

# THE PHARMACEUTICAL PRICE REGULATION IN EL SALVADOR

Based on the webinar presentation “Retos de la Regulación de Precios de los Medicamentos - La Experiencia de El Salvador” by Luis Alejandro Rivera Flores, July 2019



## 1. INTRODUCTION

This Breve is based on a webinar presented by Luis Alejandro Rivera, Chief of the Pricing Unit at the *Dirección Nacional de Medicamentos* (National Directorate of Medicines – DNM) in El Salvador. [The presentation was given on 24 July 2019 to members of CRITERIA](#), the Inter American Development Bank’s knowledge network on priority setting and health benefit plans.

Rising prices of medications are a global concern as healthcare expenditures soar and more patients are unable to access the medicines they need. Through different strategies, El Salvador has successfully lowered the price of prescription drugs for both innovator drugs and generics while maintaining a well-functioning and cost-saving pharmaceutical market.

The following Breve highlights the need for regulating the pharmaceutical market. It focuses on the experience of El Salvador and presents takeaways for other countries, such as price setting methods, the identification of homogenous sets of pharmaceutical products, and the introduction of online monitoring platforms. Finally, the Breve concludes with a framework that other policy-makers may wish to use when introducing price regulation in their pharmaceutical markets.

## 2. CONTEXT

El Salvador is a small, lower-middle-income Central American country (population 6.5 million, 2020) with a per capita health expenditure of US\$378 (2018), well below the average for LAC (US\$648, 2018). The share of its health expenditure financed through out-of-pocket spending is 28.8%, slightly below the LAC figure (30.1%).<sup>1</sup> The Salvadoran public health sector is fragmented and composed of the Ministry of Public Health and Social Assistance (MSPAS), the Salvadoran Social Security Institute

(ISSS), and several other programs and institutions that target either specific health issues (e.g., rehabilitation) or population groups (e.g., teachers and the military).

High prices for medicines are a global concern. Countries across the world and in Latin America have adopted strategies to address this issue. Some, such as Colombia, Ecuador, Mexico, and El Salvador, have introduced price regulation mechanisms in their healthcare system.<sup>2</sup> In El Salvador, roughly 80% of the pharmaceutical market is private, and out-of-pocket expenditures on medicines are still a key challenge.

## 3. EL SALVADOR’S SUCCESS IN TACKLING RISING PHARMACEUTICAL PRICES

Prior to 2012, drug prices in El Salvador had been steadily increasing, resulting in the highest prices in Central America. From the introduction of pharmaceutical price regulation in 2012 to 2019, the estimated savings in the public sector and out-of-pocket expenditures by Salvadoran households amounted to US\$689 million. Putting those savings into perspective, the 2019 budget allocation for El Salvador’s main health institutions, the Ministry of Health and the Salvadoran Social Security Institute, was US\$662.1<sup>3</sup> million and US\$630.7<sup>4</sup> million, respectively.

Not only did price regulation save the Salvadoran healthcare system millions of U.S. dollars, but contrary to expectations<sup>5</sup>, it did not affect the supply and imports of prescription drugs. In fact, after price regulation went into effect, import volumes rose by 25%. Thus, the pharmaceutical market in El Salvador, 72% of which consists of imported medications, remained adequately supplied. Furthermore, the local pharmaceutical industry continued to expand after the introduction of price regulation, with cumulative exports growing by 26% from 2014 to 2018, thanks to the certification of 38 local laboratories.<sup>6</sup>

So, what made El Salvador's pharmaceutical policy so successful? What takeaways can the rest of the region and the world obtain from El Salvador's pharmaceutical price regulation system?

## 4. WHY ARE PHARMACEUTICAL PRICES SO HIGH?

Before diving into the policies adopted by El Salvador, it is important to briefly investigate why drug prices are often so high in the first place. While, according to neoclassical economic theory, the market efficiently determines the price of a good, the pharmaceutical market is an imperfect one, with challenges in the form of price discrimination, information asymmetry, monopolies, and price inelasticity. Even the role of prescribers can hinder market efficiency. Box 1 describes these challenges in greater detail. These market failures all drive up the cost of medications beyond their optimal market price.

While there are a number of strategies to address the failures present in the pharmaceutical market, this Breve will focus mainly on the widely used strategy of price regulation.

## 5. THE PHARMACEUTICAL MARKET IN EL SALVADOR, PRE-2012

Prior to the introduction of price regulation in 2012, El Salvador's pharmaceutical market was plagued with many market failures. Consumers used price as a proxy for quality, physicians had perverse incentives to prescribe more expensive drugs, and representatives of the pharmaceutical industry sat on drug regulatory boards, posing a conflict of interest.

This helps to explain why El Salvador was paying extremely high prices for medicines before introducing several regulatory instruments. In fact, before 2012, the country had the highest pharmaceutical prices in the region. An analysis by the Pricing Unit based on IMS data shows that El Salvador and Guatemala had some of the highest prices and that these differentials were driven by price discrimination within the region, even though Central American countries shared many similarities.

### BOX 1

#### Pharmaceutical market failures in a nutshell

**Price discrimination**— Occurs when the same prescription drugs are sold to different buyers at different prices. Country-level prices are based on the income characteristics of a country, meaning that each country may buy the same prescription drug at a different price.

**Information asymmetry**— Occurs when sellers of a product (i.e. pharmaceutical manufacturers) have more information than consumers. Consumers may not be informed about the quality or composition of the medications they buy.

**Monopolies**— Occur when a particular seller is the only supplier of a good and faces little competition. Patents, for example, ensure that innovator drug manufacturers remain the only ones on the market selling a particular medication for a period of time.<sup>7</sup>

**Price inelasticity**— Prescription drugs are not very reactive to changes in price. When there are no alternatives, or when a drug has a very specific characteristic that sets it apart from its therapeutic equivalents, there is very little price elasticity. As the price of the pharmaceutical product increases, consumers are forced to purchase it, even at the higher price point.

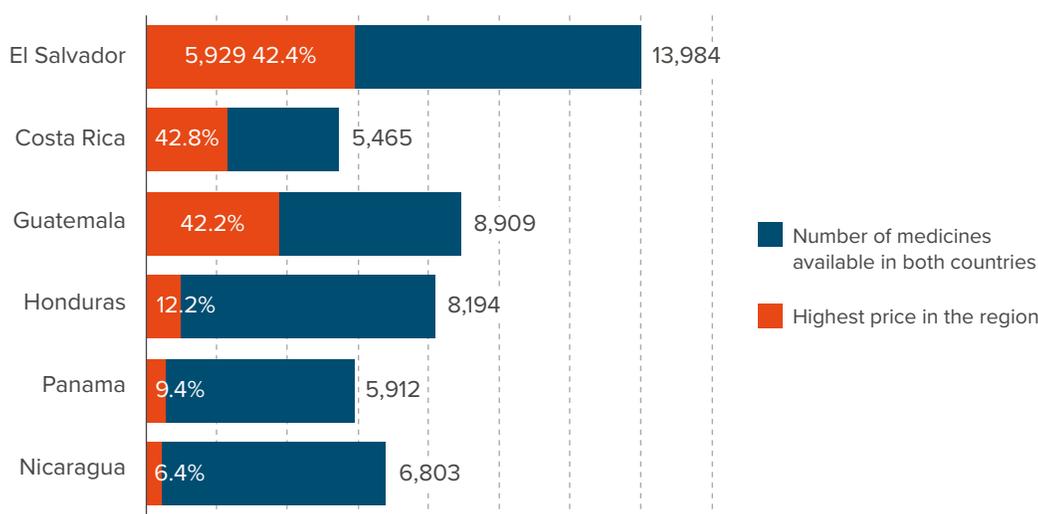
**Role of the prescriber**— Patients do not decide what to consume. Instead, medications are prescribed by health professionals. Consumers cannot influence the choice of medication based, for example, on price.

Figure 1 shows the results of this analysis, out of 13,984 products available in El Salvador and at least one other country in Central America, **42.4% of the products were priced higher in El Salvador**. Similarly, of the 8,909 products that Guatemala had in common with El Salvador, 42% had higher prices in the former. In contrast to a country like Nicaragua, where out of the 6,803 common products, only 6% were more expensive. This illustrates that prices in El Salvador were higher than in many other countries in the region and that there was price discrimination at the Central American level.

(for example, by active ingredient), but a few (Netherlands, Germany) have shifted to groups based on therapeutic equivalence. El Salvador has chosen the former approach, but instead of basing the reference price for specific products on the active ingredient only, it defines clusters as a group of products containing not only the same active ingredients but the same concentration and pharmaceutical form as well. **Regulating homogeneous groups is more efficient and less labor-intensive than regulating prescription drugs one at a time, as prices can be compared at a less granular level.**

**FIGURE 1**

**Pharmaceutical price differentials in Central America prior to 2013**



Source: DNM, data source – IMS. Taken from Slide 6 of the “Retos de la regulación de los precios de los medicamentos. La experiencia de El Salvador” webinar.

## 6. PRICING STRATEGIES IN EL SALVADOR

In 2012, the Salvadorian government passed the Medicines Law (*Ley de Medicamentos*) establishing the regulatory mechanism to be used, defining the scope of regulation, and creating a national pharmaceutical regulation directorate, the *Dirección Nacional de Medicamentos (DNM)*, to oversee the implementation of pharmaceutical price regulation. As indicated in Box 2, the DNM can only regulate prescription drugs. Notably, over-the-counter medications are not regulated.

In compliance with Article 58 of the Medicines Law (see Box 2), the DNM lowered the prices of prescription drugs in 2013. One of the most important technical questions when using External Reference Pricing (ERP) is what criteria to use in defining the clusters referenced. Most countries define the equivalent groups/clusters narrowly

In addition, in 2017, the DNM used these clusters to regulate medicines not initially included in the scope of the regulation. While the 2012 Medicines Law required a reduction in the prices of generic medicines over those of the products’ innovator equivalents (see Box 2), it did not indicate how the DNM should accomplish this. The DNM chose to proceed with Internal Reference Pricing (IRP) using these clusters and decided that generic versions must be at least 30% cheaper than the equivalent innovator drug.

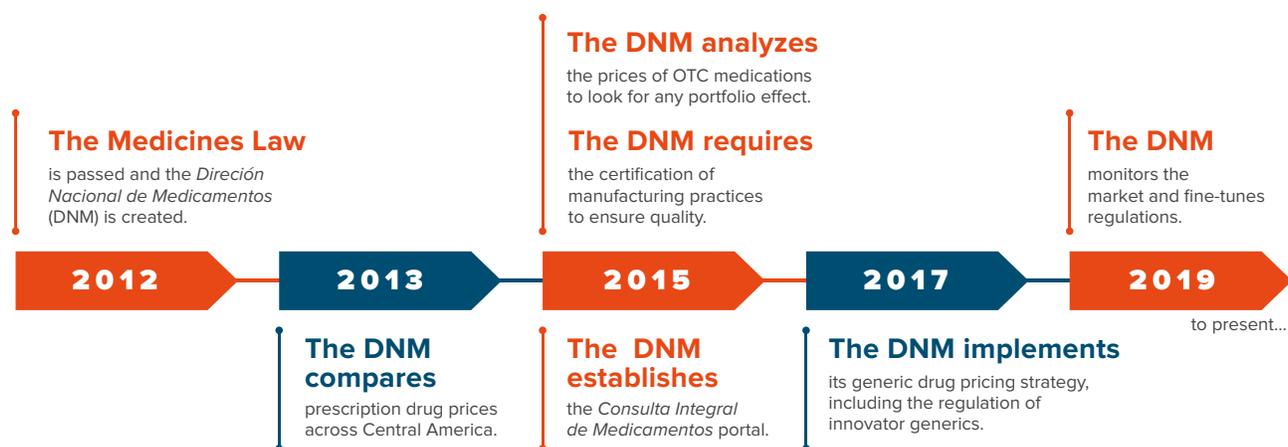
As a result, in the Salvadoran pharmaceutical market, prescription drugs were broken down into 2,000 clusters or homogenous groups that include 7,000 products; of these, 170 homogenous groups comprising 1,300 products corresponded to generic medicines. The policy’s overall coverage represents about half of all pharmaceutical products registered in the country. Figure 2 summarizes the interventions El Salvador introduced in chronological order.

**BOX 2****Key aspects of the Medicines Law (2012)****What does Article 58 say?**

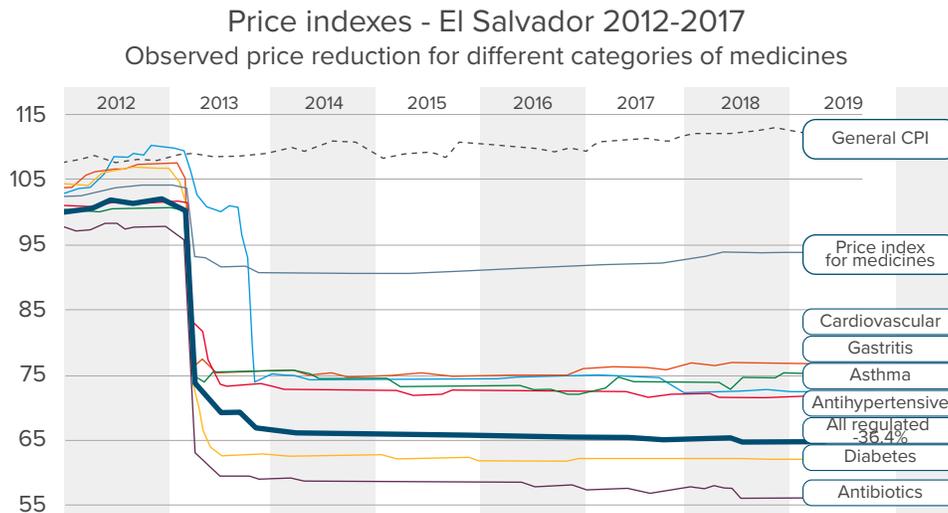
Article 58 of the Medicines Law states that the maximum price for the sale of prescription drugs to the public must be based on an international reference price, a mechanism also called **external reference pricing (ERP)**. The reference price will be determined by comparing the prices paid for medications in El Salvador with those at the same level of the distribution chain in Central America and Panama. Furthermore, Article 58 introduces a price cap, stipulating that in no case may the maximum consumer price be higher than the average price in Central America and Panama. Finally, it stipulates that the price of generic drugs should be 30% to 40% lower than the price of innovator drugs.<sup>8</sup>

**Which medications can the DNM regulate?**

The directorate is responsible for regulating the price of *prescription drugs*, both innovator drugs and their generic equivalents. However, it is not authorized to regulate the price of over the counter (OTC) medications.

**FIGURE 2****A Timeline of Price Regulation in El Salvador**

Source: Author, based on the "Retos de la regulación de los precios de los medicamentos. La experiencia de El Salvador" webinar.

**FIGURE 3****Average Prescription Drug Prices by Category of Medication**

Source: Rivera A. Taken from slide 25 of the “Retos de la regulación de los precios de los medicamentos. La experiencia de El Salvador” webinar.  
Data: DYGESTIC.

Figure 3 shows that, thanks to ERP, the average prices of these medicines plummeted in 2013 for most drug categories in the Salvadoran market. The average price of all regulated prescription drugs fell by 36.4% on average, and prices have stabilized around this price ever since. Moreover, the policy lowered the prices of generic medications to 70% of their innovator prices.

## 7. MONITORING

### GOVERNMENT TOOLS FOR MONITORING PRICE REGULATION

Monitoring of on-the-ground prices is a key building block of any policy for regulating drug prices. It is only by observing how the prices, quantities, and quality of medicines evolve that a regulatory policy can be monitored and fine-tuned. To that end, the DNM has created tools for monitoring the impact of and compliance with price regulation. The DNM’s price unit is an interdisciplinary team comprised of seven individuals with a background in economics, chemistry, computer science, and engineering. This team aids price regulation by interpreting and monitoring the market, providing pharmaceutical

chemical knowledge, and conducting economic analyses. A diverse team implies diverse perspectives, ensuring that all aspects and effects of price regulation are considered. Moreover, the DNM has an inspection and control unit charged specifically with the implementation of monitoring and evaluation strategies.

Random sampling, biased sampling, and census are three methods for gathering information on the pharmaceutical market (see Box 3). El Salvador has chosen the census approach and captures information from the country’s 2,000 pharmacies, since random and biased sampling would do so using a much smaller sample. Pharmacies must report their drug inventory and selling prices to a confidential database to which the government has access. This not only enables the DNM to ensure that pharmacies are complying with the price regulations for prescription drugs but to keep a watchful eye on supply trends and guarantee that the Salvadoran pharmaceutical market remains adequately supplied. This is important, since price regulation can sometimes lead to shortages, as some providers may no longer be interested in selling their products in the regulated market. To achieve compliance with DNM’s regulated prices, the directorate may fine any organization that fails to comply up to \$60,000—the equivalent of 200 minimum wages.

**BOX 3****Different Monitoring Methods**

**Random sampling**— randomly selecting pharmacies to audit and ensure that price regulations are complied with.

**Biased sampling**— selecting the pharmacies most likely not to comply, to maximize findings.

**Census approach**—all pharmacies self-declare their prices, revealing those that are offering a price that differs from the regulated price. This is the approach chosen by El Salvador.

## 8. MONITORING FOR EVIDENCE OF PORTFOLIO EFFECT

As mentioned earlier, the DNM does not regulate over-the-counter (OTC) medications. Initial concerns arose over whether a portfolio effect would become evident after the regulation of prescription drugs. The “portfolio effect” is an increase in the prices of unregulated medications to compensate for the loss of revenue experienced by pharmaceutical manufacturers due to the reduction in the prices of regulated prescription drugs.<sup>9</sup> In 2015, the DNM conducted a market analysis of OTC drugs, pictured below as Figure 4. The figure includes the prices of various OTC categories and compares their price from 2012 to 2014. While some OTC categories like flu and digestive medications saw a 3% and 6% average increase in their respective prices, prices overall fell by 6% from 2012 to 2014. The DNM is currently conducting a more extensive time series study to evaluate the portfolio effect with OTC drugs.

## 9. TOOLS FOR INFORMING THE CONSUMER

While price regulation helped to generate important savings, some of the challenging market failures in the pharmaceutical market persist. Information asymmetry may still lead consumers to make uninformed purchasing decisions because their provider prescribed a specific product (instead of prescribing a medication by its non-proprietary name). An informed consumer is thus critical to overcoming some of these market inefficiencies and paves the way for price regulation to remain successful on the ground. To keep the Salvadoran consumer up to date and informed, the DNM developed the *Consulta Integral de Medicamentos* [Comprehensive Drug Information Portal], an online portal where consumers can verify drug price maximums, access information on generic alternatives, and compare prices across pharmacies. This portal remains up to date, as pharmacies can efficiently provide information about the supply and price of their medications in real time. From 2015 to 2019, there were more than 640,000 visits to this portal.

**FIGURE 4****2015 Market Capture of Over-the-Counter Medications**

Price of Over-the-counter medicines  
Is there a portfolio effect on OTC pharmaceutical products?

Category	Market share (sales volume)	Variation	
		2012 to 2013	2012 to 2014
06.1.1.02 - Pain medication	30%	-16%	-18%
06.1.1.04 - Flu medication	7%	2%	3%
06.1.1.05 - Dermatological medicines antiallergic antifungal	20%	-6%	-8%
06.1.1.06 - Digestive medicines	7%	2%	6%
06.1.1.12 - Fluids	36%	2%	2%
06.1.1.13 - Vitamins and supplements	0%	0%	1%
<b>Weighted average variation*</b>	<b>100%</b>	<b>-5%</b>	<b>-6%</b>

\*Weighting made according to sales information collected by DNM in the capture of market data to 2015.

Source: Rivera A. Taken from slide 42 of the “Retos de la regulación de los precios de los medicamentos. La experiencia de El Salvador” webinar.

## 10. A FRAMEWORK FOR PHARMACEUTICAL PRICE REGULATION

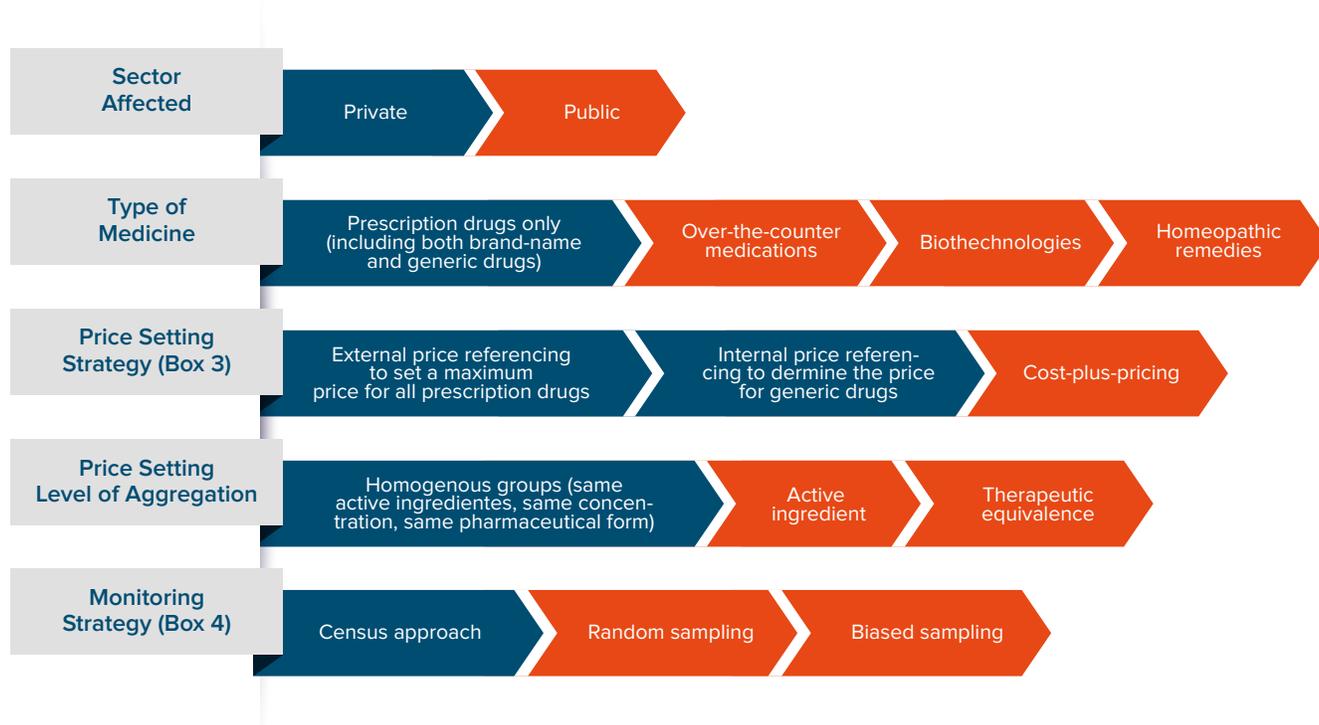
In this publication, a “framework” is understood as a list of all the dimensions, considerations, and/or choices that a country must decide on or take into account when designing and implementing its specific price regulation policy. It is like a menu of choices, in which each is explained with its pros and cons, so that when designing a new price regulation proposal, each choice can thoroughly and consciously be considered. Furthermore, it is designed to minimize the risk of omitting, ignoring or forgetting any relevant choice. El Salvador’s experience gives us a starting point but can and should be supplemented, adapted, expanded, and confirmed by other countries’ experiences, objectives, realities, and contexts. A sound framework can aid policymakers in constructing the

policies surrounding regulation, inform implementation strategies, and ensure that the interests of all are thoroughly represented.

Figure 5 is a simplified framework that summarizes the price regulation experience in El Salvador around five key decisions: sector, type of medicine, pricing strategy, cluster criteria, and monitoring strategy. The boxes in blue represent the initial strategies used by the DNM under the 2012 Medicines Law. For example, El Salvador has so far chosen to focus its efforts on prices in the private sector (the prices paid by consumers) for prescription drugs, a mix of ERP (innovator drugs) and IRP (generics) and has defined clusters narrowly (active ingredient, concentration, and pharmaceutical form). To monitor its pharmaceutical market, it uses a census approach. The boxes in orange represent the other options chosen by countries that have also introduced price regulation systems. The strategies that a country considering price regulation chooses to adopt will depend on the context of that country.

**FIGURE 5**

**A Price Regulatory Framework: El Salvador’s Experience**



Source: Author, based on the “Retos de la regulación de los precios de los medicamentos. La experiencia de El Salvador” webinar.

## 11. CONCLUSION

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While price regulation has a short history in El Salvador, the experience with its introduction in the wake of the 2012 Medicines Law has been fruitful. Using external price referencing, the *Dirección Nacional de Medicamentos* (DNM) managed to lower prescription drug prices by 35% in 2013 and maintain this regulated price.<sup>10</sup>

In 2017, the DNM widened its focus to regulate the maximum prices paid for generic drugs, which were initially excluded from regulation. Here, internal price referencing ensured that the price of generics was 30% to 40% lower than their innovator equivalents. **By regulating at the level of homogenous groups, price regulation for both innovator and generic drugs was more efficient.**

Between 2012 and 2019, the Salvadoran healthcare market saved an estimated US\$689 million. Price regulation seemed to have little portfolio effect on unregulated products like over the counter medications and had a

positive impact on the importation of prescription drugs into El Salvador. Finally, during that same period, exports of quality-certified prescription drugs increased by 36%.

**The DNM continues to monitor the effects of price regulation to adjust prescription drug prices.** To fine-tune its regulatory tools, future studies may provide more insight into the long term sustainability of a price regulation system of this nature. It is also important to note that price regulation is not a static policy tool; rather, maintaining and developing price regulation policy will continue to pose challenges for El Salvador and other countries that embrace it, namely: ensuring timely access to current data from other countries and deciding how and when to adjust or raise prices to keep the market well-supplied and consumer wallets in check; how to keep market quality high; and how to avoid the unfair distribution of price reductions among supply chain participants. **Any country embarking on price regulation must consider and monitor these challenges to tailor interventions for the best possible results while reducing unintended consequences as much as possible.**





## NOTES

- <sup>1</sup> Data from the World Bank DataBank: <https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD>
- <sup>2</sup> See Inter-American Development Bank, “Better Spending for Better Lives: How Latin America and the Caribbean Can Do More with Less” pg. 258, Table 8.4
- <sup>3</sup> <https://www.transparencia.gob.sv/institutions/minsal/documents/281717/download>
- <sup>4</sup> <https://www.transparencia.gob.sv/institutions/iss/documents/286877/download>
- <sup>5</sup> [https://scholar.harvard.edu/files/lucamaini/files/reference\\_pricing\\_as\\_a\\_deterrent\\_to\\_entry.pdf](https://scholar.harvard.edu/files/lucamaini/files/reference_pricing_as_a_deterrent_to_entry.pdf)
- <sup>6</sup> Data from Banco Central de Reserva de El Salvador
- <sup>7</sup> For a more in-depth example of patent-related monopolies, see [Breve 18: “Procurement Policies for Pharmaceuticals: The International Experience”](#), based on a presentation by Panos Kanavos.
- <sup>8</sup> 2012 Ley de Medicamentos (<https://www.defensoria.gob.sv/images/stories/descargas/Ley%20de%20Medicamentos.pdf>)
- <sup>9</sup> For an in-depth look at the portfolio effect in theory and a practical example illustrated by the Colombian case, see [“El ‘Efecto Portafolio’ de la Regulación de Precios de Medicamentos”](#).
- <sup>10</sup> This is based on the data available up to 2019.



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