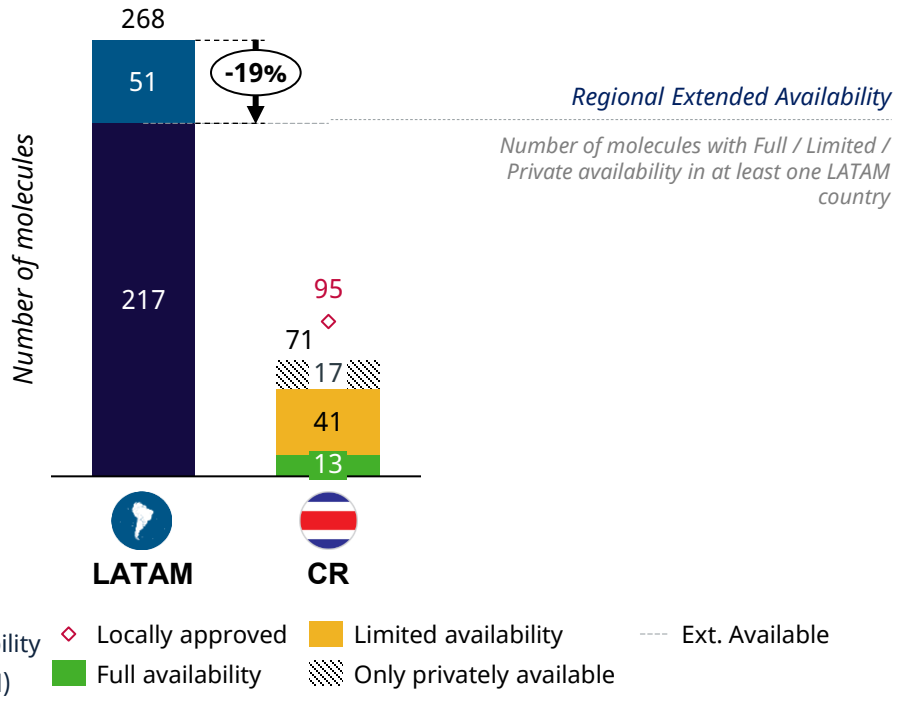
*See appendix for further detail

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

# Costa Rica's availability lags behind approval

## Lower availability in Costa Rica reflects limited conversion from approval into access compared to LATAM

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



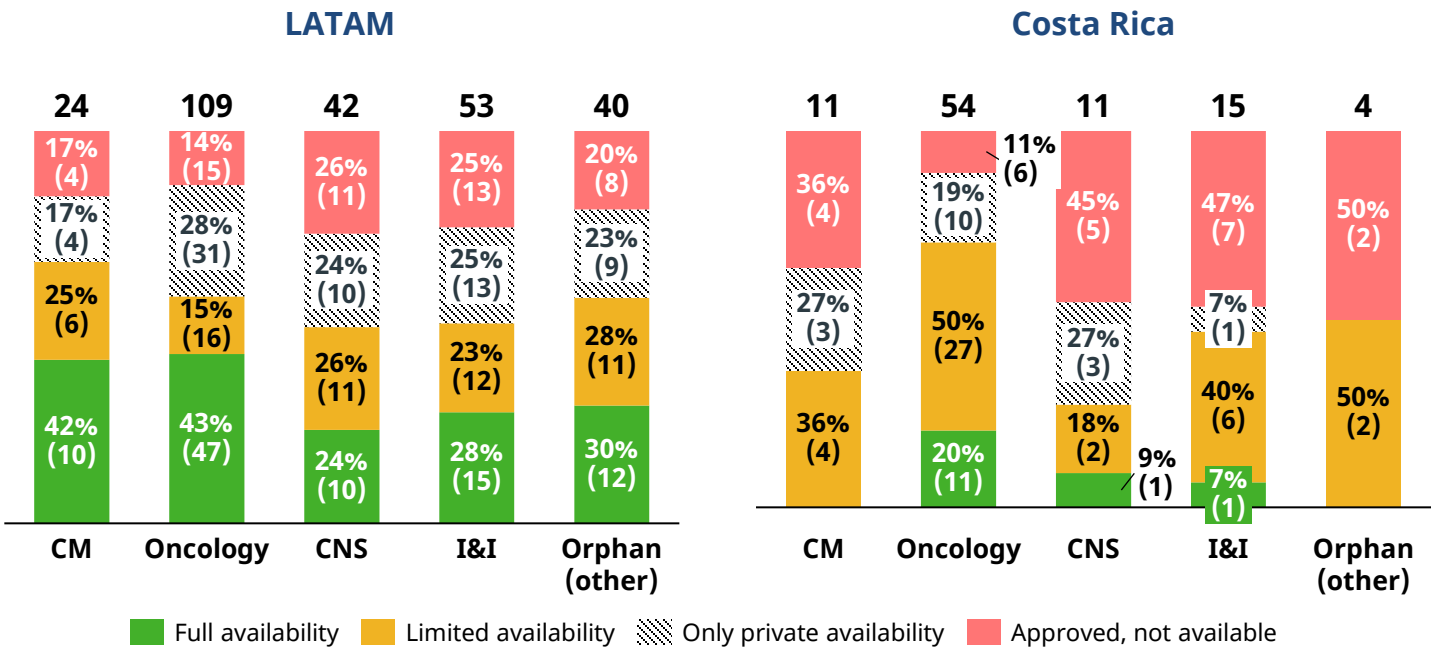

- There is an important gap between the approval (95 molecules) and the extended availability (71 molecules), indicatingg partial conversion of innovation into accessible treatments
- The availability mix is skewed toward limited (41) and only privately available (17) therapies, suggesting that access is often restricted rather than broadly integrated into the system
- Public system uptake remains constrained, as only 13 therapies achieve full availability, demonstrating that Costa Rica's Ministry of Health faces significant limitations in scaling access to innovative medicines, driven by funding constraints, prioritization, and implementation capacity
- Compared to LATAM, Costa Rica demonstrates lower progression across all availability stages, not just full access. This suggests that constraints are not only at the funding level but also in implementation and integration of new therapies into the system

*In Costa Rica, approval of innovative therapies does not consistently translate into broad availability, with structural constraints in funding, implementation, and system capacity limiting the progression from regulatory access to full patient access*

# Significant differences also exist by therapeutic area

## In Costa Rica, oncology shows the strongest availability while CM, CNS, and orphan therapies remain highly constrained

Regional and Local Availability Status by Therapeutic Area




- Costa Rica exhibits a more constrained and uneven access profile than LATAM across therapeutic areas, with meaningful full availability only in Oncology (20%), while CNS (9%), I&I (7%), and Orphan (0%) remain far below regional levels
- Oncology stands out as the strongest-performing TA, with 89% extended availability, suggesting that higher clinical visibility and prioritization help therapies move further into access, even if broad public integration is still incomplete
- CM is one of the most constrained areas, with 0% full availability and 36% approved but not available, indicating that even when therapies are approved, they struggle to translate into access in broader chronic disease segments
- CNS and I&I remain highly restricted, with 45% and 47% approved but not available, respectively, reflecting persistent bottlenecks in uptake, funding, and implementation in areas with greater complexity or lower prioritization
- Orphan therapies show no full availability and 50% approved but not available, highlighting weak conversion from approval into access

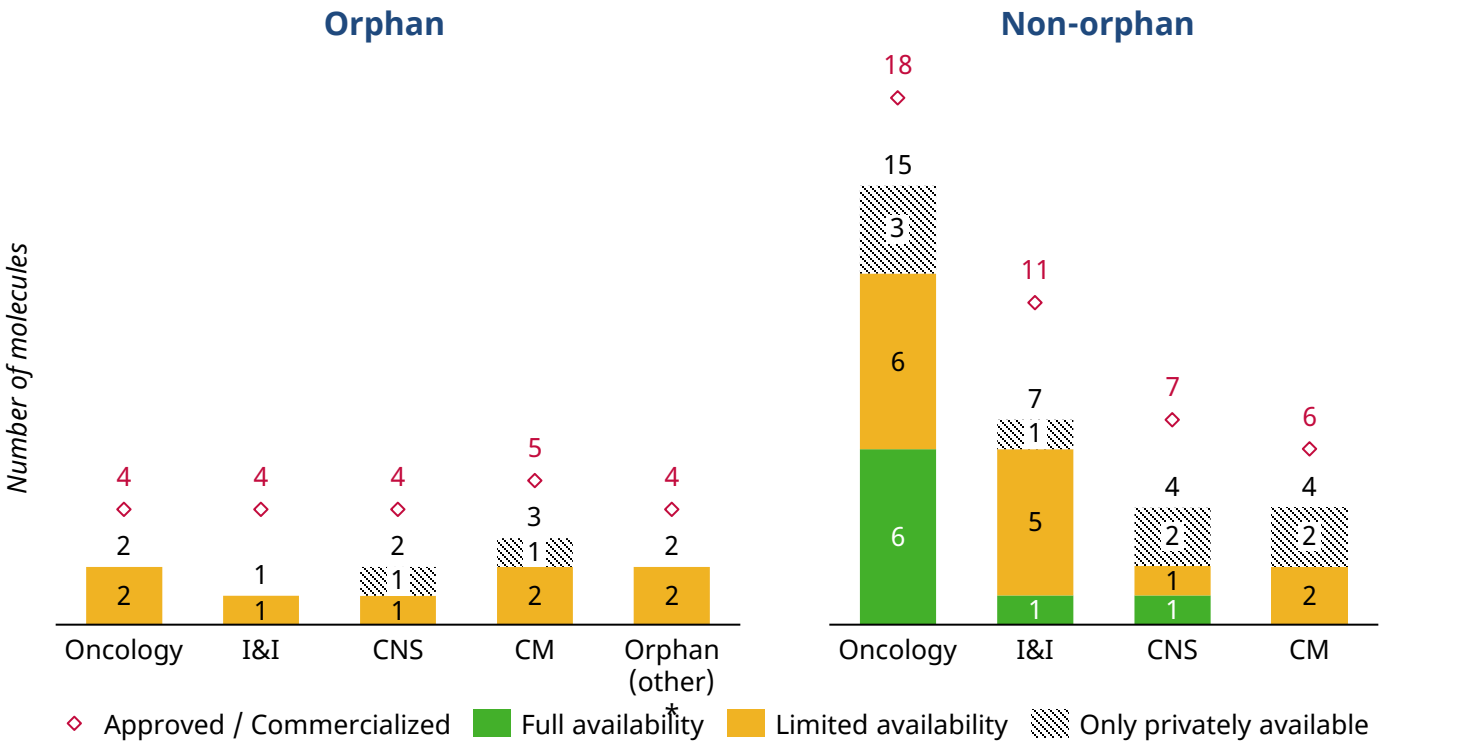
*The biggest gaps in Costa Rica compared to the region are found in CM, CNS, and orphan therapies; broader access to innovation remains limited by prioritization and uptake constraints*

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

# Non-orphan therapies show higher availability

## In Costa Rica, orphan therapies remain highly restricted, while non-orphan therapies show relatively better uptake, particularly in Oncology

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




- Orphan therapies show very limited local availability, with no fully available molecules across any TA, indicating that approved orphan products rarely translate into broad system access
- Access to orphan therapies is concentrated in limited and, in some cases, private channels, as seen in CNS and CM, suggesting that rare-disease treatments depend more on restricted access pathways than on formal system integration
- This pattern reflects limited innovation inflow and weak conversion into access, likely driven by budget constraints and limited system capacity to absorb high-cost, low-volume therapies
- Non-orphan therapies perform better than orphan therapies, particularly in Oncology, where 6 molecules are fully available and 6 are limited, showing that higher-priority, broader-demand areas are more likely to achieve some level of access
- Even so, performance outside Oncology remains uneven, with only 1 fully available molecule in I&I and CNS, and none in CM, indicating that broader population need does not automatically translate into stronger access

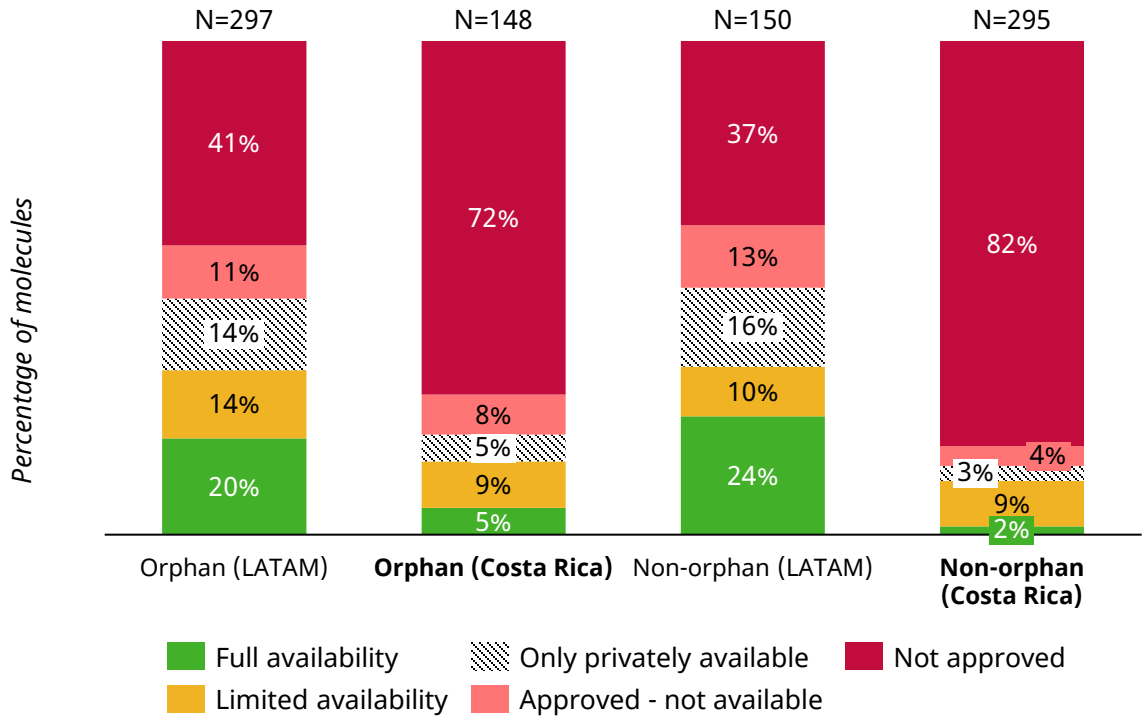
*In Costa Rica, non-orphan therapies achieve better local availability than orphan therapies, suggesting that access is shaped more by selective prioritization of therapies with clearer demand than by rarity*

* 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

## Costa Rica shows markedly lower availability than LATAM in both orphan and non-orphan therapies, driven primarily by very high non-approval rates

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



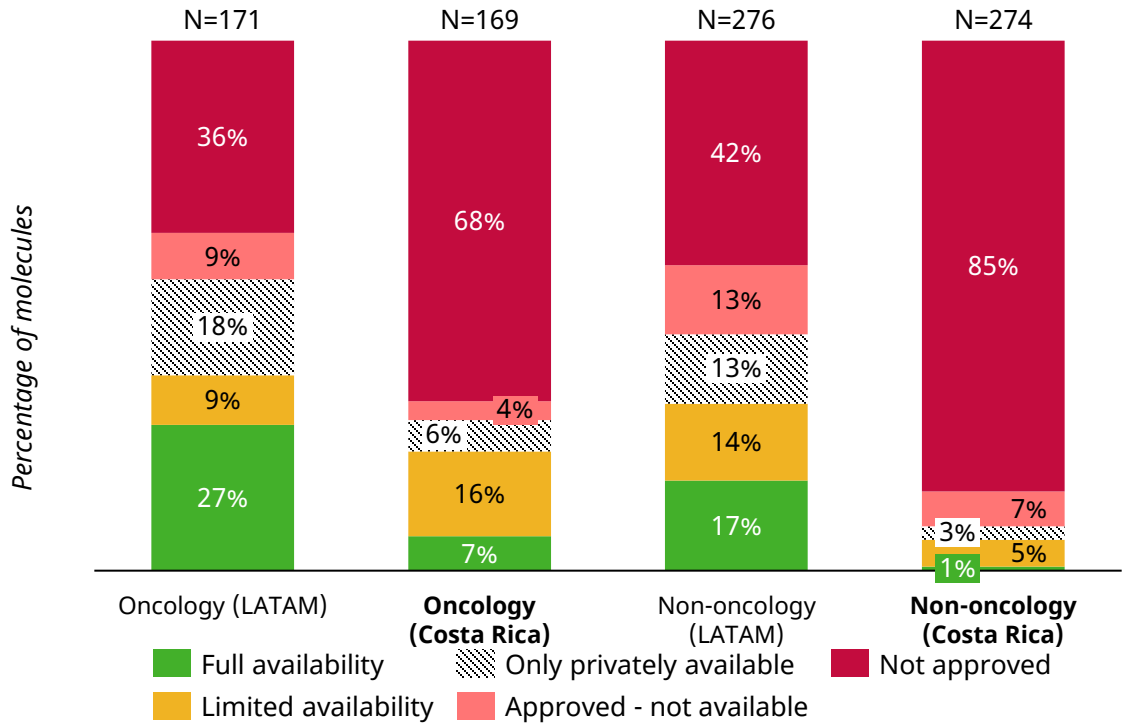

- Costa Rica underperforms LATAM across both orphan and non-orphan therapies, with only 5% full availability in orphan vs 20% in LATAM, and 2% in non-orphan vs 24% in LATAM, indicating very limited conversion into accessible treatments.
- The largest gap is in non-orphan therapies, where 82% of molecules are not approved vs 37% in LATAM, showing that innovation intake is particularly restricted in higher-volume disease areas
- Orphan therapies also remain highly constrained, with 72% not approved vs 41% in LATAM, suggesting that the country's access challenge stems not only from funding choices, but also from a much narrower entry of innovation into the system
- Orphan therapies perform only slightly better than non-orphan therapies once in the system, with 5% vs 2% full availability, but both segments remain overwhelmingly concentrated in non-approved molecules, indicating that upstream bottlenecks dominate
- Costa Rica also shows lower shares in private and limited availability than LATAM, suggesting that the challenge is not merely restricted access pathways, but a more fundamental limitation in bringing therapies into the market at all

*Costa Rica underperforms across both orphan and non-orphan therapies, indicating that limited access is driven primarily by restricted innovation intake and weak conversion into availability*

# Oncology outperforms non-oncology in Costa Rica

## Oncology shows relatively stronger conversion into availability than non-oncology, but both segments remain heavily constrained by very high non-approval rates

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



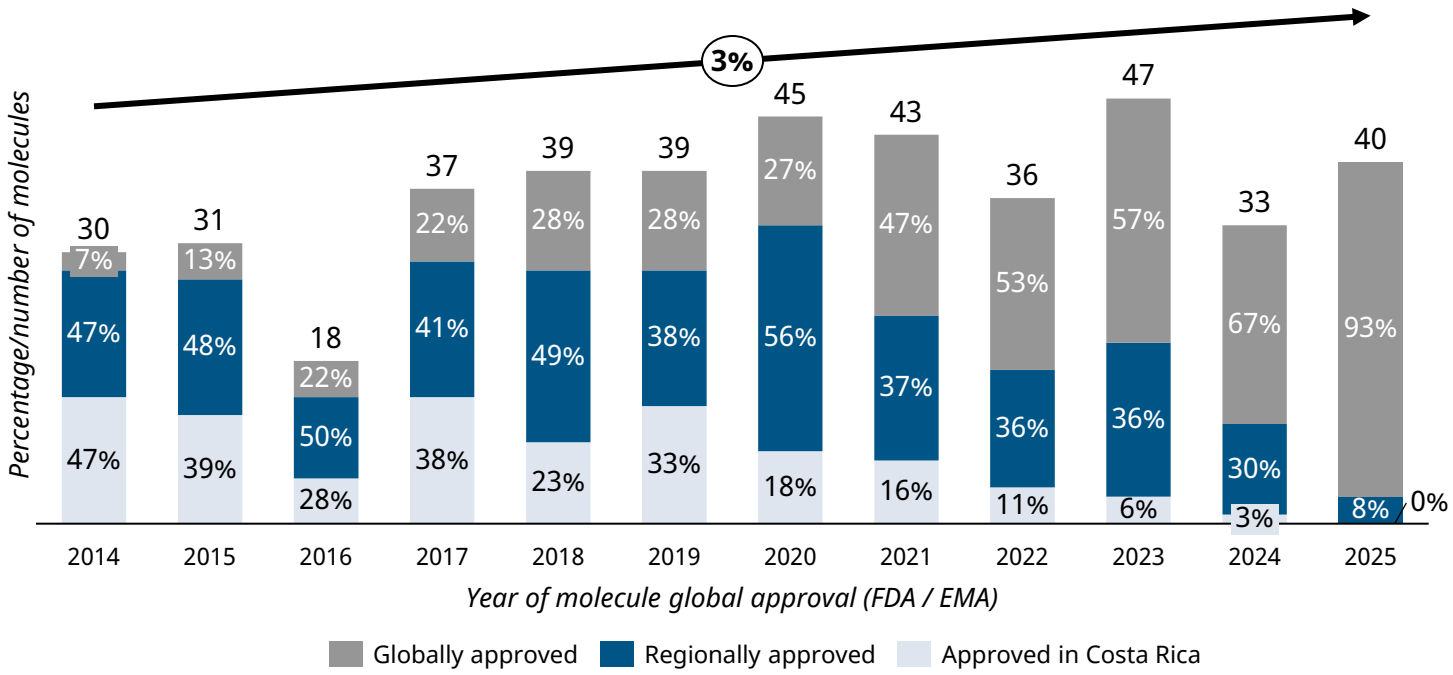

- Oncology performs better than non-oncology in Costa Rica, with 7% full availability and 16% limited availability, compared with just 1% full and 5% limited in non-oncology, indicating stronger prioritization of cancer therapies
- However, oncology remains well below LATAM, with 7% full availability vs 27% in LATAM and 68% not approved vs 36%, showing that even the better-performing segment faces major constraints in innovation intake and access
- The presence of 6% only privately available oncology molecules suggests that when access exists, it is often mediated through restricted channels rather than broad public coverage
- Non-oncology is far more constrained, with 85% not approved and only 1% full availability, reflecting weaker prioritization and tighter system capacity for broader disease areas
- Compared with LATAM, the non-oncology gap is particularly severe, as Costa Rica shows much lower full availability (1% vs 17%) and far higher non-approval (85% vs 42%), pointing to a narrow access outside oncology

*In Costa Rica, Oncology achieves relatively better availability than non-oncology, but both segments are held back by very high non-approval rates, indicating that limited innovation intake, not only downstream access, drives the country's weak availability profile*

# New medicines increase, approvals are lagging behind

## Rising global approvals contrast with consistently low local approval levels, with recent cohorts showing minimal conversion over time

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
- Costa Rica follows a similar downward trajectory in approvals, consistently lagging the regional benchmark with discrepancies ranging from 38% difference from the regional approval
- 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 Costa Rica, reaching 93% regional and 47% Costa Rica availability for 2014 cohorts, metric that continues to decline indicating persistent barriers
- 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

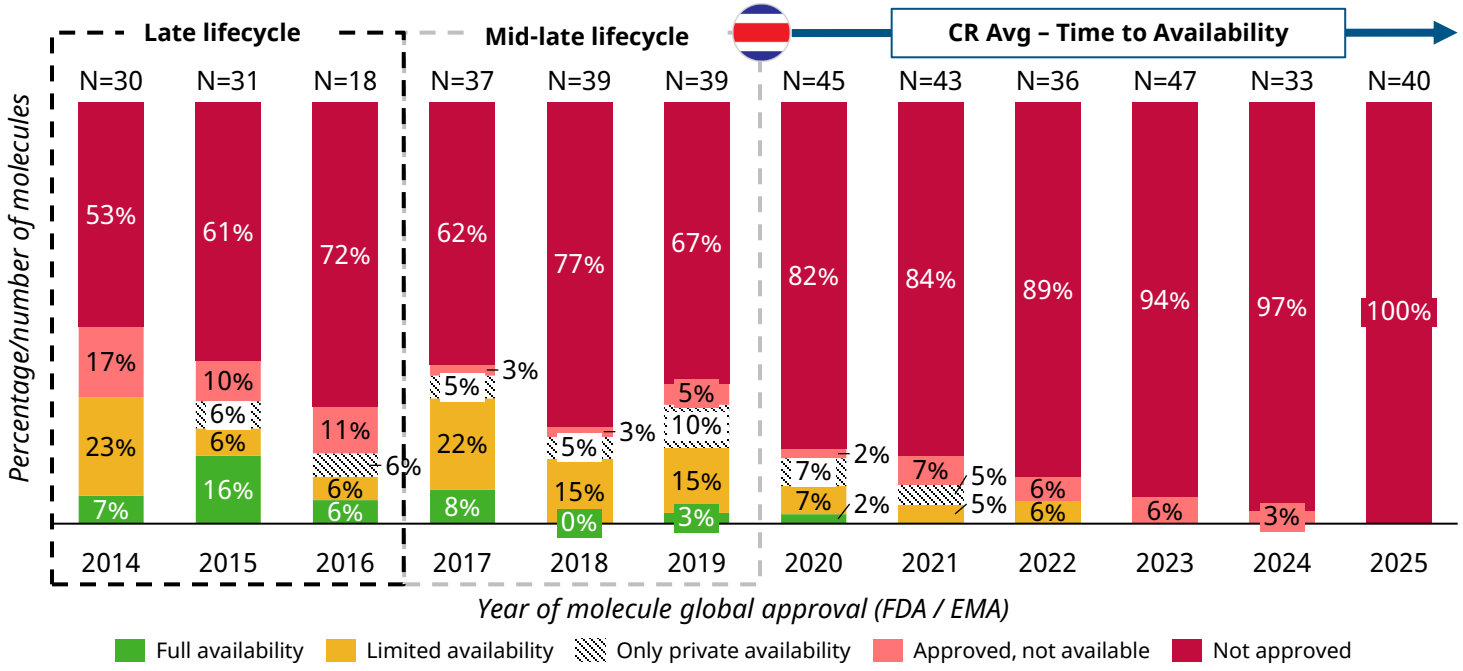
*Approval rates are declining in the region, whilst global approvals are increasing; the gap will continue to widen without concerted action*

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

# Even for older technologies, access is highly challenging

## Partial access pathways persist in early cohorts but do not translate into sustained full availability, while newer therapies are increasingly not approved

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




- Full availability remains consistently low across all cohorts and declines in recent years, dropping from 16% in 2015 and 8% in 2017 to just 3% in 2019 to 0% from 2021 onwards, indicating persistent challenges in achieving broad access
- The share of not approved molecules increases even further for newer cohorts, rising from 53% in 2014 to 62% in 2017, 82% in 2020, and 100% in 2025, highlighting the challenges in reaching consensus on both submission and approval
- Approved but not available therapies also represent a substantial share in earlier cohort, peaking at 17% in 201; however, this category declines in representation in newer cohorts exemplifying the approval bottleneck in the system
- Limited and only private availability together constitute a meaningful portion of access for earlier cohorts but show volatility over time, with no clear upward trend, indicating inconsistent pathways to partial access
- The overall distribution shifts toward lower access over time, with recent cohorts increasingly concentrated in not approved and unavailable categories, pointing to a growing backlog and widening access gap despite ongoing innovation

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

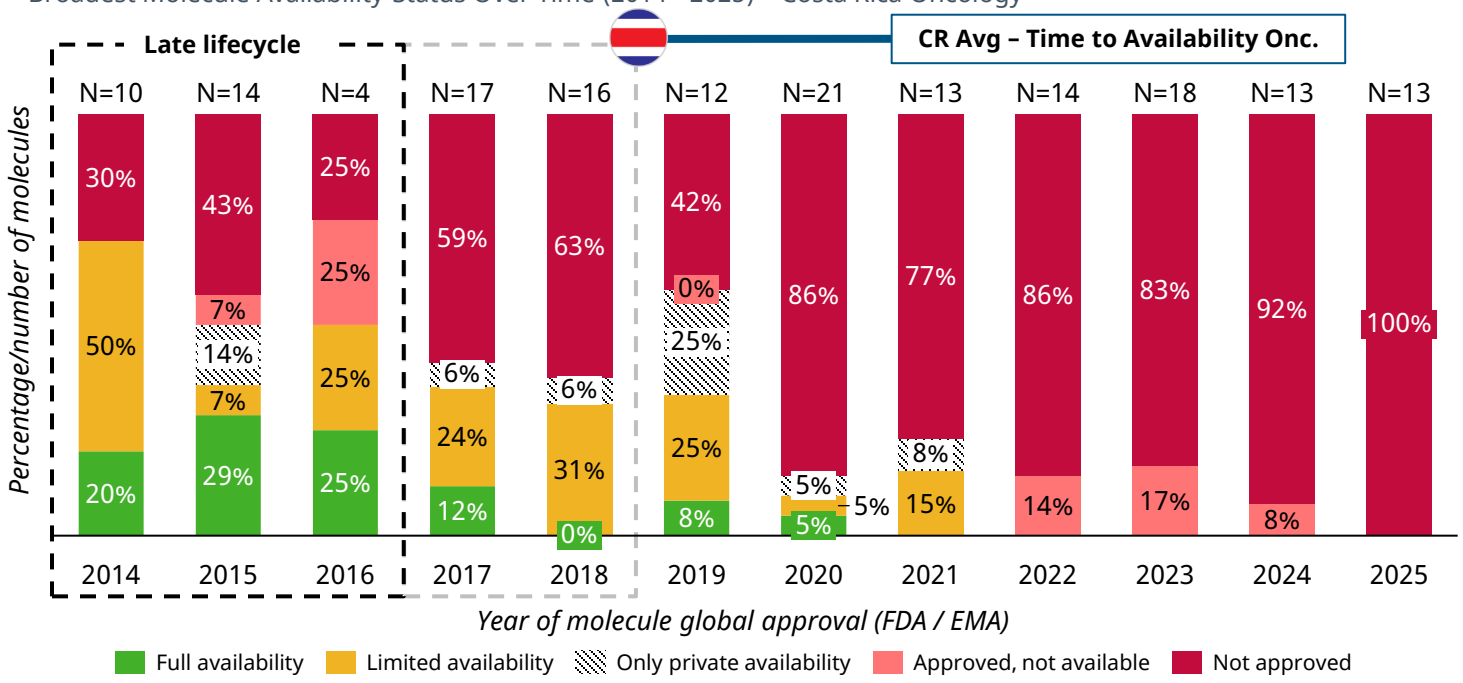
*- ex-Minister of Health*

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

# Oncology access is limited, early reliance on partial pathways

## Older cohorts show meaningful access through limited and private channels, but newer therapies are increasingly not approved and fail to enter the system

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




- Full availability of oncology molecules in Costa Rica start strong in late lifecycle molecules and declines over time, falling from 29% in 2015 to 12% in 2017, 8% in 2019, and 0% from 2021 onward; older technologies are the only ones that can secure relatively high levels of adoption and full access
- The share of oncology molecules that are not approved rises sharply in recent years, increasing from 30% in 2014 to 86% in 2021, 83% in 2023, 92% in 2024, and 100% in 2025; having volatile behavior for late and mid lifecycle molecules
- Private-only availability represents an important access pathway for earlier cohorts, accounting for 14% in 2015 and 25% in 2019, suggesting that partial access is achieved outside the public system for specific therapies
- In early cohorts, limited availability represents a significant portion of access, 50% in 2014 31% in2018 and 25% for 2016 and 2019, indicating that oncology treatments often reach patients through restricted pathways rather than full system integration
- Over time, access shifts away from partial pathways towards non-entry, with recent cohorts increasingly concentrated in not approved categories and minimal presence of limited or private availability, with no availability for cohorts after 2021

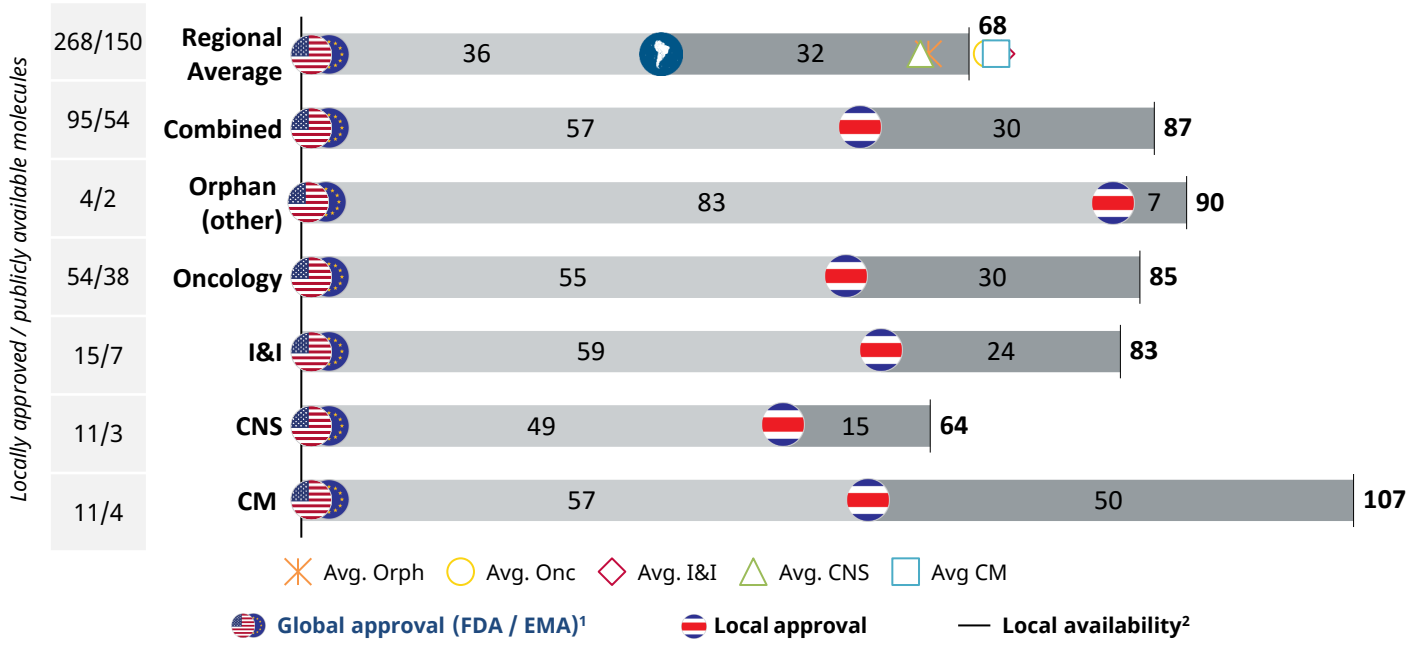
*Costa Rica's oncology access relies on partial pathways for older therapies, while newer innovations increasingly fail to enter the system*

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

# Access is a long and fragmented process

## The time to availability in Costa Rica averages 7.3 years, with a time to approval of 4.8 years and a time to availability of 2.5 years

Time to Availability from Global Approval (2014 - 2025) – Costa Rica 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 Costa Rica reaches ~87 months (~7.3 years), widely surpassing the regional average (68 months), confirming that patient access remains significantly delayed mainly driven by long approval times
- Most of the delay afflicting Costa Rica is at the approval stage (57 months vs. 36 months regional), indicating that the primary bottleneck for access is the local regulatory system
- Post approval timelines closely align with the regional benchmark, with slightly faster process (30 months vs. 32 months regional) suggesting that once therapies are approved, progression to availability is relatively more efficient
- CM therapies experience the longest timelines (107 months), with both approval (57 months) and post-approval (50 months) contributing, reflecting the complexity and budget impact of these treatments, differing significantly from the region's average
- Orphan therapies show particularly long approval timelines (83 months), despite relatively short post-approval phases (7 months), highlighting significant delays at the entry stage for low-volume, high-cost treatments

*Costa Rica's access delays are driven primarily by slow entry into the system, rather than inefficiencies after approval in most therapeutic areas*

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 approval delays

## Approval timelines are worsening across therapeutic areas, while availability shows partial improvement, resulting in longer overall time to access

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

| | Approved | Available | Total |
|---|---|---|---|
| Regional average | -5.6% | +9.4% | +1.5% |
| Combined | +8.8% | -3.3% | +4.6% |
| Orphan (other) | +16.9% | +42.9% | +18.9% |
| Oncology | +5.5% | -10.0% | - |
| I&I | +6.8% | +4.2% | +6.0% |
| CNS | +6.1% | +6.7% | +6.3% |
| CM | +17.5% | -10.0% | +4.7% |

- Costa Rica shows a +8.8% increase in time to approval vs. 2025, resulting in a +4.6% overall delay, despite the reduced time to availability; impacting directly on wait time for patients to access treatments compared to the year prior, driven by prolonged access decisions
- This pattern inverts the regional trend, where approval timelines improved (reduced by 5.6%) but availability timelines worsened (increased by 9.4%), noting a different challenge for Costa Rica, mainly focused on the effectiveness of the approval process
- Delays are not uniform across therapeutic areas, with: Orphan therapies (+18.9%) showing the largest increase, reflecting specific limitations on the access to specific or specialized treatments; I&I (+6%) and CNS (+6.3%) also experiencing deterioration, evidencing chronically evolving systemic strain
- CM and Oncology molecules show some improvements on availability (-10%) which partially offset the general delays, but they do not reverse them
- There are isolated improvements, but the overall trend indicates that system capacity is not keeping pace with innovation inflow, resulting in slower transitions from approval to availability

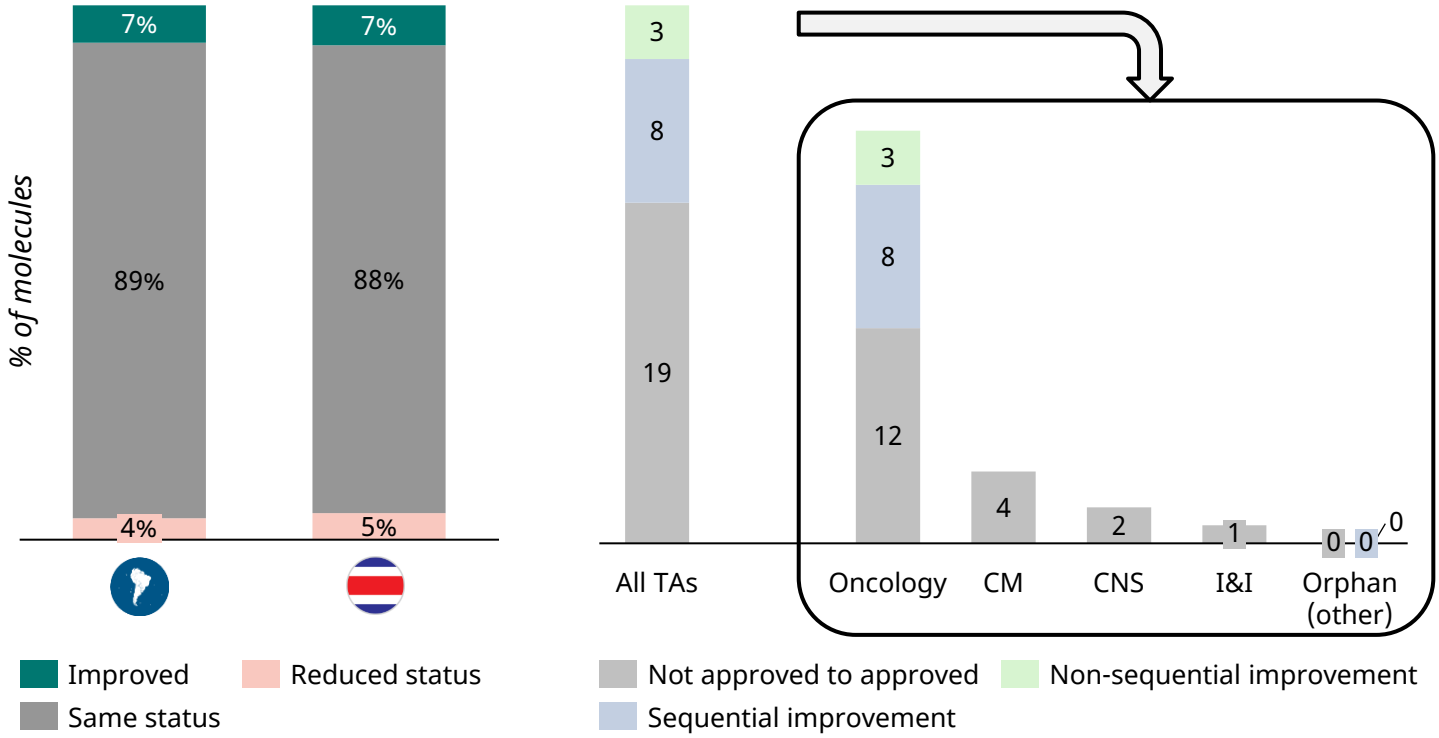
*In Costa Rica, both access and approval times are increasing with specific exceptions, with system constraints and budget pressures slowing the transition from innovation to patient access, particularly in high-impact therapeutic areas*

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

# Costa Rica mirrors the regional trend

## Access progression remains limited, with few therapies improving and most maintaining their status across therapeutic areas

Improvement Index Costa Rica (2026 vs 2025)




- Costa Rica's improvement rate is fully aligned with the benchmark both 7%; progression in the country follows the same pace as the broader LATAM market
- These gains, similarly to the region, do not offset that most molecules (~88%) remain in the same access status, with many remaining in the approval stage; highlighting that the access process remains mostly static for Costa Rica
- A portion of molecules (~5%) experienced reduced status, consistent with the regional benchmark (~4%); this can represent molecules that have become obsolete due to clinically superior options becoming available, competitive dynamics, etc.
- Progression of status in Costa Rica is mainly focused on oncology, where most changes of status are reached; with a healthy distribution between approvals, sequential, and non-sequential improvements
- Other therapeutic areas show smaller but consistent progress mainly focused on change of approval status

*Costa Rica mirrors regional trends, with limited but consistent improvement and no acceleration beyond the broader market pace*

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

# Recent system reforms are strengthening structured access

## Recent regulatory, purchasing, and procurement reforms are improving system structure and planning

Recent Health Reforms in Costa Rica



### Costa Rica is introducing structured mechanisms in regulation, purchasing and procurement

- Strategic purchasing pilot within CCSS resource allocation
- Expanded use of reference-authority evidence in medicine registration
- Strengthening of DRPIRS within the Ministry of Health
- Public procurement modernization under the General Public Procurement Law and SICOP

- Costa Rica's Social Security Fund (CCSS) began piloting a strategic purchasing model in its 2024 budget, moving away from historical budgeting toward a model that links resource allocation more closely to population needs, service delivery, and performance
- Costa Rica's Ministry of Health has an established virtual sanitary registration process for medicines, and the official registration framework explicitly includes procedures for mutual recognition of sanitary registrations and use of reference regulatory authorities for medicine registration
- A recent PAHO note highlights that Costa Rica reformed the organic regulations of the Ministry of Health, strengthening the DRPIRS with a renewed organizational structure, more specialized personnel, and clearer functional responsibilities
- Costa Rica has also modernized the public purchasing framework through the General Public Procurement Law (Ley No. 9986) and the expansion of the Integrated Public Procurement System (SICOP) as the central digital platform for state procurement

*Costa Rica's recent reforms point toward a more structured access model, but their value will depend on how effectively regulatory strengthening, strategic purchasing, and procurement modernization are translated into practice*

Sources: Global Health Expenditure Database, International Trade Administration, OECD, WHO, PAHO
Acronyms: CCSS: Caja Costarricense de Seguro Social; DRPIRS: Dirección de Regulación de Productos de Interés y Riesgo Sanitario; SICOP: Sistema Integrado de Compras Públicas; PAHO: Pan American Health Organization

# Costa Rica’s regulatory system is structured and strengthening

## The Ministry of Health is reinforcing DRPIRS as its core regulatory body, while expanding the use of reference-authority evidence and regional harmonization mechanisms

Global Reliance of Costa Rica’s Health Agencies



Ministerio de Salud Costa Rica

**Global Reliance**

*Costa Rica’s Ministry of Health is strengthening DRPIRS as the technical backbone of regulation*

- Costa Rica is strengthening its main technical regulation body the DRPIRS within the Ministry of Health; its reform in 2025 is noted by PAHO as a key enabler for a more reliable regulatory process
- Costa Rica’s registration pathway is increasingly supported by external reference-authority evidence, as the Ministry of Health explicitly allows recognition of clinical and non-clinical evaluations performed by reference regulator; this expansion was intended to reduce evaluation times for registrations
- Regional harmonization is already embedded in the medicines framework, because the Ministry’s registration page cites the Central American Technical Regulation (RTCA 11.03.59:11) and the procedure for mutual recognition of sanitary registrations
- Costa Rica’s regulatory system is still strengthening rather than fully mature, with PAHO reporting that the country has used the WHO Global Benchmarking Tool (GBT) to identify gaps and define a maturity roadmap, and Costa Rican officials stating the aim is to become a level 2–3 authority

*Costa Rica is building a more capable and structured regulatory system through institutional strengthening of DRPIRS, selective reliance on reference authorities, and regional harmonization; but the model remains one of consolidation rather than full regulatory maturity*

Sources: Global Health Expenditure Database, International Trade Administration, OECD, WHO, PAHO
Acronyms: DRPIRS: Dirección de Regulación de Productos de Interés y Riesgo Sanitario; PAHO: Pan American Health Organization; WHO: World Health Organization

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Oscar Courtney is an Associate Principal in the Value and Access center of excellence supporting commercial, strategy and market access projects.

Oscar has over 10 years of consulting experience, with the last 5 at IQVIA working with global pharmaceutical companies.

Oscar graduated with a Bachelor of Commerce in Marketing and Bachelor of Science in Psychology from the University of New South Wales, Australia.

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**Celeste Palma – Real World Insights Lead, CENCA**

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Yaneth Giha is an economist from the Universidad de los Andes, with Master's degrees in Political Sciences from the Javeriana University and War Studies from King's College, London. She has held several positions in the Colombian public sector such as Minister of Education, Vice Minister of Defense, Director of Science and she served as Executive President of AFIDRO, prior to joining FIFARMA in May 2022 as Executive Director.



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Dr. Diego Guarin is the Regional Market Access Lead for LATAM and is a founding member of the ISPOR Colombia chapter, also having served as chair of the ISPOR Latin American Consortium Industry Committees and Advisory Board. Dr. Guarin graduated as Medical Doctor from Universidad del Rosario-1653 (Colombia) and holds various master's degrees.



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Silvana has over fifteen years of management experience. Silvana is a forestry Engineer with a Master of Business Administration (M.B.A.) focused on International Business from Tulane University - A.B. Freeman School of Business.

## 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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