FIFARMA | Federación Latinoamericana de la Industria Farmacéutica

ACCESS FOR INNOVATIVE DRUGS IN COLOMBIA

Assessment of access to medicines in Colombia compared to OECD countries

March 2016

This analysis is based on the comparison between Colombia and 20 countries members of the OCDE (Organization for Economic Co-operation and Development) of registration and reimbursement times for specific molecules, and provides relevant elements that allow the parametrization of access dynamics of some prescription drugs in Colombia.

The General Social Security in Health in Colombia (*Sistema general de seguridad social en salud*), has implemented different strategies to expand coverage grounded on the principle of the universalization of the system. This is how today more than 95% of the population counts with access to health services, regardless of whether the person is affiliated to the subsidized, contributory or special scheme. The effort to achieve universal coverage implies the need to develop a high quality service to ensure effective access to cutting-edge treatments for diseases affecting the Colombian population such as cancer, arthritis, cardiovascular problems, among others.

To better assess the overall situation of access of innovative medicines in Colombia, FIFARMA commissioned IMS Health to prepare this analysis. The conclusions presented correspond to the evaluation of a universe of 247 new molecular entities (NMEs) that were registered in at least one of the twenty OECD countries that were taken into consideration in the report, between January 1, 2009 and November 20, 2014. In the particular case of Colombia, given the existence of additional information, it was decided to extend the period so that it also included relevant NMEs registered through February 2016.

The universe of NMEs analyzed includes biotechnological medicines, prescription drugs and non-seasonal vaccines. Generics, biosimilar, OTC products, seasonal vaccines, herbal products, and drugs used only for diagnosis were not considered in the study.

Fentanyl citrate was considered as an exception in Colombia since it was launched in 1990, much earlier than in some of the compared countries.

KEY DEFINITIONS

- **Registration:** it is defined as the authorization to market the product which contains the specified NMEs in a given country. The date considered in the report is that in which the authorization was granted for each domestic market. This definition applies even if the product had not been marketed or reimbursed within the time frame defined for the analysis.
- **Reimbursement:** It is defined as the status in which access to the NME is guaranteed through public funding for a large proportion of the population of a country. All reimbursement levels (full, partial, restricted, etc.) are considered. In Colombia, reimbursement is strictly associated to the inclusion in the POS list (Compulsory Health Plan) regardless of the possibility of accessing non formulary drugs through alternative mechanisms.

THIS ANALYSIS INCLUDES 247 MOLECULES BELONGING TO VARIOUS THERAPEUTIC AREAS

The 247 molecules evaluated in this analysis belong mainly to therapeutic areas of high prevalence and incidence in Colombia.

Therapeutic area	ATC	Description
Oncology	L1-L3, V3	Antineoplastic and immunomodulation agents; radiopharmaceutical for cancer treatment
Diabetes	A10	Drugs used in diabetes treatment
Cardiovascular	Most of B1, C1-C11	Antithrombotic agents (B1); cardiovascular drugs: cardiac therapy, antihypertensive
Autoimmune disease	L4, M1, M2 y M4	Anti TNF (L4B), other immunosuppressant (L4X), anti-rheumatic products, anti-gout preparations (M4)
Anti-infective	J1D	Used as anti-infective drugs
Asthma / COPD	R3	Anti-asthma and COPD products
Antiretroviral	J5C	HIV treatment drugs
Vaccines	J7	Vaccines
Other	Other ATCs	Other NMEs

20 COUNTRIES MEMBERS OF THE ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT WHERE INCLUDED IN THE ANALYSIS

This analysis compares access in Colombia to access in the selected 20 OECD countries.

Abbreviation	Country
AUS	Australia
AUT	Austria
BEL	Belgium
CAN	Canada
FIN	Finland
FRA	France
DEU	Germany
IRL	Ireland
ITA	Italy
JPN	Japan

Abbreviation	Country
NLD	Holland
NZL	New Zealand
NOR	Norway
PRT	Portugal
KOR	South Korea
ESP	Spain
SWE	Sweden
CHE	Switzerland
GBR	United Kingdom
USA	United States

A LARGE PROPORTION OF THE TOTAL ASSESED MOLECULES ARE NOT REGISTERED IN COLOMBIA

In Colombia, 97 of the 247 molecules taken into consideration for the analysis have sanitary registration and only 62 of these have been commercially released. Of these 62 molecules, only 4 are included in the POS list (Compulsory health plan).

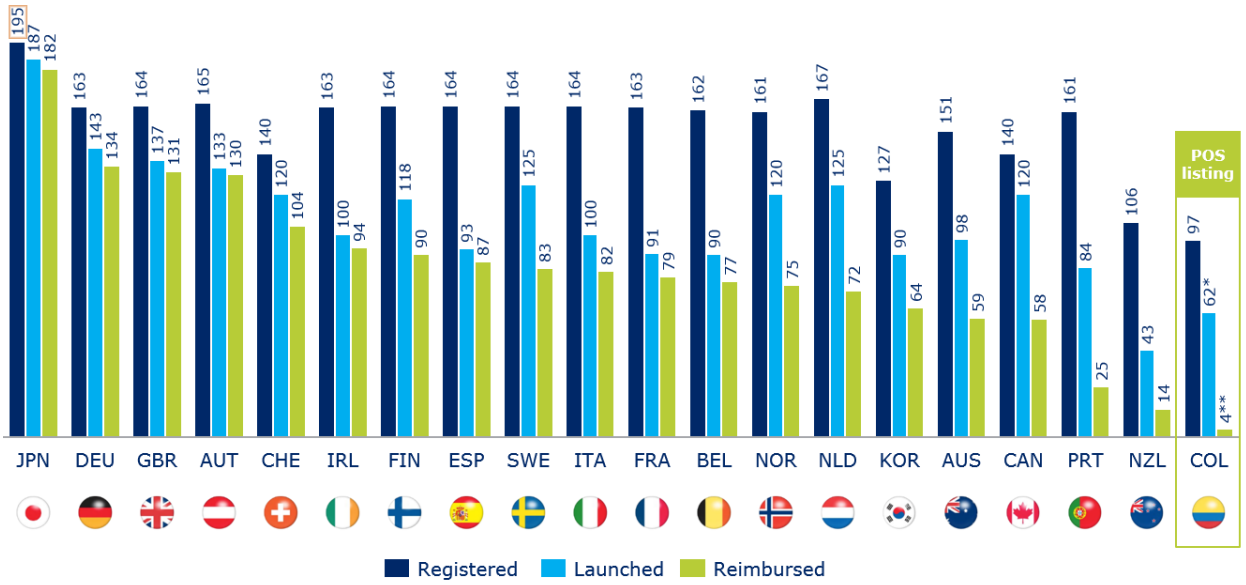

Figure 1: Number of registered, launched and reimbursed NMEs by country (2009-2014).

The average number of molecules registered across the countries analyzed is 153, which accounts for 62% of the relevant universe. In the case of Colombia, only 39% of the total molecule universe has obtained registration by INVIMA, a proportion that is far below the average rate.

In the case of reimbursement, among the OECD countries included in the study, an average of 84 molecules has already fulfilled the necessary requirements to be granted reimbursement status. The particular situation of the Colombian health system shows that there are only 4 molecules included in the POS drug list.

It is important to consider that in the case of Colombia, the time period of the information used was larger than that of the other countries as the study also included all drugs registered in Colombia until February 2016 opposed to the November 2014 deadline for the other 20 OECD countries.

COLOMBIA IS IN THE LAST PLACE IN THE RANKING POSITION COMPARING THE PERCENTAGE OF NME REIMBURSED OF THE NUMBER OF MOLECULES REGISTERED

In Colombia, 4 of the 97 registered molecules have been included in the POS list by the Ministry of Health and Social Protection.

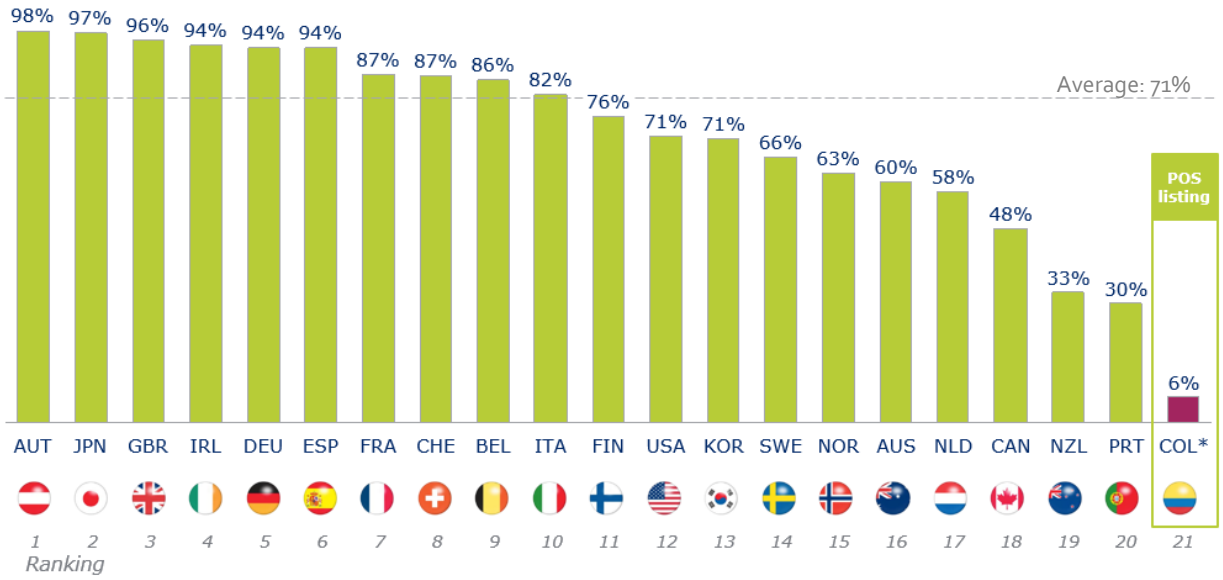

Figure 2: Proportion of new molecules reimbursed from the total of registered molecules by country (2009-2014).

Only 6% of the registered molecules in Colombia are included in the POS list. This proportion is far below the average rate of other countries analyzed which is 71%.

There are alternative mechanisms available for patients to apply for non-listed drugs, however this kind of access is not generalized and straight forward, thus it is not considered reimbursement in this analysis.

The configuration of other health systems have a definite impact on this ratio and shows considerable distances among OECD countries included in this analysis.

*This analysis includes fentanyl citrate which was added to the POS in 2002

PATIENTS IN COLOMBIA WAIT THE LONGEST TIME FOR FORMAL ACCESS TO INNOVATIVE MEDICINES THROUGH THE INSTITUTIONAL SYSTEM

The formal inclusion into the POS list of the relevant NMEs in Colombia takes longer than it does in any other country in the analysis.

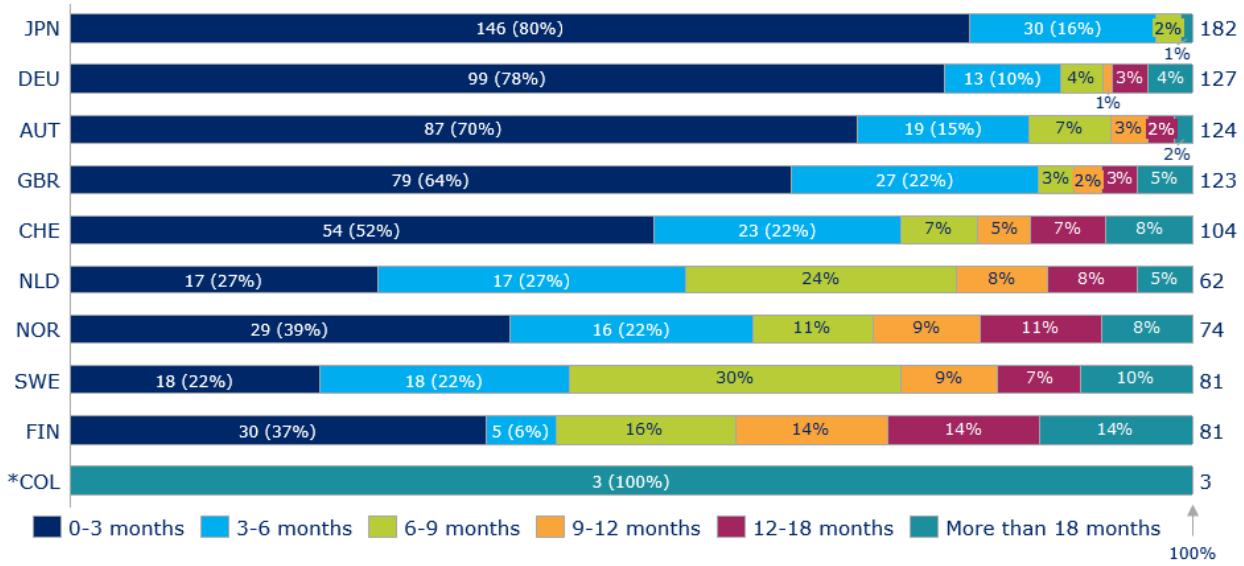

Figure 3: Comparison between OECD selected countries and Colombia in relation to the time period between registration and reimbursement (2009-2014).

In countries members of the OECD, a very low proportion of molecules take more than 18 months to reach the status for reimbursement. Before that time, at least 70 molecules became refundable in Finland, which is the country with longer repayment times from the sample of OECD countries. On the other hand, Japan and Germany are the countries that took the shortest time, reimbursing more than 100 molecules in less than 6 months after registration.

Some OECD countries grants reimbursement status for new drugs at the same time that they are registered; while in Colombia, in addition to the fact that very few molecules are reimbursed, including them in the POS list takes on average 2.3 years.

* Only 3 out of four reimbursed molecules in Colombia where considered to estimate the average time. Fentanyl citrate was excluded from analysis given it was launched and reimbursed before the beginning of this analysis' time frame.

THE DISTANCE BETWEEN COLOMBIA AND THE REST OF THE COUNTRIES BECOMES MORE EVIDENT WHEN LOOKING AT THE WEIGHTED AVERAGE OF THE SAMPLE

On average it takes an NME approximately 34 months (1,008 days) to be included in the POS list subsequent to registration.

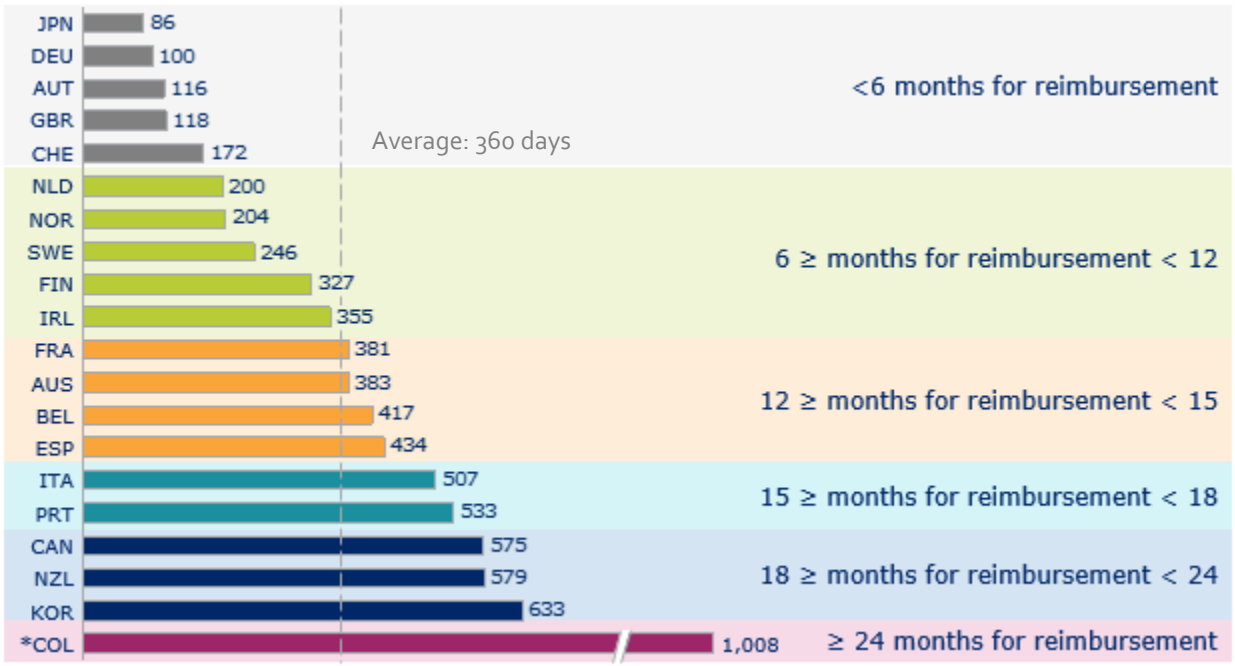

Figure 4: Average time from registration to reimbursement in days for new drugs (2019 – 2014).

In Colombia, the average reimbursement time is 5.6 times longer than the times observed in countries like Japan, Germany, Austria, United Kingdom, Switzerland and the United States. It takes almost 2.8 times more than the average among the countries analyzed, which corresponds to 360 days.

* Only 3 out of four reimbursed molecules in Colombia where considered to estimate the average time. Fentanyl citrate was excluded from analysis given it was launched and reimbursed before the beginning of this analysis' time frame.

SPECIFICALLY IN COLOMBIA, REGISTRATION TIME IS IN AVERAGE 22 MONTHS – IT VARIES DEPENDING ON THE THERAPEUTIC AREA

Considering all time relevant for this process, obtaining the sanitary registration in Colombia can take over two years.

Figure 5: Average time for registration in Colombia by therapeutic area (2009-2014).

While most therapeutic areas are close to the average, the distance from Anti infectives and Oncology registration times is significant.

Note: Pharmacological evaluation times include time required by the Applicant to respond to the Authority's requirements. This process in some cases implied several iterations; outlier cases were ignored. Time elapsed from the approval of the pharmacological evaluation to the dossier submission for the Pharmaceutical evaluation is not considered.
'Months' equal number of days divided by 30 rounded to the nearest integer.

THE VARIABILITY OF THE TIME NECESSARY FOR THE PHARMACOLOGICAL EVALUATION RESPONDS TO THE COMPLEXITY OF THE NME

The process for obtaining a sanitary registration is comprised by both a pharmacological evaluation and a pharmaceutical evaluation. The pharmacological evaluation of high complexity molecules typically consumes the larger share of the time required for registration.

However, the time necessary for the pharmaceutical evaluation, divided in this analysis on the three stages to the right in Figure #6, can be the longest in the case of biotechnological products like those included in the group of Autoimmune disease.

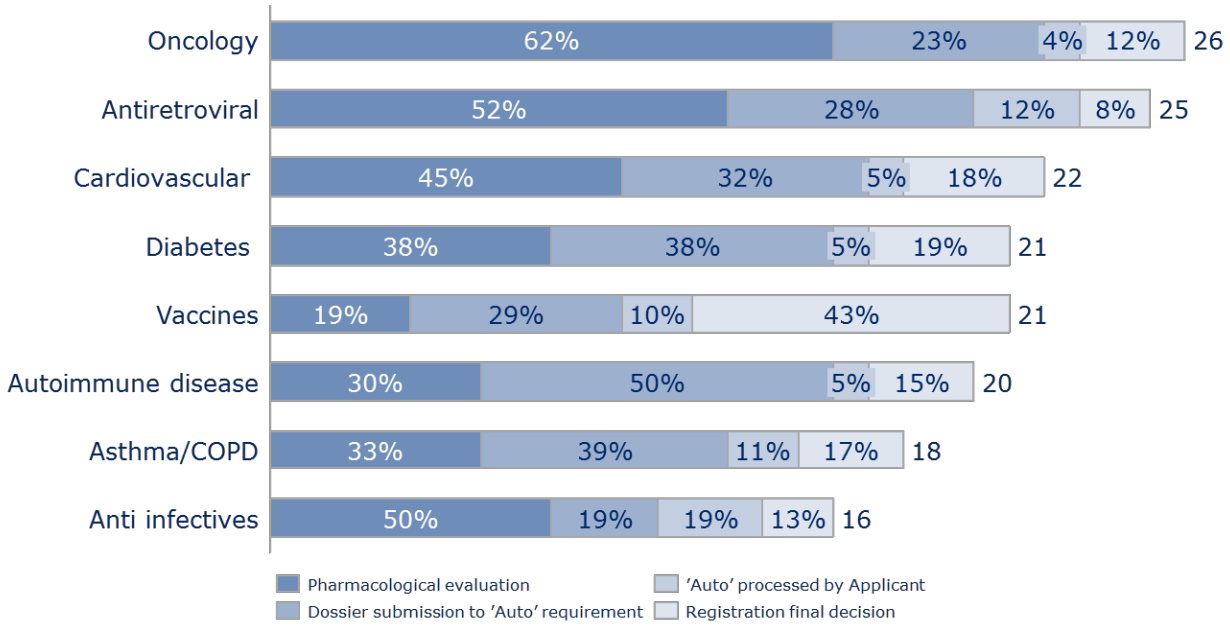

Figure 6: Average time in months it takes INVIMA to grant health registration by stage for each therapeutic area.

Note: Pharmacological evaluation times include time required by the Applicant to respond to the Authority's requirements. This process in some cases implied several iterations; outlier cases were ignored. Time elapsed from the approval of the pharmacological evaluation to the dossier submission for the Pharmaceutical evaluation is not considered.
'Months' equal number of days divided by 30 rounded to the nearest integer.

THE RELATIONSHIP BETWEEN REIMBURSEMENT AND HEALTH SPENDING (MEASURED AS % OF GDP) ALLOWS A DIFFERENTIATION BETWEEN COUNTRIES

Compared to the OECD countries included in this analysis, Colombia is in the last position with regard to access to medicines by combining reimbursement and health spending as a percentage of GDP. This analysis does not imply causality between variables.

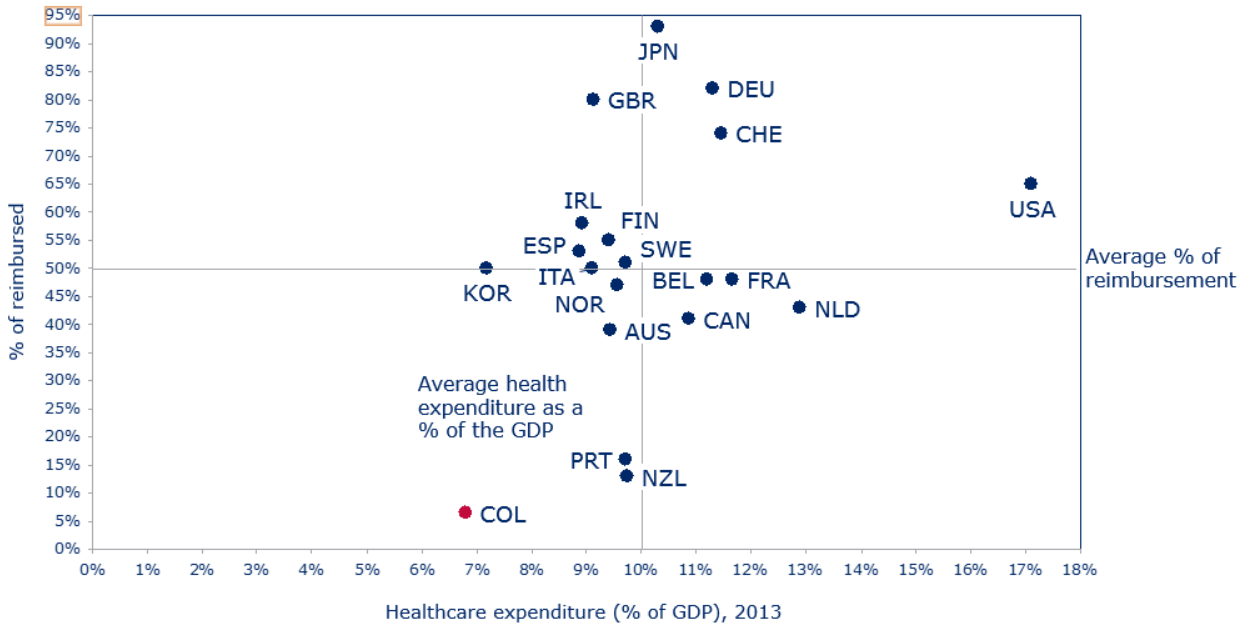

Figure 7: Reimbursement ratio vs. Health expenditure as a percentage of GDP (2013).

The availability of resources is a barrier for Access, but different levels of expenditure can be associated with similar coverage results.

Japan, Germany and the UK are countries with a high percentage of reimbursement among the sample analyzed. In all three cases, expenditure is close to the universe's average.

* World bank data was used for health spending as a percentage of GDP (2013).