

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

Comparative indicators on access to new molecular entities in Chile

November 2018

Commissioned by:



This analysis seeks to compare the timing of reimbursement or coverage of innovative molecules between Chile and 22 other member countries of the OECD (Organization for Economic Cooperation and Development), and provides relevant elements that allow parametrizing the access dynamics of some prescription drugs in Chile.

While Chile has seen improvements comparable to those in other OECD countries in recent decades, the health status of the population nonetheless falls fairly consistently below the OECD average. The average life expectancy in Chile has risen faster than the OECD average in the past forty years, and in 2015 was 79.1 years – 76.5 years for men and 81.7 years for women – compared to the OECD average of 80.6 years (77.9 for men and 83.1 for women). Like Chile's OECD peers, the burden of disease is dominated by non-communicable diseases. **(OECD, 2017)**

Chile faces great public health challenges, with high rates of obesity, smoking, increased alcohol consumption and a growing incidence and mortality from cancer. **(OECD, 2017)** that require the review of health systems and plans to address these problems.

Health care coverage in Chile is provided primarily either by the state-funded National Health Fund - *Fondo Nacional de Salud*, most commonly known as FONASA, or by the private coverage schemes, FONASA covers around 78% of the population. Since 2005 the benefit basket under the public health system in Chile has been set under a system of enforceable guarantees. Citizens are guaranteed access to those treatments defined under the "*Acceso Universal con Garantías Explícitas*", or AUGE, which is also known synonymously as GES (*Garantías Explícitas en Salud*). Additionally Ricardo Soto Law established coverage for some rare inherited diseases, including some lysosomal storage diseases, other inherited disorders of metabolism, HER2+ve breast cancer, among others. **(OECD, 2017)**

With the objective of understanding the access to new medicines in Chile, Fifarma and CIF commissioned IQVIA to prepare this analysis. The presented conclusions correspond to the evaluation of 247 new molecular entities (NME) that were registered between January 2009 and November 2014 in at least one of the OECD countries in scope for the report. In the case of Chile, the analyzed period was extended so that relevant NMEs registered until October 2017 and reimbursed until the first semester 2018 were also included.

It is important to note that among the molecules evaluated are only innovative medicines that require a prescription. Generic drugs, biosimilars, OTC products, seasonal vaccines, herbal products and drugs used only for diagnosis were not considered in the study. Fentanyl citrate was treated exceptionally in Chile since it was launched in the 1990s, much earlier than in some of the countries in scope.

Key definitions

- **Registration:** defined as the moment in which the sponsor company is granted authorization to commercialize the product that contains the NME (New Molecular Entity) or innovative medicine in a country. This definition applies even if the product has not been launched or if it has not yet been reimbursed
- **Reimbursement:** defined as the status in which the innovative medicine is granted access through public funding for a significant proportion of the country's population (broad access, not by alternate or outstanding mechanisms). All levels of reimbursement (full, partial, restricted, etc.) are considered in the analysis. In some countries it may be called "funding" or "reimbursement". For this report, in Chile, GES' pathologies (Garantías Explícitas en Salud or Healthcare Securities) or Ley Ricarte Soto's (Ricarte Soto's Law) inclusion is considered "reimbursement" in this report.










The analysis includes 247 molecules that belong to different therapeutic areas

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

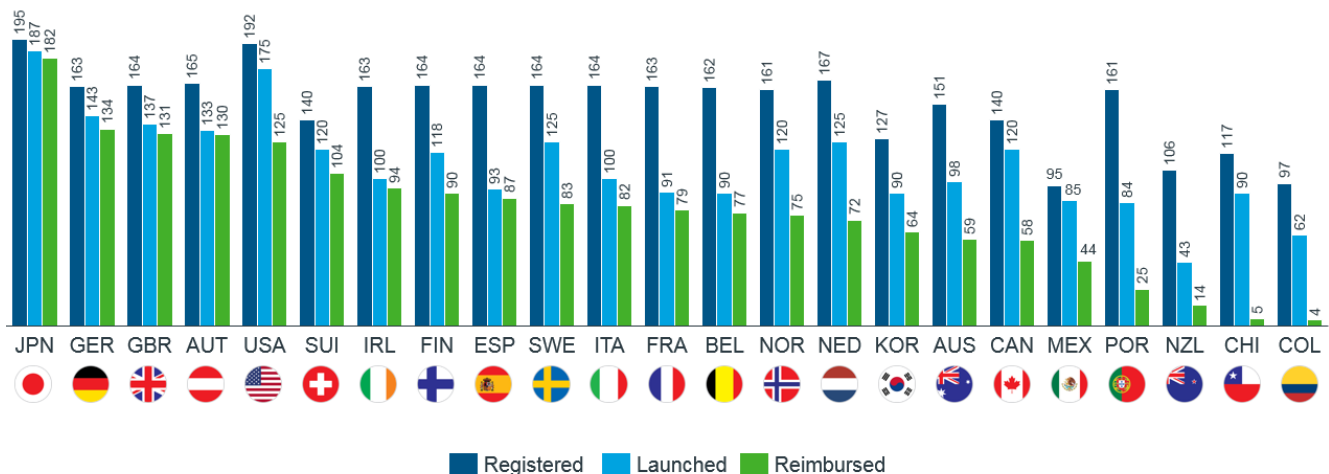
Therapeutic area	ATC code	Description
Cancer	L1-L3, V3	Antineoplastic and immunomodulating agents; radio pharmaceuticals for cancer treatment
Diabetes	A10	Drugs used in diabetes
Cardiovascular	Most B1, C1-C11	Antithrombotic agents (B1); cardiovascular drugs: cardiac therapy, antihypertensives...
Inflammatory 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

23 countries that are part of the Organization for Economic Cooperation and Development (OECD) were included in the analysis

Chile's comparison of access to medicines is against 22 other OECD countries.

Abbreviation	Country	Abbreviation	Country	Abbreviation	Country
 AUS	Australia	 GER	Germany	 POR	Portugal
 AUT	Austria	 IRL	Ireland	 KOR	South Korea
 BEL	Belgium	 ITA	Italy	 ESP	Spain
 CAN	Canada	 JPN	Japan	 SWE	Sweden
 COL	Colombia	 MEX	Mexico	 SUI	Switzerland
 CHI	Chile	 NED	Netherlands	 GBR	United Kingdom
 FIN	Finland	 NZL	New Zealand	 USA	United States
 FRA	France	 NOR	Norway		

More than 50% of the 247 molecules evaluated in the analysis have no registration in Chile



In Chile, 130 of the 247 molecules taken into account for the analysis did not obtain sanitary registration in the analyzed period. Of the 117 molecules that did obtain registration, only 5 are covered by GES or by Ley Ricarte Soto.

Figure 1: Number of innovative medicines registered, launched and reimbursed by OECD country in the evaluated period. Universe of 247 innovative medicines, ranked by the number of reimbursed medicines.

When deepening the analysis on the sanitary registration, in the OECD countries the average number of registered molecules is 153 of the 247 included in the report, that is, 62% of the total number of molecules taken into account. In Chile, 47% of the medicines analyzed have obtained sanitary registration by the ISP, 15 percentage points below the average of OECD countries.

Regarding the evaluation of reimbursement, among the OECD countries included in the study, an average of 82 innovative medicines have met the necessary access conditions to be considered reimbursed. The particular situation of the Chilean health system results in only 5 molecules of this group of medicines that are part of GES or Ricarte Soto disease pathologies, therefore considered reimbursed. The observation period for Chile was even extended, meaning that all medicines registered until October 2017 and reimbursed until November 2018 were also included, while for most of the OECD countries, only the information gathered until November 2014 was considered.

Chile ranks last when comparing the percentage of molecules reimbursed of the total of registered molecules

In Chile, 5 of the 117 registered molecules have been included in Ley Ricarte Soto or are part of GES pathologies

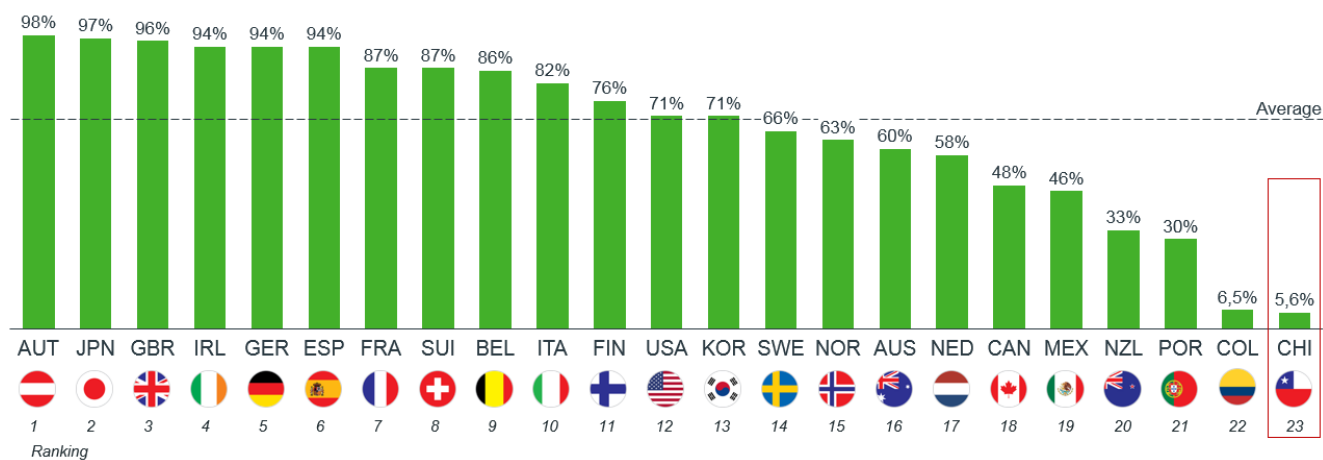


Figure 2: Proportion of innovative drugs reimbursed from those launched in each country in the evaluated period.

Less than 6% of the molecules registered in Chile are included in any of the broad reimbursement mechanisms of the country, in other words, they are covered by the country's health system in a generalized manner and not through alternate or outstanding processes. This percentage is far from the 70% average rate for the rest of the countries in the scope.

The configuration of other health systems has a definite impact on this proportion of drugs reimbursed or covered for the population and shows a huge distance between Chile and the OECD countries that are part of this analysis.

Chilean patients wait more than 18 months to access medications through reimbursement once they are launched

The formal inclusion of the medicines to the Ricarte Soto Law or that the pathology they treat has been included in GES, took an average of 18 months

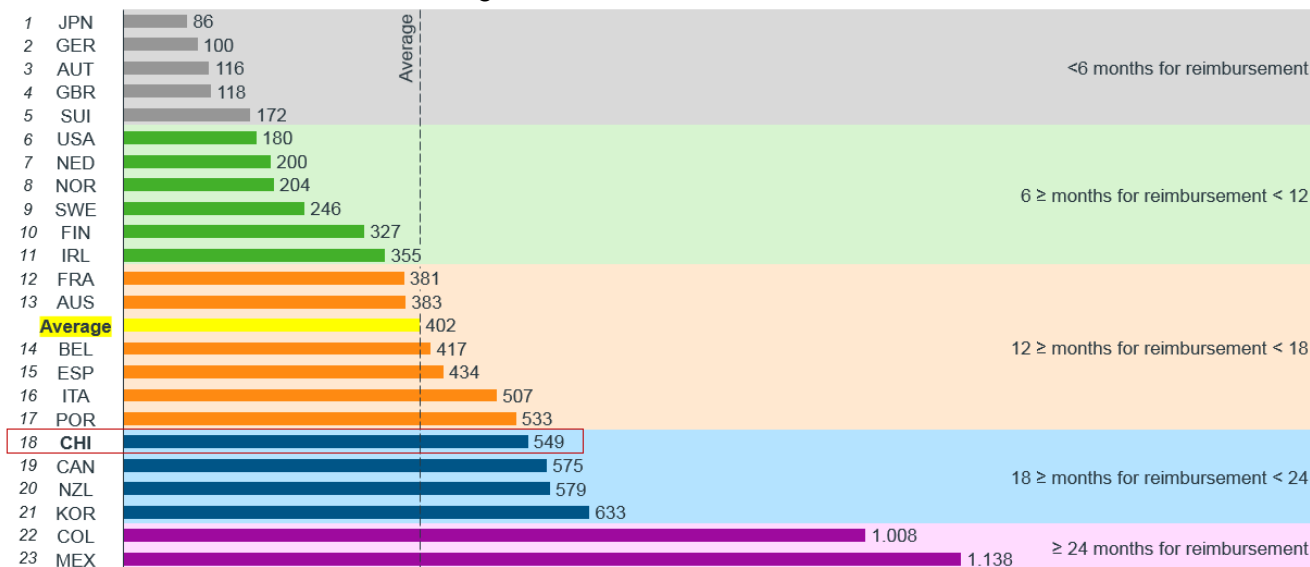


Figure 3: Comparison between selected OECD countries in relation to the time elapsed between registration and reimbursement in the period evaluated.

In the OECD countries selected for this report, innovative medicines achieve reimbursement in 13 months on average, while in very few countries the time to obtain reimbursement is greater than 18 months.

Chile ranks 18th among OECD countries in time from the launch of a product to the reimbursement of that product, only 5 of the 23 countries evaluated are below Chile.

The distance between Chile and the rest of the OECD countries becomes more evident when looking at the weighted average of the sample of molecules

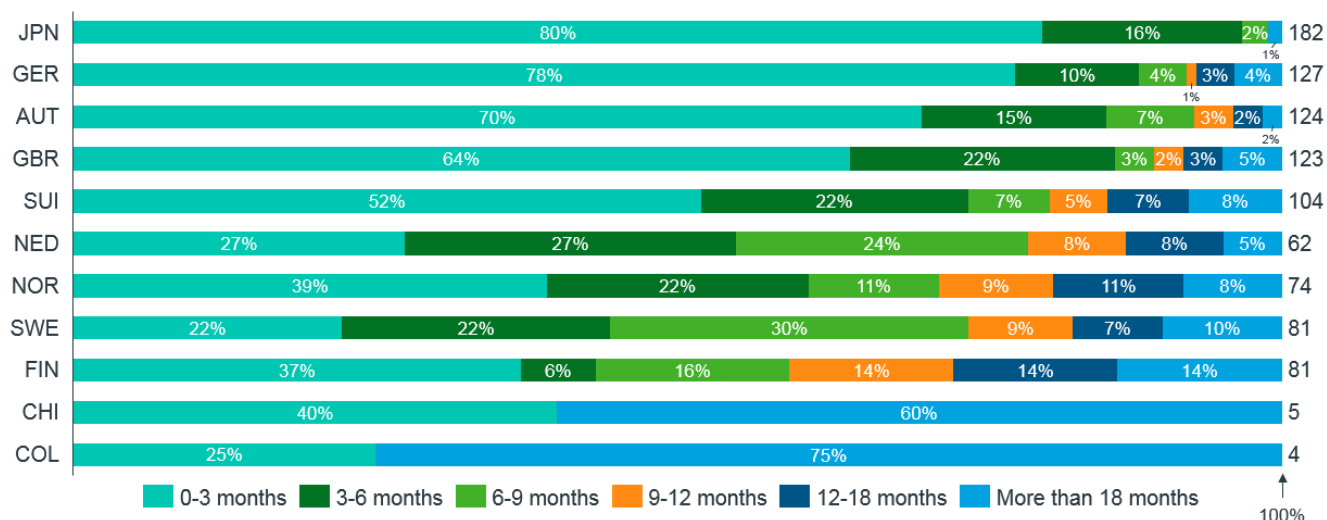


Figure 4: Comparison between selected OECD countries in relation to the time elapsed between registration and reimbursement in three-month ranges in the period evaluated.

In Chile, 3 of the 5 molecules took more than 18 months to be reimbursed, the two drugs that achieved coverage before three months were launched to the market when the pathologies that are treated with these molecules were already part of the GES list.

A very low proportion of innovative medications took more than 18 months to achieve reimbursement status. Before that time elapsed at least 90% of the molecules became reimbursed in the OECD countries. On the other hand, Japan and Germany showed the fastest access, these countries reimbursed more than 100 molecules in less than 6 months after their registration

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

The relationship between the percentage of reimbursement and GDP, as well as health expenditure of the countries evaluated, makes differentiation according to countries' income level possible*

Compared to the OECD countries included in this analysis, Chile is in the last position with regarding access to medicines defined as a percentage of reimbursed molecules.

*Este análisis no implica que exista causalidad entre las variables.

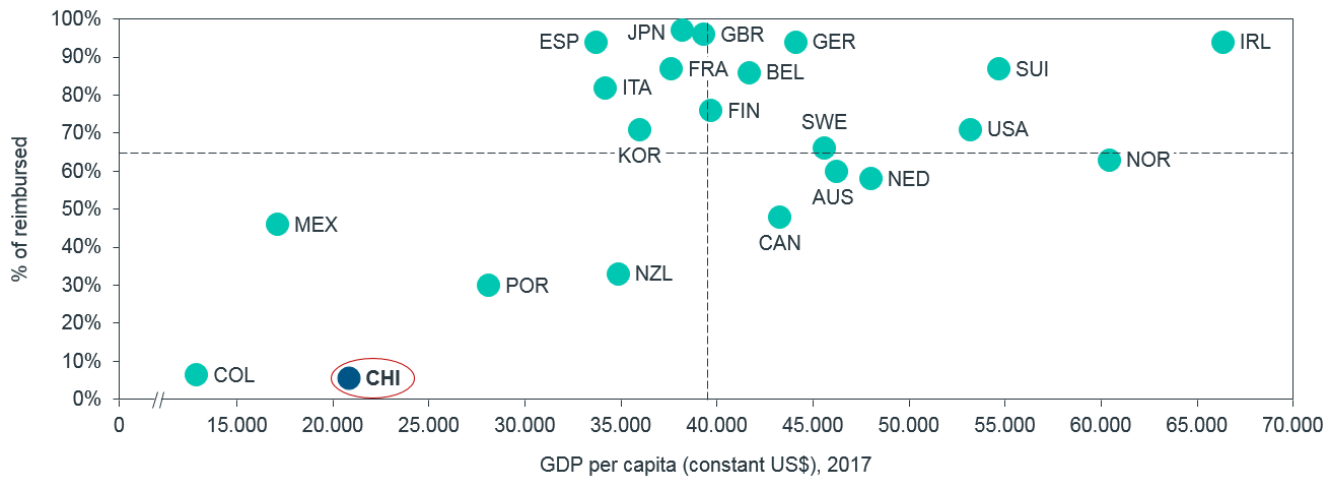


Figure 5: Proportion of innovative drugs reimbursed in the evaluated period vs. Gross domestic product (GDP) per capita. The GDP per capita was sourced from the statistics available in the OECD.

Japan, the United Kingdom, Germany and Spain are the countries with the highest percentage of drugs reimbursed among the countries analyzed, however they show a per capita gross domestic product much higher than Chile and other countries in Latin America.

Mexico, Chile and Colombia have the lowest GDP per capita in the OECD, but Chile shows the lowest rate of reimbursement among the three countries.

Chile is comparable to Korea, Ireland, Portugal and New Zealand in health spending as a percentage of GDP, although access to medicines is far behind, the % of reimbursed molecules is more than 5 times lower than in those countries

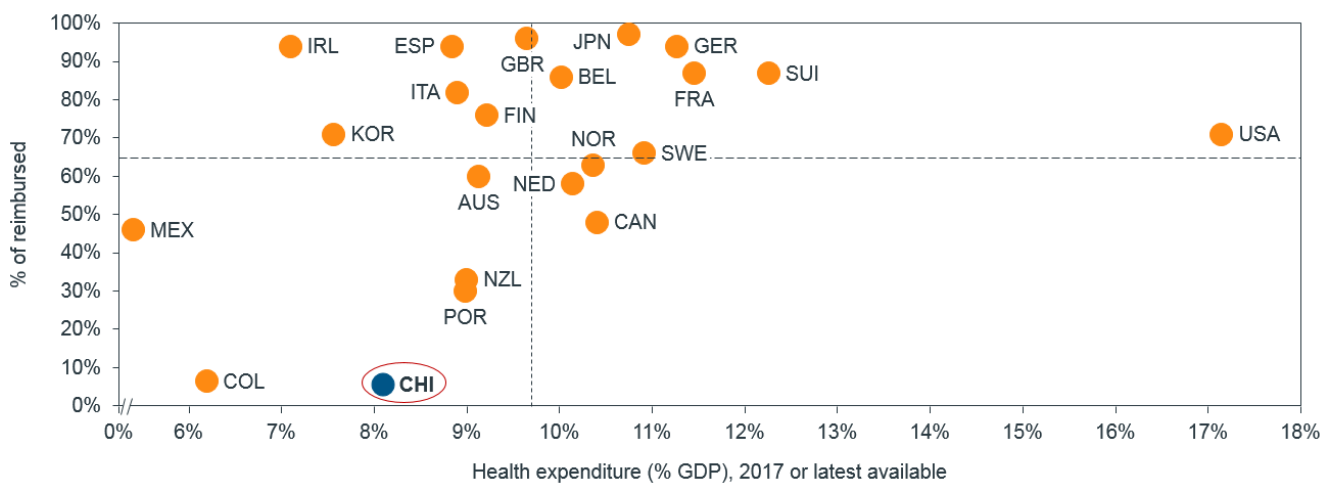


Figure 6: Proportion of innovative drugs reimbursed in the evaluated period vs. health expenditure as % of GDP. This indicator was obtained from the statistics available in the OECD.