

FIFARMA Patients W.A.I.T Indicator 2022 Survey

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Kelsey Stoddart, Consultant, Global Supplier & Association Relations Max Newton, Engagement Manager, Global Supplier & Association Relations Andre Ballalai, Associate Principal, Strategy Consulting Per Troein, VP, Strategic Partners

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The FIFARMA Patient W.A.I.T. survey indicates the level of availability to innovation across 8 Latin American countries

The report is similar to the EFPIA Patients W.A.I.T Indicator in Europe

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. (Waiting to Access Innovative Therapies) 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, Colombia, Chile, Mexico, Brazil, Costa Rica, Argentina, Ecuador, and provide a benchmark of the rate of accessibility and waiting times in LATAM countries.

Information on the 185 innovative oncology and orphan medicines globally approved* from 2014-2020 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 2022*.

Local pharmaceutical industry associations provide the information directly to IQVIA and FIFARMA. In some cases, IQVIA has gathered information from additional public sources (Argentina, Brazil, Colombia, and Mexico). The methods are included within the appendix to ensure full transparency to the study.

FIFARMA & the IQVIA team



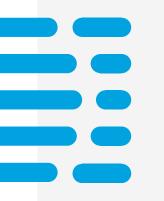
8 Latin American countries innovative medicines



Data available

e Data not available / included





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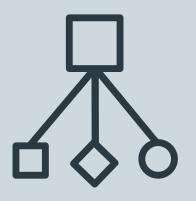
- 1. <u>Oncology</u>
- 2. Orphan medicines
- 3. Combined cohort (Oncology & Orphan medicines)
- + Appendix & detailed methodology



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The study is based on the core concept of "availability"

Definition 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



Study summary

Full methodology and definitions by country are available in the appendix of the report

Core metrics

The FIFARMA Patients W.A.I.T. Indicator shows 2 main metrics for new medicines within a 7 year cohort:

1.) Rate of availability, measured by the number of medicines available to patients in Latin American countries. For most countries this is the point at which the product gains access to the national reimbursement list (this does not necessarily indicate uptake / usage).

2.) The time to availability, measuring the average time between marketing authorisation and availability, using days from the date of local and FDA marketing authorisation.

Description	Status		
Full reimbursement through a national reimbursement system	Available		
Full automatic reimbursement by a hospital budget	Available		
Limited reimbursement to specific subpopulations of approved indication	approved indication ment on a named dual patient basis) ment while decision system permits) a special program		
Limited reimbursement on a named patient basis (individual patient basis)			
Limited reimbursement while decision is pending (where system permits)			
Availability through a special program (e.g. managed entry agreements)			
Available only within the private market at the patients expense	Only privately available		
Not reimbursed, or not reimbursed while awaiting decision	Not available		

Availability definition

Notes and caveats

Source of information: FIFARMA member associations, who either refer to information available from official sources, or gather the information directly from member companies. In some cases, IQVIA has gathered information from additional public sources (Argentina, Brazil, Colombia, and Mexico).

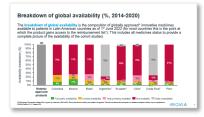
Completeness: Some country associations did not submit full datasets. Countries with substantially limited datasets are: Argentina (21% complete), Costa Rica (24% complete), Ecuador (96% complete), Chile (98% complete) this is noted on slides with an asterisk (*). IQIVA has used public data sources to plug gaps, where possible.

Average calculations: The LATAM averages noted throughout are averages for the 8 countries in the cohort.



The report includes 7 indicators of availability in Latin America

FIFARMA WAIT Indicators



Rate of regional availability (2014-2020)

Oncology Rate of regional full availability (2014-2020

1. Breakdown of global availability Composition of **globally-approved** innovative medicines available to patients in LATAM

Value: Shows the break down of public availability, privately availability and highlights data gaps

2. Rate of regional availability

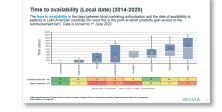
Number of **regionally-approved** innovative medicines available (full and limited) to patients in LATAM

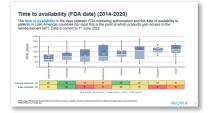
Value: Shows availability of medicines with at least one LATAM regulatory approval

3. Rate of full regional availability

Proportion of **regionally-approved** innovative medicines available to patients in LATAM without restrictions

Value: Shows availability with / without payer restrictions







5. Time to availability (local date)

Days between **local marketing authorisation** and the date of availability to patients in LATAM

Value: Shows the prioritisation of LATAM markets and length of regulatory process

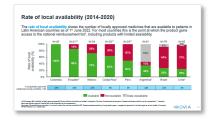
6. Time to availability (FDA date)

Days between **FDA marketing authorisation** and the date of availability to patients in LATAM

Value: Shows the prioritisation of LATAM markets following US launch and length of regulatory process

7. Time to availability (FDA, EMA and local date) Days between FDA, EMA, and local marketing authorization, and the date of availability to patients in LATAM

Value: Shows the prioritisation of LATAM markets following US and EU launch, and length of regulatory process



4. Rate of local availability

Number of **locally-approved** innovative medicines available to patients in LATAM

Value: Provides a more representative view of only products likely to be assessed for availability in each country



These 7 indicators are reported for: Oncology, Orphan medicines, Combined cohort





1. Oncology

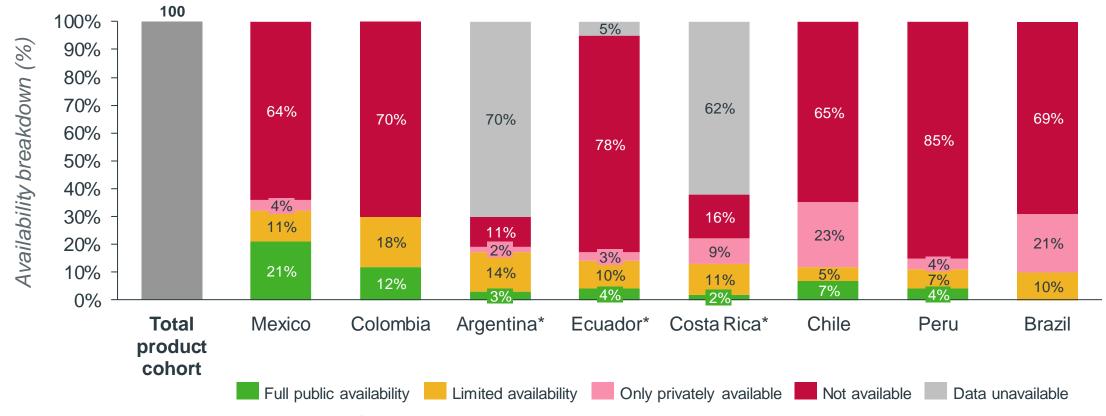
Indicators:

1.1. Breakdown of global availability
1.2. Rate of regional availability
1.3. Rate of regional full availability
1.4. Rate of local availability
1.5. Time to availability (local date)
1.6. Time to availability (FDA date)

1.7. Time to availability (FDA, EMA and local date)

Oncology Breakdown of global availability (%, 2014-2020)

The **breakdown of global availability** is the composition of globally approved^A innovative medicines available to patients in Latin American countries as of 1st June 2022 (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort studied.



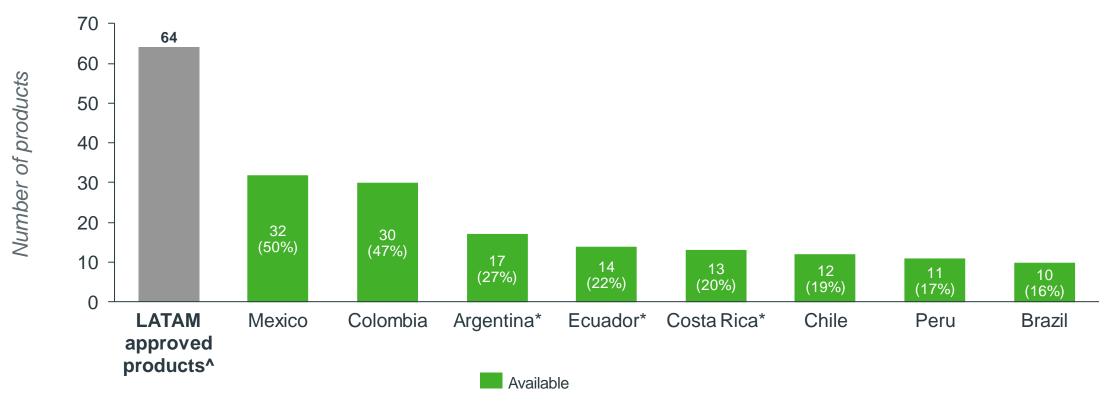
LATAM average: 17 products available (17%) ^Approval by at least one of FDA or EMA. [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



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Oncology Rate of regional availability (2014-2020)

The rate of regional availability shows the proportion of medicines with LATAM regulatory approval^A available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.



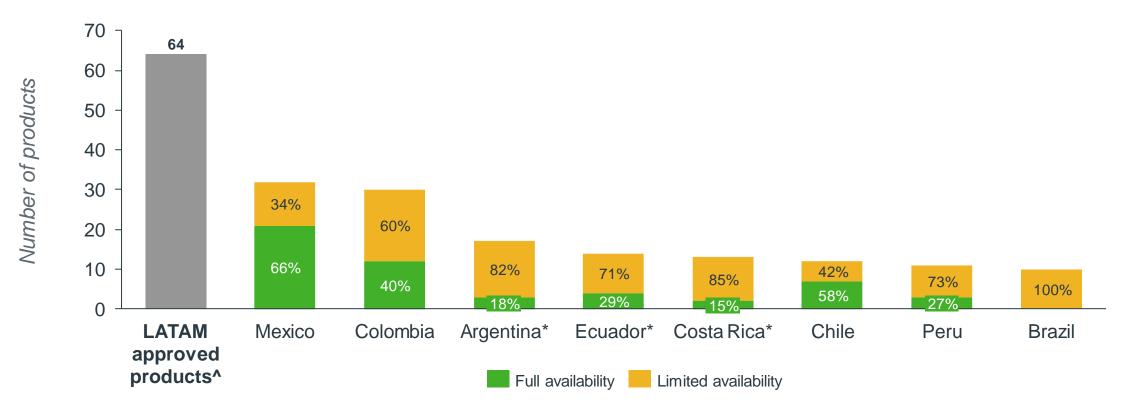
LATAM average: 17 products available (27%) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. ^{*}Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



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Oncology Rate of regional full availability (2014-2020)

The **rate of regional full availability** shows the proportion of medicines with LATAM regulatory approval^A available to patients in Latin American countries as of 1st June 2022 (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.

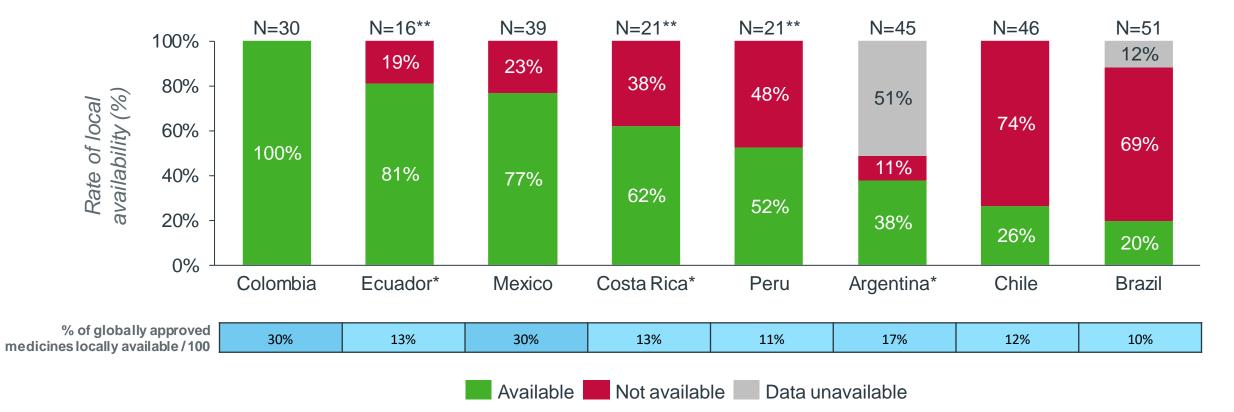


LATAM average: 17 products available (27%), Limited Availability (68% of available products) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



Oncology Rate of local availability (2014-2020)

The rate of local availability shows the number of locally approved medicines that are available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.



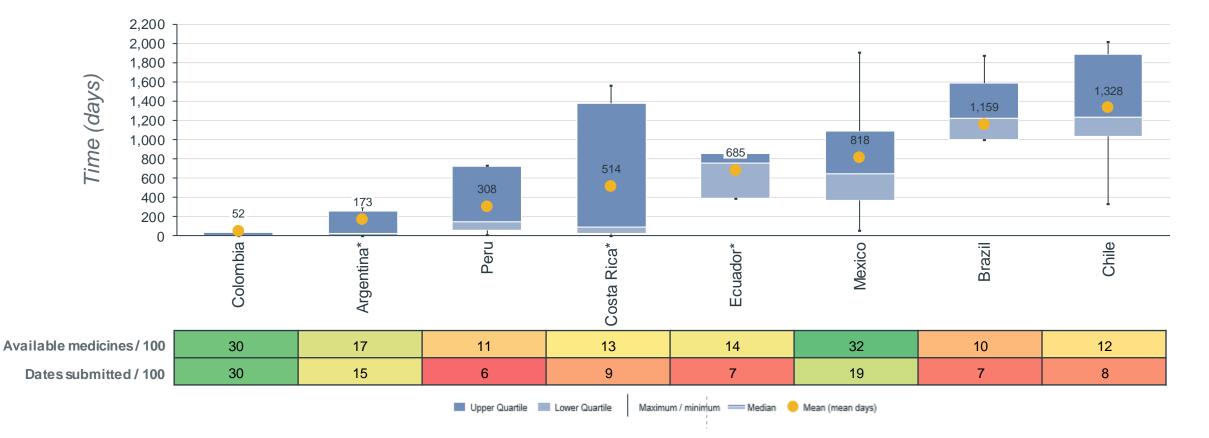
LATAM average: 57% availability (of locally approved products)[†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ** Incomplete data on local regulatory approvals, therefore total number of approvals may be unrepresentative.

Chart notes: For products that are not available, it is not known whether they have been submitted for P&R. Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. FIFARMA Patients W.A.I.T Indicator 2022



Oncology Time to availability (Local date) (2014-2020)

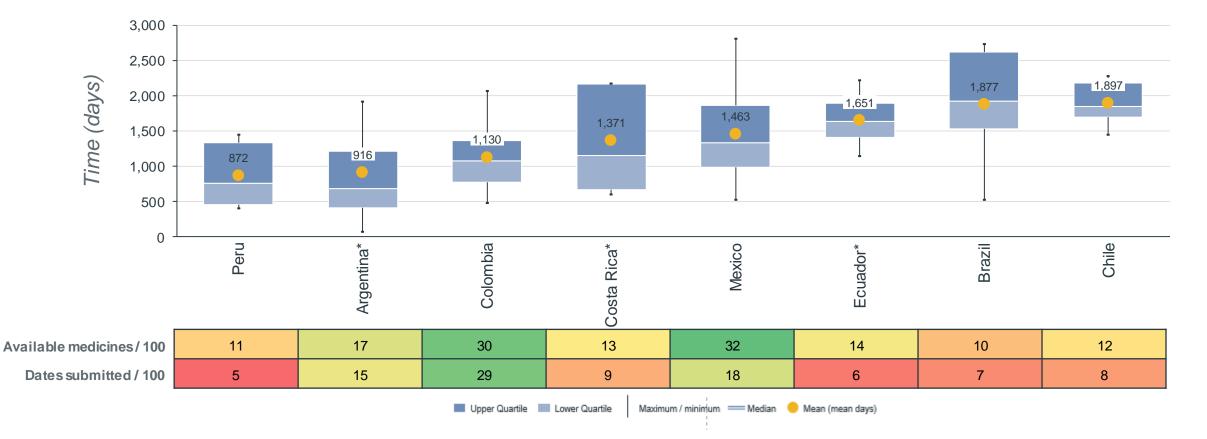
The **time to availability** is the days between local marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Oncology Time to availability (FDA date) (2014-2020)

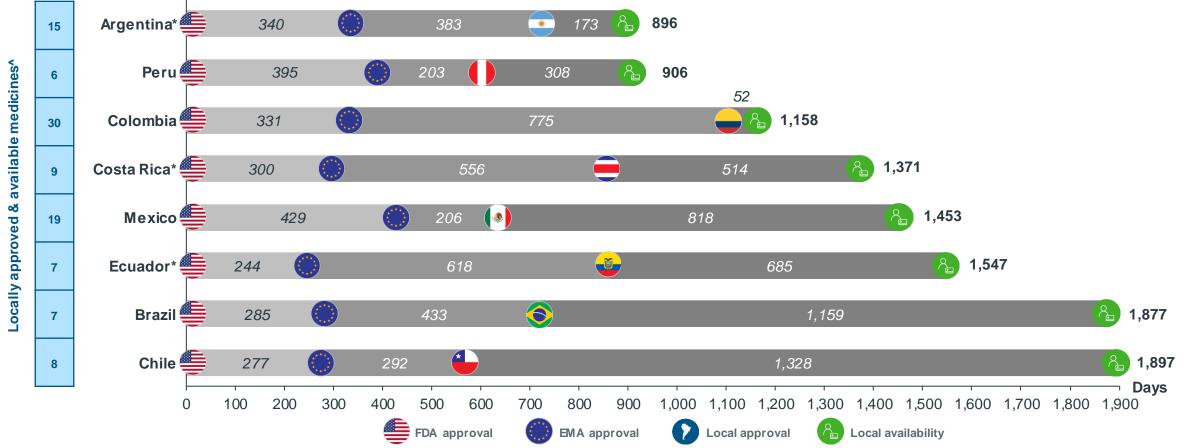
The **time to availability** is the days between FDA marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Oncology Time to availability (FDA, EMA and local date) (2014-2020)

The time to availability shows the average days between FDA, EMA, and local marketing authorization, and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.



¹Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ^Analysis is based on medicines with local regulatory approval and have availability dates submitted. Chart notes: Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. Total days delay is the sum of all average delays (FDA MA to EMA MA, EMA MA to Local MA, etc.), therefore it might differ from previous indicator averages, FIFARMA Patients W.A.I.T Indicator 2022

Executive summary

LATAM average rate of availability and time to availability

Measure	Measure Oncology Orphan		Combined cohort	
Rate of global availability	17%	12%	13%	
Rate of regional availability	27%	23%	24%	
Rate of local availability	57%	60%	58%	
Average time to availability (local dates)	1.73 Years (630 Days)	1.39 Years (509 Days)	1.48 Years (541 Days)	
Average time to availability (FDA date)	3.83 Years (1397 Days)	3.75 Years (1370 Days)	3.67 Years (1338 Days)	

Summary:

- Patient access to new innovative oncology medicines is higher than other cohorts (orphan medicines and combined cohort), with an average rate of availability of 17%.
- Availability is higher for regionally and locally approved medicines, at 24% and 58% respectively.
- The average delay between market authorisation and patient access is slightly longer than other cohorts, at 1.7 years (local dates) and 3.8 years (FDA dates).
- Many countries within the WAIT Indicator have low data availability, which provides some limitations to the comparability of data across countries.





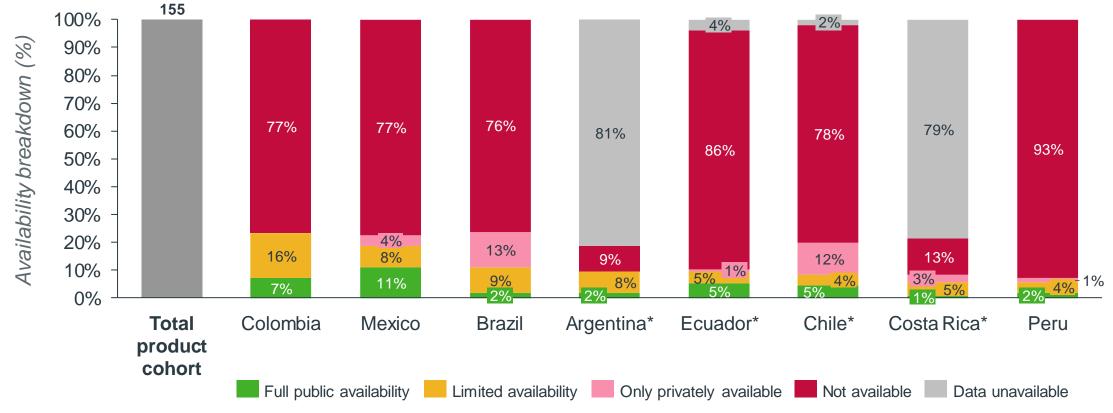
2. Orphan medicines

Indicators:

2.1. Breakdown of global availability
2.2. Rate of regional availability
2.3. Rate of regional full availability
2.4. Rate of local availability
2.5. Time to availability (local date)
2.6. Time to availability (FDA date)
2.7. Time to availability (FDA, EMA and local date)

Orphan Breakdown of global availability (%, 2014-2020)

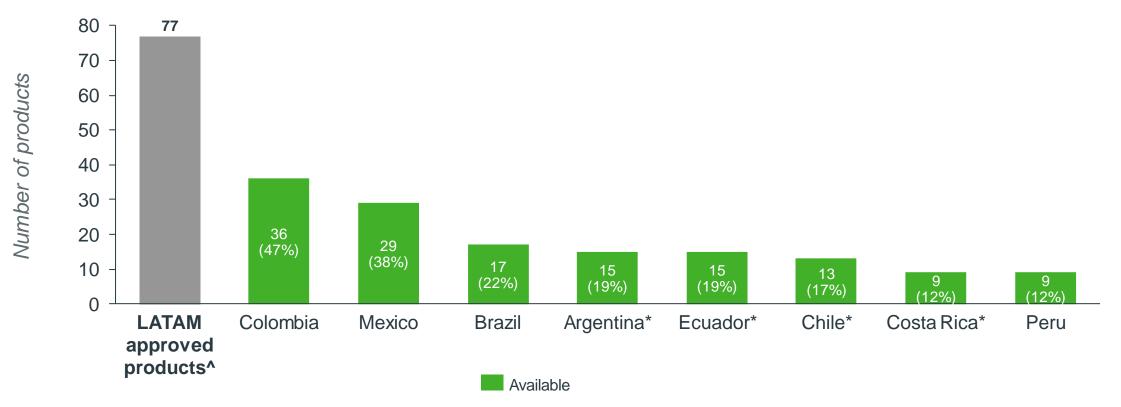
The **breakdown of global availability** is the composition of globally approved^A innovative medicines available to patients in Latin American countries as of 1st June 2022 (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort studied.



LATAM average: 18 products available (12%) ^Approval by at least one of FDA or EMA. [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022

Orphan Rate of regional availability (2014-2020)

The rate of regional availability shows the proportion of medicines with LATAM regulatory approval^A available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.



LATAM average: 18 products available (23%) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. ^{*}Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



Orphan Rate of regional full availability (2014-2020)

The **rate of regional full availability** shows the proportion of medicines with LATAM regulatory approval^A available to patients in Latin American countries as of 1st June 2022 (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.

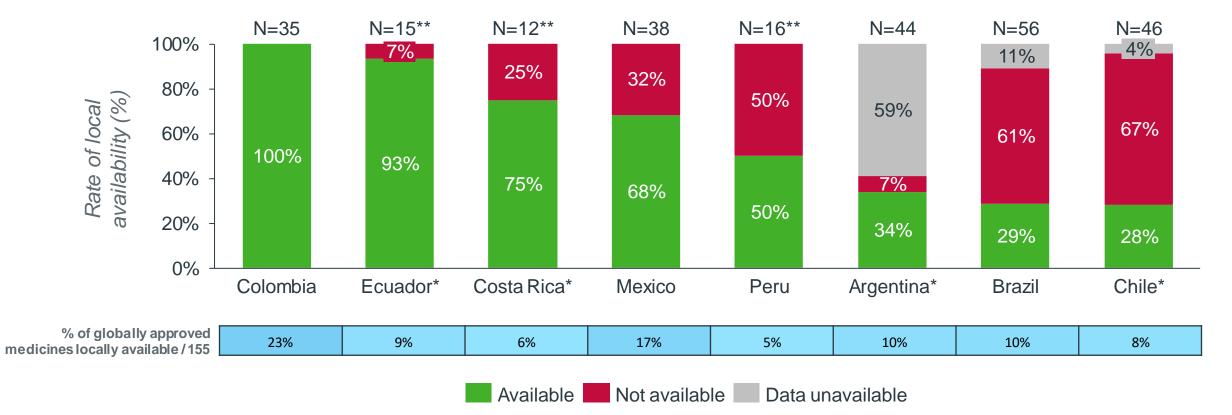


LATAM average: 18 products available (23%), Limited Availability (67% of available products) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



Orphan Rate of local availability (2014-2020)

The rate of local availability shows the number of locally approved medicines that are available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.



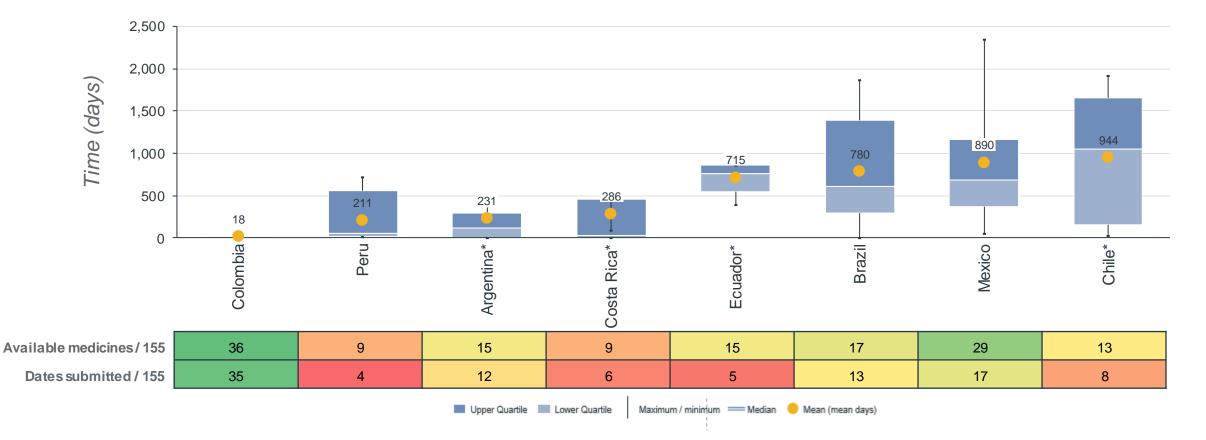
LATAM average: 60% availability (of locally approved products)[†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ** Incomplete data on local regulatory approvals, therefore total number of approvals may be unrepresentative.

Chart notes: For products that are not available, it is not known whether they have been submitted for P&R. Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. FIFARMA Patients W.A.I.T Indicator 2022



Orphan Time to availability (Local date) (2014-2020)

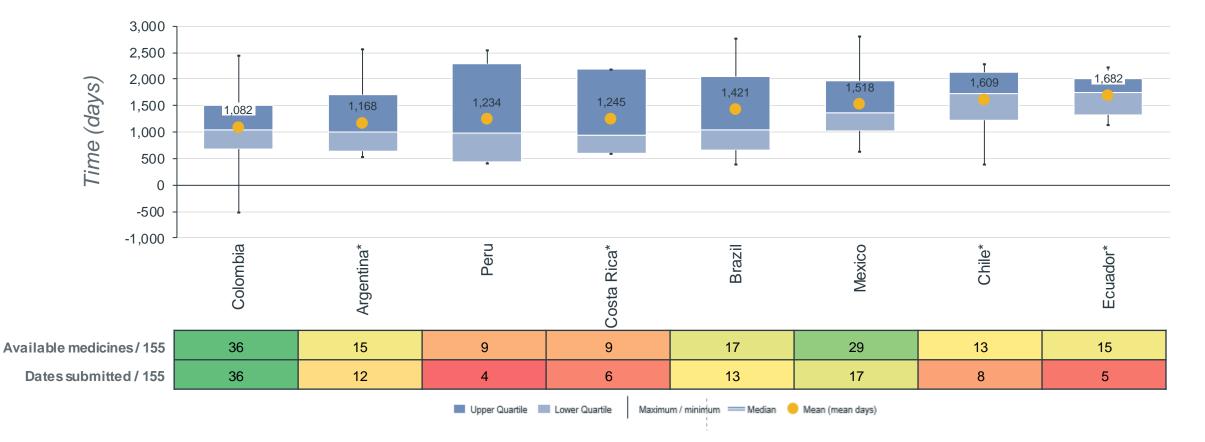
The time to availability is the days between local marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Orphan Time to availability (FDA date) (2014-2020)

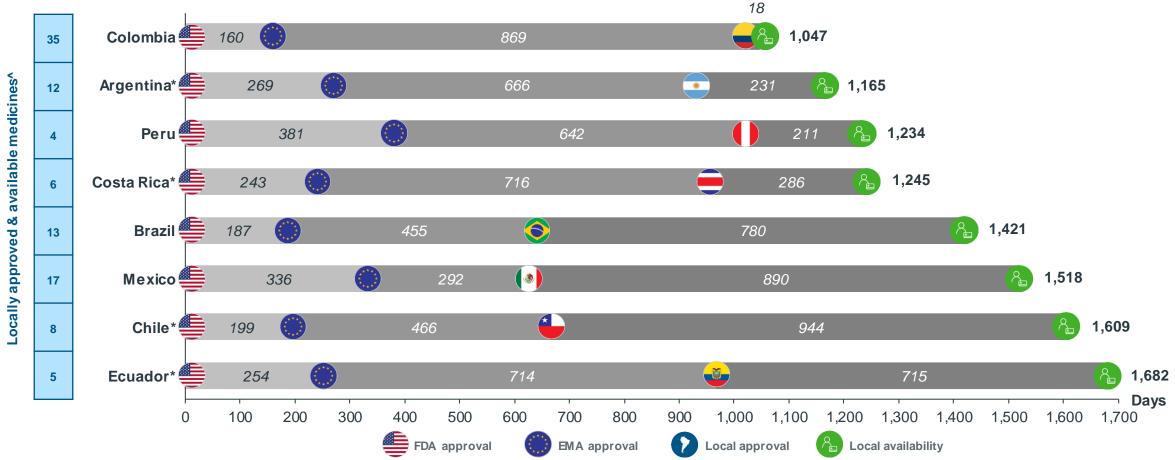
The **time to availability** is the days between FDA marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Orphan Time to availability (FDA, EMA and local date) (2014-2020)

The time to availability shows the average days between FDA, EMA, and local marketing authorization, and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.



¹Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ^Analysis is based on medicines with local regulatory approval and have availability dates submitted. Chart notes: Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. Total days delay is the sum of all average delays (FDA MA to EMA MA, EMA MA to Local MA, etc.), therefore it might differ from previous indicator averages FIFARMA Patients W.A.I.T Indicator 2022

Executive summary

LATAM average rate of availability and time to availability

Measure	Oncology	Orphan	Combined cohort
Rate of global availability	17%	12%	13%
Rate of regional availability	27%	23%	24%
Rate of local availability	57%	60%	58%
Average time to availability (local dates)	1.73 Years (630 Days)	1.39 Years (509 Days)	1.48 Years (541 Days)
Average time to availability (FDA date)	3.83 Years (1397 Days)	3.75 Years (1370 Days)	3.67 Years (1338 Days)

Summary:

- Patient access to new innovative orphan medicines is low across Latin America, with an average rate of availability of 12%.
- Availability is higher for regionally and locally approved medicines, at 23% and 60% respectively.
- The average delay between local market authorisation and patient access is shorter than other cohorts (oncology medicines and combined cohort), at 1.4 years
- Many countries within the WAIT Indicator have low data availability, which provides some limitations to the comparability of data across countries







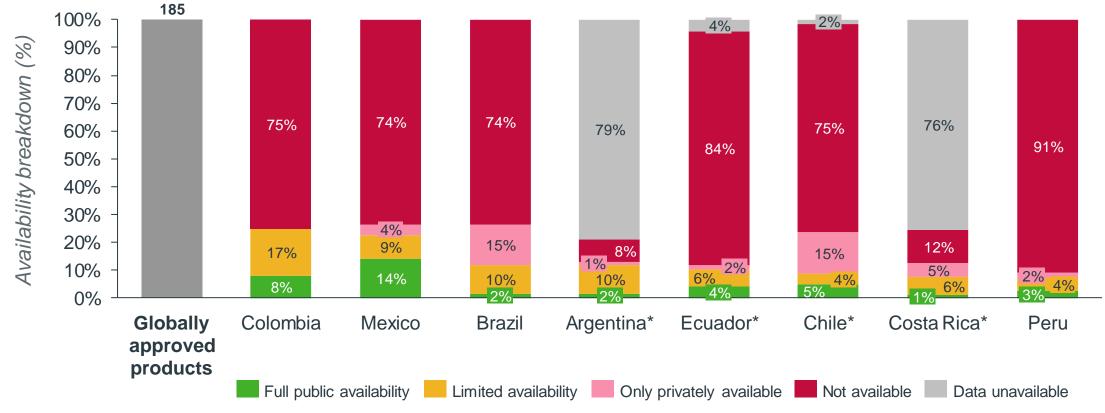
3. Combined cohort (Oncology & Orphan medicines)

Indicators:

3.1. Breakdown of global availability
3.2. Rate of regional availability
3.3. Rate of regional full availability
3.4. Rate of local availability
3.5. Time to availability (local date)
3.6. Time to availability (FDA date)
3.7. Time to availability (FDA, EMA and local date)

Breakdown of global availability (%, 2014-2020)

The **breakdown of global availability** is the composition of globally approved^A innovative medicines available to patients in Latin American countries as of 1st June 2022 (for most countries this is the point at which the product gains access to the reimbursement list[†]). This includes all medicines status to provide a complete picture of the availability of the cohort studied.

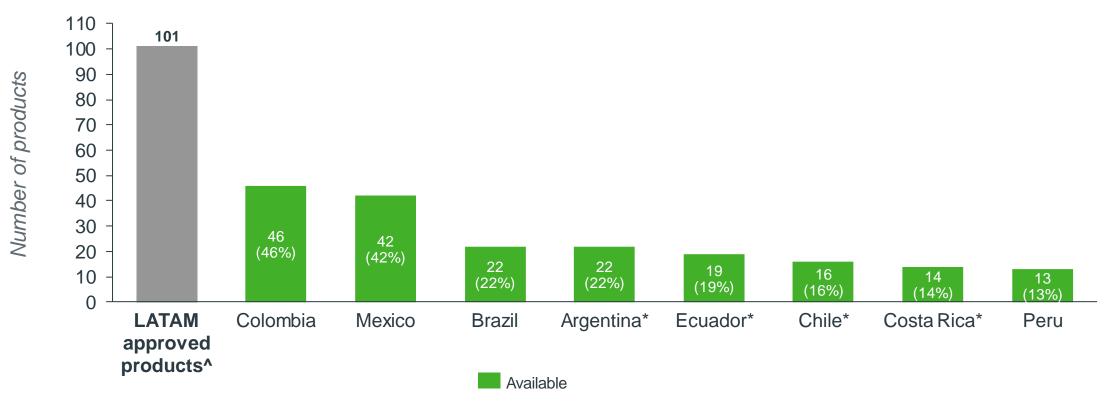


LATAM average: 24 products available (13%) ^Approval by at least one of FDA or EMA. [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022

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Rate of regional availability (2014-2020)

The rate of regional availability shows the proportion of medicines with LATAM regulatory approval^A available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.

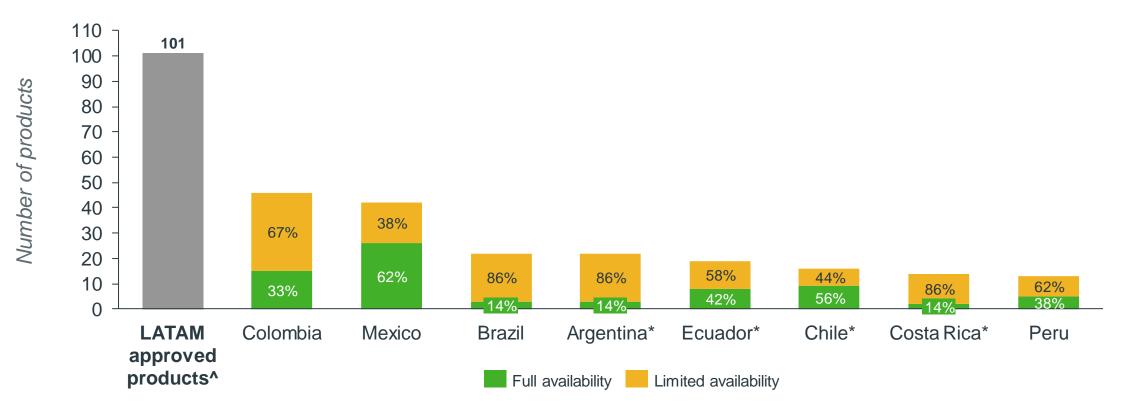


LATAM average: 24 products available (24%) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. ^{*}Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



Rate of regional full availability (2014-2020)

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 2022 (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.

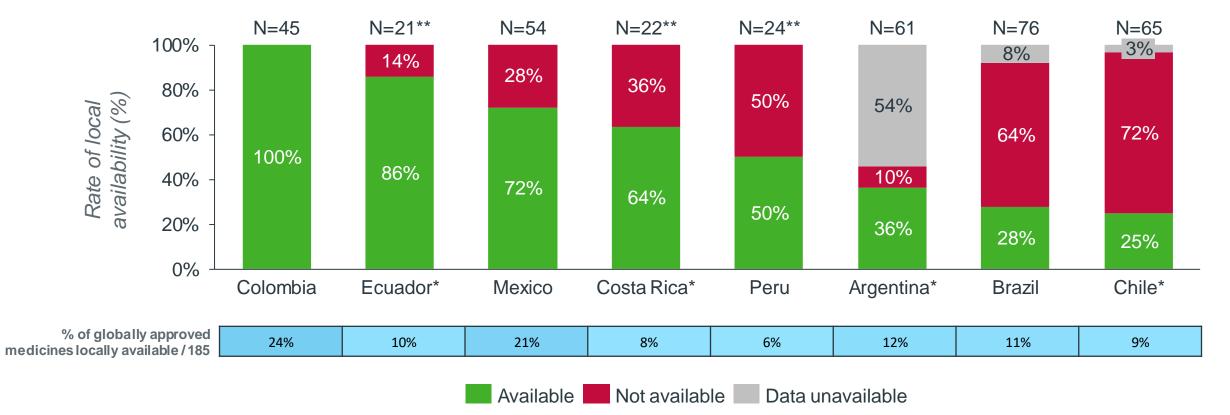


LATAM average: 24 products available (24%), Limited Availability (67% of available products) ^Market authorisation in at least one LATAM country (Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, Mexico, Peru). [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. FIFARMA Patients W.A.I.T Indicator 2022



Rate of local availability (2014-2020)

The rate of local availability shows the number of locally approved medicines that are available to patients in Latin American countries as of 1st June 2022. For most countries this is the point at which the product gains access to the national reimbursement list[†], including products with limited availability.



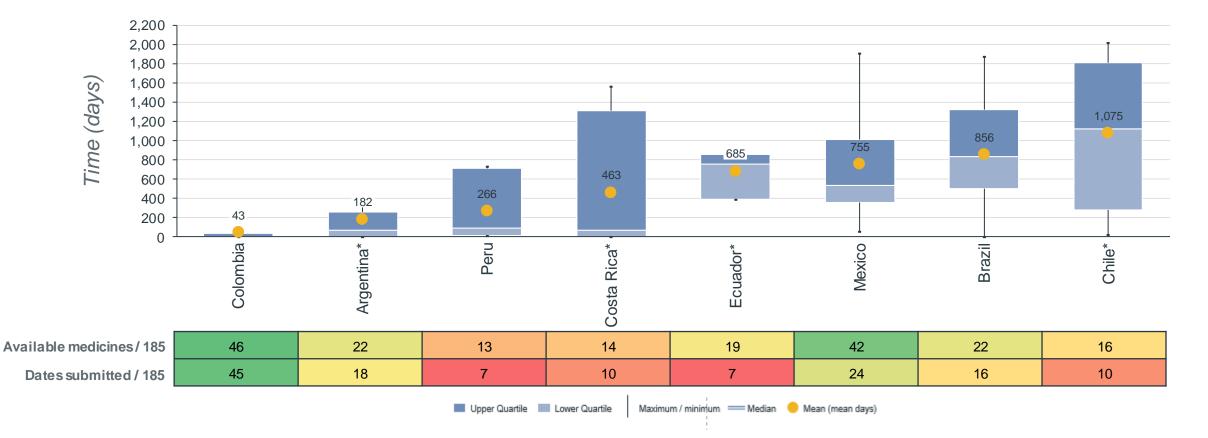
LATAM average: 58% availability (of locally approved products) [†]Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ** Incomplete data on local regulatory approvals, therefore total number of approvals may be unrepresentative.

Chart notes: For products that are not available, it is not known whether they have been submitted for P&R. Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. FIFARMA Patients W.A.I.T Indicator 2022



Time to availability (Local date) (2014-2020)

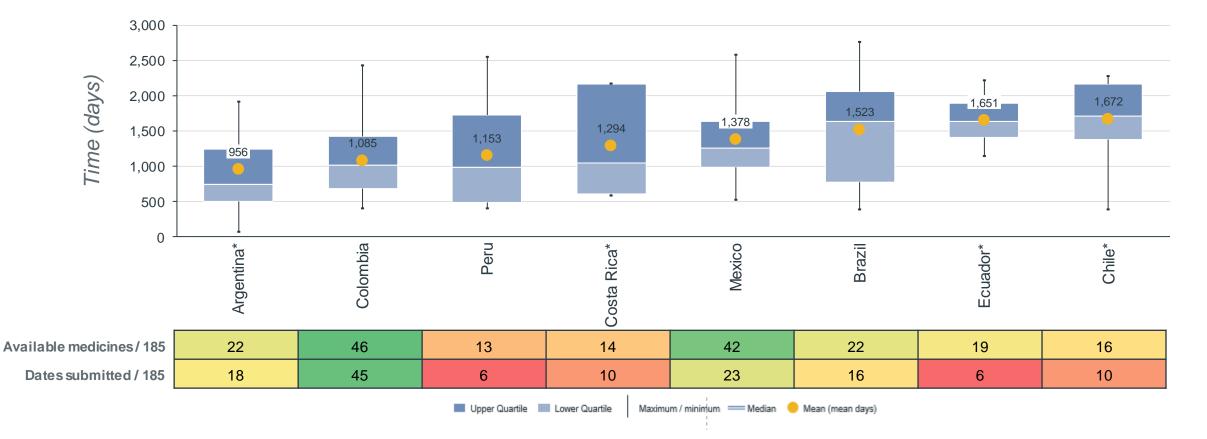
The **time to availability** is the days between local marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Time to availability (FDA date) (2014-2020)

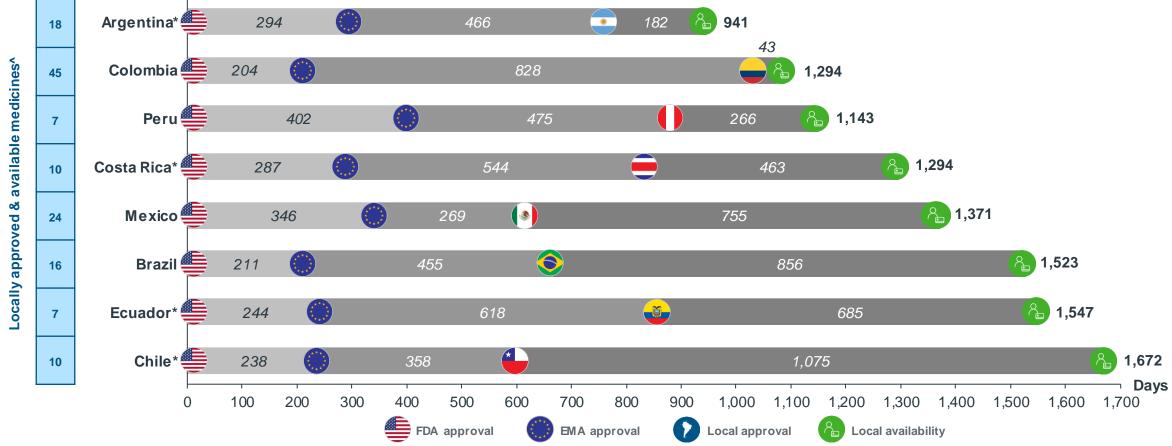
The **time to availability** is the days between FDA marketing authorisation and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.





Time to availability (FDA, EMA and local date) (2014-2020)

The time to availability shows the average days between FDA, EMA, and local marketing authorization, and the date of availability to patients in Latin American countries (for most this is the point at which products gain access to the reimbursement list[†]). Data is correct to 1st June 2022.



¹Country definitions of availability are included in the appendix. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. ^Analysis is based on medicines with local regulatory approval and have availability dates submitted. Chart notes: Products considered available (e.g. through special program/managed entry agreement) but not locally approved, are not included in this analysis. Total days delay is the sum of all average delays (FDA MA to EMA MA, EMA MA to Local MA, etc.), therefore it might differ from previous indicator averages FIFARMA Patients W.A.I.T Indicator 2022

Executive summary

LATAM average rate of availability and time to availability

Measure	Oncology	Orphan	Combined cohort
Rate of global availability	17%	12%	13%
Rate of regional availability	27%	23%	24%
Rate of local availability	57%	60%	58%
Average time to availability (local dates)	1.73 Years (630 Days)	1.39 Years (509 Days)	1.48 Years (541 Days)
Average time to availability (FDA date)	3.83 Years (1397 Days)	3.75 Years (1370 Days)	3.67 Years (1338 Days)

Summary:

- Patient access to new innovative globally-approved oncology and orphan medicines is low across Latin America, with an average rate of availability of 13%.
- A high proportion of these available medicines across all markets are only available with restrictions (limited availability, 67% of available products).
- Availability is higher for regionally and locally approved medicines, at 24% and 58% respectively.
- The average delay between market authorisation and patient access varies depending on the regulatory date used (local versus FDA date), from 1.5 years to over 3.5 years.



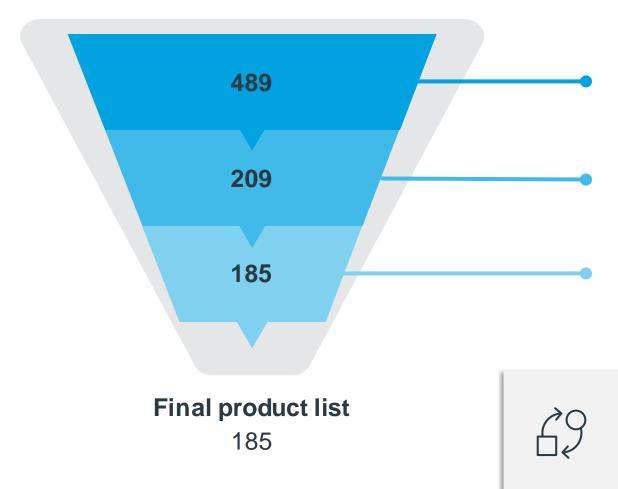


Appendix and detailed methodology

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Methodology

Process for product selection



IQVIA's global NAS list and EFPIA WAIT list 2014-2020

Orphan and Oncologics only 2014-2020

Exclude products based on rules defined

E.g., Diagnostic tools, vaccines, hospital solutions, all launches in ROW that aren't launched in US or EU

Products can have up to three marketing authorisation dates: FDA, EMA, and local



Products included in the study: 2014-2020 (n=185)

Adakveo	Brukinsa	Enhertu	Idhifa	Ledaga	Ocaliva	Ravicti	Takhzyro	Unituxin	Zolgensma
Adempas	Cablivi	Enspryng	Imbruvica	Lenvima	Odomzo	Raxone	Talzenna	Uptravi	Zydelig
Afstyla	Calquence	Epidiolex	Imfinzi	Libmeldy	Oncaspar	Reblozyl	Tavalisse	Vargatef	Zykadia
Alecensa	Cerdelga	Erleada	Imlygic	Libtayo	Onivyde Pegylated Liposomal	Repatha	Tazverik	Venclexta	No brand name (fexinidazole)
Aliqopa	Chenodeoxychol ic Acid Leadiant		Ingrezza	Lonsurf	Onpattro	Retevmo	Tecartus	Verkazia	No brand name (racotumomab)
Alofisel	Cholbam / Kolbam	Exondys 51	Inmazeb	Lorbrena	Opdivo	Revcovi	Tecentriq	Verzenio	
Alprolix	Coagadex	Farydak	Inqovi	Lumoxiti	Orkambi	Rozlytrek	Tegsedi	Viltepso	
Alunbrig	Cometrig	Fintepla	Inrebic	Luxturna	Oxbryta	Rubraca	Tepezza	Vimizim	
Amglidia	Copiktra	Fotivda	Isturisa	Lynparza	Oxervate	Rydapt	Tepmetko	Vistogard	
Anthim	Cotellic	Galafold	Jorveza	Mekinist	Padcev	Sarclisa	Tibsovo	Vitrakvi	
Arikayce Liposomal	Cresemba	Gamifant	Kaftrio	Mektovi	Palynziq	Sirturo	Tookad	Vizimpro	
Austedo	Crysvita	Gavreto	Kanuma	Mepsevii	Pemazyre	Spectrila / Rylaze	Трохх	Vyondys 53	
Ayvakit	Cyramza	Gazyvaro	Ketoconazole Hra	Monjuvi	Phesgo	Spinraza	Translarna	Vyxeos Liposomal	
Balversa	Cystadrops	Givlaari	Keytruda	Myalepta	Piqray	Strensig	Trecondi	Wakix	
Bavencio	Darzalex	Granupas	Kisqali	Mylotarg	Polivy	Strimvelis	Trepulmix	Xermelo	
Beleodaq	Daurismo	Hemlibra	Koselugo	Namuscla	Portrazza	Sunosi	Trodelvy	Xospata	
Besponsa	Dojolvi	Hetlioz	Krintafel	Natpar / Natpara	Poteligeo	Sylvant	Trogarzo	Xpovio	
Blenrep	Eloctate	Holoclar	Kymriah	Nerlynx	Pretomanid	Symdeko / Symkevi	Tukysa	Yescarta	
Blincyto	Elzonris	Ibrance	Kyprolis	Ninlaro	Prevymis	Tabrecta	Turalio	Zejula	
Braftovi	Empliciti	Idefirix	Lartruvo	Nubega	Qinlock	Tagrisso	Ultomiris	Zepzelca	



Products included in the study by segment: 2014-2020

Oncologics (n=100)

Alecensa	Gavreto	Mylotarg	Talzenna
Aliqopa	Gazyvaro	Nerlynx	Tazverik
Alunbrig	Ibrance	Ninlaro	Tecartus
Ayvakit	Idhifa	No brand name (racotumomab)	Tecentrig
Balversa	Imbruvica	Nubeqa	Tepmetko
Bavencio	Imfinzi	Odomzo	Tibsovo
Beleodag	Imlygic	Oncaspar	Tookad
Besponsa	Inqovi	Onivyde Pegylated Liposomal	Trecondi
Blenrep	Inrebic	Opdivo	Trodelvy
Blincyto	Keytruda	Padcev	Tukysa
Braftovi	Kisqali	Pemazyre	Turalio
Brukinsa	Koselugo	Phesgo	Unituxin
Calquence	Kymriah	Piqray	Vargatef
Cometriq	Kyprolis	Polivy	Venclexta
Copiktra	Lartruvo	Portrazza	Verzenio
Cotellic	Ledaga	Poteligeo	Vitrakvi
Cyramza	Lenvima	Qinlock	Vizimpro
Darzalex	Libtayo	Retevmo	Vyxeos Liposomal
Daurismo	Lonsurf	Rozlytrek	Xospata
Elzonris	Lorbrena	Rubraca	Xpovio
Empliciti	Lumoxiti	Rydapt	Yescarta
Enhertu	Lynparza	Sarclisa	Zejula
Erleada	Mekinist	Spectrila / Rylaze	Zepzelca
Farydak	Mektovi	Tabrecta	Zydelig
Fotivda	Monjuvi	Tagrisso	Zykadia

Orphans (n=155)

Adakveo	Cerdelga	Exondys 51	Jorveza	Myalepta	Ravicti	Tazverik	Vistogard
Adamaraa	Chenodeoxyc holic Acid	Fordels	Kattria	Mulatara	Devene	To conture	Vitrolui
Adempas	Leadiant	Farydak	Kaftrio	Mylotarg	Raxone	Tecartus	Vitrakvi
Afstyla	Cholbam / Kolbam	Fintepla	Kanuma	Namuscla	Reblozyl	Tegsedi	Vizimpro
Alecensa	Coagadex	Galafold	Ketoconazole	Natpar / Natpara	Repatha	Tepezza	Vyondys 53
Aliqopa	Cometriq	Gamifant	Keytruda	Ninlaro	Retevmo	Tepmetko	Vyxeos Liposomal
Alofisel	Copiktra	Gavreto	Koselugo	No brand name (fexinidazole)	Revcovi	Tibsovo	Wakix
Alprolix	Cotellic	Gazyvaro	Krintafel	Ocaliva	Rozlytrek	Трохх	Xermelo
Amglidia	Cresemba	Givlaari	Kymriah	Onivyde Pegylated Liposomal	Rubraca	Translarna	Xospata
Anthim	Crysvita	Granupas	Kyprolis	Onpattro	Sarclisa	Trepulmix	Xpovio
Arikayce Liposomal	Cyramza	Hemlibra	Lartruvo	Opdivo	Sirturo	Trodelvy	Yescarta
Austedo	Cystadrops	Hetlioz	Ledaga	Orkambi	Spinraza	Trogarzo	Zejula
Bavencio	Darzalex	Holoclar	Lenvima	Oxbryta	Strensiq	Tukysa	Zepzelca
Beleodaq	Daurismo	Idefirix	Libmeldy	Oxervate	Strimvelis	Turalio	Zolgensma
Besponsa	Dojolvi	Idhifa	Lorbrena	Palynziq	Sunosi	Ultomiris	Zydelig
Blenrep	Eloctate	Imbruvica	Lumoxiti	Pemazyre	Sylvant	Unituxin	Zykadia
Blincyto	Elzonris	Ingrezza	Luxturna	Polivy	Symdeko/ Symkevi	Uptravi	
Braftovi	Empliciti	Inmazeb	Lynparza	Poteligeo	Tabrecta	Venclexta	
Brukinsa	Enspryng	Inqovi	Mektovi	Pretomanid	Tagrisso	Verkazia	
Cablivi	Epidiolex	Inrebic	Mepsevii	Prevymis	Takhzyro	Viltepso	
Calquence	Evrysdi	Isturisa	Monjuvi	Qinlock	Tavalisse	Vimizim	



Country specific definitions of full and limited availability

Country	Definition of full availability	Country-level nuances to the definition of limited availability
Argentina	Medicines listed on the National Oncology Drug Bank	Medicines listed on PAMI, PMO, SUR formularies
Brazil	Medicines with a CONITEC recommendation (and centralised purchasing) or oncology medicines on subnational guidelines	Medicines with a CONITEC recommendation, but without centralised purchasing
Chile	Medicines reimbursed through a national reimbursement system covering more than 90% of the population (e.g.: the reimbursement of approved therapeutic indication of a drug in GES or Ricarte Soto not limited by clinical criteria)	-
Colombia	Medicines listed on PBS	Medicines available via MIPRES
Costa Rica	Medicines listed on CCSS Basic Formulary (LOM)	Medicines purchased via Special purchases negotiations (NO LOM figure)
Ecuador	Medicines on the essential list (Cuadro Nacional de Medicamentos Básicos). Reimbursement is full for all the public subsets: MSP (Ministerio de Salud Pública), IESS (Instituto Ecuatoriano de Seguridad Social), Armed Forces and National Police, in accordance with the Constitution of Ecuador	_
Mexico	Medicines listed in the National Compendium, or other specific analysis IMSS/ISSSTE/INSABI	-
Peru	Medicines is listed in the national petition (PNUME) or its complementary lists	-



Data sources and data completeness

Country	Data sources	Data completeness
Argentina	Country association; Publicly available information (SUR list)	21% complete
Brazil	Country association; Publicly available information (CONITEC recommendations, ANS list)	100% complete
Chile	Country association	98% complete
Colombia	Country association; Publicly available information (PBS list)	100% complete
Costa Rica	Country association	24% complete
Ecuador	Country association	96% complete
Mexico	Country association; Publicly available information (Compendium)	100% complete
Peru	Country association	100% complete



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Contact us for additional questions

Kelsey Stoddart, Consultant, Global Supplier & Association Relations kelsey.stoddart@iqvia.com

Max Newton, Engagement Manager, Global Supplier & Association Relations maximilian.newton@iqvia.com

Andre Ballalai, Associate Principal, Strategy Consulting andre.ballalai@iqvia.com

Per Troein, VP Strategic Partners per.troein@iqvia.com