

## CASE STUDY

EFFORTS TO IMPROVE ACCESS TO  
MEDICINES IN LATIN AMERICA

The case of CENABAST in Chile

Medicines are an essential part of healthcare systems today. However, access, i.e., the supply of available products in relation to the medical needs of the public in a given place and time, presents a challenge for all healthcare worldwide.

Latin America is no exception. Many countries in the region have adopted a number of strategies and policies in order to improve people's access to medicines. In December 2019, Act 21.198 was enacted in Chile authorizing the National Health Service System Procurement Unit (Central de Abastecimiento del Sistema Nacional de Servicios de Salud, CENABAST) to act as an intermediary for medicine sales to pharmaceutical warehouses, private pharmacies and non-profit organizations, in order to reduce the medicine prices through a pricing mechanism. Considering the importance of this initiative, this report seeks to document best practices in providing medicines to the private sector, looking at the experience of other countries in the region on this matter, and analyzing the implementation of the recent Law 21.198 in acting as an intermediary in the purchase of medicines in Chile.

## FRAMEWORK FOR THE ANALYSIS

**Market Intervention Strategies**

The main argument for government intervention in markets is based on the occurrence of “market failures.” In this case, there are significant losses, both in terms of efficiency and welfare, that justify these measures. There are several strategies through which governments seek to improve market performance: competition and regulatory policies. Within regulatory strategies, there are also distinct alternatives: direct regulation, indirect regulation, public companies. With respect to regulation in the pharmaceutical market, in this industry—with its particular characteristics—there are various tools for implementing intervention, both from the perspective of supply and demand.

**Governance**

Governance refers to the different ways in which a company organizes itself and manages its affairs collectively. This concept can be applied to institutions and systems, ensuring that the efforts such as the policy on access to medicines are carried out effectively and efficiently. For this study, the TAPIC model is used, identifying the following essential dimensions for governance: Transparency; Accountability; Participation; Integrity; Capacity (to develop policies).

## Strategy Efforts to Improve Access to Medicines in the Region

### BRAZIL

The intervention strategy for the medicine market in Brazil is based on classifying products into six categories, distinguishing between new products (subject to market entry price regulation based on international prices) and new launches (subject to a price adjustment regulation mechanism). In the first case, regulation is based on a model of domestic and foreign or international reference prices<sup>1</sup>, which allows for setting the maximum limits of the factory price (FP) or entry price. With this information, the manufacturer proposes a FP to calculate the Maximum Manufacturer's Suggested Retail Price (MSRP) and the Maximum Government Sale Price (MGSP). For the price adjustment mechanism for medicines already on the market, prices are readjusted annually according to a model that determines the Percentage Price Variation (PPV), based on productivity, relative prices between sectors, and relative prices within sectors. The Maximum Price Chart (FP, MSRP, and MGSP) is updated annually (every April) for each medicine, submission and brand in general.

During the first seven years of implementation, 147 laboratories submitted applications with pricing proposals for 1,115 submissions of 433 products. For this group, there was an average reduction of 35% between the initially requested price and the approved price (FP). The Brazilian strategy has been criticized, arguing that cost reductions are not necessarily accompanied by price reductions, and moreover, they generate incentives that may promote practices which compromise product quality, flood the market with unnecessary products, and impose higher entry prices.

### COLOMBIA

Colombian legislation began a medicine pricing regulation process by creating the National Commission on Drug and Medical Device Prices (Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos, CNPMDM), which is responsible for developing and regulating pricing policies for medicines and medical devices. Their pricing regulation establishes a maximum price based on international references to which a 7% (suggested) margin is then added to the retail price for consumers.



Product selection is based on market concentration. Upon identifying the products to be regulated, a reference price by national comparison (NRP) and a reference price by international comparison (IRP) are calculated. With NRP, the price is calculated as the weighted average (by total sales) of the price of all medicines included in the relevant market; for IRP, it is obtained as a weighted average of the price of all medicines marketed in the referenced countries<sup>2</sup>. Price setting occurs in markets where the national sales price is higher than the IRP.

An analysis of this policy implementation in Colombia shows a decrease in prices for regulated medicines between 2010 and 2018. This outcome is not without its critics. First, the industry could be applying compensation strategies: a price decrease in regulated products is compensated by an increase in the amount of regulated products sold and an increase in the price of non-regulated products. And second, the overall effect of regulation and its effectiveness in reducing prices is challenged, both because of its practical implementation issues (lags between the enforcement of regulation and effective price reduction), and its impact on the aggregate pharmaceutical market.

---

1. Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, USA, and the manufacturer's country of origin..

2. Argentina, Brazil, Chile, Ecuador, Mexico, Panama, Peru, Uruguay, Spain, USA, United Kingdom, Australia, Canada, France, Norway, Germany, and Portugal.

## Lessons from the International Experience

Intervention mechanisms have advantages and disadvantages; there is a need to pay attention to potential undesired effects of regulation. There is a practical difficulty in implementing interventions in this market, given the wide range of alternatives available. It is expected that multiple strategies may be required to address them. In this regard, regulation is more effective when it is framed within a broader general objective than lowering prices, and when it is intended as an initiative to promote access. In terms of governance, there is:

**TRANSPARENCY:** There is information on policy implementation and the availability of reports that support monitoring the policy over time.

**ACCOUNTABILITY:** Both countries have established regulation through legal amendments. However, the accountability process established for the regulatory body is unclear.

**PARTICIPATION:** Decision-making is carried out by a technical entity, with no broader participation (e.g., the pharmaceutical industry and consumers).

**INTEGRITY:** Both countries have chosen to create a responsible institutional framework, which helps to define functions and roles in the process, from price selection to supervision and disclosure of information.

**CAPACITY:** There is no information about the organizational structure of the institutions in charge. It is assumed that, to date, they have been able to function over time and carry out the actions for which they were created.

## Act 21.198 in Chile

The law establishes a specific mechanism through which these pharmacies must access CENABAST's intermediary services: i) the pharmacy requests CENABAST supply the healthcare products necessary for adequate supply and care of the population; ii) CENABAST evaluates the request and provides the products; iii) a maximum retail price is set for consumers.

In terms of how the law has been implemented to date, according to the information provided by CENABAST, between June 2020 and June 2021, a total of 199 pharmacies have requested products through the mechanism established by the law, equivalent to 306 different types of products traded. Figures show that the number of participants and transactions are growing. Regarding the impact on prices, data shows the law has achieved a price reduction of 23% in the products traded, compared to the price reported by CENABAST for the same products at independent pharmacies. In terms of well-being, CENABAST's intermediary service has shown benefits for both pharmacies and consumers. Considering all products, the potential surplus amounts to \$879 million. From this number, 23.6% is associated with profits for pharmacies, while 76.4% comes

from consumer benefits. In terms of product type, 48.5% of the total surplus comes from the sale of generic drugs, 9.8% from brand name products, and 41.7% from similar products.

As for governance, CENABAST publishes and periodically updates information on its website, which contributes to transparency. Regarding accountability, the process of supervision and penalties has been established for the regulated parties, but not for the regulatory body. Participation decisions are made by a technical entity, without any broader involvement process. For integrity, pricing decisions are the responsibility of CENABAST, and the decision-making process in practice is not defined in the law. With respect to capacity, the institution is expected to have the resources to carry out this task, given that it is an extension of its traditional tasks and powers.

# 23%

of price reduction in the products traded, with respect to the price reported by CENABAST for the same products at independent pharmacies.



# Conclusions

## 1

### STRATEGIES TO IMPROVE ACCESS CONSIDERATIONS

**Intervention Tools:** Brazil and Colombia have opted for a strategy based mainly on direct regulation through drug pricing mechanisms, while Chile's strategy, although it includes a pricing component, is more in line with policies that promote competition. This model highlights the presence of transaction and production costs, and of CENABAST as an intermediary and market participant.

**Scope of application:** It is important to consider in which part of the market the intervention takes place and the set of markets/products to be regulated. In Chile, intermediation is applied to the wholesale market and regulation is applied to the retail market. For selecting products, the suggestion is to adopt criteria aimed at solving the problem (access), such as demand, out-of-pocket expenses, etc.

## 2

### DIFFERENCES IN OUTCOMES

**Access:** There is no information available to evaluate this objective. The result is evaluated in terms of the decrease in retail prices. It would be important to generate information to evaluate the impact on access.

**Prices:** Price decreases are observed, but the effects on the aggregate market are sometimes contradictory. In Brazil and Colombia, there is evidence that lower prices on regulated products could be producing inflationary effects in other segments. CENABAST's strategy generates surplus for manufacturers and consumers, but its effects on the market as a whole are not known.

## 3

### CHALLENGES FOR CHILE

**Application scale:** One of the main weaknesses of the law, considering its limited scope in terms of market (exclusively independent pharmacies) and number of products. The potential benefits of the law could be understood if it is scaled up.

**Available products and location:** Price is not the only barrier to medicine access. The challenge here is to determine how to use the law to promote supply in geographic areas with low access.

**Governance:** It is important to include some elements that are currently weak. A transparent decision-making process, including clear accountability criteria for the regulatory entity, and broader participation are needed to help improve the various aspects of governance.