White Paper

FIFARMA Patient W.A.I.T. Indicator 2024 — Latin America

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Overview

- 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 eight 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 third 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 365 innovative molecules globally approved* from 2014-2023, 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.

*In this study the term **'availability'** is used throughout to permit **standardized measurement** across 10 healthcare systems*

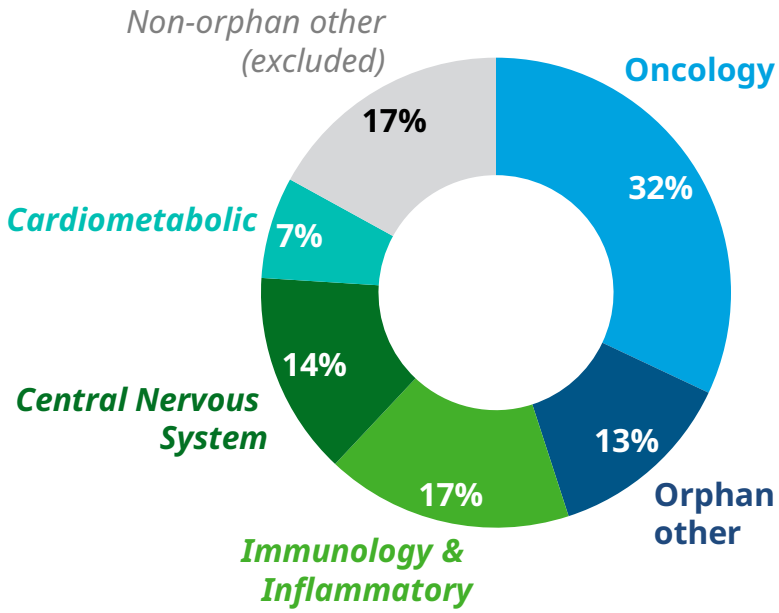
***Availability** represents the local reimbursement of a globally approved innovative medicine*

*Global approval is defined as a molecule that has regulatory approval in the United States of America by the FDA, or in Europe by the EMA
**NAS refers to New Active Substances as defined by the IQVIA Institute, see appendix for definitions and selection criteria
Acronyms: FDA: US Food & Drugs Administration; EMA: European Medical Agency

Methodological considerations

A total of 365 new active substances approved between 2014-2023 by FDA/EMA across five therapeutic areas are analyzed

Molecule selection by therapeutic area 2024



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

- A total of 365 molecules were selected based on several primary criteria:
  - New active substance
  - FDA or EMA approved between 2014-2023
  - 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

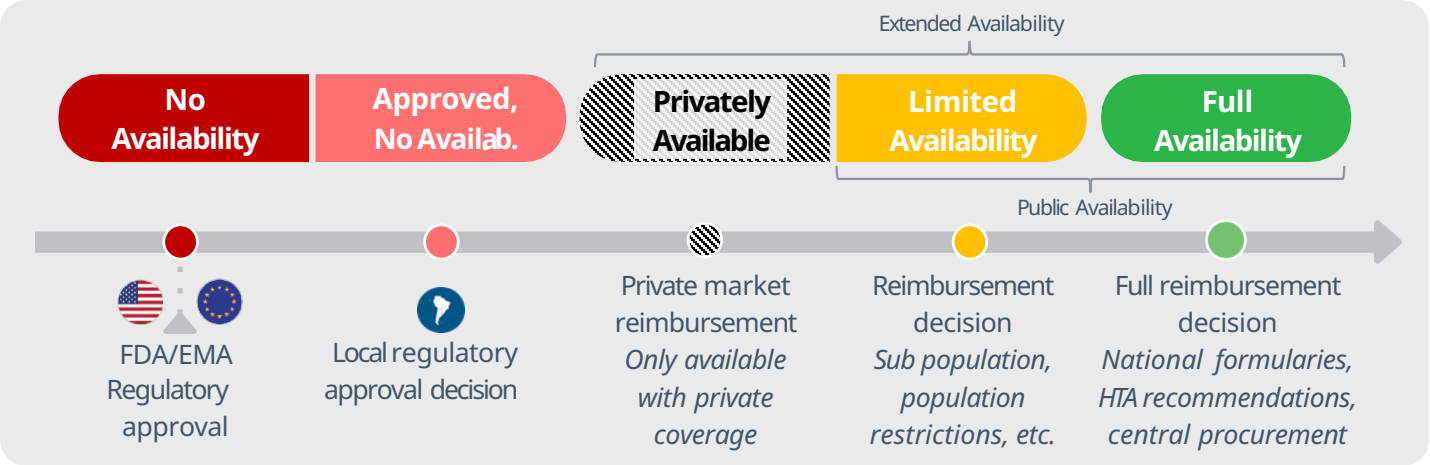
Orphan status may be determined by either the FDA or EMA

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

Methodological considerations

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

Availability definitions



NO AVAILABILITY

Not submitted, or in regulatory evaluation process

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

APPROVED, NOT AVAILABLE

Commercially available, but not reimbursed

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

PRIVATELY AVAILABLE

Reimbursed in the private market only

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

LIMITED AVAILABILITY

Reimbursement but not for a broad population

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 otherwise not granted access according to the full registered therapeutic indication

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

Methodological considerations

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

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

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

Where not otherwise stated, date of first sale was used to indicate time to reimbursement

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

Methodological considerations

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

Metric	Research Question	Content
1 Time to Availability	***How long does it take for innovative medicines to become available?***	Time from global regulatory approval to local approval, and local avaliability
2 Availability Status	***What is the availability of innovative medicines across LATAM?***	Breakdown of availability across the region, by country and by therapeutic area
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 2023 W.A.I.T. to 2024 W.A.I.T.

Important considerations

1. The study results reflect a snapshot of the **current availability of innovative medicines in LATAM** as of the 1st of September of 2024, 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*** captured, and >80% of Latin America's population across ten countries

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

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

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

Summary of key metrics from the study

Time to Availability

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

- Total time to availability is on average 57 months between the countries in scope, which reflects the total of time to marketing authorization and time to reimbursement (public or private), as of FDA/EMA approval
- Time to availability, post-marketing authorization, is 24 months on average between the countries in scope
- As with regional availability, wide disparities also exist between countries in terms of time to availability, with CR on the low end at an average of 45 months, and MX and CO on the high end, with an average of 64 months
- Comparing across TAs, orphan drugs are typically the fastest to reach availability after local marketing authorization, although there is variability by country

Patients on average have been waiting almost 5 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 (see page 4)

- 61% of molecules that are globally approved are approved in at least one of the geographies in scope in LATAM, though wide disparities exist between countries
- 35% of molecules have a degree of availability in the public market in at least one market, whilst a further 14% are available with private coverage

Availability Over Time

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

- <50% of molecules from 2018 onwards have public availability in at least one country
- <40% of molecules from 2021 onwards are approved, driven by BR and AR

Improvement Index

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

- From 2023 to 2024, 86% of molecules did not change in availability status
- 13% of molecules improved availability status

Key takeaways

There is a long, fragmented road to access

Patients on average wait ~3 yrs for a medication to be approved and a further ~2 yrs for access, often through the private sector initially, limiting coverage to a subset of the population

The majority have access to a fraction of molecules

There are wide disparities in availability between countries, broad public reimbursement is widely variable, ranging from 2-98% but so too is the percentage of globally approved molecules that are locally available 15-48%

Challenges are likely to be exacerbated as innovation increases

Public availability for molecules from 2014-2018 was 57-74%, whereas from 2019-2023 it was <50%, meanwhile global approvals have been increasing, potentially compounding challenges in the future

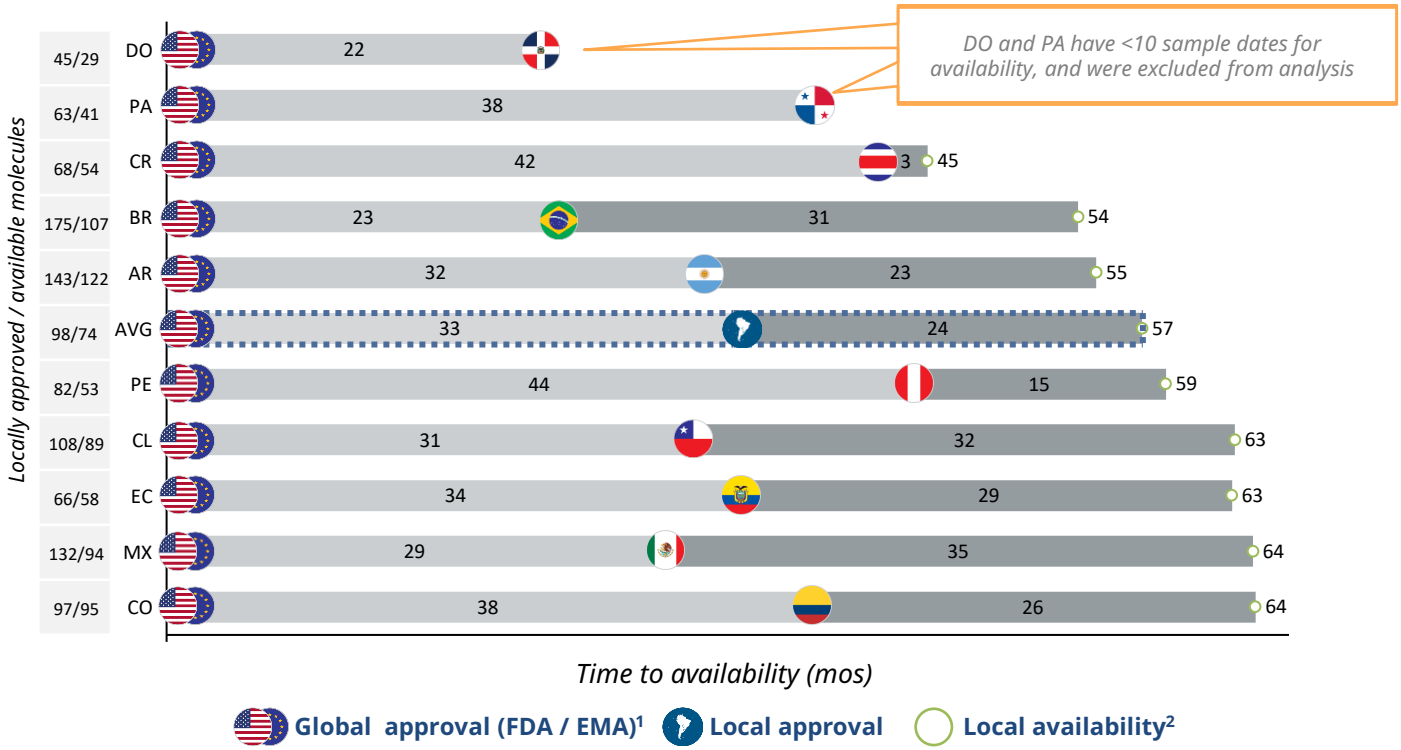
Slow and steady doesn't always win the race

13% of molecules improved in availability from 2023-2024, >75% of which were sequential improvements; this shows that paths to availability exist, however, it is a challenge to navigate them, with many molecules remaining static

Time to availability

There is a long, fragmented pathway for innovative medicines to achieve broad reimbursement, averaging close to 5 years in the region

Time to availability from global approval (2014 - 2023) – combined



- The average time to local approval is 33 months, close to 3 years after global regulatory approval (first of either FDA or EMA), though this does not consider at what time the laboratory filed a submission
- Wide disparities exist between countries, with Brazil and Dominican Republic on the low end, at an average of under 2 years, and Peru on the high end, with just under 4 years
- The average time to local availability is 24 months, or 2 years; this considers between the date of local approval and the date of first availability (public or private), and only considers the first indication
- As with regulatory approval, countries differ greatly in time to availability; Costa Rica generally sees national formulary listing shortly after regulatory approval, at an average of 3 months, whereas Mexico, Chile and Brazil are toward the high end at >2.5 years
- Though both approval and availability timelines vary by country, overall time to availability ranges from approximately 4-5.5 years across the region

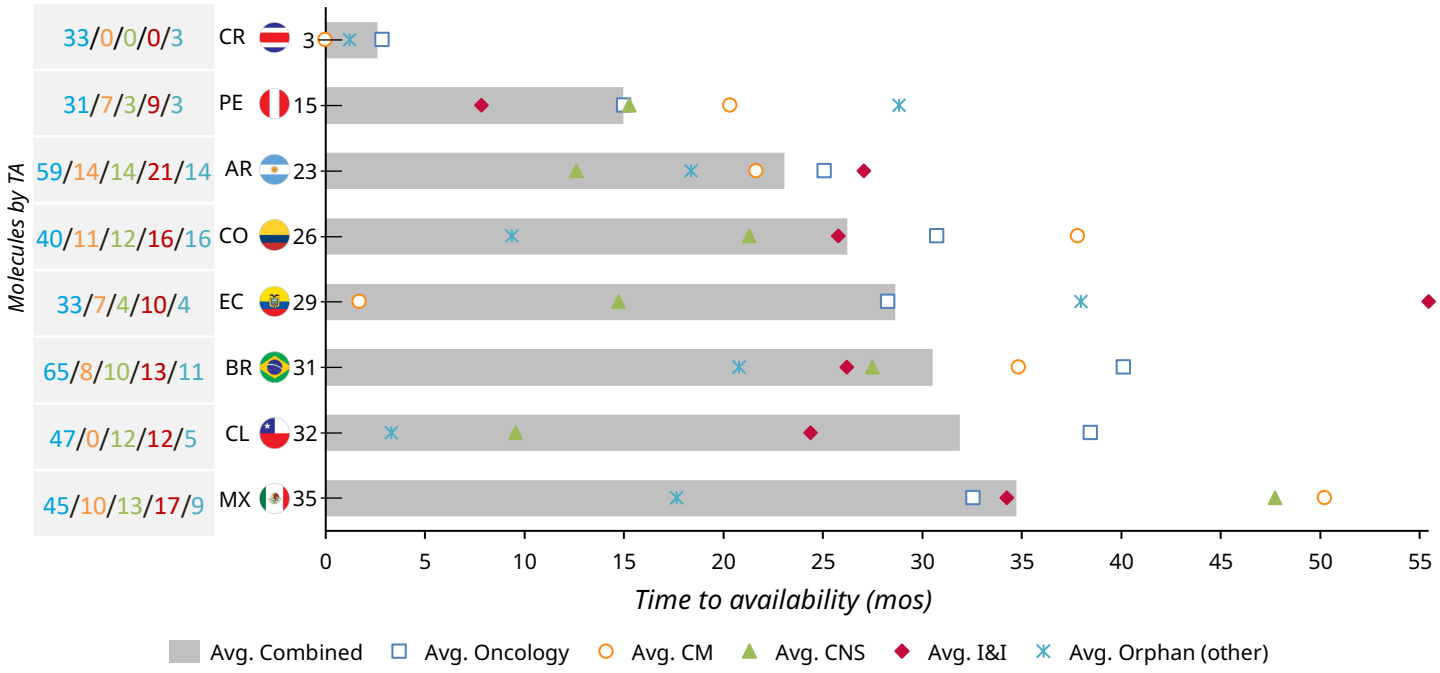
Date of first availability is just the tip of the iceberg for patients who depend on public healthcare; for many molecules it represents just the first of several therapeutic indications and in many countries, access for only a subset of the broader patient population

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

Time to availability

Orphan molecules tend to have a shorter time to availability after approval, compared to non-orphan molecules

Time to availability from local market authorization (2014 - 2023) – by TA



- There is a wide variability by TA across almost all countries, except Costa Rica where national formulary listing is typical post-marketing authorization
- Ecuador has the widest range, where cardiometabolic is on average 2 months vs. I&I at 55 months
- For Costa Rica, Brazil, Colombia, Chile, and Mexico, orphan drugs are the types of molecule with shortest time to availability when compared to other TAs, though between countries it ranges from 3 months in Chile, to 21 in Brazil
- TAs with the longest time to availability is inconsistent across countries, oncology is the longest in three instances (Costa Rica, Brazil, and Chile), and CNS is not the highest across countries
- Oncology does not feature amongst the fastest times to availability in any of the countries

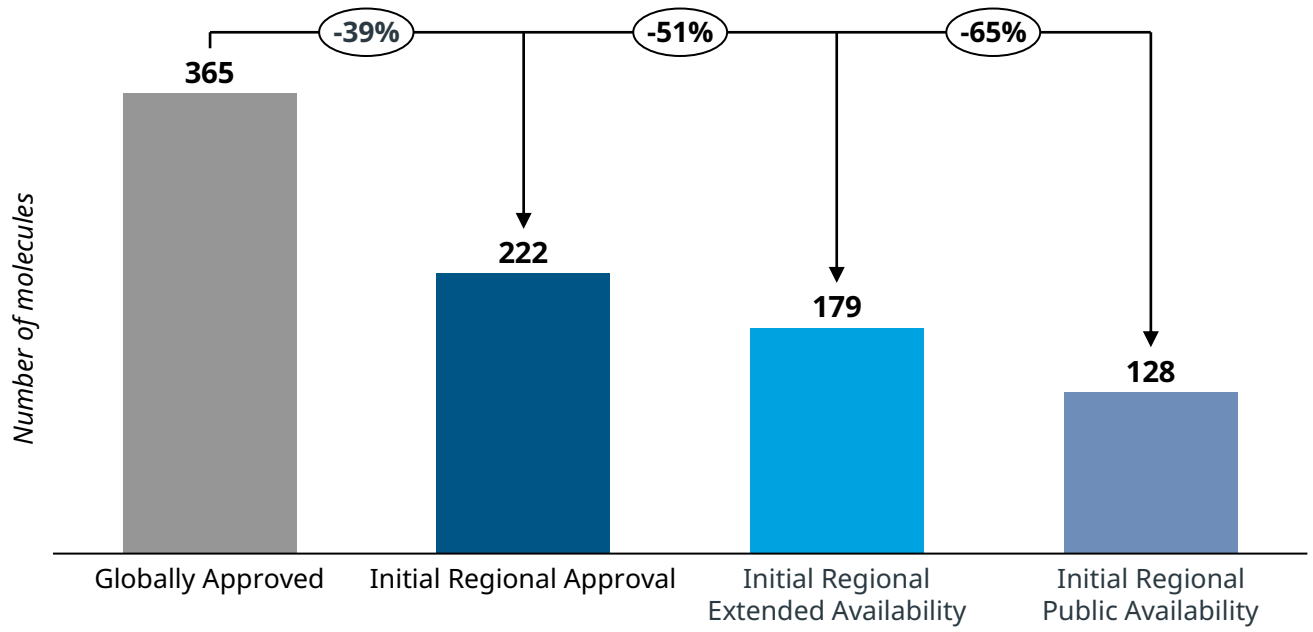
Broader, public availability is typically a drawn-out process, particularly in countries where there is a relatively large private market participation, illustrating challenges for patients in the public system in these countries

* DO and PA have no sample dates for availability
Acronyms: TA: Therapeutic Area; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammatory and Immunological

Regional availability

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

Breakdown of initial regional availability (2014 - 2023) — combined



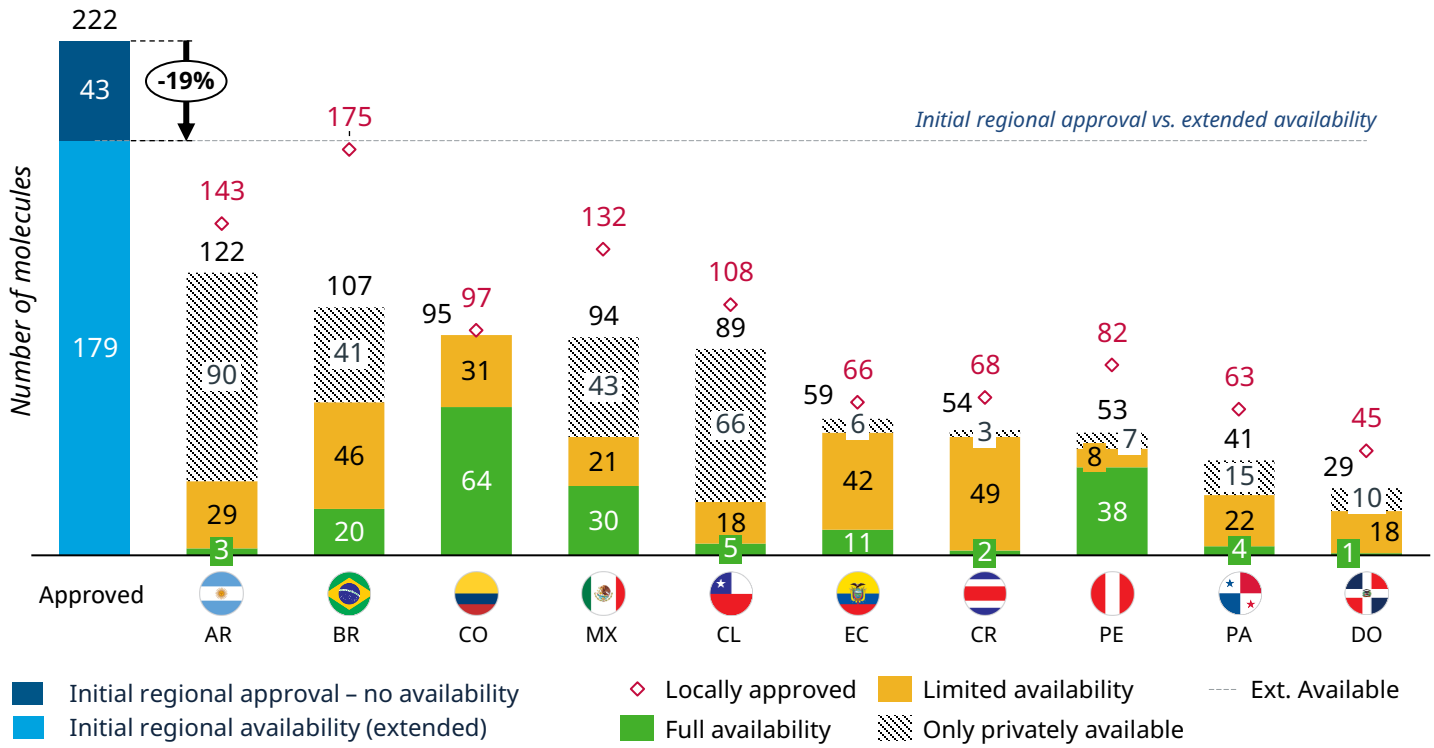
- Initial regional approval and availability represents the first time a molecule is approved or becomes available in the region
- Overall, there is a large gap between globally approved molecules and those that become available in the region in even just one country
- Out of 365 molecules, 61% of these are approved for commercialization in at least one of the ten LATAM countries in scope
- 49% have extended availability, meaning these molecules have some level of availability between public (full or limited) and/or private markets in at least one country
- 35% of globally approved molecules are available publicly, whether that be limited or full availability, in at least one country in the region
- Drivers of lower rates of approval and availability include a complex and/or lengthy regulatory submission/review process; the gap is mainly derived from the newest molecules to be globally approved

Patients across LATAM do not have access to over half of the globally available innovative medicines through the private sector, that trend is worsened when looking at the public sector where the majority of patients are covered

Regional availability

Wide differences exist in availability between countries; Brazil drives initial regional approval, Colombia initial public availability

Breakdown of local availability (2014 - 2021) — combined



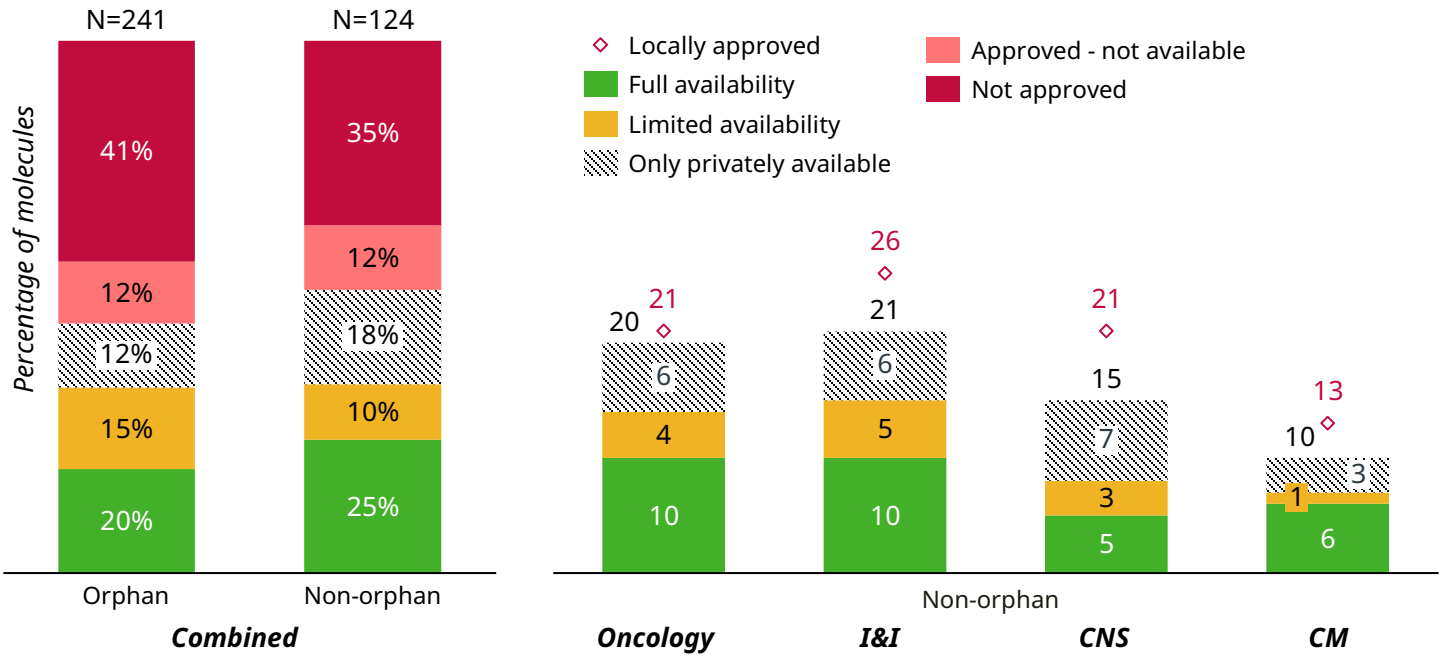
- There is a gap of 19% between molecules that are approved in at least one country in LATAM, and those that are available
- The trend in approvals vs. availability is not consistent across countries; Brazil, Mexico, Peru, Dominican Republic and Panama show a more pronounced gap between approvals and availability
- Argentina, Chile 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
- Colombia has the highest levels of public availability by a wide margin, followed by Brazil, Mexico, Ecuador, Costa Rica and Peru, highlighting the stark differences in healthcare system structure, beyond overall economic size that can contribute to healthcare coverage in the broad, national population

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

Regional availability

Orphan generally has lower availability than non-orphan drugs, and accounts for two thirds of the overall cohort of molecules

Initial regional availability, orphan vs. non-orphan (2014 - 2023) – by TA



- 2/3 of the total cohort of molecules are orphan designated by the FDA or EMA, emphasizing the pervasiveness of launches in indications with smaller populations and then expanding to broader populations with subsequent indications, which can support initial access
- Overall, non-orphan molecules have a marginally higher availability rate for broad public access (25% vs. 20%) and approval rate (65% vs. 59%) when compared to orphan
- Orphan has a higher rate of limited availability, and the overall number of molecules that are approved but not available is relatively high (28); access for these relatively small populations of patients could be driven by managed access schemes, financial assistance and importations
- The overall trend for other TAs (not-including orphan drugs) is relatively consistent, except cardiometabolic where there is a higher proportion of molecules were available prior to 2020 (>50%)
- Oncology has the smallest proportion of approved, not available, likely driven by dedicated access routes/programs for oncologics

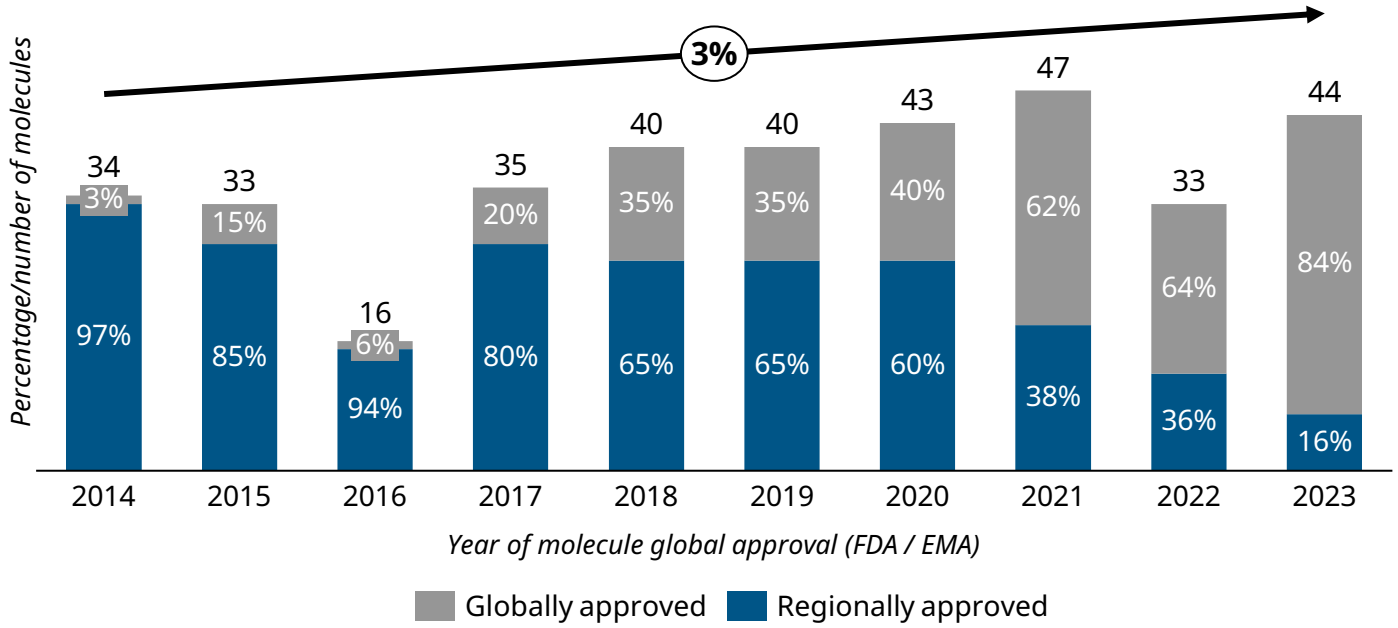
Patients often need to rely on means outside of traditional routes to access to obtain innovative medicines for orphan disease; though differences are relatively modest between TAs

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

Availability over time

Molecules that received FDA/EMA authorization after 2019 have a significantly lower authorization rate in LATAM

Initial regional approvals over time (2014 - 2023) – combined



- Overall, globally approved molecules have been increasing 3% on a year over year basis since 2014, despite significant dips in approvals in 2016 and 2022
- From 2014-2017, the rate of initial regional approval is ≥80%, showing that given enough time, molecules are generally approved in at least one country in the region
- From 2017 onwards, it drops from 80% to 16% in 2023 in a linear fashion, with a steep drop to below 50% in 2021
- In addition to the generally long, fragmented path to availability, two potential key drivers affect the 1) the impact of the COVID 19 pandemic, and 2) increasing clinical innovation

1) COVID19 caused significant strain on healthcare systems, which acted to exacerbate underlying systemic challenges

2) There is a broader trend toward increasing innovation over time, which compounded with the pandemic, is contributing to a backlog for local regulatory/HTA agencies and delaying further availability timelines

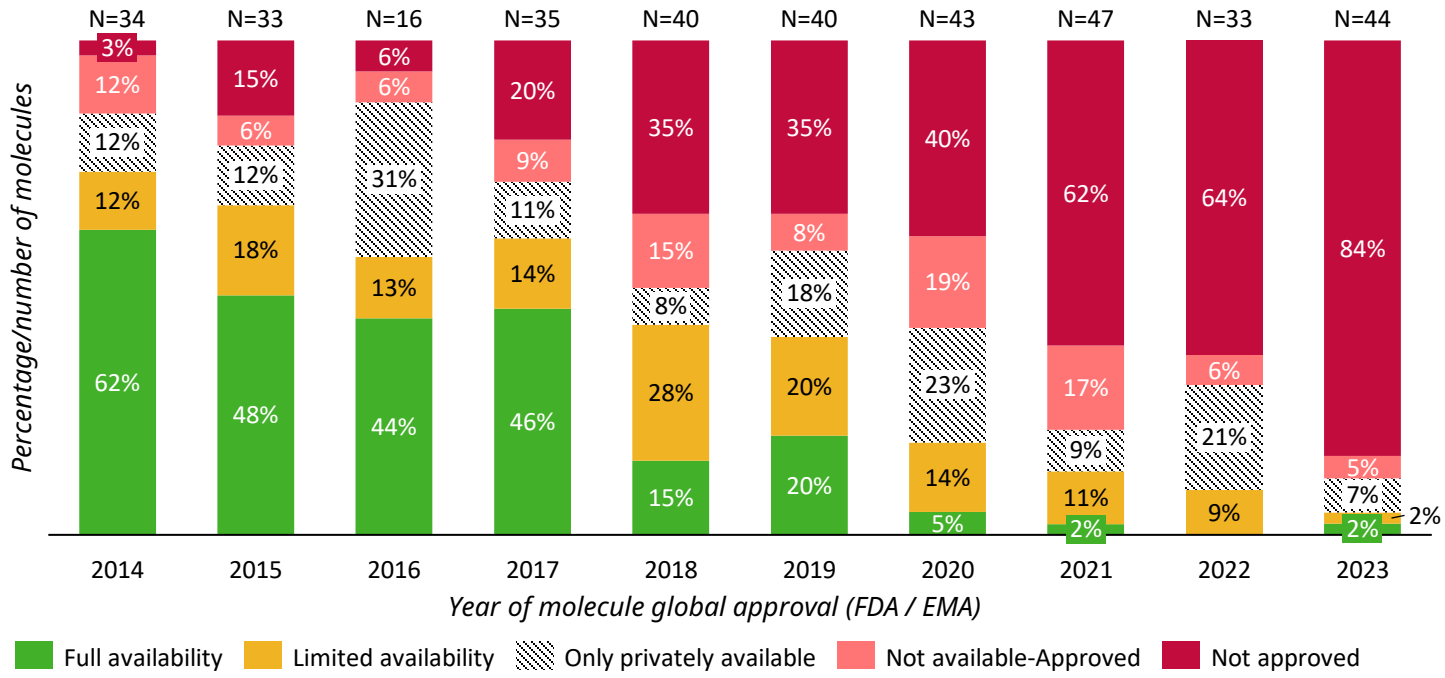
Given increasing clinical innovation and greater strain on budgets persisting after the COVID-19 pandemic, times for patients to access innovative medicines in the region may increase

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

Availability over time

Availability follows a similar trend with the highest maturity for those approved earliest, though with an additional lag, particularly in the public sector

Broadest molecule availability status over time (2014 - 2023) – combined



- The overall trend, though not completely linear, shows a general decrease in public availability and increase in molecules not approved from 2014-2023
- Once molecules have an initial approval, the proportion of molecules with availability is generally >80%, with the largest gaps between approval and availability from 2018-2021
- The highest variability, besides molecules not approved, is derived from broad public availability which ranges from 62% for molecules that received global approval in 2014 where it's at its highest, to 0% in 2022, highlighting the significant hurdles in reaching the broader population, even in a single country across the region
- privately available and limited availability percentages do not have such wide ranges at a regional level, with only privately available molecules ranging from 7% in 2023, to 31% in 2016, and limited availability ranging from 2% in 2023 to 28% in 2018, though this trend varies significantly between countries

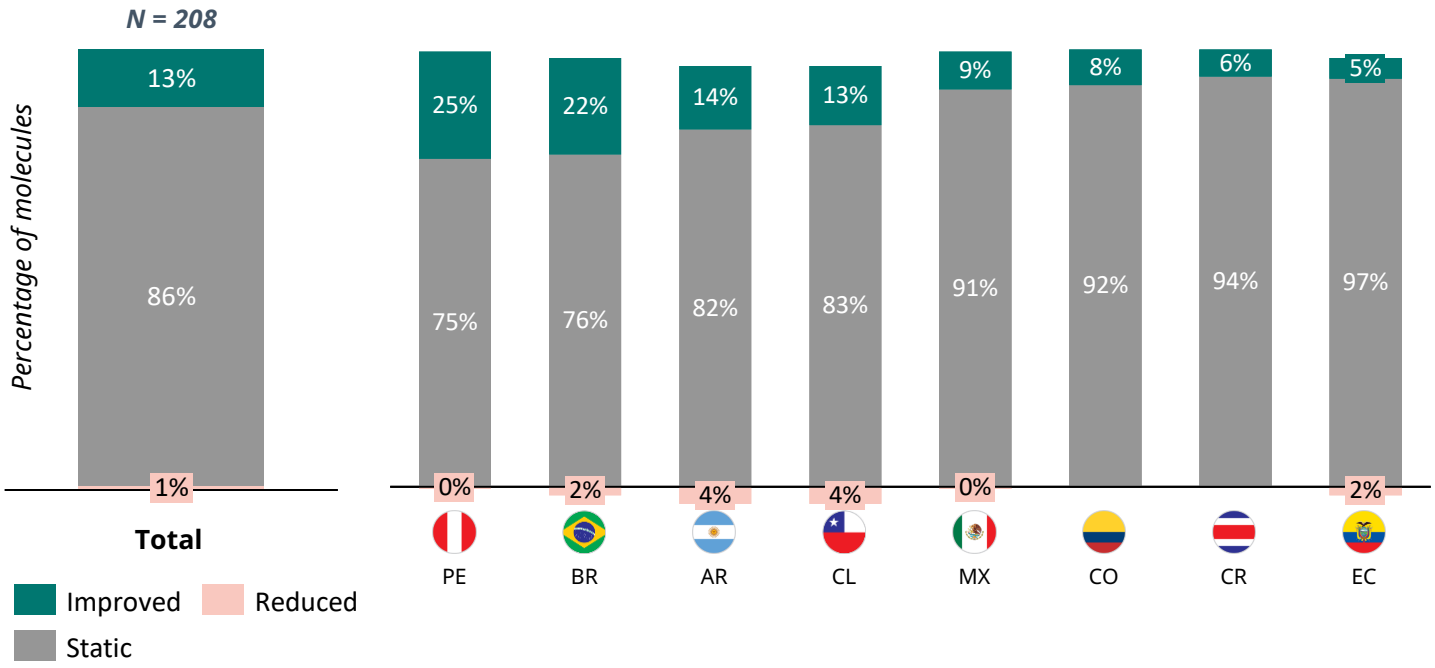
Availability for a limited subset of patients at a regional level is a stop-gap on the long road to broad, public access; however, there is no guarantee that broad access will be attained in any given country

In recent years, the number of fully available molecules has decreased, together with molecule approvals
Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Improvement index

From the 2023 W.A.I.T. Report to 2024, 13% of molecules improved in availability status, whilst 86% remained static – their status did not change

Improvement index by country (2014 - 2021) – oncology & orphan



- Overall, movement between availability status classifications varied by country, but <25% except in Peru, where policy reform for the RENETSA and centralized purchasing programs, enabled improvement for almost 50 oncology molecules
- Drivers of improvement across other countries are varied, but likely are for the most part a result of laboratories' submissions for innovative medicines, and outcomes being published from regulatory and HTA agency assessments
- Across remaining countries, improvement varied with Brazil following Peru at 24% movement, and then Mexico, Colombia, Costa Rica and Ecuador all <10% movement (summing improvement and reduction)
- Reductions in availability status in Argentina and Chile were mostly from limited availability to only privately available, and likely to have been driven by changes in clinical practice and corresponding shifts in public purchasing; in other countries reductions were minimal (<2%)

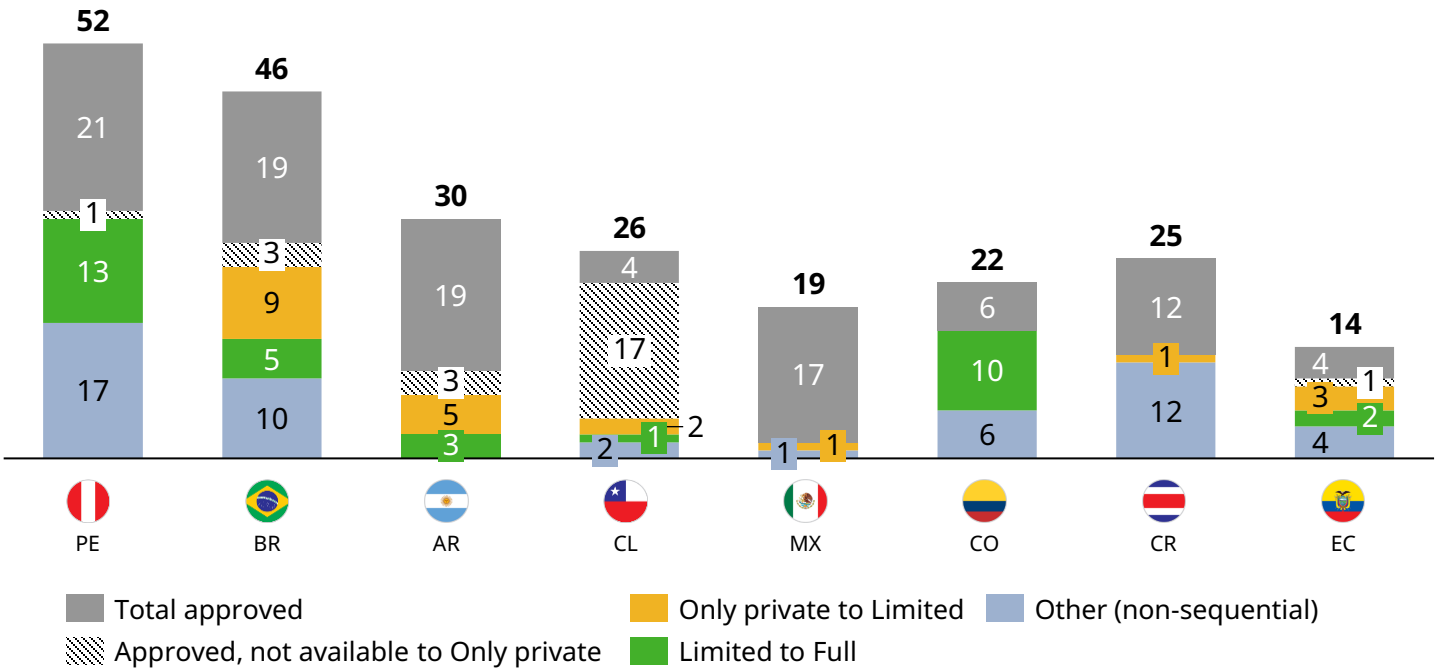
With increasing clinical innovation, regulatory and HTA agencies may have increasing backlogs of assessments, compounding challenges for patients in gaining access to innovative molecules

Note: The total number of molecules compared to 2023 W.A.I.T. report differs as the sample selection criteria were refined, with 20 molecules excluded from the 2024 study. Furthermore in EC/ BR, 5/2 molecules respectively, were excluded based on refined availability definitions

Improvement index

>75% of improvement was sequential in nature, i.e., approved to either approved-not available / private availability, private to limited, or limited to full

Improvement index by country, breakdown of improvements (2014 - 2021) – oncology & orphan



- Overall, the trend in improvement is towards sequential improvement, with >75% of improvement falling into this category
- Overall approvals account for approximately 50% of improvement, going from not approved to either approved - not available, or only privately availability, whereas private to limited or limited to full accounted for <25% of movement
- Mexico and Argentina had very limited movement in availability, potentially driven by public assessment backlogs and relatively recent elections creating instability in the local landscape
- The remaining, non-sequential movement is driven by Peru and Costa Rica primarily, given policy reform for oncology agents and healthcare system structure respectively, though Brazil and Colombia also have a number of molecules that improved non-sequentially, driven by limited availability status granted post-regulatory approval

Availability is generally a bottoms-up process across the region that risks becoming increasingly cumbersome for molecules to reach improvements in availability

About the authors

Project Leader

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André Ballalai is a researcher in the field of International Health Systems and Policy and Global Director of Value and Access Consulting at IQVIA in New York, USA.

He has more than 15 years of experience at companies such as Roche and IQVIA, where he currently develops value-based healthcare projects, alternative financing models and health policy strategies in various geographies, including the US and emerging economies such as the Americas. Latin, Middle East and Asia.

He has a bachelor's degree in Chemical Engineering from UFPR (Federal University of Paraná) and a specialization in Financial Management from Insper.

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Oscar Courtney is a Manager in the Value and Access center of excellence supporting commercial, strategy and market access projects.

Oscar has over 8 years of consulting experience, with the last 4 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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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 2014-2023 in relevant TAs
2. Global launch rest of world - (w/o 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, Mpox), and respective treatments may be subject to exceptional routes to access and procurement dynamics
4. Vaccines - also have different routes to access, confounding comparison; FIFARMA Time to Vax study in development to assess these separately
5. Other non-comparable agents e.g., imaging/diagnostics - agents not directly used in treatment and also not directly comparable
6. Withdrawn/not launched - typically a repeal of conditional approval based on not meeting evidence requirements and resulting in global withdrawal/or not launched

	Overview of additional TAs selected		
	I&I	**CNS**	**CM**
ATC2 Examples**	L4, M1, D5, A7	N3-7, L04	B1, C2, C10, A10
Class Examples	ILis, JAKis	CGRPis, antiamyloid mAbs	PCSK9i, GLP1s, GH
Product Examples	Skyrizi, Olumiant, Cibinqo, Ultomiris, Tremfya	Leqembi, Zurzuvae, Nurtec, Ubrelvy	Ozempic, Mounjaro, Repatha, Entresto
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 MIDAS™ is a unique platform for assessing worldwide healthcare markets. It integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and provides estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history. IQVIA MIDAS was used by each local IQVIA team to provide the existing data

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

LABORATORY INTERNAL DATA was asked via a Smartsheet survey and collected from each of the manufacturers included in the study

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

The **2023 W.A.I.T INDICATOR STUDY** data was also leveraged to include and validate for the 2024 W.A.I.T Indicator results. Data was included in order to expand the cohort to 10 years (2014-2023)

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

The initial selection of molecules as described on page 21 is made the core IQVIA project team and validated by FIFARMA

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

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

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

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

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

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

Argentina - CAEME

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

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

Brazil - Interfarma

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

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

Chile - CIF

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

Costa Rica - FEDEFARMA

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

Colombia - AFIDRO

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

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

Dominican Republic - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1]	*Medicines listed on PBS-SISALRIL*	SISALRIL PDSS[1] (document) DAMAC Website	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Medicines available via High-Cost Medicine Program (DAMAC), not listed on PBS-SISALRIL Listed on DAMAC LOM*		
	Only Private[2]	*Broad coverage by prepaid plans, no special purchase negotiations, no DAMAC/SISALRIL coverage*		
	Not Available	*Ministerio de salud approval, no DAMAC/SISALRIL coverage, no special purchases negotiations, no broad coverage by prepaid plans Only OOP sales, mostly in the Retail Setting*	Not available	

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

Ecuador – IFI-Promesa

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

Mexico - AMIIF

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

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

Panama - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full[1]**	*Listed on CSS and ION* Basic Formulary (LOM)*	MOH website CSS Document (LOM) ION Document (LOM)	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited[2]	*Medicines available via special purchase process for non-LOM medicines on CSS / ION*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no CSS formulary*		
	Not Available	*Ministerio de salud approval, no CSS, no special purchases negotiations, no broad coverage by prepaid plans Only OOP sales, mostly in the Retail Setting*	Not available	

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

Peru - ALAFARPE

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1]	*National petition (PNUME) and its complementary listings, RENETSA/RM purchases*	MOH website PNUME document IETSI dictum INEN evaluation	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited[2]	*Not listed but with limited access*		
	Only Private	*Products covered OOP with no possibility for reimbursement, no essential listing*	Not available	
	Not Available	*DIGEMID approval, no listing or other access*	DIGEMID Website	

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