

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

The purpose of this analysis is to evaluate the access to innovative medicines in Peru and compare them with the OECD countries (Organization for Economic Cooperation and Development) considering key elements such as the number of innovative molecules registered and reimbursed, times to obtain the sanitary registry and the reimbursement of innovative medicines, providing relevant elements that allow establishing parameters of the dynamics of access to prescription drugs in Peru.

The health sector in Peru has shown important advances in recent years. Currently life expectancy is 75.1 years, an improvement of 5.1 years since 2000. Maternal and infant mortality have been reduced and are converging to the regional average. At the same time, there has been a significant advance in health coverage that has increased from 37% in 2004 to 83% of the population in 2017 (OECD Reviews of Health Systems: Peru 2017). However, there are still gaps in access and health status of the population in relation to the levels reached by the OECD countries. The average life expectancy of this group of countries is 80.8 years (78.1 for men and 83.4 for women). On the other hand, in terms of qualified human resources, Peru has 1.7 doctors per thousand inhabitants while the OECD average is 3.3 doctors per thousand inhabitants. (OECD Reviews of Health Systems: Peru 2017).

Public health in Peru faces great challenges, which are reflected in a reduction in healthy life years mainly motivated by the incidence of mental illness and substance abuse, cancer, gastrointestinal diseases, musculoskeletal diseases, cardiovascular disease and diabetes. Like the OECD countries, the burden of disease in Peru is dominated by non-communicable diseases.

The health system is fragmented among the following entities:

- Ministry of Health (MINSA)
- 25 regional health directorates that respond to 25 regional governments
- Ministry of Labor and Employment Promotion with EsSalud
- Ministry of Defense with attention to the Armed Forces
- Ministry of the Interior with attention to the Police Forces
- Private sector

The government of Peru has set itself the objective of achieving universal health coverage (CUS) in 2021 (OECD Reviews of Health Systems: Peru 2017) through the expansion of the population covered by the Comprehensive Health Insurance of the Ministry of Health; However, the achievement of this ambition in a context of high proportion of informal work, limited public resources devoted to health and fragmentation of the system becomes a significant challenge.

To know the panorama of access to new medicines in Peru, FIFARMA commissioned IQVIA to prepare this analysis. The conclusions that derive correspond to the evaluation of a universe of 247 new molecular entities (NEM) that were registered in at least one of the OECD countries that were taken into account for the report, between January 2009 and November 2014. In the case of Peru, taking advantage of the existence of additional information, it was decided to extend the period in such a way that the NEMs registered and reimbursed until September 2018 are included.

The evaluated molecules included in the study correspond to innovative medicines and biological products that require prescription. Generic, biosimilar, OTC, seasonal vaccines, herbal products and drugs used solely for diagnosis were not considered in the study. Fentanyl was considered an exception in Peru since it was launched in the 1990s, much earlier than in some of the comparison countries.

Key Definitions

- **Registry:** defined as the moment in which the authorization is granted to market the product that contains the NEM (New Molecular Entity or New Molecular Entity in English) or innovative medicine or biological product in a country. This definition applies even if the product has not been launched or if it has not yet been refunded.
- **Reimbursement:** understood as the guaranteed access to the NEM for a large proportion of the population of a country. In some countries, "reimbursement" is called "financing" or "inclusion." For this report, in Peru, the "reimbursement" refers to the inclusion in the Unique National Request for Essential Medicines (UNEP), complementary lists of the Ministry of Health, EsSalud's list or authorizations for the use of medications outside the EsSalud Petition through preliminary opinions of the Institute for the Evaluation of Health Technologies and Research (IETSI).

The analysis includes 247 molecules belonging to different therapeutic areas

The 247 molecules evaluated in the present analysis belong mainly to therapeutic areas of high prevalence and incidence in Peru.

Therapeutic area	ATC	Description
Cancer	<i>L1-L3, V3</i>	Antineoplastic and immunomodulating agents; radio pharmaceuticals for cancer treatment
Diabetes	<i>A10</i>	Drugs used in diabetes
Cardiovascular	<i>Most B1, C1-C11</i>	Antithrombotic agents (B1); cardiovascular drugs: cardiac therapy, antihypertensives
Inflammatory diseases	<i>L4, M1, M2 and M4</i>	Anti-TNF (L4B), other immunosuppressants (L4X), anti-rheumatic products, anti-gout preparations (M4)
Anti-infectives	<i>J1D</i>	Drugs used as anti-infectives
Asthma / COPD	<i>R3</i>	Anti-asthma and COPD products
Antiretroviral	<i>J5C</i>	Drugs used for HIV treatment
Vaccine	<i>J7</i>	Drugs used as vaccines
Others	<i>All others ATCs</i>	Other NEM for various diseases related to endocrinology, gastroenterology, psychiatry, ophthalmology, gynecology, hematology, dermatology, urology, congenital diseases and multidrug-resistant tuberculosis. Analgesic medications are also included

The comparison of Peru regarding access to medicines is made with 23 OECD countries.

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
 ESP	Spain
 SWE	Sweden
 SUI	Switzerland
 GBR	United Kingdom
 USA	United States

55% of the 247 innovative molecules evaluated in the analysis have no registration in Peru and only 18 molecules are reimbursed

The refund of the 18 molecules in Peru is distributed as follows:

- 1 of the 18 molecules is reimbursed by the MINSA
- 1 in the EsSalud institutional form
- 17 by preliminary authorizations of the IETSI of EsSalud

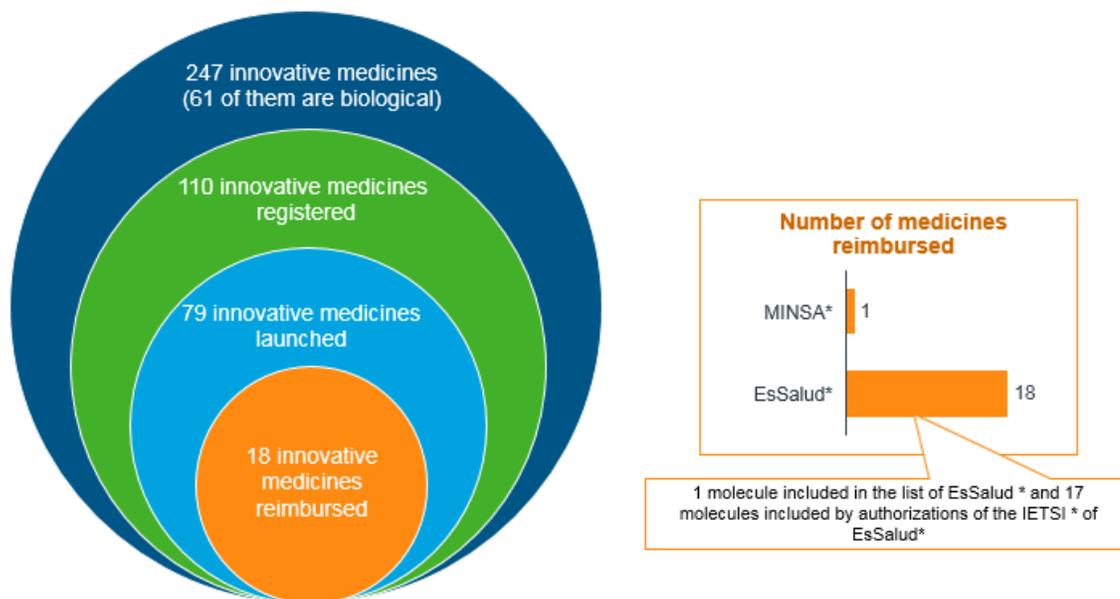


Figure 1: Access to innovation in Peru

The average time for obtaining a sanitary registry has doubled since 2012 and reaches up to 27 months for biological medicines in 2017

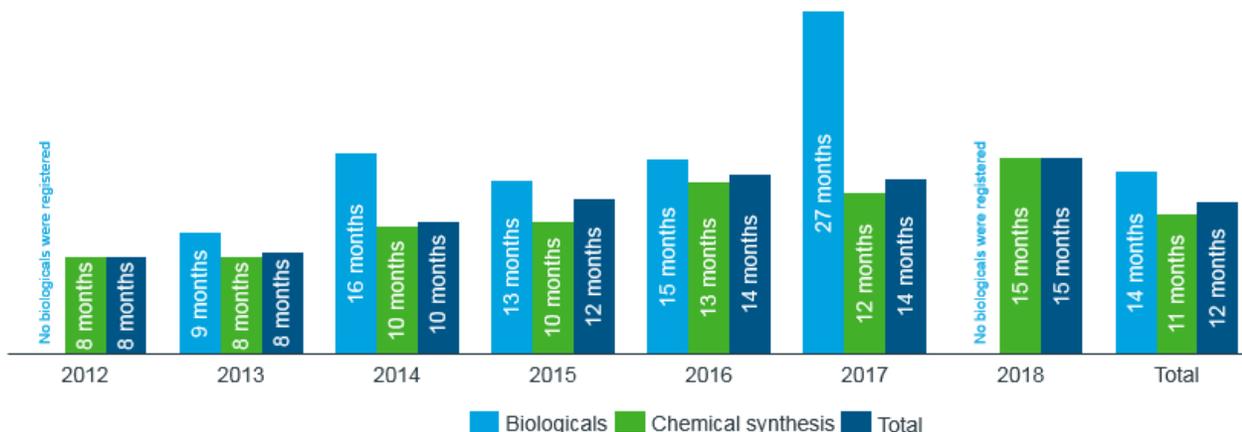


Figure 2: Average time from presentation of the file to registration by type of medication (#): Number of Molecules

In the last 3 years, the time to obtain a sanitary registry of innovative medicines has increased consistently to reach between 12 and 15 months for drugs in general and 27 months for biologics in 2017. In 2018, no biological product was approved. that an increase in the approval times of more than 36 months is expected for 2019. Comparing Peru with the OECD countries, only 45% of the medicines analyzed have obtained sanitary registration part of the DIGEMID, 17 percentage points below the average of OECD countries.

The number of innovative products with acces in Perú is lower tan the average of the OECD countries

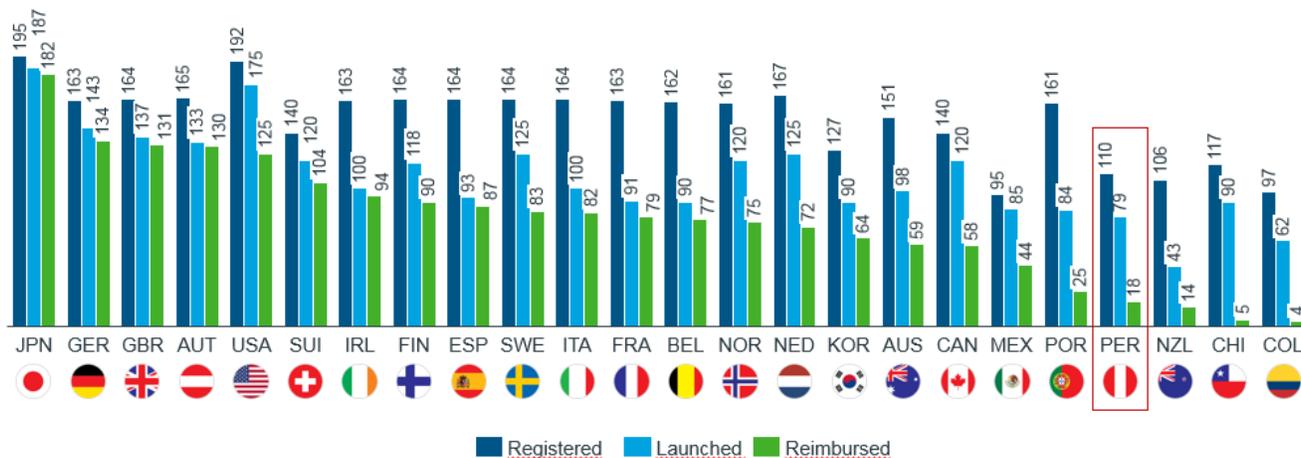


Figure 3: Number of innovative medicines registered, launched and reimbursed by OECD country. Note: The results may overestimate the level of acces in Peru in relation to all countries including MEX, CHI and COL since the results of these countries correspond to the realization of the study in previous years.

On the evaluation of reimbursement, among the OECD countries analyzed, an average of 82 innovative medicines have met the access conditions to be considered reimbursed. Of the total of molecules evaluated, in Peru only 18 were included in MINSA (1 of them within the request) and EsSalud (17 of them are approved by preliminary evaluations that authorize the reimbursement per patient through the IETSI). The analysis of Peru contemplated a broader observation period, that is, all drugs registered and reimbursed until September 2018 were included, while for most of the OECD countries, only the information was used until November 2014.

With a reimbursement rate for innovative medicines of 10%, Peru is below the average rate of 65% of the OECD countries.

This 10% considers the innovative reimbursed medicines launched in Peru through the MINSA from a UNEP list, complementary lists from the Ministry of Health, EsSalud and IETSI authorizations, 17 of the 18 molecules are reimbursed by IETSI approvals, without necessarily being molecules that are in the current listings.

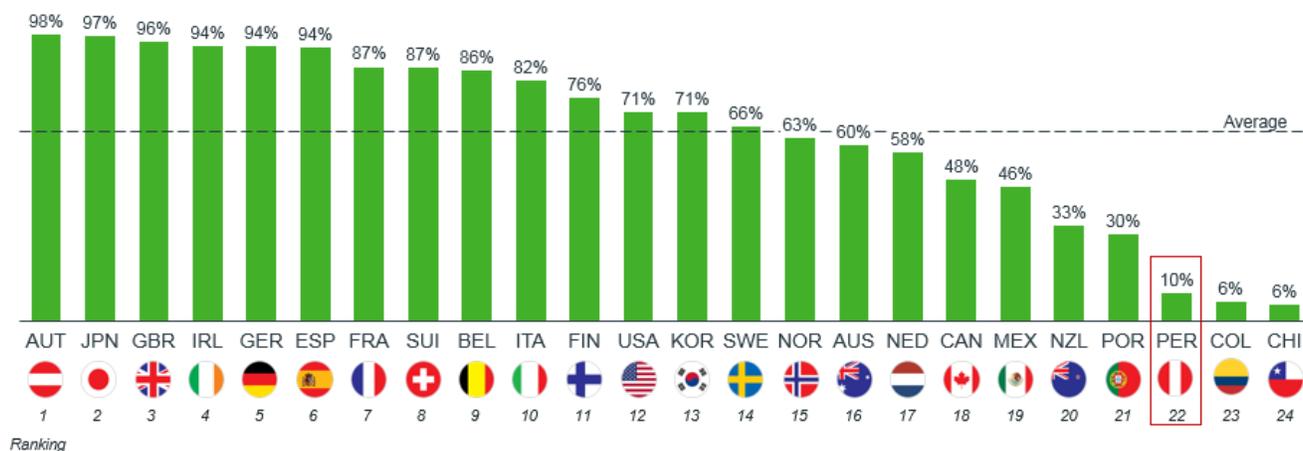


Figure 4: Percentage of innovative medicines reimbursed from those launched in each country.

Peruvian patients wait 35 months to access innovative medicines since their registration, much longer than the average of 13 months in OECD countries.

In Peru, the time to obtain reimbursement of innovative medicines from the registry is 35 months. The time in MINSA, which offers coverage to 55% of the population, is 38 months, while in EsSalud, which covers approximately 35% of the population, is 31 months.

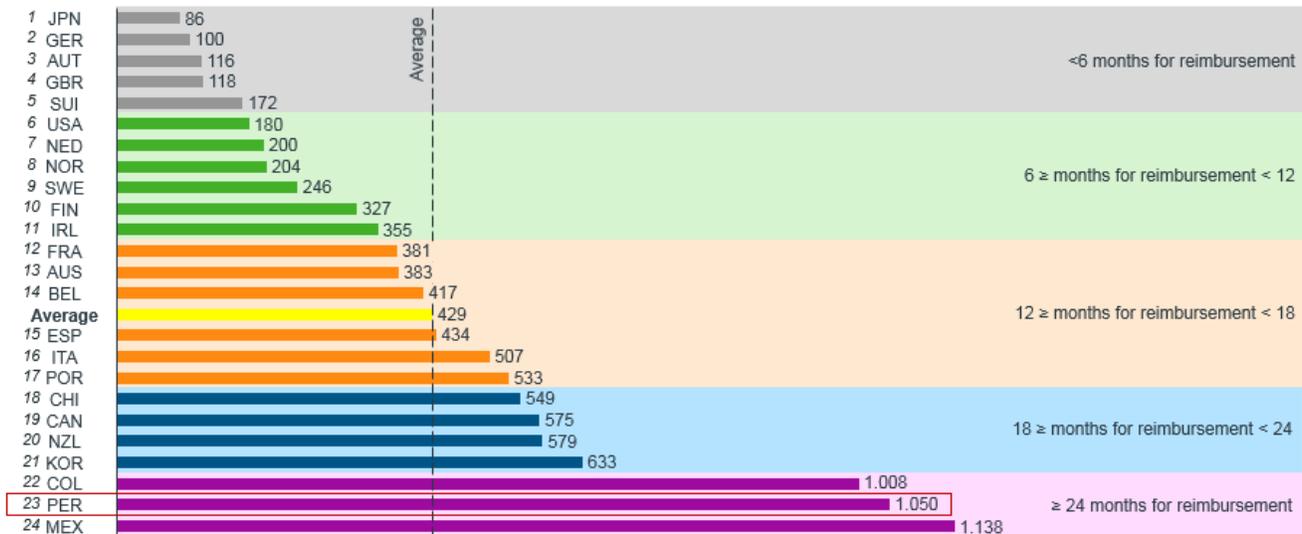


Figure 5: Average time in days from registration to reimbursement of innovative medicines

In the OECD member countries selected for this study, innovative medicines are reimbursed in a period of 13 months. Only in a few countries the time to obtain a refund is greater than 18 months.

Peru occupies the penultimate position among the OECD countries, with its longest periods of time from registration to the reimbursement of an innovative molecule.

In Peru, access to the 18 innovative molecules reimbursed took more than 18 months, the remaining 17% got it in less time.

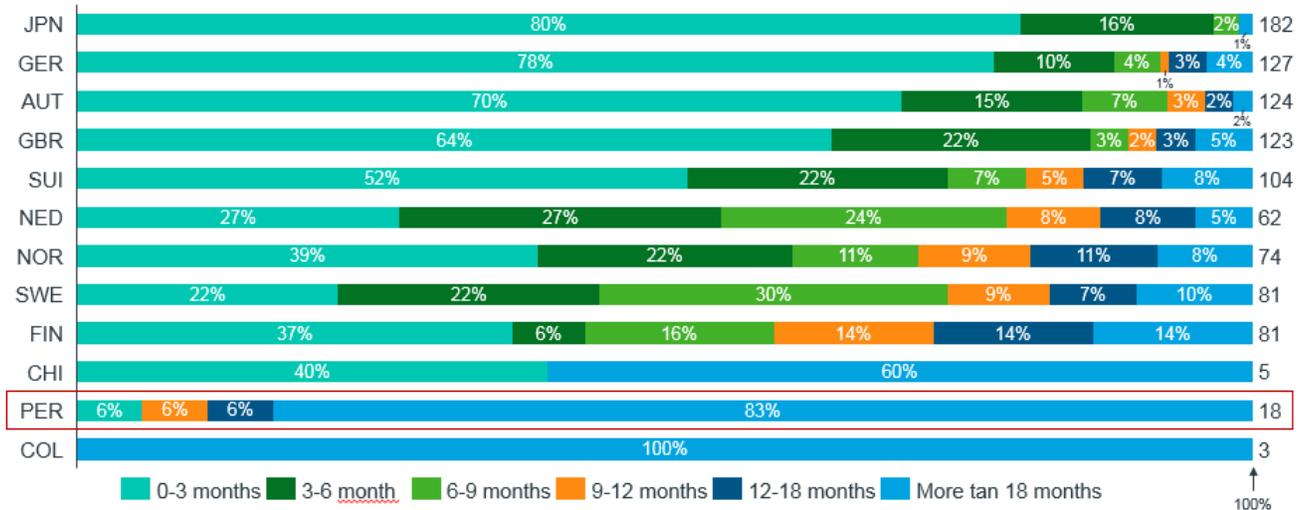


Figure 6: Main segments of time from registration to reimbursement of innovative medicines

In the OECD countries, the percentage of innovative medicines whose reimbursement exceeds 18 months is low. At least 90% of the molecules under study were reimbursed in less than a year and a half in these countries. On the other hand, Japan and Germany are the countries that have the shortest times since they reimbursed more than 100 molecules in less than 6 months after their registration.

Many of the OECD countries reimburse or include new drugs in the listings at the same time they are registered; More than 58% of the drugs analyzed were considered for reimbursement in less than 3 months or almost automatically.

Peru shows the lowest levels among the countries analyzed in terms of GDP per capita, health expenditure as% of GDP and health expenditure per capita. Additionally, Peru is among the countries with the lowest proportion of innovative molecules reimbursed or covered by the system, far from the average of the OECD countries *

Compared to the OECD countries included in this analysis, Peru is lagging in terms of access to medicines defined as a percentage of reimbursable molecules.

* This analysis does not imply that there is causality between the variables.

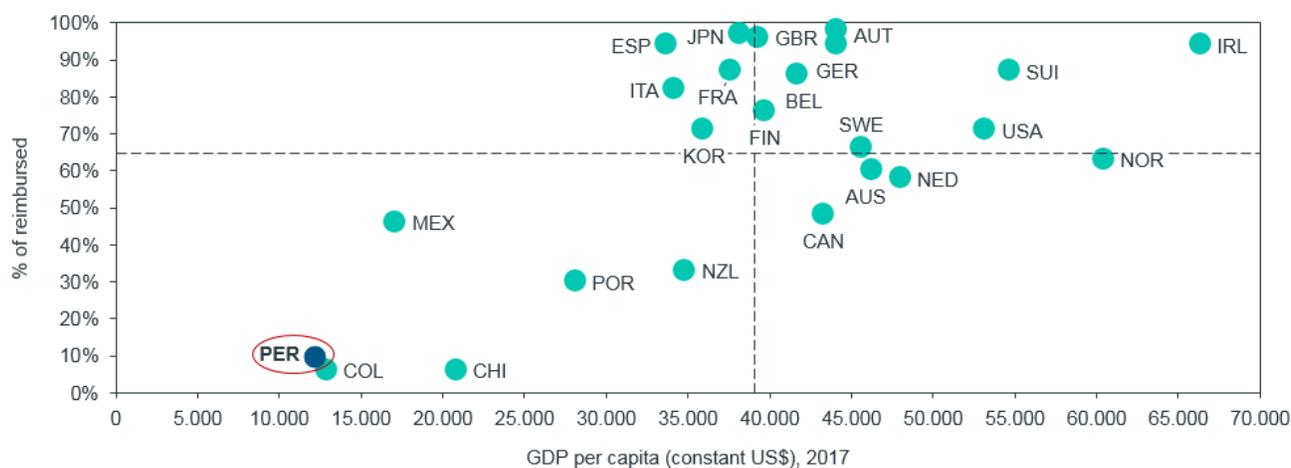


Figure 7: Percentage of innovative drugs reimbursed vs. GDP per capita

Japan, the United Kingdom, Ireland, Germany and Austria are the countries with the highest percentage of drugs reimbursed among the countries analyzed; However, they have a per capita gross domestic product that is much higher than in Peru and other Latin American countries.

In terms of percentage of health spending, we could say that Peru, Colombia, Mexico, even Ireland and Korea (Korea in English) are similar, however, Peru lags when talking about health spending as a percentage of GDP.

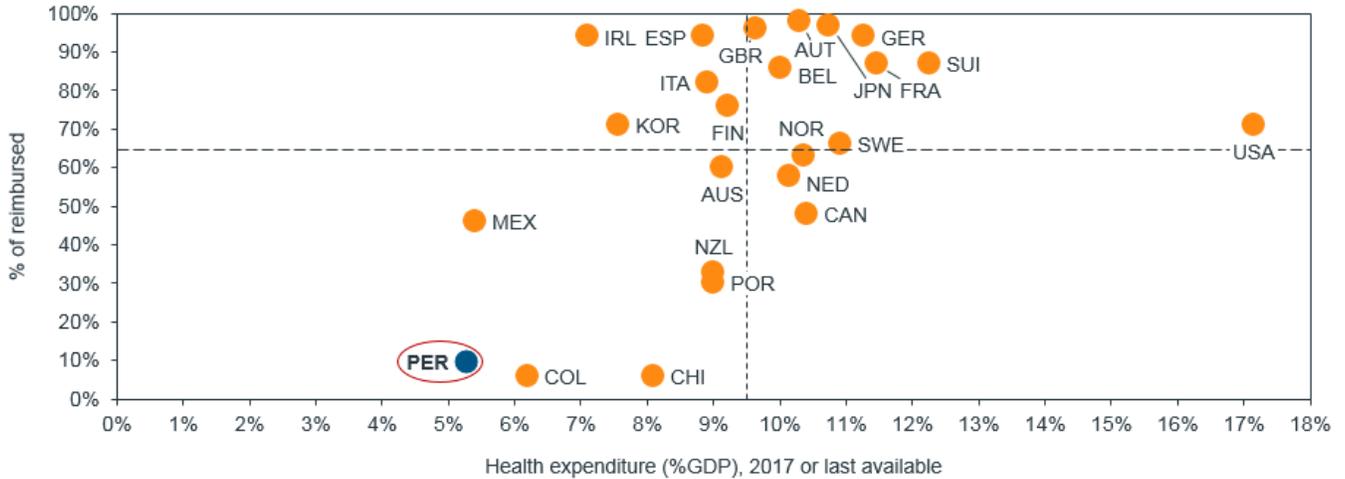


Figure 8: Percentage of innovative drugs reimbursed vs. spending on health as% of GDP

Although the health sector has had more resources because of economic growth and a higher priority from the government, the progress has not been enough to significantly reduce the investment gap in health with respect to the region, placing Peru among the countries with lower investment in health among Latin American countries and well below the OECD countries.

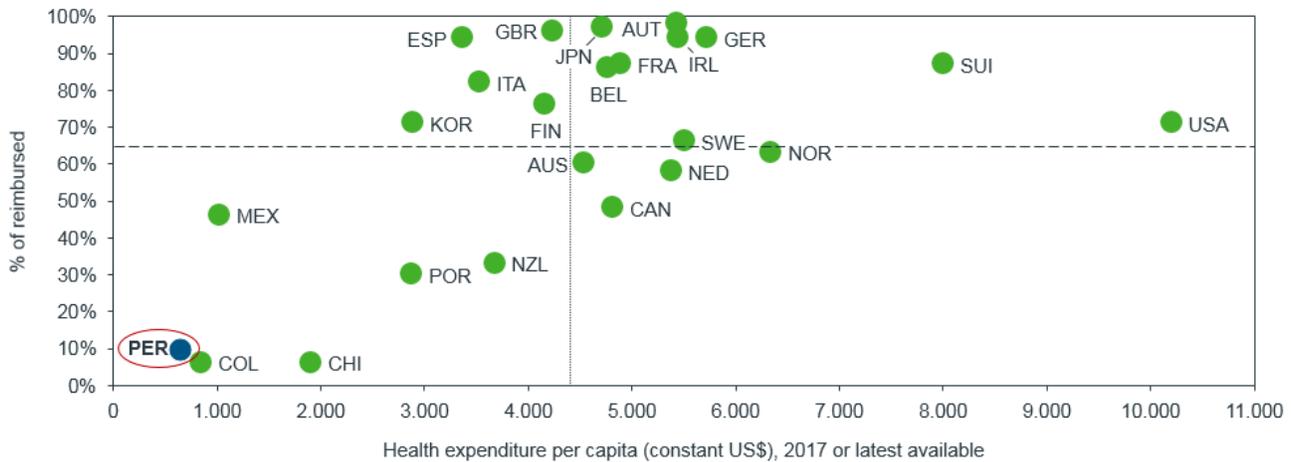


Figure 9: Percentage of innovative drugs reimbursed vs. health expenditure per capita