

IMPROVING HEALTH SYSTEM EFFICIENCY

EL SALVADOR

The New Law on Medicines and its implementation

Takayoshi Jose Yamagiwa



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CONTENTS

ABBREVIATIONS	4
EXECUTIVE SUMMARY	5
1. INTRODUCTION	6
2. EFFICIENCY CONCERNS IN EL SALVADOR'S MEDICINES REGULATORY SYSTEM	7
3. CAUSES AND CONSEQUENCES OF THE EFFICIENCY PROBLEM	10
4. MEDICINES REGISTRATION SYSTEM REFORMS AIMED AT ADDRESSING THE LACK OF EFFICIENCY	16
4.1 Main points of the Medicines Law	16
4.2 Methodology for setting maximum retail prices implemented by the regulation on prices	18
5. EFFECTS OF THE REFORM ON THE LACK OF EFFICIENCY	20
5.1 Effects on medicine accessibility and availability	20
5.2 Other effects on improving efficiency	25
6. CONCLUSIONS	29
REFERENCES	30

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.

THE IMPACT OF THE MEDICINES LAW IN EL SALVADOR IN 2012

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