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Analysis of access to innovative medicines in Peru compared to other OECD countries

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FIFARMA

Federación
Latinoamericana
de la Industria
Farmacéutica

Table of Contents

- + Objectives of the project
- + Project methodology and general considerations
- + Key findings
- + Summary

Objectives

Main objective

Evaluate access to innovative medicines in Peru and compare it with other OECD countries

Specific objectives

- Analyze the access to innovative medicines in terms of the time necessary to obtain sanitary registration and admission in petitions of wide coverage in Peru.
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- Consolidate indicators to evaluate access to innovative molecules that compare OECD countries.
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Table of Contents

- + Objectives of the project
- + **Project methodology and general considerations**
- + Key findings
- + Summary

This study compares access to innovation in Peru to other OECD countries

Countries included in the analysis additional to Peru 

Abbreviation	Country
 AUS	Australia
 AUT	Austria
 BEL	Belgium
 CAN	Canada
 COL	Colombia
 CHI	Chile
 FIN	Finland
 FRA	France
 GER	Germany
 IRL	Ireland
 ITA	Italy
 JPN	Japan

Abbreviation	Country
 MEX	Mexico
 NED	Netherlands
 NZL	New Zealand
 NOR	Norway
 POR	Portugal
 KOR	South Korea
 SPA	Spain
 SWE	Sweden
 CHE	Switzerland
 GBR	United Kingdom
 USA	United States

Time to access is assessed at country level, but also for 8 major therapeutic areas

Therapeutic areas are categorized with anatomical therapeutic chemical (ATC) codes

Therapeutic area	ATC	Description
Cancer	L1-L3, V3	Antineoplastic and immunomodulating agents; radio pharmaceuticals for cancer treatment
Diabetes	A10	Drugs used in diabetes
Cardiovascular	Most B1, C1-C11	Antithrombotic agents (B1); cardiovascular drugs: cardiac therapy, antihypertensives...
Inflammatory diseases	L4, M1, M2 and M4	Anti-TNF (L4B), other immunosuppressants (L4X), anti-rheumatic products, anti-gout preparations (M4)
Anti-infectives	J1D	Drugs used as anti- infectives
Asthma / COPD	R3	Anti-asthma and COPD products
Antiretroviral	J5C	Drugs used for HIV treatment
Vaccine	J7	Drugs used as vaccines
Others	All other ATCs	All other innovative medicines

Note: "Others" includes drugs for specialties such as endocrinology, gastroenterology, psychiatry, ophthalmology, gynecology, hematology, dermatology and urology. It also includes analgesics and anti-histaminic products.

Source: IQVIA Analysis

The evaluation of access in the selected OECD countries was grounded on the analysis of 247 innovative medicines

Considered in the analysis

- Innovative pharmaceutical medicines (called NMEs*), including biological medicines, composed by a molecule first registered in any of 20 OCDE assessed countries (excluding Chile, Colombia and Mexico) between January 1st, 2009 and November 20th, 2014.
- In the case of Peru, innovative medicines were included among the 247 analyzed that have been registered after November 2014 until September 2018. Therefore, the total analysis period runs from January 2009 to September 2018.
- In the case of Chile, innovative medicines were included among the 247 analyzed that have been registered until October 31, 2017.
- For Mexico, the analysis included relevant innovative medicines registered and launched between January 1st, 2010 and December 31st, 2015
- For Colombia, the analysis considered the drugs registered until February 29, 2016
- Only the NEM * were analyzed that require prescription, which aren't the OTC ones.
- Non-seasonal vaccines are considered in the analysis.

Omitted in the analysis

- Products containing a molecule already registered and launched before 2009 in a country, even if they are under a different product name or formulation, are not considered innovative medicines in that country.
- Generics, biosimilars, OTC and herbal products are not considered in the study.
- Radiology products, contrast agents and products used only for diagnostics are not included.
- Seasonal vaccines (such as the flu virus) are not considered in the analysis.
- For Chile, Colombia and Peru all vaccines are excluded from the reimbursement analysis because neither healthcare system guarantees access to a specific vaccine, only that the disease is prevented. A vaccine can have sanitary registration and the population might not have access to it because another one that prevents the same disease won the tender.
- For OECD countries (except Chile, Colombia and Mexico), innovative medicines registered before 2009, or after November 2014 were not included.
- Fentanyl citrate is treated exceptionally for the analysis of Chile, Colombia and Peru, and loteprednol etabonate in the case of Peru because they were released before the analysis period.

Note: The list of 247 innovative medicines is available in the appendix

* These terms are described in the glossary of terms in greater depth (plates 33-34)

Data sources include regulatory agencies, IQVIA proprietary information and funding bodies in the 24 countries in scope



Registration

- Regulatory agencies in each country in scope.
- E.g. TGA in Australia, EMA in the European Union, FDA in USA, INVIMA in Colombia, COFEPRIS in México, ISP in Chile, DIGEMID in Peru.



Reimbursement

- Reimbursement status and reimbursement date:
 - Information gathered and/or validated from funding bodies in each country in scope, depending on availability.
 - IQVIA MIDAS, IQVIA Pricing Insights and IQVIA PharmaQuery.
 - Special permission to use country Hospital data provided to IQVIA in some countries.

* These terms are described in the glossary of terms in greater depth (plates 33-34)

The access comparison was built on the information available for all countries

Pre-registration

Time between submission of pharmacological evaluation to approval of pre-registration.

Product registration

Time required to obtain a health record of the NEM * from the application for registration.

Product Launch

Time elapsed between the sanitary registry and the commercial launch of the NEM *

Product reimbursement

Time required for an NEM * to be included in the country's reimbursement mechanisms since registration.



Information available for Colombia



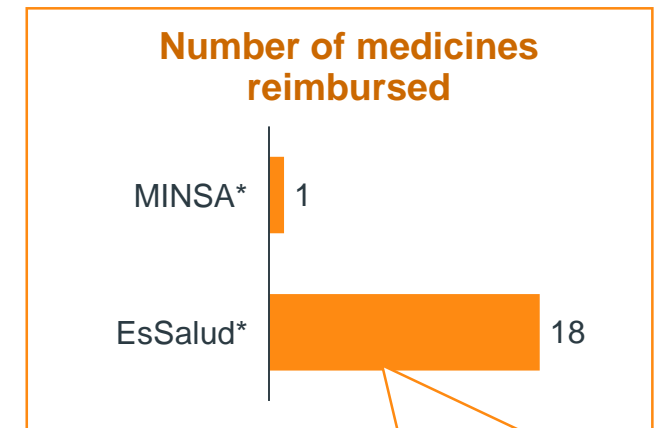
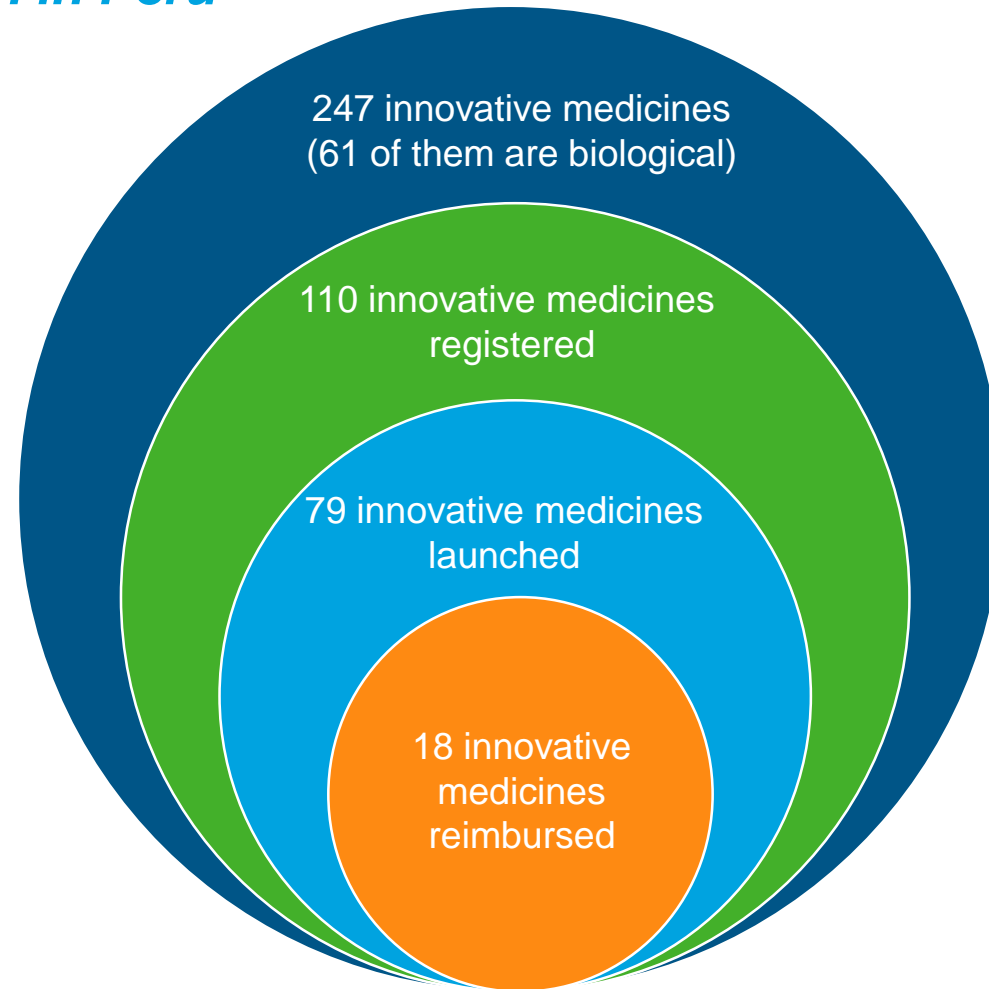
Information available for Chile, Mexico and Peru

Information available for the other OECD countries

* These terms are described in the glossary of terms in greater depth (plates 33-34)

45% of innovative medicines have been registered in Peru and 18 have reimbursement

Access to innovation in Peru



1 molecule included in the list of EsSalud* and 17 molecules included by authorizations of the IETSI* of EsSalud*

Note: Innovative medicines registered until September 2018 of the univers of 247 molecules.

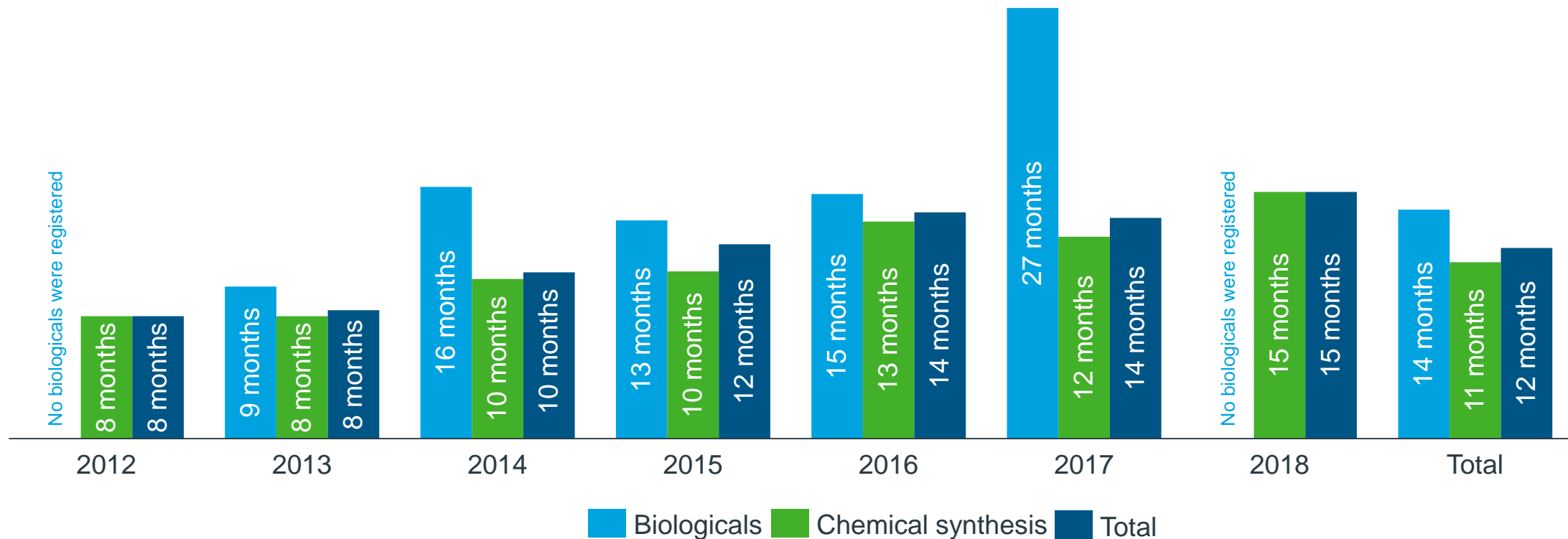
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Table of Contents

- + Objectives of the project
- + Project methodology and general considerations
- + **Key findings**
 - **Peru: Time to obtain the health record**
 - Peru and the other 23 OECD countries: Comparison of access to medicines and reimbursement
- + Summary

The average time to obtain the sanitary registration of biologicals is 14 months and increases to 24 after the regulation of 2016

Average time from presentation of the file to registration by type of medication



* Data disaggregated between the "pre" and the "post" implementation of the New Regulation to obtain the sanitary registry of biologicals in August 2016

Note: The months are equal to the number of days divided by 30 rounded to the nearest whole number. There is no information on the time of registration in 19 molecules because Digemid does not have available the date of registration request dates before 2011

(#): Number of Molecules

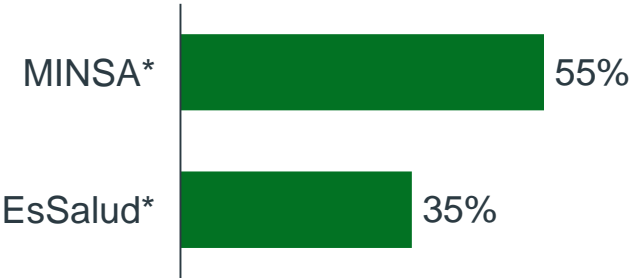
Table of Contents

- + Objectives of the project
- + Project methodology and general considerations
- + **Key findings**
 - Peru: Time to obtain the health record
 - **Peru and the other 23 OECD countries: Comparison of access to medicines and reimbursement**
- + Summary

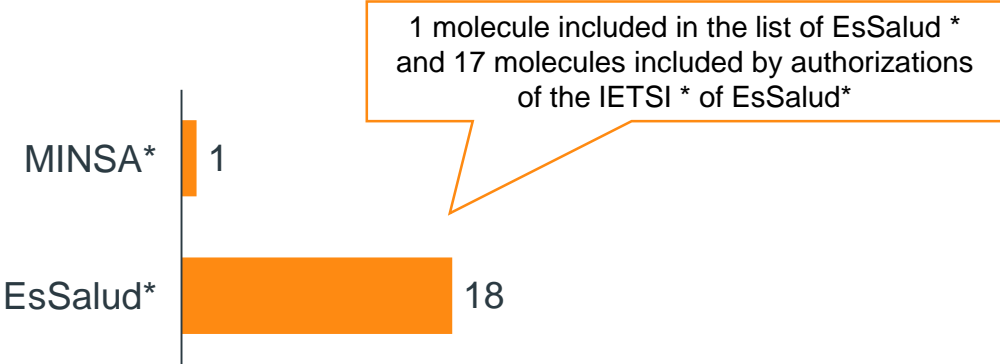
The percentage of innovative medicines reimbursed in MINSA * or EsSalud * of those launched is 10% in Peru

Population coverage and number of innovative medicines reimbursed from those launched

% population coverage

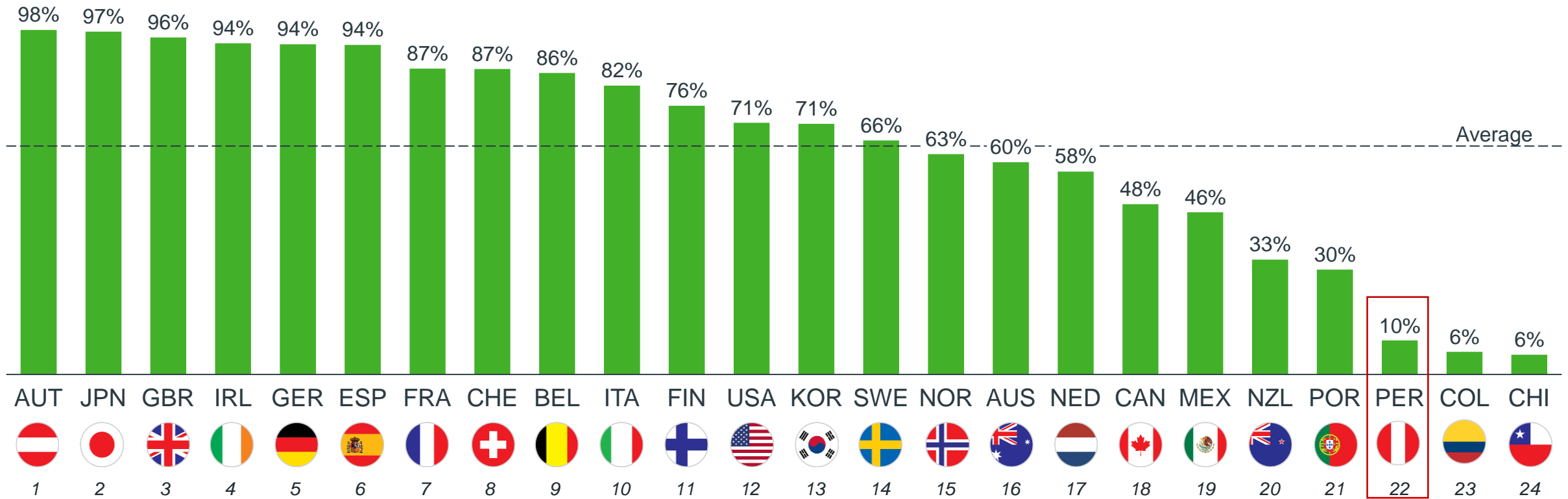


Number of medicines reimbursed



The percentage of innovative medicines reimbursed in Peru is 10%, significantly lower than 65% of the OECD countries

Proportion of innovative medicines reimbursed of those launched in each country



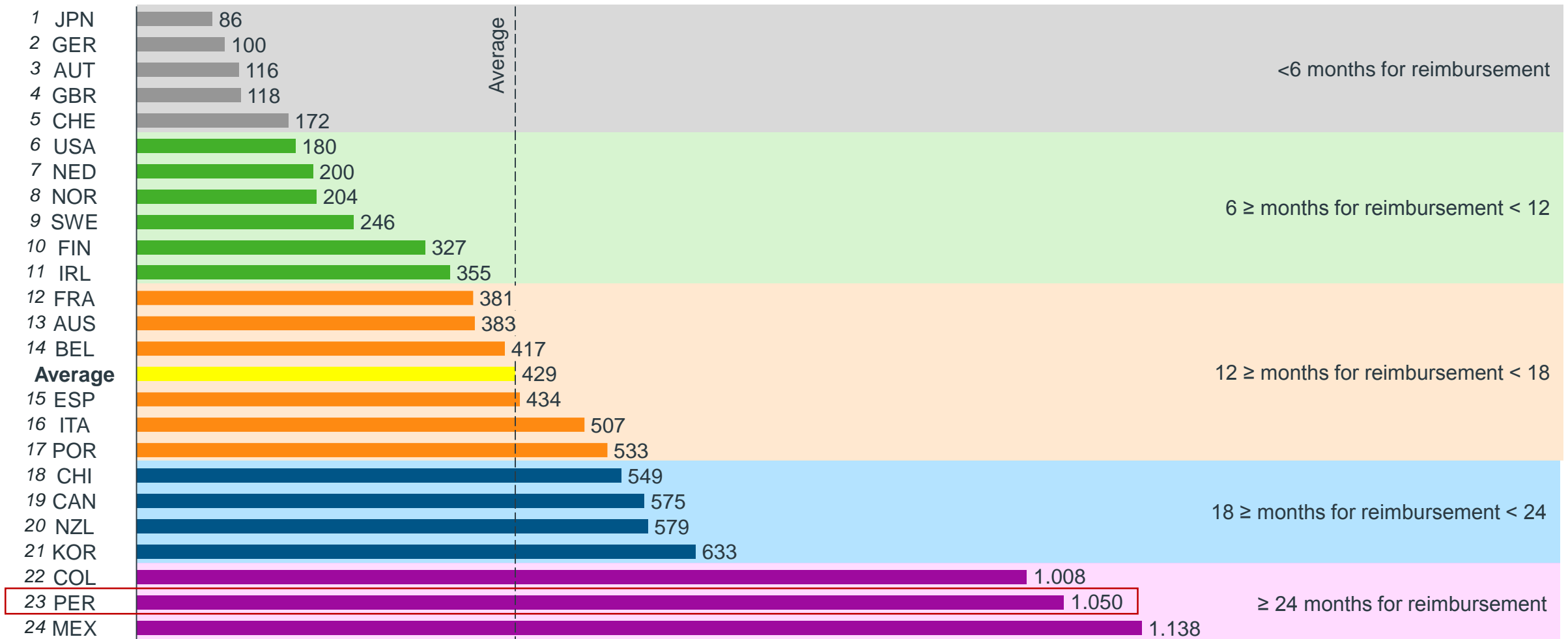
Ranking

Note: Peru's launch and registration data were obtained until September 2018. The data for the launch and registration of Chile was obtained until October 2017. The launch data for Colombia were obtained until December 2015 and the registration data until February 2016. Data from Mexico was collected until December 2015.

The proportion of drugs reimbursed in Peru is a weighted average of the proportion of MINSAs * and the proportion of EsSalud * taking into account the coverage of the population 10% of Peru includes the 17 molecules included by authorizations from the IETSI * of EsSalud *

Peru ranks 23rd among the OECD countries in time from health registration to the reimbursement of a molecule

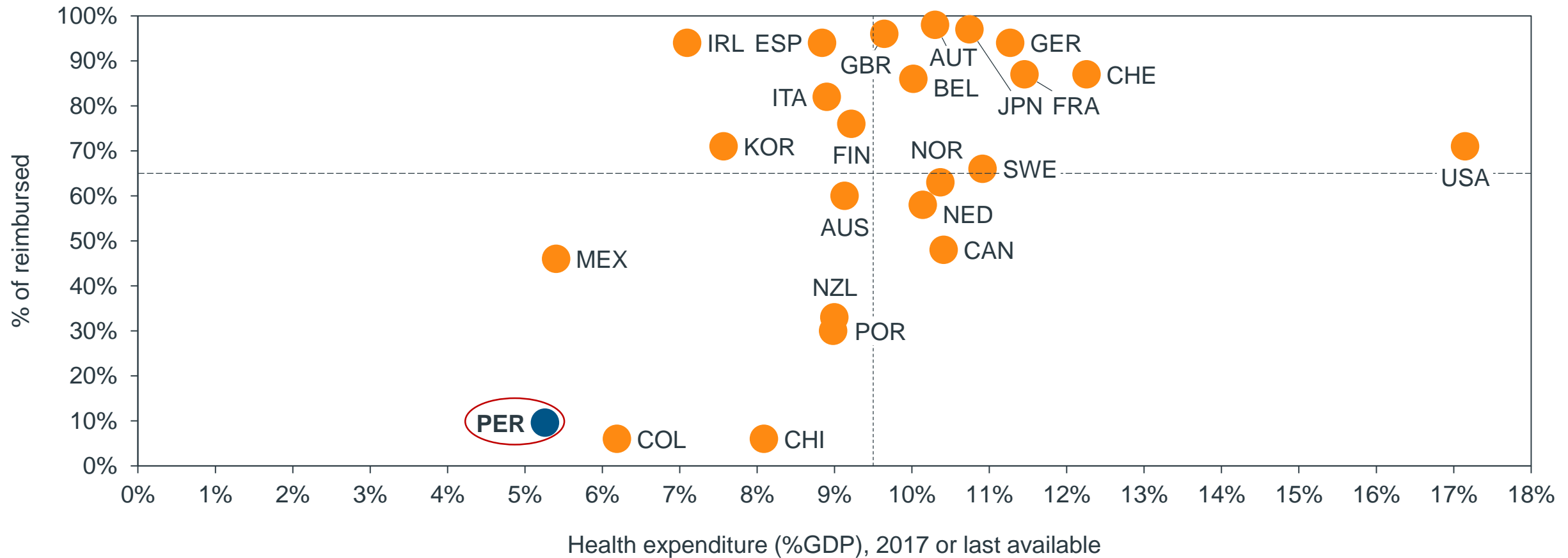
Average time to reimbursement from registration (days) for the analyzed innovative medicines



Note: The average time in Peru was calculated considering 18 molecules included in PNUME *, complementary lists MINSA *, list of EsSalud * or authorizations of the IETSI * of EsSalud *. The reimbursement time was estimated from the registration of the molecule until the inclusion in these lists. The time of reimbursement of Peru from the registry is a weighted average of the time of the Ministry of Health and the time of EsSalud taking into account the coverage of the population.

Peru has the lowest level of health spending as % GDP and one of the lowest levels of reimbursement, far from the OECD average

Percentage of innovative medicines reimbursed vs. GDP per capita



Source: Health expenditure was obtained from the statistics available in the OECD. The statistics for Colombia and Peru are from 2015, the latest available.

The proportion of medicines reimbursed in Peru is a weighted average of the proportion of MINSAs * and the proportion of EsSalud * taking into account the coverage of the population.

Table of Contents

- + Objectives of the project
- + Project methodology and general considerations
- + Key findings
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Summary of findings of access to innovative medicines in Peru.

Peru lags behind OECD countries in reimbursement

THE SANITARY REGISTRATION PROCESS

In Peru approval times in the process of innovative medicines registration have been increasing in recent years.

- From 2012 onwards there has been an increase in waiting times from the presentation of a file to the registration, being 15 months for 2018.
- In the last year (2017) the waiting times were increased in 14 months in the total of molecules and 27 months for the biological ones.
- The number of registered biologics was reduced from the new regulation in 2016.
- We are facing an opportunity to avoid further deterioration in the approval waiting times.

Summary of findings of access to innovative medicines in Peru.

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REIMBURSEMENT IN PERU

In Peru, the percentage of innovative medicines reimbursed is 10%

- MINSA that covers ~ 55% of the population reimburses 1 innovative molecule and EsSalud that covers ~ 35% of the population reimburses 18 innovative molecules.
- MINSA reimburses only an innovative drug, based on UNEP and its complementary lists. On the other hand, EsSalud reimburses 17 innovative medicines through its institutional request and the approvals of use granted by the IETSI *
- There are opportunities to generate greater access to innovation, simplifying the inclusion processes of innovative molecules in the lists of both MINSA and EsSalud

Summary of findings of access to innovative medicines in Peru.

Peru lags behind OECD countries in reimbursement

COMPARISON OF INDICATORS PERU vs. OECD

The reimbursement in Peru is lagging vs the OECD countries.

- The percentage of drugs reimbursed in Peru is 10% versus an average of 65% of the OECD countries.
- The average time from approval of the sanitary registry to its reimbursement is 35 months in Peru vs. 14 months in the OECD countries.
- Peru has the lowest GDP per capita, health spending as % GDP, health expenditure per capita and one of the lowest levels of reimbursement, far from the percentage of OECD countries.
- The time to obtain the sanitary registry of an innovative medicine in Peru takes twice as long as in the USA for 2017.



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