

CHAPTER 2.4

Medicine Prices in Latin American Countries

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LIST OF ABBREVIATIONS

| | |
|-----------|---|
| ANMAT | Administración Nacional de Medicamentos, Alimentos y Tecnología Médica/National Administration of Medicines, Food and Medical Technology |
| ANVISA | Agência Nacional de Vigilância Sanitária/National Health Surveillance Agency (Brazil) |
| CIF | Cost, Insurance, and Freight |
| CMED | Câmara de Regulação do Mercado de Medicamentos/Pharmaceutical Market Regulation Council (Brazil) |
| CONCADECO | Centroamericano de Protección al Consumidor/Central American Council of Consumer Protection |
| DIME | Decisiones Informadas sobre Medicamentos de alto impacto financiero/Informed Decision about high-budget impact |
| EPR | External Price Referencing |
| GATT | General Agreement on Tariffs and Trade |
| GAUMU | Grupo Técnico de Acceso Universal a Medicamentos/Technical Group of Universal Access to Medicines |
| HAI | Health Action International |
| HBP | Health benefits package |
| HHI | Herfindahl–Hirschman index |
| HIC | High-income country/countries |
| IADB | Interamerican Development Bank |
| IMSS | Instituto mexicano del Seguro Social |
| INN | International Nonproprietary Name |
| IPR | Intellectual Property Rights |
| IRP | International reference pricing (a pricing policy that is also known under different names such as external price referencing, external reference pricing, international price referencing) |
| ISAGS | Instituto Suramericano de Gobierno en Salud/South American Health Government |
| IU | International Unit |

| | |
|--------|--|
| LA | Latin America(n) |
| LIC | Low-income country/countries |
| LMIC | Lower middle-income country/countries |
| MoH | Ministry of Health |
| MPR | median price ratio(s) |
| OECD | Organisation for Economic Co-operation and Development |
| PAHO | Pan American Health Organization |
| PP | Pharmaceutical policy |
| PROAM | Programa de Accesibilidad a los Medicamentos/Program of Access to Medicines |
| R&D | Research and Development |
| SISMED | Sistema de Información de Precios de Medicamentos/ Information system of medicine prices (Colombia) |
| UMIC | Upper middle-income country/countries |
| UNASUR | Unión de Naciones Suramericanas/Union of South American Nations |
| WB | World Bank |
| WHO | World Health Organization |
| WTO | World Trade Organization |

2.4.1 THE PRICE OF MEDICINES IN LATIN AMERICAN COUNTRIES

2.4.1.1 Introduction

To adequately understand the dynamics of medicines markets when analyzing the evolution of prices and quantities, it is essential to identify and assess the factors that determine them, such as the structure of the demand and supply and the role and policies of the public authorities. Unfortunately, there are few detailed and up-to-date studies of the medicines markets and policies in Latin American (LA) countries, including price regulation. From the perspective of the global pharmaceutical market, LA countries can be considered, mainly consumers, rather than producers of medicines, although in a number of countries—especially in Brazil, Mexico, Colombia, etc.—a relevant domestic industry has emerged, usually a generics manufacturing industry, with limited innovative and exporting capacity and aimed at supplying local and regional markets. In that context, one would expect national authorities to be more sensitive and inclined to support the needs and interests of the consumers and the health system rather than those of the industry. Although this is often the case, national authorities and regulators are often under big pressure by both the domestic

and the foreign regional and multinational industry, with the ideological and political support of the governments of industrialized countries and some international organizations, such as the World Bank (WB) and the International Monetary Fund, which in line with the prescriptions of the "Washington Consensus," favored deregulation, international trade, and stronger intellectual property protection, as well as the noninvolvement of governments in pharmaceutical production. Around the 1990s, governments in LA were first pressured to abandon price regulation in the name of the virtues of the "free market" and later, as part of the globalization trends led by the General Agreement on Tariffs and Trade and the World Trade Organization, to consolidate and reinforce monopolistic market structures by introducing and strengthening intellectual property rights (IPR), which were told to be required to secure the level of investment in R&D that would lead to the continuous flow of technological innovations needed to bring solutions to all pending health problems [1].

As governments started to take responsibility for the access of their citizens to health services, the price of health technologies became a policy concern, especially, when the involvement of the public sector implied some form of collective financing or mandatory insurance. The options available to authorities to contain or reduce medicine prices are manifold. Traditionally, analysts have distinguished two types of public market intervention approaches, namely, demand-side and supply-side policies, according to the market actors at which measures are aimed at [2].

Tobar et al. [3] take a different perspective by distinguishing between two basic approaches to contain prices: procompetitive approaches, aimed at promoting competition in the medicines markets, and direct intervention of medicine prices, which aims at substituting or correcting an inefficient market mechanism. The authors classify the medicine price control systems of LA countries in 2008 in three models:

1. Free pricing: Argentina, Bolivia, Chile, Costa Rica, El Salvador, Guatemala, Panama (with direct price control between 2001 and 2004), Peru, Dominican Republic, and Uruguay.
2. Price regulation: Brazil, Ecuador, Honduras, Nicaragua, and Paraguay.
3. Mixed systems: Colombia, México, and Venezuela.

Tobar et al. state that while in Europe most countries have increased the degree of price intervention, in LA the trend is less clear, and several countries have turned to more unregulated regimes. A second difference is that medicine price regulation systems are more heterogeneous and frequently changing than in Europe. Finally, the enforcement of price regulation is weaker in LA than in Europe, probably due to the limited institutional capacity in this area.

The description of medicine regulation systems of individual LA countries provided by Tobar et al. [3] is very brief and does not allow readers to obtain a precise understanding of how regulation works either in theory or in practice. Some of the information of this study has nevertheless been used below, complemented with other sources, to provide a brief country overview of price regulation in LA.

There are other reports that include a description of the pricing regulation system in LA countries. For example, Chapter 4 of the PAHO report “Access to High-Cost Medicines in the Americas: Situation, Challenges, and Perspectives” includes a summary of negotiation and regulatory practices in LA countries (Table 2.4.1).

The information provided in the PAHO report is based on a survey made by ANVISA and PAHO in 2009. According to the survey, six countries—Brazil, Colombia, Cuba, Ecuador, Mexico, and Nicaragua—were using at that time some form of price regulation, whereas Panama had used it from 2001 to 2004. The two most frequent criteria for determining the price were international prices (six countries) and production costs (four countries). The report also mentions public procurement as a powerful tool to improve access to medicines and quotes some experiences in this domain in countries of the region.

A recent study [5] focused on international reference pricing (IRP, also called external price referencing/EPR, this term being used in other chapters) retrieved information from 100 countries worldwide (for further in-depth findings of this study, not only on LA, see Chapter 12). 55 out of the 100 respondents declared to be using an IRP system. In LA, Colombia, and Brazil, they declared that they were using IRP, whereas Argentina, Ecuador, Grenada, and Haiti used other price regulation systems. Chile was using no price regulation. Moreover, informants from 14 countries with and without price regulation—three of them in LA (Chile, Ecuador, and Haiti)—stated that they were planning to use IRP in the future.

Impact studies that try to assess the effects of regulatory and other pharmaceutical policies in LA are even scarcer than descriptive studies [6–8]. A recent study [9] published by Prada et al., stated that “The Colombian experience clearly shows that price controls do not necessarily decrease overall real pharmaceutical expenditures,” mainly due to the increase of the demand. In this sense, the authors commented that “Increased demand of pharmaceutical products may be a positive thing, as long as the increase is the result of greater access to effective medicines rather than the result of induced demand by pharmaceutical producers.”

Table 2.4.1 Economic regulation of pharmaceuticals in the Americas

| Country | Pharmaceutical price regulation | Responsible institutions | Price criteria based on: | | | | | |
|----------|---------------------------------|--|--------------------------|---------------------|---------------------------|---------------------|-----------------|--------|
| | | | Therapeutic efficacy | Economic evaluation | Cost of similar treatment | International price | Production cost | Others |
| Brazil | × | Interministerial board, presided by the Ministry of Health, with ANVISA acting as the executive secretariat | × | × | × | × | | × |
| Colombia | × | Ministry of Social Protection, Ministry of Trade, Industry, and Tourism, and a delegate representing the Office of the President of the Republic | | | | × | × | |
| Cuba | × | Ministry of Finance and Ministry of Public Health | × | | × | × | × | |

Continued

Table 2.4.1 Economic regulation of pharmaceuticals in the Americas—cont'd

| Country | Pharmaceutical price regulation | Responsible institutions | Price criteria based on: | | | | | |
|-----------|---------------------------------|---|--------------------------|---------------------|---------------------------|---------------------|-----------------|--------|
| | | | Therapeutic efficacy | Economic evaluation | Cost of similar treatment | International price | Production cost | Others |
| Ecuador | × | Ministry of Health, Ministry of Industry, and the National Federation of Chemical and Biochemical Pharmaceutical Industries | | | | | × | |
| Mexico | × | Secretariat of the Economy and Office of the Federal Prosecutor for Consumer Affairs | | | | × | | |
| Nicaragua | × | Ministry of Public Works, Industry, and Trade | | × | | × | | × |
| Panama | 2001–2004 | Executive Branch and Consumer Protection Authority | | | | × | × | |

Reproduced from Pan America Health Organization. Access to high-cost medicines in the Americas: situation, challenges and perspectives. Technical series No. 1 essential medicines, access, and innovation. Washington; 2010.

In conclusion, the available knowledge on medicine price regulation regimes and other medicine market regulations in LA countries is very limited. This applies both to descriptive and to analytical studies. Most documents are informal reports and gray literature, which raises some concerns about the validity of the information provided.

2.4.1.2 Examples of Price Regulation in the Latin America Region

2.4.1.2.1 Colombian Medicines Pricing Regulation

Colombia is moving faster than other LA countries toward universal health coverage. Nearly 97% of its citizens have access to health insurance. Furthermore, income does not determine the health benefits package (HBP) whatsoever, and out-of-pocket expenses are the lowest in the region [10]. Over the past 4 years, the HBP has grown more than those in other countries, and coverage goes beyond the recommendations of the latest update of the World Health Organization (WHO) Essential Medicines List, including biological medicines for cancer, diabetes, and rheumatoid arthritis [11].

Expanding the Essential Medicines List poses a huge financial challenge for the Colombian government. To manage this burden, the Ministry of Health (MoH) issued a pharmaceutical policy (PP) based on three components: strengthening of health technology assessment processes, price control of medicines, and the promotion of competition in the pharmaceutical market. Since then, Colombia has been implementing price control mechanisms for medicines, using national and international price references.¹

In 2011, the MoH introduced a price cap on medicines reimbursements by active ingredient. The price cap was calculated as the median Colombian wholesaler price less a fixed percentage (20%). Two years later, another price control reform was introduced using IRP systems. The IRP system includes three main phases: (1) identification of relevant markets; (2) analysis of market power using the Herfindahl–Hirschman index; and (3) setting up of IRP for each relevant market, using available information of wholesaler prices of 17 countries from the Americas, Europe, and Australia. The IRP reflects the percentile 25 of the observed prices [12].

Until 2013, the IRP system had been applied to 837 medicines. 576 medicines (69% of those analyzed) had a national average price higher than

¹ Departamento Nacional de Planeación Gobierno de Colombia. Conpes 155 de 2012 “Política Farmacéutica Nacional”. Available from: <https://www.minsalud.gov.co/Documentos%20y%20Publicaciones/Politica%20Farmac%C3%A9utica%20Nacional.pdf>.

the IRP and enjoyed some degree of market power, and therefore their prices were regulated. They represented 80% of public expenditure on medicines not covered by the HBP. The average price reduction for those medicines was 40% [13].

Recently (2017) the MoH started preparing a regulatory proposal of value-based pricing linked to the marketing authorization, like Brazil does since the early 2000s.

Colombia was able to apply the IRP system thanks to the existence of its information system of medicine prices (SISMED), an official source of Colombian prices and quantities of medicines sold in the market. Since 2010, it is mandatory to quarterly report all medicines trade transactions in the market.

2.4.1.2.2 Brazilian Medicines Pricing Regulation

The Brazilian pharmaceutical market is the second largest in the emerging world. The medicines pricing regulation in Brazil was set up in 2004. It establishes that once the market authorization for a pharmaceutical product has been granted, the supplier must file for a list pricing registry at the Pharmaceutical Market Regulation Council (CMED), which sets prices for the public and private sector. The list price is the official fixed price for a product. In the case of generics, this price might be adjusted annually according to which market it is sold into.

CMED sets the prices according to specific criteria that apply for the six categories a substance can fall under:

Category I. New patent-protected medicines that present better efficacy or safety profile compared with established treatments. The price is set by the IPR system and must not exceed the medicine's lowest price in any of the following countries—Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, the United States, and the country of origin.

Category II. “Me-too” medicines, where a cost minimization assessment applies.

Category III. New presentation in the same dosage of a medicine already marketed. The price is worked out based on the arithmetic mean of the prices of previously launched products.

Category IV. New presentations in a different dosage of a medicine already marketed. The price must not exceed the average price, weighted by sales, of available presentations of the medicine that have the same active ingredients, strength, and dosage form.

Category V. New presentations of a medicine that is a new dosage form in Brazil or a new combination of active ingredients already available in Brazil. The price is set by IRP and must not exceed the medicine's lowest price in any of the countries listed in category I.

Category VI. Generic medicine cannot have a price that exceeds 65% of the respective reference medicine.

2.4.1.2.3 Price Regulation in Other Latin American Countries

Ecuador had a direct price control mechanism based on the costs declared by the manufacturer or importer plus a profit markup (20% of the total cost). A system established in 2011 set up three regimes: monitored freedom, regulated freedom, and direct control. At present (2018), Ecuador is trying to implement a new system approved in 2014, which is based on IRP for new medicines that show a therapeutic advantage or are supplied under monopolistic conditions and on internal prices for multisource medicines.

El Salvador applies an IRP system, where the maximum price is set as the average of the Central American countries.

Honduras regulates the maximum profit.

Mexico calculates international reference prices, but suppliers define the maximum selling price based on the estimated cost structure plus a defined profit margin.

Nicaragua fixes cost, insurance, and freight prices for imported products. Comparative prices are calculated for locally manufactured products. Wholesale and retail markups are also regulated.

Paraguay applies different coefficients to locally manufactured products, imported finished products, and in bulk imported products. Negotiations are carried out with the pharmaceutical sector to reduce prices.

Venezuela only regulates the price of essential medicines, by setting a maximum profit margin [3].

2.4.2 ONLINE SOURCES OF MEDICINES PRICES IN LATIN AMERICA

Online sources of medicines prices are few, maybe because, as it has been shown in the previous section, medicines pricing policies and regulation are also incipient.

Nevertheless, nine LA countries have developed some form of online information systems and platforms: Argentina, Brazil, Colombia, Chile,

Ecuador, Mexico, Panama, Peru, and Uruguay (see Table 2.4.2). Eighteen different online sources, apps, or databases to consult medicines prices are available for these seven countries. Some countries have more than one online source of medicine prices (Brazil, 2; Chile, 2; Colombia, 3; and Peru, 4). None of these online sources are documented at the publications revised for this chapter, except that of Brazil (ANVISA, the Drug Regulatory Authority from Brazil), which was mentioned at a working paper on International Reference Price Systems [14].

Only one platform has been developed so far at regional level to provide comparative medicines prices, even though there are some ongoing initiatives.

The type of price usually included at platforms is the official or institutional price (in 12 out of the 18 online sources), which represents the price to governmental institutions and is often associated to a centralized negotiation or to a tendering process. The ANVISA database provides three kinds of prices (ex-factory, institutional/regulated, and retail). Two of the online sources, Argentina and Peru, provide information of retail prices both of them belonging to the Drug Regulatory Authority. Only Colombia's medicine price databases include wholesaler price information.

Some of the online sources of medicines prices (Brazil, Colombia, and Peru) are based on robust information systems, and two of them (Colombia and Brazil) offer the possibility to download excel files, which allows external analysts to build time series of prices. The Colombian database also includes quantities sold. These databases constitute an adequate source for conducting econometric and impact studies.

Almost all databases reflect either observed or reported prices,² whereas two countries provide regulated prices (Brazil and Colombia).

It is also worthwhile to highlight the Colombian effort to ensure the transparency of the medicines prices throughout apps focused on the consumer. One of them provides national mean prices of medicines on competition and without any regulation, and is implemented as a mobile app called Clic salud.³ This mobile app allows to consult the price by active ingredient, brand name, or specific market presentation and it shows the

² Reported prices: pharmaceutical market sellers are obliged by the government to report its prices. Observed prices: price observed (by independent body or researcher) on the market.

³ TERMÓMETRO DE PRECIOS DE MEDICAMENTOS. Available from: <https://www.minsalud.gov.co/salud/MT/Paginas/termometro-de-precios.aspx>.

Table 2.4.2 List of medicines prices databases in the Americas

| | Country | Source | Medicines price setting | Website | Price type | Unit of price |
|---|-----------|--|--|---|--|-------------------------|
| 1 | Argentina | Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) | ANMAT is a Drug Regulatory Authority. Its website includes information of retail prices. | https://servicios.pami.org.ar/vademecum/views/consultaPublica/listado.zul | Retail | Price per trade package |
| 2 | Brazil | Banco de Preços Em Saúde ^a | The data bank of health prices is a government's system of purchase prices of medicines and other medical products | http://bps.saude.gov.br/login.jsf | Institutional (price to government institutions) | Price per unit |
| 3 | | Agência Nacional de Vigilância Sanitária (ANVISA) | Agência Nacional de Vigilância Sanitária (ANVISA) is a Drug Regulatory Authority. Its website includes information of retail, ex-factory, and institutional prices. | http://portal.anvisa.gov.br/listas-de-precos | Ex-factory institutional retail | Price per trade package |
| 4 | Colombia | SISMED | The medicines prices system is a compulsory report system of prices for every medicine seller (companies, wholesale, hospitals, insurers, etc.). It does neither include pharmacy information neither retail prices. It includes the updated price (minimum, median and max price) every three months. | http://www.sispro.gov.co/recursosapp/app/Pages/SISMED.aspx | Ex-factory Wholesale | Price per trade package |

Continued

Table 2.4.2 List of medicines prices databases in the Americas—cont'd

| | Country | Source | Medicines price setting | Website | Price type | Unit of price |
|---|---------|---|---|---|--|----------------|
| 5 | | Clic salud | It is a mobile app (it is an app web, too) to consult a median wholesale price from SISMED by international nonproprietary name (INN), trade package, and trade name for every medicine in the market. | https://www.minsalud.gov.co/salud/MT/Paginas/termometro-de-precios.aspx | Wholesale | |
| 6 | | Termómetro de precios internacionales ^a | It is a web app to consult the international reference prices (IRP) by INN, trade package, and trade name. It includes the latest wholesale regulated price based on IRP for more than 350 medicines. | https://www.minsalud.gov.co/salud/MT/Paginas/herramienta-interactiva-de-consulta-de-precios-regulados-de-medicamentos.aspx | Wholesale | |
| 7 | Chile | Portal de compras públicas (Chilecompra) | Chilecompra is the electronic platform where the 850 public agencies in Chile carry out their purchasing processes and suppliers offer their products and services. Any transaction with medicines from public health institutions and the lowest prices achieved can be consulted. | http://www.mercadopublico.cl/Portal/Modules/Site/Busquedas/BuscadorAvanzado.aspx?qs=2 | Institutional (price to government institutions) | Price per unit |
| 8 | | Central de abastecimiento del Sistema Nacional de servicios de Salud (CENABAST) | It is the Chilean National Health Supply Service System for the customers belonging to the National Health Services. It reflects the minimum prices achieved for public tendering. It allows the access to the discounts to the Ministry of Health. | http://www.cenabast.cl/precio-y-cantidad-de-productos-adjudicados/ | Institutional (price to government institutions) | Price per unit |

| | | | | | | |
|----|---------|--|--|---|--|----------------|
| 9 | Ecuador | Sistema Oficial de Contratación Pública | Government Procurement System is the organization that leads and regulates the public procurement services which include medicines. | https://www.compraspublicas.gob.ec/ProcesoContratacion/compras/PC/buscarProceso.cpe?sg=1 | Institutional (price to government institutions) | Price per unit |
| 10 | Mexico | Instituto mexicano del Seguro Social (IMSS) | The Mexican Institute of Social Security it is a national public health-care supplier for formal workers and their families. It includes minimum prices achieved throughout tendering and negotiation process. | http://compras.imss.gob.mx/?P=search_alt | Institutional (price to government institutions) | Price per unit |
| 11 | | Instituto mexicano del Seguro Social—Rubro Medicinas | The Mexican Institute of Social Security it is a national public health-care supplier for formal workers and their families. It includes minimum prices achieved throughout tendering and negotiation process. | http://compras.imss.gob.mx/?P=imsscomprotipoproddet&tip=l&sub=010&pr=2016&corder=mn&corderdir=do#detailresultane | Institutional (price to government institutions) | Price per unit |
| 12 | Panama | Plataforma de compras públicas (Panamacompra) | Panamacompra is the public procurement platform, managed by the General Directorate of Public Procurement, which carries out the selection of government suppliers | http://www.panamacompra.gob.pa/ambientepublico/AP_BusquedaAvanzada.aspx | Institutional (price to government institutions) | Price per unit |

Continued

Table 2.4.2 List of medicines prices databases in the Americas—cont'd

| | Country | Source | Medicines price setting | Website | Price type | Unit of price |
|----|---------|--|---|---|--|-------------------------|
| 13 | Peru | Observatorio de Precios de DIGEMID | DIGEMID is a Drug Regulatory Authority. Its website hosts a platform that provides information of retail prices | http://observatorio.digemid.minsa.gob.pe/ | Retail | Price per trade package |
| 14 | | Sistema Electrónico de Contratación del estado (SEACE 2) | The SEACE is the electronic system that allows the exchange of information on the government contracting and the accomplishment of electronic transactions. It is administered by the State Procurement Supervisory Agency. | http://www2.seace.gob.pe/?scriptdo=PKU_CONSULTA_TOP.doview&_CALIFICADOR_=_PORTLET.1.117.0.21.81&_REGIONID_=1&_PORTLETID_=117&_ORDERID_=0&_PAGEID_=21&_CONTENTID_=81&_USERID_=%3c%21-USERID-%3e&_PRIVILEGED_=1 | Institutional (price to government institutions) | Price per unit |
| 15 | | Sistema Electrónico de Contratación del estado (SEACE 3) | The SEACE is the electronic system that allows the exchange of information on the government contracting and the accomplishment of electronic transactions. It is administered by the State Procurement Supervisory Agency. | http://prodapp2.seace.gob.pe/seacebus-uiwd-pub/buscadorPublico/buscadorPublico.xhtml | Institutional (price to government institutions) | Price per unit |

| | | | | | | |
|----|-----------------------------|--|--|---|--|------------------------------|
| 16 | | Dirección de Abastecimiento de Recursos Estratégicos en Salud (DARES) | The Directorate for Supply of Strategic Health Resources (DARES) acquires and distributes vaccines, antiretrovirals, antituberculosis, contraceptive methods, antimalarials, among other products for the supply of health services at the national level. | http://intranet.cenares.minsa.gob.pe/DARES/ABASTECIMIENTO/COMPRA/S/wf_BusquedaProducto.aspx | Institutional (price to government institutions) | Price per unit |
| 17 | Uruguay | Unidad Centralizada de Adquisiciones | The Centralized Procurement Unit is in charge of acquiring food, food services, medicines, medical supplies, and related products according to the quantity and quality required, in conditions of transparency and accessibility for suppliers, with opportunity and at a minimum price. | https://www.mef.gub.uy/480/13/areas/insumos-medicos.html | Institutional (price to government institutions) | Price per trade package |
| 18 | Latin America online source | Decisiones Informadas sobre Medicamentos de alto impacto financiero (DIME) | DIME is a platform that includes comparative information of minimum prices from eight Latin American countries. It includes other comparative information about coverage, health technology assessment and patent status for a priority medicine list. ^b It is a regional public good impulse by Inter-American Development Bank. | www.proyectodime.info | Institutional (price to government institutions) | Price per Defined Daily Dose |

^aRegulated prices.

^bDIME tutorial to consult international prices. Modified from Ministry of Health Colombia tool for calculation International Reference Prices, www.proyectodime.info.

mean prices ordered from the lowest price (on green) to the highest price (on red).

The other tool available to consult prices is a web app called *thermometer of international reference prices*.⁴ This web app allows to consult the international reference price established in 2013 for more than 800 medicines in the market, most of them are single source products. The web app allows consulting the price by active ingredient, brand name, or specific market presentation and it shows the price by minimum unit of active ingredient, ordered from the highest to the lowest country's prices. Fig. 2.4.1 is the output of a query at the web app thermometer of international reference prices. It shows 12 different referenced prices. The Colombian regulated price corresponds to the percentile 25. United States has the highest price per International Unit (IU) and Norway, the lowest one.

There have been many efforts in the region to develop a regional medicine prices observatory to support joint negotiation strategies or to leverage the negotiating capacities of countries vis à vis pharmaceutical

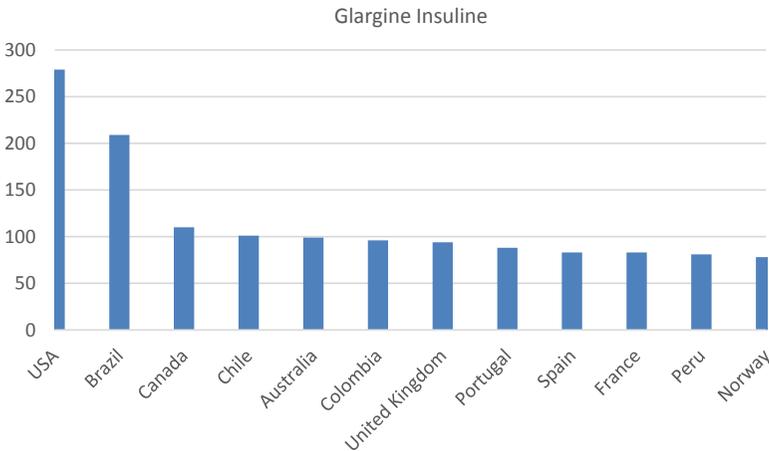


Figure 2.4.1 Comparison of Prices (in Colombian Pesos) for Glargine Insuline in IU. (Reproduced from: <https://www.minsalud.gov.co/salud/MT/Paginas/herramienta-interactiva-de-consulta-de-precios-regulados-de-medicamentos.aspx>)

⁴ TERMÓMETRO DE PRECIOS DE REFERENCIA INTERNACIONAL DE MEDICAMENTOS. Available from: <https://www.minsalud.gov.co/salud/MT/Paginas/herramienta-interactiva-de-consulta-de-precios-regulados-de-medicamentos.aspx>.

suppliers. There is an ongoing initiative led by ISAGS and UNASUR,⁵ still at the design stage. Perhaps the most advanced initiative in this regard is the platform called Decisiones Informadas sobre Medicamentos de alto costo (DIME), a regional public good sponsored by the Inter-American Development Bank (IADB). DIME is a platform that includes comparative information of the minimum public purchase prices for a list of 38 medicines selected for its high financial impact on the public budgets of eight LA countries (Mexico, Costa Rica, El Salvador, Dominican Republic, Colombia, Ecuador, Peru, and Chile).⁶ The platform includes other important information for those managing the pressure of technologies over public health expenditure (coverage, health technology assessment, competition, and patent status). The most important weakness of this platform, as other similar projects, is the lack of updating along time.

Fig. 2.4.2 displays the output of a query of the DIME project. It shows the minimum price of public purchase for 12 different countries, included 8 LA countries.

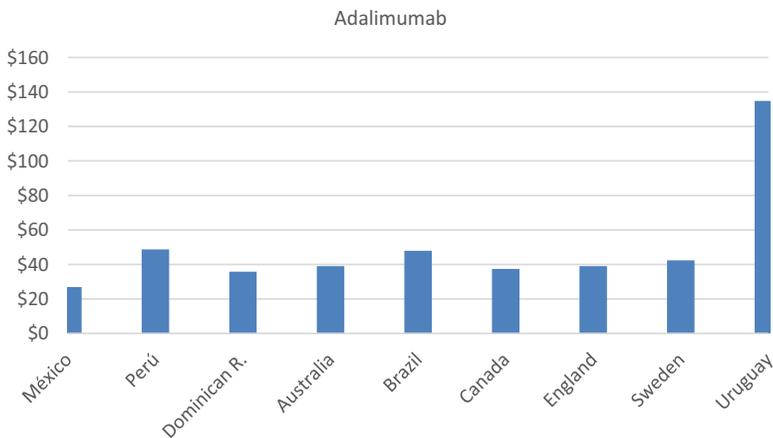


Figure 2.4.2 Comparison of prices for Adalimumab (in Defined Daily Dosis). (Reproduced from: <http://www.proyectodime.info/>.)

⁵ Grupo Técnico de Acceso Universal a Medicamentos (GAUMU) y el Instituto Suramericano de Gobierno en Salud (ISAGS) impulsan banco de precios de medicamentos de UNASUR (Unión de Naciones Suramericanas). [http://www.isags-unasur.org/uploads/eventos/ev\[3117\]ling\[2\]anx\[569\].pdf](http://www.isags-unasur.org/uploads/eventos/ev[3117]ling[2]anx[569].pdf).

⁶ <http://www.proyectodime.info/>.

2.4.3 MEDICINE PRICE STUDIES IN LATIN AMERICAN COUNTRIES

2.4.3.1 Introduction

There are few studies in LA comparing medicines prices. The main likely reason that accounts for this situation is the lack of price regulation in most countries. When prices are regulated it is relatively simple to provide a list of regulated prices; in its absence, time-consuming data collection procedures are necessary to build price databases; the absence of public prices databases makes it difficult to carry out analyses of the market dynamics and inter-country comparisons. During the last few years more countries have been starting to regulate medicines prices, trying to control or lower them. At the same time, there are new initiatives to build medicine price databases, as explained in [Section 2.4.2](#) of this chapter. Unfortunately, these initiatives do not use a common methodology, which limits the comparability and hence the usefulness of the available information. In the past, several countries made studies using the WHO/(Health Action International) HAI methodology to survey the price, availability, and affordability of medicines (see Chapter 6.2 in Part 2 for further information on this methodology). These studies focused on low- and middle-income countries, where some LA countries were selected. The results of the studies were used in some countries (El Salvador, Colombia, and Perú, for example) as an argument for a more rational approach to medicines pricing.

2.4.3.2 Methodology

To identify articles and studies on medicine prices in the region, we carried out two literature searches in February 2017. The first search was on Pubmed and Econlit, two academic databases focusing on medicine and economy, respectively. The second literature search was based on Google Scholar, which provides both academic articles and gray literature.

Six articles were identified: four studies on medicine prices in LA [\[15-18\]](#) and two international medicine prices studies [\[19-20\]](#) that included at least one country from LA in the analysis. Most studies reported results not only on prices but also on availability. Additionally, we found a press release of the Ministerio de Economía, Industria y Comercio of Costa Rica, reporting a comparative study of medicines prices in the Centro American region done by CONCADECO, the Centro American Council of Consumer Protection Agencies that has been also mentioned in the results.

2.4.3.3 Results and Findings

In a study made in Guatemala by Anson et al., [15] using WHO/HAI methodology, the authors found that public programs (for example, the Programa de Accesibilidad a los Medicamentos/PROAM) had a lower average availability than the private sector (25% vs. 35%), and that the prices in the private sector were on average 16.7 times more expensive than the international prices used for comparison (highest 22.7; lowest 10.7 times). They concluded that medicines were generally unaffordable for the majority of the population.

In a study made in Haiti by Chahal et al., [16] the availability of medicines was found higher in the private retail sector (37%) than in public (20%) and nonprofit (23%) sectors. As an example, they reported that a government worker needed 2.5 days' wages to treat an adult respiratory infection with generic medicines from public sector, but the treatment for hyperlipidemia would require 13.7 days' wages. As a result of the study, the authors concluded that medicine prices were lower in Bolivia, Colombia, Mexico, and Nicaragua (see Table 2.4.3). As in the previous study [15] in Guatemala, most medicines were priced higher than the international reference prices used in the WHO/HAI methodology.

Madden et al. [17] published in 2010 a study in Peru using WHO/HAI survey methodology, and, contrary to the previous studies in other LA countries, they did not find significant differences in overall availability or prices by retail location (urban, semiurban, and rural). It was not possible to compare the medicine prices between public and private sector because in the public sector of Peru there is normally only one generic version of each medicine and, consequently, comparisons between alternative products in the public sector are only occasionally possible.

An earlier study [18] in Peru by WHO/HAI found similar results: the private sector originator brands were approximately 28 times the international reference price and the lowest priced generics in the private sector were almost four times the price of those in the public sector, but in the public sector generics were approximately 1.3 times the reference price.

The study by De Lima et al. [19] focuses on opioids; price comparisons are made at global level. The countries are categorized according to the WB classification: high-income country (HIC), upper middle-income country (UMIC), lower middle-income country (LMIC), and low-income country (LIC). The LA countries included are Chile, Argentina, Brazil, Uruguay, and Guatemala; all these countries are classified as UMIC, except for

Table 2.4.3 Availability and median price ratios (MPR) of 12 essential lowest priced generic medications in Haiti compared with four neighboring countries

| Medication (strength) | Haiti | | Nicaragua | | Mexico | | Colombia | | Bolivia | |
|-----------------------------|-------------------------------|------|------------------|------|------------------|------|------------------|------|------------------|------|
| | Availability (%) ^a | MPR | Availability (%) | MPR |
| Amitriptyline 25 mg | 11.4 | 13.3 | 51.6 | 11.2 | 0 | N/A | 93.2 | 6.4 | 50 | 3.3 |
| Amoxicillin 500 mg | 97.1 | 4.3 | 100 | 2.2 | 53.3 | 4.3 | 96.6 | 2.5 | 100 | 2.3 |
| Atenolol 50 mg | 74.3 | 15.9 | 61.3 | 4 | 6.7 | N/A | 11.9 | 10.1 | 73.3 | 6.15 |
| Captopril 25 mg | 57.1 | 10.5 | 93.5 | 4 | 86.7 | 5.5 | 96.6 | 1.5 | 0 | N/A |
| Ceftriaxone 1 g/vial | 71.4 | 5.5 | 90.3 | 3.6 | 73.3 | 6.6 | 49.2 | 3 | 93.3 | 1.1 |
| Ciprofloxacin 500 mg | 91.4 | 5.1 | 100 | 8 | 80 | 12.7 | 100 | 4.8 | 96.7 | 4.4 |
| Co-trimoxazole 8 + 40 mg/mL | 62.9 | 4.5 | 83.9 | 4.2 | 80 | 4.5 | 86.4 | 4 | 86.7 | 4 |
| Diclofenac 50 mg | 85.7 | 25.2 | 96.8 | 11.3 | 6.7 | N/A | 96.6 | 7.9 | 100 | 7.9 |
| Glibenclamide 5 mg | 80 | 20.4 | 83.9 | 10.4 | 46.7 | 5.2 | 91.5 | 7.3 | 90 | 13 |
| Omeprazole 20 mg | 97.1 | 4.2 | 96.8 | 6.3 | 80 | 9.3 | 94.9 | 2.2 | 96.7 | 3.3 |
| Salbutamol 100 µg/dose | 85.7 | 2.3 | 71 | 3 | 53.3 | 2.1 | 96.6 | 1.4 | 60 | 2.4 |
| Simvastatin 20 mg | 57.1 | N/A | 83.9 | N/A | 6.7 | N/A | 35.6 | N/A | 6.7 | N/A |

N/A, not available or not applicable.

^aPercent (%) of retail outlets with medication.

(Reproduced from: Chahal HS, St Fort N, Bero L. Availability, prices and affordability of essential medicines in Haiti. Journal of Global Health 2013;3:020405).

Guatemala, which is an LMIC. Curiously, in spite of its classification, Guatemala had an availability of opioids of 61.5%, compared with 7.7% in Uruguay and Brazil. In relation to affordability, the results show that for a 30-day treatment of morphine oral medication 6.5 days wages are needed in Argentina and 8.1 in Guatemala.

The study by Cameron et al. [20] reports the differences between country groups, aggregated by income level according to the WB classification, but not individually, and it is therefore not possible to derive specific information for LA countries.

A press release of the Ministerio de Economía, Industria y Comercio of Costa Rica, 2009, reports a comparative study of medicines prices in the Centro American region done by CONCADECO, the Centro American Council of Consumer Protection Agencies. The comparison was based on a basket of 30 medicines, both in their originator as in generic versions. The information was collected between October and November 2008 in pharmacies of the respective capitals following the WHO/HAI methodology. The values in US\$ of the originators and the generics baskets were Nicaragua 54/10, Honduras 63/15, Panama 69/21, Costa Rica 62/22, El Salvador 76/32, and Guatemala 78/35, respectively. The price differentials between originators and generics that can be derived from the previous figures are larger for the lower-priced countries, for instance, 424% in Nicaragua versus 122% in Guatemala. The report states that out of the six countries analyzed, only Nicaragua has regulated prices.⁷

2.4.4 CONCLUSIONS

Available studies on medicine prices in LA are scarce and carried out in different years. Moreover, the methodologies are often heterogeneous and, hence, the results are not comparable. It is therefore difficult to draw reliable conclusions on medicine price differences across LA countries.

Most of the studies found in the literature used the standardized methodology developed by the WHO and HAI to survey the price, availability, and affordability of medicines; in fact, the results focus more often on availability than on affordability, i.e., on the price–income relationship.

⁷ Unfortunately, we have not been able to identify the original study summarized in the press release, because the link it referred to for the original information was not available on July 2017.

Medicine price databases are needed to increase and improve transparency on medicine prices and to assess the effectiveness and impact of pricing policies applied in the countries. The scarcity of medicine price information in LA countries might be related to the limited use of price regulation. The situation seems to be changing (the availability of information on medicine prices seems to be associated to the development of an explicit regulatory system of medicines prices in the country), but there is still a long way ahead. National authorities and international organizations should promote the establishment of publicly available, national, and multicountry medicine prices databases to (1) enhance competition in the drug markets, (2) reduce prices and hence affordability, (3) facilitate and improve the accountability of regulatory and procurement agencies, and (4) make possible studies on the evolution of medicine prices and on the impact of policy measures.

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