FIFARMA

IQVIA

Patient WAIT Indicator 2023 Latin America

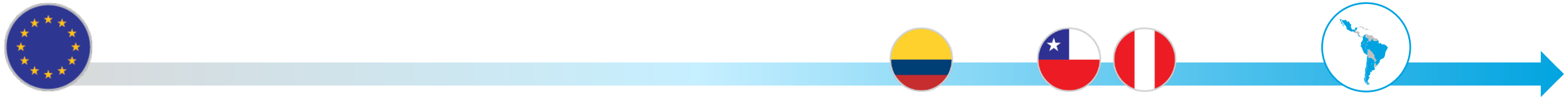
Final Report

February, 2024

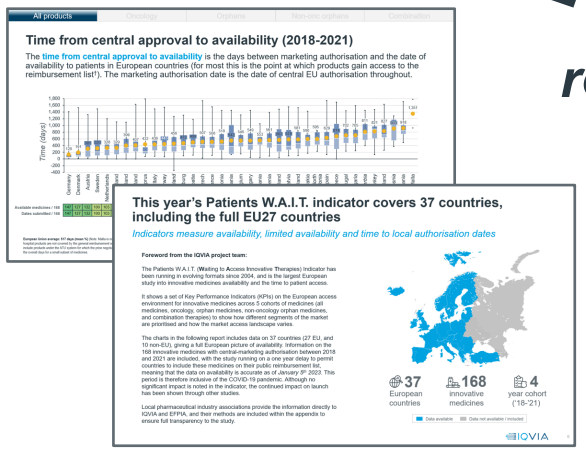
01

Context

The WAIT Indicator is a longstanding study originating in EU, that is now in its second edition in LatAm



The first **EFPIA Patients W.A.I.T. Indicator** was developed, based on the concept of "availability", providing a standardized form of comparing access to innovative medicines across distinct healthcare systems.



"Local reimbursement of a globally approved innovative medicine"

FIFARMA

Fifarma developed indicators in a similar vein in CO (2016), CL (2018) and PE (2019), eventually leading to the **first LatAm-wide edition in 2022.**

This year is the second regional edition, several steps in the **methodology in LatAm** are being **implemented in EU.**

AR BR CL CO CR EC MX PE

~90-95% of LatAm drug sales

The FIFARMA Patient W.A.I.T. survey indicates the level of availability to innovation across 8 Latin American countries, and is based off an EU study

Improving the availability of innovative medicines in Latin America is a key priority for the pharmaceutical industry, policymakers, and patients. Building on the longstanding EFPIA Patients W.A.I.T. (**W**aiting to **A**ccess **I**nnovative **T**herapies) Indicator, which has been running in evolving formats since 2004, 8 member associations in LATAM have supported the creation of the FIFARMA Patients W.A.I.T Indicator.

The charts in the following report cover 8 Latin American countries (90-95% LATAM sales): Peru (PE), Colombia (CO), Chile (CL), Mexico (MX), Brazil (BR), Costa Rica (CR), Argentina (AR) and Ecuador (EC), and provide a benchmark of the rate of accessibility and waiting times in LATAM countries.

Information on the 228 innovative oncology and orphan medicines globally approved* from 2014-2021 are included within the coming pages, with a delay to permit countries to include these medicines on their public reimbursement list, meaning that the data on availability is accurate as of *June 1st 2023.*

In some cases, local pharmaceutical industry associations provide the information directly to IQVIA and FIFARMA through their affiliated manufacturer representatives, the full dataset however is collected and analyzed by local IQVIA representatives in each geography, using public information and IQVIA sales data. The full methodology is outlined later in this document, and sources for local information gathering are listed.

FIFARMA & the IQVIA team

8
Latin American countries

228
innovative medicines

8
year cohort (2014-2021)

The study objective is to create a comprehensive dataset with an aggregated view of access across LatAm, to leverage in the public access discourse

1. Create a dataset that accurately reflects the **current availability of innovative medicines in LATAM**

2. Provide meaningful results to **trigger government and agency discussions** about **improving access**

3. Offer data to improve **company understanding** of their product portfolio for **industry benchmarking**

This reports' results do not seek to explain the drivers behind availability in the region e.g., regulatory processes; the accompanying White Paper will explore this in more detail

02

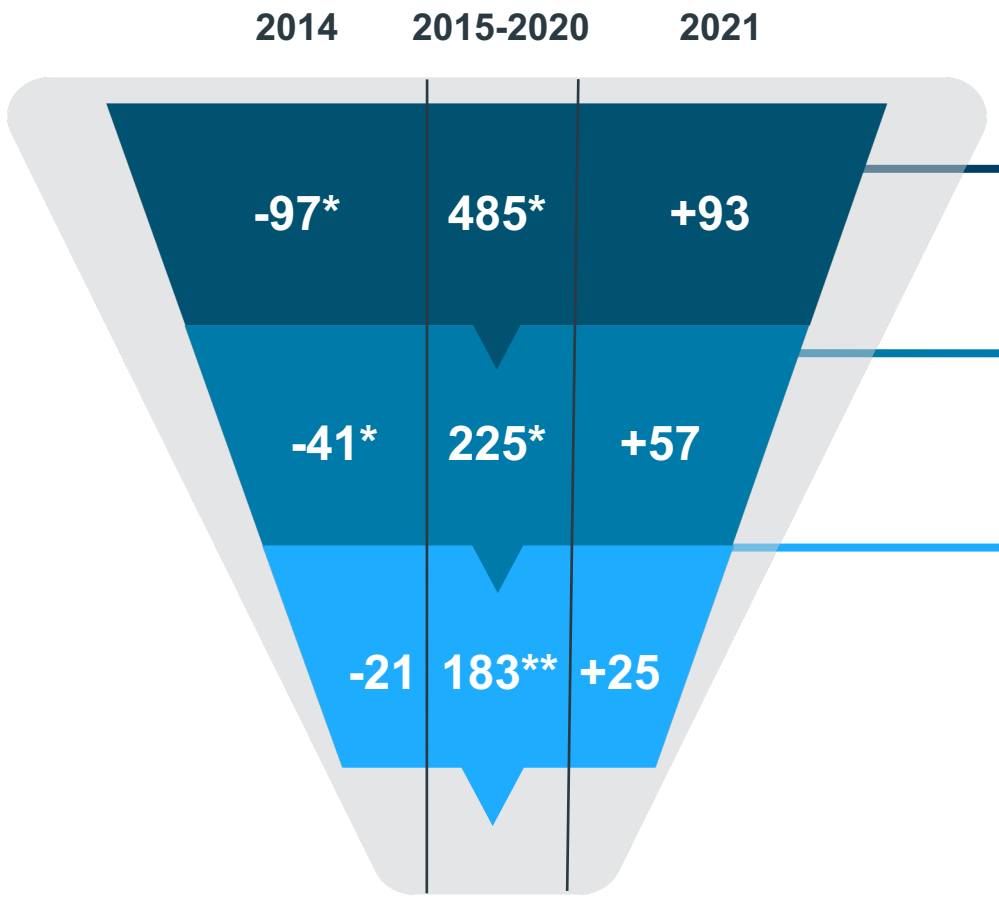
Methodology

The process for the WAIT Indicator involved participation primarily from local association representatives, local IQVIA teams, and manufacturers

Define molecules	Refine definitions	Completion of survey	Data QC & analysis	Finalize Data and Report Results
Central IQVIA team and Fifarma: • Reviewed inclusions from 2022, with some adjustments made based on updated rules • Defined list of NAS for inclusions (2021) and exclusions (2014)	Local IQVIA teams and local assoc. representatives: • Refined the regional definition, adjusting to reflect additional specifications e.g., indication • Updated local definitions of availability, most notably, AR, CL, MX and PE	Central IQVIA team: • Developed an online survey through SmartSheets for data collection Local MNF and local IQVIA updated: • Validating 2022 data, and inputting 2023 datasets (228 molecules in total) across 8 markets	Central IQVIA team: • QCed the data provided • Analyzed the full dataset to generate preliminary results Local IQVIA teams and local assoc. representatives: • Reviewed the preliminary results, and updated gaps in the data	Central IQVIA team: • Incorporated feedback and finalized dataset • Developed final report of results Central IQVIA team and Fifarma: • Presented final results

IQVIA central team and Fifarma team worked between stakeholders to ensure broad alignment and consistency

We have used a similar methodology for selecting molecules for analysis as was used for the 2022 WAIT indicator project



IQVIA's global NAS 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, all launches in ROW that aren't launched in US or EU first

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

Updates were made to the exclusion rules to define more precisely the molecule set, in addition to a shift in the cohort ('14 exlusions and '21 inclusions)

There are three main updates for this year's inclusion and analysis that impact the selection from last year, and the classification

Updates on molecule selection criteria

- Molecule selection criteria was updated since last year's analysis
- Due to this selection criteria update, a total of 10 molecules were revised for the 2023 analysis

Updates on regional and local availability definitions

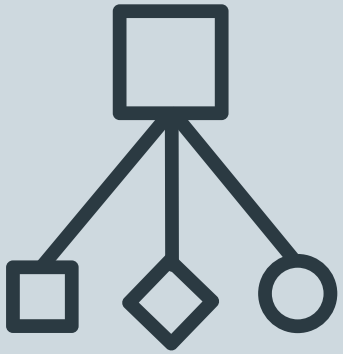
- The 2022 definition was used as a base, and updated by the local associations for 2023
- New definitions will better reflect availability in LATAM countries

Inclusion of 52 molecules and exclusion 21 molecules

- Based on FDA and EMA approval dates 2014 approved molecules were excluded and 2015 and onwards molecules were included in the 2023 cohort

Manufacturer participation was limited to ~25% of molecules, which largely corresponded with local IQVIA team analysis using public/IQVIA data

For molecules included in the study, they are classified based on the core concept of “availability”



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

“Local reimbursement of a globally* approved innovative medicine”

Where appropriate it takes into consideration things like managed entry agreements, line-of-therapy or formulary restrictions. However, it does not have a correlation to the use / uptake of the medicines.

Country-specific nuances are considered to ensure correct interpretation of the data.

*Approval by at least one of FDA or EMA

To better reflect the LATAM access and reimbursement environment, we also considered additional criteria this year

Indication Sequencing

1

MNFs were given the option to report the first indication approved in the country and the first reimbursed indication in the survey, identifying a “most relevant indication” where it differs from first FDA/EMA approved indication

Access Restrictions

2

In the case that there are access restrictions beyond the label e.g., use in a subpopulation, manufactures can add those details via the online excel survey

Local Formularies

3

IQVIA pulled information from the local formularies that are publicly available, and MNF associations supported IQVIA to access local formularies when possible

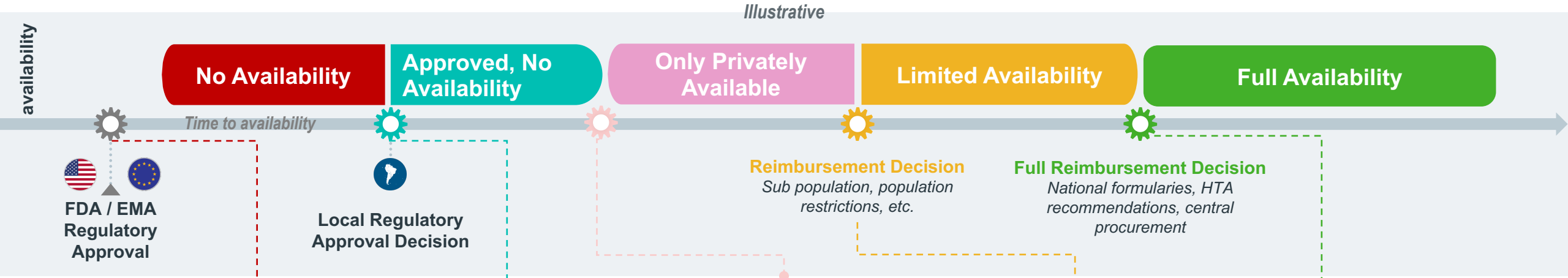
Exceptional Routes

4

In the case that product sales are coming exclusively through “exceptional routes” e.g., early access, MNF were also able to designate this via the online survey

These additional categories were aligned on and refined by the working group of local associations, however largely depend on MNF data and thus have limited representation in the dataset

An updated regional definition was used to better capture local public access, however many aspects are dependent on MNF data



Not submitted, or in regulatory evaluation process

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

Includes MAS e.g., named patient programs

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.***

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.***

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.*

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.*

Availability was defined according to FIFARMA / IQVIA and validated by local manufacturer associations

Local definitions of availability were refined by association representations vs. 2022, and used to compare availability across the region

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 subnational 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

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

Detailed country definitions can be found in the appendix

03

Summary of Results

Multiple factors can influence the availability and time to access across countries in LatAm, these will be explored more in depth in the White Paper

Critical Factors Influencing Availability of Innovative Medicines in Latin America

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

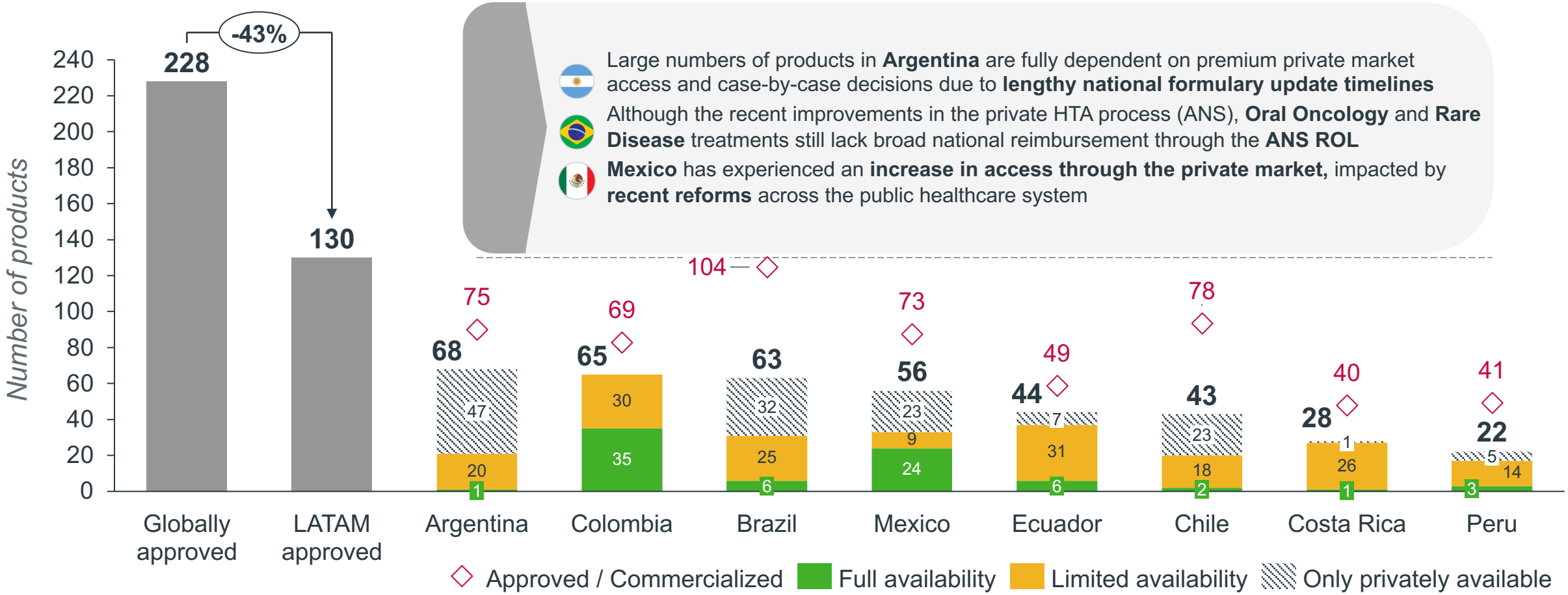
Reimbursement in LATAM is bottoms-up, starting with private HMOs, then public sector before broad national formularies. In markets such as BR and CL, a private market often delays public subnational access before broad public access

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

The expanded cohort analysis increases both overall and full availability rates highlighting extended regulatory approval timelines

Rate of regional availability (2014-2021) – combined



Large numbers of products in **Argentina** are fully dependent on premium private market access and case-by-case decisions due to **lengthy national formulary update timelines**

Although the recent improvements in the private HTA process (ANS), **Oral Oncology** and **Rare Disease** treatments still lack broad national reimbursement through the **ANS ROL**

Mexico has experienced an **increase in access through the private market,** impacted by **recent reforms** across the public healthcare system

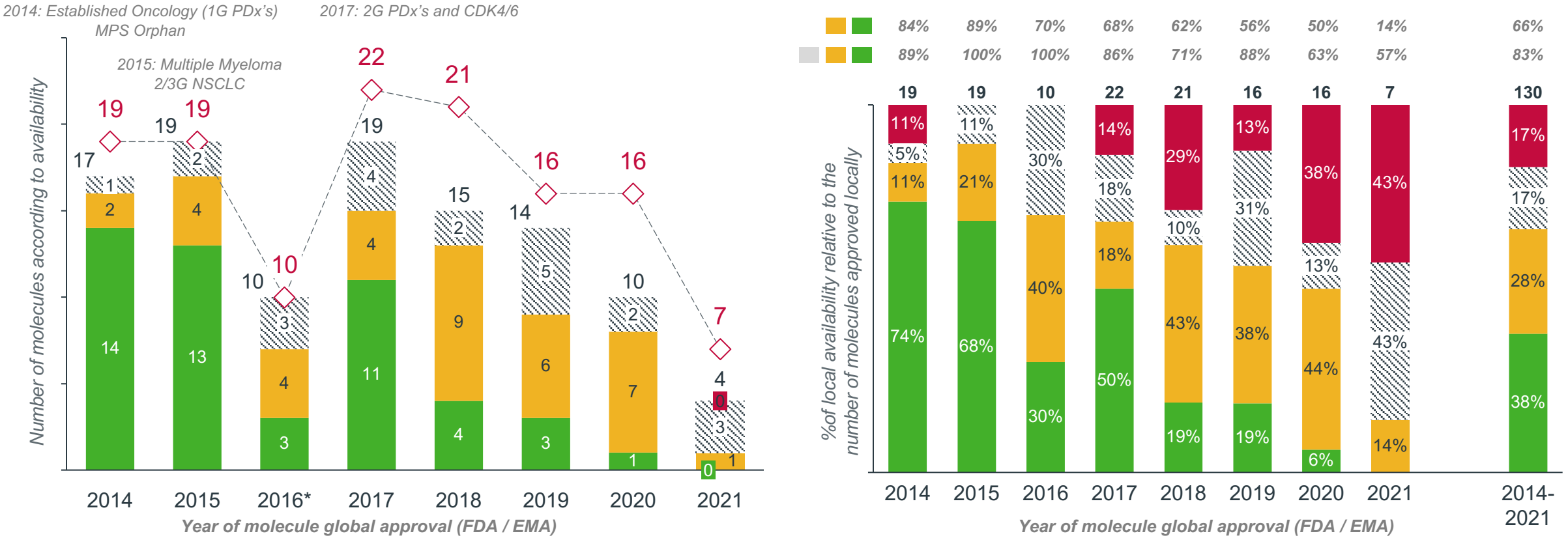
The **rate of regional full availability** shows the proportion of medicines with LATAM regulatory approval^ available to patients in Latin American countries as of 1st June 2023 (for most countries this is the point at which the product gains access to the national reimbursement list†) with or without any restrictions to the patient population, or through named patient basis schemes.

LATAM Average: 29%

Availability rates decreases as global launch timelines gets more recent as a result of the LATAM bottom up reimbursement dynamics

Rate of local availability per year (2014-2021) – combined

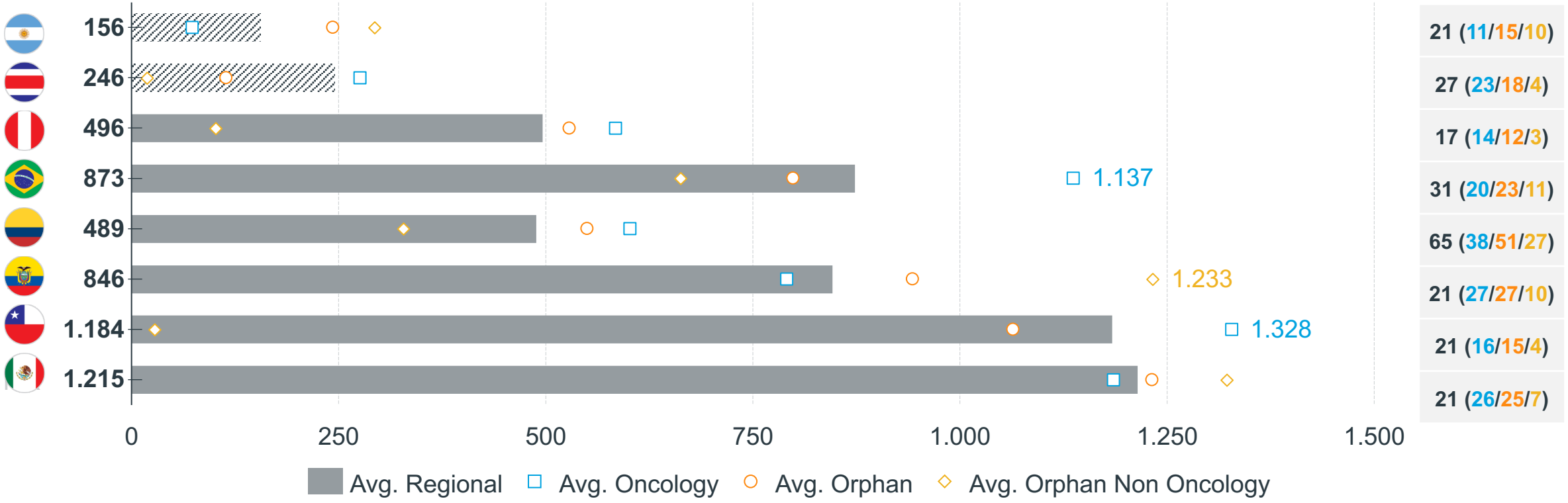
- Most of the molecules with Full Availability status have been approved between 2014-2017, being concentrated on established Oncology molecules
- In 2016, there were a substantial drop in the number of global approved drugs including in Oncology and Rare Diseases – FDA / EMA has got back on track on the number of approvals from 2017 on until a new decrease as a result of COVID19



There is a wide variability between countries in terms of time to availability by orphan vs. oncology, as in the combined cohort

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

- **Time to availability is higher for oncology when compared to orphan disease in most cases**, although AR, MX and EC 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**



4

Extended

Combined, Oncology and Orphan

Executive summary for extended cohort

LATAM average rate of availability and time to availability (2014-2021)

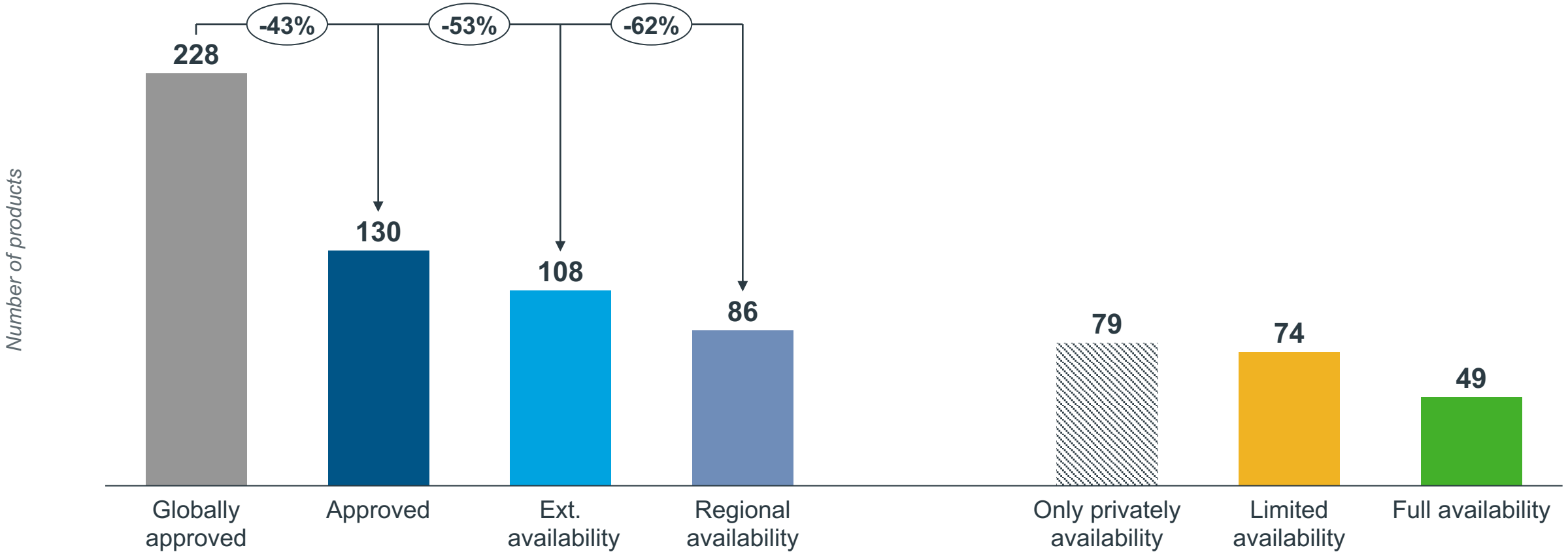
Measure	Combined cohort	Oncology cohort	Orphan cohort
Rate of global availability	38%	43%	36%
Rate of expanded global availability	47%	58%	44%
Rate of regional availability	66%	68%	67%
Rate of expanded regional availability	83%	**92%**	81%
Average time to availability (local dates)	**1.89 Years** (688 Days)	**2.05 Years** **(747 Days)**	**1.87 Years** (681 Days)
Average time to availability (FDA date)	**4.50 Years** (1,641 Days)	**4.70 Years** (1,714 Days)	**4.54 Years** (1,656 Days)

Definitions:
Availability: Full and Limited availabilities
Expanded Availability: Full, Limited and Only Private availabilities

Combined 2014-2021 cohort

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

Breakdown of regional availability (2014-2021) – combined



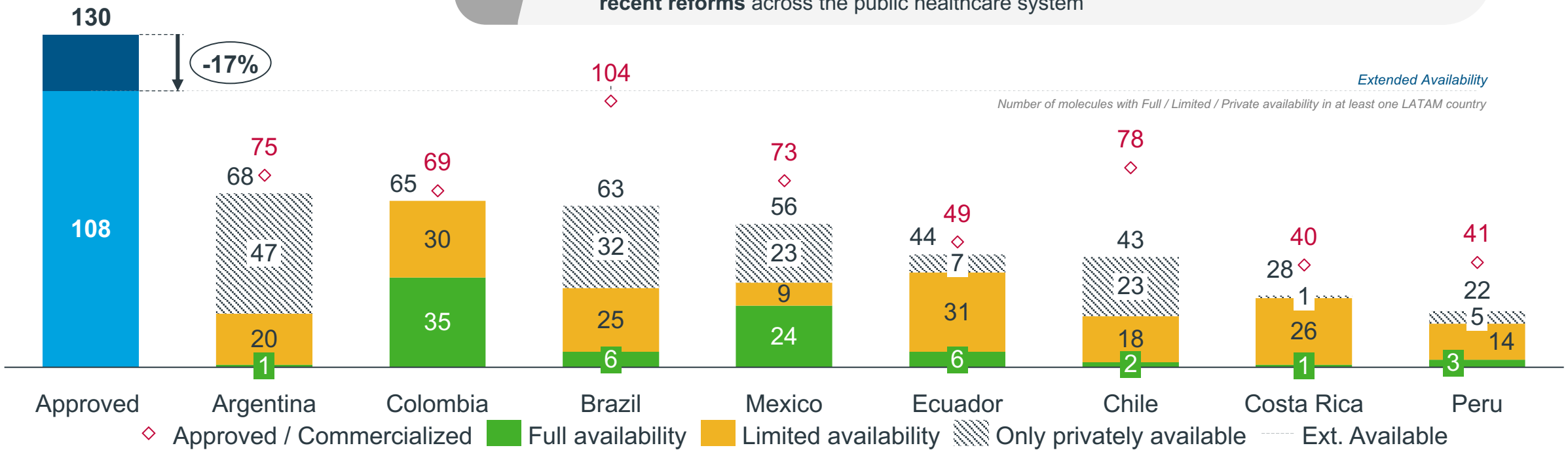
The **rate of regional full availability** shows the proportion of medicines with LATAM regulatory approval^ available to patients in Latin American countries as of 1st June 2023 (for most countries this is the point at which the product gains access to the national reimbursement list†) with or without any restrictions to the patient population, or through named patient basis schemes.

LATAM Average: 29%

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

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

- Large numbers of products in **Argentina** are fully dependent on premium private market access and case-by-case decisions due to **lengthy national formulary update timelines**
- Although the recent improvements in the private HTA process (ANS), **Oral Oncology** and **Rare Disease** treatments still lack broad national reimbursement through the **ANS ROL**
- **Mexico** has experienced an **increase in access through the private market,** impacted by **recent reforms** across the public healthcare system



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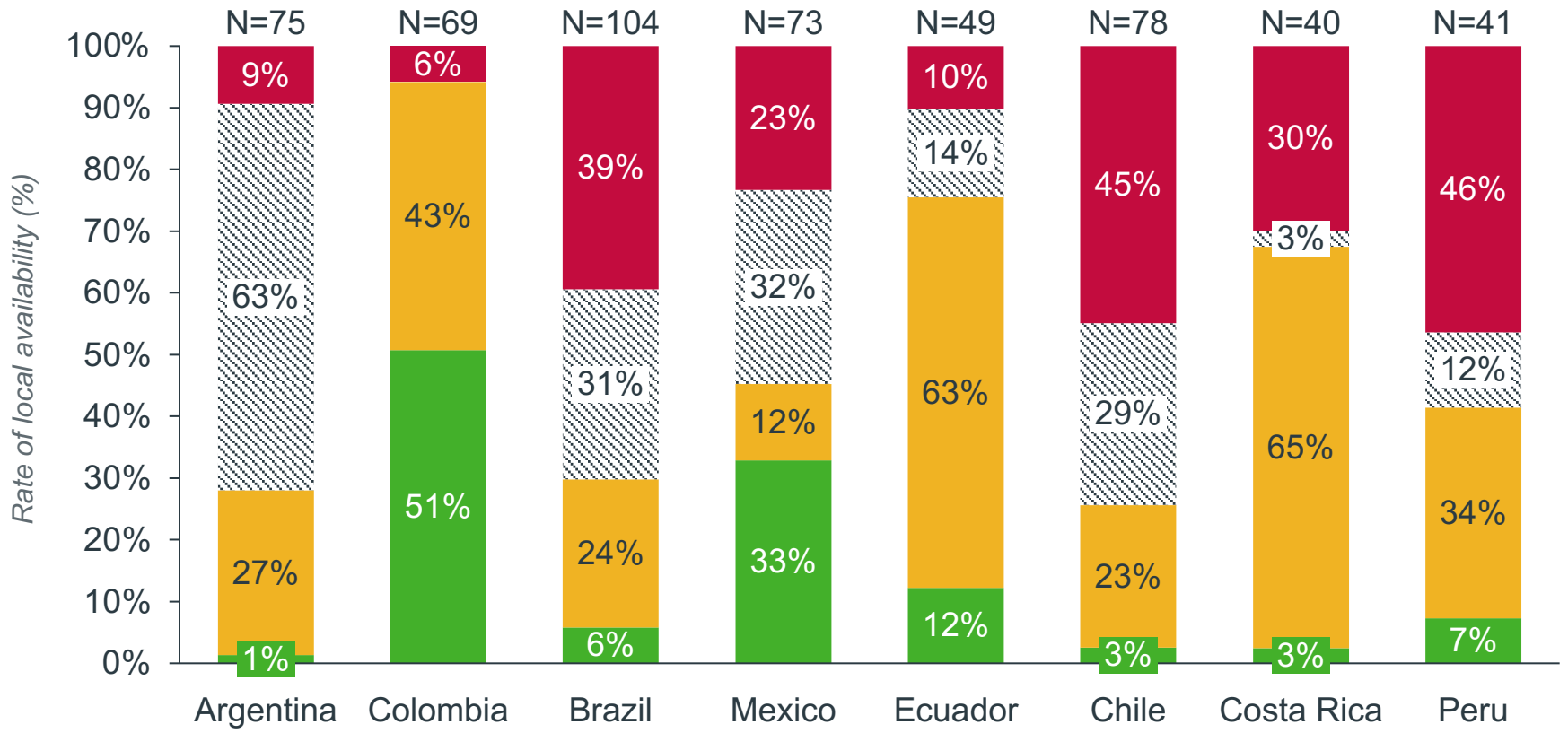
LATAM Average: 29%

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

Rate of local availability (2014-2021) – combined



	Argentina	Colombia	Brazil	Mexico	Ecuador	Chile	Costa Rica	Peru	
	28%	**94%**	**30%**	**45%**	**76%**	**27%**	**68%**	**41%**	**% of Availability (Full and Limited)**
	91%	**94%**	**61%**	**77%**	**90%**	**57%**	**70%**	**54%**	**% of Expanded Availability (Full, Limited, Priv)**
	33%	30%	46%	32%	21%	33%	18%	18%	**% of globally approved medicines locally available / 228**

LATAM Average: 29%

Full availability | Limited availability | Only privately available | Not available-Approved

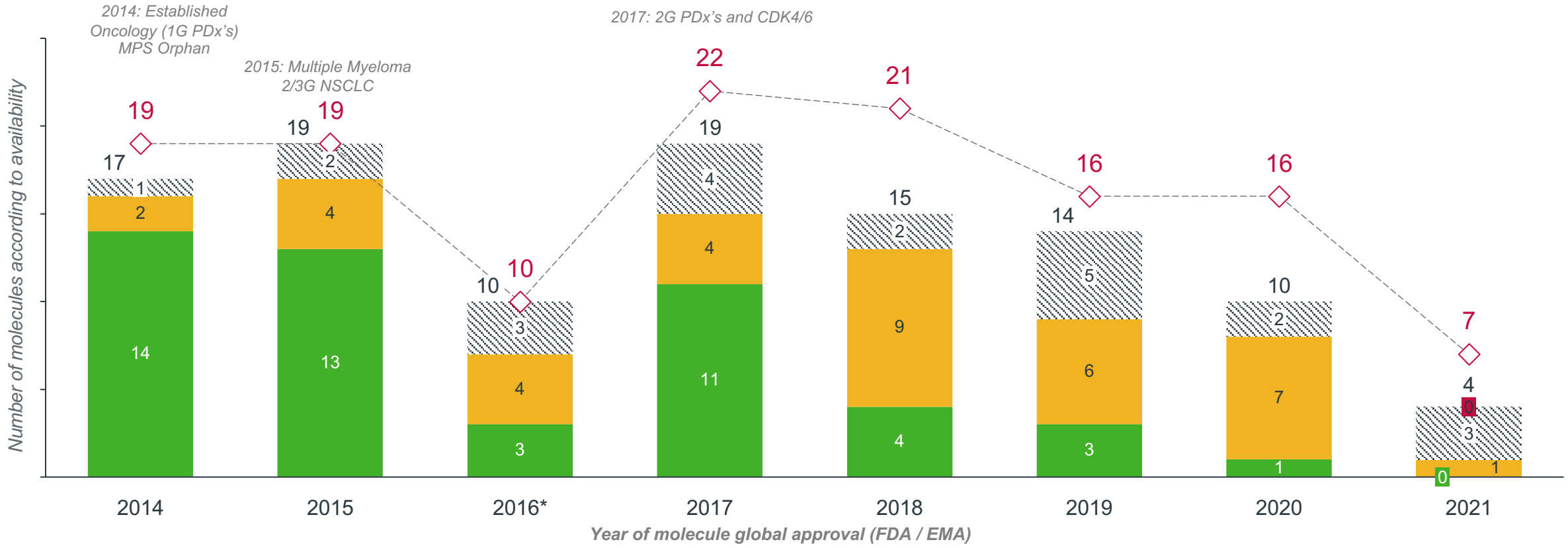
Key Insights

- 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 ≤10%
- An important portion of the molecules in the study are from **small / mid sized manufacturers** which have **no footprint in LATAM**
- Therefore, **Oncology and Orphan drugs** can **take longer** to be launched in LATAM

Availability rates decreases as global launch timelines gets more recent as a result of the LATAM bottom-up reimbursement dynamics

Rate of local availability per year (2014-2021) – combined

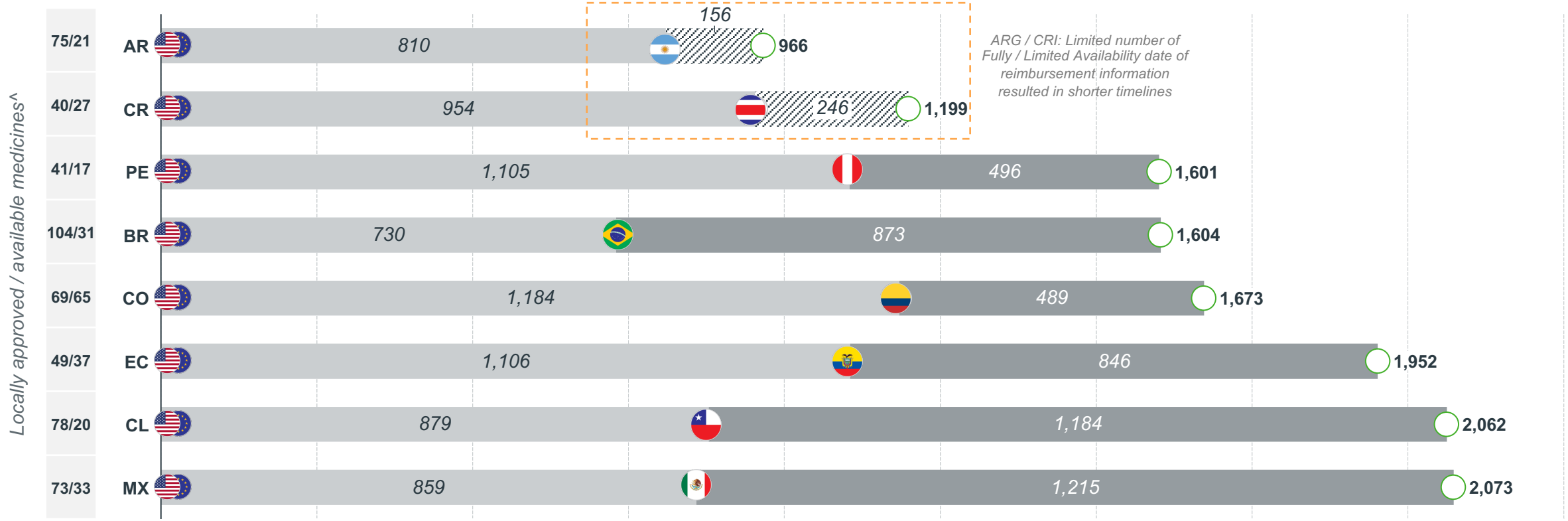
- Most of the molecules with Full Availability status have been approved between 2014-2017, being concentrated on established Oncology molecules
- In 2016, there were a substantial drop in the number of global approved drugs including in Oncology and Rare Diseases – FDA / EMA has got back on track on the number of approvals from 2017 on until a new decrease as a result of COVID19



There is a long pathway for innovation to achieve broad reimbursement through widely a fragmented reimbursement system

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

- **Colombia** is the country with **longer regulatory** approval **timelines** - **availability timelines** are small as a result of a **high degree of limited availability** through MIPRES that is granted pretty fast, yet **still restricted** to only **a subset of the population**
- **Brazil and Mexico** typically are the **first countries to grant regulatory approval** in the region, but a **complex and fragment** environment results in very long timelines until **achieving broad reimbursement**



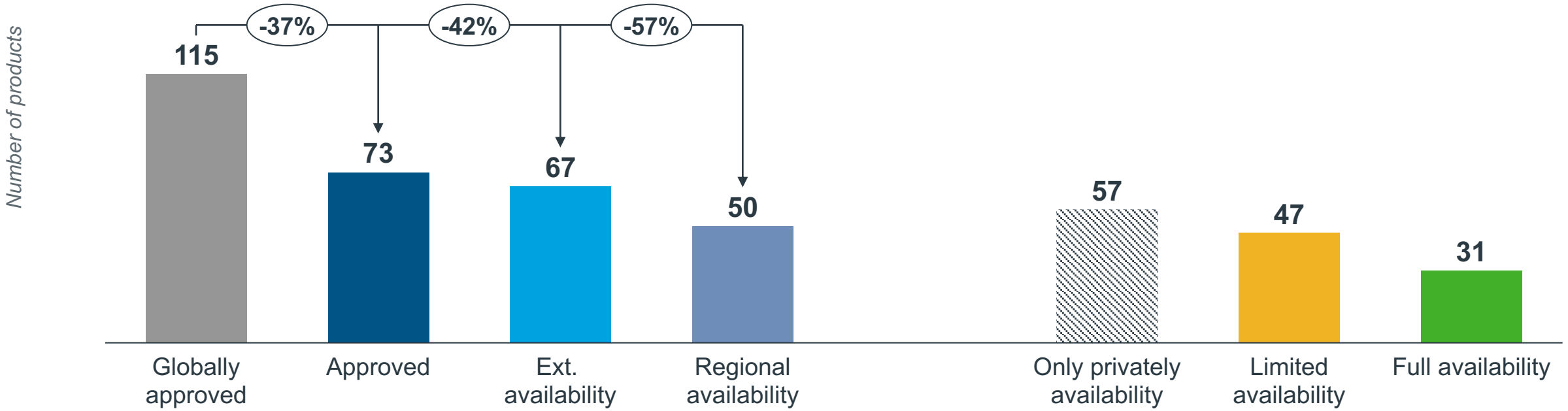
LATAM Average: 1,641 days

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

Oncology
2014-2021 cohort

Regional availability is broken down into decreasing subtypes, with just 43% of molecules included in the study regionally available

Breakdown of regional availability (2014-2021) – oncology



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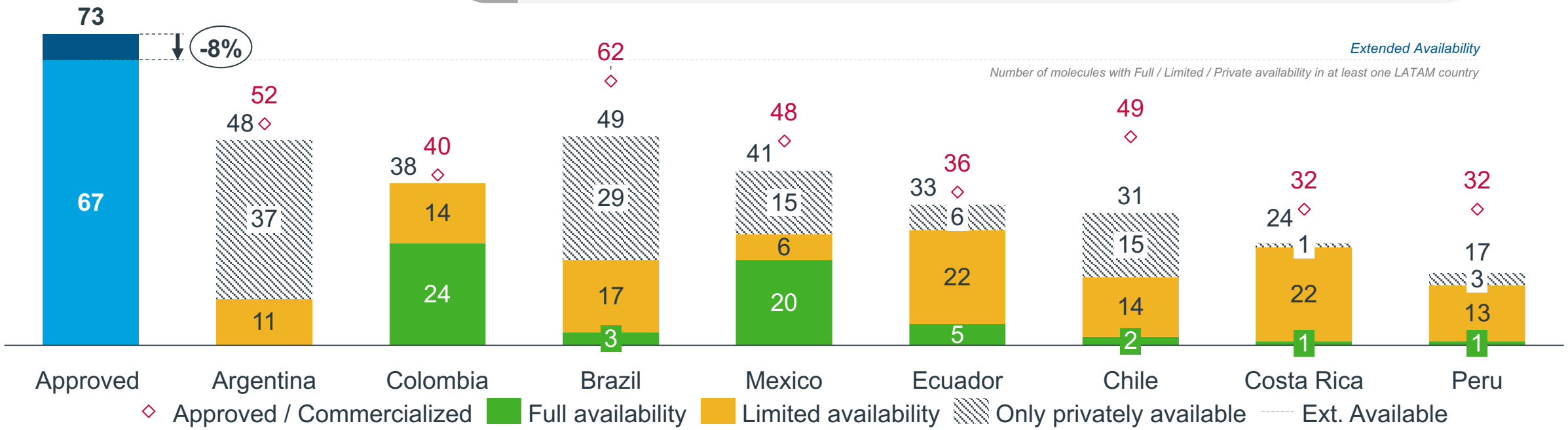
LATAM Average: 38%

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

Rate of regional availability (2014-2021) – oncology

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 Mexico have the **most molecules that are 'fully available'** for both the oncology and orphan cohorts, in line with general availability trends



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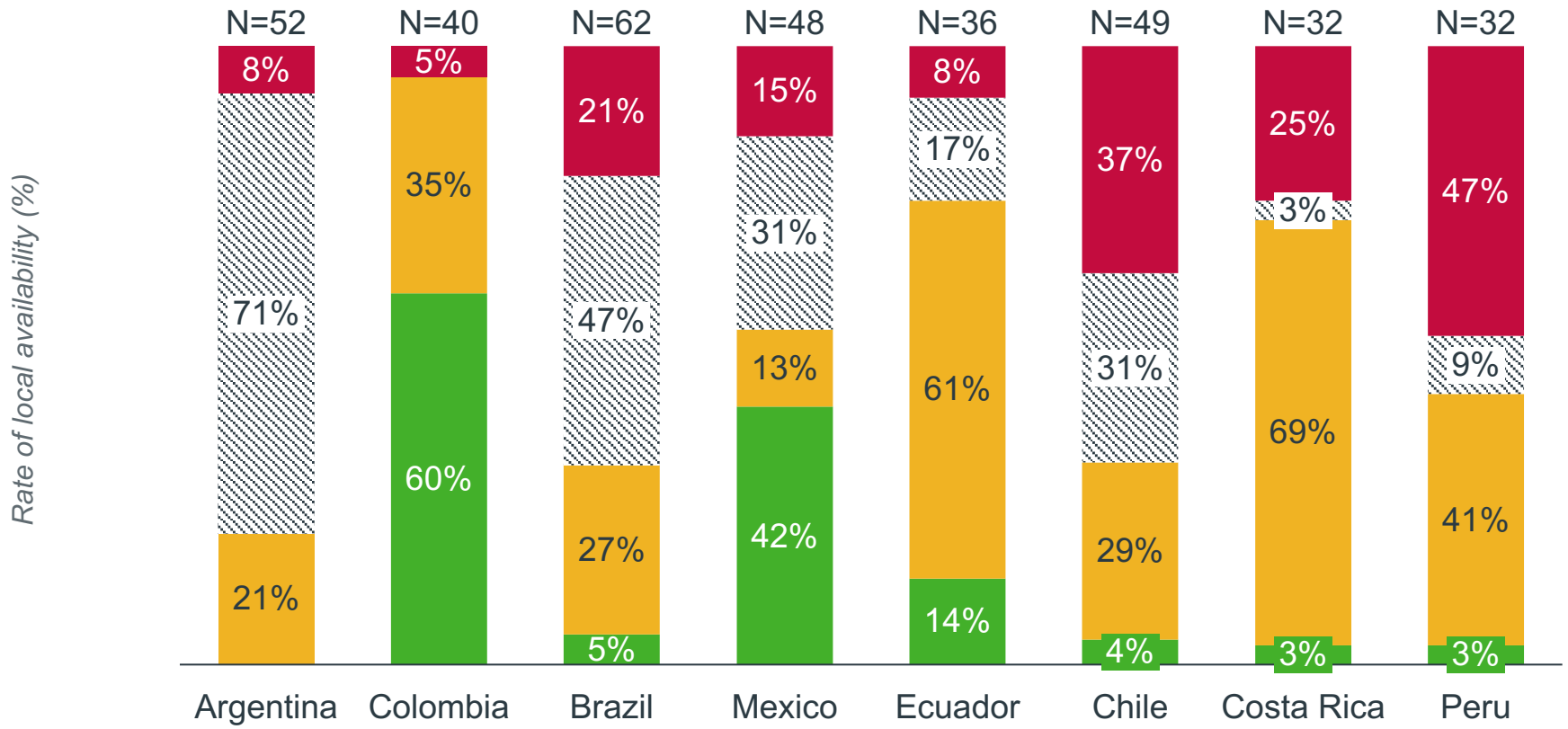
LATAM Average: 29%

Full availability rates are low across all markets in LatAm, likely largely as a result of a lengthy and fragmented process of reimbursement

Rate of local availability (2014-2021) – oncology



	Argentina	Colombia	Brazil	Mexico	Ecuador	Chile	Costa Rica	Peru
% of Availability (Full and Limited)	21%	95%	32%	54%	75%	33%	72%	44%
% of Expanded Availability (Full, Limited, Priv)	92%	95%	79%	85%	92%	63%	75%	53%
% of globally approved medicines locally available / 115	45%	35%	54%	42%	31%	43%	28%	28%

LATAM Average: 38%

Full availability | Limited availability | Only privately available | Not available-Approved

Key Insights

- A substantial portion of **Fully Available** molecules were approved by FDA between **2014-2015**
- An important portion of the molecules in the study are from **small / mid sized manufacturers** which have **no footprint in LATAM**
- Therefore, **Oncology and Orphan drugs** can **take longer** to be launched in LATAM
- **Including the 2014 cohort** to the current analysis provides a **broader picture** of the degree of **availability** in the region

Availability rates decreases as global launch timelines gets more recent as a result of the LATAM bottom-up reimbursement dynamics

Rate of local availability per year (2014-2021) – oncology

- Most of the molecules with Full Availability status have been approved between 2014-2017, being concentrated on established Oncology molecules
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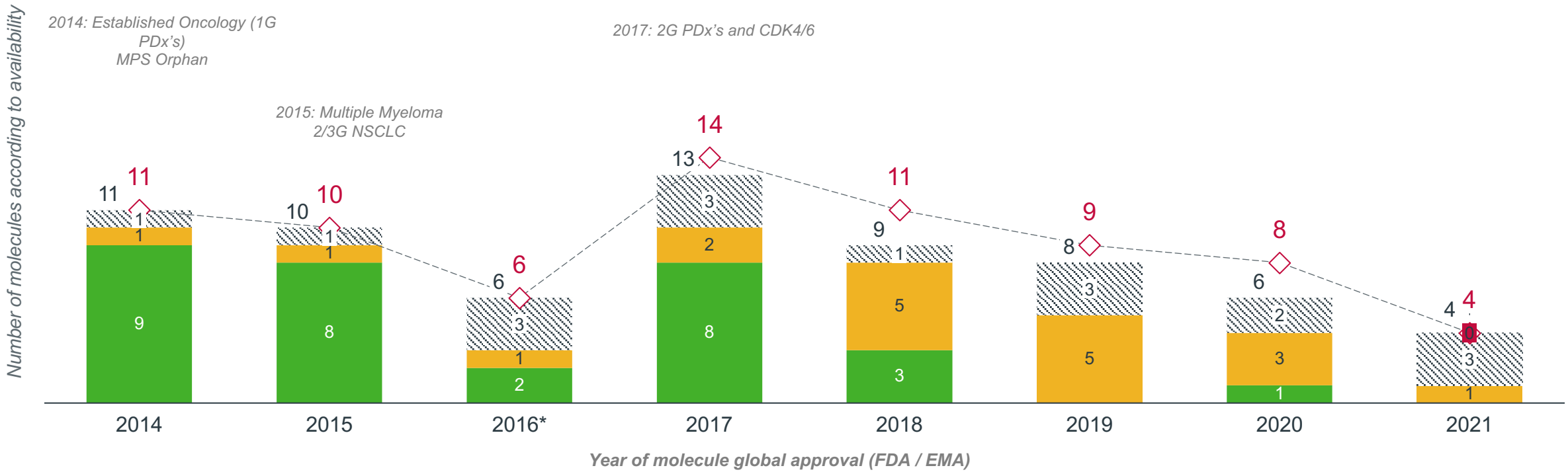

There is a long pathway for innovation to achieve broad reimbursement through widely a fragmented reimbursement system

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

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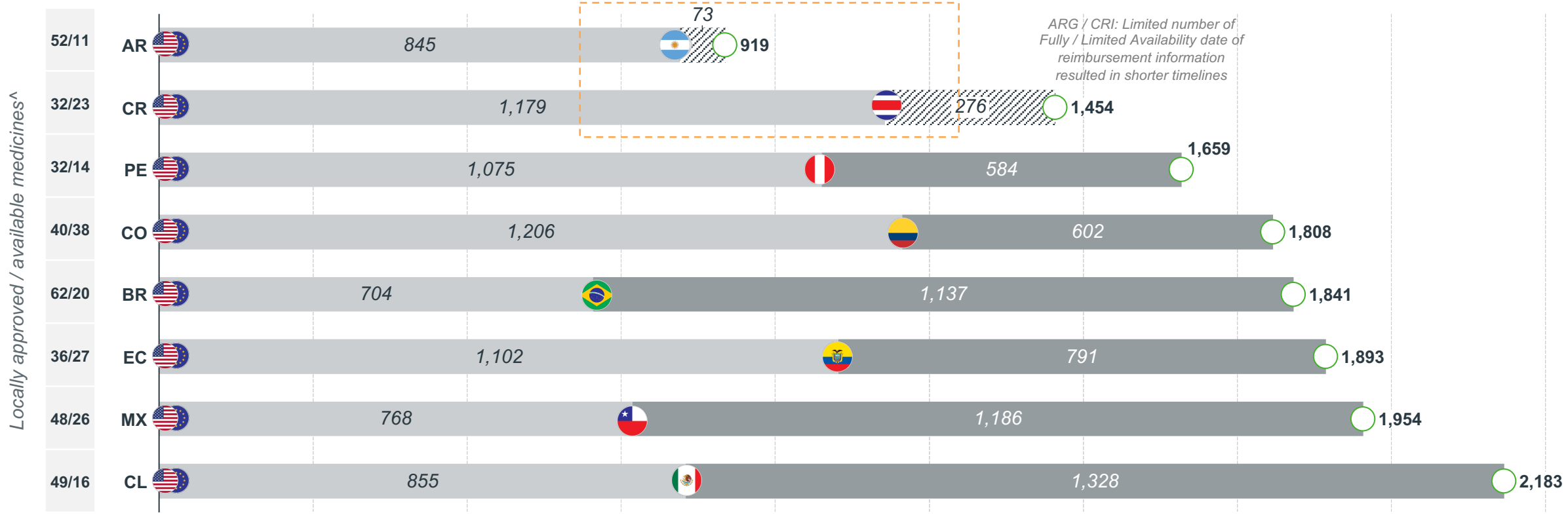

LATAM Average: 1,714days

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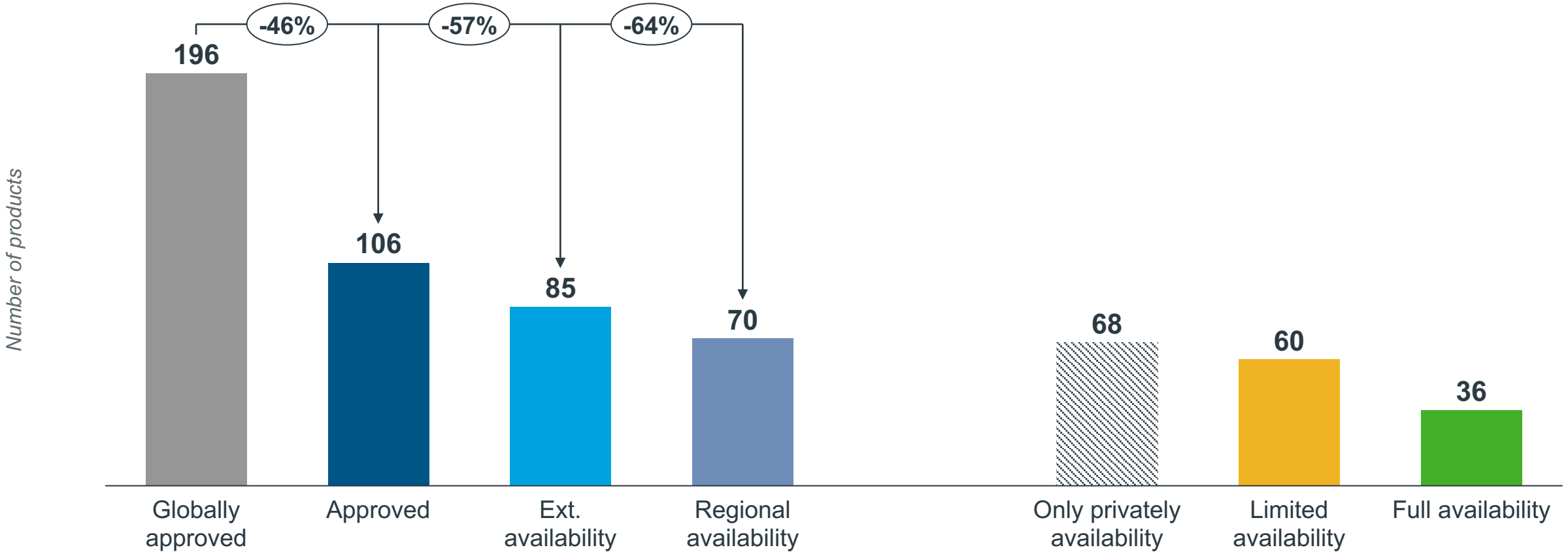
Orphan
2014-2021 cohort

Regional availability is broken down into decreasing subtypes, with just 36% of molecules included in the study regionally available

Breakdown of regional availability (2014-2021) – orphan



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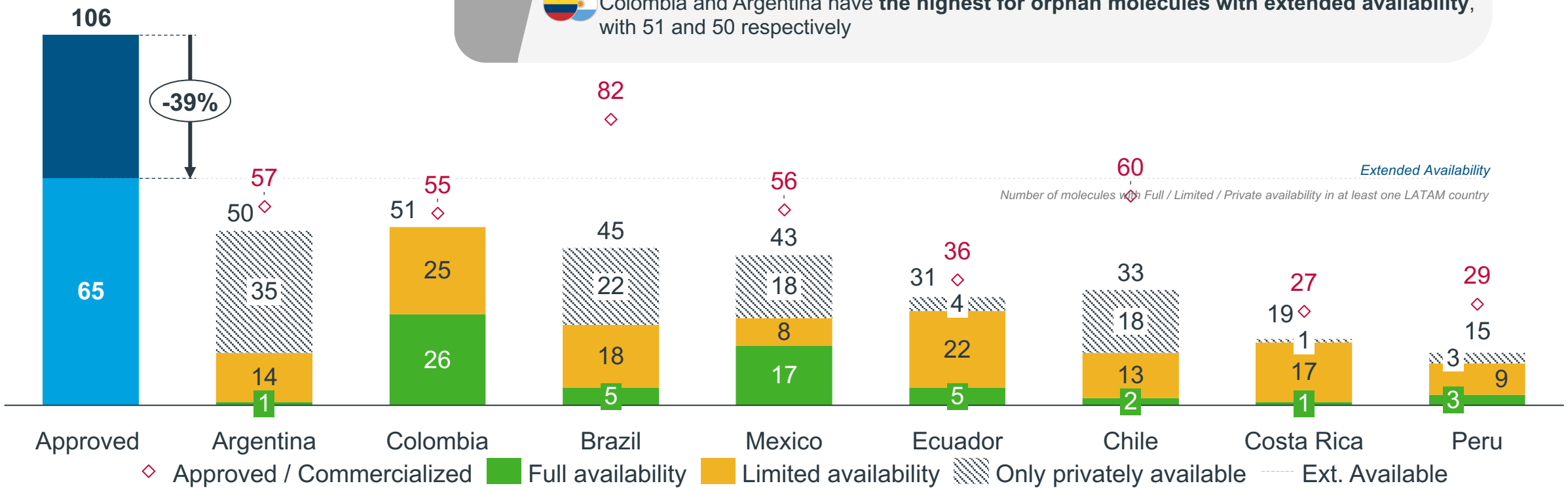
LATAM Average: 26%

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

Rate of regional availability (2014-2021) – orphan

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

Colombia and Argentina have **the highest for orphan molecules with extended availability**, with 51 and 50 respectively



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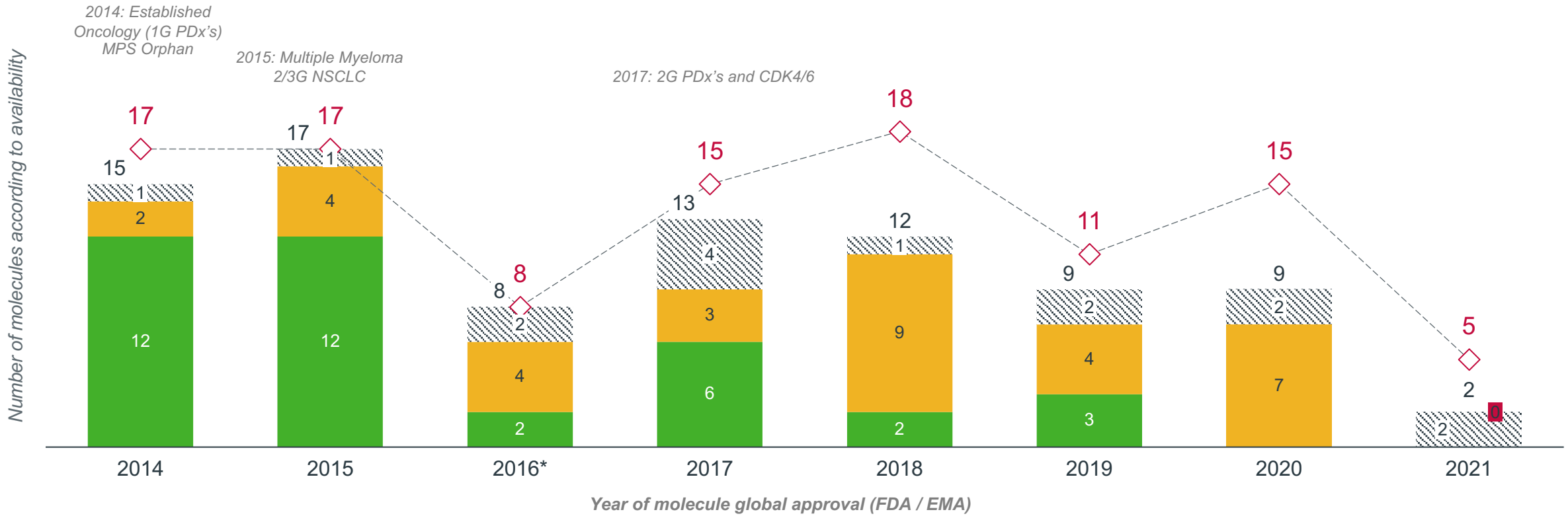
LATAM Average: 29%

Availability rates decreases as global launch timelines gets more recent as a result of the LATAM bottom-up reimbursement dynamics

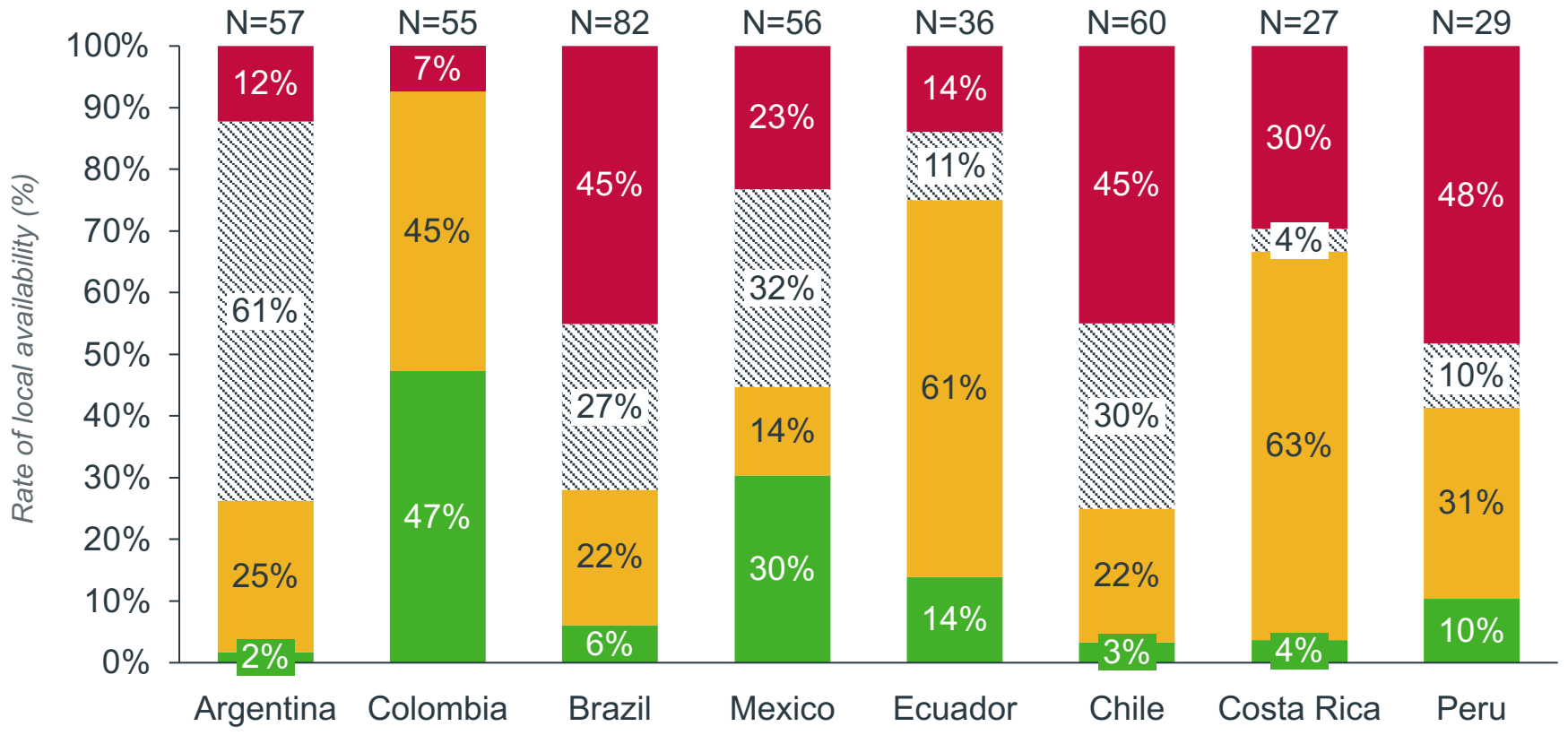
Rate of local availability per year (2014-2021) – orphan

- Most of the molecules with Full Availability status have been approved between 2014-2017, being concentrated on established Oncology molecules
- In 2016, there were a substantial drop in the number of global approved drugs including in Oncology and Rare Diseases – FDA / EMA has got back on track on the number of approvals from 2017 on until a new decrease as a result of COVID19



Full availability rates are low across all markets in LatAm, likely largely as a result of a lengthy and fragmented process of reimbursement

Rate of local availability (2014-2021) – orphan



Argentina	Colombia	Brazil	Mexico	Ecuador	Chile	Costa Rica	Peru	
26%	**93%**	**28%**	**45%**	**75%**	**25%**	**67%**	**41%**	**% of Availability (Full and Limited)**
88%	**93%**	**55%**	**77%**	**86%**	**55%**	**70%**	**52%**	**% of Expanded Availability (Full, Limited, Priv)**
29%	28%	42%	29%	18%	31%	14%	15%	**% of globally approved medicines locally available / 196**

LATAM Average: 26%

Full availability | Limited availability | Only privately available | Not available-Approved

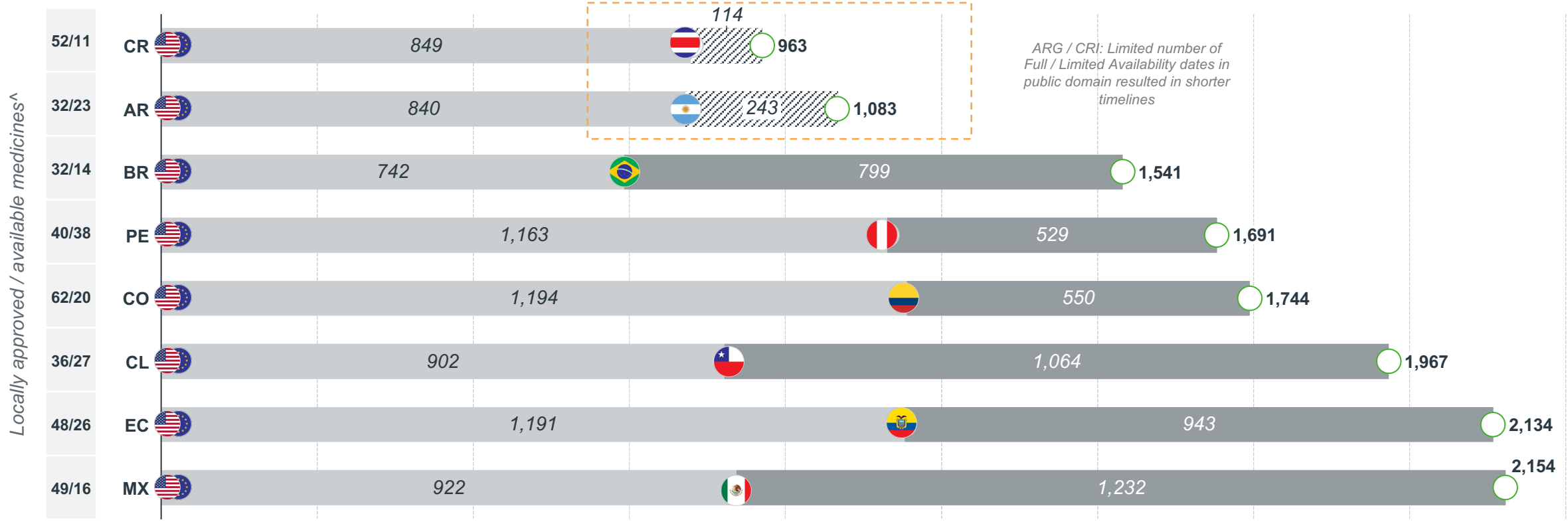
Key Insights

- A substantial portion of **Fully Available** molecules were approved by FDA between **2014-2015**
- An important portion of the molecules in the study are from **small / mid sized manufacturers** which have **no footprint in LATAM**
- Therefore, **Oncology and Orphan drugs** can **take longer** to be launched in LATAM
- **Including the 2014 cohort** to the current analysis provides a **broader picture** of the degree of **availability** in the region

There is a long pathway for innovation to achieve broad reimbursement through widely a fragmented reimbursement system

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

- **Colombia** is the country with **longer regulatory** approval **timelines** - **availability timelines** are small as a result of a **high degree of limited availability** through MIPRES that is granted pretty fast, yet **still restricted** to only **a subset of the population**
- **Chile and Mexico** typically are the **first countries to grant regulatory approval** in the region, but a **complex and fragment** environment results in very long timelines until **achieving broad reimbursement**



LATAM Average: 1,656 days

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

05

Key Takeaways and Next Steps

Key takeaways for future editions of the study

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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