

FIFARMA

IQVIA

W.A.I.T Indicator 2023 – Latin America

WHITE PAPER



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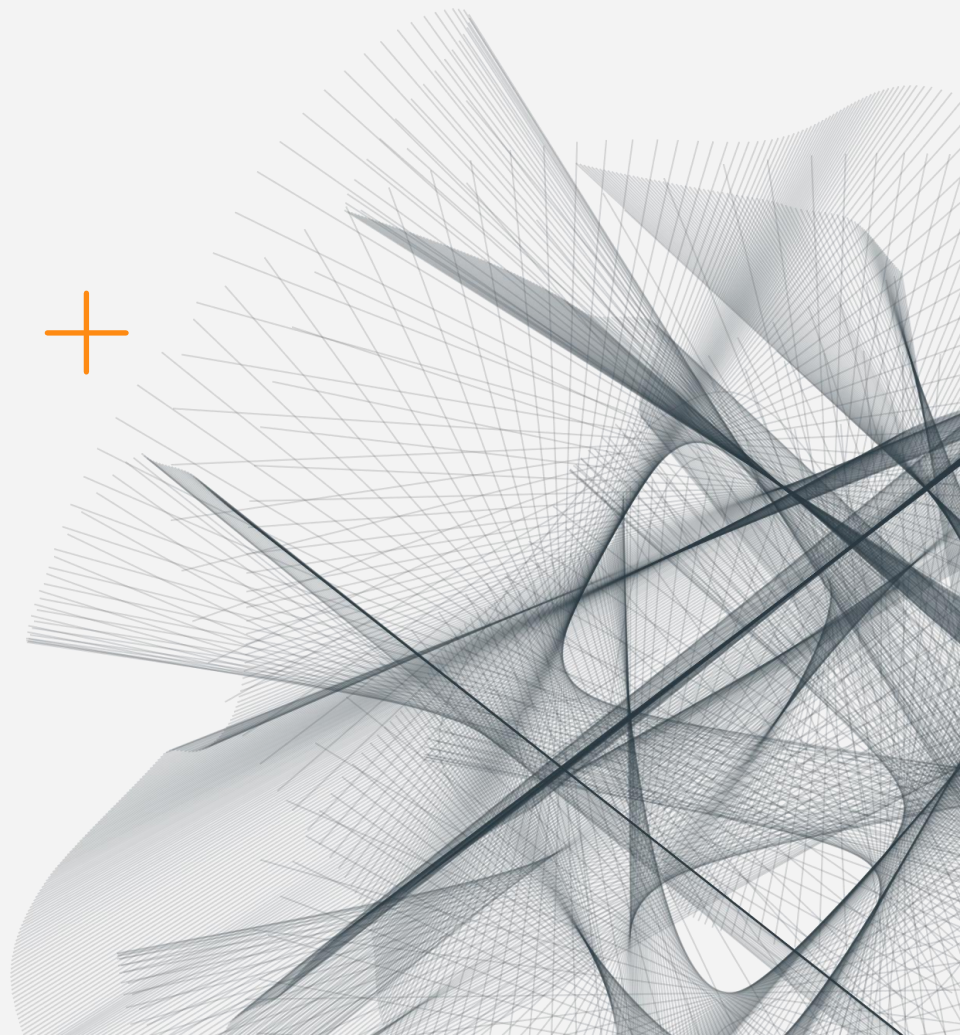


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Overview



- 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 (EFPIA) 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.
- The following pages feature analyses that benchmark the rate of availability and accessibility of innovative orphan and oncology molecules in each of the eight LATAM countries, including analysis on regional availability, and how it has evolved over the period of investigation. This year’s study includes 228 innovative oncology and orphan molecules globally approved* from 2014-2021.
- 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 look 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 about improving access.



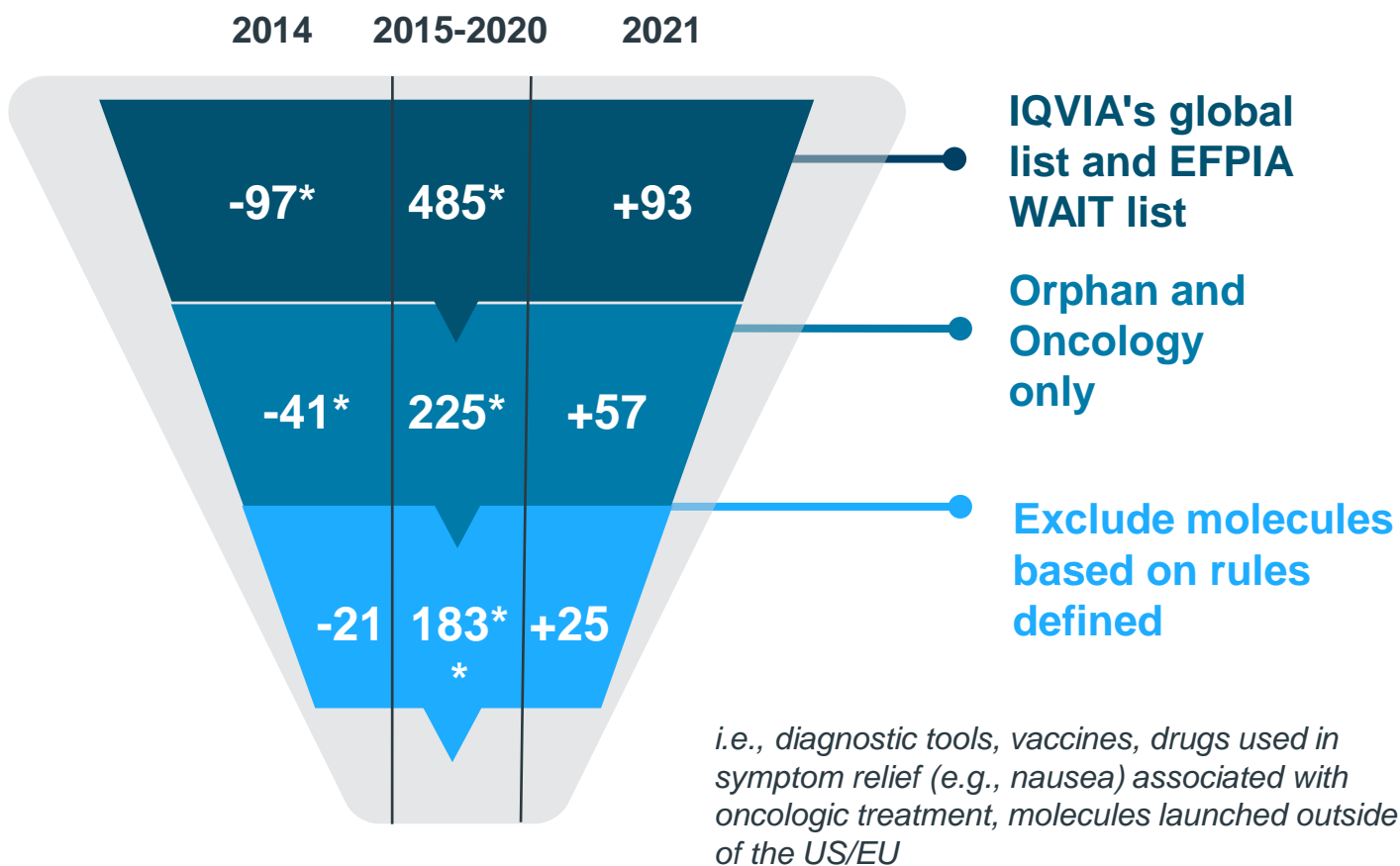
*In this study the term ‘**availability**’ is used throughout to permit **standardized measurement across 8 healthcare systems***

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

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

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

Study Cohort Selection Criteria

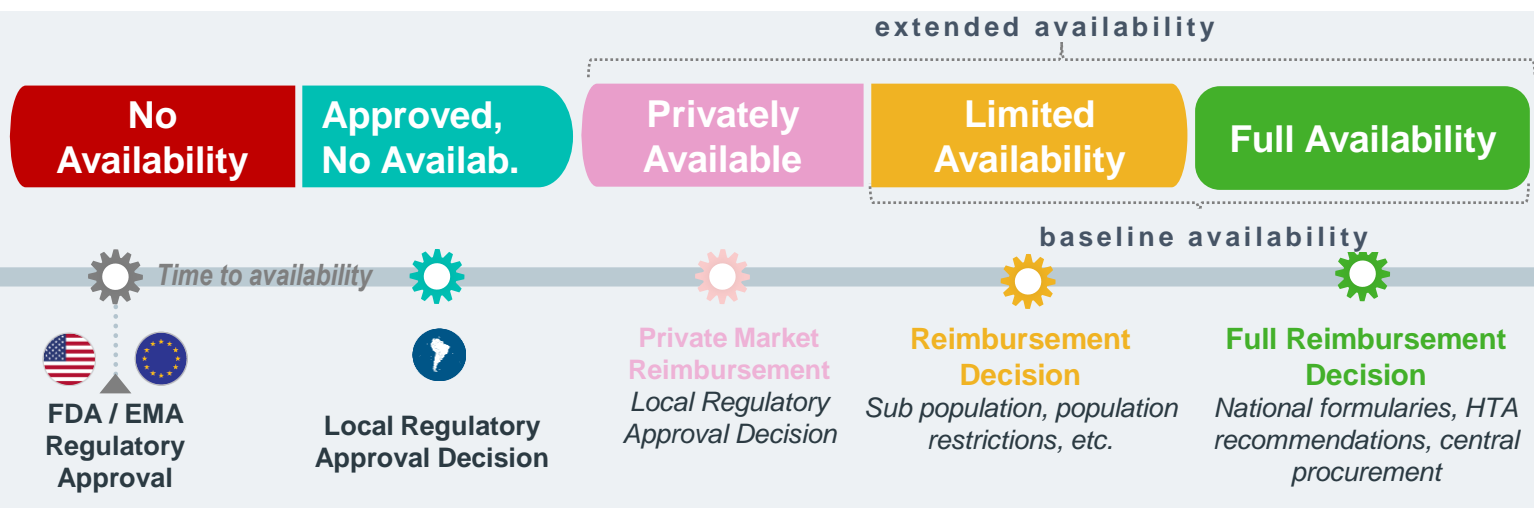


- Molecules can have up to three marketing authorization dates: FDA, EMA, and local
- Orphan status may be determined by either the FDA or EMA

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 and compared across countries

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.

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 	EC 	MX 	PE 	
Availability Def.	Full	PAMI/ SURGE or PAMI and PMO	CONITEC and centralized purchases	Broad FONASA reimbursement	PBS-UPC	CCSS (LOM)	Essential list e.g., MSP, IESS	Compendium, 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 reimbursement, special programs, multiple ISAPRE	ADRES / MIPRES	Special purchases	Typically exception processes	Decentralized formularies	Not listed but with limited access
	Private	Broad prepaid coverage	ANS ROL placement	CAEC	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	Compendium, 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 comprehensive	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:nstituto Nacional de Enfermedades Neoplásicas; CAEC:Cobertura Adicional para Enfermedades Catastróficas

Summary of key findings from the study

Regional availability

- 57% 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
- 38% of molecules have a degree of availability in the public market in at least one market, but again, wide disparities exist
- 21% of molecules have broad availability in at least one market, with Mexico and Colombia accounting for >80% of the full availability in the region
- Significant gaps exist between approval and availability (private or public) in many markets, with Peru (46%), Chile (45%), and Brazil (39%) at the forefront, and to a lesser extent Costa Rica (30%), and Mexico (23%), with other countries ≤10%
- Argentina (63%), Mexico (32%), Brazil (31%), and Chile (29%) have important participation in the private market, as a likely driver of availability, with remaining countries all <15%



“A substantial portion of molecules face reimbursement restrictions, resulting in a high degree private and /or limited availability – the is still a long journey for national and broader access in LATAM”

Availability Timelines

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

- Time to availability is on average 1,641 days 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 688 days, or ~2 years, on average between the countries in scope
- As with regional availability, wide disparities also exist between countries in terms of time to availability, with Argentina on the low end at an average of 966 days, and Mexico on the high end, with an average of 2,703 days

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: from 2014-2017 the number of approved molecules was 70, and the rate of availability of approved molecules is 93%, whereas from 2018-2021 there were 60 molecules approved, and the rate of availability is 72%



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 BR and CL, a private market often delays public subnational access before broad public access



COVID Impact

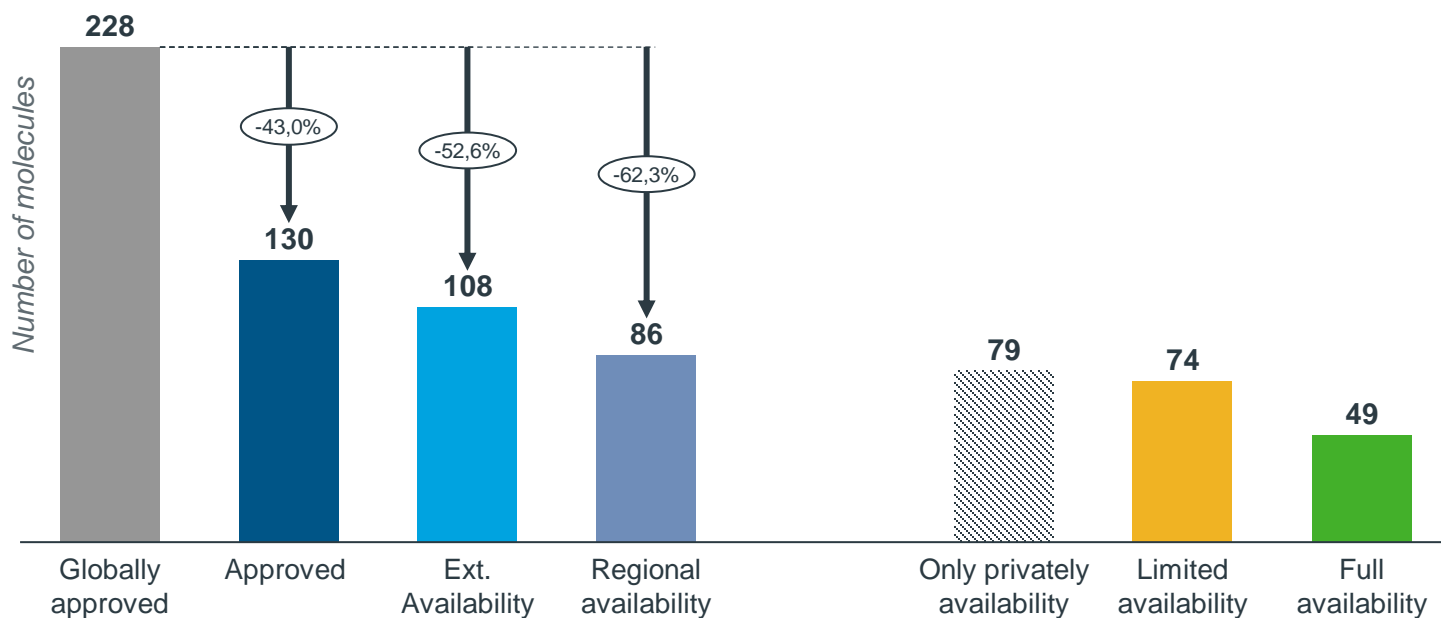
During the COVID period, a decrease in high cost / specialty care HTA activity was observed, resulting in fewer molecules being included in both subnational and national formularies



Regional availability is broken down into subtypes, with just 38% of molecules included in the study available regionally

Breakdown of regional availability (2014-2021) – combined

Number of molecules by availability status



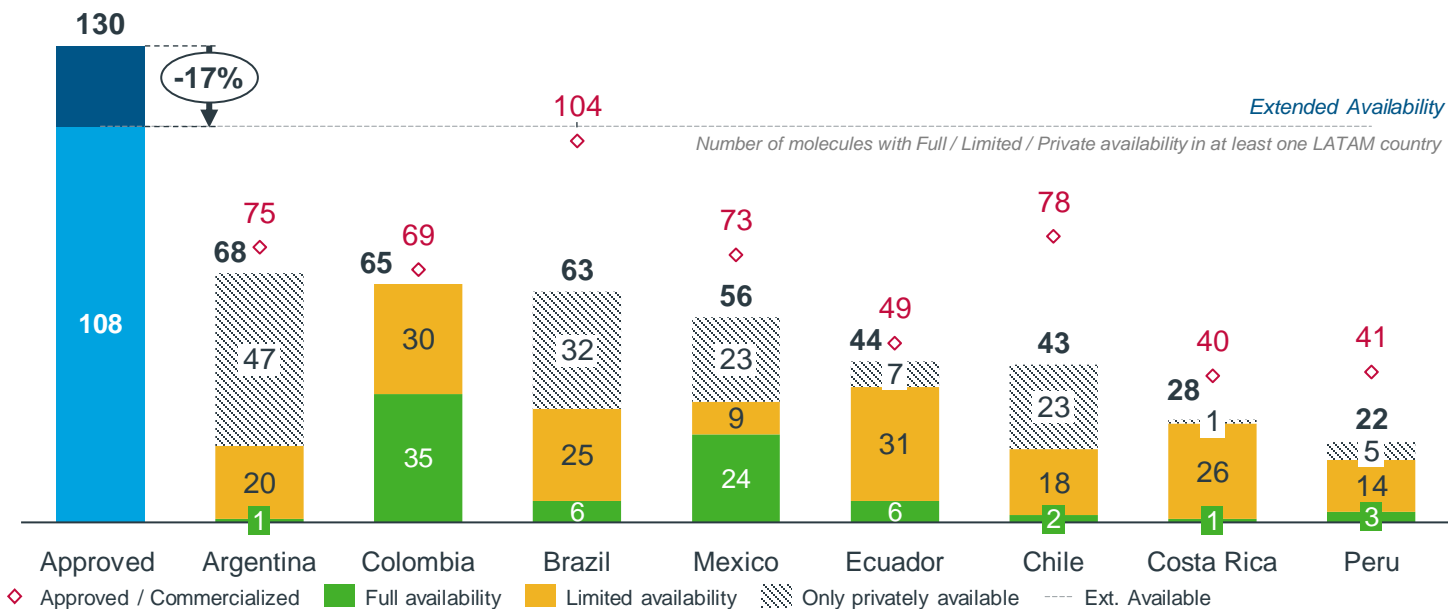
- There are a total of 228 molecules globally approved from 2014-2021 that are included in the study as part of the combined cohort (i.e., oncology, and rare disease)
- Out of 228 molecules, 57% of the are approved for market authorization in at least one of eight LATAM countries
- From there, 47% of molecules have regional extended availability, meaning these molecules have some level of availability between public (full or limited) and/or private markets in at least one geography
- 38% of globally approved molecules are available regionally i.e., public, whether that be limited or full availability
- Drivers of lower rates of approval and availability include a complex and/or lengthy regulatory process timelines, and high dependency on the private market channel for some countries. Furthermore, broad access or full availability is a lofty target in many countries given the level of fragmentation of the healthcare system

REGIONAL AVAILABILITY

Overall, wide differences exist in regional availability between countries, with availability and approvals following different trends

Regional extended availability (2014-2021) – combined

Number of molecules by availability status



- On average, there are 58 molecules available in a country, across those included in scope, compared to 66 approved
- There is a gap of 17% between molecules that are approved in at least one country in LATAM, and those that are available; representing a meaningful percentage of molecules that are approved but not reimbursed
- The trend in availability, does not follow the same trend as sanitary registry, with Brazil, Chile and Peru in particular, bucking the trend and contributing to the difference between approvals and availability
- The trend in availability also does not correspond in a linear fashion to market size, with Brazil, the

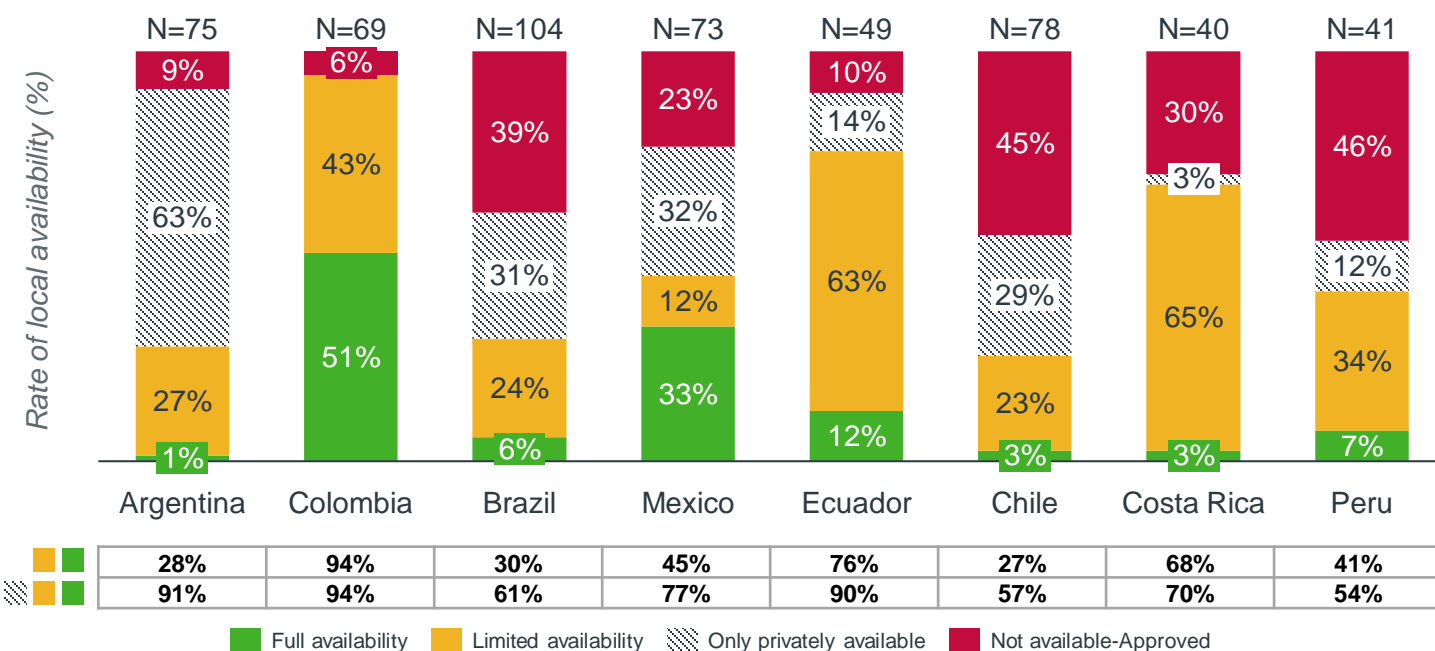
largest pharmaceutical market in LATAM in third place with respect to number of molecules available. Although, the four historically largest markets: Brazil, Colombia, Mexico and Argentina, are clustered at the high end

- There are significant gaps between the two clusters, with the average of the larger pharmaceutical markets at 80 molecules approved, and 63 available, compared to 52 and 34 respectively

REGIONAL AVAILABILITY

Full availability rates are generally low across LATAM, and rates of approved, not available strikingly high in some countries

Rate of regional extended availability (2014-2021) – combined



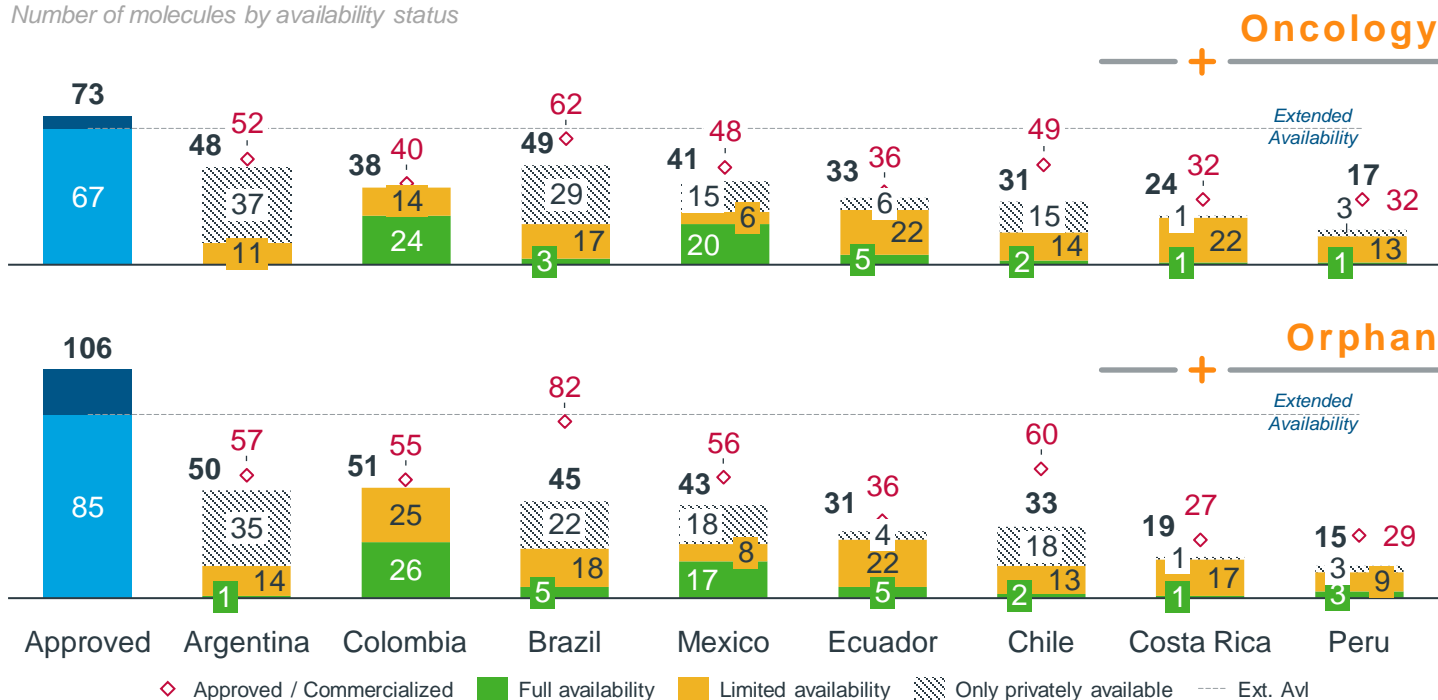
- Significant gaps exist between approval and availability (private or public) in many markets, with Peru, Chile, and Brazil at the forefront, and to a lesser extent Costa Rica, and Mexico, with other countries $\leq 10\%$
- Argentina and Colombia show a stark contrast as the two countries with the most molecules available: those available in Argentina are largely accounted for by the private market, whereas those in Colombia, have a high percentage of full availability
- For markets where private market has a high level of participation, i.e., Argentina, Mexico, Brazil, and Chile (remaining countries all $< 15\%$), this is an important driver of access, although it does not have a linear correlation with overall availability
- Other aspects related to manufacturer commercial opportunity, and capabilities are likely important drivers too; 68% of the molecules in the study are from small-mid sized manufacturers, with limited-no organizational footprint in LATAM
- Some markets have experienced recent changes in access e.g., reform in Mexico, fragmenting further the path to broad availability; recent improvements in the private HTA processes in Brazil via the ANS ROL have improved access to oncology medications, but not consistently across formulations

REGIONAL AVAILABILITY

When compared to regional extended availability, oncology and orphan follow somewhat different trends

Regional extended availability (2014-2021) – oncology vs. orphan

Number of molecules by availability status



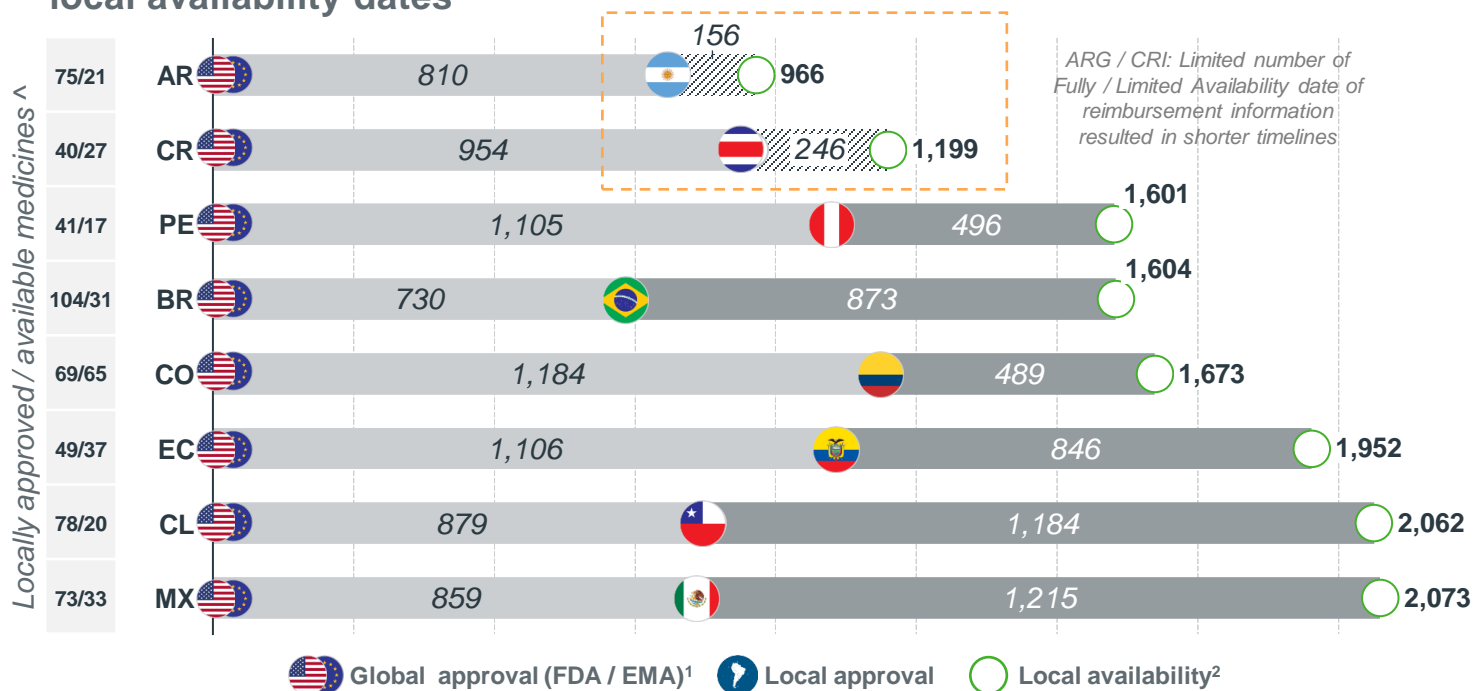
- Orphan molecules see a larger gap between approval and availability when compared to oncology in many markets, most notably Brazil, but also Chile and Costa Rica to some extent too
- Argentina and Brazil have the highest number of oncology molecules with extended availability (48 and 49 respectively), with the private market paving the way for access in both these markets
- Colombia and Argentina have the highest for orphan molecules with extended availability, with 51 and 50 respectively
- Colombia and Mexico have the most molecules that are 'fully available' for both the oncology and orphan cohorts, in line with general availability

trends

- Peru maintains the widest gap between approved oncology (53%) and orphan (52%) molecules and those that are available, though gaps are almost as wide in Chile (55%) and Brazil (55%) for orphan molecules
- As reforms continue in health systems, improvement in reimbursement of orphan molecules through creating specific routes to access in a similar way that some exist for oncology, will be crucial to closing this gap

There is a long pathway for innovation to achieve broad reimbursement

Time to availability (2014-2021) – combined, FDA / EMA, marketing auth., and local availability dates



As with regional availability, wide disparities also exist between countries in terms of time to availability, with Argentina on the low end at an average of 966 days, and Mexico on the high end, with an average of 2,703 days, which reflects the total of time to marketing authorization and time to reimbursement (pub / pri), as of FDA/EMA approval

- Time to availability is on average 1,641 days between the countries in scope, with an average of 739 days for marketing authorization, and 688 days between marketing authorization and availability
- Brazil and Mexico typically are the first countries to grant regulatory approval in the region, but a complex and fragmented access/reimbursement environment results in long overall timelines to achieve broad availability

Colombia is the country with the longest regulatory approval timelines, though availability timelines are relatively short as a result of a developed access pathway through MIPRES, yet still restricted to only a subset of the population



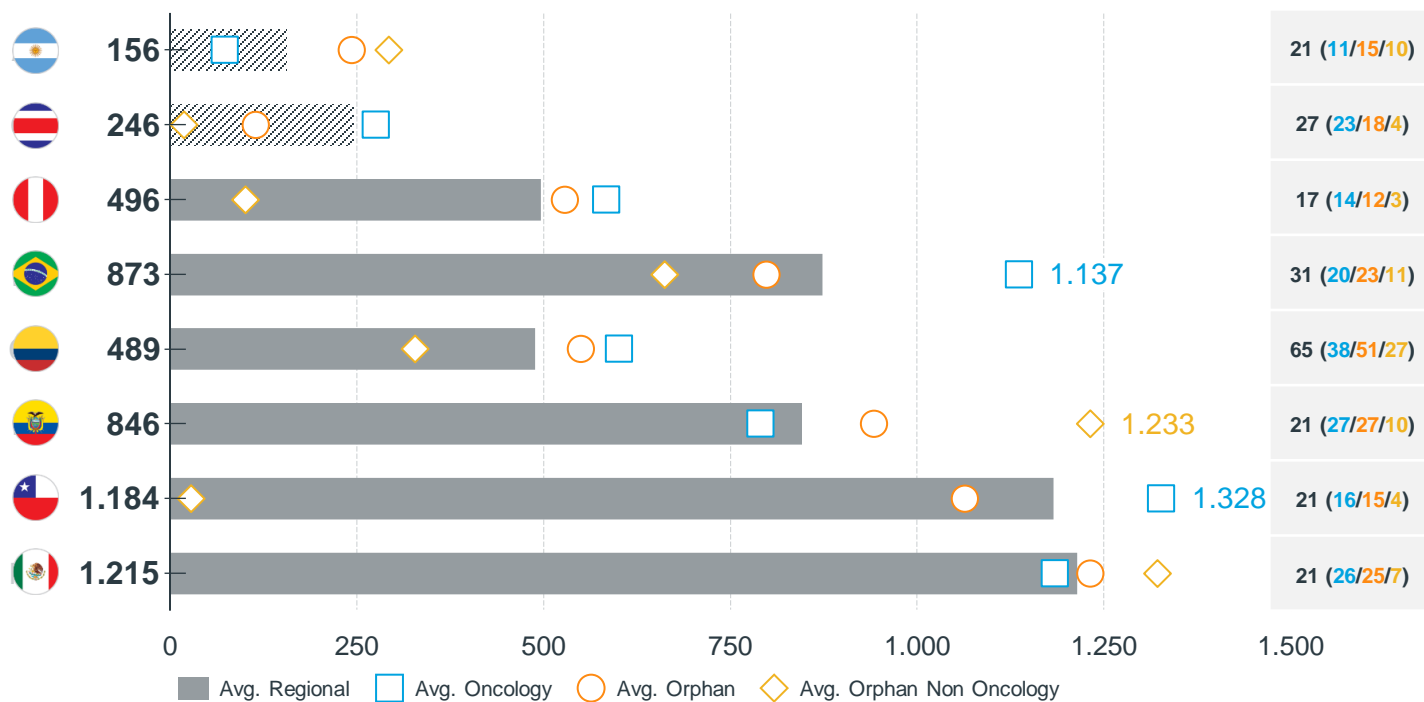
*Although having shorter timelines for Marketing Authorization, **Brazil and Mexico** the two major markets in LATAM experiment longer timelines for molecules availability as a result of a fragmented **subnational public market** and an expanding environment of **private insurers***

¹ Global approval date considered the earliest date between FDA or EMA

² Considering molecules with Full and / or Limited Availability

Usually, oncology molecules take longer to achieve availability than orphan molecules

Time to availability from market auth. (2014-2021) – orphan vs oncology



- There is a similarly wide variability between countries in terms of time to availability by orphan vs. oncology, as in the combined cohort
- Time to availability is higher for oncology when compared to orphan disease in most cases, although Argentina, Mexico and Ecuador have shorter timelines for oncology
- Orphan molecules (inclusive of orphan-oncology) generally have shorter times to availability than oncology, but orphan non-oncology has the highest variability of all the molecules
- There is also wide variability between oncology, orphan, and orphan non-oncology between countries, underpinning the impact of individual

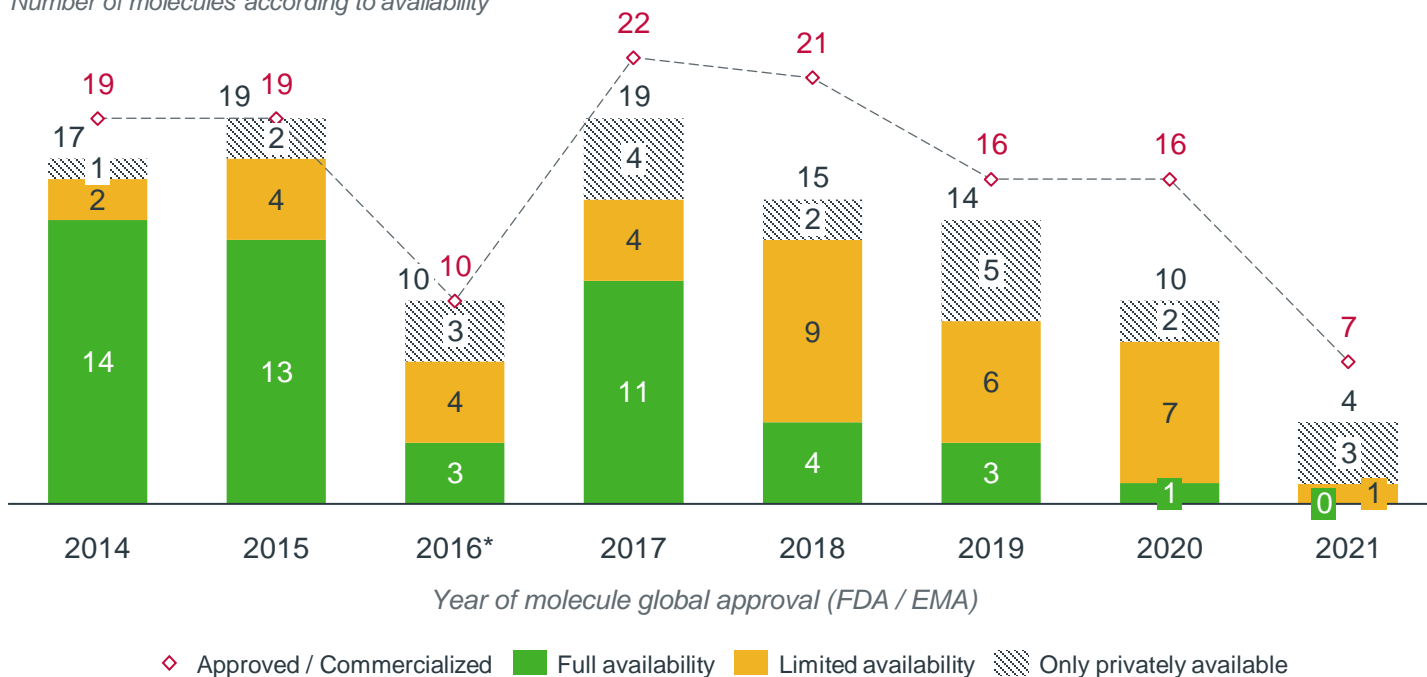
country reimbursement/access dynamics

- Argentina and Costa Rica have the lowest time to availability, driven by the private market, whereas countries with higher public market participation see longer timelines overall, illustrating part of the tradeoffs of the private market route to access
- Overall, results highlight the fragmentation across LATAM, and disparities that exist

In recent years, the number of fully available molecules has decreased, together with molecule approvals

Regional extended availability over time (2014-2021) - combined

Number of molecules according to availability



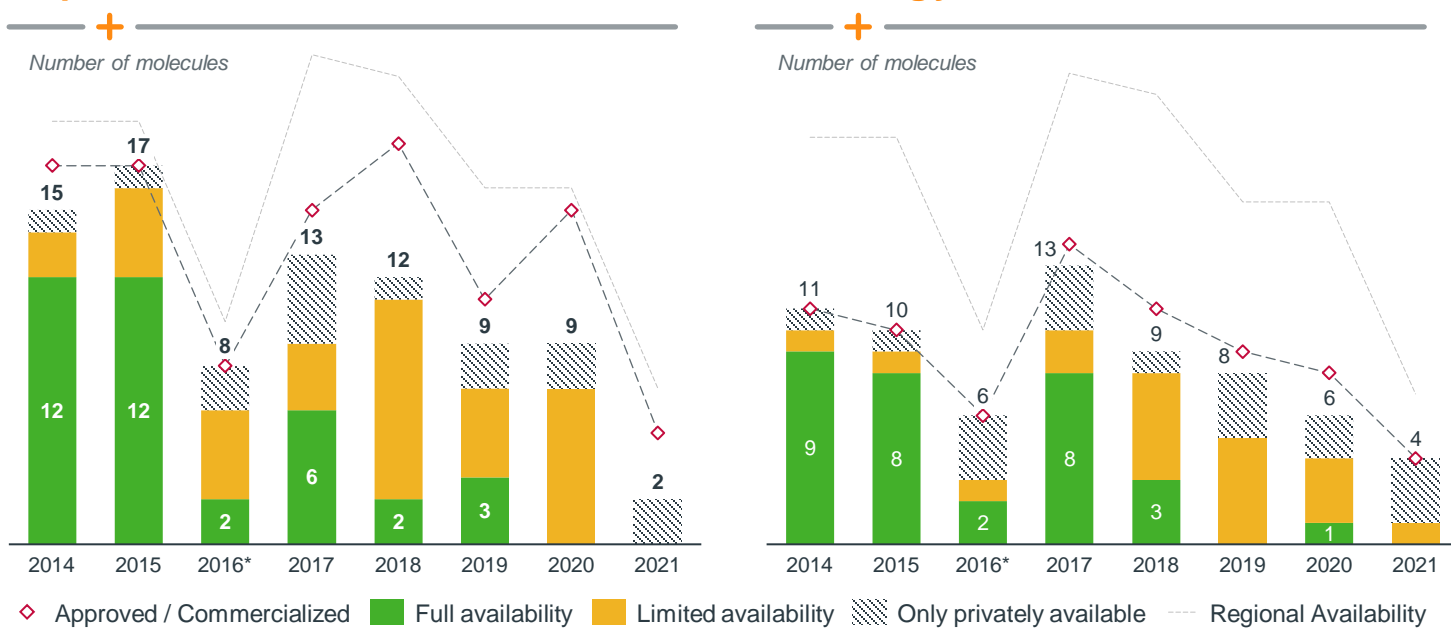
- From 2014-2017 the number of approved molecules was 70, and the rate of availability of approved molecules is 93%, but there is a decrease in both aspects from 2018-2021, where there were 60 molecules approved, and the rate of availability is 72%
- Most of the molecules with full availability status were approved between 2014-2017 (84% of the total), this trend has a number of potential drivers, that vary in their impact by country; in addition to the generally long, fragmented path to availability, two additional potential issues are:
 - COVID and associated strain on healthcare systems, which in many cases is likely to have acted to exacerbate underlying systemic challenges e.g., budget impact
- Coupled with increases in investment and clinical innovation in oncology/rare disease in recent years, leading to new standards of care e.g., PD1s, CDK4/6 inhibitors (2014-2015), but then more gradual increments of clinical benefit, and lesser priority for reimbursement

There are important differences in the orphan vs oncology results, although the overall trend remains similar for both over time

Regional extended availability over time (2014-2021) – orphan vs. oncology

Orphan

Oncology



- Oncology and orphan molecules show a similar overall trend across 2014-2017 and 2018-2021 groups, with an important reduction of approvals and available molecules.
- There was also a relatively consistent ratio of private-to-public and full-to-limited availability across both cohorts.
- Molecules for orphan disease however showed a less consistent pattern of decline in approvals compared to oncology, as well a wider gap between approvals and availability, likely driven by specific routes to access by country that exist in oncology e.g., ANS ROL in Brazil.
- In addition to trends in oncology mentioned previously, a trend in both oncology and rare

disease of expanding indications, going from most niche or smallest patient population to broader more prevalent conditions, also may be driving the trend, whereby:

- High unmet need in later stages of disease i.e., metastatic drives availability
- Delayed launches in LATAM compared to US/EU, where further clinical data is available, shifting launch indications and rendering HTA submission, price negotiation etc. more challenging

*Orphan approved molecules n=106; Oncology approved molecules n=73

Conclusions and limitations

1

The study results reflect the **current availability of innovative medicines in LATAM** and will increasingly shed light on its evolution across the years, given 2020-2021 were atypical in light of the COVID pandemic.

2

Indication sequencing nuances are likely to bring additional insights as indication expansions form an increasingly important role in lifecycle management for innovative therapies in oncology and rare disease; publicly available data for these events is limited, and as such, manufacturer participation in the survey is the only means of obtaining it and is not consistent across molecules

3

Expanding the analysis to alternate TAs, and diving deeper into subgroups within oncology / rare disease e.g., by lines of therapy, will also enable identification of **further trends** associated with the unique aspects of each, with further investigation planned in this respect the next edition

4

Consistency of data and comparability by countries can continue to improve, though IQVIA data and publicly available information provides a comprehensive panorama, there is still limited availability of certain aspects e.g., dates of approval for multiple indications, pinpointing availability decisions in subnational plans, etc. that depend on manufacturer participation, which is limited largely to manufacturers with a global footprint.



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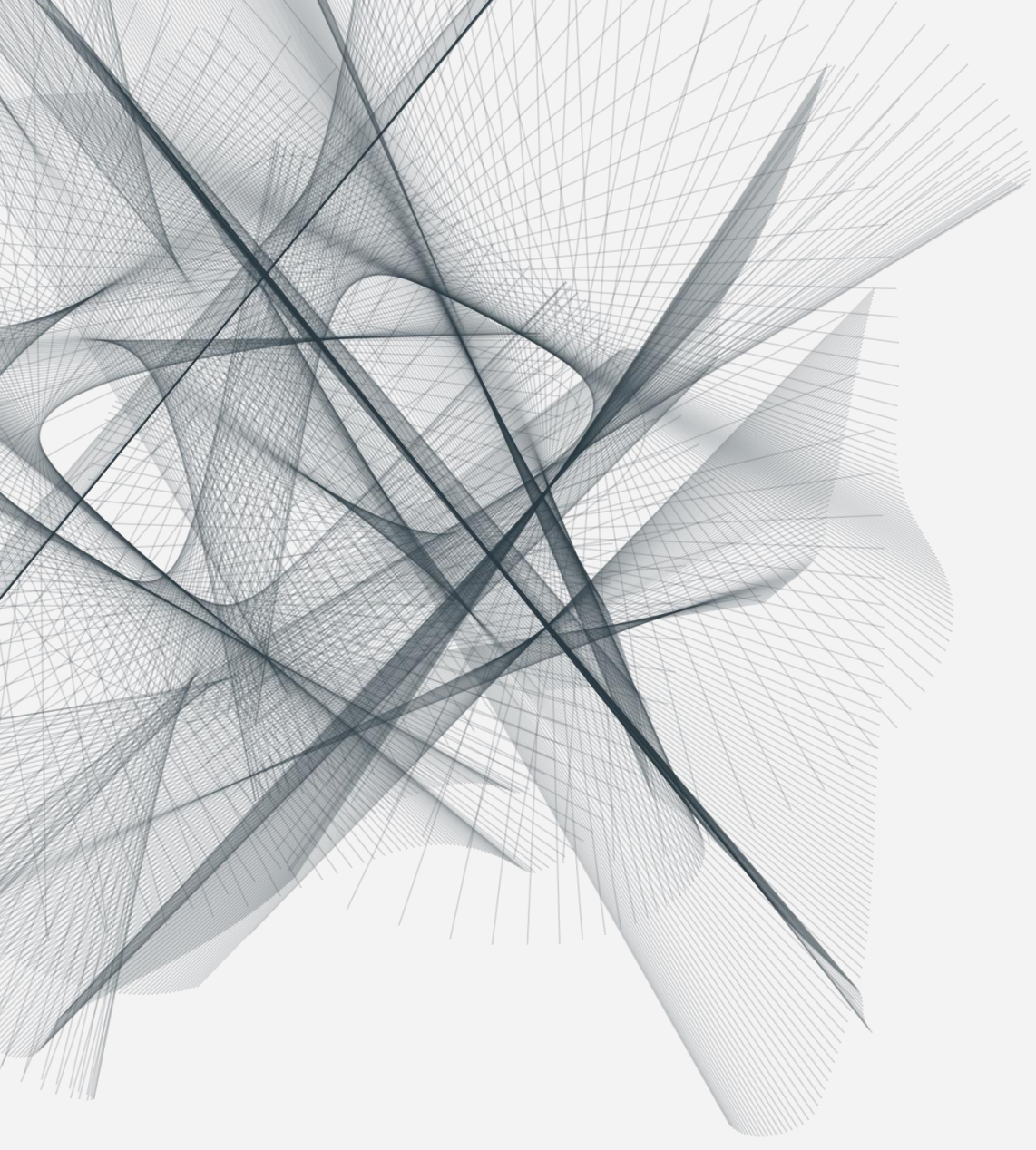
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