IMPROVING HEALTH SYSTEM EFFICIENCY

# EL SALVADOR

## The New Law on Medicines and its implementation

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# ABBREVIATIONS

| | |
|---|---|
| ARENA | Nationalist Republican Alliance of El Salvador |
| CPI | Consumer price index |
| CSSP | Superior Council of Public Health |
| DIGESTYC | General Directorate of Statistics and Census |
| DNM | National Directorate of Medicines |
| FEDEFARMA | Central American Federation of Pharmaceutical Laboratories |
| GDP | Gross domestic product |
| GMP | Good manufacturing practices |
| ISSS | Salvadoran Institute of Social Security |
| NRA | National regulatory authority |
| OTC | Over-the-counter (medicines) |
| PAHO | Pan American Health Organization |
| WHO | World Health Organization |

# EXECUTIVE SUMMARY

The Medicines Law of El Salvador was approved in 2012 and implementation began that year with the establishment of the main implementing agency, the National Directorate of Medicines (DNM). This law, supported by officials of the government, modernized the regulation of drugs, breaking the traditional mould of public administration in El Salvador.

Notwithstanding the broad scope of the reforms in the domain of medicines, the issue that drew the most attention was the regulation that introduced maximum prices at which medicines could be marketed. This measure, which faced strong opposition led by the pharmaceutical industry, allowed for substantial price reduction, thus benefiting a large proportion of the Salvadoran population that has seen its spending on medicines reduced.

Reforms in medicines regulation are far from complete in El Salvador, as reflected in the fact that the DNM still does not have laboratory analysis results for the vast majority of drugs marketed in the country. Furthermore, the standards of good manufacturing practices applied in inspections of pharmaceutical laboratories are not up to date, so further measures are necessary to improve the quality of medicines consumed in El Salvador. Nevertheless, the Medicines Law has resulted in visible and significant improvements in the short time since its implementation, thus enabling the country to advance ever closer towards universal health coverage.

# 1 INTRODUCTION

El Salvador formerly had some of the highest medicine prices in the world. However, in just one year following the implementation of the Medicines Law, the country achieved a significant reduction in medicine prices, leading to greater access to drugs for the population

This feat was achieved under the leadership of the National Directorate of Medicines (DNM), an institution that was created by the Medicines Law with a clear mandate to allow the Salvadoran population to have access to the medicines it needed at lower costs.

While significant progress was expected as a result of this law that aimed to improve universal health coverage, especially in terms of access to and quality of medicines, the law also required important steps to be taken in other aspects of regulation. In this manner, El Salvador became one of the most pioneering developing countries in the area of regulation of medicines.

The Medicines Law has had a high impact in El Salvador as it required important steps in related areas. Because of deficiencies in the medicine regulatory system that existed before the law, a national regulatory authority – the DNM – was created.

The Medicines Law was also significant in that it benefited not only the poorest citizens but also the middle class which has often been considered to have received less political attention than other groups in recent years. The reduction in drug prices applied to many products that tended to be purchased by more affluent groups, as well as medicines consumed by the poor.

From an economic perspective, it is clear that the price reductions achieved by the Medicines Law imply a correction of distortions of the drug market, which allows one to conclude that better efficiency in the functioning of the market has been achieved. The medicines market is a significant proportion of the Salvadoran economy and it is possible to envisage that the law may even be used to boost the domestic production of medicines.

This report describes how the Medicines Law, passed in El Salvador in 2012, has made the medicines regulatory system more efficient. The report opens with an explanation of the efficiency concerns with regard to El Salvador's regulatory system, followed by a chapter on the causes and consequences of the lack of efficiency. Chapter 4 explains the reforms of the medicine registration system which aimed at addressing efficiency problems, while the ensuing chapter presents the effects on the reform, followed by concluding remarks.

# 2 EFFICIENCY CONCERNS IN EL SALVADOR'S MEDICINES REGULATORTY SYSTEM

El Salvador is a small country in Central America. The population of about 6 million is characterized by limited purchasing power, as reflected by the country's gross domestic product (GDP) per capita of approximately US$ 3800. In this context, one of the concerns about the efficiency of El Salvador's medicine registration system is the extremely high medicine prices compared to those of other countries. Table 1 summarizes studies that present comparisons of medicine price levels in El Salvador (before the reforms) with those in other countries.

**Table 1. Comparison of prices of medicines in Central America and Panama, and at international level**

| Study | Date | Activity level | Product characteristics | Results |
|---|---|---|---|---|
| Competition conditions in the medicines sector in Central America (Petrecolla, 2011) | 2007-2009 | Ex-factory | All drugs marketed in Central America | ES prices are the second highest (after Costa Rica). |
| Central America Drug Price Survey 2008 (CONCADECO, 2009) | 2008-2009 | Pharmacy | 30 original and lowest cost generic medicines in Central America | The Greater Metropolitan Area of San Salvador has the second most expensive drugs basket (slightly behind Guatemala, the most expensive). |
| Price discrimination by pharmaceutical companies across Central American countries (Rojas, 2009) | 2002 | Ex-factory | Approximately 600 identical products sold by 17 leading international manufacturers in Central America | ES prices are the highest or among the highest (along with Guatemala). |
| Availability and price of essential drugs in El Salvador during the second half of 2006 (Espinoza & Guevara, 2007) | 2006 | Pharmacy | 24 generic and 24 innovative medicines in 30 countries worldwide | Prices in ES are the highest in the case of 17 innovative drugs and 20 generic drugs. |

ES = El Salvador.
*Source:* DNM (2013d).

As Table 1 shows, El Salvador's price levels were among the highest in Central America. In the 30-country comparison, El Salvador's prices were the highest for 71% of the innovative drugs studied and for 83% of the generics considered. In another study, El Salvador's cumulative mark-up was found to be astonishingly high when compared to 10 other countries, as El Salvador was the only country with a mark-up that exceeded 1000% (Table 2).

**Table 2. Cumulative margin between ex-factory price and retail price in the public and private sectors**

| Country | Total cumulative % mark-up public sector | Total cumulative % mark-up private sector |
|---|---|---|
| China (Shandong)* | 24-35% | 11-33% |
| El Salvador* | | 165-6 894% |
| Ethiopia* | 79-83% | 76-148% |
| India** | | 29-694% |
| Malaysia*** | 19-46% | 65-149% |
| Mali* | 77-84% | 87-118% |
| Mongolia* | 32% | 68-98% |
| Morocco** | | 53-93% |
| Uganda*** | 30-66% | 100-358% |
| United Republic of Tanzania* | 17% | 56% |
| Pakistan*** | | 28-35% |

*Country surveys of price components using WHO/HAI standard methology.
**Kotwani A, Levison L. Price components and access to medicines in Delhi, India. http://apps.who.int/medicinedocs/documents/s19208en.pdf (accessed 20 June, 2008).
*** Levison L. Investigating price components: medicine costs between procurement and point of delivery. Draft report on initial field studies. Unpublished (2008).

*Source:* Cameron et al. (2008).

Given the combination of low income and extremely high prices in El Salvador, access to medicines was limited as the cost of obtaining those essential health products was too high for many of the population. With regard to considerations of equity in access to medicines by level of household income, it should be noted that the out-of-pocket spending on medicines has historically been regressive, with people in the highest income quintile in El Salvador disbursing 41.36% of their household health expenditure on medicines, while the third, fourth and fifth quintiles spent between 71.48% and 81.26% of their household health expenditure on medicines (Ministry of Health, 2010). Therefore, in relation to income level in each quintile, high medicine prices have a greater impact on households with fewer resources than on the wealthy.

The inefficiency of El Salvador's health sector was not, however, solely due to medicine prices but also to medicine quality which was the responsibility of the Superior Council of Public Health (CSSP). Although a variety of medicines has been available in the country, there was no assurance as to their quality, with the result that the outcome of treatment was uncertain. The lack of medicine quality was due to several factors, including foremost the poor medicine registration system. One of the necessary basic elements for assuring medicine quality is registration, as it is important both to know which products exist and to have information about them. However, due to the poor quality of the registration system, reliable information was absent prior to the Medicines Law and the creation of the DNM. Thus, although there were crude estimates of the number of medicines that were available or officially registered, it was not possible to have the precise number of medicines or a complete list of them, and accurate detailed information on those medicines was even less likely.

While an evaluation by the Pan American Health Organization (PAHO, 2010) indicates that there were procedural manuals, forms and instructions for drug registration, and that the legal, pharmaceutical, laboratory and clinical components of registration were reviewed, the process had several limitations.[1] One limitation was that the registration of a product took a long time, since the paperwork had to pass through various units of the CSSP. Added to this, the response time of each area was variable because this was a vertical process, with one record being evaluated at a time, in addition to which the entire documentation was reviewed at each stage of evaluation. This long response time was contrary to the provisions of the internal procedures manual which were unrealistic (PAHO, 2010).

1 According to the CSSP (2012), in 2011 there were 13 812 registered pharmaceutical products in El Salvador.

Another important point is that the medicine authorization was given without requiring the essential documents to support the efficacy and quality of drugs. For example, in some cases stability studies were not obtained or formulas were accepted without specification of excipients and without chemical analysis. Similarly, occasionally there was no requirement of packaging information or other legal, technical or medical documentation to back up the product registration and guarantee quality medication for the population. In a similar manner, there were processes such as evaluation of modifications to the registry which did not have forms and procedures. Additionally the requirement for clinical studies was only for molecules for which data protection was requested. This last point means that no information was required for the registration of new entities, dosage forms, salts, routes of administration, new active ingredient associations, etc.

In addition to the above, multiple records were in practice characterized by inconsistencies in the physical documentation. For instance, some resolutions issued by the CSSP had not been incorporated into the pharmaceutical record. There were also inconsistencies in the electronic records as these often differed from the physical files. There were inconsistencies in the authorization of pharmaceuticals, such as where the same medicine was authorized under two prescription categories - i.e. for sale with or without medical prescription - for different manufacturers.

Medicine quality could also not be assured due to the lack of laboratory testing and inspection both previous to and following registration. Regarding market surveillance, although an evaluation by PAHO (2010) recognized that control of imports was satisfactory, that was not the case with regard to controlling the distribution of batches of pharmaceutical products, so there was room to improve product traceability. Also the CSSP did not work in coordination with the Attorney General's Office. Market surveillance tended to be sporadic since there was no workplan setting out priorities for action based on key inputs such as a proactive sampling and subsequent sample analysis, investigative inspections and the collection of complaints about product quality. Nor was there legislation to support the removal of pharmaceutical products that infringed quality standards, thus hampering CSSP activities.

Regarding surveillance of other regulated aspects, PAHO (2010) recognized that El Salvador's Health Code authorized inspections to monitor compliance with regulations, best practices and standards, also contemplating sanctions and fines for infringement. However, although the assessment of CSSP reveals that there were procedures for inspections, these were not carried out with a satisfactory frequency. As for the rules on good manufacturing practices (GMP), these were based on the standards of 1975, while in Central America a transition to the 1992 standard was in the making. The assessment of GMP was made by points, while the recommendations of PAHO (2010) were to conduct them from an overall risk assessment. The inspection concerned only national manufacturers, so it was necessary to apply to foreign ones working together with the national regulatory authorities (NRAs) of other countries. There was no quality management system for inspection procedures, and risk-based management in the planning of activities, as well as a training programme, were also absent. Finally, at a more basic level, transport services for surveillance activities were insufficient for what was actually required.

# 3 CAUSES AND CONSEQUENCES OF THE EFFICIENCY PROBLEM

El Salvador's efficiency problem was due to several factors. The most important may be policy capture by the industry and lack of interest to improve medicine regulation by some political parties. Among the main opponents of improvement in the medicines sector and the proposed Medicines Law were the pharmaceutical industry, which includes the various activities of the manufacturers, the distributors and the pharmacies, as well as other outlets (such as first aid posts and hospitals) selling medicines to the public. Among the toughest opponents of regulation, for example, was the Central American Federation of Pharmaceutical Laboratories (FEDEFARMA).[2] Another group of opponents comprised doctors, including medical sales representatives, represented by the Medical College of El Salvador. Among the political parties, the one that stands out was the Nationalist Republican Alliance of El Salvador (ARENA).[3] Traditionally, the power of these actors, which had vested interests in an unregulated medicine market, was very strong, so that attempts to reform the sector were not very successful.

A consequence of the powerful anti-reform lobby was the absence of a strong regulatory framework. In El Salvador, the Pharmacy law had been implemented in 1927, and the law of the Supreme Council of Public Health (CSSP) and Surveillance Boards of Health Professions designated the CSSP as the national medicines authority, initiating its registration activities in 1960. Although the above legislation existed previously, as noted by the Superintendence of Competition (2007a), there was a wide gap between what was prescribed by the law and the practice of regulation which did not fulfill the legal requirements. The lack of implementation could have been due to the fact that, under the previous law, access to essential medicines and technologies as an element of the right to health was not recognized in the Constitution or national legislation (Ministry of Health & PAHO, 2011). In the absence of such a vision, it is possible that the issue was not a priority for the responsible institutions. Further, in the realm of politics, this lack of vision must have been influenced to a non-trivial degree by the power exercised by the pharmaceutical industry to ensure that regulation of the sector would not be on the national agenda. The combination of forces in the Assembly would make it difficult to make progress towards the regulation of medicines in view of the powerful bloc of the political right.[4]

Another set of impediments to efficiency relate to the regulatory agency. One such problem was the conflict of interest that existed in officials who were directly or indirectly related to the same industry that they were regulating. This situation made it difficult to ensure that the decisions made by the regulatory agency were in the best interests of the population. In addition, the regulatory agency was fragmented and was responsible to several institutions (Table 3).

2 FEDEFARMA is the association which represents the major transnational laboratories such as GlaxoSmithKline, Sanofi, Roche, Astra Zeneca, Merck, Bayer, Eli Lilly, Novartis and Pfizer.

3 Notwithstanding this simplification, it is worth noting that it was necessary to obtain support from actors on the political right for the Medicines Law to be approved because of the minimum number required in the vote count. It must also be recognized that not all laboratories that are members of a specific association with a contrary point of view agreed with the position taken by their association, so there were some laboratories that were more accepting of the changes in the law.

4 However, while in general terms the industry may have benefited from limited regulation, it is also true that this situation generated certain practices that ran counter to the interests of at least some companies. One example is the practice of corruption that existed such as, according to anecdotes, tariffs set so that inspection results that were not favorable for a particular company would not be reported. Thus, rightful companies may have been competing unfairly with less responsible ones who managed to evade responsibilities that even the previous law required.

**Table 3. Institutions in charge by function**

| Institution in charge | Functions |
|---|---|
| Supreme Council of Public Health | Marketing authorization/registration<br>Inspection<br>Control of imports<br>Licensing<br>Quality control (pre-registration)<br>Advertising and promotion of drugs |
| National Committee of Clinical Research | Supervision of clinical trials |
| Ministry of Health | Quality control (post marketing)<br>Pharmacovigilance |

*Source:* Author's elaboration based on Ministry of Health & PAHO (2011).

Because of the multiplicity of regulators, it is easy to understand how that resulted in having different information, criteria and guidelines in the different institutions. This in turn led to several types of processes with weak or problematic communication attempting to obtain a picture of the reality in the manufacturing laboratories or owners of each drug and of the drug itself. As a result, the institutions struggled to exercise sufficiently effective control to ensure product quality.

More specifically – for instance in the case of control and surveillance that depended on the various boards related to public health – this made it difficult in practice to coordinate between the different institutions. From the point of view of the facilities subject to surveillance, this resulted in an excessive bureaucratic burden could lead to an unnecessary increase in operating costs (Superintendence of Competition, 2007a).

On the other hand, although the lack of efficiency of public administration was a major impediment to the effective regulation of drugs in the past, the lack of resources in the responsible institutions has been pointed out by several studies (Espinoza & Guevara, 2007; Superintendence of Competition, 2007a). Another problem related to how the financial resources were spent. A review of the executed budget of the CSSP from June to December 2011 (the last year that this institution was the drug regulatory authority) showed that 83% of the budget was spent on salaries, while only 14% went to procurement of goods and services, and 2% to investments in fixed assets.[5]

As a consequence of these institutional constraints, the medicines regulatory system suffered from several limitations according to PAHO (2010), which conducted a pre-evaluation of the NRA of El Salvador. For instance, the lack of a strategic approach to prioritizing activities was notable, as in the case of the quality control laboratory of the Ministry of Health which focused most attention on government-procured medicines which accounted for a much smaller proportion of medicines than those in the commercial market.

Another area with limited development was the formal and effective coordination between the responsible institutions – i.e. the CSSP and Ministry of Health. The coordination between these institutions was mainly informal, resulting in, for instance, decisions made on the basis of unbalanced information. Additionally, there was a lack of coordination not only between the regulatory institutions but also between different units within the same institution. Deficiency in communication arose in part from the lack of an institutional quality management system. Lack of coordination was also evident in relation to entities outside the country, indicating that relations with NRAs in other countries should have been established so that technical and scientific knowledge could be obtained and discussions of common interest could be advanced.

5 In contrast, from July to December 2012 the DNM devoted a significantly lower proportion (40%) to salaries, while 31% was allocated to procurement of goods and services, and 29% to investment in fixed assets. While these figures certainly reflect the need of a new entity to invest in assets, the difference is considerable.

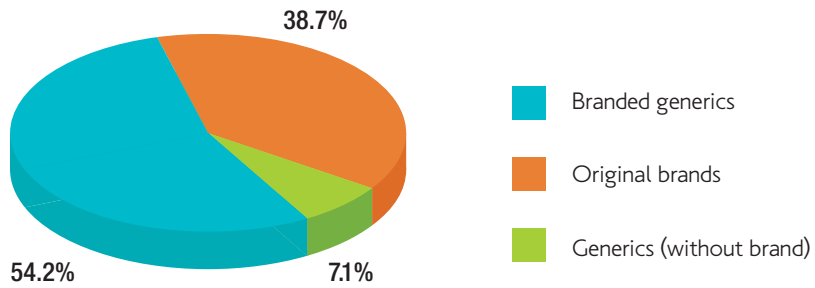
On relationships with industry, the assessment of the NRA indicates a lack of explicit mechanisms to protect the confidentiality of information handled within the institution. As for the relationship with the public, deficiencies are noted in the technical communications by the NRA on topics and activities it developed. Further, tariffs for services provided by the CSSP, which were very low compared to regional and global levels, were emphasized, and it was noted that they should be adjusted so that the institution could provide higher-level services.

Achieving an efficient medicines system was also restricted by certain characteristics of the market. One such problem was the fact that the medicines market was characterized by an asymmetry of information between patient and physician, as well as between physician and manufacturer. In other words, the patient does not have the level of information on the drug that the physician has, and the latter may prescribe a medicine that meets his own interests. It is clear that the interests of patients to improve their health status is shared by the physician but, in the situation as in El Salvador, the doctor may have additional interests such as royalties that some manufacturers provide as a reward for prescribing their medications. As for the asymmetry between the doctor and the manufacturer, the manufacturer may have information about the effectiveness of its drug which it may share with the doctor depending on whether doing so is in its interests or not. In the event that the manufacturer does not make that information available to the physician, the only way the physician has to check the effectiveness of the medicine is through the experiences reported by patients who tried it. For this last reason, generic drugs in El Salvador can be considered as an experience good whose benefits to the consumer are difficult to appreciate until the good is actually consumed (Superintendence of Competition, 2007a).

As with any good, patients see medicine price as an indicator of quality. Yet, in the case of experience goods, this relationship does not exist in practice since firms have an incentive to increase their prices without paying the cost of improving the quality as this characteristic is not observable to the patient who tries the drug for the first time. It is important to note here that even the patient induces higher prices because the consumer is concerned that low prices may reflect lower quality, so that risk aversion makes them favour the more expensive drugs. Also of importance to note, however, is that the patient behaves that way because of the lack of information provided by public authorities.

The implication of the above discussion is that in El Salvador two medicines markets coexist. In one market, consumers with low incomes buy generic drugs because of the price (Superintendence of Competition, 2007a; and Rojas, 2009, cited in the same Superintendence of Competition study). The other market, which is larger because of the substantially higher prices for innovative medicines and since most of the patients that can afford medicines in the private market consume innovative drugs, is that in which consumers have the ability to acquire innovative medicines at high prices (Figure 1). The first market exists since that segment does not have the means to purchase innovative products. Although these products are less expensive than the innovators, it is worthwhile to remember that even these are sold at higher prices than in other less distorted markets because the lack of information on their effectiveness encourages manufacturers to increase their prices to imply they are higher-quality products.

**Figure 1. Composition of the pharmaceutical market in Central America**




*Source:* Petrecolla (2011).

In addition to the above explanation, according to Petrecolla (2011), citing the study of Rojas (2009) who shows that prices of brand-name medicines are higher in El Salvador and Guatemala than in the other countries of the region and Panama, this occurs because in these countries the average levels of income, income inequality and size of population help maintain very different segments in the market for drugs. An opposite case to this is Costa Rica, where there is less income inequality, the population is smaller, and the strong health insurance system does not allow this level of segmentation. In the case of Honduras and Nicaragua, the lower levels of income prevent polarization of markets.

Thus, information asymmetry exerts a tremendous influence on the purchase of medicines by patients since, according to the Consumer Advocacy organization (2008), 76.3% of drug purchases are made on prescription. This incidence is higher than self-prescription, which nonetheless tends to be high in El Salvador compared to other countries and which represents all other purchases.[6]

Another impediment in the market relates to the number of medicine distributors. While there are many distributors, most of the commercial value is concentrated in about four of them. This may be due to the function that is to be performed by a distributor, which is to maintain a stock of drugs of sufficient magnitude and range (Superintendence of Competition, 2007a). In other words, distributors should have sufficient capital and efficient logistics distribution, which reduces the number of companies that can meet these conditions.

It is also worth noting that the previous drug legislation, the Pharmacy Law, restricted participants in the medicines market by limiting the entry of participants and by requiring that each product could only be imported by one importer. Thus, rather than promoting competition, this legislation reduced the participation of a greater number of agents, helping to maintain high prices.

The state of regulation of medicines before the Medicines Law is reflected in the fact that, according to a survey of the Consumer Advocacy organization (2008), only 57.3% of consumers surveyed showed positive levels of satisfaction with the medicine market. This puts medicines around the average satisfaction level for the goods and services investigated in the study.[7] Furthermore, 19.8 % of survey respondents said they were dissatisfied with medicines, which was also around the average for the products studied. Of particular interest is that the survey indicates that most dissatisfaction with price related to medicines rather than other products, with 40.2 % in the range between very and somewhat dissatisfied.[8]

One of the consequences of the limitations was that more pressure was exerted on the weak public health system as many patients could not solve their health problems in the private market due to high prices. Furthermore, lack of quality assurance implied that the effectiveness of treatment was uncertain. Some of the main beneficiaries of such schemes were the pharmaceutical industry, physicians who were owners of clinics, and medicine sales representatives.

Table 4 summarizes the problems and causes of inefficiency. In the third column, the table also presents additional information which is discussed in ensuing chapters. This information includes the intervention that the Medicines Law allowed and the improvements implemented even without the mandate of the law.

6 According to the Consumer Advocacy organization (2008), 29.8% of purchases are made on the recommendation of the salespeople of pharmacies, and 20.7% on the recommendation of friends and family. Since some purchases are due to all three reasons, the percentages do not sum to 100%.

7 Other products investigated in the study by the Consumer Advocacy organization (2008) were the fixed and mobile telephone, food, drinking-water, financial services, urban public transport, and electricity.

8 Notwithstanding this level of dissatisfaction with prices, the Consumer Advocacy organization (2008) reports high levels of satisfaction with the attention and service received from drug suppliers (68.9%), information provided by these (61.2%) and compliance with conditions and/or terms offered (56.2%). Consistent with this, the study indicates that pharmacies were the only types of firms that were rated satisfactorily in terms of trust.

**Table 4. Summary assessment of the Medicines Law**

| Identification of problems | Causes | Proposal for intervention by the Medicines Law (and improvements in practice) |
|---|---|---|
| • **High prices** of medicines<br>• Limited access to medicines by the population<br>• Unequal access to medicines<br>• Limited consumer satisfaction with the market for drugs | • Lack of regulation of drug prices<br>• Lack of correction of market distortion<br>• Consumers consider price as an indication of medicine quality<br>• Limited penetration of market by generics<br>• Limited competition between distributors<br>• Limitation on actors allowed to import medicines | • Medicine price regulation setting maximum retail prices by homogeneous groups of medicines<br>• Renewed obligation of physicians to prescribe by active ingredient<br>• Reiteration of prohibition on giving of royalties to physicians and others by the pharmaceutical industry for the promotion of its products<br>• Removal of restrictions on import of drugs by specific companies |
| • (**Transversal causes** that cause various problems) | • Regulation of drugs was not a priority<br>• Lack of strategic focus on activities of the regulatory agency (suboptimal orientation of funds)<br>• Lack of resources<br>• Lack of institutional quality management system<br>• Lack of relationship with counterparts in other countries and with international organizations<br>• Low tariff for service charges<br>• Lack of risk-based management in planning activities<br>• Lack of training programme<br>• Limited transport arrangements for inspection activities | • Creation and positioning of the DNM in government as an autonomous institution directly under the President<br>• Financial independence from the central government<br>**Improvements in practice**<br>• The Medicines Law considered by the government as a main project<br>• Prudent implementation of the law<br>• Approval by the Assembly to increase rates of charges for services provided by the DNM<br>• Close work with counterparts in Latin America<br>• Request for accreditation by PAHO as reference national regulatory authority<br>• Acquisition of vehicle fleet for inspections<br>• Reduction of average personnel costs |
| • Lack of **quality assurance** of medicines | • Lack of market surveillance<br>• Lack of control of the distribution of medicine lots<br>• Lack of legislation to support product recalls<br>• Lack of implementation of established inspection procedures<br>• Application of outdated standards of good manufacturing practice (GMP) with low compliance requirements, without risk assessment and applying only to national manufacturers | • Legalization of procedures for product recalls<br>**Improvements in practice**<br>• GMP inspections based on more recent standards<br>• Periodical GMP inspections of laboratories and pharmacies<br>• Full inspections and not partial<br>• Post-authorization inspections of distributors that were not conducted previously<br>• Start of quality analysis of all registered medicines |

| | | |
|---|---|---|
| • **Excessive bureaucracy** and lack of orientation to serving the population and industry | • Fragmentation of regulation between various institutions<br>• Lack of inter-institutional coordination<br>• Lack of coordination between units of the regulatory agency<br>• Cumbersome and redundant registry processes, resulting in backlog | • Integration of market regulation under a single institution<br>• Development of information on the market (i.e. list of maximum retail prices, list of OTC medicines, official list of medicines, etc.)<br>• Regulation on advertising of medicines<br>**Improvements in practice**<br>• Interagency coordination of shared tasks (i.e. development of official list of medicines, inspections, etc.)<br>• Coordination between DNM units (e.g. between the Registration and Prices units to prepare list of maximum retail prices, etc.)<br>• Streamlining of registration and inspection procedures and paperwork, which has reduced the backlog<br>• Improved communication with users |
| • Lack of development of certain activities (pharmacovigilance and clinical trials) | • Lack of legal basis for developing certain activities | |
| • **Corruption** | • Conflicts of interest by officials<br>• Lack of assurance of confidentiality of the institution's information<br>• Lack of enforcement of punitive measures against companies that violated the law | • Ban on hiring DNM officials who are directly or indirectly related to the pharmaceutical industry<br>• Prohibition on providing medical consultations in pharmacies |
| • Lack of awareness by the population of the activities of the regulatory agency<br>• Lack of credibility of the institution | • Lack of communication with citizens | • The DNM should publish the list of maximum retail prices once a year<br>**Improvements in practice**<br>• Use of information from the public for inspection |

# 4 MEDICINES REGISTRATION SYSTEM REFORMS AIMED AT ADDRESSING THE LACK OF EFFICIENCY

After a history of limited attention to medicines regulation, in 2012 an effective implementation of regulation was finally begun with the enactment of the Medicines Law.[9] With this law and the establishment of the institution embodying its mandates, not only is there now one main institution responsible for implementation but also the quality assurance of drugs is improved, medicines are controlled after their initial registration, partnerships with institutions inside and outside the country are coordinated, interagency coordination is developed, and additional resources are provided. In addition, critically this law allows, through the reduction of drug prices, improved access of the population to medicines in the private sector. The scope of the achievements of this law is such that even some actors of the right have recognized its benefits (FUSADES, 2013).

It is important to note that it was intended that the lack of efficiency should be addressed by creating a new regulatory authority, with the correct structure and arrangements, and by setting new maximum medicine pricing rules that the industry would have to follow. However, the law has some inconsistencies and lack of clarification, allowing room for maneuver. The law could have been implemented differently. For example, given that the government has been one of the main forces for making the Medicines Law a reality, the implementation of the law could have been more drastic – for instance, by reducing medicine prices even more than was done. However, that was not the case since both the government and the DNM felt that a more dramatic enforcement of prices could in fact create problems such as shortages in the medicines market. Consequently, the law was implemented pragmatically and the result has been successful. It is also worth noting that, as is described later, not all reforms that were implemented were necessarily due to the new Law but to the strong will of the government to improve the situation.

In brief, the reform has three pillars: the creation of a single strong national regulatory authority with no conflict of interest, initiatives led by authorities with firm political will for reform, and the establishment of maximum retail prices.[10] This chapter emphasizes the main points of the Medicines Law. The following section presents in detail a main aspect of the law, namely the maximum sales price for the public.

## 4.1 Main points of the Medicines Law

The Medicines Law (Legislative Decree No. 1008) was approved by the Legislative Assembly in February 2012 and entered into force on April 2 of that year. The DNM was created as the law came into force, taking over the CSSP's authority to regulate drugs.[11] Thus, the main institution responsible for implementing the Medicines Law becomes the health authority for the approval of registration, importation, manufacture, price control, control of the distribution chain, and even dispensing of medicines and related products to the final

9 Note that a year prior to the enactment of the Medicines Law the administration launched its "National Medicines Policy" (Ministry of Health, 2011). While it may be considered that the Medicines Law has made that policy obsolete, it is important to appreciate that the policy reflects the strong intention of the government to bridge the gap between what it considered as the mandate of regulation and what could be implemented under the previous legislation.

10 The reader is referred to Table 4 in the preceding chapter, which summarizes the interventions presented in the present chapter.

11 The CSSP remains responsible for the monitoring of professionals of the sector (doctors, dentists, veterinarians, pharmaceutical chemists, etc.).

consumer. Therefore, the problem of dispersion of functions across multiple institutions has been solved by integrating all market regulation into one.[12] Another aspect of the authority of this institution is that it is an independent body directly under the President of the Republic and has a high level of autonomy in its operation. The law states that the management team of the DNM is composed of delegates from some ministries – such as the ministries of health, economy and finance – as well as from the Salvadoran Institute of Social Security (ISSS), the Consumer Advocacy organization, the University of El Salvador and a private university. The DNM's source of funding does not depend on the general budget of the nation, which tends to contain various restrictions and is usually limited in amount. Instead, the DNM obtains its own revenue by charging for the services it provides to the pharmaceutical industry.

The new element of this law that drew the most attention, especially because El Salvador is one of the countries with the highest prices worldwide, is the fixing of a maximum sales price to the public for products that are not over-the-counter (OTC) medicines.[13] The law states that the retail price of any medicine must exceed neither the average Central American price nor the international reference price, so the lower of these two would be used to establish the maximum retail price. As for the international reference price, it should include as part of its calculated price, 3-5 times the marketing margin. The maximum retail price must be printed on the price sticker that must also show the price at which the product is sold and which must not exceed the maximum retail price. The DNM must publish a list of maximum retail prices which must be updated every year and the institution is also responsible for monitoring compliance, with penalties for noncompliance established.[14] Thus, this law establishes the conditions for significantly reducing medicine prices in El Salvador, especially because they were at much higher levels compared to the Central American average.

The Medicines Law also includes other provisions granting greater flexibility, such as having a larger number of players in the market and reducing barriers to entry to the medicines market. The reiteration of the prohibition on the industry's giving of royalties to doctors and other market players to promote their products is also noteworthy. Additionally, physicians are obliged to prescribe by active ingredient and not by brand. Another point that is prohibited by the law is the provision of medical consultations in pharmacies since this is considered a conflict of interest that encourages pharmacies to increase sales of their drugs.[15]

As for institutional aspects, this new law addresses possible conflict of interest by the DNM and prohibits employees from being directly or indirectly related to the pharmaceutical industry.

Following the entry into force of the Medicines Law, the DNM prioritized the development of some key regulations for its implementation. Those listed below had entered into effect by the end of 2014:[16]

- Regulation for Determining the Maximum Retail Sales Prices of Medicines and its Verification (Executive Decree No. 244 of 2012);
- Regulation on the Organization and Functioning of the National Directorate of Medicines (Executive Decree No. 242 of 2012);
- General Regulations of the Medicines Law (Executive Decree No. 245 of 2012);
- Regulation on Narcotic Drugs, Psychotropic Substances and Chemical and Additive Precursors, Substances and Products (Executive Decree No. 20 of 2013);
- Special Regulation for the Recognition of Foreign Health Records (Executive Decree No. 34 of 2013);
- Regulation for Protection of Test Data of New Pharmaceuticals (Executive Decree No. 65 of 2008).

12 It is worth noting that an important function that is omitted despite the integration is that of pharmacovigilance.

13 Since the concept of OTC did not exist in the previous institution and at the start of implementation of the law, medicines classified for sale without prescription were considered as equivalent to those being regulated.

14 The lists of maximum retail prices for 2014 and 2015 are available on the DNM website at: www.medicamentos.gob.sv.

15 Notwithstanding this provision, as a result of a lawsuit of unconstitutionality filed by some private-sector groups, the Constitutional Chamber of the Supreme Court of Justice accepted the argument that the prohibition goes against economic freedom and the act of hiring by companies. Therefore, for the moment, pharmacies have been allowed to resume the provision of this service.

16 These regulations are available on the DNM website at: www.medicamentos.gob.sv.

While the Medicines Law is a significant improvement in terms of regulation of the sector, some of its weaknesses should be acknowledged. Overall, the law has several inconsistencies. For example, the law establishes the concept of equating the innovator drug with medicines that have protection under the law, so it can be assumed that this refers to drugs under patent. However, these medicines are compared to their generic counterparts which, as a general rule in El Salvador, do not exist for a drug that has a valid patent. Partly because of such inconsistencies, this law leaves much room for interpretation of its articles. This is especially critical with respect to the provisions on prices, since, as noted above, there are sectors of society who preferred the lack of regulation. Therefore, these weaknesses of the law leave room for interpretation that could be used by future government administrations to reverse the progress that has been made.

## 4.2 Methodology for setting maximum retail prices implemented by the regulation on prices

While the Medicines Law makes clear that the maximum retail prices of medications that are not OTC should not exceed either the average prices in Central America and Panama or the international reference price, the law leaves ambiguity regarding how to calculate the average of the region or the international reference price. Because of this, the regulation on maximum retail prices has clarified these points.

The clarifications that were made in the rules include first that the establishment of maximum prices should be made at the level of homogeneous groups of medicines which are specified for each combination of active ingredient, strength and dosage form.[17] This arrangement allows for implementation of the pharmaceutical equivalence principle, implying that the maximum retail price for two drugs with such equivalence should be the same. However, in the case of biological and biotechnological products, the regulation clarifies that the maximum retail price of these products will be calculated by product and not by group of medicines. The exception made for these products results from the recognition that they cannot contain the same substance because of the biological or biotechnological process by which the substance is elaborated.

In addition to biological and biotechnological products, there is another exception to the establishment of maximum retail prices by homogeneous groups of medicines. This applies to differentiated products with technology that provides additional benefits to patients, which are products that are associated with a health risk and those with patents in the countries with which El Salvador has a trade agreement.[18]

When clarifying that the maximum retail price would be calculated by homogeneous groups of medicines, the regulation on maximum prices also indicates that the average retail price in Central America is calculated first by averaging the price at the level of each homogeneous group of medicines for each country. However, the price at which the calculation begins is the price charged by distributors to pharmacies, which differs from the retail price since it is at an earlier step in the distribution chain. Therefore, a marketing margin is added to the price of the distributor to pharmacies, which differs by country but is usually around 30%. Following the calculation of average price per country including the marketing margin, which must be in US dollars, the country values are averaged to obtain the average Central American price.[19]

Another clarification is made regarding how to apply 3-5 times the marketing margin to calculate the international reference price, and the data that would be used to calculate the price. The regulation states that data from South American countries would be used to calculate the international reference price. Once the harmonic mean is obtained by country and converted to its equivalent in US dollars, the simple average of the region is calculated. Then, the marketing margin, which is 28% according to the regulation, is extracted from this price. Then 3-5 times that margin is added to this value without margin, by means of which the

17 For purposes of standardizing the specification of homogeneous groups of medicines, the DNM designed specification rules, which are in the process of being published. The rules include technical aspects such as classification of dosage forms and allowable units for each pharmaceutical form and price, as well as rules to ensure order, such as the name to use for active ingredients with many possible names, and the order of description of active ingredients for medicines with multiple ingredients.

18 Note that this exception is enabled by a resolution issued by the DNM after implementation of the regulation began.

19 The US dollar is the official currency in circulation in El Salvador.

international reference price is obtained.[20] The exchange rates to be used are those used by the Central Reserve Bank of El Salvador.

Given that when new maximum retail prices are published, industry requires some time to make them effective, the regulation indicates that the list should take effect 90 days after its publication. This delay in price change is allowed to pharmaceutical firms that present their inventories of regulated medicines. The regulation also states that the list of maximum retail prices should be published both in the Official Journal and on the DNM's website. Furthermore, the regulation allows a period during which manufacturers can submit appeals regarding the calculations of the DNM. The DNM evaluates these appeals, after which, if the institution finds errors in its calculations, it may make appropriate modifications on the maximum retail price list.

Also noteworthy is a reform of the regulation that was implemented with the 2014 list of maximum retail prices. The reform states that no drug can be sold in El Salvador at a higher price than its average price in Central America and Panama. This means that, for products that cost more in El Salvador than their average price in the region, the maximum retail price would be the regional average price of the same product and not the maximum retail price for the group of medicines to which it corresponds. Notwithstanding this, in the case of products which have regional average prices higher than the maximum retail price for the corresponding group of medicines, the maximum retail price must adhere to that of the respective medicine group.



20 In practice, due to the addition of "3-5 times the marketing margin", for most of the homogeneous groups of medicines this international reference price is so high that the Central American average price usually ends up being the maximum retail price.

# 5 EFFECTS OF THE REFORM ON THE LACK OF EFFICIENCY

The reform presented in the preceding chapter, together with initiatives that were developed by the government, resulted in resolving problems with medicine regulation efficiency. This chapter presents the quantitative and qualitative evidence for evaluating the effectiveness of the reform, noting first the evidence of improvement in medicine accessibility and availability, followed by the effects in other areas.

It is important to note that the reform is still relatively recent, as implementation of the Medicines Law and the creation of the DNM began only in 2012 and it was in 2013 that price regulation came into force. Therefore, not all of the reforms may be reflected in the results, and some of the impact that is observable now may not adequately reflect the effect of the reform since not all the ensuing effects may have permeated the system. Nonetheless, the following sections describe some of the impacts that can be appreciated at this early stage. A review of this evidence indicates that the reform may result in improved health outcomes for the Salvadoran population as they can now rely on a more efficient medicines regulatory system.

## 5.1 Effects on medicine accessibility and availability

The prices of a large number of medicines in El Salvador have been regulated by calculating their maximum retail prices, published in three parts in 2013, as shown in Table 5.

**Table 5. Medicines with regulated prices in El Salvador by published list**

| | Type of regulated medicines | Published date | No. of medicine groups with published maximum retail price | No. of medicines (aproximate) | Date of entry into force |
|---|---|---|---|---|---|
| First list | Single active ingredient (original) | 3 January 2013 | 1 182 | 7 000 | 4 April 2013 |
| | Single active ingredient (modified) | 15 March 2013 | 1 175 | 7 000 | |
| Second list | Multiple active ingredient | 22 February 2013 | 631 | 1 500 | 24 May 2013 |
| Third list | Single and multiple active ingredients | 26 July 2013 | 676 | 1 500 | 25 October 2013 |
| Total | | | **2 482** | **10 000** | |

*Source*: DNM (2013c).

According to impact assessment estimates of the first listing based on a small sample of pharmacy chains, price reduction averaged 20-25% for the products concerned (DNM, 2013b). Therefore, the price cut has been significant.

It is noteworthy that, of the 2482 homogeneous groups of medicines published in 2013, only 40 original products were differentiated with their own maximum retail prices differing from the maximum price of their

homogeneous groups for the reasons indicated in section 4b above. While maximum retail prices allocated to these products are higher than those of the groups of medicines considered as generic, this number is quite low compared to the total number of homogeneous groups of medicines published, so the impact of granting higher maximum retail prices to these products does not significantly undermine the objective of reducing prices.[21]

After the first experience of implementing the list of maximum retail prices in 2013, the list for 2014 was published in January of that year in accordance with the provisions of the regulation on maximum retail prices. The 2014 list contained some 1900 homogeneous groups of medicines; this was fewer than in 2013, mainly because some groups of medicines were omitted as they were classified as OTC medicines in the list of such medicines published by the DNM in December 2013.[22]

In order to illustrate the price changes with specific examples, Table 6 presents, for 11 groups of medicines that have differentiated maximum retail prices for original products, the price of the original product at pharmacies prior to regulation, the maximum retail prices in 2014 for the original product and generic products, and the two price differences (i.e. between the maximum retail price of the differentiated product and its previous price in pharmacies, and the generic maximum retail price as a percentage of differentiated maximum retail price). All prices are presented as unit prices.

To assist in the interpretation of the table, the product Lipitor, which is the original product of the homogeneous group, consisting of 10 mg tablets of atorvastatin, cost US$ 2.0810 per tablet before the regulation. The regulation established the maximum retail price for that product at US$ 1.8941, so the price reduction was 9.0%. On the other hand, the generic product has a maximum retail price of US$ 0.9579, which means that the generic product was 49.4% cheaper than the original product.

It should also be mentioned that some of the products in the table are part of the Official List of Medicines, published by the DNM, which includes essential medicines that should be available at affordable prices to the population because they meet priority health needs. These medicines are marked with asterisks in the table.

**Table 6. Price changes in sample high consumption products**

| Homogeneous group of medicines | Diferentiated product | Previous differentiated price at pharmacy | Maximum retail price 2014 | | Difference | |
|---|---|---|---|---|---|---|
| | | | Differentiated | Generic | Differentiated/ previous | Generic/ Differentiated |
| ATORVASTATIN 10 mg tablets and similar [per unit]*** | LIPITOR/ PFIZER | US$ 2.0810 | US$ 1.8941 | US$ 0.9579 | -9.0% | -49.4% |
| ATORVASTATIN 20 mg tablets and similar [per unit]*** | LIPITOR/ PFIZER | US$ 3.0870 | US$ 2.9862 | US$ 1.3509 | -3.3% | -54.8% |
| ATORVASTATIN 40 mg tablets and similar [per unit] | LIPITOR/ PFIZER | US$ 3.1315 | US$ 2.9965 | US$ 1.8887 | -4.3% | -37.0% |
| ATORVASTATIN 80 mg tablets and similar [per unit] | LIPITOR/ PFIZER | US$ 4.0621 | US$ 3.6902 | US$ 2.1525 | -9.2% | -41.7% |

21 This assessment is evaluated quantitatively for a sample of differentiated products in the following section.

22 The price reduction effect of this and all ensuing lists is not large since the large price reduction was achieved in the first year of implementation.

| Homogeneous group of medicines | Diferentiated product | Previous differentiated price at pharmacy | Maximum retail price 2014 | | Difference | |
|---|---|---|---|---|---|---|
| | | | Differentiated | Generic | Differentiated/ previous | Generic/ Differentiated |
| CHLORPROMAZINE 100 mg tablets and similar [per unit]*** | LARGACTIL/ SANOFI AVENTIS | US$ 0.8866 | US$ 0.6163 | US$ 0.5543 | -30.5% | -10.1% |
| ESOMEPRAZOLE 20 mg tablets and similar [per unit] | NEXIUM/ ASTRAZENECA | US$ 2.1979 | US$ 1.5700 | US$ 1.0949 | -28.6% | -30.3% |
| ESOMEPRAZOLE 40 mg tablets and similar [per unit] | NEXIUM/ ASTRAZENECA | US$ 3.4543 | US$ 2.4600 | US$ 1.6994 | -28.8% | -30.9% |
| PHENYTOIN 125 mg/5 ml oral liquid [per ml] | EPAMIN/ PFIZER | US$ 0.1401 | US$ 0.1068 | US$ 0.1018 | -23.8% | -4.7% |
| MONTELUKAST 4 mg tablets and similar [per unit] | SINGULAIR/ MERCK SHARP & DOHME | US$ 2.8637 | US$ 2.4157 | US$ 1.3120 | -15.6% | -45.7% |
| NIFEDIPINE 30 mg retarded liberation tablets [per unit] | ADALAT OROS/ BAYER | US$ 1.5810 | US$ 1.4208 | US$ 0.7663 | -10.1% | -46.1% |
| TIMOLOL 0.5% ophthalmic drops [per ml]*** | TIMOPTOL XE/ MSD | US$ 10.0674 | US$ 8.2080 | US$ 1.6165 | -18.5% | -80.3% |
| **Average** | | | | | **-16.5%** | **-39.2%** |

*Source:* DNM.

Notes: Prices shown are per unit presented in the first column. The above prices are differentiated pharmaceutical products for a period before the entry into force of the regulation on maximum retail prices. ***The medicines indicated by asterisks in the first column are part of the Official List of Medicines published by the DNM.

Table 6 allows for analysis of the price reduction that has occurred for some original products so that some conclusions can be reached. First, even for these differentiated products it can be seen that the reduction in prices has been strong since prices have fallen on average by 16.5%. On the other hand, one can also note that the price reduction differs substantially from one product to another with, for these products, a range of 3.3-30.5%. This is a result of the fact that maximum retail prices are established according to reference prices, whether at the Central American regional level or internationally. Therefore, the reduction may differ according to how much the previous prices in El Salvador diverged from those averages. Additionally, the differences in maximum retail price between the original and generic products also vary since the range for these products is 4.7-80.3%. Again, these differences are governed by the average prices observed in the reference countries, which reflect variables such as the marketing of drugs, the perception of the population and the pricing strategy of manufacturers.

It should be noted that the reduction in prices for products of the Official Drugs List is substantial, as the average change for the corresponding differentiated versions is 15.3%. For these drugs, the average difference between the original and generic versions is 48.6%.

The above analysis is extended to higher-value products in order to show that the price reduction was seen not only with products of mass consumption. Table 7 presents some regulated products that feature some of the highest retail prices and maximum retail prices in El Salvador.[23]

23 Some of the products presented in Table 7 are original while others are not. The products are chosen according to data availability.

**Table 7. Price changes in sample of high-value products**

| Homogeneous group of medicines | Product | Previous price | Maximum retail price 2014 | Differrence maximum retail price/previous |
|---|---|---|---|---|
| PEGYLATED DOXORUBICIN 20 mg primary pharmaceutical package (PPP) liquid injection (by PPP) | DOXOPEG/ ASOFARMA | US$ 1050.90 | $ 709.25 | -32.5% |
| TEMOZOLOMIDE 250 mg tablets and similar [unit] | TEMODAL/ SCHERING PLOUGH | US$ 478.34 | $ 385.83 | -19.3% |
| GEMCITABINE 1000 mg/PPP liquid injection [by PPP] | GEMZAR/ELI LILLY | US$ 350.74 | $ 280.55 | -20.0% |

*Source:* DNM.

Notes: Prices shown are per unit presented in the first column. The prices above at pharmacies for differentiated pharmaceutical products pertain to the period before entry into force of the regulation on maximum retail price. PPP refers to primary pharmaceutical packaging, a concept that refers to the smallest packaging in which the drug is stored – which is, for most of the products for which this term is used, an ampoule, vial or a set of blisters or vials.

For these expensive drugs, as is evident from the high unit prices, it is clear that the reduction in prices has been quite significant. The range of reduction is 20.0-32.5%, which is in line with the average reductions experienced. Therefore, it is clear that strong price reductions are observed not only for high consumption volume medicines but also for low consumption volume medicines with high prices.

It is worth analysing the price reduction by manufacturers during 2013. The medicines of FEDEFARMA manufacturers showed the greatest reduction on average of 20-32% from their prices prior to the implementation of the law. This result was expected because these products are more expensive and, since in principle the maximum prices are set at the level of generic homogeneous groups of medicines, these products had the highest level of reduction.[24] At the opposite end are medicines of Salvadoran national manufacturers, which are generic and are of lower price. These experienced an average price reduction in the range 12-17%, so the impact felt is less than the reduction for FEDEFARMA products. All other products, which are produced by manufacturers that are not Salvadoran or members of FEDEFARMA, underwent an average price reduction of 20-25%.

To evaluate changes in the list price for 2014, it should be noted that, of the approximately 1900 homogeneous groups of medicines published, only about 300 underwent changes in their maximum retail price, and prices of other groups were unchanged. Also, for those homogeneous groups of medicines whose maximum retail prices changed, large changes in retail prices as they had experienced in 2013 were not to be expected, since even those had already experienced significant reductions. Therefore, it is not surprising that the average level of reduction in maximum retail price for the listing of homogeneous groups of medicines is only about 3% when compared to the 2013 list, so that the cumulative reduction from before the implementation of the law remains at around 20% to 25%.

The above analysis leads one to conclude that access to medicines has improved as medicine prices dropped substantially. Concomitant to this conclusion, it is worth noting that calculations by the DNM estimated that the Salvadoran population is saving around US$ 60 million yearly in expenditure on medicine, which is a

24 The assessment of price changes was to be done preferably by classifying drugs by the original and generic drugs. However, that was not possible since it was not possible to obtain access to information that identifies the original products. Therefore, products were classified according to the type of manufacturer: FEDEFARMA, local Salvadoran and the rest. The group of FEDEFARMA's medicines is a close approximation to original drugs, although there are several generic brands too. Local Salvadoran drugs are generic ones that are usually sold at a lower price, while other laboratories' drugs are priced between those of FEDEFARMA and the local ones.

great relief to the household economy in a country whose GDP growth has been 2-4% in recent decades (DNM, 2013b). As such, the Medicines Law has helped to some extent to improve the Salvadoran people's economic position.

In fact, the impact of price reduction on the national economy was such that it made a dent in the low prices of goods throughout the economy through negative inflation in the consumer price index (CPI) calculated by the General Directorate of Statistics and Census (DIGESTYC) of the Ministry of Economy for April 2013. The month-to-month variation of the overall CPI for the month was -0.630%, within which the health component was -0.324 points, with the vast majority of the reduction corresponding to the drop in medicine prices, representing 51.4 % of the fall in prices of all goods and services in El Salvador (Table 8). In other words, more than half of the reduction in prices in April was due to reduced drug prices, which is attributable to the regulation that was implemented.

**Table 8. Monthly incidence and share by category in consumer price index for April 2013**

| | Monthly incidence | Share |
|---|---|---|
| **General Index** | **-0.630** | **100%** |
| 01 – Food and non-alcoholic drinks | -0.179 | 28.4% |
| 02 – Alcoholic drinks, tobacco and narcotics | 0.001 | -0.2% |
| 03 – Clothes and footwear | -0.008 | 1.3% |
| 04 – Housing, water, electricity, gas and other fuels | 0.008 | -1.3% |
| 05 – Furniture, household items and for upkeep of the home | -0.021 | 3.3% |
| **06 – Health** | **-0.324** | **51.4%** |
| 07 – Transport | -0.169 | 26.8% |
| 08 – Communication | -0.003 | 0.5% |
| 09 – Recreation and culture | 0.012 | -1.9% |
| 10 – Education | 0.000 | 0.0% |
| 11 – Restaurants and hotels | 0.030 | -4.8% |
| 12 – Various goods and services | 0.021 | -3.3% |

*Source:* DIGESTYC's CPI Bulletin for April 2013.

To evaluate sales volumes, Table 9 shows the change in units of some medicines between January 2013 and January 2014 in five major pharmacy chains in El Salvador.[25] According to this information, the units in inventory have increased for each of these products and the increases are quite strong in most cases, so that the average increase in the units in inventory is 616%.[26] Since the inventory level is a reflection of the units sold, one can conclude that the sales volume increased after the enactment of the regulation on maximum retail prices. Consequently, it can be argued that access to medicines in El Salvador improved as a result of the Medicines Law, and that availability improved.

25 The source of the data used for this analysis is information submitted by pharmacies and other pharmaceutical establishments in January of the respective years, in order for them to benefit from the 90-day postponement of compliance with the new prices. The products presented were chosen randomly.

26 Some of the reasons for the increase may be due to the fact that in January 2013 pharmacies were waiting to see how implementation of the regulation on maximum retail prices would take place in practice, so it is possible that they had reduced their inventory then until they could have more knowledge about this situation.

**Table 9. Changes in inventories in five major pharmacy chains for some products covered**

| Product | January 2013 (units) | January 2014 (units) | 2013 to 2014 change | |
|---|---|---|---|---|
| | | | Units | Percentage |
| Ana-dent Todo Dolo Tabl X 100 | 16 550 | 75 900 | 59 350 | 359% |
| Amoebriz Tabl X 2 | 692 | 7 158 | 6 466 | 934% |
| Augmentin Tab.recu.bid 875 Mg X 14 (/125) | 434 | 7 336 | 6 902 | 1 590% |
| Amoxicilina Mk Caps 500 Mg X 30 | 36 496 | 52 908 | 16 412 | 45% |
| Adalat Oros Tabl 30 MG X 30 | 5 941 | 14 910 | 8 969 | 151% |
| **Average** | | | | **616%** |

*Source:* DNM.

In addition, anecdotal evidence tends to indicate that, since the entry into force of price regulation, pharmacies are promoting the sale of generic products at the expense of the original products. This may take place because, contrary to the situation prior to the Medicines Law, the profit margin for pharmacies may now be greater for generics than for original drugs since the latter now have ceiling prices that have forced their prices down considerably. At the same time, the prices of generic drugs may have been increased closer to their respective maximum retail prices, since the law does not prevent that. The result is that the previous situation whereby pharmacies had incentives to sell original medicines rather than generic ones seems to have been reversed.

## 5.2 Other effects on improving efficiency

While economic impact is the outcome of the Medicines Law most appreciated by the population, improvements in the efficiency of institutions has also been important in view of the weaknesses that persisted previously.

Following the enactment of the Medicines Law, the DNM has been working to ensure that the quality of registered medicines is supported by probative studies such as quality analysis, clinical analysis when necessary, and stability studies that prove the shelf-life, without neglecting the technical requirements in the formulations, as well as legal and medical aspects.

Efforts in surveillance have also enhanced medicine quality because the DNM conducts periodical inspections of laboratories to verify compliance with GMP. Pharmacies are also periodically inspected to ensure that products on the market have met the necessary requirements for being marketed and that they provide people with safe and effective medicines. In this effort, the DNM's credibility among the population has been vital; citizen participation through the submission of complaints, enquiries and comments has served to verify the outcome of inspections and to generate punitive administrative processes when appropriate.

Placing responsibility for overall supervision of medicines in a single institution has facilitated the easier access to the information required for the different stages and processes that are necessary to assure the quality of the product.

Other improvements include the beginning of inspection of the pharmaceutical industry and the suspension of the practice of making partial inspections. In addition, full inspection of GMP is implemented for pharmaceutical, cosmetic and hygiene product laboratories. Distributors are also now inspected for good storage practices which previously was not performed after the distributor had been authorized.

The DNM has acquired a fleet of vehicles which has greatly improved the mobility of inspectors and their speed in scheduling inspections. Procedures that in the CSSP were scheduled for two or three months later are now programmed by DNM's Inspection and Supervision Unit in no more than eight days, and the report is delivered in a maximum of 15 days.

In this area, the inspections have resulted in tangible outcomes that were not achieved previously; for instance, joint inspections with the National Civil Police and the Attorney General of the Republic have been

conducted, and have resulted in arrests and the immediate closure of illegal establishments. Progress has also been made in inspections of laboratories, verifying GMP at multiple national pharmaceutical laboratories.

Thus, although the important issues for the population are greater access to medicines and lower prices, the DNM is making major progress in the regulation and verification of GMP in line with WHO recommendations (WHO, 1992), developing technical standards for registering biological and biotechnological drugs, and promoting good storage and distribution practices.

Furthermore, with DNM's quality control laboratory, the impact of the Medicines Law should be felt more in terms of health surveillance and quality assurance of medicines because, in three years, the analysis of post-registration quality of all registered products in El Salvador is planned at a rate of 7000 medicines per year.

At the beginning of DNM's work, there was considerable backlog in registration applications. However, the backlog has been reduced to one month, and now the goal is to provide decisions on new registrations in three months. Reducing the backlog has been achieved by evaluating the documentation by competencies. The review has sub-areas on pharmaceutical chemistry, manufacturer and physicians. Documents are evaluated simultaneously, so that the submission steps previously evaluated in the CSSP by the Board of the Pharmaceutical Chemical Profession and by the Supervisory Board of the Medical Profession are omitted. The most common procedures have been redesigned and each process is being written to describe the person in charge, the maximum time, and the goals for each technical analyst. Furthermore, there is now a job description manual.

Regular communication has been established with users of the registration unit so as to permit review of the procedures and obstacles in order to ensure legality and speed of processes.

For prices, the DNM had to design a completely new structure since there was no prior experience of price regulation. By leveraging information technology resources, such as digital databases and computer programs for analysing the database, it was possible to develop a system to calculate the maximum retail prices. Because this calculation depends on classification of the records of medicines in different homogeneous groups, which in turn depends on information from a different unit of the DNM that is in charge of calculating maximum retail prices, coordination between different units has been important in the development of this task.

Education of the public and physicians is another DNM function that is beginning to be developed. This is of vital importance in the regulatory process. Guidelines, instructions, lists of maximum retail prices, an Official Medicines List, an OTC list and a list of products subject to control and supervision have been issued. Medicine advertising has also been regulated in order to comply with the principles of ethical drug promotion, avoiding market distortion and misleading advertisements.

Currently the DNM has training sessions aimed at strengthening the technical capacity of its staff. For instance, training has been a priority in the registration unit since the future of that unit is considered to depend on the technical and academic growth of its members.

As for equipment, the DNM has ensured supplies of what is necessary. For instance, the inspection unit previously had no institutional vehicles, making transport of staff difficult. The unit was obliged to seek alternatives in other governmental institutions that gave immediate support . Other government institutions also supported the DNM in training administrative and logistical staff according to their skills and capabilities.

Part of the improvement was made possible by the increased resources available to the DNM, especially since the legislature approved new tariffs in July 2013 whereby the fees charged for services provided to industry were increased to levels similar to those in other countries of the region. Tariffs that were effective until July 2013 had been in existence for several decades; consequently, neither the CSSP for many years nor the DNM in its initial phase had the resources necessary to operate properly.

The DNM has experienced a substantial increase in the resources to carry out its activities. Table 10 shows the budget of the CSSP in its last year as the competent authority for drug regulation, while Table 11 presents that of the DNM in its first year as the competent authority.

## Table 10. CSSP's planned and executed budgets (June-December 2011)

| Concept | 2011 approved budget | 2011 executed budget | Pending execution | % of executed values by concept |
|---|---|---|---|---|
| Salaries | US$ 1 441 009.93 | US$ 1 409 740.83 | US$ 31 269.10 | 98% |
| Acquisition of goods and services | US$ 277 935.73 | US$ 234 747.29 | US$ 43 188.44 | 84% |
| Financial expenses and others | US$ 18 044.84 | US$ 10 618.28 | US$ 7 426.56 | 59% |
| Investment in fixed assets | US$ 42 033.65 | US$ 42 033.65 | US$ – | 100% |
| **Total** | **US$ 1 779 024.15** | **US$ 1 697 140.05** | **US$ 81 884.10** | **95%** |

*Source:* CSSP (2012).

## Table 11. Executed budget of the DNM (July-December 2012)

| Concept | Value |
|---|---|
| Salaries | US$ 704 821.34 |
| Goods and services | US$ 533 626.51 |
| Financial expenses | US$ 351.04 |
| Fixed assets | US$ 511 019.13 |
| **Total** | **US$ 1 749 818.02** |

*Source:* DNM (2013).

Clearly the DNM currently has more financial and personal resources which have allowed it to develop its work more effectively than previously.

Table 12 summarizes the situation with regard to DNM staff in 2013, with a total of 122 professionals.

## Table 12. DNM employees by profession

| | Human resources | Administrative area | Technical area |
|---|---|---|---|
| **Professionals** | Physicians | | 8 |
| | Pharmaceutical chemists | | 37 |
| | Chemical engineers | | 3 |
| | Lawyers | 6 | 5 |
| | Business administrators | 5 | |
| | Industrial engineers | 2 | |
| | Economists | | 3 |
| | Accountants | 3 | |
| | Civil engineers | | 1 |
| | Marketing and communication | 1 | 1 |
| | Journalists | | 1 |
| | Systems engineers | 2 | |
| **Technicians** | Electronic engineering technicians | 1 | |
| | Information technology technicians | 1 | |
| | Secretaries | | 7 |
| | Maintenance | 2 | |
| | Drivers | 5 | |
| | Archivist | 3 | |
| | University students | 7 | 8 |
| | **Total of human resources** | **38** | **74** |

*Source:* DNM (2013).

According to the Ministry of Health and PAHO (2011), in 2011 the CSSP had 161 employees working permanently. This higher number of staff may be partly a reflection of more diverse responsibilities that the CSSP had, as it regulated not only medicines but also health professionals. However, it should be remembered that the DNM also has a wider authority since it is responsible not only for the regulation of drugs but also for control of the medicines market, including the regulation of medicine prices that did not exist previously.

In terms of cost per person, this was US$ 1250.88 per month for the CSSP, while for the DNM it is US$ 962.87 per month. These figures show that the staff cost per month divided by the number of staff, is lower for the DNM. One can conclude that, because the DNM has a smaller number of staff, this has meant lower costs for the institution, which in turn has produced greater results than the CSSP in the regulation of medicines.

While several aspects of human resources have improved, a key limitation required by the Medicines Law is that employed staff may not have worked in the pharmaceutical industry.[27] The intent of the law is clear as it seeks to limit the risk of conflict of interest that may be associated with professionals who have a relationship with the industry that may be harmful to the regulator. However, it is also acknowledged that this provision is a tremendous burden for a new institution that requires deep knowledge of the industry it regulates, which could be obtained more readily from their former members.

27 Similarly, the DNM cannot hire professionals who have a family relationship within three degrees of consanguinity.

# 6 CONCLUSIONS

The implementation of the Medicines Law in El Salvador broke the mould of successful public policies. Few public policies that clearly involve both social and the economic dimensions have had so much impact in the country, improving the lives of people in a wide range of socioeconomic areas. Thus, it can be safely said that the Medicines Law represents one of the most democratizing policies in the history of El Salvador. As such, El Salvador's reform on medicines regulation sheds light on a few success factors, including the possibility of quickly changing a country's position on an issue that has long been under the control of economic and political powers. El Salvador's experience demonstrates that a strong movement backed by popular support can achieve a reform that is beneficial for the greater portion of the population.

Nevertheless, behind the success of this law there is considerable room for improvement. The law should be clearer on important issues such as price regulation, for instance, since the ambiguity could allow subsequent administrations with less vision to try to change its interpretation and reverse the improvements made in favour of universal health coverage. The law could also incorporate, as a function of the DNM, issues such as pharmacovigilance that are currently outside its scope in order to complete the integration of medicnie issues in a single institution. As regards the implementation of the law, the DNM faces challenges that must be resolved, such as implementing more modern standards of best manufacturing practice, which would contribute not only to ensuring better quality of medicines for the Salvadoran people but also to promoting a more competitive local pharmaceutical industry at the regional level and beyond.

While these and other issues remain, the steps taken by the Medicines Law are monumental. It is expected that it will help El Salvador to move forward in pursuit of higher levels of human development for its people.

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