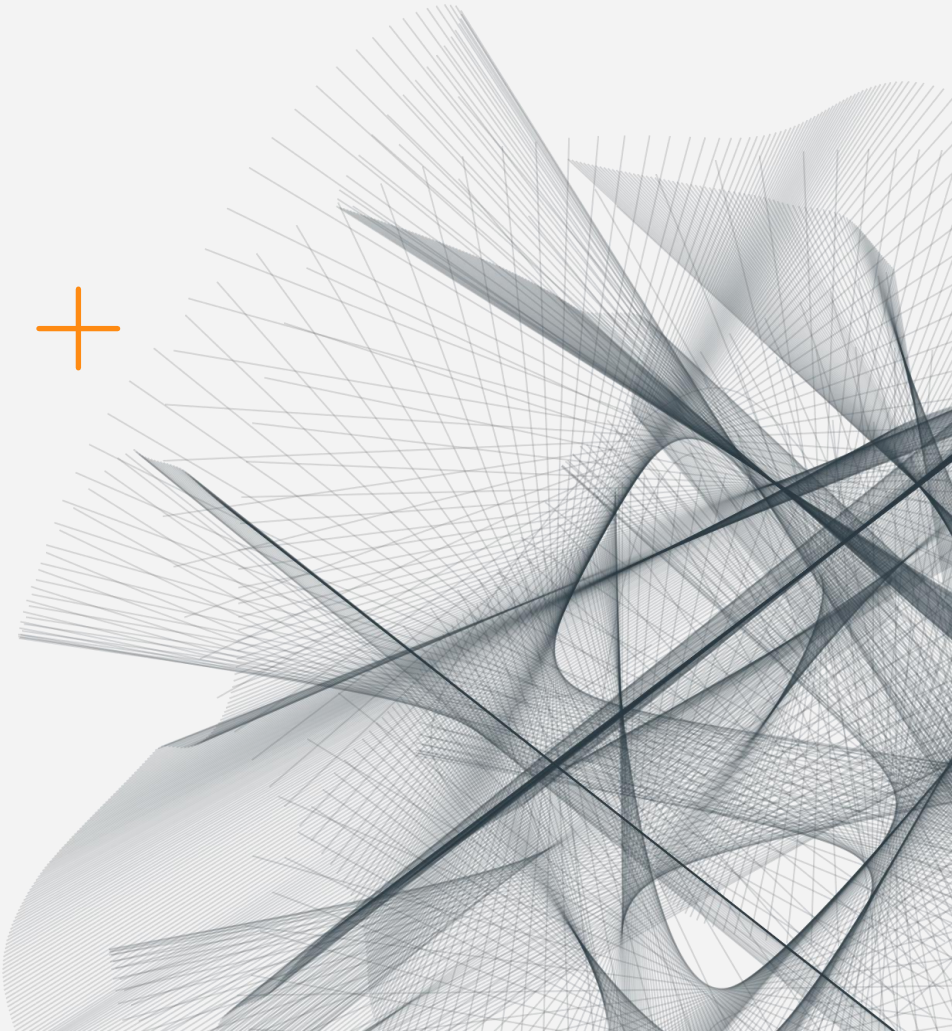
FIFARMA

IQVIA

Patient W.A.I.T Indicator 2023 LATAM

Brazil

AN ASSESSMENT OF INNOVATIVE MEDICINES AVAILABILITY ACROSS LATIN AMERICA



MARCH
2024

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Summary of key findings from the study

Availability in Brazil vs LATAM region

- 57% of molecules are globally approved in at least one country in LATAM, 20% are privately available, 34% have limited availability, and 45% are fully available
- In Brazil, 60% of molecules that are approved have at least private, limited or full availability with a majority (51% or 32 molecules) having only private availability
- More orphan molecules are approved (85 orphan vs 67 oncology) in at least one country in LATAM- this trend does not carry through to Brazil (45 orphan vs 49 oncology)
- As a larger number of oncology molecules are available, oncology molecules boast higher rates of availability in Brazil
    - 79% of oncology molecules vs 52% orphan molecules that are approved in Brazil have at least private, limited or fully availability with a majority (59% oncology and 49% orphan) maintaining only private availability

Though many molecules face reimbursement restrictions and uncertainty surrounding systemic changes exists, ***Brazil performs better than LATAM regional averages***

Availability Timelines in Brazil vs LATAM region

Time to availability *represents the length of time from both global and local market authorization until full or limited availability is reached*

- Time to local approval/market authorization on average in LATAM is 953 days, where time to availability (between marketing authorization and availability) is on average 1,641 days
- Brazil is the country with the shortest regulatory approval timelines overall, though availability timelines are relatively longer
- Time to availability for orphan molecules are slightly faster in LATAM on average (1,637 days vs 1,700 days), and Brazil follows a similar trend with 1,551 days to availability for orphan molecules and 1,841 days to availability for oncology molecules

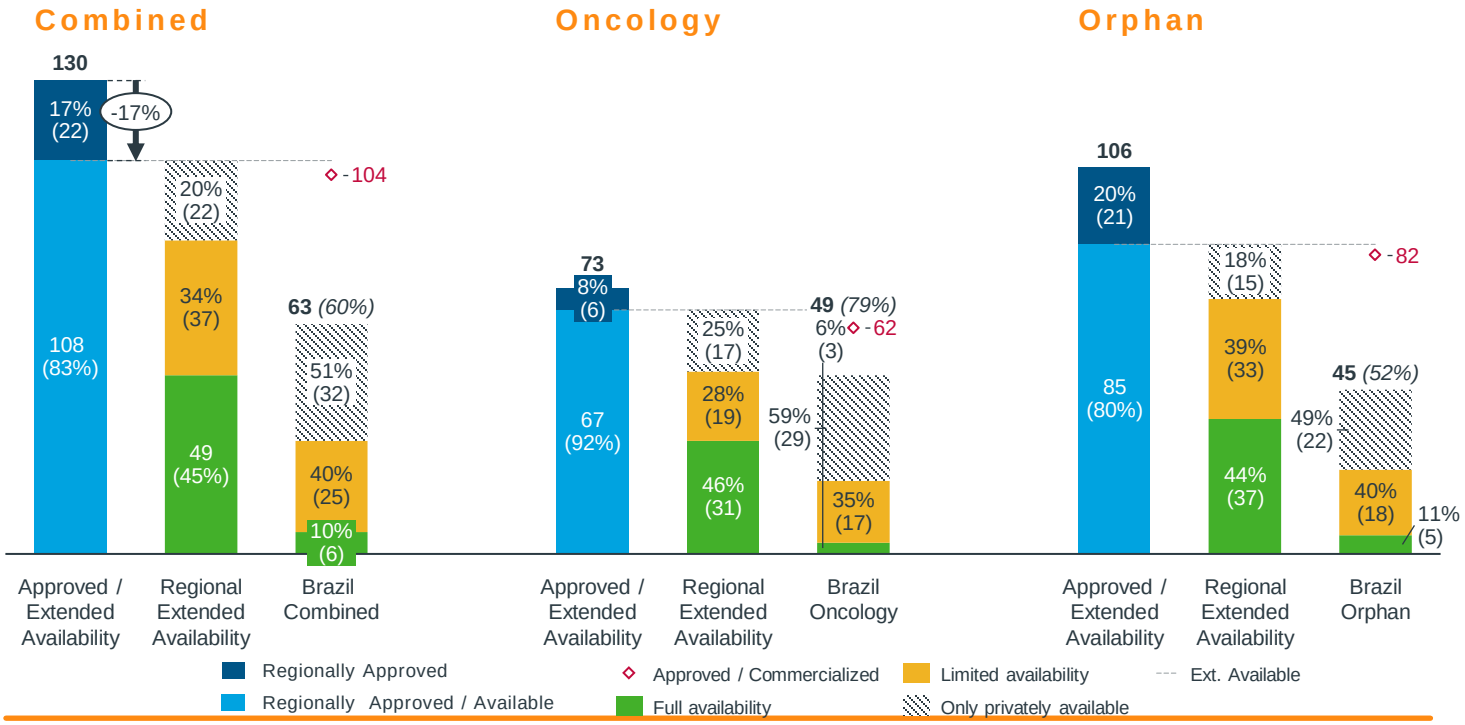
Availability over time *pinpoints the degree of availability according to global market authorization year to estimate the maturity of available molecules*

- Availability over time reflects these trends and is likely to also have been affected by COVID: most molecules with full availability status were approved in Brazil between 2014-2017 (66%) and similar trends are seen for at the oncology (79%) and orphan (52%) level

Note: Global availability is defined as a molecule that has regulatory approval in the United States of America, or in Europe; *Argentina and Costa Rica had a reduced dataset for timelines and may not reflect them accurately

Brazil boasts a higher number and higher percentage of oncology molecules available vs orphan molecules

Regional extended availability (2014-2021) – Regional and Brazil



- Of the 108 molecules approved in at least one country in LATAM, 20% are privately available, 34% have limited availability, and 45% are fully available
- In Brazil, 60% of molecules that are approved have at least private, limited or fully availability with a majority (51% or 32 molecules) having only private availability
- 67 oncology molecules are approved in at least one country in LATAM, while 25% are privately available, 28% have limited availability, and 46% are fully available
- 79% of oncology molecules that are approved in Brazil have at least private, limited or fully availability with a majority (59% or 29 molecules) having only private availability
- More orphan molecules are approved (85 orphan vs 67 oncology) in at least one country in LATAM, while 18% are privately available, 39% have limited availability, and 44% are fully available
- Unlike LATAM regionally, there are more oncology molecules available than orphan molecules (49 vs 45) and higher rate of available oncology molecules as well (79% vs 52%)

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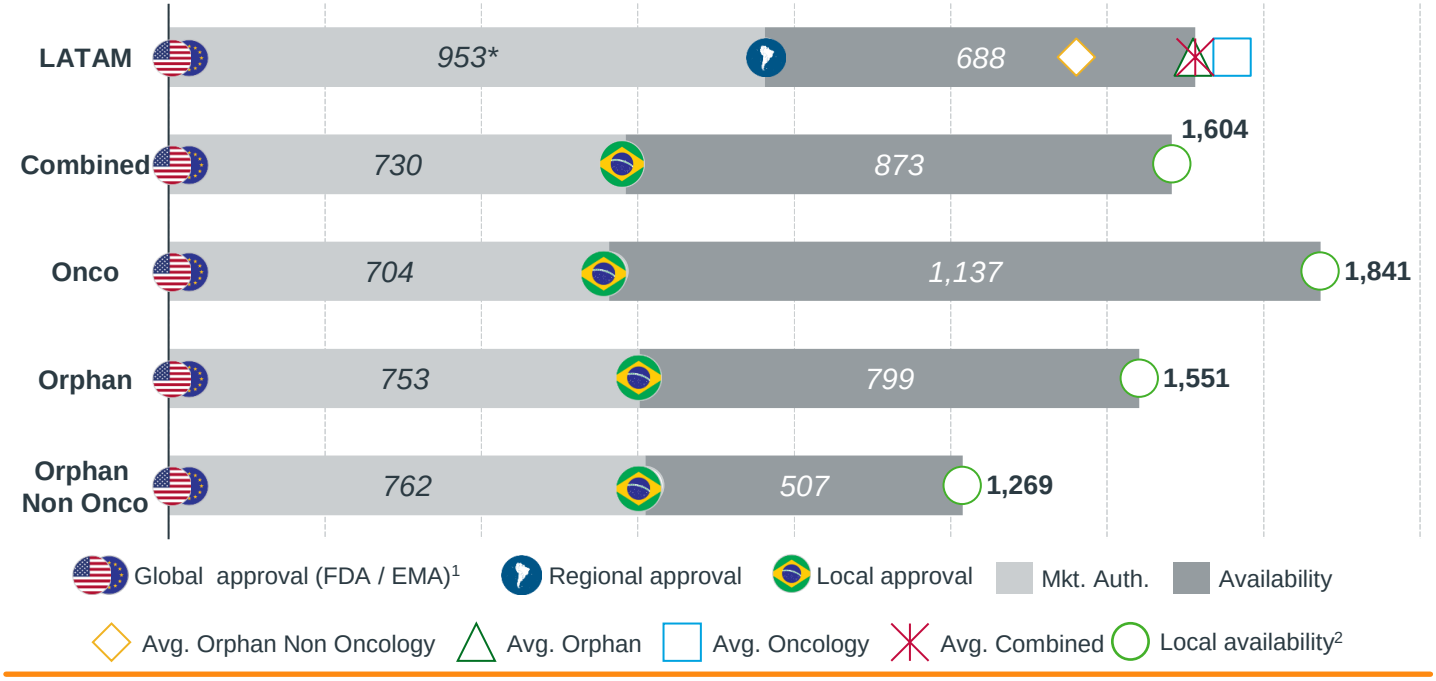
*Although availability **regionally reaches 83%**, Brazil performs at **60% combined availability and 79% and 52% respectively for oncology and orphan** molecules*

*Note: Global availability is defined as a molecule that has regulatory approval in the USA, or in Europe;*Approved in at least one LATAM country*
[1] Not considering Argentina extended availability as a result of its fragmented private market based on case-by-case decisions

Length of time to availability varies regionally in LATAM, with Brazil having long availability timelines

Average time to availability (2014-2021) – Regional and Brazil, FDA / EMA, marketing auth., and local availability dates



- Wide disparities exist between countries in terms of time to availability, with Argentina on the low end at an average of 966 days, Colombia towards the middle with 1,673 days, Brazil with 1,604 days and Mexico on the high end, with an average of 2,073 days, which reflects the total of time to marketing authorization and time to reimbursement (pub / pri), as of FDA/EMA approval
- Time to local approval/market authorization on average in LATAM is 953 days, where time to availability (between marketing authorization and availability is on average 1,641 days)
- Brazil is the country with the shortest regulatory approval timelines overall, though availability timelines are relatively longer, likely as a result of the public sector
- Time to availability for orphan molecules are slightly faster than oncology molecules in LATAM on average (1,638 days vs 1,700 days), and Brazil follows a similar trend with 1,551 days to availability for orphan molecules and 1,841 days to availability for oncology molecules

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*Although it has short **regulatory approval times**, **time to availability is relatively long,** likely driven by the public sector; **orphan molecules become available faster than oncology molecules***

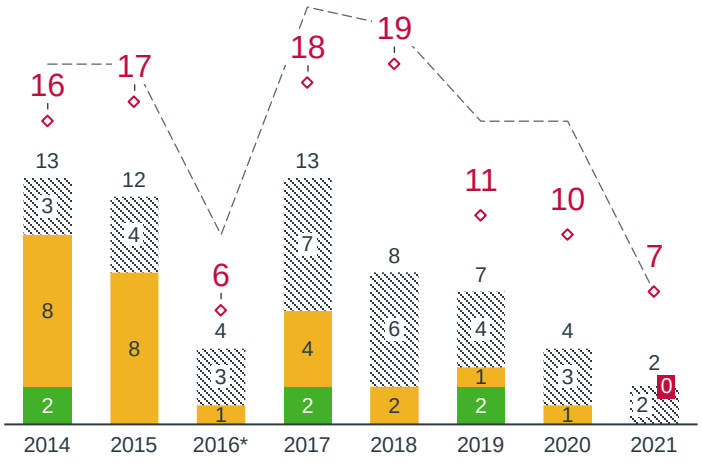
[1] *Global approval date considered the earliest date between FDA or EMA*
[2] *Considering molecules with Full and / or Limited Availability*
[2] *ARG / CRI: Limited number of Fully / Limited Availability date of reimbursement information resulted in shorter timelines*
**Orphan category includes Orphan Oncology molecules*

The overall trend observed regionally in LATAM remains similar in Brazil for both oncology and orphan molecules over time

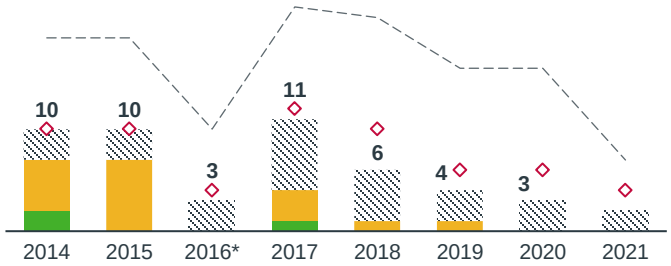
Extended availability over time (2014-2021) – Regional and Brazil

Combined

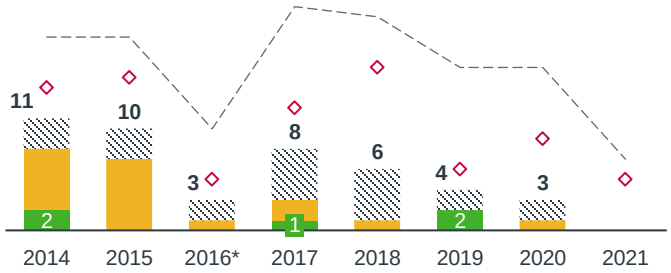
As seen regionally in LATAM**, most molecules with full availability status **were approved in Brazil between 2014-2017

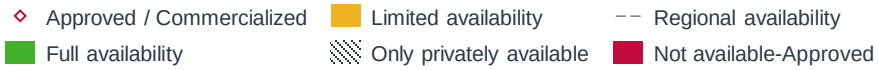


Oncology



Orphan





- As was observed regionally in LATAM, most molecules with full availability status were approved in Brazil between 2014-2017 (66% of the total molecules with full availability)
- Similar trends are seen for molecules that are fully available between 2014-2017 in Brazil at the oncology (79%) and orphan (52%) level
- A number of potential drivers can explain this; in addition to the generally long, fragmented path to availability, three additional potential issues are:
    - The COVID-19 pandemic and associated strain on healthcare system likely exacerbating underlying systemic challenges e.g., budget impact
    - Increases in investment coupled with clinical innovation in oncology/rare disease in recent years has led to new standards of care e.g., PD1s, CDK4/6 inhibitors (2014-2015), but also more gradual increments of clinical benefit, and lesser priority for reimbursement
    - Expanding indications, going from most niche or smallest patient population to broader more prevalent conditions

Key drivers of availability in Brazil

Four main drivers emerge when analyzing availability of orphan and oncology molecules in Brazil

1

In Latin America, Brazil is the largest market, ahead of Mexico, Colombia and Argentina, resulting in a high degree of local manufacturer presence, local market access teams and oftentimes the regional headquarters for LATAM based locally.

2

Private market access in Brazil is one of the most developed in the region, providing access for patients according to the ANS rol, as well as often paving the way for access in the public sector.

3

Recent changes to the ANS rol have impacted approvals and availability of molecules and are likely to continue to do so in the coming years, in particular, **oral oncology is now automatically included in the ANS** rol according to label indication.

4

ANVISA is looking to increase the use of expanded access programs, which may support, in particular, access for molecules seeking approval in orphan disease.

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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.

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Oscar has over 7 years of consulting experience, with the last 3 at IQVIA working with global pharma companies.

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Acknowledgements

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Peru

Regional LATAM

Notes on Sources

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

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

Brazil: ANVISA

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

MANUFACTURERS ASSOCIATIONS' DATA as well as MNFs data, was asked and collected from associations included in the study. Associations also participated in the local definition's alignment. Associations that participated are:

Brazil: INTERFARMA

2022 W.A.I.T INDICATOR STUDY data was also leveraged to include and validate for the 2023 W.A.I.T Indicator results. Data was included in order to expand the cohort to 7 years (2014-2021)

Data was validated and QCed across all sources by a data analysis model generating comprehensive and visual results

Definitions & Methodologies

Molecules were selected from US/EU approvals for novel oncologics and molecules indicated in rare disease from 2014-2021

1. Molecules with global approval from 2014-2021 were first identified via IQVIA's global list and EFPIA WAIT list
2. List was narrowed to include only orphan and oncology molecules
3. Some molecules were further excluded if they fell into the following categories: diagnostic tools, vaccines, drugs used in symptom relief (e.g., nausea) associated with oncologic treatment, molecules launched outside of the US/EU

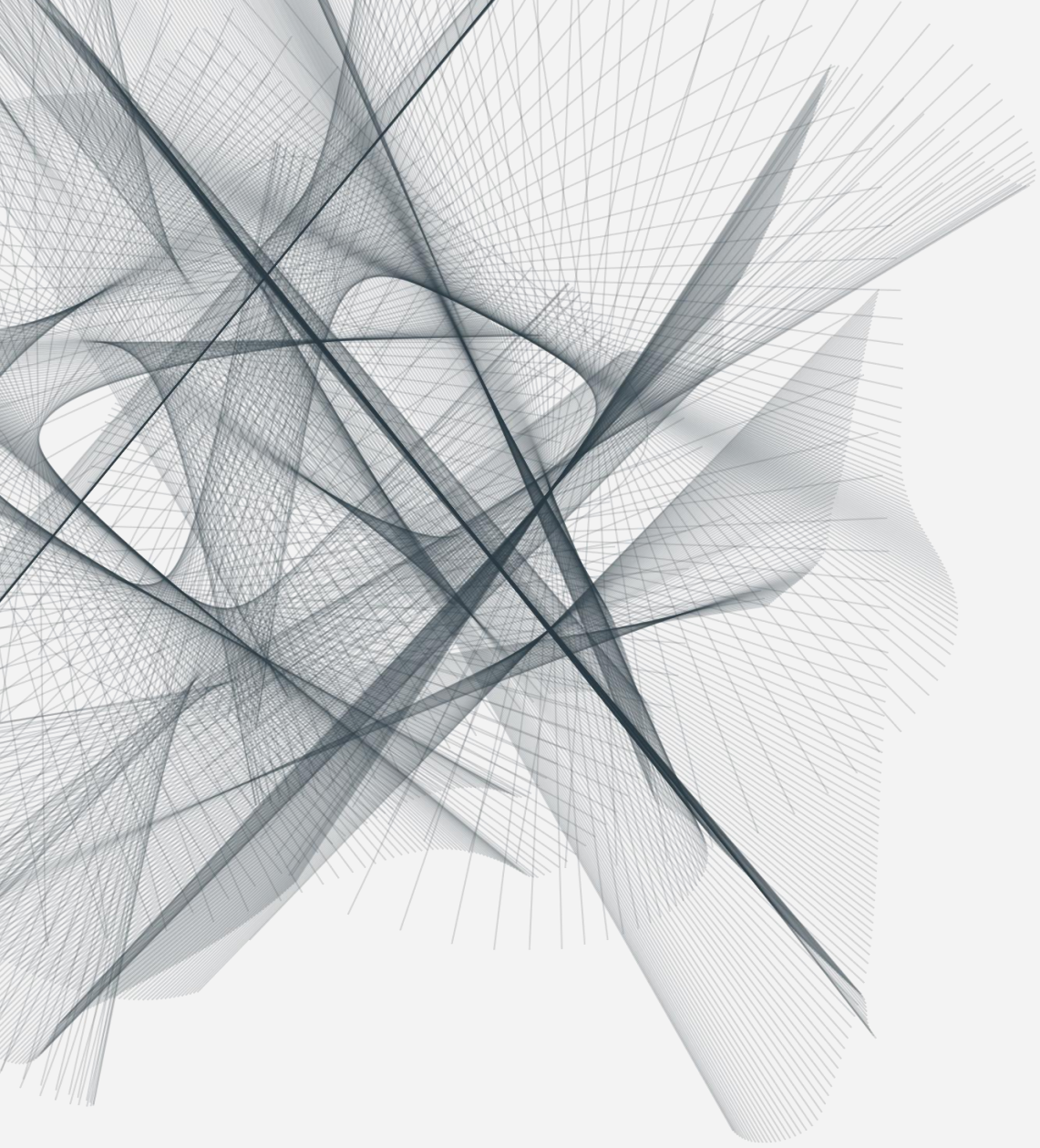
- A few additional points were noted: (a) Molecules can have up to three marketing authorization dates: FDA, EMA, and (b) local Orphan status may be determined by either the FDA or EMA

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

1. ***No Availability: Not submitted, or in regulatory evaluation process***
   - Time required by local regulatory bodies evaluating market authorization submissions to make a final approval publicly available.
2. ***Approved, not available: Commercially available, but not reimbursed***
   - As being approved by regulatory bodies, medicines are authorized to be commercialized in the country. In this stage, there is reimbursement from neither private nor public payers; patients typically pay full OOP. This is inclusive of managed access schemes.
3. ***Privately available: Private market reimbursement***
   - Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage by private insurance policies.
4. ***Limited availability: Reimbursement but not for a broad population***
   - Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage by private insurance policies.
5. ***Full availability: Broad and national reimbursement***
   - Medicines are fully available at national level for a broad population in both public and private market. Full availability is frequently tied to national formulary listing, positive HTA recommendations, or central procurement.

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

- ***Ecuador Definitions of availability:*** full: Essential list e.g., MSP, IESS; limited: Typically exception processes; private: n/a



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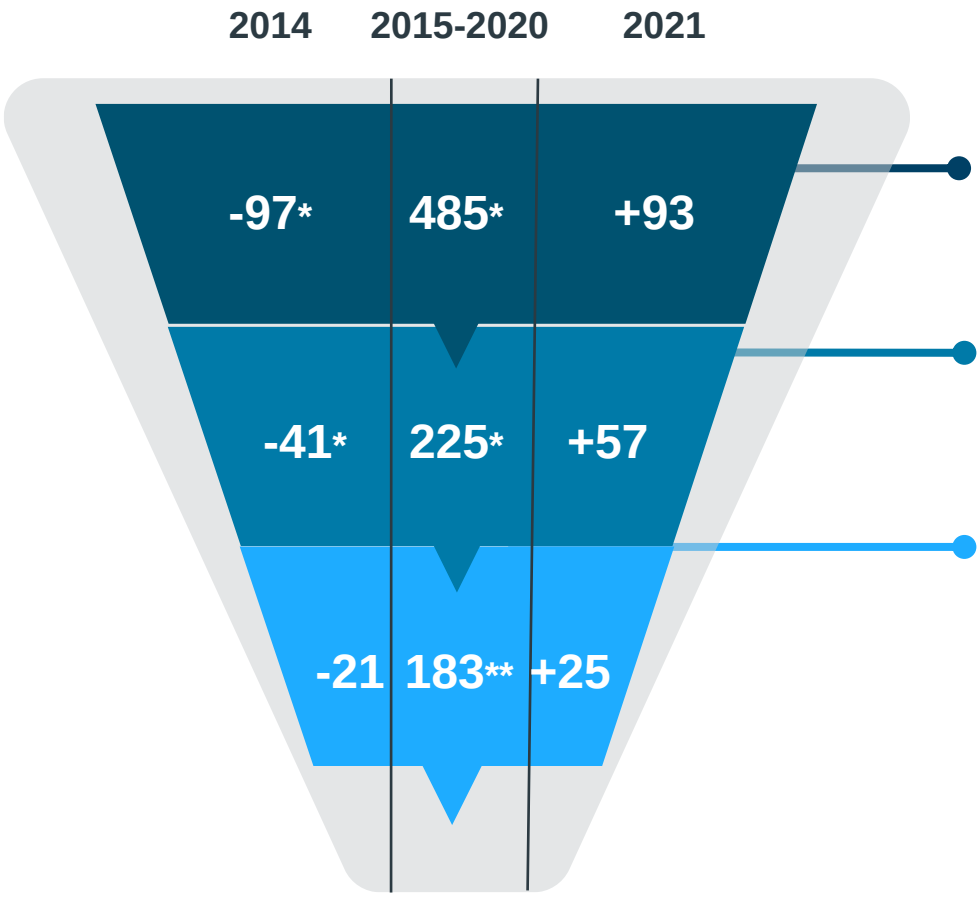
Molecules were selected from US/EU approvals for novel oncologics and molecules indicated in rare disease from 2014-2021

Study Cohort Selection Criteria

Molecules were selected from a universe from IQVIA's global and EFPIA WAIT list. Filters were used to identify only orphan and oncology molecules. Further exclusions were based on rules defined and aligned with FIFARMA



IQVIA's global list and EFPIA WAIT list

Orphan and Oncology only

Exclude molecules based on rules defined

i.e., diagnostic tools, vaccines, drugs used in symptom relief (e.g., nausea) associated with oncologic treatment, molecules launched outside of the US/EU

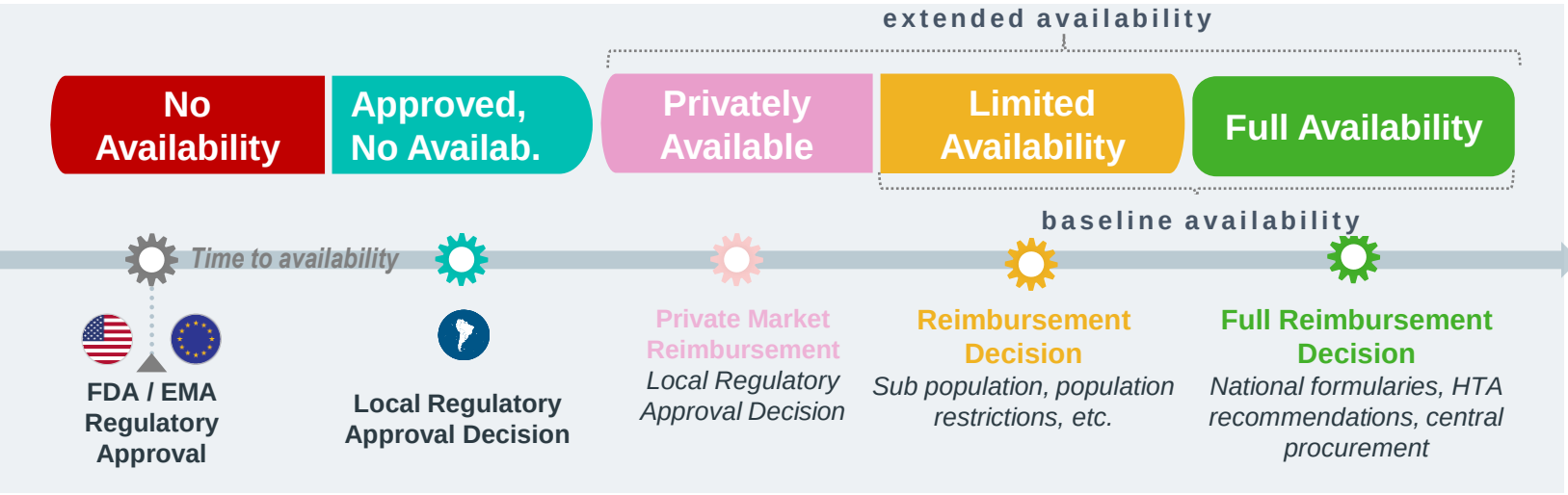
- Molecules can have up to three marketing authorization dates: FDA, EMA, and local
- Orphan status may be determined by either the FDA or EMA

*Numbers used are for illustrative purposes only; ** Reflects the total after inclusions (+27) and exclusions (-9) based on updated exclusion rules

Acronyms: EFPIA: European Federation of Pharmaceutical Industries and Associations; WAIT: Waiting to Access Innovative Therapies; FDA: Food and Drug Administration; EMA: European Medicines Agency

Results from the study are shown in terms of different levels of availability

Availability Definitions



No Availability:

Not submitted, or in regulatory evaluation process

- Time required by local regulatory bodies evaluating market authorization submissions to make a final approval publicly available.

Approved, not available:

Commercially available, but not reimbursed

- As being approved by regulatory bodies, medicines are authorized to be commercialized in the country. In this stage, there is reimbursement from neither private nor public payers; patients typically pay full OOP. This is inclusive of managed access schemes.

Privately available:

Private market reimbursement

- Medicines available only in the private market for a limited number of patients. Typically, medicines are reimbursed by private payers (e.g., HMOs) or have total or partial coverage by private insurance policies.

Limited availability:

Reimbursement but not for a broad population

- The availability of medicines is limited to specific patient sub-populations, restricted to a limited number of treatment centers, or otherwise not granted access according to the full registered therapeutic indication.

Full availability:

Broad and national reimbursement

- Medicines are fully available at national level for a broad population in both public and private market. Full availability is frequently tied to national formulary listing, positive HTA recommendations, or central procurement.

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	EC	MX	PE
Availability Def.	Full	PAMI/ SURGE or PAMI and PMO	CONITEC and centralized purchases	Ley Ricarte Soto or GES	PBS-UPC	CCSS (LOM)	Essential list e.g., MSP, IESS	Compen-dium, and federal inst. purchases	PNUME, and RENETSA /RM purchases
	Limited	1+ country formulary and broad coverage by OSN / prepaid	CONITEC, no centralized purchasing	Limited FONASA reimburse ment, special programs	ADRES / MIPRES	Special purchases	Typically exception processes	Decentra-lized formularies	Not listed but with limited access
	Private	Broad prepaid coverage	ANS ROL placement	CAEC, ISAPREs	n/a	Prepaid plans	n/a	Large private formularies	n/a
Data	Public	SURGE, Drug Banks	CONITEC, ANVISA, ANS ROL	National websites, tenders	MinSalud, respective circulars	MOH, CCSS	MSP, IESS	Compen-dium, INEFAM, tenders	PNUME, IETSI, INEN
	IQVIA*	Retail, *non-retail*	Across channels	Retail, *non-retail*	Across channels	Retail, *non-retail*	Retail, *non-retail*	Across channels	Retail, *non-retail*
Caveats		Data coverage for sub-national plans not comprehe nsive	Relatively high visibility through available data	Private coverage data through CAEC is highly limited	Relatively high visibility through public data	Public data on approvals not available	Relatively high visibility through available data	Relatively high visibility through available data	Recent changes i.e., RENETSA and RM included

Definitions were aligned on and refined by the working group of local associations and IQVIA local teams

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

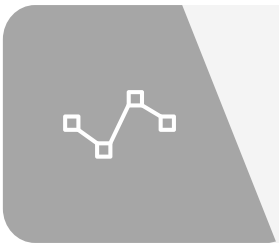
Acronyms: PAMI:Programa de Asistencia Médica Integral; SURGE:Sistema Único de Reintegros por Gestión de Enfermedades ; PMO: Programa Médico Obligatorio; CONITEC: National Committee for Technology Incorporation; FONASA: Fondo Nacional de Salud; PBS-UPC:Plan De Beneficios En Salud Con Cargo A La UPC; CCSS: Caja Costarricense De Seguro Social; LOM: Lista Oficial de Medicamentos; MSP:Ministerio de Salud Pública ; IESS:Instituto Ecuatoriano De Seguridad Social; 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; CAEC:Cobertura Adicional para Enfermedades Catastróficas; GES: Garantías Explícitas en Salud

Factors influencing availability across markets

*Though this report does not aim to exhaustively identify and assess the impact of the multiple **factors that can influence availability across countries in LATAM**, there are several recurring themes that emerged through the research*

Commercial Partnerships

Oncology and Orphan drugs have a high number of emerging biotech's that have limited presence in the region, and typically require a local commercial partner to launch



Indication Sequencing

The study considers the approval and reimbursement date of the first indication to arrive in each market; but the first indication may not fully represent the availability status of a molecule

Role of the Private Market

Reimbursement in LATAM is bottoms-up, starting with private HMOs, then public sector before broad national formularies. In markets such as Brazil and Chile, a private market often delays public subnational access before broad public access

COVID Impact

During the COVID period, a decrease in high cost / specialty care HTA activity was observed, resulting in fewer molecules being included in both subnational and national formularies

Detailed Country Availability Definitions, as developed by Interfarma - Brazil

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[2]	*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[3]	*ANVISA Approval and ANS ROL placement, no positive CONITEC decision, no centralized purchasing* *ANS DUT publishing date to be used as the reference for all products except by Oncology IV which consider 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*		

[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]Access exclusively through exceptional access routes (e.g., legal injunctions) will be considered as limited access
[3]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