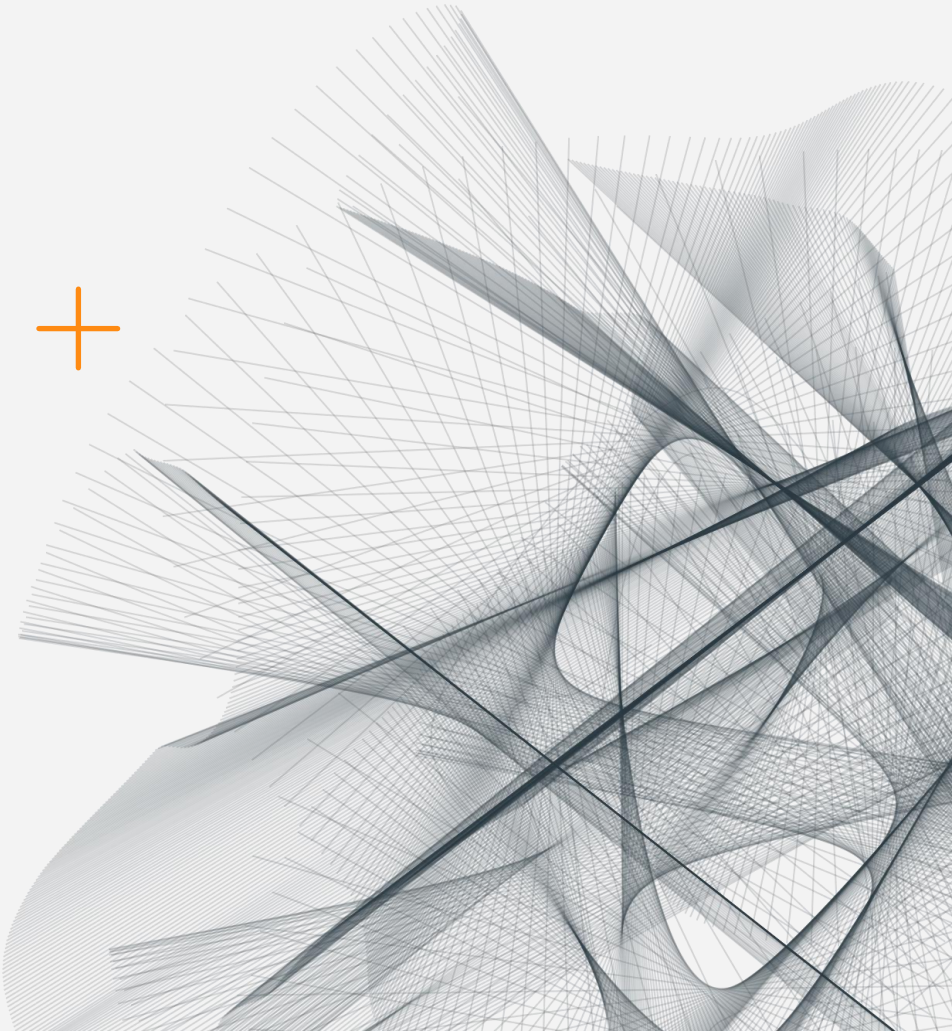
FIFARMA

IQVIA

Patient W.A.I.T Indicator 2023 LATAM

Chile

AN ASSESSMENT OF INNOVATIVE MEDICINES AVAILABILITY ACROSS LATIN AMERICA



MARCH
2024

Table of contents

Summary of key findings from the study

Availability in Chile vs LATAM region

- The study reflects data from 228 FDA/EMA approved molecules from the period 2014-2021
- 57% of the total molecules are globally approved in at least one country in LATAM, 20% are privately available, 35% have limited availability, and 45% are fully available
- In Chile only 55% of molecules are available, of those that have extended availability in at least one LATAM country (private, limited or full availability), with a majority (53% or 23 molecules out of the 43 available in Chile) having only private availability
- Of the total cohort, more orphan molecules (includes onco-orphan) are approved (85 orphan vs 67 oncology) in at least one country in LATAM- this trend carries through to Chile (33 orphan vs 31 oncology)
- Though a larger number of orphan molecules have extended availability, oncology molecules boast higher rates of availability in Chile
    - 63% of oncology molecules vs 55% orphan molecules that are approved in Chile have at least limited or fully availability with a majority (48% oncology and 55% orphan of available molecules in Chile) maintaining only private availability

Availability Timelines in Chile 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
- Chile is the country with the second longest availability timelines
- Time to availability for orphan molecules are slightly faster in LATAM on average (1,637 days vs 1,700 days), and Chile follows an opposite trend with 2,183 days to availability for orphan molecules and 1,954 days to availability for oncology molecules

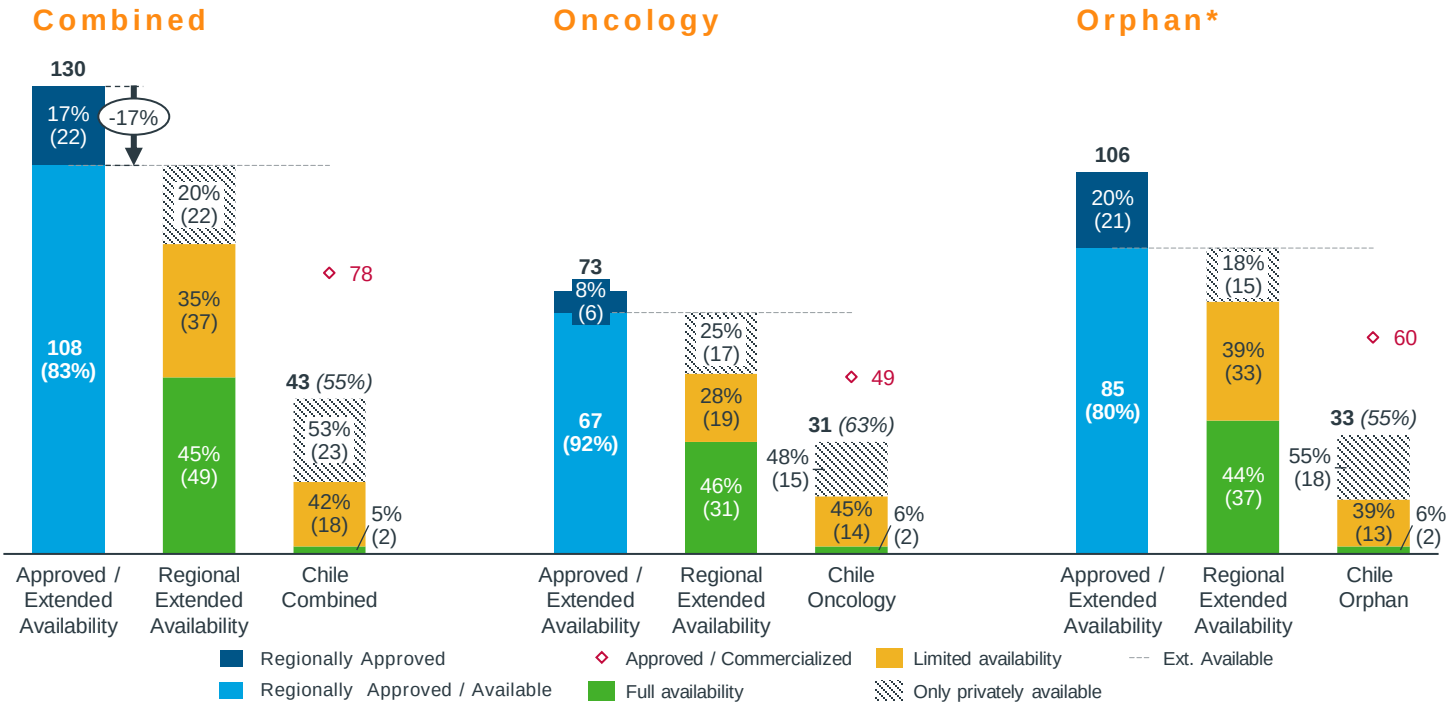
Availability over time *pinpoints the degree of availability according to global market authorization year to estimate the maturity of available molecules*

- 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 Chile between 2014-2017 (100%) and the same trend is seen for oncology and orphan

Note: Global availability is defined as a molecule that has regulatory approval in the United States of America, or in Europe

Chile boasts a higher number of orphan molecules available approved with less availability rate vs oncology molecules

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



- Out of the 228 global FDA/EMA approved molecules, 130 are approved in at least one LATAM country
- Of the 108 molecules approved in at least one country in LATAM with extended availability, 20% are privately available, 34% have limited availability, and 45% are fully available
- In Chile, 55% of molecules that are approved have at least private, limited or full availability with a majority (53% or 23 molecules out of the 43 available in Chile) 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
- 63% of oncology molecules that are approved in Chile have at least private, limited or full availability with a majority (48% or 15 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
- As LATAM regionally, there are more orphan molecules available than oncology molecules (33 vs 31) and higher rate of available oncology molecules as well (63% vs 55%)

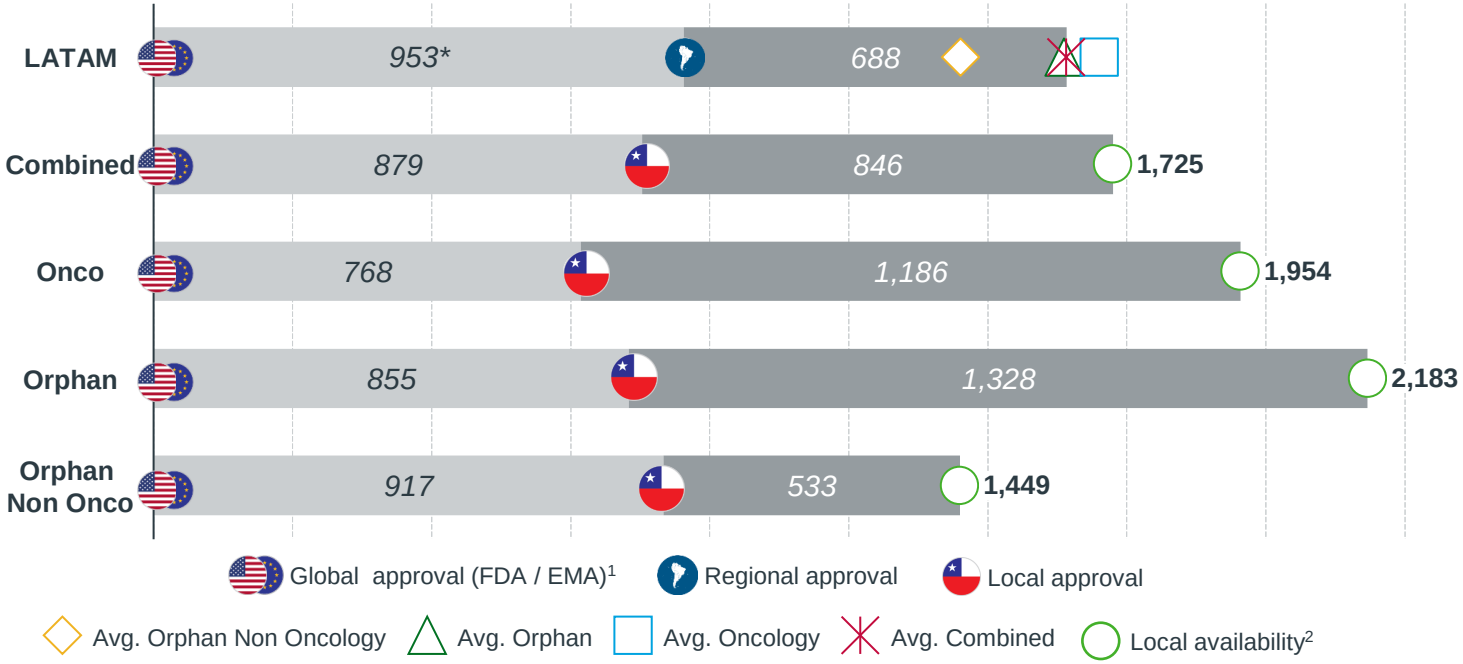
+

***Regionally availability reaches 83%**, Chile sees challenges at **55% combined availability,** with a high proportion of approved molecules not available*

*Note: Global availability is defined as a molecule that has regulatory approval in the USA, or in Europe; *Orphan includes orphan-oncologic molecules*
[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 Chile having shorter regulatory and longer availability timelines

Average time to availability (2014-2021) – Regional and Chile, 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
- Chile is the country with the second longest availability timelines, potentially exacerbated by delays in coverage by the Ricarte Soto law and DAC and policies related to the inclusion of molecules with low budget impact
- Time to availability for orphan molecules are slightly faster than oncology molecules in LATAM on average (1,638 days vs 1,700 days), and Chile follows an opposite trend with 2,183 days to availability for orphan molecules and 1,954 days to availability for oncology molecules

+

*Although it has shorter **regulatory approval times**, **time to availability is relatively long**; **orphan molecules become available slower than oncology molecules***

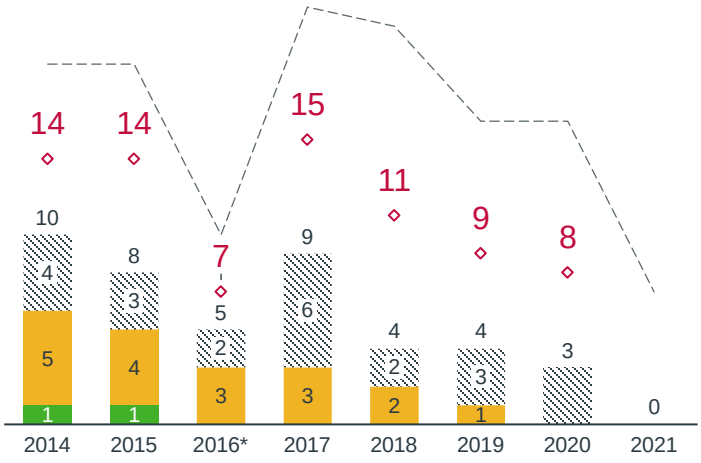
[1] *Global approval date considered the earliest date between FDA or EMA*
[2] *Considering molecules with Full and / or Limited Availability*
**Orphan category includes Orphan Oncology molecules*

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

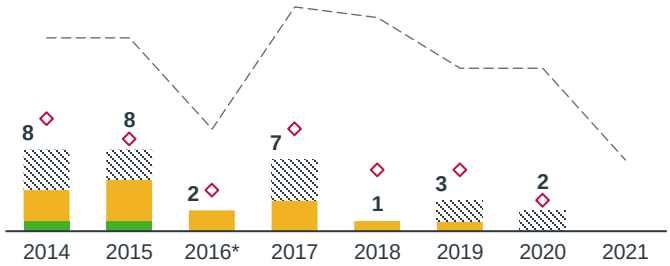
Extended availability over time (2014-2021) – Regional and Chile

Combined

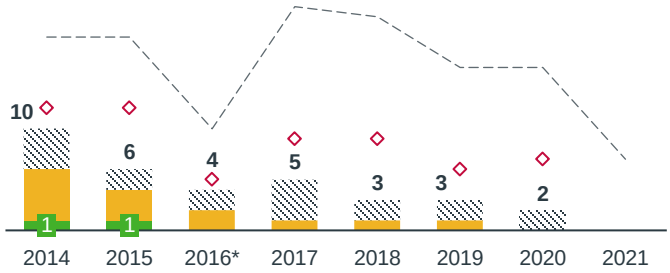
All molecules with full availability status ***were approved in Chile between 2014-2015***



Oncology



Orphan



Approved / Commercialized | Limited availability | Regional availability
Full availability | Only privately available | Not available-Approved

- As was observed regionally in LATAM, most molecules with full availability status were approved in Chile between 2014-2015 (100% of the total molecules with full availability)
- Similar trends are seen for molecules that are fully available between 2014-2015 in Chile in oncology and orphan disease
- A number of potential drivers that may exacerbate challenges in to reaching access, some 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 Chile

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

1

Pharmaceutical companies' presence is variable in Chile, with some countries opting for local presence and others incorporating it as part of a cluster; this may impact timelines to access given local nuances in the submission of regulatory/reimbursement evaluation dossiers.

2

A historically important mechanism for access in the private sector, in recent years there has been **instability** in the ISAPRES, which recently came more limited in their coverage of high-cost therapies, such as those seen for rare disease.

3

DAC (Drogas de alto costo) was established to grant public access for principally orphan diseases. But also high cost drugs in oncology may qualify, **however** COVID19 impacted healthcare budgets creating significant challenges in funding and implementing the program, that still persist.

4

Continued uncertainty surrounding the political and economic environment, as well as social challenges such as high unemployment rates exacerbate the lingering issues from the COVID pandemic, and cast a shadow over the near-term future for improvements in the DAC and public sector particularly, and thus for access to innovative medicines.

About the authors

Overall Project Leader

Andre Ballalai
Associate Principal
IQVIA | Value & Access

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

Regional Project Manager

Oscar Courtney
Manager
IQVIA | Value & Access

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

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

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

Co-Authors and Contributors

IQVIA Project Team and Co-Authors

Jessica Lopez
Associate Consultant
IQVIA | Strategy Consulting

Jessica Lopez is an Associate Consultant within IQVIA's consulting practice in New York, USA.

She has experience managing different value-based health projects in various geographies, including the US and emerging economies such as Latin America, the Middle East, and Asia.

Jessica holds a degree in Socio-Cultural Anthropology from Haverford College.

Rosa de Lourdes Bonilla
Consultant
IQVIA | Strategy Consulting

Rosa de Lourdes Bonilla is a Consultant within IQVIA's consulting practice in Mexico City, MX.

She has 6 years of financial consulting experience prior to IQVIA. Rosa holds a bachelor's degree in Economics from Instituto Tecnologico Autonomo de Mexico (ITAM), Mexico City, and a degree in Political EU Economy from the London School of Economics.

Regional Contributors and Co-Authors

Silvana Lay
Director of Access & Public Affairs, **Fifarma**

Silvana is the Corporate Affairs Director at FIFARMA, the Latin America association of the innovative pharmaceutical industry. She 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.

Diego Guarin
President of Regional Chapter
ISPOR LATAM

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.

Francisca Rodriguez
Gerente de Inovacion y Salud,
CIF Chile

Francisca currently works at the Chamber of Pharmaceutical Innovation where she promotes high standards of industry relations, encouraging greater investment in R&D by the industry in Chile. She is a Medical Epidemiologist with degrees from Universidad del Desarollo, Universidad de Chile, and Unidversidad de los Andes.

Acknowledgements

The completion of this study could not have been possible without the support of numerous stakeholders across all countries included on the research

FIFARMA Leadership

Yaneth Giha

Executive Director

Maria Alejandra De Guzman

Operations and Communications Director

Manufacturer associations and their local representatives

Karla Baez - AMIIF

- kbaez@amiif.org.mx

Roy Benchimol - CAEME

- roy.benchimol@caeme.org.ar

Catalina Bello Durán - AFIDRO

- cbello@afidro.org

Francisca Rodriguez - CIF CHILE

- francisca.rodriguez@cifchile.cl

Edgar Tenorio - FEDEFARMA

- edgar.tenorio@fedefarma.org

Renata Nunes - INTERFARMA

- renata.nunes@interfarma.org.br

Gonzalo Marrero- ALAFARPE

- gmarrero@alafarpe.org.pe

Álvaro Maldonado - IFI

- amaldonado@ifi-promesa.com.ec

IQVIA country experts based locally

Argentina

Brazil

Chile

Ecuador

Costa Rica

Ecuador

Mexico

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

Chile: CL Ministry of Health Registry

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:

Chile: CIF

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

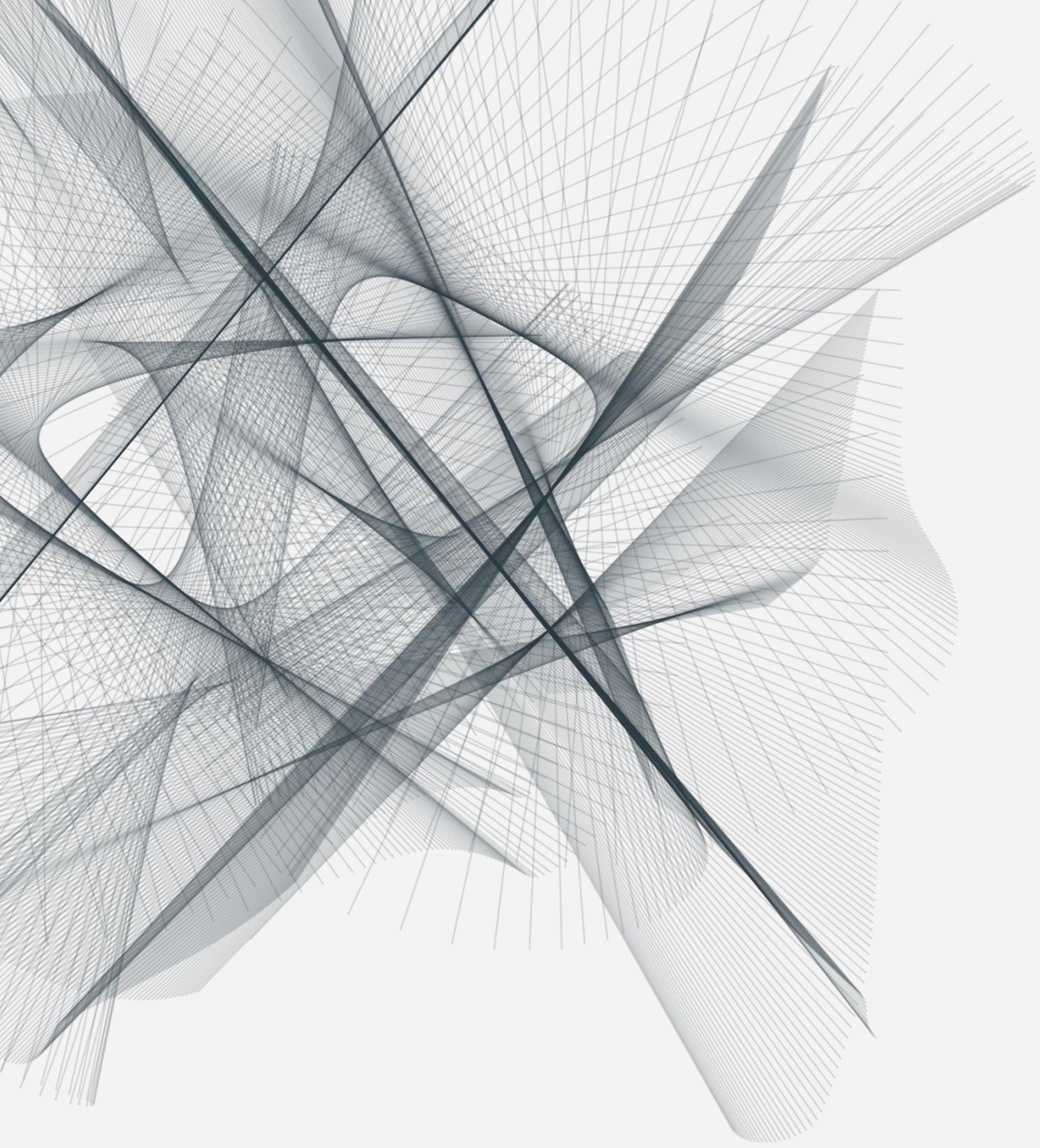
- A few additional points were noted: (a) Molecules can have up to three marketing authorization dates: FDA, EMA, and (b) local Orphan status may be determined by either the FDA or EMA

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



CONTACT US

Andre Ballalai, Associate Principal, Strategy Consulting Services

andre.ballalai@iqvia.com

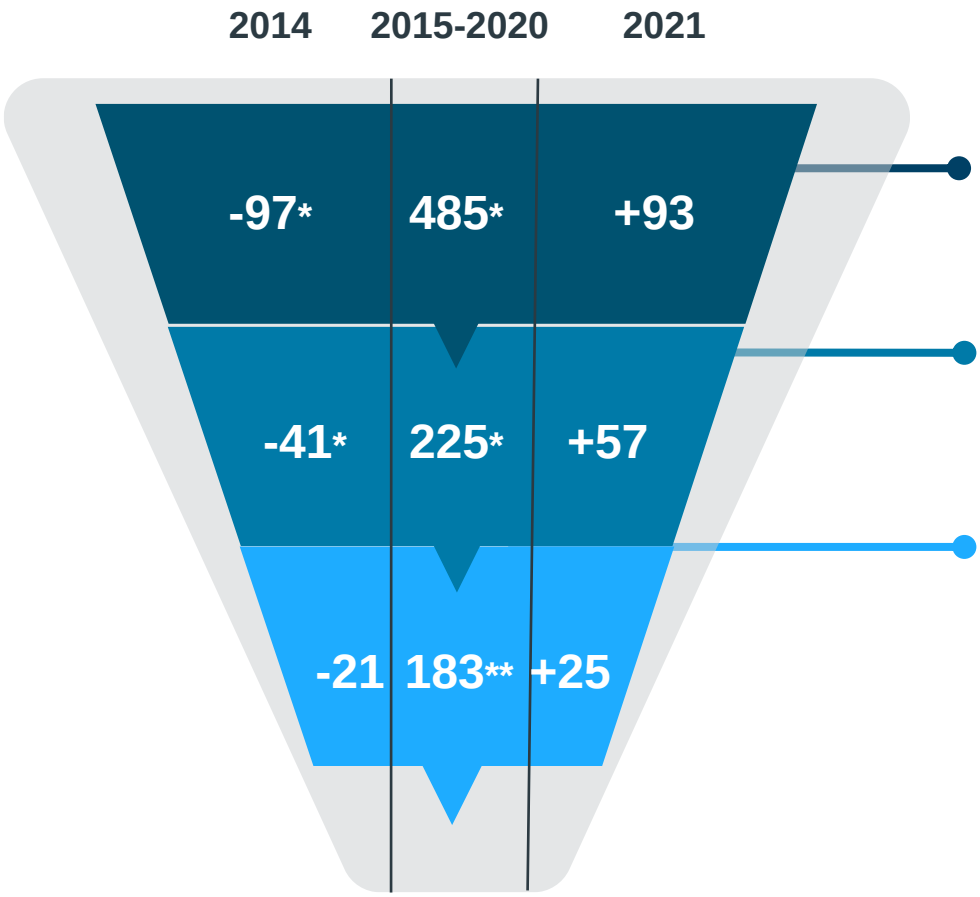
Oscar Courtney, Manager, Strategy Consulting

oscar.courtney@iqvia.com

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

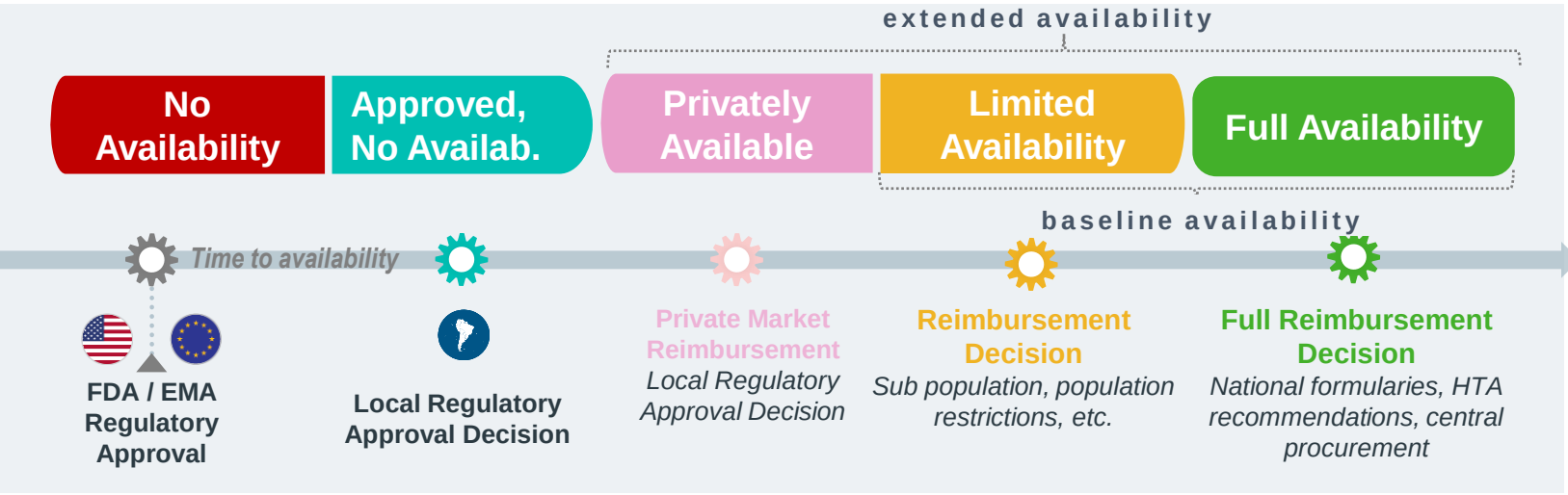
- Molecules can have up to three marketing authorization dates: FDA, EMA, and local
- Orphan status may be determined by either the FDA or EMA

*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

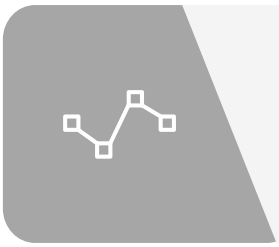
Acronyms: PAMI:Programa de Asistencia Médica Integral; SURGE:Sistema Único de Reintegros por Gestión de Enfermedades ; PMO: Programa Médico Obligatorio; CONITEC: National Committee for Technology Incorporation; FONASA: Fondo Nacional de Salud; PBS-UPC:Plan De Beneficios En Salud Con Cargo A La UPC; CCSS: 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 CIF - Chile

Country	Availability	Definitions	Public Data	IQVIA Data
	Full	*Broad reimbursement through FONASA formularies (e.g., GES, Ricarte Soto), accounting for approx. >90% of the patient population, considering available therapeutic indications*	Ricarto 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 (<90% approx.); availability through a specialized programs e.g., DAC – centralized, ministry of health programs, or decentralized local/regional programs, also applies whilst decision is pending, use is restricted to specialists*		
	Only Private	*Partial or full reimbursement only for patients via CAEC or extracontractual Benefit, multiple ISAPREs formularies through CAEC or BEC*	Not available	
	Not Available	*Available in the out of pocket market, or is not reimbursed until the evaluation or decision*	Not available	