NATIONAL CAMPAIGN ON THE IMPACT OF INNOVATION AND INTELLECTUAL PROPERTY PROTECTION IN THE COMPETITIVENESS LEVELS OF MEXICO

White paper on international benchmarking on freedom of prescription and access barriers to medicines

Audience: Federal legislators

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Contents

1 KEY ELEMENTS OF FREEDOM OF PRESCRIPTION IN INTERNATIONAL BENCHMARKING

This document describes how several different countries, including Mexico, address the issues related to freedom of prescription through their policy designs and implementation models. The following table provides a summarized description of key concepts for each country.

Table 1. Key elements of freedom of prescription in selected countries

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
Health pillar position on The World Economic Forum's Index	68/144	85/144	74/144	34/144	22/144	3/144	11/144
Health pillar position on IMCO's Competitiveness Index	35/46	37/46	28/46	17/46	12/46	N.A.	8/46
Out of pocket expenditure (%total health)	50.6%	25.2%	53.0%	54.1%	24.1%	69.0%	42.7%
Public sector health financing	State (IMSS, ISSSTE…) and contributions from employees and employers	State (Plan Obligatorio de Salud-POS), Subsidized Regime (RS)	State (FONASA, SNSS)	Primarily State and Federal governments (some municipalities have local share contributions to Medicaid)	National sickness funds (contribution, taxes)	Medisave (employees' contribution), Medishield (not compulsory to low income citizens)	National Health Insurance System (NHI)

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
Private sector health financing	Out of pocket, private insurance. Some companies provide private insurance to their employees	Contribution Regimen (employees), salary contribution, out of pocket expenditure	Out of pocket, private insurance (ISAPRE)	Out of pocket, private insurance	Out of pocket, private insurance	Medisave (employees' contribution), Medishield (not compulsory to low income citizens)	Out of pocket, private insurance
Low-income population healthcare financing	• Private sector employees (IMSS) • Puplic sector employees (ISSSTE) • Informal sector (Seguro Popular)	Subsidized Regime (RS)	FONASA	Medicaid, state **and** government	Statutory Health Insurance (GKV)	Medifund (government endowment fund)	• Low income population: Government subsidies financed by a national tax • Extreme poverty: Medical Aid Program
General health institution	Ministry of Health	Colombian National Health Insurance (SGSSS)	FONASA	Department of Health and Human Services state Medicaid agencies	GKV	Minister of Health and Central Provident Fund	Ministry of Health and Welfare (MoHW)
Prescription mechanism	A limited drug list (*cuadro basico* and *catalogue of consumables)* is produced from the universe of registered drugs	Manual of Essential and Therapeutics Medicines	*Formulario Nacional de Medicamentos* which is a subset form the National drugs registry	Medicaid: freedom of prescription for drug companies that are member of the program Medicare: protected classes	Negative list	Absolut freedom of prescription	Positive list system

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
				and discretion by insurers			
Authority in charge of approving prescription drugs	Cofepris	Medicines and Food Vigilance Institute (INVIMA)	Pharmacy and Therapeutic Comity	FDA	Federal Joint Committee (GBA) Institute for quality and efficiency in health care (IQWIG)	Health Sciences Authority	Health Insurance Review Assessment Service (HIRA)
Prescription mechanism in private sector	Freedom of prescription over registered drugs	Freedom of prescription any drugs if patient asks for it	Free to prescribe any drugs that doctors consider necessary	Freedom of prescription according to the specific insurance program	Freedom to prescribe any drug that is not in the negative list	Freedom of prescription over legal drugs in the country	Freedom of prescription over drugs included in the Positive List System
Prescription mechanism in public sector	Limited freedom of prescription to drugs that belong to *cuadro basico and catalogue of consumables*	Same as in private sector	Same as in private sector	Freedom of prescription with Medicaid medicines and a formulary in each Medicare Part D plan	Same as in private sector	Same as in private sector	Same as in private sector
Why this system is better than Mexico's?		Doctors explain all the information available about their patients' therapeutic options and they are allowed to	Doctors may adapt their prescription to patients' needs, patients have the information and can make a their own	Medicaid is essentially a free market economy: pharmaceutical companies enroll in each state program	Negative list encompass only lifestyle and over the counter medications. All other therapeutic areas (and their	-Patients' right to be informed and to make choices about their treatment options is guaranteed. -Access to first	Patients have better access to medicines, due to: 1)drugs from the Positive List System are reimbursable, and 2)doctors

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
		prescribe drugs that are not included in the Manual of Essential and Therapeutics Medicines	choices	and all their products are available for prescription and reimbursement / Medicare allows for copayment schemes and avoids catastrophic expenditure	medications) are part of the public system and the reimbursement mechanism	class medications	are free to prescribe what they consider the most appropriate treatment even if it does not belong to the PLS.

2 INTRODUCTION

This document pursues the aim of assessing the impact of freedom of prescription in the Mexicans' health levels. Freedom of prescription has a direct effect in the access to medicines and treatments appropriate for each patient. It affects people's health and quality of life, and, therefore, a country's competitiveness and productivity.

The document describes how several different countries, including Mexico, address the issues related to freedom of prescription through their policy designs and implementation models. Particular attention will be drawn to the impact of these policies on the access to medicines and the impact in health and competitiveness indexes.

The paper will provide highlights about the system of prescription, with the objective of initiating a discussion among those responsible of designing and implementing healthcare public policy in Mexico. This discussion should strive to establish a new legal and policy framework to solve more efficiently the intrinsic problems of concurrence of rights between doctors, patients and the government's distributive justice alternatives.

Freedom of prescription states that, considering scientific discoveries, doctors should be free to prescribe what they consider the most appropriate treatment, given a patient's specific illness and circumstances. Doctor's choice of a patient's treatment must be shaped by clinical need efficiency, security, and high quality standards. Doctors should consider the advantages, the opportunities, and the consequences of each possible treatment.

Freedom of prescription is one of the core debates countries face over the adequate distribution of health resources. Each country has to meet the challenge of implementing a fair distribution of public resources, while, at the same time, it takes care of its citizens' healthcare rights. Freedom of prescription is also intimately linked to the professional responsibility of doctors and the patients' right to make choices about their own treatments. This is the reason why both conditions must be included simultaneously in public policies, legal frameworks, and bylaws related to the provision, financing and efficiency of healthcare services.

The first question to answer is if freedom of prescription and the patients' right to make their own choices should imply the selection of any treatment or if it should be constrained to certain services and products. There's no doubt that in a context of limited public resources, the methodology to allocate, prioritize, and select affordable treatments is very important. An adequate methodology will provide better health outcomes, as well as improvements in productivity and competitiveness.

The legal framework of most countries considers the right to health as a fundamental right. Generally, it is considered as a social right, that is to say, politically established, and determined ethically, irrespective of the legal framework.

Considering the public resources' distribution, the pharmaceutical financing policies are highly controversial discussions over the world. The increasing adoption of the concept of health as a social commodity implies that prescription policies should also be adapted. Nowadays, thanks to the internet, patients have access to much more information than a few years ago, while doctors consider that their principal ethical and professional obligation is to attend the therapeutic needs of each patient in particular, irrespective of the society in general. The society is only regarded as a "statistical patient". Today, legislators and regulators must consider the following arguments, sometimes contradictory:

- Doctors' freedom of prescription
- Patients' right to choose among different therapeutic alternatives
- Patients' right to know and understand different therapeutic alternatives
- Fair and equal distribution of limited public resources

Freedom of prescription is the representation of the doctors' Hippocratic Oath to recommend the best treatment for each patient. However, there is a tension over this responsibility when the patients' right to choose their treatment is considered. The tension continues even if the patient's right is respected when the patient has enough information upon the different therapeutically options. This situation only occurs when doctors exercise their obligation to inform the patient of these options, their efficiency, implications, costs and secondary effects, and it continuous because even with all the information available, the patient lacks the medical training to understand the consequences (short and long term) of one treatment or the other.

To this debate between doctors' and patients' rights, it should be added the rights of society (as a whole) of the adequate distribution of public resources. In the absence of the health right in the legal framework of each country, this last link will get less importance.

The universal coverage of health public services, a phenomenon in which Mexico has been immersed since *Seguro Popular* was implemented, and which aims to provide the necessary healthcare to every citizen, is based in principles of equity and sustainability. This creates new challenges: there are, unquestionably, important opportunities in the aim of universal coverage, but also some highly complex tensions that need to be attended by: 1) the adequate distribution of resources through solid clinical evaluations, 2) the doctors' responsibility to prescribe what they consider appropriate, while they inform to their patients about different therapeutic options, 3) patients' rights to receive information and choose their treatment, and 4) scientific discoveries that result in more effective treatments but accessible at very high costs or in more "patient friendly" treatments (better routes of administration, milder side effects, tolerability, etc)

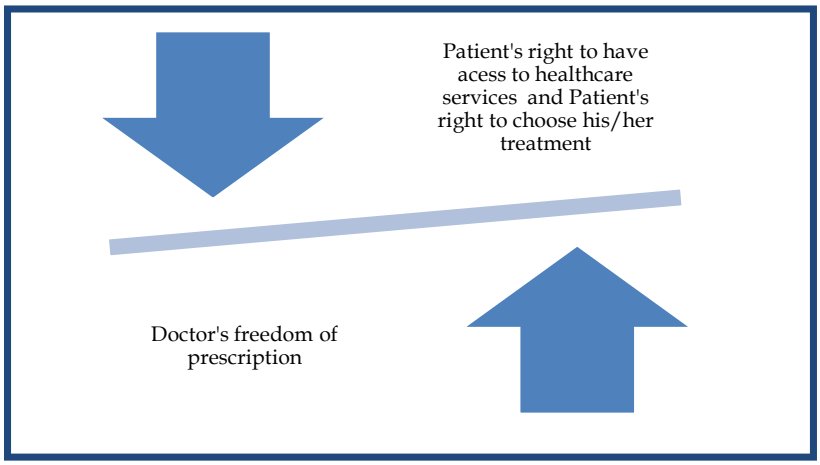
From the economic perspective, drugs are qualitatively different from other goods in many aspects. For example, in general terms, consumers, that is to say patients, do not choose the product, given the fact that they do not have enough information to

make the appropriate decision about either the product's quality or the need they have of it.

In contrast with other rights, freedom of prescription has no gold standard since it comprises an overlap of rights between patients' rights to be informed, doctors' freedom of prescription to explain existent treatments, and distributive justice. Having scarce resources, each government faces the challenge of choosing a framework that can reach a desirable equilibrium between patients' and doctors' rights.

In the context of a government's scarcity of resources, freedom of prescription introduces the coexistence of rights, which is described in the following graph:

Graph 1. Balance between patients' and doctors' rights



Regarding the patient's rights, each country has adopted a specific framework. However, most of the existing legal instruments have some rights in common:

Table 2. Rights in the Declaration of Lisbon on the Rights of Patient, 1981

Right to medical care of good quality

- The patient shall always be treated in accordance with his/her best interests. The treatment applied shall be in accordance with generally approved medical principles.
- Quality assurance should always be a part of health care. Physicians, in particular, should accept responsibility for being guardians of the quality of medical services.

Right to self-determination

- The patient has the right to self-determination, to make free decisions regarding himself/herself. The physician will inform the patient of the consequences of his/her decisions.

Source: Declaration of Lisbon on the Rights of the Patient, adopted in 1981 by the 34th World Medical Assembly, Lisbon, Portugal. Available at: http://www.wma.net/en/30publications/10policies/l4/

For example, in France freedom of prescription remains as a fundamental feature of the healthcare system. It gives doctors the absolute liberty to prescribe a medicine to their patients, but it implies many responsibilities for the doctor. According to the article R.4127-8 of the Health Public Code, the freedom of prescription is justified by guaranteeing the right of all citizens to receive the most appropriate treatment according to their needs. However, the moral limit of freedom of prescription is the doctors' responsibility: doctors should constrain their prescriptions and acts to what they consider most appropriate for patients' treatment, according to quality, security and clinical effectiveness criteria.

According to the law, French doctors do not have an *obligation of result*, but an *obligation of means* which represents that doctors could face justice if they fail to report sufficiently on the patients' treatments and risks, and if they also fail to prescribe the most appropriate treatment.

Pursuing a mechanism to allocate public resources to cost-effective medicines within a framework that aims to be fair for patients and doctors and effective for governments represents the reason why freedom of prescription embraces an ethic dimension:

Which is the fairest distribution of resources considering the patient's and doctor's rights in a context of a tight budget?

Thus, freedom of prescription is not absolute but it does affect people's lives. This calls for our reflection on how the Mexican government can improve its framework to better address the concurrence of patients' and doctors' rights within the context of an environment with limited resources.

Other debates surrounding freedom of prescription include the role of doctors and other healthcare professionals in the prescription process. This debate addresses issues such as asymmetric information (the doctor has information and medical training that the patients lack), treatment preferences of each doctor (their treatment preferences might not be necessarily the best treatment available), the need of a

doctor to prescribe a treatment that is affordable for the patient, and the right of the patient to be aware of treatment alternatives available for their conditions, regardless of the doctor's preferences, the patient's financial capability from his own purse or from his access to public or private insurance, and the systems structure and functioning. The reasons why patients are sometimes not aware of all the treatment alternatives for a given condition, as can be seen, are not always financial.

When speaking about freedom of prescription a common misunderstanding amongst analysts and decision makers is that it implies universal access to a non-restricted market of medications and medical devices for all the population. This notion of freedom of prescription is unachievable because it does not consider the following:

- Both state government and private healthcare institutions and systems do not have unlimited resources.
- States, in the fulfillment of the obligations to preserve the health levels of all their citizens, must, many times, choose between quantity (reaching out to the largest possible amount of patients/citizens in the least amount of time) and quality (granting first rate medical care to all its patients).
- The need of the State to protect general levels of health and not to focus solely on access to medicines. This implies that the state must many times choose, in the allocation of its budget, between guaranteeing access to a given world class, highly innovative medicine for specific group of patients or developing and strengthening the whole of the national and regional healthcare systems through measures that might include the development of healthcare infrastructure, healthcare human resources, education and prevention and many other areas. The decision is not always easy.

In the context of freedom of prescription, countries have developed different models to achieve a balance between patients' right to know and understand all the possible treatment options for their condition, the doctors' right to prescribe what they believe to be the best alternative (with all the considerations that such prescription allows for, such as the doctor's knowledge of his/her patient economic reality) and, what it is even more relevant, the public system constraints in matter of resources and evolution. These balances might, sometimes, call for tensions both in the system and amongst doctors' and patients' rights.

A clear example of this situation is when the condition of a patient that seeks medical attention in the public system could be alleviated by an expensive and innovative medication (outside of the national list of drugs), and the doctor assigned by the system has to prescribe taking into consideration the following:

- His/her knowledge of the existence of the said medication (which, in the case of the Mexican *cuadro basico* is not always the case, since doctors are many times only aware of the medicines available in *cuadro basico*)
- His/her knowledge of the patient's economic condition and his/her lack of financial resources to pay for said medication
- His/her knowledge of the available medications in the national list

- The regulation of public healthcare institutions on prescription process, including mechanisms such as lists of drugs and the possibility of following an alternative route to prescribe medicines not included in the lists of drugs for exceptional cases (as is the case in Mexico).
- His/her particular treatment preferences (it is possible that under the hypothetical case of absolute freedom of prescription in a public system, a doctor would still prefer a less innovative medication because he/she is familiar with it)
- His/her knowledge of the restricted resources and the need to optimize them. This is particularly true in the case of rural doctor that practice medicine in isolated communities, where they are well aware of the scarce supply of medications, regardless if they are, or not , in the national drugs list

A given public healthcare system addresses the issues surrounding freedom of prescription in different ways within the functioning and structure of the system itself. These measures include public policies, federal laws, federal bylaws, codes of ethics, surveillance mechanisms and many others, which shall not be address in this document. This document aims solely to describe the current state of freedom of prescription in the Mexican public healthcare system, and how other governments have addressed the challenge of freedom of prescription (as understood by WHO), in terms of budget, system management and prescription mechanisms.

The countries selected are: Germany, Chile, Colombia, Korea, Singapore, and the United States. For each country we shall provide the following:

- the reasons for being in this sample,
- the state of freedom of prescription in their public healthcare system,
- the description of said system and its financing mechanism,
- the legal framework that allows for it, and
- the resultant health outcomes in terms of health indexes and other health quality data.

We shall also analyze the current state of prescription in the public healthcare system of Mexico and the areas for improvement and increased certainty.

2.1 Access to medicines and competitiveness

It is an unchallenged truth that a healthy population favors high competitiveness levels. Several competitiveness indexes, both in Mexico and abroad, grade and evaluate the performance of national health systems and their impact in the main health indicators of the population, such as life expectancy, child mortality, cancer incidence, weight, vaccination levels, among many others. Some of these indexes include those of the World Economic Forum[1], and the Mexican Institute for Competitiveness[2].

[1] The Global Competitiveness report 2012-2013, Klaus Schwab, World Economic Forum, Committed to improving the state of the world, Geneva, http://www3.weforum.org/docs/WEF_GlobalCompetitivenessReport_2012-13.pdfd

[2] Indice de Competitividad Internacional 2013, IMCO, México

On the other hand, the World Health Organization (WHO) provides several indicators to assess the performance of national healthcare systems in the aim to develop a healthy and productive population that is able to achieve the highest levels of productivity thanks to its access to good healthcare in terms of medicines, infrastructure, and medical attention.

Access to adequate medicines and treatments depends on the doctors' possibility to prescribe what they consider the best treatment in a broad sense. This occurs in the very last link of the consumption chain of medicines. Although all countries have control mechanisms that limit freedom of prescription, the functioning of these limitations determines, at the end of the day, the real access to medicines.

Research is the first step in the pharmaceutical chain. As a consequence of a successful **investigation**, the drug is submitted to healthcare authorities in charge of determining its safety and effectiveness for treating one or more conditions. After a process of clinical trials, the healthcare authority grants the registration or permit to distribute and sell the drug, if proven safe and effective. These registered drugs, both with existing patents or generics whose patent has expired, constitute the universe of drugs that can be prescribed by doctors.[3] So far all healthcare systems are similar, some are more efficient than others, but serve the same function. It is also worth mentioning that, in most countries, for the private sector the availability requirements of a given medicine through prescription stop here. In other words: doctors in the private sector may prescribe any drug that has been approved by the regulatory sanitary agency (in the case of Mexico, Cofepris).

Regarding freedom of prescription in the public sector, where the State faces the challenge of financing the medication, each country decides how to achieve the balance between patients and doctors' rights in a context of scarce resources. From a highly regulated perspective, there are countries that establish health registries and drugs lists which limit prescriptions to the usage of the medicines included in the drugs lists, as is the case of Mexico. In such a scenario it is forbidden to prescribe treatments which are not included in the lists, even if they are more appropriate for the patient's needs.

Other countries position themselves in the opposite side of the regulation spectrum, and offer negative drugs lists. This type of lists describes medicines that are not allowed to prescribe (doctors may prescribe all the medicines they consider appropriate for their patients needs, except for those who belong to the negative list). In other countries with less regulated systems, doctors have absolute freedom to prescribe. These systems could also have drugs lists, but if doctors judge it more appropriate, they are allow to prescribing treatments that do not belong to it.

In this quest, the access to medicines that a given population might have is crucial. The innovative medication allows not to only for the protection against infectious

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http://imco.org.mx/indices

[3] Although there are also prescriptions called magisterial in which the doctor writes the chemical formulation to be prepared by the pharmacist, are now obsolete.

diseases, but also for the treatment of chronic illnesses, and the prevalence of individual productivity and quality of life, even in face of continuous diseases.

In spite of the clear link between innovative medication and health and productivity levels, patients many times lack access to said medications. This is due to many factors among which are the financial capabilities of each patient and the financial and economical resources of the State, who has the obligation to provide, in the first instance, the medication to its citizens.

Other factors include the access of the population to private and public insurance, the different notions of the outreach and scope of social security in each country and the specific characteristics of each national pharmaceutical market.

Freedom of prescription in the countries that should be analyzed in this paper complies with the WHO definition of the rational use of medications

"*Patients receive medications appropriate to their clinical needs in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community*". To this notion has been added "*with the maximum information available*"[4].

Therefore, while absolute freedom of prescription seems both unattainable and many consider, undesirable, freedom of prescription under the notion of the WHO is both attainable and can be a pillar of national healthcare and competitiveness.

[4] World Health Organization, Promoting Rational Use of Medicines: Core Components - WHO Policy Perspectives on Medicines, No. 005, September 2002, available at: http://apps.who.int/medicinedocs/en/d/Jh3011e/1.html

3 FREEDOM OF PRESCRIPTION IN MEXICO

3.1 SUMMARY

- In private practice, doctors can prescribe all medications with a sanitary registration. Regarding the approbation process, the sanitary registry in charge of Cofepris has reduced waiting times, as a result of improvements in the management and the equivalence agreements with regulatory agencies in Australia, Canada, United States, Switzerland, and European Union.
- Doctors in public institutions must prescribe drugs that are included in *cuadro basico* and *catalogue of consumables*, which is a list of drugs and medical devices selected by the Consejo Nacional de Salubridad, an executive body formed by representatives of the federal government, public health institutions, academia, NGO's and state governments.
    - Each public institution has established supplementary versions of *cuadro basico* that further limit available treatments. According to health regulation institution's list of drugs only could be constituted as a reduced version of *cuadro basico* and *catalogue of consumables,* and never exceed it. The financial resources that each institution is able to allocate to medicine expenditure, determines the content of each institutional list of drugs. This implies:
        - A clear disadvantage and inequality in public healthcare quality for citizens that rely solely on social security and other public health systems,
        - Besides *cuadro basico* limitations, *Seguro Popular* recipient´s coverage is limited to a selected list of ailments.
- Although the process is long and seldom explored, public healthcare institutions allow for exceptions to prescribe medicines that are not part of the *cuadro basico* in special cases.
- Freedom of prescription is constrained by the *cuadro basico* and the multiple supplementary drugs lists because doctors' responsibility to attend patient's health needs is compromised by not being able to prescribe what they consider most appropriate from all medications and treatments that have a sanitary registration and that have been registered by Cofepris.
- Patients' rights are also violated by limitations to freedom of prescription because they are not provided with information about all treatments available that the physician considers best, and therefore, they are unable to make an informed decision about their treatment options.

3.2 CURRENT PRESCRIPTION MECHANISM

Freedom of prescription is not established positively by statute. Freedom of prescription is defined negatively by the limitations health professionals have on how and what to prescribe.

The legal framework that regulates freedom of prescription in Mexico is the following:

The General Health Law

- Healthcare services are the actions required to benefit the person and the society in general with the objective of protecting, promoting and restoring the person's and collectivity's health levels. Article 23
- All public institutions are obliged to use *cuadro basico* for primary care (general healthcare services), as well as *catalogo de insumos* (catalogue of consumables) for secondary and tertiary care (medical specialists and higher specialized equipment and expertise). Article 28

The Interior bylaw of health consumables

- A medical prescription is a document that contains, among other elements, the prescription of one or more drugs and that can be produced by: doctors, homeopaths, dentists, veterinary surgeons, residents, nurses and midwives. Article 28
- The medical prescription must have printed with ink the name, address, and the doctor's registration number. It must include the doctor's signature. Article 29
- The prescriber will indicate in the prescription dosage, presentation, administration, frequency, and dosing period. Article 30
- If the drug is included in the Catalogue of interchangeable generic drugs, doctors must write the **generic denomination** and, if they prefer to do so, indicate the distinctive denomination (Article 31). The latter refers to "the name that as a commercial trademark is assigned by the laboratory or manufacturer to the pharmaceutical specialties thereof in order to distinguish them from other similar denominations approved by the sanitary authority and registrations before the proper authorities"[5].
- If the drug is not included in the Catalogue of interchangeable generic drugs, doctors can express either the distinctive denomination or the generic denomination and the distinctive denomination together. Article 31
- Prescription in all public institutions must only use the generic denominations of drugs included in *cuadro basico* and *catalogue of consumables.* There could be some exceptions of prescriptions with drugs not included in the *cuadro basico* and *catalogue of consumables*, but they need a special authorization. Article 32

Healthcare services bylaw of the General Health Law

- The public healthcare institutions must comply with *cuadro basico* and *catalogue of consumables*. The Minister of Health will promote the usage of them in the private and social sectors. Article 38

[5] Menocal Lozano, A., Pharmaceutical trademarks in Mexico, Olivares & Cia., in World Tradmark Review, Country correspondents: pharmaceutical trademarks, may/june 2008, p. 95.

- The medical prescriptions must have the doctor's name, the institution that granted the doctor's degree, address, date, and the doctor's registration number. Article 64
- If the prescriber has a specialization degree, the medical prescription must also include the specialty registration number. Article 65

Interior bylaw of the Inter-institutional Commission of *cuadro basico* and *catalogue of consumables*

- Public institutions can generate their own institutional drugs list based on *cuadro basico* and *catalogue of consumables*, but their lists can no longer exceed the content of *cuadro basico* and *catalogue of consumables*. Article 50

Agreement of the Mexican public health institutions

- Public institutions should only use drugs established in the *cuadro basico* for primary care and, the *catalogue of consumables* for the second and third level. Article 1

The legal framework of freedom of prescription is also affected by the fact that public health institutions are, by law, forced to provide the whole medical treatment (including pharmaceutical). The following legal instruments reflect this fact in two of the key healthcare insurance mechanisms (Imss and Seguro Popular):

The General Health Law

- Every Mexican, regardless of its social condition, is entitled to be enrolled in the Social Health Protection System (*Sistema de Protección Social en Salud)* in accordance with Article 4 of the Mexican Constitution. Article 77 bis 1 (Title 3 bis Seguro Popular)

  The Social Health Protection is a mechanism through which the State shall guarantee the access to medical services, surgical services, hospital services and **pharmaceutical services** in a manner that is effective, timely, with quality standards and **without expenditure at the time of usage** (…) as a minimum, it shall contemplate the services of external consult for primary attention, external consult and hospitalization for secondary attention in the following areas: general medicine, gyneco-obstetrics, pediatrics, and geriatric attention.

IMSS Law (*Ley del Seguro Social)*

- In case of an ailment not derived from labour risks[6], the Institute shall provide the insured[7] with medical and surgical services, **pharmaceutical** and hospital services (as needed), for 52 weeks, with the possibility of a prorogate of 52 more weeks. Article 91 (which means that drugs are dispensed with no cost)

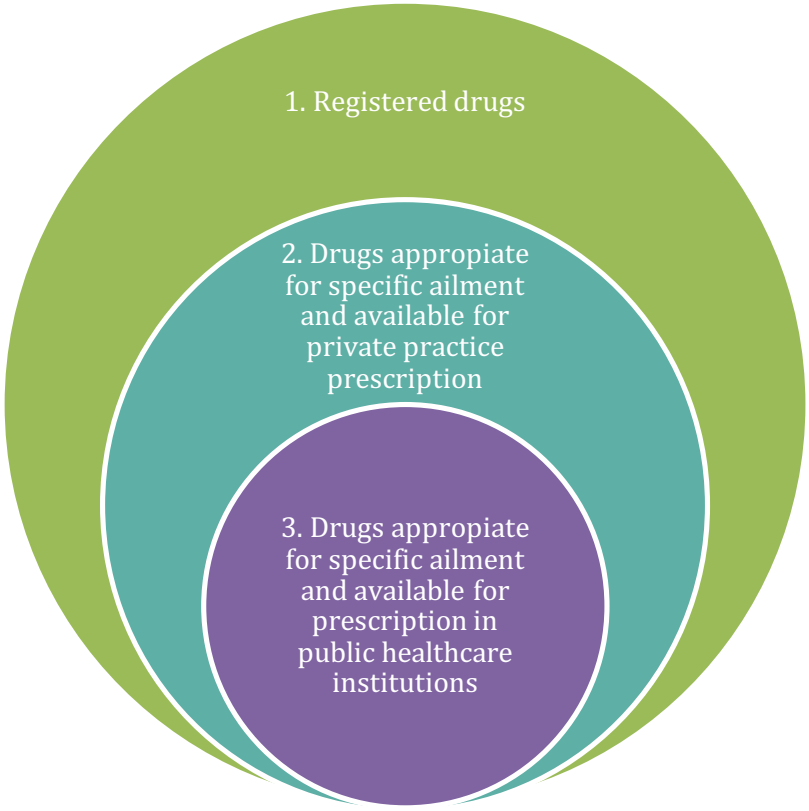
[6] Article 68 refers to ailments derived from labour risks and contemplates the same pharmaceutical coverage

[7] Article 93 includes the family and dependants

Exceptions

Although the process is long and seldom explored, public healthcare institutions allow for exceptions. For instance, Imss provides a route to prescribe medicines that are outside the *cuadro basico* in special cases (article 111 of the regulation of the medical attention inside). The legal instrument establishes: *Regarding drug prescriptions, doctors will adjust Cuadro basico of Imss. Prescribing and dispensing medicines outside Cuadro basico of Imss will be held for those exceptional cases that need them, subject to the norms and requirements issued by the Technical Counsel.*

3.3 THE UNIVERSE OF DRUGS



3.3.1 Registered drugs

In Mexico, legal framework regarding sanitary regulation is vast. Laws, inlaws and norms establish the process providers need to follow to obtain the sanitary registration, which is handled by the Secretary of Health through the *Comision Federal para la Protección contra Riesgos Sanitarios* (Federal Commission for the Protection against Sanitary Risks, Cofepris). Based on the type of medicine (allopathic, generic, or homeopathic medicine), procedures to get the sanitary registration differ.

On the final stage, an approval process for the medication for its commercialization takes place, and Cofepris continues to regulate the process. This stage includes the production, storage and distribution, licensing and marketing authorization, and the post-commercialization of the drug, among other things. Regarding the approbation process, as well as the coordination among institutions, Cofepris has reduced waiting times, as a result of improvements in the management and the equivalence agreements with regulatory agencies in Australia, Canada, United States, Switzerland, and European Union.

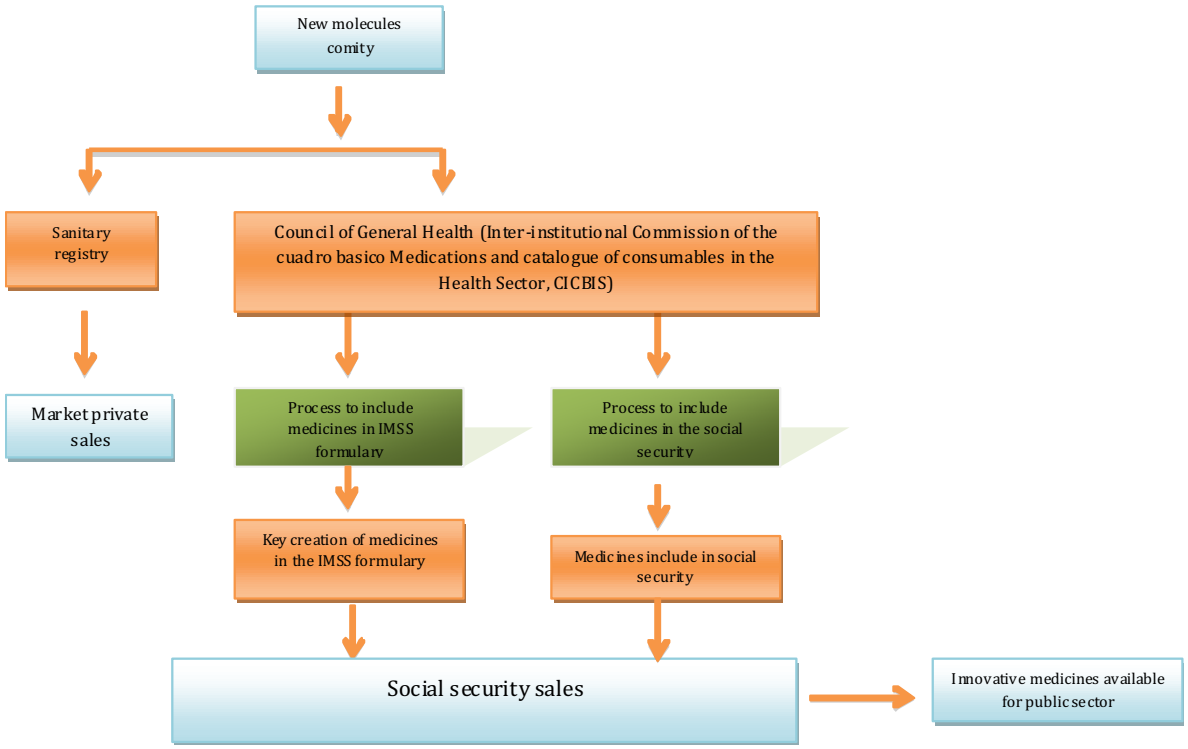
3.3.2 Drugs appropriate for specific ailment and available for prescription in public healthcare institutions

Once the commercialization of the medication throughout the population has been authorized, it becomes possible for the medication to be included in the *cuadro basico* and *catalogue of consumables* that is offered to the population by the government to attend their health needs. It is important to remember that public physicians' prescriptions are limited to the products included in this predetermined universe, unless the physician presents medical evidence that demonstrates that a patient needs a medication not included in *cuadro basico* or *catalogue of consumables*.

Aside of *cuadro basico* and *catalogue of consumables*, the legal framework analyzed in the previous section, allows public institutions to have supplementary lists of drugs, which cannot longer exceed the contents of *cuadro basico* and *catalogue of consumables.* Imss has the *cuadro basico Institucional del Imss*, Issste the *Catalogo Institucional de Insumos para la Salud del ISSSTE,* Pemex *the Catalogo Nacional de Medicamentos,* Sedena a list of drugs, and Seguro Popular *the Catalogo de Medicamentos y otros insumos del Catálogo Universal de Servicios de Salud (CAUSES).* Each list has its own regulation, thus if a pharmacy wants to submit a medicine, it needs to initiate independent approval processes in each institution. Moreover, there are few public healthcare institutions such as Pemex and Sedena that do not allow private providers to carry out the process, so the public institution is the only authority in charge of assessing new drugs and updating the list of drugs.

Regarding *cuadro basico* and *catalogue of consumables*, the process to approve, modify or cancel the medications used by public health institutions in Mexico is contained in the Ley General de Salud and the Reglamento interior de Consejo de Salubridad General (General Health Law, Interior regulation of the Council of General Health Services, CSG). The CSG is the highest government entity responsible on issuing obligatory ruling concerning health matters. This collegial and transversal organism depends directly on the President, without any mediation from other branches of the federal government or governors. One of its main functions is defining the *cuadro basico* for primary healthcare and the *catalogue of consumables* (Catalogo de Insumos) for secondary and tertiary healthcare services.

Graph 2. Approval process



** The period of time changes if it's a new molecule, imported drugs or a modification in the registry.*

To carry out these duties, the Comision Interinstitucional del Cuadro Basico y Catálogo de Insumos del Sector Salud (Inter-institutional Commission of the *cuadro basico* Medications and *catalogue of consumables* in the Health Sector, CICBIS) was created , and it is made up by the Secretary of the CSG, as well as representatives from the Department of Health, Imss, Issste, the Sistema Nacional para el Desarrollo Integral de la Familia (National System for the Integral Development of Families, DIF), Sedena, Semar, Pemex, and representatives from the Department of Health of the Federal District.

Apart from updating the *cuadro basico* and the *catalogue of consumables*, the Commission has the responsibility of receiving, analyzing, and ruling on applications for updates, incorporating scientific and technological advancements in medicine into their decision. This legal scheme defines health consumables as medications, psychotropic substances, narcotics and prime and additive materials used in their elaboration; as well as medical equipment, prosthesis and orthopedic procedures, functional assistance, diagnostic agents, dental procedures, surgical equipment, recovery equipment, and hygienic products.

To carry out its functions, the CICBIS meets at least once every year and decisions are made by the simple majority, as long as the majority of members are present at the hearings. In the case that a tie between votes is reached, the President of the Commission has the decisive vote. During a CICBIS session, members generate acts and documents that are sustained for a period of four years, in accordance to the sixth section of the 14th article of the Ley Federal de Transparencia y Accesso a la

Informacion Publica Gubernamental (Federal Law of Transparency and Access to Public Governmental Information).

Additionally, there is a group of Technical Specific Committees (CTE) that assists CICBIS and these include: I. Committee on medications; II. Committee on healing materials; III. Committee o tools for diagnosis; IV. Committee on medical instruments and equipment; V. Committee on herbalist remedies; VI. Committee on homeopathic medications; and VII. Committee on Acupuncture Consumables. The CTEs are responsible for receiving and reviewing applications submitted to CICBIS to update the basket of medications. They are the entities that rule on the validity of the requests being submitted and are in charge of gathering professional opinions on the matter.

Generally, the procedure to approve medications to be included in the *cuadro basico* takes place in three stages:

Table 3 Stages in the process of approval of a new medicine in *cuadro basico*

First stage *Validity of application*	*Application for inclusion:* verifies the manufacturer's reliability in regards to technological surveillance and an economic evaluation, among other factors.	*Application for modification or exclusion:* verifies the sanitary record and the reasons behind the modification or exclusion.
	Applications are kept confidential during the process of deliberation (as stipulated by the 14th article in the Federal Law of Transparency and Access to Public Governmental Information) The Technical Secretary of the Commission deliberates on whether the process will continue or not.	
Second stage *Evaluation of clinical and economic evidence*	A numerical grading system is used in order to preserve an objective and standardized evaluation. The evaluation is carried out by committee members and experts and is subdivided into three phases: ○ Internal validity (adequate methodology, it answers the clinical hypothesis, etc) ○ Study results (statistical significance, clinical relevance, etc) ○ External validity (the results are applicable to a clinical situation in particular).	
Third stage *Ruling*	• Committees consider the risks, benefits, and costs. • The members vote and an institutional opinion is issued • If approved, CIBCIS proceeds to update the Basket of Medications.	

Source: Internal bylaw of the Inter-institutional Commission of cuadro basico and catalogue of consumables

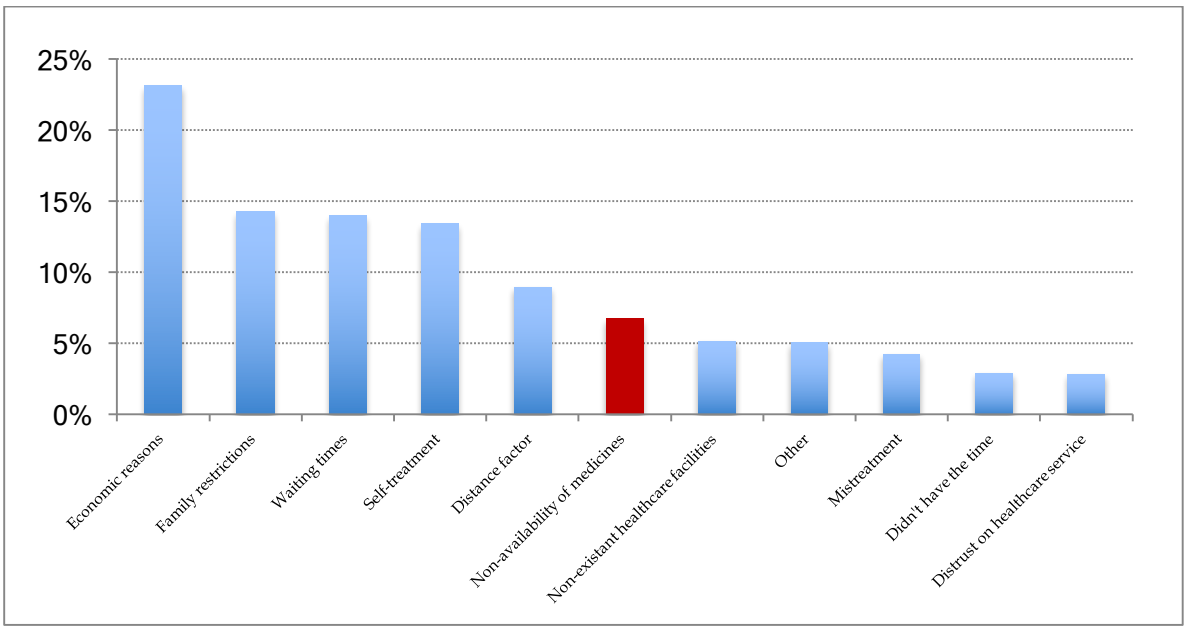
As can be seen in the table above, the approval process encompasses several stages, which are not uncalled for, given the importance of the decision of approving or not a new medicine.

3.3.3 Challenges in drugs' access

The system has important failures in terms of a patient's access to world class medications. In the 32 states, only three out of five prescriptions are provided in public institutions.[8]

Other relevant indicator of the inefficiency of the system lies amongst the many reasons why people prefer not to go to the doctor even when they need it, as reported by the National Survey of Household Income and Expenditure (*Encuesta Nacional Ingreso Gasto de los Hogares, Enigh*). On the top of the list there are economic and distance factors. The third main reason is self-treatment, which is a widespread practice among the Mexican population. A recent study revealed that almost four out of every five Mexicans continue to self-prescribe and one third of them still do it because "it is very expensive to go to the doctor". The other part found "lack of information" as a reason for self-prescribing, as well as "time restrictions".[9] These problems represent an obstacle to healthcare's access. (Graph 3).

Graph 3. Reasons why people do not go to the doctor when they need to be treated



Source: Enigh 2012

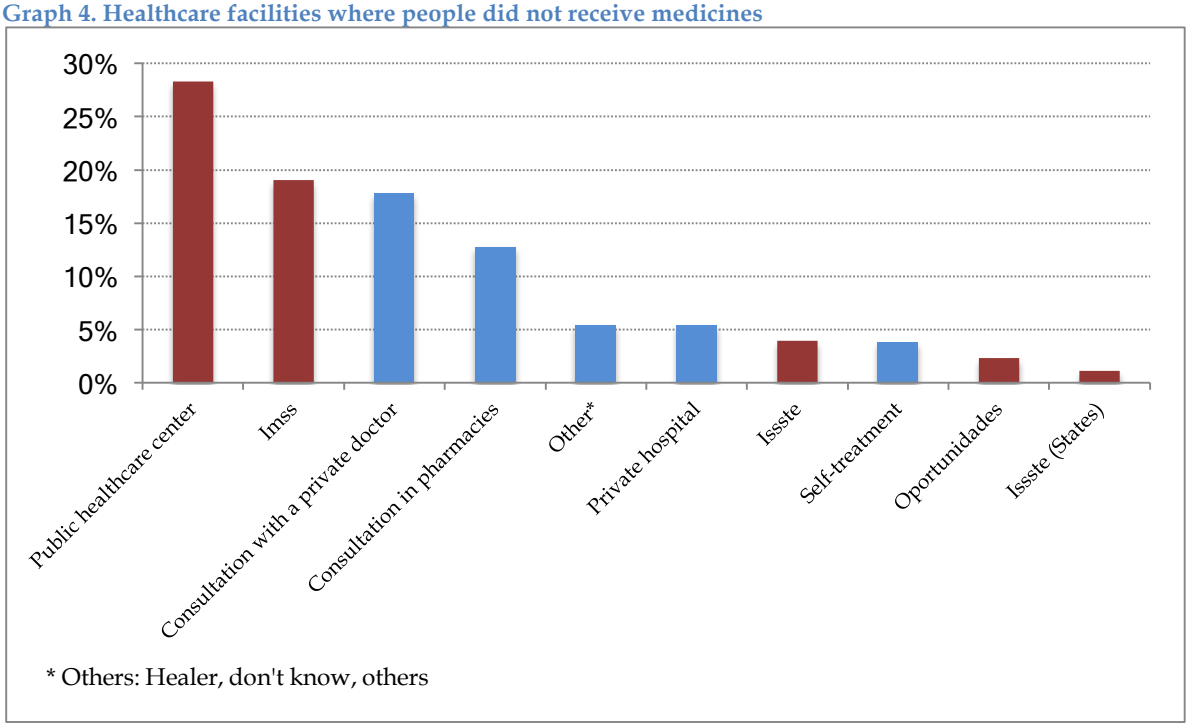
It is also worth analyzing the universe of people that claimed they did not visit the doctor *because they do not receive the medicine.* ENIGH allows us to analyze this universe by its affiliation to a given public or private healthcare coverage. The results are the following: among the people that prefer not to go to the doctor

[8] Partido Verde Ecologista www.partidoverde.org.mx/pvem/vales-de-medicinas/

[9] Encuesta telefónica sobre Automedicación, Centro de Opinión Pública Universidad del Valle de México, 2013.

because there were no medicines, 28% were on public medical centers, 19% in IMSS, 18% in private facilities and 13% in pharmaceutical ones. The fact that more than half of the people were in public institutions may show the lack of public services quality. (Graph 4)

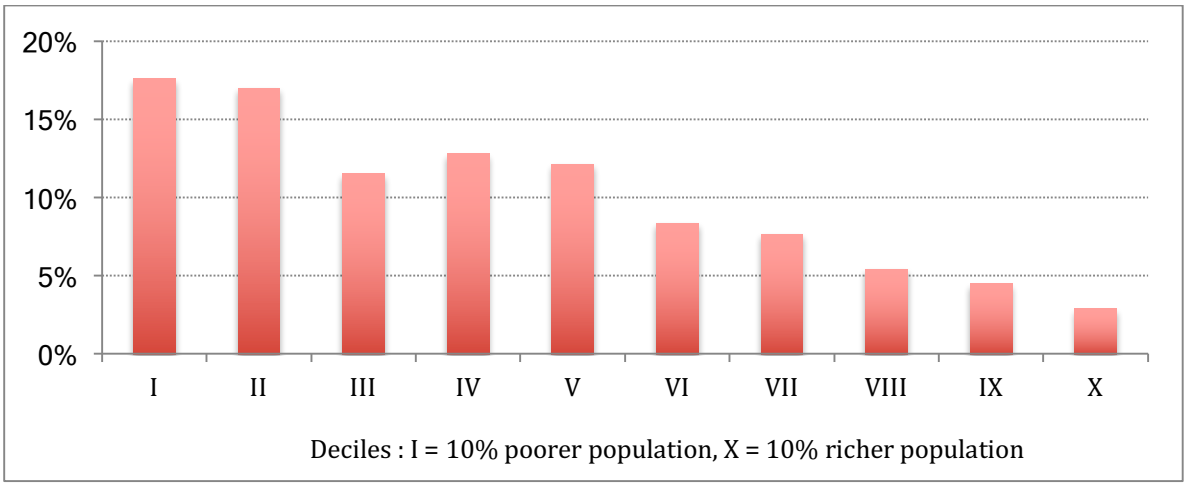
Graph 4. Healthcare facilities where people did not receive medicines



Source: Enigh 2012

The non-availability of medicines was not equally faced by all the population. In fact, 35% of households with at least a member who did not receive medicines when he/she asked for them belong to the poorest 20% population (decile I and II). Among the richest 20% (decile IX and X), only 7% experienced the lack of drugs in their healthcare institutions, mostly private practice. (Graph 5)

Graph 5. *Income level of the households with members that did not receive medicines*



Source: Enigh 2012

All these graphs represent examples of the lack of healthcare quality services that impact the access and equality to medicines in all spheres of society: public and private.

The institutions of the national healthcare system cover three kinds of users and include: a) wage-earning workers, retired workers and their families; b) the self-employed, informal workers, the unemployed, and people not currently in the labor market, and c) the population with enough resources to pay for their own private insurance. Access to medications for each of these groups is different:

- Wage-earning workers, retired workers, and their families have access to healthcare when:
  - Working for the private sector through Instituto Nacional del Seguro Social (Imss)
  - Working for the public sector through Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (Issste), Petroleos Mexicanos (Pemex), Secretaría de la Defensa (Sedena) and local public institutions

- Self-employed, informal workers, the unemployed, and people not currently in the labor market
  - Seguro Popular

- Population with enough resources to pay for their own insurance
  - Private insurance

Access to medications for each sector considered above is the following:

Table 4. Access to medication and prescription mechanism for each sector

	Wage-earning workers, retired workers and their families	Self-employed, informal workers, unemployed, and people not currently in the labor market	Population with enough resources to pay for their own insurance
Who pays for the medicine	The state through Imss, Issste, etc	The Federal and local governments through Seguro Popular for a limited set of ailments	Out of pocket or insurance medicine small discount depending on each company
Out of pocket as a percentage of the total healthcare expenditure	2.6% (as percentage of total household income in 2010)*	3.2% (as percentage of total household income in 2010)*	n.a.
Who prescribes	Doctors from each institution: Imss, Issste, Pemex, and Sedena	Doctors from the Seguro Popular affiliated hospitals	Doctors in private practice. Some insurance companies provide lists of allowed doctors
Available medicines	*Cuadro basico* and each institution's list of drugs, which must be their own version of *cuadro basico* and *catalogue of consumables*	*Catalogo de Medicamentos y otros insumos* del *Catálogo Universal de Servicios de Salud (CAUSES)*, the program's list of drugs which is a reduced version of *cuadro basico* and *catalogue of consumables.*	All drugs with a sanitary registration
Prescription restrictions	Doctors can only prescribe medicines included in each *institution's list of drugs* (own version of *cuadro basico*)	Doctors can only prescribe medicines included in the *Catalogo de Medicamentos y otros insumos del CAUSES* of Seguro Popular	Doctors can prescribe any medication in the National Pharmaceutical Market that has Sanitary registry
Legal framework	• The General Law of Health • The Internal bylaw of health consumables • Internal bylaw of the Inter-institutional Commission of *cuadro basico* and *Catalogue of Consumables* • Agreement of the Mexican public health institutions signed by December 20th 2002		The General Law of Health (Article 23)

n.a. Not available

** Knaul, F. M, González-Pier, E. et. al., The quest for universal health coverage: achieving social protection for all in Mexico, Lancet, vol. 380, October 6, 2012, p. 1272.*

As can be seen in the table above **doctors in the Mexican public healthcare sector are restricted to prescribe to their patients the drugs and medical devices that are included in each *institutional drugs list*.**

3.4 FINANCING MECHANISMS

Access to world class medications and medical devices due to limitations on freedom of prescription **is** a key element for the development of a better healthcare system and one that can be achieved with in-depth revision of its mechanisms. In order to engage in such an exercise it is convenient to understand how each part of the system is financed.

Public social security institutions are financed primarily by government contributions, contributions made by employers, and contributions made by employees. The institutions of the Department of Health and State Services receive resources mainly from the federal government, state governments, and from users that pay copayments when receiving medical services.

Table 5 Financing of each social security scheme

Private sector employees (Imss)	Public sector employees (Issste, Sedena, Pemex)	Uninsured population (Seguro Popular)	Out of pocket expenditure
The employee (contribution is based on salary)	The employee (contribution is based on salary)	The person (depending on its financial capabilities the most impoverished do not pay anything at all)	The patient
The employer	The federal government	The federal government	
The federal government		The state government	

The table above reflects some of the key aspects of the financing mechanism of the current access to medication system in Mexico: individuals contribute to the financing of the medication in the public healthcare system up to a certain extent, **but in spite of this are able to cash out said investment only through the prescription mechanisms of the *cuadro basico*, since the only point of distribution and sale are the pharmacies of each public health institution.**

This represents many challenges:

- The system to include a given medicine or medical devices in the *cuadro basico* and also in each of the different *institutional drug list* is cumbersome, lacks judicial certainty, and in spite of important advances in terms of transparency, is still vulnerable to corruption.
- The listing of medications is limited, and it rewards the coverage of basic ailments and not the necessary innovation needed to treat chronic or rare diseases. This problem is the result of the logical decision taken by the state

where it must distribute its limited resources to the most persons possible to treat the most prominent infectious diseases, essentially sacrificing the provision of innovative medications.

For doctors in public institutions, the timely and adequate prescription of both drugs and medical devices encompasses other challenges besides the restricted offer of the *cuadro basicos* and *institutional drug lists*:

- A given medication and/or medical device might be included in the *cuadro basico* or *institutional drug list*, but this does not guaranteed that it will be available for the patient in pharmacies. **The supply of drugs and/or medical devices in the Mexican public healthcare institutions has to be done through the pharmacies of each institution**[10]
- This situation hinders efficient access to medication well beyond *cuadro basico* and *institutional drug list* for many reasons:
    - Supply in each institutional pharmacy is not always timely and sufficient.
    - Medication and/or medical devices' supply for institutional pharmacies is controlled by distributors, a situation that sometimes allows for manipulation of the market.
    - There is ample room for corruption, black market and even thefts.

Thus, Mexicans who are limited to use the public healthcare institutions and are no able to afford private healthcare (including out of pocket expenditure for medications), face a supply of medications that is often poor, archaic and insufficient to meet their needs. Moreover, patients are not, though they should be, informed of alternatives to their prescription (usually alternatives are more expensive, but also more innovative and effective) to have the option to choose to finance these alternatives through their own expenditure if they see fit.

The many challenges of the Mexican public healthcare system are, of course, not limited to the supply of medications and medical devices; they encompass many others such as saturation of public institutions, lack of sufficient human resources (which many times accounts for poor and untimely diagnosis), and insufficient healthcare infrastructure, especially in isolated communities.

It is worth mentioning that in the private sector, Mexican employers complain that their expenditure per employee in social security is high and inefficient, since the Imss system is so strained that their employees are sometimes not able to access it and the employer faces the dilemma of paying for a private insurance, with the consequence of duplicating health expenditure.

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[10] There are some exceptions: the states of Nuevo Leon, Guanajuato, Campeche and Queretaro have implemented incipient mechanisms to supply medical prescriptions from the public system in the private sector pharmacies. By 2012 the percentage of prescriptions supplied through this mechanism was very small, it accounted only for 2% of all the medical prescriptions of the public healthcare system of each state.

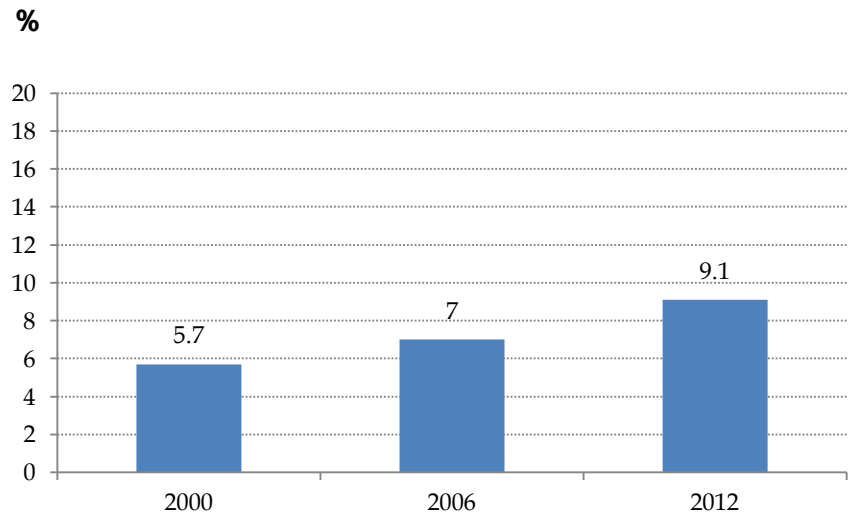
On the other hand, workers both in the private and public sector complain that their monthly contribution to the public healthcare system is high and results in poor quality healthcare, since they are not able to enjoy timely diagnosis, freedom of prescription, prevention mechanisms, quality hospital infrastructure and all the other elements of world class healthcare that, nevertheless, they pay for through their contributions.

3.5 HEALTHCARE PERFORMANCE

Regarding public government expenditure, Mexico has increased its public healthcare expenditure over GDP by 21.4% in eleven years. This has allowed for a dramatic enhancement of the general healthcare profile. Nevertheless this improvement has not sufficed to guarantee quality public healthcare to all the population and, moreover, it shall not suffice to address the future needs of the system with the new health profile of the Mexicans.

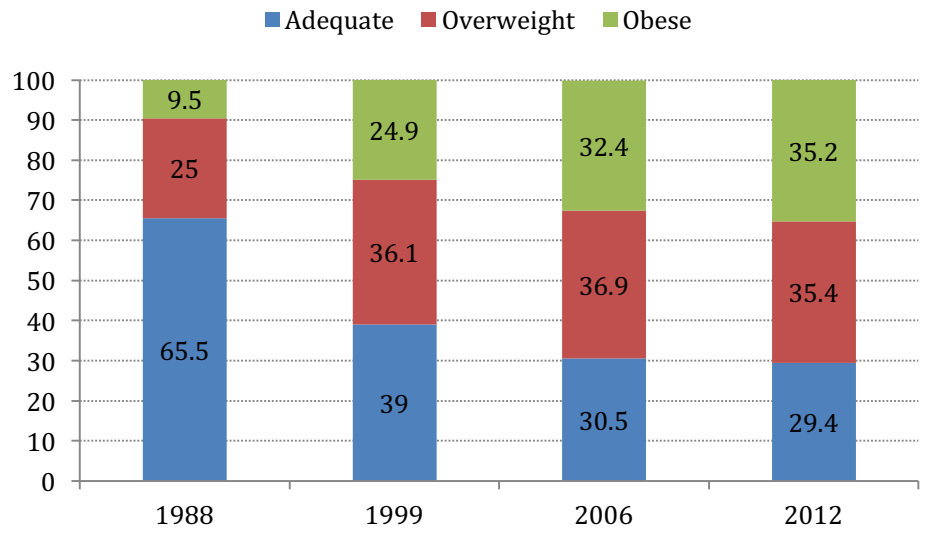
These challenges are already evident: prevalence of patients with diabetes mellitus in Mexico increased 59.6% between 2000 and 2012; the percentage of women that present obesity levels increased 270% (from 9.5% in 1998 to 35.2% in 2012); and patients with hypertension account for 62% of the population over 40 years of age.

Graph 6. Prevalence of patients with Diabetes mellitus diagnosis



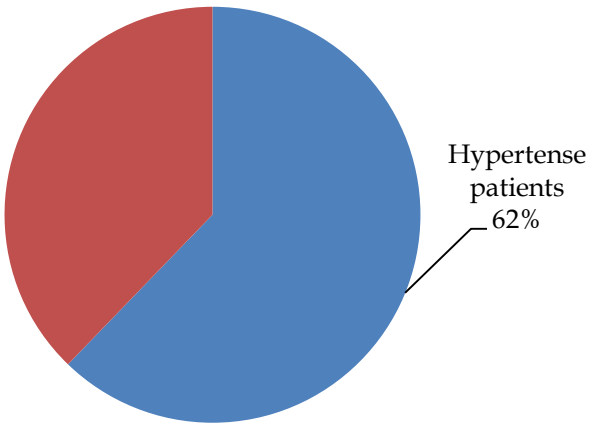
Source: ENSANUT 2012

Graph 7. Body mass index (%)



Source: ENSANUT 2012

Graph 8. Population over 40 in Mexico 2013



Source: ENSANUT 2012

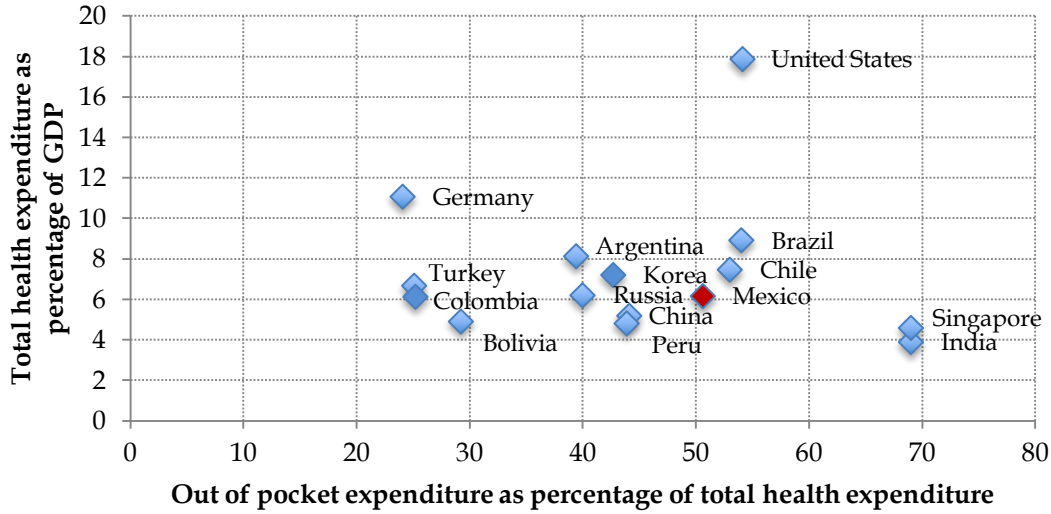
Another clear symptom of the inefficiency of the Mexican public healthcare system is the fact that private pharmacies have opened *in-situ* medical premises that are many times headed by recently graduated doctors and residents who have just obtained the certification to prescribe. Out of 23,000 private sector pharmacies in Mexico, 43% provide the service.[11] The results are ambiguous: while these medical premises alleviate the stress over public healthcare institutions, diagnosis in them is often

[11] GALVÁN OCHOA, Enrique, in *MVS noticias with Carmen Aristegui*, MVS, Mexico City, August 29th 2013.

poor and untimely. **Not only the evident conflict of interest derives in overprescription, a dangerous practice that requires better government regulation and surveillance, but also out of pocket expenditure increases among families with low and middle income.**

But the evidence of the Mexican public healthcare system low performance is not only in the future but in the current available data. As can be seen in the graph below, Mexico has a very high rate of out of pocket expenditure over GDP percentage allocated to healthcare.

Graph 9. Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011



Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

The graph above is very enlightening in terms of the analysis of how efficiently are public healthcare systems able to cover the healthcare needs of its population. An efficient public healthcare system should aim to cover the healthcare needs of its population with direct proportion to its healthcare expenditure as a percentage of GDP. In other words, a country that allocates a high percentage of its GDP to healthcare, should not have a high out of pocket expenditure because this implies that the country has an expensive public healthcare system that is not able to address the needs of its population (hence their need to incur in out of pocket expenditure).

There are some exceptions, though. A country that does not aim to guarantee universal coverage through its public healthcare system and rather aims to build the economic conditions for its population to afford private healthcare will indeed have a very high out of pocket expenditure but its percentage of GDP allocated to healthcare expenditure should be low, this is the case of Singapore. Nevertheless, governments usually aim to the opposite: providing universal healthcare coverage to

its population, or at least to the most vulnerable groups, through public healthcare system.

Mexico is inefficient in its public healthcare expenditure. The graph above shows that it expends 6.15% of GDP in health but faces 50.6% of out of pocket expenditure. The case of another high population country, such as Russia, that has 142 million of inhabitants, allocates 6.2% of GDP to healthcare and only 40% of out of pocket expenditure. The inefficiency of the Mexican is evident.

Moreover, in Latin America, whose countries are more easily comparable to Mexico in terms of their economic and cultural profiles, Colombia achieves with a 6.1% of healthcare expenditure over GDP an out of pocket of merely 25.2%.

The challenge of Mexico in terms of the financing of its healthcare systems is, therefore, **in the efficiency of the system and in spending its resources wisely. In this task freedom of prescription has a key role to play. It can contribute to improve the access to quality drugs and open the door for a more efficient financing medication schemes in the public sector, that are as to date, absent in the Mexican system, namely co-payment and reimbursement.**

3.5.1 Competitiveness

How does freedom of prescription in Mexico impact competitiveness? In order to answer this question, information on competitiveness levels in Mexico is included in the following paragraphs.

In the last decade, Mexico has improved its general competitiveness due to many factors, which include macroeconomic stability, inflation control, trade opening, and the general improvement of social indicators such as health, education, housing, financial access, and many others.

In spite of these improvements, Mexico has not been able to reach the level of competitiveness of the advanced economies and of its main trade partners. The reasons for this are many, but one of the most relevant is the fact that Mexico is immersed in what Claudio Loser and Harinder Kohli have labeled *the trap of the low income,* this is a common characteristic of the countries that are no longer able to offer as a comparative advantage at low cost work force, but whose work force are not yet sufficiently qualified to develop top of the art innovation and technology.

Healthcare is well rooted in the causes for this impasse. According to the World Economic Forum (WEF)[12], a healthy workforce is vital to a country's competitiveness and productivity. *Workers who are ill cannot function to their potential and will be less productive. Poor health leads to significant costs to businesses as sick workers are often absent or operate at lower levels of efficiency.* Amongst the health indicators closely related to competitiveness and measured by the WEF are: business impact of malaria, malaria incidence, business impact of tuberculosis, tuberculosis incidence, business of HIV, HIV prevalence, infant mortality and life expectancy. Meanwhile, the Mexican Institute for Competitiveness (IMCO) measures the following health

[12] Schwab, K., *The Global Competitiveness Report 2012–2013,* World Economic Forum, 2013.

indicators: life expectancy, out of pocket health expenditure, teenage pregnancy, and infant mortality. In both indexes Mexico ranks poorly.

Table 6. Mexico's position in competitiveness indexes

Mexico's general position	
World Economic Forum	IMCO
53th/144	32th/46
Mexico's position in the healthcare pillar	
World Economic Forum	IMCO
68th/144	35th/46

Source: Imco and WEF

The health challenges of Mexico are many and diverse, depending on the sector that is analyzed. In spite of its economic performance of recent years, the country has an important percentage of its population experiencing levels of poverty that rank from extreme to moderate; this sector's health challenges are similar to those in least developed countries: infectious diseases, malnourishment, lack of immunization, low weight at birth, etc. On the other hand, the buoyant middle class in the Mexican urban centers experiences health challenges related to a sedentary life style, increased economic capacities and longer life expectancy; some of these challenges are chronic illnesses, weight conditions and mental illnesses, among many others.

Both facts represent an important stress over the national budget allocated to healthcare. National and state governments most struggle between the responsibility to address the needs of the population in poverty conditions, and the ever so pressing health demands of the middle class. Diabetes, an illness clear linked with a sedentary life style is, for example, one of the most expensive conditions in Mexico and one that implies a burden to the health budget.

Therefore, it is clear that middle class Mexicans require to access first rate medications that provide efficient treatment to chronic illnesses, but this access would constrain the public budget that still has to be allocated both to the attention of health conditions in impoverished sectors and to the strengthening of the whole of the national public healthcare system.

In this challenge, freedom of prescription has an important role to play.

3.6 Assessment of the Prescription mechanism in the Mexican public healthcare system

The Mexican framework constrains freedom of prescription in several ways:

- First, the legal requirements to prescribe limit the freedom of prescription. However, these conditions are considered rational. Expressing the drugs'

generic denomination and the prescriber's professional information in the medical prescription are two **conditions existent in almost all countries**.

- Second, *cuadro basico* and *catalogue of consumables* are government mechanisms to achieve the balance between patients' and doctors' rights in a context of scarce resources. These mechanisms limit the freedom of prescription in public institutions, but represent a minimax government decision. However, **it fails to consider the WHO notion about the rational use of medication**, specifically, because patients in public institutions are not informed with the maximum information available about the appropriate medications to their clinical needs, independently of the inclusion of such treatments in the *cuadro basico* and *catalogue of consumables*.

- Third, as long as each public institution produces its own institutional drugs list (its own version of *cuadro basico),* freedom of prescription will be constrained by the fact that the **universe of drugs covered by these lists differs** from one institution to the other. The more restricted the institution's budget, the poorer the number and quality of drugs included in the *institutional drugs list*. This is particularly true in the case of Seguro Popular, which limits ailments subject to coverage.

- Fourth, the approval process to register drugs into the *cuadro basico*, and *catalogue of consumables* is inefficient due to **limited information**: the cost-effective assessments to decide whether a drug is included in *cuadro basico* and *catalogue of consumables,* does not consider dimensions such as the patients' quality of life.

- Fifth, the main criterion that currently determines *cuadro basico*, *catalogue of consumables* and the *institutional drugs lists* is the budget. Amongst the three composite elements in freedom of prescription, that is to say, patients' rights, doctors' rights and responsibilities, and government scarce resources, the latter **prevails in the daily practice** with arbitrary limits to the yearly costs of treatment.

4 FREEDOM OF PRESCRIPTION IN UNITED STATES

4.1 SUMMARY

The USA is one of the richest countries in the world and one that strongly champions both intellectual property protection and freedom of prescription. Most of its population enjoys private insurance and, thus, almost absolute freedom of prescription.

For those that are not able to access private insurance, there are four main public programs: Medicaid (for people with low incomes), Medicare (for the population over 65), the Children's Health Insurance Program (children of families that are not poor enough to be in Medicaid but cannot afford private insurance) and the Veterans' Health Administration.

Freedom of prescription in this document shall be analyzed only for Medicaid and Medicare. In each system, the prescription mechanism is the following:

- Medicaid: Pharmaceutical companies enroll in a drug rebate program in each state.
- Medicare: Access to medicines is through Part D of the program, and **financed** through private insurance companies, the government and the patient. There are different plans, and each plan has a medicine formulary or list.

The system is far from perfect, but it allows for better access to medicine than the Mexican one, since only 10.3% of the population responded in 2011 that money was the reason they got "*did not get or delayed medical care due to cost*"[13] while the Mexican Household Income and Expenditure Survey shows that nearly 25% of the surveyed universe manifested that economic reasons were behind the fact that they did not receive timely medical attention (Graph 3).

The strength of the American healthcare system is centered in the following factors:

- A large percentage of its population is able to afford private insurance
- For those who are not able to afford private insurance, the public programs are not financed solely by the government, but allowed for mixed schemes of discounts and copayments

4.2 PRESCRIPTION MECHANISM

The United States is one of the few OECD (Organization for Economic Co-operation and Development) countries that do not automatically offer its citizens healthcare. The majority of Americans have private health insurance, usually provided by their employers, or in the case of public servants, by the federal or state governments, depending on the case.

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[13] *National Health Interview Survey 2012, family core, sample child, and sample adult questionnaires (includes all races, unknown health insurance status, unknown education level, and unknown disability status).*

Medical prescription in private health insurance is, indeed, very ample in terms of freedom of prescription. Doctors can prescribe any medication which has been approved by the Federal Drug Administration (FDA) and the financing of said medication depends on each private insurance scheme.

Medical prescription in the percentage of the American population that lack private insurance is provided by the different public programs. These programs are:

- **Medicare**: provides medical services to people aged over 65 and the disabled.
- **Medicaid**: provides medical services to people with low incomes. Every state in the country has a Medicaid program.
- **Children's Health Insurance Program:** provides medical services for children belonging to families that lack the sufficient resources to be covered by Medicaid or a private health insurer.
- **Veterans Health Administration:** An independent medical system established for veterans that administers its own medical facilities such as hospitals, health clinics, long term care centers, and residence centers.

Thus, in order to analyze the level of freedom of prescription in the American public healthcare system it is necessary to describe how such prescription is applied in Medicare and Medicaid.

4.3 Legal framework of Medicaid and Medicare

Medicaid and Medicare have similar legal frameworks and share similar legislative genesis. They were created in 1965 by the **Social Security Amendment** in order to help state governments to provide medical coverage for low income families and the elderly. The United States Government aimed to create a social security mechanism that encompassed the following[14]:

- Establishment of a program to provide medical assistance for the needy or medically needy aged, blind or disabled persons and dependent children.
- Increased federal sharing in assistance payments to the aged, the blind, the disabled and dependent children.
- Removal of limitations on federal participation in assistance payments with respect to aged persons in tuberculosis and mental disease hospitals under certain conditions.
- Establishment of two related national programs for the aged (a basic plan affording protection establishment of two related national health insurance programs for the aged) and a voluntary supplementary plan covering payments for physicians services and other medical and health services.

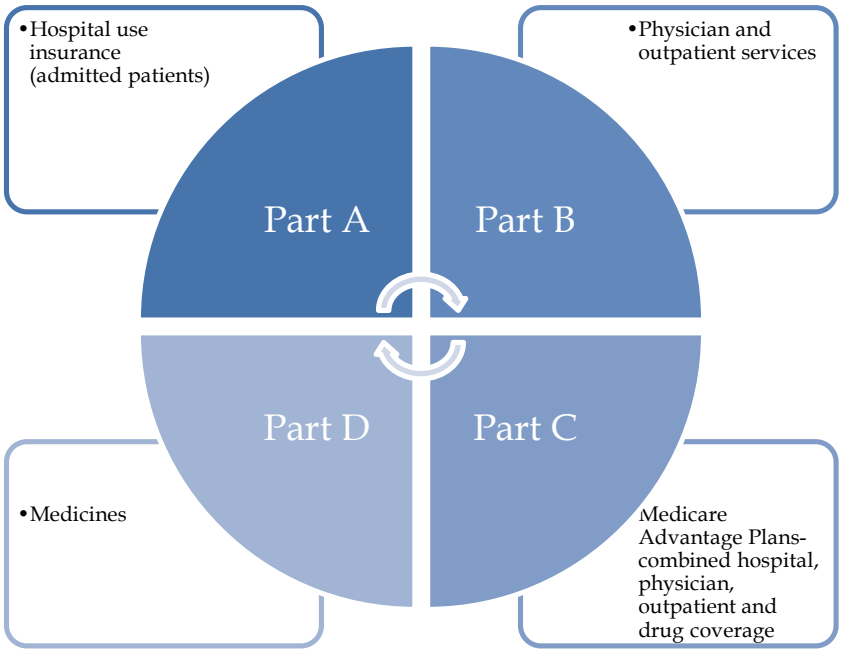
Other key legal sources of Medicaid and Medicare are the Omnibus Budget Reconciliation Act of 1993 (OBRA-93) and The Patient Protection and Affordable Care Act of 2010, that although is focused on the private market can be expanded to Medicaid and encompasses relevant changes to Medicare.

[14] Cohen and Ball, Social Security Amendments of 1965: Summary and Legislative History.

4.4 MEDICARE: UNIVERSE OF DRUGS

Medicare[15] is structured for adults older than 65 years, **the disabled, and patients with ESRD**, and is made up by four key elements: A, B, C, and D.

Graph 10. Medicare key elements



The following section will be focused on part D, the one related to medicine administration. Depending on their choice of plan to Medicare patients can acquire a variety of medicines that are covered in part D.

Part D is also called The Medicare Prescription Drug Benefit and it is a **federal program** to subsidize the cost of prescription drugs for Medicare beneficiaries.

Unlike Parts A and B, which are administered by Medicare itself, Part D is "privatized." That is, Medicare contracts with private companies that are authorized to sell Part D insurance coverage, or **plans**.

Within parameters established in law, plans are free to establish their own formularies. There is an appeal process for members who need drugs that are not on their plan's formularies. However, there are 4 protected classes as well, for which all or substantially all drugs must be covered.

The only restriction for the elaboration of a Part D formulary is that the latter does not discourage enrollment by certain Medicare beneficiaries. Part D plans that follow the formulary classes and categories established by the United States Pharmacopoeia will pass the first discrimination test. Plans can change the drugs on their formulary during the course of the year with 60 days notice to affected parties.

[15] Center for Medicare Advocacy Inc. www.medicareadvocacy.com

Plans may revise their formularies every year, adding new drugs, eliminating others. Beneficiaries may re-evaluate their plan options every year to be sure their chosen plan will continue to meet their financial and medical needs.

Part D drug coverage excludes drugs that are not approved by the FDA and drugs not available in the United States. Some drugs are covered by both Part B and Part D.

It is worth mentioning that Part D of Medicare also excludes drugs that **may** be excluded from specific Medicaid coverage (meaning state coverage). Those drugs will be enlisted in the Medicaid section.

4.5 MEDICAID: UNIVERSE OF DRUGS

Although pharmacy coverage is an optional benefit under federal Medicaid law, all States currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their Medicaid programs.

In Medicaid (the health insurance scheme that the government designed to assist members of the population that have low incomes), medicines are allocated based on the *Medicaid Drug Rebate Program* (MDRP). The MDPR is a strategic association between Medicaid, the Children's Health Insurance Program, and pharmaceutical companies by which pharmaceutical companies provide **the medicines required by patients** under a specific program of discounts and rebates.

4.6 FINANCING MECHANISMS

The financing systems of Medicare and Medicaid are as follows:

4.6.1 Financing system of Medicare's prescription mechanism

Prior to 2006, Medicare paid for some drugs administered during a hospital admission (under Medicare Part A), or a doctor's office (under Medicare Part B). Medicare did not cover outpatient prescription drugs until January 1, 2006. One of its key components is the drug benefit (also known as "Medicare Rx"), that helps Medicare beneficiaries to pay for outpatient prescription drugs purchased at retail, mail order, home infusion and long-term care pharmacies.

As mentioned before, unlike Parts A and B, which are administered by Medicare itself, Part D is "privatized." That is, Medicare contracts with private companies that are authorized to sell Part D insurance coverage. These companies are both regulated and subsidized by Medicare, pursuant to one-year, annually renewable contracts. In order to have Part D coverage, beneficiaries must purchase a policy (i.e., enroll in a plan) offered by one of these companies.

The costs associated with Medicare Part D include a monthly premium, an annual deductible (sometimes waived by the plans), co-payments and/or co-insurance for specific drugs, a gap in coverage called the "Donut Hole", (which as mentioned before the Patient Protection Act aims to eliminate) and catastrophic coverage once a threshold amount has been met.

Qualified low income individuals can receive help with their Part D costs for premiums, deductibles and co-pays through the Part D Low Income Subsidy

(known as "LIS" or "Extra Help"), which is administered by the Social Security Administration.

Medicare does not administer Part D directly. It contracts with private companies that are approved to sell Part D insurance coverage. There are two main sources of prescription drug coverage:

- **PDPs (Prescription Drug Plans)** – these are stand-alone companies that sell prescription drug coverage only. They do not offer hospital or medical coverage.
- **MA-PDs (Medicare Advantage Prescription Drug Plans)** – these plans offer hospital, medical and prescription drug coverage under a single policy, (Medicare Advantage is equivalent to Part C).

To meet medicinal costs, Medicare has a payment scheme that combines discounts, copayments made by patients (amounts vary depending on patient contributions but generally premiums are $100 and deductible expenses are set at $325 for 2013), payments made by the government to cover catastrophic expenditures, and a financial gap that exists in the payment scheme known as the "donut hole". The scheme is structured as following:

Table 7. Part D benefit 2010-2013

	2010	2011	2012	2013
Annual Deductible Maximum	$310	$310	$320	**$325**
Member pays 25% of the next…	$2,520 (25% = $630)	$2,530 (25% = $632.50)	$2610 (25% = $652.50)	**$2645** (25%=$661.25)
Initial Benefit Period Maximum (what the member AND the plan have spent)	$2,830 ($310 + $2,520)	$2,840 ($310 + $2,530)	$2,930 ($320 + $2,610)	**$2,970** ($325 + $2645)
DONUT HOLE	$3,610	$3,607.50*	$3725.50	**$3763.75**
Member pays 100% of the next… ("TrOOP")	(starting in 2010, $250 rebate)	(starting in 2011 prices are discounted, see below)	(brand discount 50%, Generic discount 14%)	(brand discount 52.5%, Generic discount 21%)
Catastrophic Coverage	$4,550	$4,550	$4,700	**$4,750**
Begins when member (NOT plan) has spent a total of…	($310 + $630 + $3,610)	($310 + $632.50 + $3,607.50	($320 + $652.50 + $3,725.50)	($325 + $661.25 + $3763.75)
Cost sharing during Catastrophic Coverage	$2.50/$6.30 or 5% (which-	$2.50/$6.30 or 5% (whichever	$2.60/$6.50 or 5% (whichever is higher)	**$2.65/$6.60** or 5% (whichever is higher)

	ever is higher)	is higher)

4.6.2 Financing system of Medicaid's prescription mechanism

As mentioned, the Medicaid drug rebate program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) **in exchange for State Medicaid coverage of most of the manufacturer's drugs**. Manufacturers are then responsible for paying a rebate on those drugs each time that they are dispensed to Medicaid patients. These rebates are paid by drug manufacturers on a quarterly basis and are shared between the States and the Federal government to offset the overall cost of prescription drugs under the Medicaid Program.

In addition to signing a national rebate agreement, drug manufacturers are required to enter into agreements with two other Federal programs in order to have their drugs covered under Medicaid: a pricing agreement for the Section 340B Drug Pricing Program, administered by the Health Resources and Services Administration, and a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule.

Despite the fact that Medicaid faces a number of challenges, the discount program offers an array of advantages: Low-income patients can access an enormous pool of medications with a discounted price (including innovative medications) whose supply is dependent on the pharmaceutical market (medicines are obtained at pharmacies) and not on a health institution (as is the case in Mexico).

Medicaid's list of discount medications is much more comprehensive than Mexico's *cuadro basico and catalogue of consumables* of medications because:

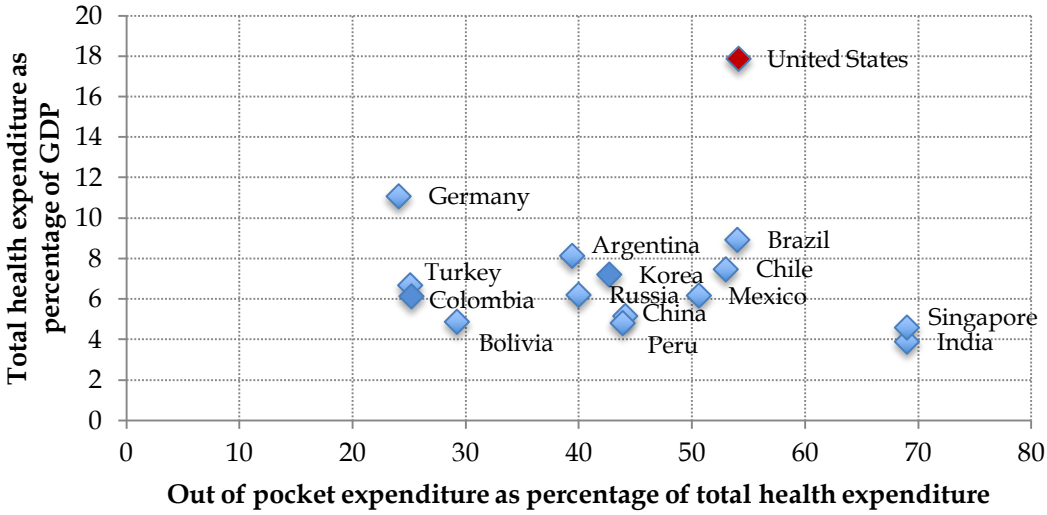
- Pharmaceutical companies have a lot of incentives to participate with Medicaid (guaranteed government financed reimbursement for the expenses that pharmaceuticals have to make to cover the discounted medication prices offered to patients, state and national coverage, in function of the application submitted by pharmaceuticals to join a state's Medicaid program).
- **Physicians have the freedom of prescription with Medicaid medicines (there are about 550 pharmaceuticals registered with Medicaid).**

The amount of rebate due for each unit of a drug is based on statutory formulas as follows:

- **Innovator Drugs** – the greater of either 23.1 % of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.
- **Blood Clotting Factors** – the greater of either 17.1 % of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.

- **Drugs Approved by FDA Exclusively for Pediatric Indications** – the larger of 17.1 % of the AMP per unit or the difference between the AMP and the best price per unit and adjusted by the CPI-U based on launch date and current quarter AMP.
- **Line Extensions –** For a drug that is a new formulation (line extension) of a brand name drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:
    - the AMP for the line extension drug,
    - the highest additional rebate for any strength of the original brand name drug, and
    - the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).
- **Cap on Total Rebate Amount for Innovator Drugs –** The limit on the total rebate amount for each innovator drug is at 100 percent of the AMP.
- **Non-innovator Drugs** – 13 % of the AMP per unit.
- In terms of the efficiency of healthcare expenditure as percentage of GDP when compared with the out of pocket expenditure of the population, the USA is one of the most inefficient, but a clear reason for this is the fact that the majority of its population has private insurance (which is expensive) and, even so, many times patients have to face copayments in insured schemes besides having access to the most expensive and top of the art drugs.

- **Graph 11. Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011**



Note: Out of pocket expenditure as a percentage of health expenditure
Source: Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

As can be seen in the graph above, USA has nearly 18% health expenditure over GDP and 54.1%of out of pocket expenditure. The graph could seem deceiving as to the general profile of health in the USA. In spite of the high amount of out of pocket

expenditure, the country has some of the **best** health indicators in the world, as will be seen in the section below.

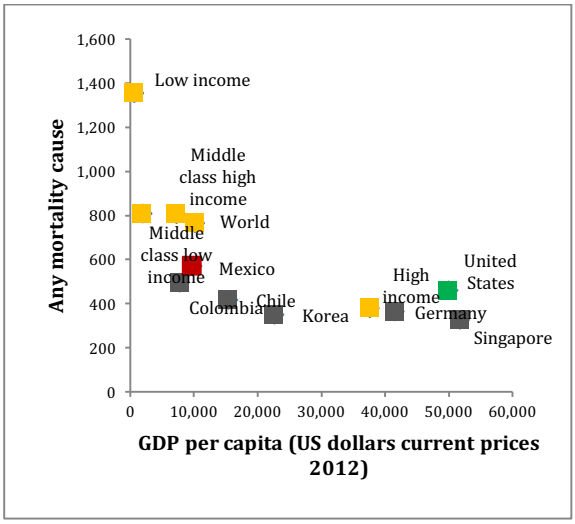
4.7 HEALTHCARE PERFORMANCE

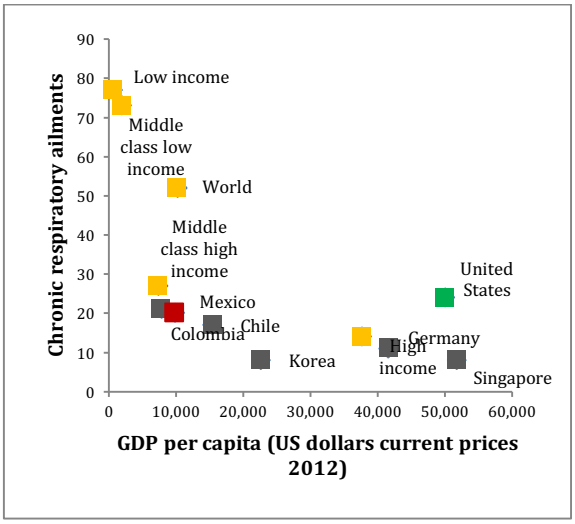
4.7.1 Main indicators

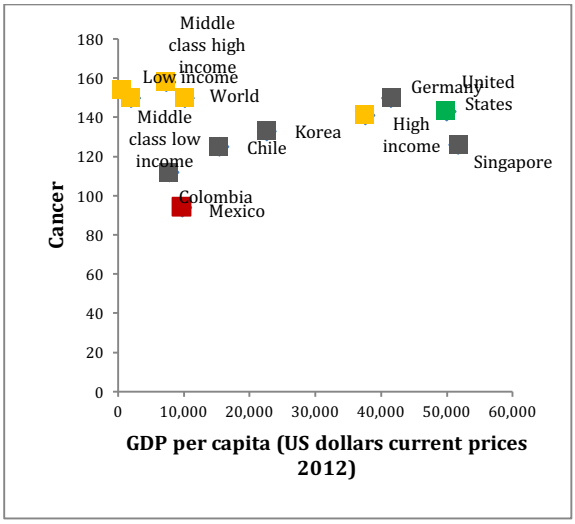
How do we analyze the performance of a health system in face of its level of freedom of prescription? The most logical answer is through ailments whose treatment is heavily dependent on innovative medications and treatments (hence, patent medication). Therefore we have chosen health indicators regarding these ailments that are provided by the World Health Organization: diabetes, cancer and chronic respiratory diseases. We also provide basic health indicators, such as life expectancy and the mortality rate of infants under 5 years of age (death probability before turning 5 years per 1000 live births).

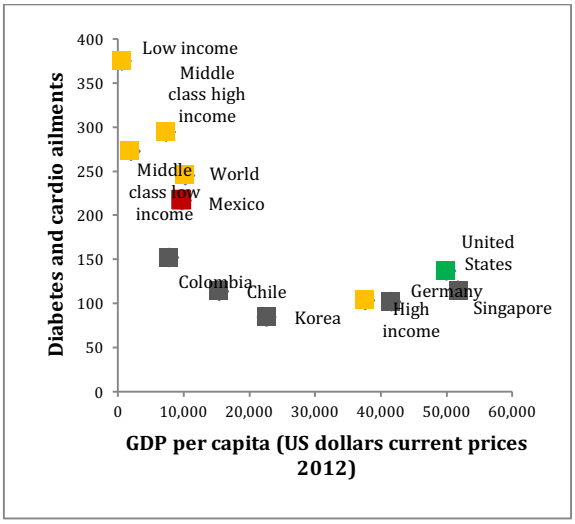
The WHO provides indicators both for each country and for countries grouped by income level (low income, middle class low income, middle class high income and high income). Thus, it is possible to analyze not only the national indicator for each ailment, but also its relation with the income levels of the population. **The results are clear: countries that achieve a lower mortality rate in these ailments are also countries with high GDP per capita indicators.**

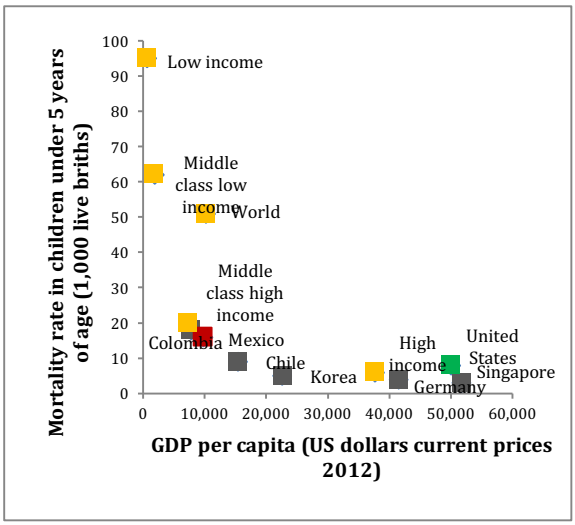
Graph 12 Key performance indicators for the USA health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

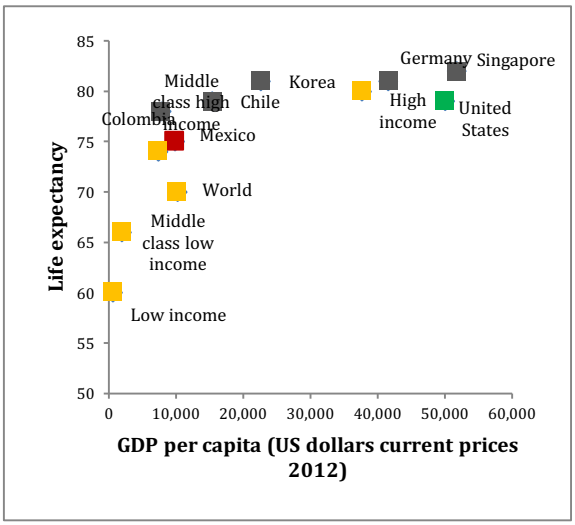












Source: World Health Statistics 2013

The fact that the United States does not provide universal public healthcare coverage to its population has resulted in a significant number of Americans not having a "usual source of healthcare", which in 2011 it amounted to 19.6% of the population[16]. It is important to note that this portion of uninsured Americans includes both employed and unemployed.

Nevertheless, the efficiency of the system can be traced in the graphs above: the country ranks very highly in terms chronic respiratory ailments (low rate of mortality), life expectancy (79 years), and mortality rate in children under 5 years of age /1000 live births, 2011. It is also worth mentioning that although the USA shares with Mexico the obesity challenges, **the country has achieved a much better treatment for diabetes indicator (mortality rate)**. In the year considered (2008), the mortality rate for Mexico in diabetes was 217 and 137 for the United States.

4.7.2 Competitiveness

USA ranked in the 34th position out of 144 in the World Economic Forum Health Pillar and in position 17th out 46 in the International Competitiveness Index of the Mexican Institute of Competitiveness (IMCO). In the Global Competitiveness Index of WEF it ranked 5th out of 144 countries analyzed and in IMCO it ranked 12th out of 46.

Table 8. United States' position in competitiveness indexes

USA general position	
World Economic Forum	IMCO
5th/144	12th/46
USA position in the healthcare pillar	
World Economic Forum	IMCO
34h/144	17th/46

The analysis of USA ranking in the Health Pillar of the WEF index serves as a clear indicator of the country's strengths and challenges concerning healthcare: the USA ranked 1st amongst the 144 countries analyzed in terms of the business impact of malaria and the malaria cases/100,000 inhabitants (malaria is fully eradicated from the USA), and ranked in the 8th position on tuberculosis cases/100,000 inhabitants. In spite of these indicators that suggest that the USA has achieved the levels of healthcare of developed countries, the indicator of infant mortality is surprisingly high considering the country's development levels (6.4/1,000 births) which implies a position of 41 out of 144 countries.

[16] National Health Interview Survey, access to care

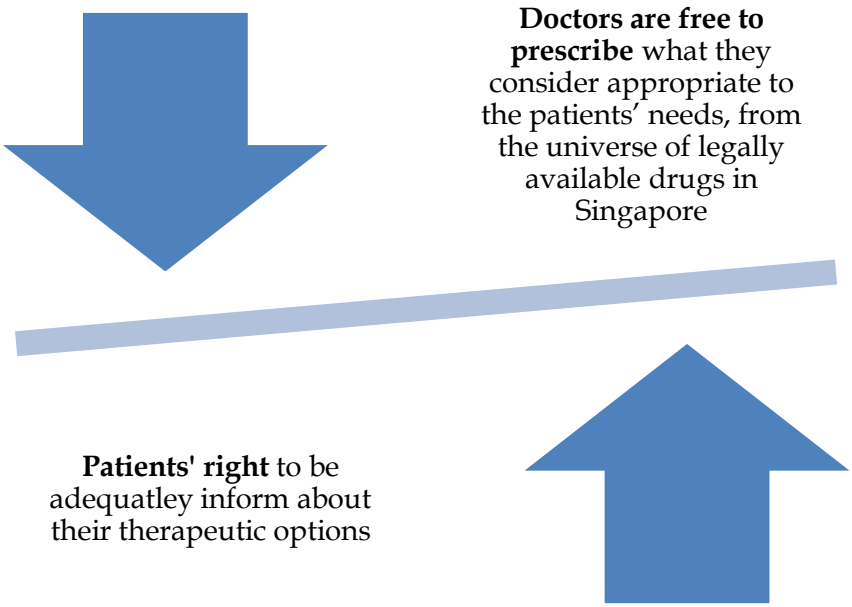
5 FREEDOM OF PRESCRIPTION IN SINGAPORE

5.1 SUMMARY

- Doctors have absolute freedom to prescribe over the universe of drugs that only meet the legal requirements to be sold in Singapore
- Singaporeans have access to first class medication
- Freedom of prescription applies both for doctors of public and private healthcare institutions
- Drugs are classified in four categories; two of them need a prescription to be dispensed
- Framework is flexible and implements efficiently drugs reclassification process
- In the last decade, government has increased its resources on health, since out of pocket expenditure is considerable high
- Singaporeans under 5 years of age have one of the lowest mortality rates in the world
- Singapore ranked 2º position in the latest Global Competitiveness Report of the World Economic Forum

5.2 PRESCRIPTION MECHANISM

Singapore has a healthcare system that enforces the participation of private institutions and where the medical profession is considered as a self-regulating activity. This approach influences freedom of prescription, as well. Singaporean framework achieves a balance between patients' and doctors' rights in a context of scarce resources as follows:



Doctors have freedom to prescribe upon the universe of drugs that meet the legal requirements to be sold in Singapore, which is one of the broadest sets of medicines that can be prescribed. This means that in Singapore, **doctors have almost absolute freedom of prescription**.

Patients are appropriately informed about the purpose of the drugs, contraindications and possible side effects so that they can make informed choices about their therapeutic options. This activity is considered part of **doctor's responsibility**.

Doctors' responsibility to prescribe what they consider adequate to the patients' health condition does not have differences among doctors of public and private institutions, since **the universe of permitted drugs to prescribe is the same**. The fact that a citizen could receive a prescription with any legal drug in Singapore, contrasts with other countries, where a limited list of drugs is compulsory for doctors of public institutions.

The government overcomes the problem of limited resources not by producing a limited list of drugs, like many countries, but instead through **insurance schemes with co-payment** offered by government, and subsidies for low income citizens, both will be explained in the Financing section.

5.3 LEGAL FRAMEWORK

The legal framework regulating the prescription process comprises a group of acts. First, the *Medicines Act* controls drugs (mainly Chinese and Western ones) and regulates the licensing process. Then the *Health products Act* was set up in 2007, a regulation instrument aiming to provide the classification of health products according to their different uses, and to shape their utilization to protect consumer's health. Third, the role of the *Private hospitals and medical clinics Act* is to allow healthcare facilities such as hospitals, medical centers, nursing home and community health centers to have license and operate in Singapore. The aim of this licensing

requirement is to provide a good standard of medical and clinical services, which is very high in Singapore.

As mentioned above, in Singapore doctors' practice is conceived as a self-regulated activity. However, there is one key instrument that serves as a reference to guide doctors' practice. The *Ethical code and Ethical guidelines* produced by the Singapore Medical Council, describes patients' rights to information and self-determination as well as doctors' responsibilities with patients, that is to say, the balance between patients' and doctors' rights and limited resources in freedom of prescription. However, this instrument is only an invitation to guide doctors' practice, and lacks of legal grounds sometimes required to implement its contents.[17]

5.4 UNIVERSE OF DRUGS

All drugs that are legally sold in Singapore are susceptible to be prescribed. This universe is composed by medicinal products defined as *any substance or article which is manufactured, sold, supplied, imported or exported for a medicinal purpose*[18], granted with a license. **Since most of these drugs are imported, the licensing process represents a key element for freedom of prescription.**

Medicines are divided into: 1) Prescription only Medicines (POM), 2) Pharmacy only (P), and General Sales List (GSL). The first group is exclusively supplied by a doctor or by a pharmacist through a prescription. The second group is sold by a pharmacist, who is obliged to record patient's personal data to track medication usage. The third and last set includes medicines that can be purchased off the shelves.

This **classification represents the core of the medicines supply system because it determines the requirements and doses to have access to medicines.** Moreover, the classification seems to be flexible enough to allow exemptions. In fact, HSA performs several reviews every year to identify POM's exemptions, which are defined as POM's medicines that may be supplied without prescription as they are proved to be safe for use with reduced medical supervision. Not only the healthcare legal framework regulates POM's exemptions, but also the HSA includes them as *Products safety alerts*, for example:

> *"24 Aug 2012: Updates on Prescription-Only Medicines (POMs) with exemptions for limited sale and supply without prescription. […] Table 1- Exemptions for supply of POM medicine without prescription with effect from 1 January 2012: 1) Desloratadine/Pseudoephedrine modified release oral solid dosage forms containing desloratadine 2.5mg and pseudoephedrine 120mg; 2) Fexofenadine/Pseudoephedrine modified release oral solid dosage forms containing fexofenadine 60mg and pseudoephedrine 120mg; and 3) Ketotifen eyedrops not exceeding 0.25 mg/ml"*

Product Safety Alerts 2012, Health Sciences Authority

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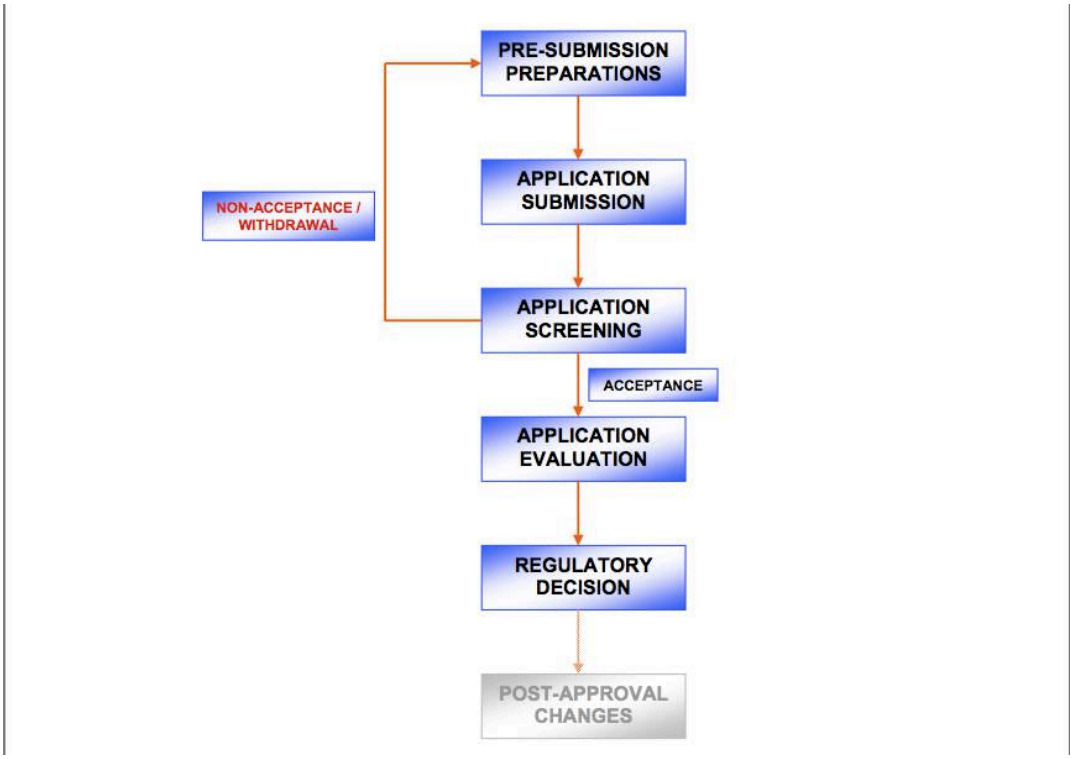
[17] Singapore Medical Council, Ethical code and Ethical guidelines, available at: http://www.healthprofessionals.gov.sg/content/dam/hprof/smc/docs/guidelines/SMC%20Ethical%20Code%20and%20Ethical%20Guidelines.pdf

[18] Medicines Act

Safety alerts like the one shown above are developed by collecting data and information on the different medicines in order to detect any evolution of the drug's risk. In order to make this happen, a vigilance branch of the HSA performs five different functions that permit a permanent *post-market surveillance activity*.

To determine if a drug might be dispensed through a prescription, it needs to go through the Medicinal Product Registration either in New Drug Application for an innovative product or in a Generic Drug Application for a product very similar to a currently registered medicine in Singapore.[19] This application process is summed up in the following graph from the Health Sciences Authority.

Graph 13.Application process



According to the *Medicines Act* (Chapter 176, section 29), the conditions for a POM order are:

> (a) the prescription shall be in computer or in writing and signed by the practitioner giving it with his usual signature and dated by him;
>
> (b) the prescription shall contain the following particulars:
>
> > (i) the address of the practitioner giving it;
> >
> > (ii) where the practitioner giving it is a doctor or dentist, the name and address of the person for whose treatment it is given;

[19] Ms Yusyanti Mat Tahir, 2009, Guidance on Medicinal product registration in Singapore, Singapore, HSA

(iii) where the practitioner giving it is a veterinary surgeon, the name and address of the person to whom the prescription only medicine is to be delivered;

(iv) where the practitioner giving it is a dentist or a veterinary surgeon, a declaration by the practitioner that the prescription is "For dental treatment only" or "For animal treatment only", as the case may be; and

(v) indicate the total amount of the prescription only medicine to be supplied and the dose to be taken;

(c) in the case where the prescription does not specify whether it is a repeatable prescription or not, the prescription shall not be dispensed more than once;

(d) in the case of a repeatable prescription that does not specify the number of times it may be dispensed, it shall not be dispensed more than 3 times;

(e) in the case of a repeatable prescription that does not specify the time period between which the next dispensing may take place, it shall not be dispensed more than once in 3 days;

(f) at the time of dispensing, the person dispensing the prescription shall note on the face of the prescription, above the signature of the practitioner, the name and address of the person dispensing it and the date on which the prescription is dispensed; and

(g) in the case of a repeated prescription, if the prescription is being dispensed for the last time, it shall be retained after dispensation by the person dispensing it.

These conditions are the only restrictions for the prescriptions of medicines in Singapore. These limitations (name, date, quantity of medicines, address, etc) represent a *minimax* decision scenario in which Singaporeans privilege regulating the minimum to maximize the results. The government chose to allow a relatively big room for maneuver for doctors and pharmacists to prescribe.

5.4.1 Reclassification process

If product licensed holders judge their classification inadequate (safer than classified) they may be able to ask for a reclassification. They only need to fulfill a demand of reclassification according to the Drug Registration Guide. The system is built upon request from the pharmaceutical companies, instead of a bi-annual basis review of all medicines, like in other countries.

According to the Drug Registration Guide (section 10.3.2 MAV-2 Applications) "a change of forensic classification of a POM drug product may be considered if basic criteria are met: 1) The use of the product has been sufficiently extensive; 2) The POM has been marketed for a period of time sufficient to establish a post-marketing adverse event profile; and, 3) The POM's safety profile gives no cause for concern during the marketing period.

This process has shown to be very flexible and efficient. For example, during the first semester of 2013, three medicines have been already reclassified from POM.

5.5 HEALTHCARE SYSTEM

The Ministry of Health (MOH) and the Central Provident Fund (CPF) work together and are in charge of supporting the members of the population who do not have the necessary resources to cover their medical expenses. **In Singapore, private and public efforts are combined to offer a network of healthcare services. This is the reason why freedom of prescription in this country does not encompass a difference between private and public institutions.**[20]

The healthcare system is structured by the type of attention that patients need: *one-point* of attention only (primary services) or hospitals and specialty centers. Regarding primary healthcare services, the public sector has 18 outpatient polyclinics in the country, which meet 20% of the total demand for primary healthcare. Polyclinics offer the following services: immunizations, diagnosis, medical monitoring after surgery, prevention and certain medical treatments. If patient needs specialized treatment, they would be referred to a hospital.

Table 9. National Healthcare Structure

Polyclinics (public sector) + **Private clinics**		Primary Healthcare (*one-stop* services)
Public hospitals and specialty centers + **General private hospitals**		Medium and long term treatments

Source: Minister of Health http://www.moh.gov.sg/content/moh_web/home.html

Thus, 80% of the demand for primary healthcare is dealt with by the private sector, which is formed by 2,400 medical clinics, which means that private general practitioners treat the majority of the population. In 2010, only one out of five attendees in healthcare went to a polyclinic, while the rest visited a private general practitioner (GP) clinic. This means that primary care, the main pillar of the healthcare system, depends heavily on private operators.

In contrast, hospital services are mainly provided by the public sector through a network of 15 public hospitals and specialty centers which offer 85% (9,143) of the

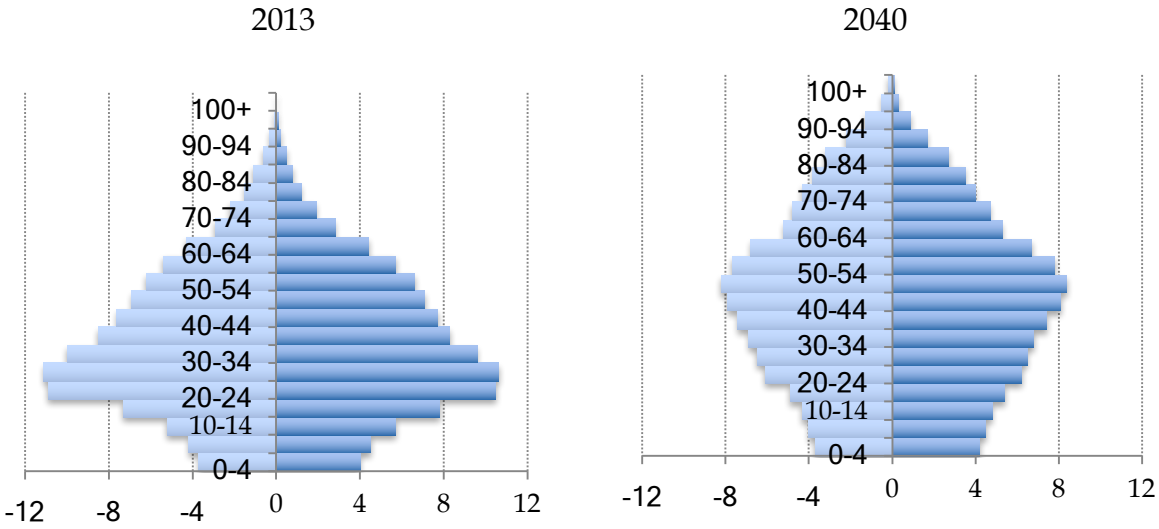
[20] BAI, Chaoran SHI, Xiaoteng LI,& Feifei LIU, 2012, Healthcare system in Singapore, Singapore

total hospital beds available in the country. In these hospitals patients are able to choose from different types of accommodation: class B2 and C which are significantly subsidized or class B1 with a 20% subsidy, or class A with no subsidy. The private sector has a further 10 hospitals, which happen to be smaller than the public ones.

An ageing population is one of the major challenges for the Singaporean healthcare system. Firstly, in 2011, almost one out of ten Singaporeans was older than 65 years of age. Secondly, the elderly tend to have chronic diseases that need to be treated on a long term basis, instead of in the *one-stop* or primary healthcare services. Unfortunately, the premise that underlies this healthcare system is that most patients would only demand short term attention.

This situation will change in two decades, because the population of this island country is getting older. In 2040, 24.4% of the population will be above the age of 60. Although Singapore follows the population growth scheme of an advanced economy (with an ageing population) it should be noted that it maintains a stable fertility rate, as shown by the base in the following pyramid. The percentage of people younger than 14, is around 13% in 2013, the same as in 2040.

Graph 14. Age population pyramid

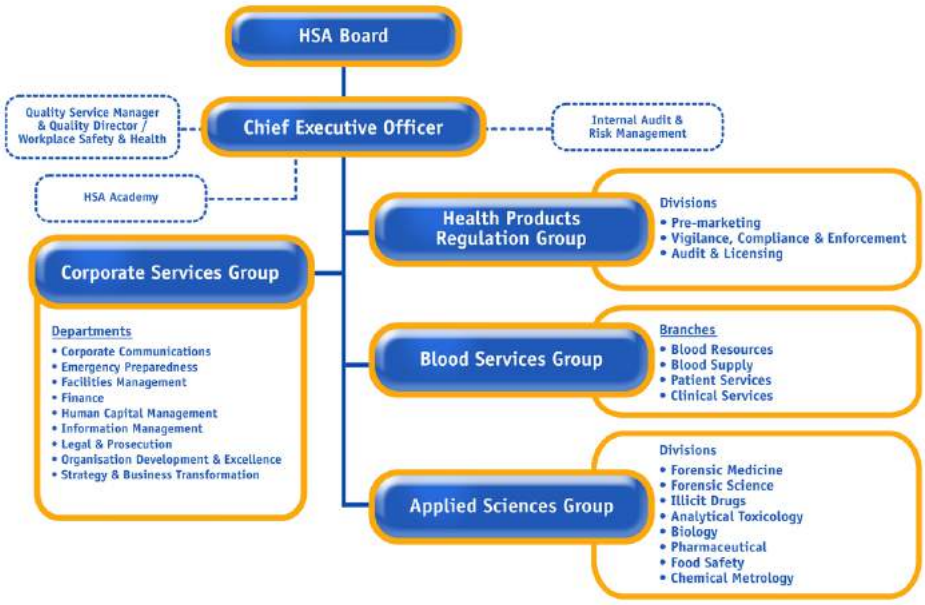


Source: US Census Bureau

The MOH supervises the provision and regulation of healthcare through a series of tasks that include reviewing the accessibility and quality of medical services, and allocating resources to healthcare entities that promote health to ensure that residents maintain healthy lifestyles. The regulatory framework has two parts: 1) the regulator, which is the MOH together with its statutory boards; and 2) the regulated, which are the providers, public or private. In addition, the Health Sciences Authority (HSA) is in charge of regulating medicinal products, such as medicines, medical devices, supplements, etc.

The HSA is a statuary board of the Ministry of Health which was created in 2001. The organism is formed by several institutions: the Centre for Drug Evaluation; Institute of Science and Forensic Medicine; National Pharmaceutical Administration; Product Regulation Department; and Singapore Blood Transfusion Service. **This entity faces the double challenge of regulating healthcare products and protecting the public health.**

Figure 3. HSA structure



In 2009 the HSA Academy was created as an expertise body to reinforce the efficacy of the HSA by engaging internal and external professionals. The HSA Academy permitted to discuss different points of views about healthcare regulation from a professional and academic horizon.

Moreover, in an effort to improve, HSA formed an international group with the following partners: US, Canada, Switzerland, Australia, China, Korea, Japan and Germany. The group allowed the HAS to have international accreditation to certify the security and effectiveness of healthcare products in Singapore.

5.6 FINANCING MECHANISMS

The Central Provident Fund[21] (CPF) is in charge of managing the national health insurance and a fraction of the salaries of all domestic workers to offer a plan to

[21] Sources for this section are: Rob Taylor and Simon Blair, 2003, Financing Health Care, Public policy for the private sector, World Bank /Ng Tze Lin Tania, 2012, Enhancing Universal Health Coverage through Public-Private Partnerships in Primary Care-The Case of Community Health Assist Scheme in Singapore, Singapore, Lee Kuan Yew School of Public Policy / Tilak Abeysinghea, Himania and Jeremy Limb, 2010, Singapore's healthcare financing Some challenges, Singapore, Department of Economics National University of Singapore

cover medical expenses. The CPF is the base of the national health insurance system but also raises funds to cover other living expenses of members registered with the CPF. Currently, all employees must contribute a portion of their monthly income together with their employer. This guarantees health insurance, a pension and a mortgage plan, among other things.

Contribution rates depend on the employee's age. For example, employees who are under 35 years must contribute 16% of their monthly salary, while the employer must add 20% of the salary of the employee, resulting in a total contribution of 36%. The CPF receives this amount and channels it into three accounts per employee which includes the ordinary account, the special account and the medical bill.

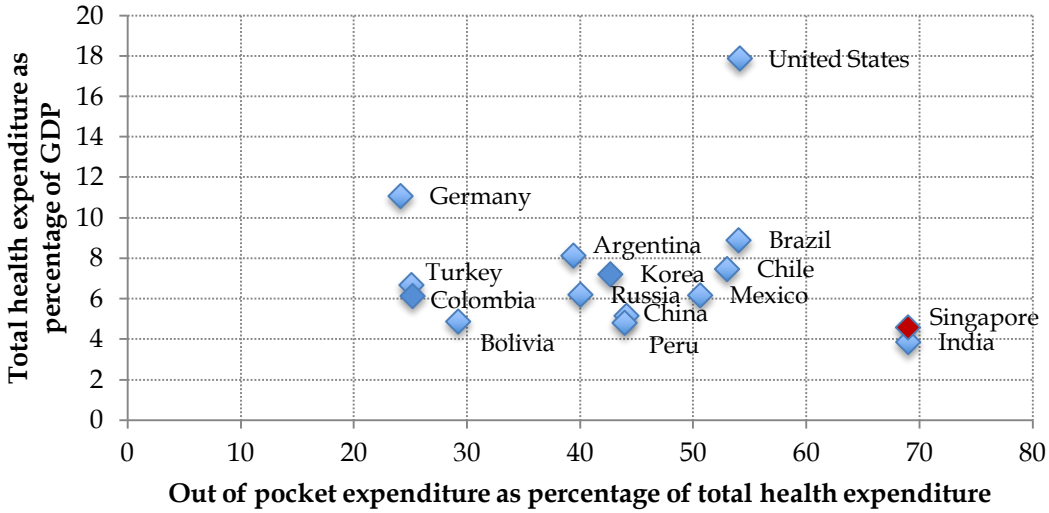
The CPF distributes the received amount depending on the age of the contributor. If they are less than 35, then most of the contribution, or 23%, goes to the ordinary account (which is related to mortgages, for example), and only 7% of the amount goes to the medical bill. In contrast, if the employee is over 65 years, 11.5% of the monthly balance contributes towards the medical bill.

Specifically, the financing system for healthcare in Singapore is based on a scheme involving the 3M's. Thanks to the 3M's system Singaporeans are able to finance their healthcare and drug's access. This scheme is structured by the following three measures:

- Medisave: employees contribute from 7% to 9% of their income in order to be beneficiaries of their insurance. In order to increase the individual responsibility of healthcare expenditure, the government set up a minimum sum which is regularly adjusted in accordance with the rate of inflation. This standard allows everybody to benefit of Medisave in the case of any health problems.
- Medishield: Permits the cover of hospitalization bills for the treatment of catastrophic illness or prolonged hospitalization. It's not compulsory for low income and self-employed citizens, which implies that low-income people do not enjoy its benefits.
- Metifund: Singapore's government endowment fund which helps needy Singaporeans to pay for medical expenses with the interest of the fund.

The 3M's scheme has a problem: the major part of the private expenditure in healthcare is concentrated in out of pocket payments. According to World Bank, the out of pocket expenditure is defined as *any direct outlay by households to goods and services, whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups*. We should note that Singapore is the country with the highest percentage of private health expenditure in the region, and with the highest rate of out of pocket payments. It means that Singaporeans are paying a very large amount of money for their own health, compared to other countries in the region. This is the reason why the World Health Organization (WHO) ranked Singapore 6th of 191 countries respectively to the efficiency of the health care system, but it also ranked it in 101st place according to the inequity of the system.

Graph 15. Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011



Note: Out of pocket expenditure as a percentage of health expenditure
Source: Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

Indeed, the large percentage of out of pocket expenditure for Singaporeans reflects the inequity of the system since it represents the real cost of health. Moreover, according to WHO, uninsured people (with a low income) might pay twice the amount of out of pocket expenditure than insured population. In the same way, elderly people without family might pay higher out of pocket expenditure than elderly people with a family that can benefit from Medisave.

This unequal scheme could decrease with time, since the Singaporean government is increasing its spending on healthcare. The Economist Intelligence Unit expects that out of pocket payments will fall as government-backed insurance schemes expand.[22]

Due to the healthcare system, which privileges private expenditure, Singapore is facing issues regarding the inequity nature of its healthcare system problem. As mentioned before, the demographic issue of Singapore relating to an ageing population reinforces the problem. Indeed its population is getting older and the financing of Medisave is a source of concern as the elderly tend to consume more medical services than the young. The government tried to resolve these problems by: 1) cutting main costs in public hospitals by giving only generic medication; and 2) creating the Community Health Assist Scheme (CHAS) to enhance the use of primary care and to decrease the unequal nature of its health system.

For low and middle income Singaporeans of 40 years of age or above or with a disability, the government offers subsidies. The CHAS is a public-private project which was designed to expand the supply of medical services, given the long

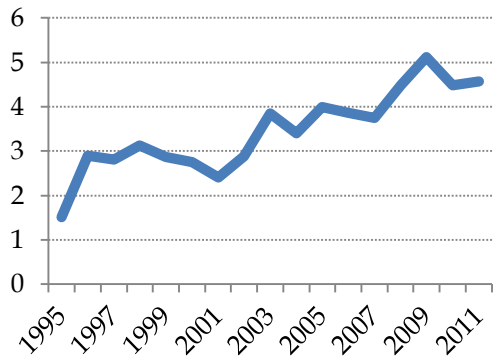
[22] Economist Intelligence Unit, 2012, Industry Report Healthcare in Singapore, United Kingdom

waiting times patients face in polyclinics. The policy aims to improve the population's access to medical services and the treatment of chronic conditions.

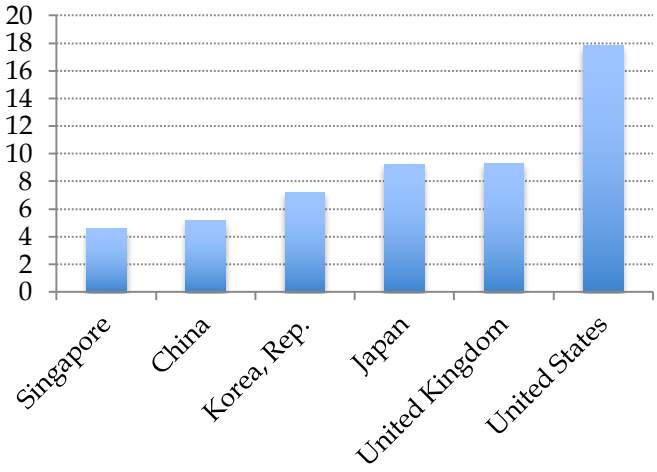
CHAS potential beneficiaries are people with a monthly income below $1,500 US. The eligible population receives an orange or blue card which is valid for two years. The blue one is for the lowest incomes (below $900 per month), who receive $18.50 in subsidy for the treatment of regular illness, as well as a year's subsidy of $320 US to $420 US for chronic conditions. The orange card also gives an annual subsidy of $200 to $300 US for chronic conditions.

In 15 years, Singapore has tripled its investment in health expenditure as a percentage of GDP (from 1.51% to 4.5%). This fast evolution shows the growing importance that Singapore gives to its health system. In spite of the increasing health expenditure in Singapore, its rate as a percentage of GDP shows to be very low, comparing it with other advanced economies. China and Japan, among others, have bigger investments in healthcare than Singapore.

Graph 16. Singapore's health expenditure

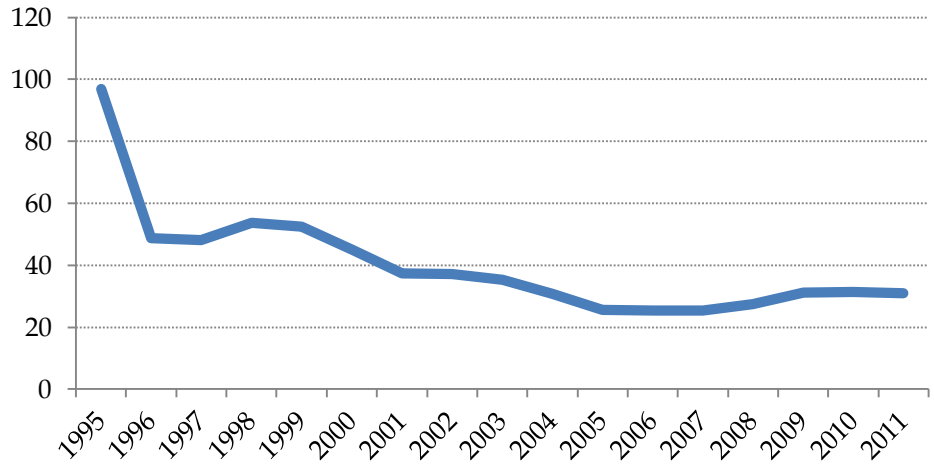


Graph 17. Comparative health expenditure (%GDP)



Source: World Bank

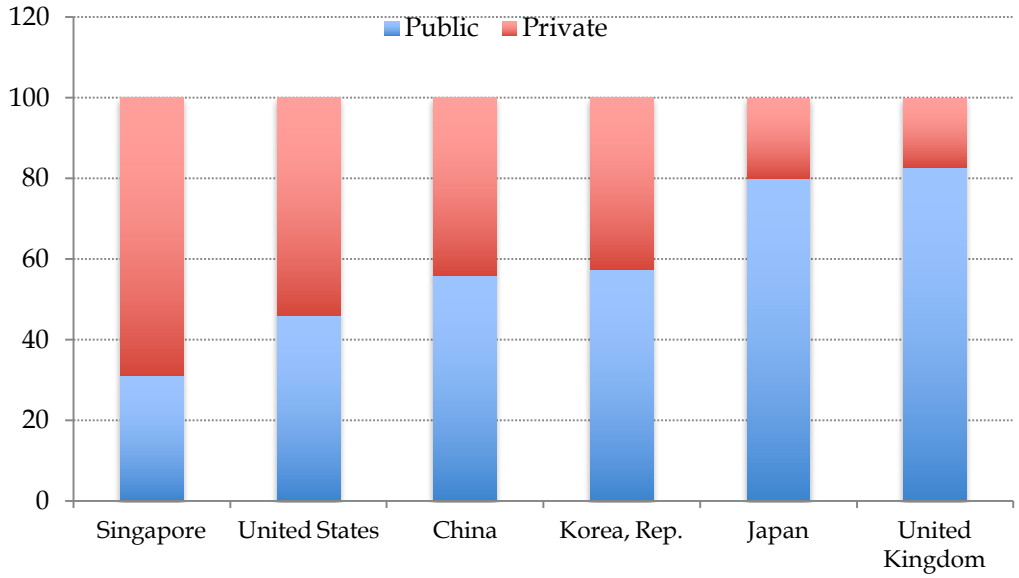
Graph 18. Public health expenditure (% total health expenditure)



Source: World Bank

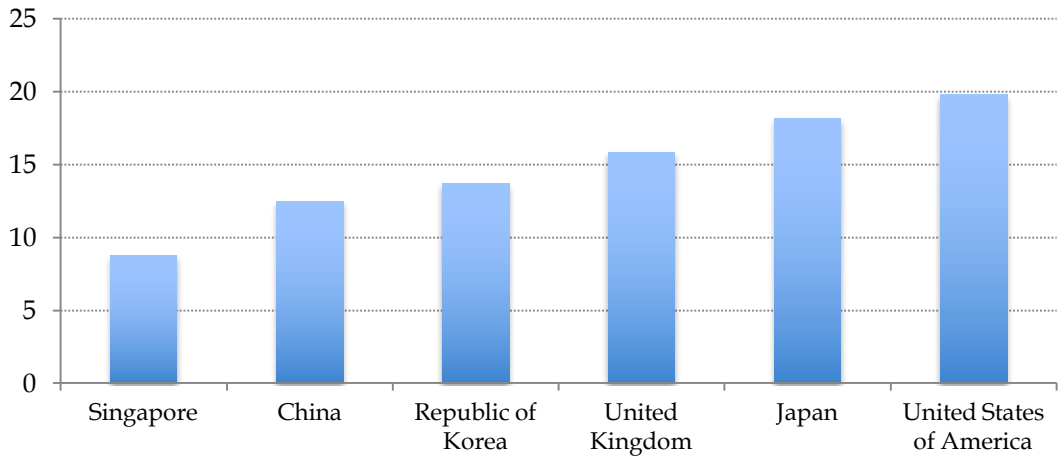
The behavior of the health public expenditure in Singapore shows a very big change in the policy of the government. Indeed, this indicator falls from 97% in 1995 to 31% in 2011.

Graph 19. Public and private expenditure in healthcare services



Source: WHO, 2011

Graph 20. Government health expenditure (% of total government expenditure)



Source: World Bank, 2011

The share of public spending in terms of total health expenditure is very low in Singapore. Compared to other advanced economies (as shown in the graph above), Singapore is the country that dedicates the lowest percentage of its total budget to healthcare. Although Singapore does not spend a lot of public money on health, it has one of the lowest mortality rates of children under five in the world (2.6 children dying for 1,000 live births), and life expectancy at birth is again one of the highest (82 years) along with Canada, Australia and some European countries (WHO, 2011).

5.7 HEALTHCARE PERFORMANCE

5.7.1 Main indicators

Bringing access to good and affordable healthcare to a population of 5.3 million inhabitants represents the main aim of Singapore's government. Although is a small country in territory (697 km^2 or 3.5 times the size of Washington D.C.) and population size, Singapore's healthcare model is very innovate and exemplifies that private and public sectors could work together with good results. The high rates of economic development during the last decades have helped the majority of the population to contribute to the healthcare system. In this context, the government has faced fewer problems in collecting enough resources to finance the healthcare system, than Mexico, for example, which needs more income to cope with the healthcare demand.

The attention of the healthcare international community has been focused in the model due to its results. In 2000 the World Health Organization ranked Singapore 6th out of 191 countries on overall health system performance. Ten years later, the World Health Statistics ranked Singapore 2nd for Infant Mortality Rate and 9th for Life Expectancy at birth.

Table 10. Infant mortality and life expectancy in selected countries

Country	Child mortality probability (per 1,000 live births)	Life expectancy
Singapore	3	85 females, 80 males
Japan	3	86 females, 79 males
Malaysia	9	76 females, 72 males
Australia	5	84 females, 80 males
China	14	77 females, 74 males
Philippines	30	73 females, 66 males

Source: World Health Organization Statistics

As shown in the table above, the contrast with other Western Pacific countries shows that, although there is still room for improvement, Singapore's health system is achieving remarkable results.

In 2009, cancer, ischemic heart disease and pneumonia together represented approximately 60% of the total causes of death in Singapore. A sedentary life, smoking, not-exercising, obesity, and alcohol consumption are shown to be some of the risks factors. Regarding smoking rates, in the same year, 16% of the population were current smokers, most of them were younger (18 to 34 years old), male and with lower education levels[23]. Singapore is affected by overweight and obesity epidemic as well, since one out of every ten adults is considered obese and 11% of children. According to National health surveys diabetes prevalence shows a similar behavior: 11.3% of adults and 1 in 3 Singaporeans will have diabetes by age 70[24].

As mentioned, to analyze the performance of a health system in face of its level of freedom of prescription one should analyze the ailments whose treatment is heavily dependent on innovative medications and treatments (hence, patent medication). The following set of graphs shows health indicators related to these ailments that are provided by the World Health Organization: diabetes, cancer and chronic respiratory diseases. We also provide basic health indicators, such as life expectancy and the mortality rate of infants under 5 years of age (death probability before turning 5 years per 1000 live births).

The WHO provides indicators both for each country and for countries grouped by income level (low income, middle class low income, middle class high income and high income). Thus, it is possible to analyze not only the national indicator for each ailment, but also its relation with the income levels of the population.

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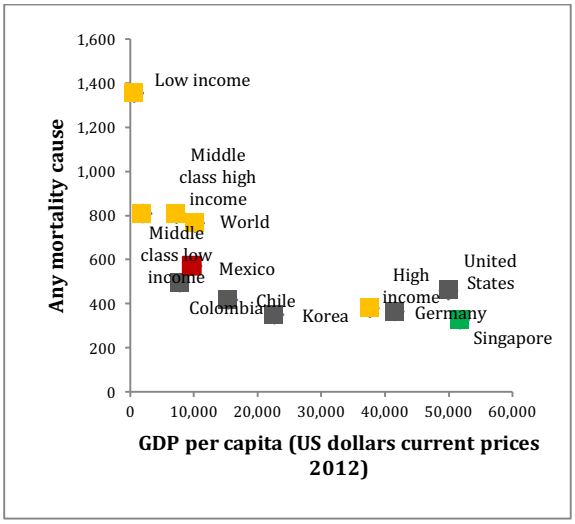
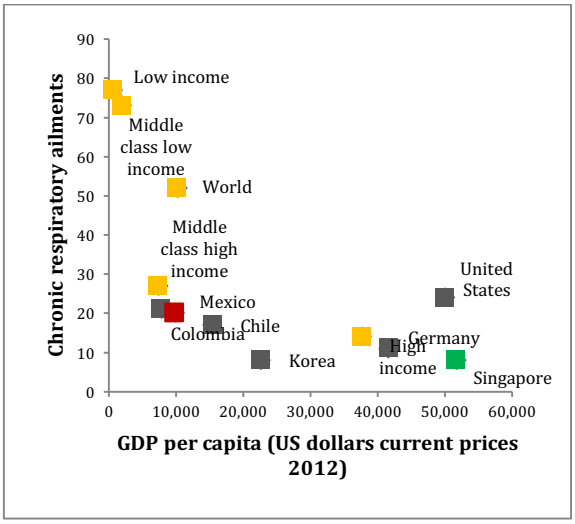
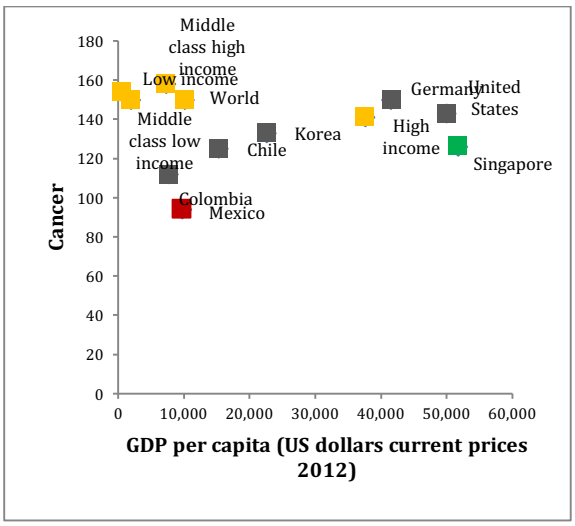
[23] Picco, L., Subramaniam, M., *et. al.*, Smoking and Nicotine Dependence in Singapore: Findings from a Cross-Sectional Epidemiological Study, Ann Acad Med Singapore 2012; 41:325-34.

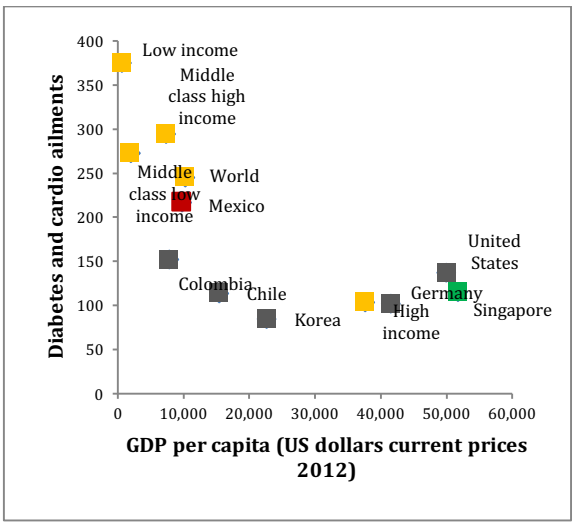
[24] M. van Dam, The Public Health and Economic threat of Diabetes in Singapore, National University of Singapore, November 29, 2012, available at: http://www.ciaprochef.com/wohfasia/Presentations/RobvanDam.pdf

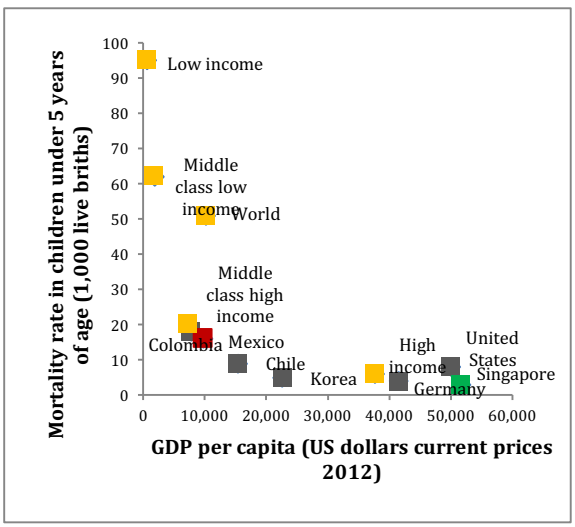
Graph 21 Key performance indicators for the Singapore health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

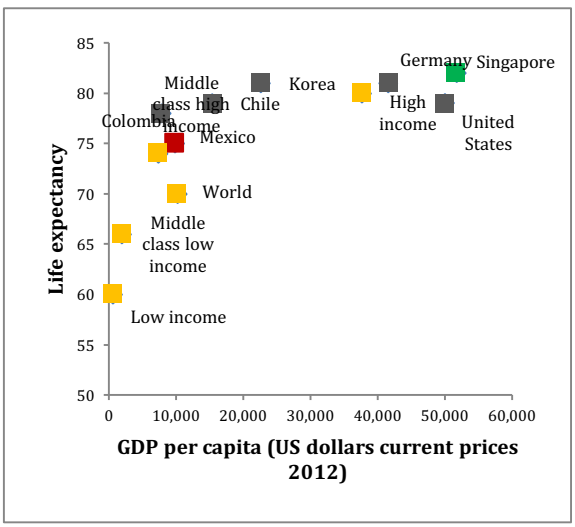












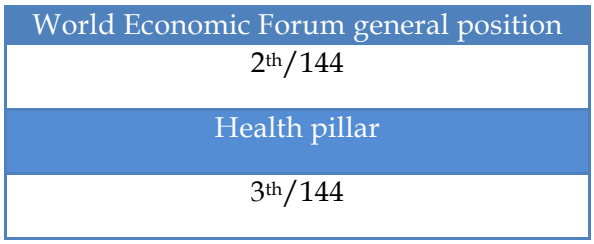
Source: World Health Statistics 2013

The Singapore health system has an outstanding performance in the following indicators: chronic respiratory ailment mortality, diabetes and cardio, mortality in children over 5 years and life expectancy. Nevertheless, its performance in terms of cancer is not as good as Mexico's.

5.7.2 Competitiveness

For the third time, the World Economic Forum ranking has placed Singapore in the second top position, just below Switzerland. Its' economic indicators and institutional framework represents an example not only for the Western Pacific region, but also for countries such as United States and Germany that were ranked in the 5th and 6th position.[25]

Graph 22. Singapore's position in health pillars of Competitiveness Indexes



Source: World Economic Forum, Global Report on Competitiveness, 2013 and Instituto Mexicano para la Competitividad, International Competitiveness Index 2013.

The fact that all Singaporeans are able to get first class medication thanks to absolute freedom of prescription has an impact in the country's competitiveness performance. This positive relationship is evident when Singaporeans achieve high health levels, partly due to high class medication, and eagerly participate in productive activities. In this cycle, the probability of disease or not being able to recover from illness is smaller.

[25] Unfortunately Imco's Competitiveness Index didn`t include Singapore in its estimates.

6 FREEDOM OF PRESCRIPTION IN GERMANY

6.1 SUMMARY

Germany's healthcare system is unique mainly because of the use of a negative formulary (a list of medications that are not covered by the public system) instead of a positive list, which is the mechanism that is most commonly used.

This implies that the German public healthcare system will cover all the medications except those in the negative list. Since the medicines encompassed in the negative list are those related to lifestyles and over the counter medication, the system is one especially keen to freedom of prescription.

Not even in Germany is freedom of prescription absolute. Doctors, pharmacists, patients and pharmaceutical companies face certain restrictions to achieve it. Nevertheless, the system relies heavily on a patient's right to best available care and in a doctor's right to prescribe the best possible treatment for a given patient regardless of its cost to the public system.

To achieve this, Germany designed through a large set of reforms a financing mechanism that encompasses copayment, reimbursement and other mechanisms. The reforms to the system are frequent, and they aim to perfect those mechanisms and to address the evolving conditions of the German health profile.

Freedom of prescription in Germany is framed in the obligation for pharmaceutical companies to sell the cheapest medicine of the same compound for the exact indication prescribed by doctor, and framed also in the rights of doctors to contest this. The system also includes, in certain cases, the need of a second opinion in cases where medications are either too expensive or might have negative secondary effects.

Undoubtedly, one of the key indicators of the system's achievements are the health indicators of the German population, and, more than anything else, the fact that more than 90% of the Germans are members of the system and few choose private insurance.

6.2 PRESCRIPTION MECHANISM

In Germany, doctors' have freedom of prescription and Germans are insured for a wide range of medications and are reimbursed for their expenses either through Statutory Health Insurance's (*Gesetzliche Krankenversicherung*, GKV) or private insurance; and medications have value added taxes.

The mandatory coverage of medicines that is offered by statutory insurance companies includes most medications with the exception of selected types of medications that are excluded from mandatory coverage by the government. In this sense, Germany is diametrically opposite from Mexico as it has an exclusive list (*Negativliste)* of state covered medications, rather than an inclusive list of state covered medications that is subject to different public health institutions (ISSTE, IMSS, Seguro Popular, etc.).

Some of the components of Germany's negative list that are excluded by law include[26]:

- Medications used by adults for minor illnesses, i.e. "drugs used in the treatment of cold and flu syndrome, including cold medications, cough suppressants and expectorants, and painkillers; mouth and throat medications other than antifungal; laxatives; and drugs for motion sickness".

- "Over-the-counter drugs are not covered unless they are prescribed to children up to 12 years (up to 18 years in certain cases) or they are used in standard treatment of serious diseases according to guidelines established by the Federal Joint Committee."

- "Pharmaceuticals whose main indication aims to improve the of quality of life, particularly treatments of the erectile dysfunction, smoking cessation treatments, slimming drugs, appetite suppressants, anti-obesity drugs, and capillary treatments".

In 1989, Germany was the first European country to introduce **maximum reimbursement amounts** for clusters of products. The general principle of this policy is now well-known: health insurance funds define a reimbursement level for a cluster of products considered to be therapeutically equivalent; the pharmaceutical company is still free to set any price above this reimbursement amount, but patients are required to pay any difference between the price and the reimbursement amount. This policy is often referred to as "reference price policy" though it does not aim to regulate the prices of pharmaceuticals.

In Germany, products are clustered by the Federal Joint Committee according to three different levels:

- At the first level, clusters include products with identical active ingredients and comparable administration mode and/or bioavailability;
- At the second level, clusters include products with therapeutically or pharmacologically comparable active ingredients
- At the third level, clusters include products with comparable therapeutic effects.

In many cases, Germans must make copayments when accessing medications whose amounts are subject to government regulations and depend on a range of factors. However, as was mentioned, there are several cases when patients can be exempt from having to make copayments and these include:

- Medications for children under the age of 12 will not require a copayment.
- Medicines for children up to the age of 18 that suffer from growth problems or serious illnesses will not require a copayment.

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[26] Paris V. Docteur E., Pharmaceutical Pricing and Reimbursement Policies in Germany, OCDE, Paris. 2008. p. 14.

- There is a limit on treatment copayments for all adults of up to 2% of their household income, or 1% in the case of adults suffering from chronic diseases.

Physicians are responsible for the choice of prescription medicine and may prescribe drugs with a price differential to the reimbursement amount scheme with or without any substitution opportunity and even prevent any substitution whenever possible. In doing so, they take into consideration the willingness of the patient to pay for any perceived value added to the product. The patient, nevertheless, has the option to select a product without a price differential to the maximum reimbursement in each therapeutic class[27].

Ideally, at the moment of prescription, doctors would explain to their patients why they chose to prescribe a more expensive product (perhaps by listing the advantages of a product over others in the same group), but in reality this is not always the case and patients are sometimes left with limited information.

It is also important to consider that the existence of reimbursement amount have actually led to pharmaceuticals pricing their products more competitively. Likewise, a reform passed in 2007 created a set of incentives to spur contracting possibilities between sickness funds and pharmaceuticals, by obliging "pharmacists to substitute, whenever possible, a contracted product for the prescribed medicine".[28] Additionally, sickness funds can sign contracts with physicians and pharmacists to encourage them to supply products that have been contracted with manufacturers.

Until August 2002, pharmacists could only substitute a generic product for the prescribed product **if the physician had expressly authorized it on the prescription form.** In a way, these restricted the rights of the German population to access quality generics, although it is not related to freedom of prescription.

The situation has changed: since 2002 pharmacists have been **obliged** to substitute, whenever possible, prescribed medicine for a cheaper drug but identical compound for the same indication, but whose price is included in the lower tercile of price distribution of a given substance. The physician is allowed to oppose this substitution for medical reasons. This is commonly known as the *aut idem* rule

However, in spite of the 2002 reform, substitution for cheaper medicines has been low, since pharmacists have no incentive to do so.

In 2007, there was a change in the substitution for cheaper drugs requirements: pharmacist have been required, whenever possible, a given medicine for one for which the health insurance fund of the patient contracted for with a given manufacturer, without taking into account listed prices. If this is not possible, the 2002 substitution rule applies.

[27] Idem
[28] Ibid. p. 21

6.3 LEGAL FRAMEWORK

Some of the most important recent reforms made to the German health system occurred near the conclusion of the Cold War where the two German states began to make preparations to reunite. The following section will briefly summarize the series of steps taken in Germany between 1989 and 2000 and how these steps affected the system's structure to have it work as it does today.

The **Health Care Reform Act of 1989** was the "first step" taken to codify social insurance legislation, something that had not been done since 1911.[29] One of the most important aspects of this reform was that it updated Germany's social insurance to meet the new needs of the German population and reinforced its presence in the country, also this reform was the one that introduced the negative list.

The "second step" was taken in 1992 with the passing of the **Health Care Structure Act** that had the objective of containing public spending on health by promoting competition and efficiency in the system[30], it was also during this year that there were intents to create a positive list, but it was opposed.

Between 1996 and 1997 the administration implemented measures to foster competition in the country's economy and incorporated in these measures was the **Health Insurance Contribution Exoneration Act** of 1996 that limited public spending on health by reducing the social insurance's coverage of services and medications (i.e. dental treatment).[31]

In 2000, the German administration introduced the **Reform Act of Statutory Health Insurance** that aimed to tackle many of the Statutory Health Insurance's (*Gesetzliche Krankenversicherung*, GKV) weaknesses. This was an ambitious reform that altered several aspects of the GKV including the extent of its coverage, the relationship between doctors and health institutions, and the reimbursement policies for services and medications.[32] Overall, the reforms that were enacted between these years updated the GKV and prepared it for the 21st century. In 2000 there was also a second intent to create a positive list and in was, in fact, introduced in the act, but it has not been implemented.

The **Pharmaceutical Expenditure Limitation Act** of 2002 is the name of the legislation that introduced the *aut idem* rule described in the prior section.

The **Contribution Safeguard Act** of 2003 opened the door for SHI funds to contract with pharmaceutical companies to obtain rebates.

In 2004, there was another ambitious piece of legislation: the **Health Insurance Modernization Act** which set new copayment schemes: 10 in coinsurance, with a minimum of 5 euros and a maximum of 10. It also introduced a cap for patients copayments: 1% instead of 2% of revenues.

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[29] Ibid. p. 110
[30] Ibid. p. 111
[31] Ibid. p. 112
[32] Ibid p. 114-116

The key aspect of the 2007 reform, the **Health Insurance Enhancing Competition Act** is the fact that it introduces the requirement of having a second opinion to prescribe special pharmaceuticals that have either a high price or a high risk potential.

Additionally, in 2009 the German government passed another key reform that **made it mandatory for every German and long term resident** to have medical insurance[33]. For those making less than 49,500 euros a year, the German government provides medical insurance through the GKV that works with health insurance funds (sickness funds) to insure all members of the population.

6.4 UNIVERSE OF DRUGS

As mentioned above, Germany does not have a positive medicine formulary, but rather a negative list, that excludes from the federal government reimbursement mechanisms medicines such as lifestyle treatments and over the counter medications.

6.5 HEALTHCARE AND DRUG FINANCE SYSTEM

Patients are generally required to contribute to the cost of the pharmaceuticals they use. Cost-sharing takes two different forms: statutory copayment applying to all reimbursed medicines and "extra billing" for products subjected to maximum reimbursement amounts, and whose price exceeds that maximum.

As mentioned in the previous section, since January 2004 copayments have taken the form of a 10% co-insurance, with a maximum of 10 euros and a minimum of 5 (**Health Insurance Modernization Act).**

Regarding public healthcare coverage, since 1990, people that are automatically insured by the GKV (or that make less than 49,500 euros a year) are free to choose between the different **sickness funds** that exist throughout the country.

Sickness funds are non-profit, non-governmental autonomous entities that are regulated by German public law and act as individual insurance companies. An important aspect of sickness funds is that German residents and citizens are free to switch between funds once every 12 months, thus promoting competition between the funds.[34] Since sickness funds are regulated by law and must offer the GKV's insurance package with fixed prices for goods and services, funds compete based on quality of service resulting in an overall higher quality of healthcare provision throughout the country. Currently there are about 160 sickness funds operating in Germany.

Conversely, people in Germany that make over 49,500 euros a year have the choice to insure themselves and their families with a private insurance company, thus satisfying the legal requirement of having medical insurance. **However, over 85% of**

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[33] BLÜMEL, Miriam The German Healthcare System Berlin University of Technology

[34]AbelSmith, B. and Mossialos, E., 'Cost containment and health care reform: a study of the European Union health policy', *Health Policy*, 28, 1994, pp. 89–132.

Germany's population including people that make over 49,500 euros a year are insured by the GKV, evidencing the quality of its services. Only about 10% of the German population **chooses** to insure privately.

Furthermore, the government has enacted several measures that force private insurers to offer coverage at least as comprehensive as what is offered by the GKV, like the requirement to offer a basic insurance package similar to the GKV's.

The most significant difference between private health insurers and the GKV is that private companies insure their clients based on a risk-related formula that considers personal factors (i.e. age and sex) while the GKV insures its members uniformly.

Another important difference between the private and public insurance schemes is that private insurance companies generally only insure the account holder and will not automatically insure his or her dependents, unlike the GKV that automatically insures all family members and dependents. In 2010 the private insurance sector represented 9.3% of Germany's total health expenditure, something that demonstrates the population's reliance on GKV insurance.[35]

Sickness funds have a significant degree of independence in regards to what they can offer their members and this is one of the key features of the GKV as it promotes competition and therefore efficiency by part of the sickness funds.

Currently, national sickness funds are financed primarily by payroll taxes that are taken as premiums or contributions and are legally fixed at 15.5% of the employee's wage and split between employee and employer (employees pay 8.2% of the amount and employers pay the remaining 7.3%).[36]

In the case of the unemployed, sickness funds generate resources from the benefits that the unemployed receive from the state or from donations gathered by social funds or civilian associations.

Private medical insurance companies are free to design and implement their own financial schemes and are generally used as additional or supplementary insurance services. Usually, families that have enough resources to hire private insurance do so in the interest of having a wider medical coverage (i.e. better dental treatment, private rooms in hospitals) and less out of pocket expenses. However, the government has created a set of regulations for the private health insurance sector to ensure that private companies maintain certain universal standards.

In 2009 a major financing reform in the Statutory Health Insurance System created the Central Health Fund (CHF), which pools all GKV sickness funds contributions with government revenues destined for health.[37] The CHF re-distributes resources to sickness funds based on a risk equalization formula that takes into account the age,

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[35] Blümel M, The German Health Care System, 2012, The Commonwealth Fund, EUA, 2012. p. 48
[36] Gerlinger T. Health Care Reform in Germany. German Policy Studies. 2010. p. 107-42.
[37] Göpffarth D, Henke K-D. The German Central Health Fund—Recent developments in health care financing in Germany. Health Policy (2012)

gender, and morbidity rates of 80 chronic and/or rare diseases throughout different parts of the country.[38]

In other words, if the members of a sickness fund in one part of the country have a higher rate of cancer then the members of another sickness fund, then the first sickness fund is going to receive more resources to deal with the necessities of its members. If a sickness fund does not consider that the resources given to it by the CHF are broad enough to deal with the necessities of its members, then it can charge them additional premiums but at the risk of losing them to another sickness fund that does not charge those additional premiums.

By establishing this system, the German government was able to find a way to expand available resources for sickness funds without spending more of its own resources and in fact, in 2012 there was a 20 million euro surplus in the system.[39] Since 2003, instead of directly paying health providers, sickness funds pay the value of their members' medical coverage to Regional Medical Associations, and these associations distribute the resources among health providers.[40]

Aside from the premiums that are paid by the insured population, many of the medicines and services covered by the GKV also have attached copayments that must be financed by patients. Introduced in 1977, copayments take the form of a percentage of the total cost of the service or medication being provided to the patient.[41]

On average, around half of all medical prescriptions do not require payments from patients and in the cases were patients are required to pay a fee, copayments usually represent around 20% of the price of the contents of prescriptions.[42]

In terms of efficiency of a system measured as percentage of GDP expenditure on healthcare and out of pocket expenditure, Germany has achieved one of the lowest out of pocket expenditures, but it does so with a high % of GDP expenditure in healthcare, as can be seen in the graph below.

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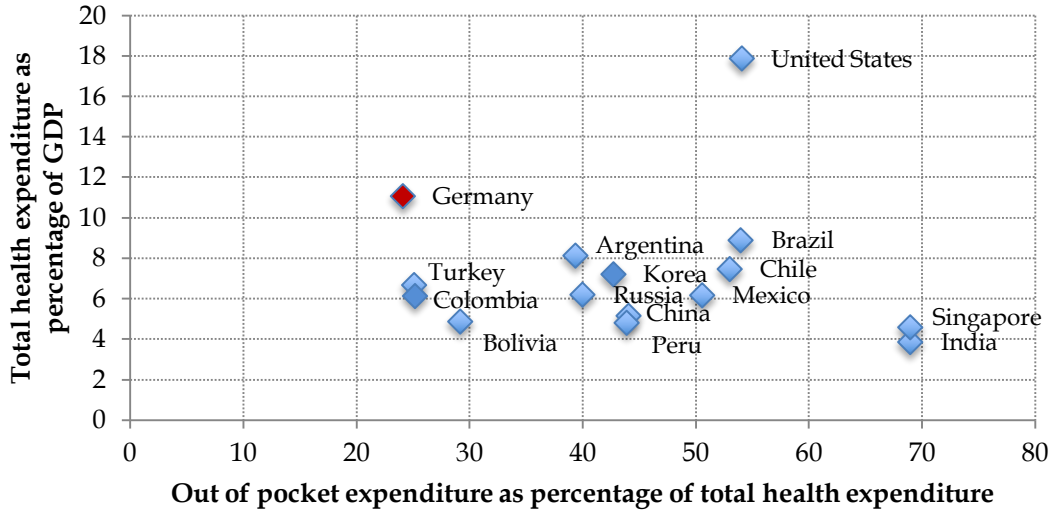
[38] Civitas, Healthcare Systems: Germany, 2013.
[39] Weiss R. Bloomberg. German health care insurers have $26 billion cash, Seuddeutsche says, 8 March 2012.
[40] Organización Mundial de la Salud, Health Systems in Transition Series, Alemania. 2004.
[41] Paris V. Docteur E., Pharmaceutical Pricing and Reimbursement Policies in Germany, OCDE, París. 2008. p. 15.
[42] *Idem*

Graph 23. Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011



Note: Out of pocket expenditure as a percentage of health expenditure

Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

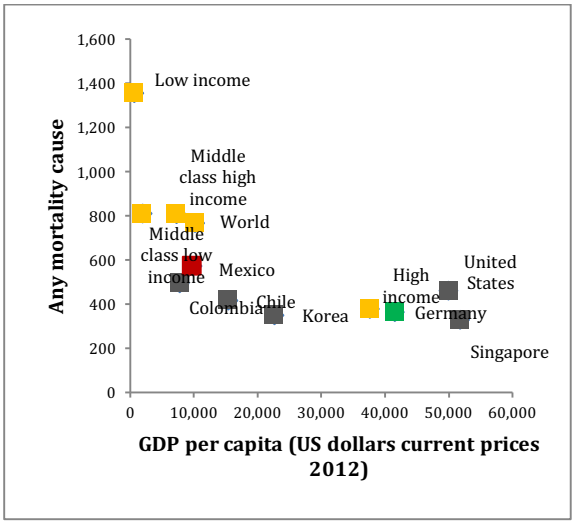
6.6 HEALTHCARE PERFORMANCE

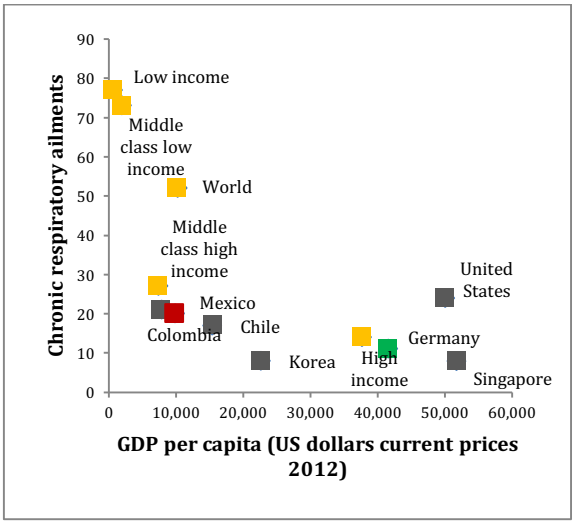
6.6.1 Main indicators

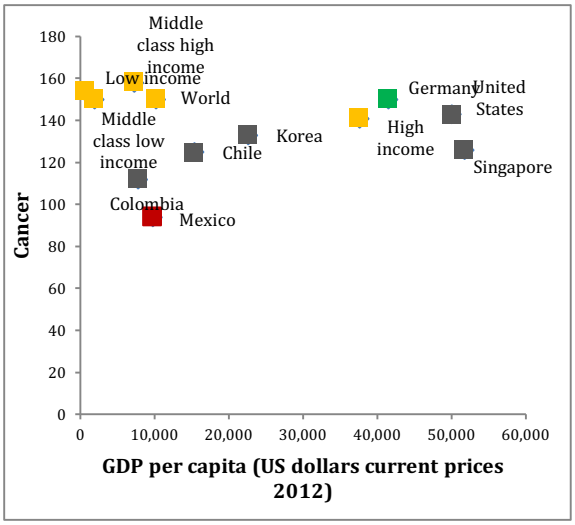
Germany has achieved one of the highest health standards in the world, as will be reflected on the analysis of its competitiveness indicators. This is due to a number of factors, including the quality of the statutory healthcare coverage and the performance of the negative lists, which allow for most medicines to be included in the treatment of any ailment that a German citizen might present.

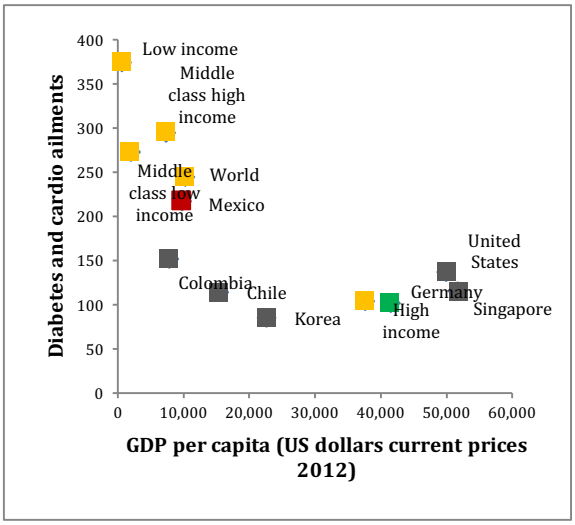
The analysis of the WHO indicators related to the treatment of ailments heavily linked with freedom of prescription also highlights the performance of the German healthcare system.

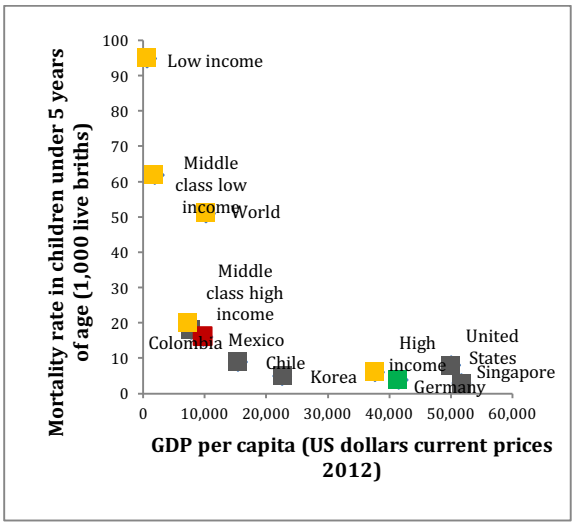
Graph 24 Key performance indicators for the German health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

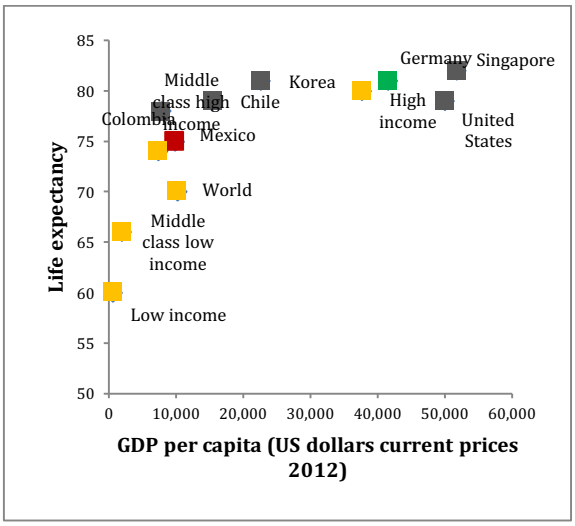












Source: World Health Organization 2013 Statistics

The German healthcare system has achieved some of the best results in the lowering of mortality rates for chronic diseases. As can be seen in the graphs above, the country ranks highly (low mortality) in terms of chronic respiratory ailments, diabetes and mortality of children under 5 years. Cancer mortality, nonetheless, is not as good as the Mexican indicator.

6.6.2 Competitiveness

Germany shows one of the highest competitiveness levels, both according to the World Economic Forum and to the index of IMCO. In terms of its position on the healthcare pillar, it's also high on both indexes, although in the WFE's is low when compared with the country's high performance in the general competitiveness indicators.

Table 11. Germany's position in competitiveness indexes

Germany general position	
World Economic Forum	IMCO
4th/144	15h/46
Germany position in the healthcare pillar	
World Economic Forum	IMCO
22h/144	12h/46

Source: World Economic Forum, Global Report on Competitiveness, 2013 and Instituto Mexicano para la Competitividad, International Competitiveness Index 2013.

7 FREEDOM OF PRESCRIPTION IN CHILE

7.1 SUMMARY

With a life expectancy at birth equal to the most developed country of 79 years, with the lowest per capita pharmaceutical expenditures of the OECD country and with 77% of people with medical insurance, we can say that Chile healthcare system is very efficient. Chile got these good results thanks to:

- The low price of medications thanks to the increasing presence of generics medicines and the respect of the international norm as the International Nonproprietary Name.
- The high coverage system of existing insurances as well for the public as for the private one.
- The low-regulated mechanism of prescription that allows doctors to adapt their prescription to patient needs.

The Chilean healthcare system is a guarantee of a good health thanks to an easy access to medicines through cheap medicines and doctor's freedom of prescription. Patients get information of what they need, they are able to buy the medicines they want, and doctors are able to give the medicines they think the more appropriate.

In Chile, even if a national list of medicines exists, it is still possible to prescribe medicaments that do not belong to the list. The reimbursement process might be different according to the coverage insurance.

7.2 PRESCRIPTION MECHANISM

In Chile, doctors are free to prescribe whatever medications if they believe are necessary to restore the health of their patients, taking into consideration financial implications and availability. They might prescribe medications from the National Medication List, but also from the registry sanitary, which regulate all the medicines produce, import, and sell in the country.

Health providing centers (i.e. clinics and hospitals) must base their pharmaceutical inventories on the National Medication List **but are not limited to the contents of the list.** In other words, **they are free to purchase goods not included in the list but are subject to market prices for the goods**, rather than the discounted bulk prices that are acquired by CENABAST, the entity responsible for purchasing the contents of the list for public use.

On the other hand, all pharmacies are required to be stocked with the entire contents of the medications list, though specific exceptions can be made.

There are three compulsory norms that should be written in a medical prescription:

- Information about the patient and the doctor (date, address, names…)
- The chemical compound or generic name of the medicines and the dose should be written.
- Date and signature of the doctor.

It is worth mentioning that only surgeons and dentist surgeons are allowed to make a prescription for legal control substances and there is a different prescription mechanism for narcotics and psychoactive drugs with more control for its dispensation.

By law, the national medication list must be accessible to everyone and the National Health Fund (*Fondo Nacional de Salud*, *FONASA)* **guarantees its affiliates 100% financial coverage for the medications included in the list.**

Nevertheless, it is worth mentioning that this guarantee is under a scheme of copayment.

7.3 LEGAL FRAMEWORK

According to the **resolution n°1089-95**, it's the role of the **Pharmacy and Therapeutic Committee** to elaborate and update the National Medication List and of the local pharmacologist arsenal. The National Medication List is updated every two years in accordance to the **country's national pharmaceutical policy**.

Essentially, the pharmaceutical policy aims at ensuring that medications in Chile are safe and efficient and accessible to the population**.** In order to achieve this, pharmacists are positioned as strategic contributors to therapeutic goals and as promoters of the rational use of medications.[43]

As stated in the first article of **Decree Number 264/03 (2004),** "the national medications list is the Republic of Chile's official document that contains the list of selected indispensible pharmaceutical products that is based on the epidemiological reality of the country and scientific evidence".[44]

The medicines available in the National Medication List are quoted in the article 5 of the decree number 264 and comply with the list of essential medicines set up by the World Health Organization:

- *Indispensable products*
- *Demonstrated efficiency and security medicines*
- *Products which meet the medicines principle with the sanitary objective of the country*
- *Products that show a best efficacy according to its cost*

Decree 264 is also the piece of legislation that states that health providing centers must base their inventories in the National Medication List but are free to purchase goods not included in it.

According also to Decree 264 the medicines must appear with their International Nonproprietary Name (I.N.N) as defined by the World Health Organization. Which means that all medicines should be written with their generics name on the medical

[43]Implementación de la Política Nacional de Medicamentos de la Reforma de la Salud: percepción del profesional químico farmacéutico, Paulina Núñez, Claudio Méndez. 2011. p. 21
[44] Decreto Nº 264/03, 2004. Gobierno de Chile

prescription, a fact that allows patients to choose between products that comply with their doctor's prescription.

Thus, decree 264 supports the sale of generic medicines (without prohibiting the sale of branded medicines) and in doing so decreases the cost of medicines and in general, the financing cost of the overall health system. Furthermore, all generic medicines should have a yellow line in their packaging in order to inform the patient what he or she is buying and to provide them with an easily recognition tool of generic medications and, in doing so, facilitate their election process within the scope of the doctor's prescription.

Other key pieces of legislation in the Chilean legal healthcare framework are the **Guide of Good Prescription Practice** and the **Decree 466** of 1984 (article 38) regulate the prescription requirements mentioned in the section above.

7.4 UNIVERSE OF DRUGS

The National Medication List is approved by the National Health Ministry. The medications it encompasses must be, by law, available for all the Chileans in pharmacies.

The list is structured with the following inclusion priorities, which are, namely, the expression of any government budgetary restrictions:

1. Products defined as indispensable
2. Products whose security and efficiency is well demonstrated
3. Products that comply with the principles of evidence, especially those that integrate pharmacopeia incorporated to clinical norms, therapeutic guides or protocols that are approved to addressed the most pressing pathologic needs or health policies of the country.
4. Products that have a verified efficiency over cost relation.

The Undersecretary of Public Healthcare is in charge of creating a Commission (technical and scientist) that is in charge of updating and administering the list. The list is updated every 2 years.

Every medications of this registry stays on it for 5 years long (if the pharmaceutical surveillance do not find any risk for its commercialization), at which date it will be re-considering from the national system of pharmaceutical product control (article 11-12 of the decree 1876 of 1995).

7.5 FINANCING MECHANISMS

Chile has a mixed health system where both the public and private sectors cover members of the population. Currently, 77% of the population is medically insured by the public sector while 23% of the population is privately or alternatively insured, or not insured at all.

The public sector is primarily administered by the National Health Fund (Fondo Nacional de Salud, FONASA) and the National System of Health Services (Sistema Nacional de Servicios de Salud, SNSS), created in 1979 by the law 2763.

The SNSS is organized according to the Institutional Bys of Health Services (Reglamento Orgánico de los Servicios de Salud, 1980) and is composed by the Ministry of Health and its dependencies, which include: 29 State Health Services, the Public Health Institute (Instituto de Salud Pública, IPS), the Central Supply Clearinghouse (Central de Abastecimiento del Sistema Nacional de Servicios de Salud, CENABAST), the Health Superintendence (Superintendencia de Salud), and FONASA.[45]

The 29 State Health Services (Servicios de Salud) are **not** healthcare providers (as in the case of Mexico) but rather administrators of health services that coordinate with actual health providers to ensure that the population has access to health services, as mandated by the government.

The Public Health Institute (Instituto de Salud Pública, ISP) is a legal entity that acts as a national reference and collaborates with a wide range of public and private actors. Some of the ISP's most important responsibilities include regulating medications and checking their quality and safety; authorizing the establishment of pharmaceutical laboratories/factories in the country and inspecting them; and, licensing any medical related products that are to be sold in the market.[46]

The Central Supply Clearinghouse (Central de Abastecimiento del Sistema Nacional de Servicios de Salud, CENABAST) is the public entity, created in 1979 by the law 2763, in charge of acquiring and distributing medications, medical goods and devices, and foods for the hospitals and clinics of the Chile's Assistance Network (Red de Asistencia) so that these are in compliance with the Ministry of Health's agenda.[47] The Assistance Network helps the SNSS carry out is functions and has three different levels of specialization: primary, secondary, and tertiary assistance levels. Essentially, CENABAST is the government's supply house and it ensures that the state has the medical goods required by the SNSS. One it its key features is that it buys goods in bulk to obtain the most economic prices.

The Health Superintendence, created in 2005 by **Law 19.937**, is a decentralized entity that supervises the private insurance sector to ensure that it complies with national

[45] Chile's Health System: The Historical and Legal Context of the Chilean Health System, Colegio Médico de Chile
[46] Instituto de Salud Pública, Potestades, competencias, responsabilidades, funciones, atribuciones y/o tareas. Gobierno Transparente website
[47] CENABAST website

law and makes sure that FONASA respects the peoples' right to health coverage and services.

Finally, FONASA is the financial representative of the public health system and manages all of the system's finances. Specifically, it is responsible for gathering, administering, and distributing state resources allotted to health in accordance with the policies set out by the Ministry of Health. The fund is also in charge of collecting all mandatory contributions levied on Chile's inhabitants for health services and investing these in the system. Additionally, it takes care of the part of the population that is not able to contribute towards their health expenses through subsidies. Currently, FONASA covers 13.4 million people in Chile, or about 77% of the population.[48]

Thus, the overall structuring of Chile's public health sector is well established and tied to national law. It is important to consider that these entities are subdivided throughout the country's territory, making them decentralized and increasing their capacity to attend to the specific needs of different parts of the population.

In 1981, a private system of Provisional Health Institutions (Instituciones de Salud Provisional, ISAPRE) was established and it covers around 16% of the population that elects to insure themselves privately. The 14 existing ISAPRE are free to structure their coverage schemes as they see fit and competition is prevalent in the system.

The ISAPRE Authority was created in 1990 and it records and audits the legal and financial aspects of private health institutions and resolves disputes between them and beneficiaries.[49] It is a public entity and is part of Chile's Ministry of Health.

In the 1990's, around 25% of the population was insured through ISAPRE but alterations in health laws have reduced the total number of affiliates. The explicit guarantee regimen and modifications to the federal fiscal and regulatory policies imposed on ISAPRE have both favored affiliation with the public sector. Consequently, ISAPRE have attempted to enhance their insurance benefits and packages by offering more attractive insurance plans.

There are also a few additional health insurance providers that include non-profit organizations and institutions that offer work-related accident insurance, insuring a small fraction of Chile's population.

7.5.1 Financing Chile's Health Care System

In 2011, Chile's total health expenditure represented 7.5% of its gross domestic product. Almost half of this amount (47%) was spent by the government, while the remaining 53% expenditure came from the private insurance sector. Of total government expenditures in 2011, 15.1% was spent on health. Conversely, ISAPRE expenditures represented 29.9% of total private health expenditures while out of pocket payments made up the rest (70.1%).[50]

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[48] FONASA website, total population obtained from most recent World Bank Data.
[49] World Health Organization, Profile of the Health Service System: Chile
[50] Chile – National Expenditure on Health, World Health Organization

By law, all employees in Chile must contribute 7% of their income to FONASA or ISAPRE, depending on the nature of their affiliation. Based on the plan they choose, people that insure themselves with ISAPRE may pay additional contributions, also deducted from their income. Employers are required to contribute small amounts and some firms must offer their workers labor insurance, by which their contribution requirements differ from others.

The state also subsidizes some of FONASA's activities and directly pays health providers for a percentage of their services. Federal resources spent on health are gathered from federal taxes and contributions from other ministries and government entities that must allot a portion of their budgets to health. **Citizens are also subject to out of pocket expenditures such as copayments and charges for services that are not covered by insurance plans.**

In FONASA, affiliates are subject to copayments based on their income. Affiliates are placed into one of four categories (A, B, C, D) and depending on how much their incomes vary from the national minimum monthly income, are required to pay a percentage of the total cost of the service they are receiving. The A and B categories include members of the population that make less than the minimum monthly income or no money at all and are subject to 0% copayments. People in the C and D categories are those who earn more than the minimum monthly income and are subject to 10% or 20% copayments and can receive health treatment from the private network of health providing centers. Furthermore, as the level of attention increases, wealthier affiliates receive less coverage by FONASA and must pay for a greater proportion of their services.[51]

Additionally, social funds and non-profit organizations also donate and contribute resources. These make up the main financing sources in Chile's health system enabling it to carry out its operations in the benefit of the population. The following chart shows the FONASA and ISAPRE distribution of resources in Chile's health system:

Health Care Provision and Coverage

In 2000, the Chilean government proposed an initiative to modify the health system in order to make health provision more equal in the country. Known as the AUGE reform, it is considered to be the most important initiative in recent years and it introduced minimum required guarantees (garantias obligatorias exigibles) that established certain standards in Chile's health care provision. **Based on the population's experience with healthcare provision the AUGE reform selected a number of problems in the healthcare system and established opportunity guarantees that among a number of things set up maximum waiting times for patients, instituted minimum accreditation requirements for medical practitioners, and limited out of pocket expenditures to ensure that people do not face catastrophic health expenses, among other things.**

[51] Cobertura Plan de Salud, FONASA

Some of the reform's principal objectives included improving equality in the system, reducing the disparity of health service quality that exists throughout the population (as a function of income), and responding to the necessities expressed by the population.[52]

AUGE stands for Universal Access with Explicit Guarantees, (Acceso Universal con Garantías Explícitas), created in 1985 by the law 18.469 and 18.933, and reinforced by the law 19.966 in 2004, and the key feature of this reform was that it **set out to create a method to universally insure the entire Chilean population, regardless of whether they are insured by FONASA or ISAPRE, against a selected list of diseases.** Again, it does this by guaranteeing certain requirements and as with the financials behind FONASAS's basic health plan, attends the needs of the population based on their income. On 1 July 2013, the government added eleven diseases to the AUGE list resulting in a total of 80 AUGE diseases and it is estimated that 9 million Chileans benefit from the AUGE 80 list.[53]

7.5.2 FONASA Coverage

As was mentioned, there are 29 Health Services that work with an assistance network made up of actual healthcare providers to safeguard and foster the wellbeing of the population. Health services offer primary, secondary, and tertiary levels of attention, depending on their location and the population's need.

- The primary level covers most of the population's needs through ambulatory care that includes visits to the doctor, health education and awareness, and vaccination services. Providers that offer primary level assistance are equipped with basic medical and diagnostic technologies and are staffed by a variety of practitioners ranging from auxiliaries to general physicians.

- The secondary level covers a wider range of services and can include ambulatory and hospital care. More resources are invested in this level of assistance providing it with a larger base of specialists and more advanced technologies.

- The tertiary level is characterized by its high complexity and specific coverage. This level of care is meant to look at cases that cannot be covered by the preceding levels and has the most specialized physicians and advanced medical technologies and equipment. Like the secondary level, it offers both ambulatory and hospital care but only treats cases that cannot be dealt with by the other levels of assistance.

Based on its affiliates' incomes, FONASA offers a Plan de Salud that covers primary level care, specialized and hospitalized attention, and AUGE guarantees. Primary healthcare is completely covered for all affiliates but secondary and tertiary levels of care differ depending on affiliates' incomes.

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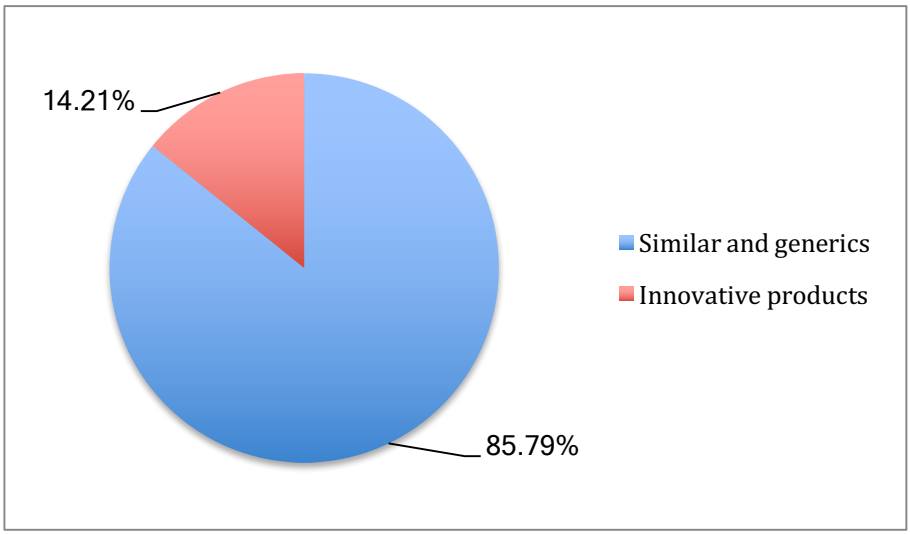
[52] La Reforma de Salud en Chile – UNDP. p. 10
[53] AUGE, Ministerio de Salud, Gobierno de Chile

As mentioned, by law, the national medication list must be accessible to everyone and **FONASA guarantees its affiliates 100% financial coverage for the medications included in the list. Because products must be listed under their international nonproprietary names, generic medications play an important role in the public pharmaceutical market;** according to a document published by the Panamerican Health Organization in 2010, generic medications represented 39.3% of sales in the pharmaceutical market, brand sponsored generic medications represent 38.5% of sales in the market, and brand products represent 22.2% of sales in the market.[54]

The high number of generics that are present in the pharmaceutical market result in Chile's total expenditure on pharmaceuticals and other medical non-durables per capita being significantly lower than the OECD average; in 2011 Chileans paid an average $197.4 USD per person for medical goods while the OECD average was $498, **making Chile the OECD country with lowest per capita pharmaceutical expenditures.**[55]

Furthermore, the Central Supply Clearinghouse's (*Central de Abastecimiento del Sistema Nacional de Servicios de Salud, CENABAST*) bulk purchases of medications make them significantly cheaper for consumers. A presentation prepared by CENABAST provides a chart illustrating the kind of medications that are purchased by said institution.

Graph 25. Purchased medications



Source: Cenabast

7.5.3 ISAPRE Coverage

As of 1 July 2013, a Guaranteed Health Plan (Plan Garantizado de Salud, PSG) was created for the ISAPRE system and must be offered by all private health insurers. There are four main components that the PSG covers and these are AUGE diseases,

[54] Salud en Chile 2010 – Panorama de la situación de salud y del sistema de salud en Chile, Organización Panamericana de la Salud. p. 75
[55] OECD Health Data 2013 - Frequently Requested Data, June 2013

non-AUGE diseases, coverage for catastrophic expenditures, and preventive medicine examinations.[56]

ISAPRE are free to price the PSG as they see fit, promoting price competition, but it must be exactly the same in all of them. Additionally, patients that desire or require more insurance can acquire complimentary plans along with their PSG. ISAPRE can offer complimentary benefits, through extra plans, though they require extra payments from affiliates. There are no restrictions for affiliates wishing to switch between private insurance providers, once again promoting competition between ISAPRE.

Currently there are 229 private health establishments that access medications directly and 1,662 private pharmacies out of which 93% belong to three main suppliers.[57] Like public pharmacies, private pharmacies are required to offer the national list of medications though there are exceptions. In the private assistance sector (i.e. hospitals and clinics), 80% of the medications acquired are the same ones that are available in the public sector.

It is important to note that the ISAPRE assistance network of health providing institutions may treat patients that are insured by either the public or private sector; FONASA affiliates with enough resources can choose to refer to private institutions.

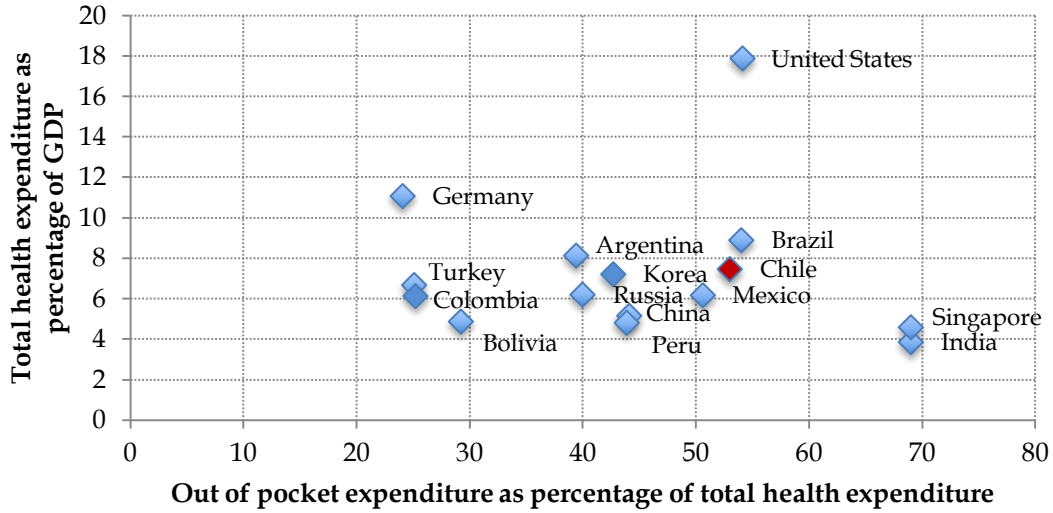
The 2008-2009 Health Superintendence survey found that 50% of ISAPRE affiliates use private health clinics and hospitals, 37% of them visit doctors privately, and 27% see radiologists and other specialists.[58]

Thus, although the majority of the population relies on public health providers, a significant portion of FONASA affiliates resort to private institutions removing some of the pressure from public institutions, once again evidencing the balance that exists in Chile's health system.

This is shown in the graph below, where it can be seen that Chileans face a heavy out of pocket expenditure, even more so than Mexico.

[56] Proyecto Ley que Crea el Plan Garantizado de Salud en Isapres, Luis Romero Strooy, Superintendencia de Salud, Gobierno de Chile
[57] El Rol de la Central de Abastecimiento en la Regulación de Precios de Medicamentos en Chile, Cenabast, 2008
[58] Salud en Chile 2010 – Panorama de la situación de salud y del sistema de salud en Chile, Organización Panamericana de la Salud. p. 82

Graph 26 Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011



Note: Out of pocket expenditure as a percentage of health expenditure
Source: Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

7.6 HEALTHCARE PERFORMANCE

These politics did have good results since, as mentioned before, they made Chile the OECD country with lowest per capita pharmaceutical expenditures ($197.4USD per person). The lowest cost of medication in Chile implies a large access to the healthcare for its people and a lower cost of social security through the coverage system. And Chile has succeeded to that low medication price despite of its low regulation of drugs prices.

7.6.1 Main indicators

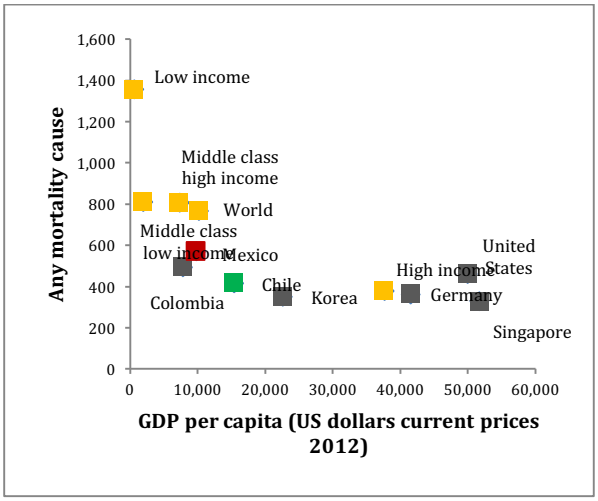
In the last 30 years, Chile has attained impressive levels of development and its human development index (HDI, constructed by the United Nations Development Program) has grown by 28% since 1980 (0.8% annual growth), placing it in the very high human development category. Life expectancy at birth in the country stands at 79.3 while in 1980 it stood at 69.2; between the same periods expected years of schooling increased from 11.4 to 14.7; and, gross national income grew by 175% since 1980, amounting to $14,987 (2005 PPP$).

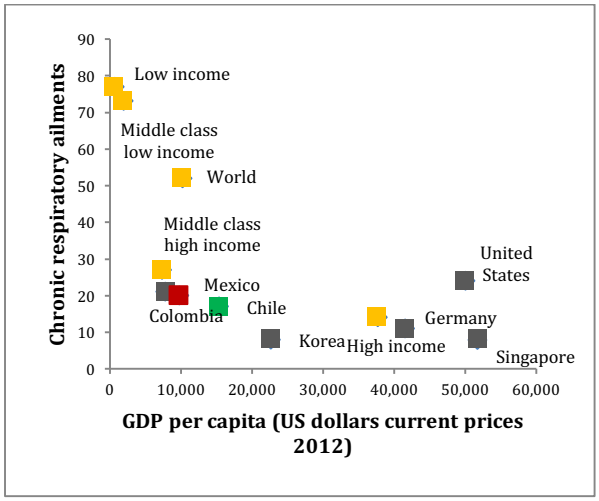
Even if Chile has showed a lot of amelioration in its healthcare system and in its general population health, we can still see that it's a developing country with some delay from other countries. Obesities and diabetes indicators are growing more and more every year. However, thanks to its healthcare system, Chile is still much better than México. Regarding the diabetes figures, in 2008 according to WHO, the age-standardized (30-70) mortality rate for diabetes causes was de 114 for 100 000 inhabitants whereas it was 217 for México.

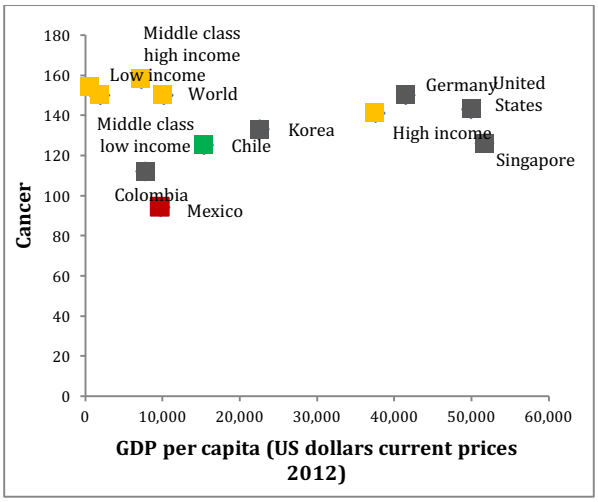
Moreover the probability of dying under five years old is the double in México than in Chile. These figures are very important since according to WHO, in 2030, diabetes

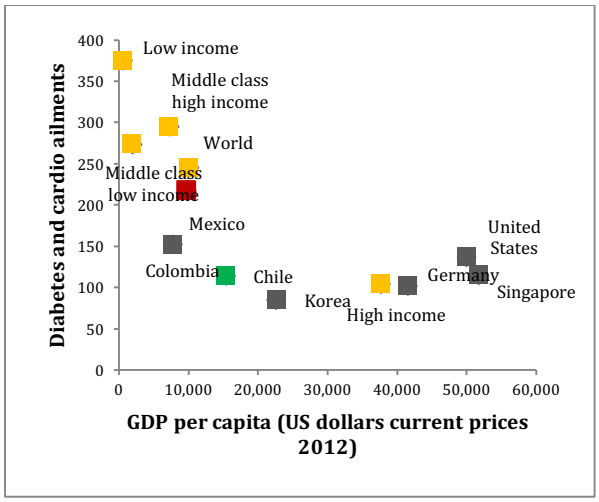
will be the 7th mortality cause in the world. This fact shows the urgency for developing country to follow healthcare system which are really working, as in the more developing country as South Korea, Germany, Singapore.

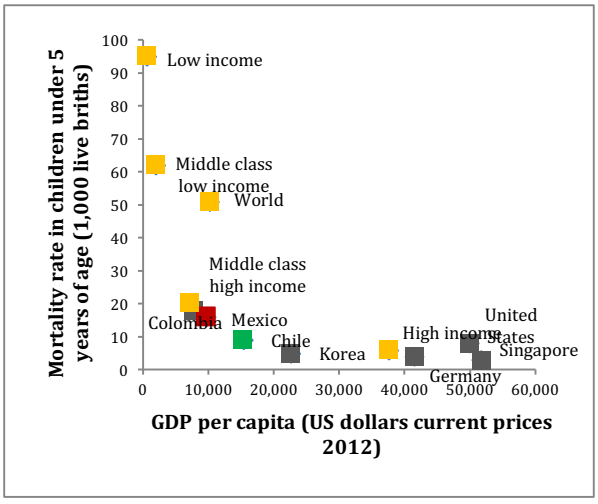
Graph 27 Key performance indicators for the Chilean health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

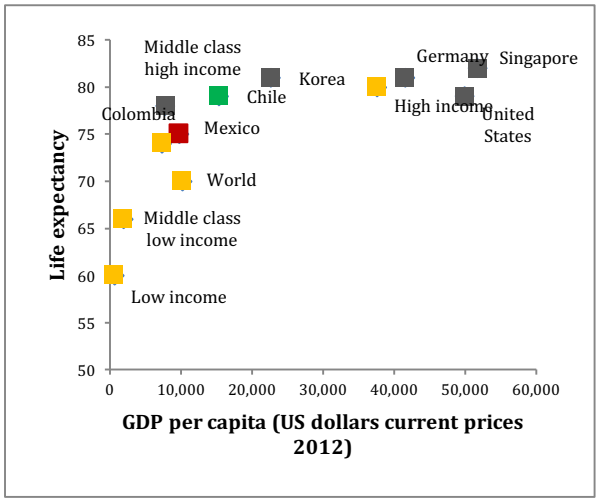












Source: World Health Organization 2013 Statistics

As can be seen in the graphs above, Chile performs better than Mexico in all the indicators, except the cancer mortality.

7.6.2 Competitiveness

The link between a healthy population and a wealthy economy is very strong. Indeed a population with a good health is going to be more productive in its work, fact that will permit the country to be more competitive with others.

The availability and the easy access of medicines are guaranteed by the freedom of prescription and ensure the good health conditions indispensable to a wealthy economy. As we already known the low prices of medicines in Chile is one of the main reasons that permits a good access to medicines and to efficient care. Thanks to that, Chile, according to IMCO and to the World Economic Forum is one of the 30th countries the most competitive in a world.

Table 12 Chile's position in competitiveness indexes

Chile's general position	
World Economic Forum	IMCO
33th/144	24th/46
Chile's position in the healthcare pillar	
World Economic Forum	IMCO
74th/144	28th/46

Source: World Economic Forum, Global Report on Competitiveness, 2013 and Instituto Mexicano para la Competitividad, International Competitiveness Index 2013.

8 FREEDOM OF PRESCRIPTION IN COLOMBIA

8.1 SUMMARY

- The Colombian healthcare system is behind others countries in this analysis, in terms of medications costs and healthcare access. Life expectancy at birth is below than the continent's average, mortality rate is also higher and the cost of medicines *per capita* is higher than OECD countries. Moreover challenges in the Colombian healthcare system are also linked to corruption and economic instability.
- Nevertheless Colombia has one of the lowest out of pocket expenditure rates, which is a good indicator of the healthcare system's equality.
- The general system of social security is quite young since it was created by the law 100 in 1993, and it should take more than 10 years to produce tangible benefits.
- Freedom of prescription is one of the policies that government has adopted to ameliorate its healthcare system and facilitate access to medicines. These policies should facilitate the access to healthcare in terms of price and availability of pharmaceutical products in Colombia.
- Although freedom of prescription is absolute under patients' demand, government only dispenses those medicines that are part of the Manual of Essential and Therapeutic Medicines.

8.2 PRESCRIPTION MECHANISM

The prescription mechanism in Colombia is simple and it's framed by the law 1938 of 1994. This instrument states that medical prescriptions won't be admitted if drugs are not enlisted in the Manual of Essential and Therapeutic Medicines, unless patients ask for a specific prescription, recognizing, thus, that if drugs do not belong to the Manual of Essential and Therapeutic Medicines, they have to be covered at patients' expense.[59]

Patients' rights are respected as patients have the freedom to ask for information about their treatment needs, and options, and they can have access to first class medication, if they pay for them.

Moreover, according to WHO, social security prescription in Colombia **must** include International Non-proprietary Name and **may** include brand name. The aim is to increase sales of generic medicines in order to decrease the overall cost of pharmaceutical products in the country. It also allows patients to choose the drugs they want in the pharmacy, as they may substitute the generic for the brand one or

[59] Capítulo IV. Artículo 23, Parágrafo 4to.

the opposite. This brings evidence that the Colombian framework respects the patients' power of decision about their own health.

8.3 LEGAL FRAMEWORK

In Colombia medicines are classified in five groups (Law of medicines, article 37):

1. Medicines that do not need a prescription
2. Medicines that patients can be acquired in accordance with the *Norm on narcotic and psychotropic substances*
3. **Medicines that need a specific control and can only be acquired with a valid prescription**
4. **Medicines that need a prescription. The provider has to keep the prescription in order to register it in a special archive**
5. **Medicines that need a prescription and could be dispensed as many times as the doctor indicates**

Regarding the group of medicines that require prescription, the law 1938 issued in 1994, provides a legal framework for healthcare providers to make prescriptions:

- Only authorized medical personnel should be able to make a prescription
- All prescriptions should be handwritten once the patient evaluation and the diagnostics have been done
- It is compulsory to inform the patient about the way medicines have to been taken, about risks, side effects and usage conditions
- It is compulsory to inform the patient about the way medicines need to be stored, how to measure the dose and when to reject it or destroy it. For no reason should the patient change the concentration, or the pharmaceutical form or the prescribed amount
- **Medical prescriptions won't be admitted if they're not listed on the Manual of Essential and Therapeutic Medicines, unless the patient asks for it, but medicines will have to be covered at patients' expense as part of a complementary plan.**

Colombia's National Health Insurance (Sistema General de Seguridad Social en Salud, SGSSS) was formally established in 1993 as a result of the approval of Law 100. This legal instrument states that "*the integral social security system is responsible of guaranteeing the population of Colombia their fundamental rights to ensure that they have access to a quality of life in accordance with human dignity, by protecting it from the*

contingencies that affect it… The State guarantees the population its coverage of all economic, health, and complementary services".[60]

8.4 UNIVERSE OF DRUGS

The aforementioned law 100 created the integral health security system. This system is a mixture of laws, regulations and institutions that provided access to high quality public healthcare services. Through this law, the Medicines and Food Vigilance Institute (INVIMA) was designed to formulate regulation policy on the price of medicines, quality standards and security. INVIMA has to inform about the prices and legal status of every single medicine that is sold in the country.

One of the most important tasks of INVIMA is to develop the Health Registry every ten years, which is a collection of the medicine products that have the authorization to be produced, exported, imported, and sold in the Colombian territory. INVIMA performs evaluations in order to assess whether a medicine product could be included in the Health Registry.

According to the article 26 of the decree 677 of 1995 which describes the regulatory process of medicines and foods, there are three compulsory evaluations which must take place before a medicine product can be included in the Health Registry:

- Pharmacological evaluation: technical evaluation of the risks, efficiency, toxicity, interaction, and contraindication
- Pharmaceutical evaluation: is an assessment which relates to the capacity of the producers to create a safe and high-quality product (technical capacity of the producer, production process, product quality)
- Legal evaluation: is the assessment of all the documents a producer needs in order to include its product in the Health Registry

The Health Registry is the list of all medicines authorized in the country, and the Manual of Essential and Therapeutic Medicines describes the list of all medicines that are part of the Health National Plan, which are susceptible to be dispensed with no cost or reimbursed by the Health Ministry. This Manual contains a list of the most needed medicines:

- Medicines for special program which will be free of charge for every person who aren't registered on a health program entity and for all the population in case of amplified immunization program.
- Medicines for chronic pathology which represent very high costs
- Medicines for ambulatory use
- Medicines for hospital use

[60] Diario Oficial No. 41.148 de 23 de diciembre de 1993. Colombia.

- Medicines of special use, with high risk

The aim of INVIMA is also to pursue a pharmaceutical surveillance, by running the National Program of Pharmaco-viligance (NPPH-V). Its purpose consists in identifying and estimating different risks related to the utilization of medicine products with the aim to protect patient health. It also informs and educates the population about medicine usage. To reinforce the NPPH-V, INVIMA organized a network of experts and institutions that have permanent contact with INVIMA. The goal of this group is to inform each other about any information they get related to unsecure medicines or incorrect usage of medical products. The network represents an alternative to activate and support the diffusion of the information and knowledge about medical problems.

8.5 FINANCING MECHANISM

The national pharmaceutical policy in Colombia began to develop 40 years ago when the government started to formulate initiatives that "*aimed to rationalize therapeutic and economic usage of medications in the country. For example, a medications list and centralized purchasing model were adopted as well as a mechanism to finance exceptionally expensive treatments for serious illnesses*".[61]

Since the creation of the system and the approval of the 100 law in 1993, the Colombian government has been able to insure the majority of its population. In 1992 only about 20% of the population had some form of medical insurance and by 2009 this amount had increased to more than 90% of the population.[62] Regarding the lowest income population, while in 1995 less than 10% had some form of medical insurance; by 2008 this amount had grown to 80% making this part of the population the one with the largest affiliation growth rate.[63] Conversely, the insurance growth rate of the richest segment of the population changed by much less, as in 1995 more than half of this quintile was already insured.

The differences of insurance affiliation levels throughout the Colombian population are important because they evidence the inequality and disparity that exists in the country. Like Mexico, Colombia's inequality index which is a part of its Human

[61] Documento CONPES Social 155, Consejo Nacional de Política Económica y Social, Departamento Nacional de Planeación, Colombia. 2012. p. 5.
[62] Pinto D, Muñoz A, Colombia: Sistema General de Seguridad Social en Salud, Estrategia del BID 2011-2014. Inter-american Development Bank. 2010. p. 22
[63] *Ibid* p. 23.

Development Indicator, is quite unequal, standing at 0.519 (a 0 represents total inequality while a 1.0 represent total equality).[64]

However, because of the establishment of the SGSSS, the wellbeing of the Colombian population has increased substantially in recent years and its level of human development is now very close to the Latin American and Caribbean average and higher than the world average. The following sections will outline Colombia's SGSSS scheme and discuss some of the effects that it has had on the wellbeing of the population.

The Law 100 states that all members of the Colombian population must be affiliated to a Health Promoting Entity (Entidad Promotora de Salud, EPS) under the SGSSS. People primarily affiliate themselves with one of the two main regimes, Contribution Regime (Régimen Contributivo, RC) and the Subsidized Regime (Régimen Subsidiado, RS).

The RC includes "all employees, the self-employed, and pensioners" while the RS exists for the low-income part of the population that is unable to generate the resources needed to join and finance the RC.[65]

Unfortunately, the SGSSS is subject to an enormous financial pressure as 51% of the population depends on subsidies and is affiliated with the RS, while only 40% of the population is affiliated with the RC and is financially contributing to the overall system.[66] Additionally, 2% of the population is affiliated with Special Regimes (i.e. military, court members) and a small percentage of the population has no affiliation at all.[67] Thus, Colombia is on the way to achieving universal health care but still has some ground to cover before it can fully tackle the objectives set out by its government in 1993.

The pensions system works in collaboration with the affiliates of the RC. Since pensioners were formally employed, they keep the relationship with their original EPS that insured them when they were still working. The difference is that pensioners can define their contribution rates and these go to the Pensions Fund, rather than the EPS.

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[64] International indicators on human development, Colombia, UNDP. 2013. The Human Development Index looks at 187 countries and is annually performed by the United Nations Development Program.
[65] Pinto D, Muñóz A, Colombia: Sistema General de Seguridad Social en Salud, Estrategia del BID 2011-2014. Inter-american Development Bank. 2010. p. 3
[66] *Ibid.*
[67] *Ibid.* p. 4.

According to a study undertaken by the Colombian National Council on Economic and Social Politics[68], the lack of a well-developed national pharmaceutical policy has created a series of problems that hinder the SGSSS's effectiveness, and these include:

- Inadequate and irrational usage of medications
- Lack of quality in health services
- Inefficient use of financial resources
- Inequalities when accessing medications
- The inefficient supply and availability of essential medications, partly due to the lack of regulation and transparency
- Low quality information on performance of the system as a whole
- Scarce monitoring of the pharmaceutical market

To overcome some of these obstacles, in 2007 a legislation established a Control, Inspection, and Monitoring System for the SGSSS that works in collaboration with the National Health Superintendence (Superintendencia Nacional de Salud, SNS). The SNS is part of the Ministry of Social Protection and inspects, surveys, and controls the activities undertaken by the EPS and Health Providing Institutions (Instituciones Prestadoras de Servicios de Salud, IPS), amongst other actors that will be discussed further on.

Moreover, the SNS is divided into five delegations that are allowed to impose sanctions and issue immediate orders to ensure that all SGSSS entities (i.e. EPS, IPS) operate correctly. Unfortunately though, the lack of resources largely subdues the efforts undertaken by the SNS to regulate the SGSSS and ensure its proper operation.

Additionally, there are two other entities that supervise the quality of services being offered by the SGSSS. The National Health Institute "is the national health, scientific and technical authority responsible for promoting, guiding, and supporting scientific research in health and bio medications to develop, apply, and transfer technologies into their fields of action".[69] With its research, the Institute provides the Ministry of Social Protection with a guide to how services in the SGSSS should operate.

The other entity that supervises quality in the SGSSS is the National Surveillance Institute of Medications and Food and it is the "entity responsible for enforcing policies on sanitary surveillance and the quality control of medications" and other substances.[70] In theory, both Institutes provide a measure of quality control for the

[68] Documento CONPES Social 155, *op. cit.* p. 9
[69] Pinto D, Muñóz A, Colombia: Sistema General de Seguridad Social en Salud, Estrategia del BID 2011-2014. Inter-American Development Bank. 2010. p. 22
[70] Idem

administration to guide the SGSSS but in practice, the government's lack of resources and the disparity that exists between health services throughout the country makes it difficult for the government to apply some of the policy suggestions that are issued by both Institutes.

8.5.1 Financing the Contribution and Subsidized Regimes

The RC generates its resources through the mandatory contributions that are deducted from the monthly salaries of all members. The contribution that is paid directly to the EPS, is split between the employee and the employer at 4% and 8.5% respectively, amounting to 12.5% of the employee's monthly salary. [71]

Being affiliated to the RC entitles a person to "a wide range of services, the automatic affiliation and insurance of their family members and dependents, monetary subsidies in case of incapacity by illness, and compensation for maternity leave".[72] All RC contributions are gathered and managed by the Social Security and Guarantee Fund (Fondo de Seguridad Social y Garantía, FOSYGA), the entity responsible for administering the SGSSS's resources.

On the other hand, the RS obtains its resources from a number of sources including FOSYGA. All RC contributions have a 1.5% deduction that is transferred to the RS form FOSYGA. Additionally, the RS is the recipient of federal resources transferred by the General Participation System that distributes national resources throughout the country.

Since 2001, Law 715 requires that 24.5% of federal resources be spent on public health. The financial scheme of the RS poses a serious challenge to the government since the regime must subsidize the medical insurance of more than half the population by partially deducting potential resources from the section of the population that financially contributes to the system. To some extent this is due to irregularities in the country's labour market (i.e. 10.3% unemployment rate[73], informal labour markets), something that exceeds SGSSS competence.

8.5.2 Health Promoting Entities, EPS

Upon joining any of the principal affiliation regimes (RC, RS), members obtain the right to insure themselves with any of the country's EPS, which are entities that

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[71] Ibid. p. 3.
[72] Sistema de Seguridad Social en Salud, Ministerio de la Protección Social. Colombia, p. 7
[73] Indexi 2012 estimate

cover medical costs for the Colombian population by exchanging risks for primes. EPS have contracts with Health Providing Institutions (IPS) that include hospitals, health clinics, doctors' offices, and laboratories and are responsible for providing health services to the population.

People are free to choose which EPS they want to be insured with and can change insurance once every 24 months. Because the law mandates that all EPS must offer the same benefits package (Plan Obligatorio de Salud, POS) at the same price, EPS are only able to compete in terms of the extent and quality of their coverage, reflecting the government's interest in making the National Health system competitive. Once a person has signed up with an EPS, the affiliate and their immediate family and dependents obtain the right to "receive all the services and medications included in the POS"[74], that is regulated by the Health Regulation Commission (Comisión de Regulación en Salud, CRES). Among a number of things, the CRES annually "defines and modifies the list of essential and generic medications that are to be included in the benefit packets", and regulates the financial scheme of the SGSSS.[75]

8.5.3 The Mandatory Health Plan (Plan Obligatorio de Salud, POS)

The POS is a set of health services that offers an array of medical services like, "*general and specialized medical consultation on any medical area, hospitalization and surgery for any case that is required, and essential medications in their generic form*".[76]

People affiliated through the RC are entitled to receive a different POS from those affiliated through the RS, or a Special Regime. In other words, **basic health coverage relies on the affiliation regime**.

As stated by the Ministry of Social Protection, regardless of the cost or complexity that it takes to treat the health of a patient, the POS includes medical services needed to treat any illness, as long as the services are included in it. Additionally, patients may be provided and covered for services not included in the POS if they are in a critical condition.[77]

Furthermore, a resolution (number 0002851) published in the Official Journal of Colombia on 19 September, 2012 states that if patients requires a medication not included in the POS, their EPS will remain responsible for the coverage of that

[74] Sistema de Seguridad Social en Salud, Ministerio de la Protección Social. Colombia. p. 7
[75] Pinto D, Muñoz A, Colombia: Sistema General de Seguridad Social en Salud, Estrategia del BID 2011-2014. Inter-American Development Bank. 2010. p. 17
[76] Sistema de Seguridad Social en Salud, Ministerio de la Protección Social. Colombia. p. 7
[77] Ibid. p. 18.

affiliate, as long as the patient has a valid medical justification explaining why he or she required a medication not included in the POS (in the case of this specific resolution, the documentation can be through a receipt of the medication).[78]

One of the biggest challenges that the government currently faces is the existence of different POS and the need to merge these into one universal benefits package. However, the government's lack of resources hinder its abilities to synthesize the different POS, which is why today the only truly universal package that the government can offer is the Public Health Plan of Collective Interventions. Unfortunately the extent of its coverage is significantly limited.

8.5.4 The Copayment System

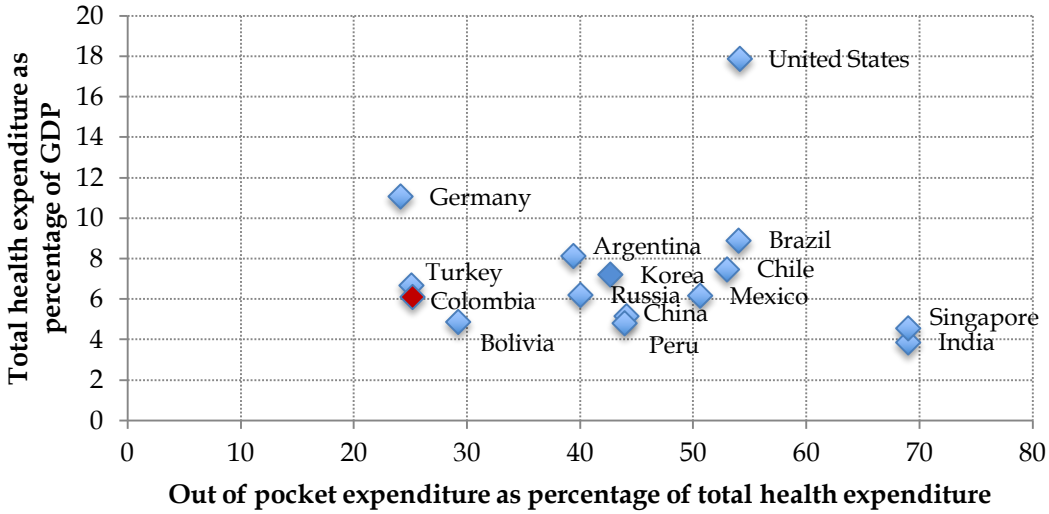
When receiving services under the national insurance scheme, patients must pay "moderating fees" that serve as demand reducers. The fees depend on a patient's base income contribution rate and are annually established and updated by the CRES.

Users of the SGSSS are also required to make copayments, which represent a fraction of the total cost and depend on the socioeconomic status of patients. Copayments have maximum value caps per visit and per year. Thus, out of pocket payments represent an important source of income for the SGSSS, especially in the Contribution regime. In 2009, out of pocket expenses in the RC added up to 12.7% of the SGSSS's revenues while the same payments in the RS represented 2% of revenues.[79]

In the international sphere, Colombia as a very efficient country in terms of health expenditure, as only one out of every four pesos is considered out of pocket, while in Mexico or Chile this expenditure increases to 50.6% and 53% respectively. The contrast differs even more if we consider that the total health expenditure in Colombia represents 6 GDP points. In this regard, as is shown in the graph above, Colombia differs clearly from Germany, where the total health expenditure adds up 11% of GDP with almost the same out of pocket expenditure as Colombia.

Graph 28.Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011

[78] Resolución Número 0002851, Diario Oficial 48.558. Bogotá, Colombia.
[79] Ramírez, Barón. Cálculos basados en datos: ECV2008, DNP, FOSYGA.



Note: Out of pocket expenditure as a percentage of health expenditure
Source: Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

The Colombian out of pocket expenditure is a good indicator of equality in the healthcare system. It shows that, even if the cost of medicines is quite high in the country, there is not a direct cost for the citizen, but a general cost for the country through tax contributions. Colombia has a good healthcare structure, but the country's environment (economy, insecurity and corruption) represent the main obstacles for its implementation.[80]

The technical group of the Medication Price Regulation Commission has introduced in 2013 the control of price medicines for 195 medicaments. It represents 30% of the public health spending and this new regulation should cause an average reduction of 40% of the price of medicines (Ministry of Commerce, Industry and tourism).

As it has been mentioned before, the government's lack of resources is problematic because it reduces the efficiency of the SGSSS and puts a limit on how well it can perform. One of the most noticeable problems in the SGSSS is the lack of medications available to the majority of the population. Recently, the Colombian National Council on Economic and Social Politics prepared a document that found that in 2003, 45% of members in the RC failed to receive or only partially received the medications that had been prescribed to them by health providers (55% of them

[80] Chernichovski, Dov, El sistema de salud en Colombia: "Una sinfonía inconclusa y arriesgada", en Observatorio de Políticas Públicas, available at: http://www.achc.org.co/documentos/investigacion/estudios/externos/varios/2.%20El_sistema_de_salud_en_colombia.pdf

received them completely). In the RS, the numbers were 53.4% and 46.6% respectively.

However, the Colombian government has been able to reduce the deficit in medications and in 2009 only 32.1% of the members of the RC failed to receive or only partially received their medications (a 13.1% improvement) while in the RS the amount was 33.3% (a 20.1% improvement).[81]

Still, lack of medications continues to plague the SGSSS's efforts to adequately cover the Colombian population and forces Colombians that are wealthy enough to hire an additional private insurer, while those Colombians that cannot afford an additional service are left with no alternatives.

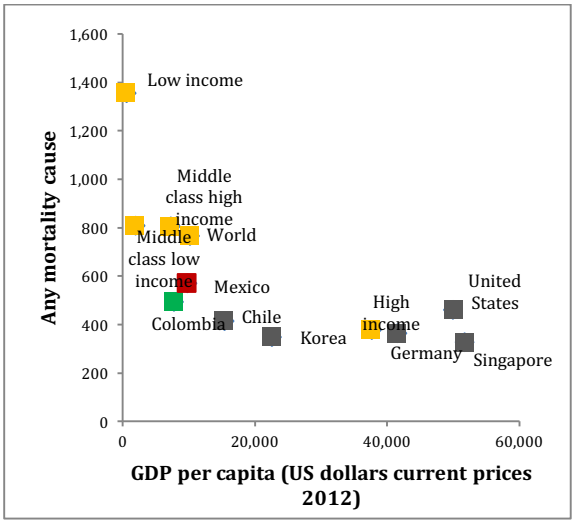
8.6 HEALTHCARE PERFORMANCE

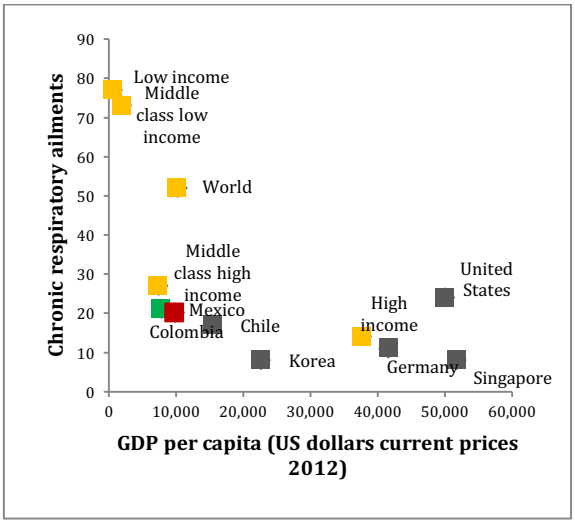
8.6.1 Main indicators

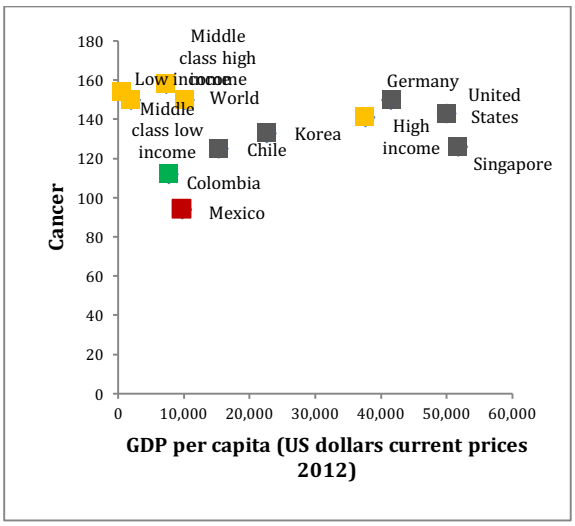
There are several diseases, whose healing, rehabilitation or amelioration process depends heavily on first class medication. Diabetes, cancer, and respiratory diseases represent some of these ailments. Measuring healthcare performance on these diseases allows knowing the level of access to drugs as well as the consequences of the country's regulation on freedom of prescription.

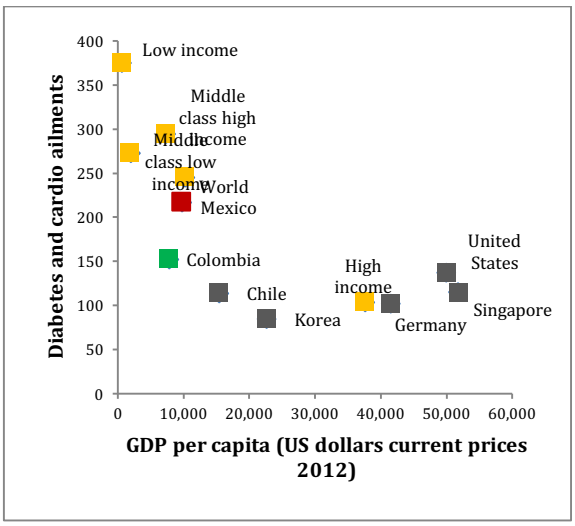
[81] *Idem.*

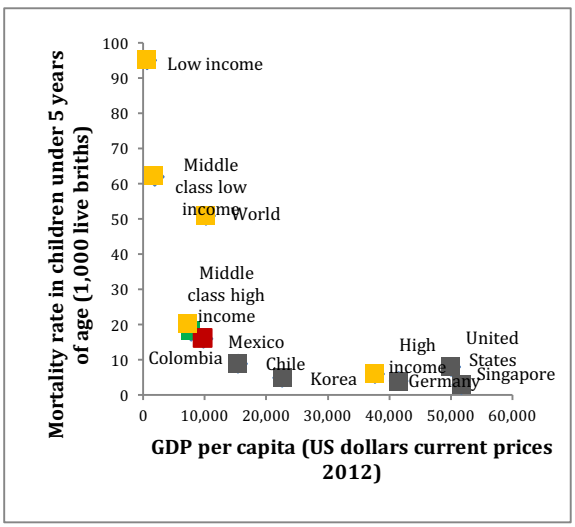
Graph 29. Key performance indicators for the Colombian health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

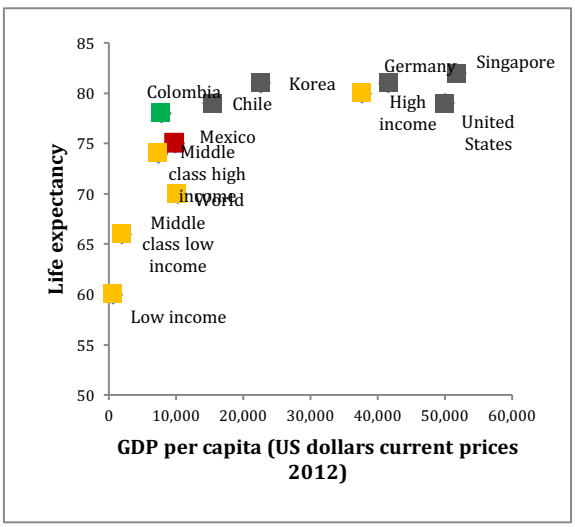












Source: World Health Statistics 2013

As shown in the graphs above, Colombia has a healthcare performance similar to Mexico, especially in the probability of dying of chronic respiratory diseases, and in infant mortality rate. Colombians face a very low probability of dying of cancer, even smaller than countries such as Singapore and Chile. From the graphs is possible to sustain that Colombia behaves closer to middle class high income countries, except for cancer, diabetes and any cause, where Colombia performs even better than them.

8.6.2 Competitiveness

Colombia's score in the World Economic Forum competitiveness ranking is positioned in the middle of the table, as insecurity, corruption and economic issues still affect the country. Thanks to recent measures in social security, Colombia's position in the healthcare pillar should improve for the next years, when access to medicines and high quality healthcare services will be generalized.

Colombian healthcare system has several problems related to the high cost of medications, which derives in limited access and an expensive healthcare cost per capita, mainly due to a deficient price regulation. However price regulations have recently been introduced for 195 medicaments that should drop the general price of medicines.

The system shows some positive aspects related to the multiple treatments and medicines that could be offered to patients. Indeed patients keep their right to be informed about their therapeutic options and ask for medicines that could be used for their treatment, even if they won't be covered by the State, but rather at the patients' expense. The prescription regulation in Colombia allows patients to get appropriate treatments for people that need other medicines than those included on the National Registry. Moreover, patients could have access to innovative medicines, if they pay for them.

Table 13.Colombia's position in competitiveness indexes

Colombia's general position	
World Economic Forum	IMCO
69th/144	41th/46
Colombia's position in the healthcare pillar	
World Economic Forum	IMCO
85th/144	37th/46

Source: World Economic Forum, Global Report on Competitiveness, 2013 and Instituto Mexicano para la Competitividad, International Competitiveness Index 2013.

9 FREEDOM OF PRESCRIPTION IN KOREA, REP

9.1 SUMMARY

- Doctors in Korea have freedom of prescription that is restricted to a Positive List System (PLS). PLS contains only medicines that are reimbursed by the National Health Insurance System, but it doesn't restrict doctors' right to prescribe medicines that don't belong to it.
- There are two different classifications of drugs: **Health registry** for all legal medicines in the country, and a subset constituted as a **positive list** for drugs that can be prescribed by doctors of public healthcare institutions.
- The balance that government achieved between patients' and doctors' rights in a context of limited resources transited from a scheme where pharmacists and doctors were the most benefited actors, to a mechanism that privileges patients instead. Before the reform of 2000, doctors and pharmacists were able to prescribe and sell medicines. Once the two reforms (2000 and 2006) were implemented, doctors could only prescribe to avoid the conflict of interest and patients expenses on medicines would be reimbursed if they belonged to the PLS. This transition placed patients in the center of the debate over freedom of prescription as they currently have the right to be informed about treatments for specific needs, even if they are not included in the PLS.
- The success of the country's national health program can be measured by looking at health indicators gathered by institutions like the World Economic Forum and IMCO, where Korea ranks highly throughout the different indicators.
- Korea has achieved the largest increase in life expectancy in the OECD area.

9.2 PRESCRIPTION MECHANISM

A key feature of the Korean national health system is that it acts in accordance to free market principles. Because the National Health Insurance system does not limit what services or doctors can prescribe, they can benefit from prescribing new medications or technologies, and this provides an incentive to innovate throughout the country.

Through the Ministry of Health and Welfare (MoHW), the government defines what requirements must be satisfied by the National Health Insurance System (NHI) and what will be included in the list of reimbursable medicines. However, the NHI and health providers (mostly from the private sector) are responsible for handling the

insured population and are free to implement catalysts for competition. Currently, around 90% of medical service providers in Korea are from the private sector.[82]

The list of covered medical services and medications offered by the NHI is formed in part by the recommendations issued by the Health Insurance Review Agency (HIRA) and is known as the **positive list system (PLS)**, accessible by anyone who is covered by the NHI, thus making it similar to the Mexican *cuadro basico and catalogue of consumables*.

When a patient receives medical attention, he or she is required to pay a fraction of the service/medication to the health provider and the NHI takes care of compensating the provider with the rest of the cost. The NHI and pharmaceutical companies negotiate the reimbursement prices for the contents on the positive list and the NHI consequently regulates the prices offered to patients.[83]

The NHI fully covers services and medications that it considers essential while services and medications not included on the positive list are covered partially and require contributions made by patients. Currently, copayments amount to about 14% of total health expenditure in the country.[84]

The percentage of what the patient must pay for the service or medication depends on whether he or she must be hospitalized or is just an outpatient visiting a clinic, hospital, etc. The copayment for hospitalized patients is fixed at 20% of the total service cost while copayments for outpatients range in between 30-60% of the total cost.[85]

Because health providers have the freedom to prescribe medications not included in the Positive List of HIRA, patients must frequently make out of pocket payments to acquire services and medications not included in the positive list. However, doctors are required to inform patients of alternatives to expensive medications.

Although this aspect of health provision in Korea results in patients having to deal with out of pocket expenditures, it also means that patients are better informed on what choices they can make to receive the best, or in the case of less endowed individuals, most economic treatments.

Nevertheless, freedom of prescription in Korea poses several challenges in the financing behind the public health system and out of pocket expenses account for 21% of total health expenditure.[86] The limitations of NHI coverage evidenced by the high rate of copayments made by patients has also resulted in a number of Koreans seeking alternative private insurance that includes more services and medications and require less immediate expenditure.

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[82] WHO, MohW, Health Service Delivery Profile: Republic of Korea, 2012
[83] Idem
[84] Jones S. Randall, Health Care Reform in Korea, OECD, Paris, 2010
[85] Idem
[86] Idem

9.3 LEGAL FRAMEWORK

The Korean legal framework of the healthcare system is based on patients' rights to receive information about therapeutic options and to have access to high quality healthcare services. This system is the result of two very important reforms that changed the healthcare system in Korea at the beginning of the 21th century.

The first one took place in 2001 with the aim of avoiding the over-prescription problems and the conflict of interest faced by physicians and pharmaceutical companies. It was expected that this reform would limit doctors' ability to prescribe and supply medications to patients.[87]

Prior to 2000, doctors in Korea were free to directly provide their patients with medications rather than just prescribing them and having the patients acquire them at pharmacies. This was problematic because doctors could profit from directly supplying their patients with medications (sometimes at distorted prices) and they did not always provide them with the most efficient ones.

Furthermore, it was often more convenient for physicians to directly negotiate with pharmaceutical companies and obtain medications not covered by the NHI and in fact, there are evidenced cases where domestic pharmaceutical firms sold lesser quality goods to doctors at a discounted price to boost their own sales.

Thus, prior to the 2000 reforms spending on medications (including over-the-counter drugs) represented 24% of the total health expenditures, an amount significantly higher than the OECD average of 17%.[88] Moreover, the lack of regulation in the supply of medicines greatly damaged domestic pharmacies because the majority of patients would get their medications directly from their doctor. However, pharmacies were also able to sell patients any medication, without the prescription of a doctor, so they too had an incentive to over supply customers with drugs.

The separation reform of 2000 altered the status quo by differentiating types of medications and limiting doctors' and pharmacists' abilities to supply medications to patients. Now there are "professional" medications and over the counter medications and to get a "professional" medication a patient must have it prescribed by a doctor and sold by a pharmacist.[89] It should be emphasized that the reform only assigned the distribution of medications to pharmacies, but did not in any way limited doctors' freedom of prescription. Thanks to the introduction of the requirement of showing a medical prescription in order to purchase a drug, the reform was successful in reducing the level of medicine consumption throughout the country and it also made the process of accessing medications more transparent.

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[87] Kwon, S, "Payment System Reform for Health Care Providers in Korea", Health Policy and Planning, Vol. 18. 2003

[88] OECD, Economic Survey of the Republic of Korea, OECD, Paris. 2004

[89] Kwon, S, "Payment System Reform for Health Care Providers in Korea", Health Policy and Planning, Vol. 18. 2003

The second reform was approved in 2006, and is called the *Drug Expenditure Rationalization Plan*, with the aim of building the Positive list of medicines that would be reimbursed by the NHI. Its main purpose was to decrease the overall cost of medicines through four general measures: Before 2006, only a negative list existed, in which that drugs that couldn't be reimbursed were listed. The reform of 2006 (*Drug expenditure rationalization plan*) gave the power to HIRA to change the list from negative to a positive one. From that moment on, about half of drugs weren't anymore subject to reimbursement

- The existing negative list of drugs was turned into a positive list system of medicines that would be reimbursed by the NHI.
- HIRA would decide what medicines could enter in the positive list after a cost-effectiveness assessment.
- Pricing of drugs would be a negotiation between NHI and pharmaceutical companies, considering the medicines' prices in other countries. In the case of generics drugs, prices would be fixed at 68% of patents' cost.

9.4 UNIVERSE OF DRUGS

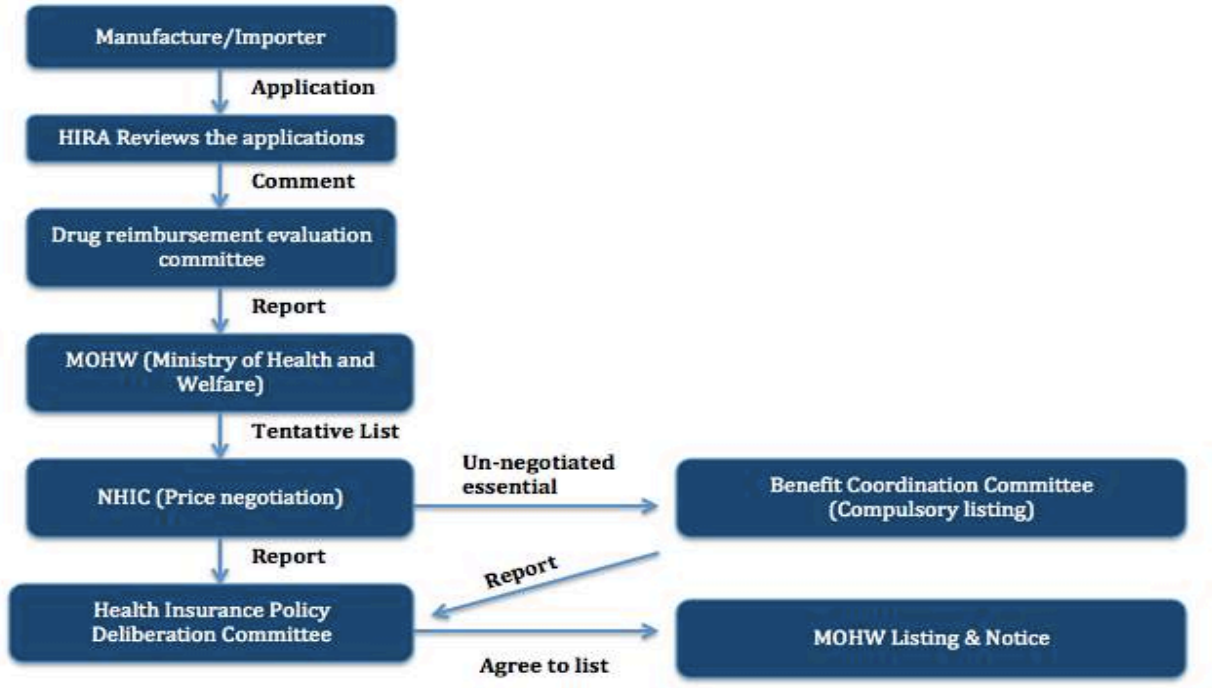
In Korea there are two institutions that supervise the healthcare system. First, the Ministry of Food & Drug Safety (MFDS) takes care of safety control, laws and guidelines that frame the importation, sells and use of drugs inside the country. All drugs must be approved by this entity in order to be sold and use in Korea. Security tests and pharmaceutical evaluations are undertaken to guarantee that drugs don't represent a risk for population. The group of drugs that are successfully approved by MFDS forms the universe of drugs in Korea, known as Health Registry. About 62% of these drugs need a prescription from a physician, and 38% are classified as "non-prescription drugs".

The following graph shows the two classifications of drugs. The big circle represents all drugs that can be prescribed, sold, and used in Korea. The small one represents those which are partially or totally reimbursed by the NHI.

The second institution is the Health Insurance Review Assessment Service (HIRA), its role is to list all drugs out that are subject to reimbursement. The list represents a subset of the Health Registry. The drug acceptation system of HIRA is based on the principle of *cost effectiveness standard,* which means that it only keeps drugs that prove to have good efficiency with a low cost.

The following scheme shows the different steps drugs must follow to be included in the Positive List System (PLS):

Graph 30. Positive list process to include medicines



Source: Pharmaco-economic Guidelines and their Implementation in the Positive List System in South Korea.

9.4.1 Healthcare system

Despite the consequences resulting from years of conflict, it is notable that Korea has been able to regain and surpass the levels of development that it had prior to the Second World War and the Korean Civil war, allowing it to compete with today's most advanced economies.

Although public health legislation began being drafted shortly after the conclusion of the civil war, the origins of the NHI should be traced to 1977, when Korean legislation approved the Medical Insurance Act that stipulated that "all companies with more than 500 employees were required to provide a health insurance program" and established separate health insurance societies.[90] In 1979, the act was modified to extend the requirement to offer a health insurance program to include companies with more than 300 employees, public servants, and private education practitioners and staff.[91] Then, in 1988 the act underwent another alteration by which it extended its coverage to include self-employed people that lived in rural areas. One year later, Korea established a universal health care system providing the entirety of its population with medical services and attention.[92] Finally, as it was

[90] National Health Insurance Corporation (www.nhic.or.kr)
[91] Idem

[92] Idem

mentioned before, in 2000 an integration reform was passed that grouped all of the health insurance societies established in 1977 into a single entity called the National Health Insurance Corporation (NHIC) while also defining the national basket of medical goods.

Under the supervision of the MoHW, the NHI has the task of administering and providing health insurance to all citizens living in the country. It is responsible for "operating the health insurance program including enrolment, collecting contributions, contracting with medical suppliers, setting reimbursement levels and making payments".[93] Put in another way, the NHI has the job of managing the relationship between the patient and the medical service providers.

9.5 Financing Mechanisms

The best way to understand how the public health system is financed is to identify its different components and its own means of generating and gathering resources to operate.

First, every member of the population covered by the NHI must pay a premium and a federal tax. Premium contributions are determined based on a person's type of work:

- **Insured employees** (62.5% of the population) split their premium equally with their employers and the amount is fixed at 5.33% of the employee's income.
- **Self-employed workers** (34.2% of the population) are required to pay a premium that is derived from a formula that takes into account the person's wage, age, sex, ownership of property, etc.[94]
- On the federal side, the government subsidizes a percentage of the premiums paid by **people with low incomes** (excluding people that have no incomes or living in extreme poverty – they are covered by a separate scheme) amounting to 17% of total health expenditures and financed by a national tax levied by the MoHW on all citizens.[95]
- The Medical Aid Program was established to fully pay the premiums of the members of the population not capable of generating any income and/or living in **extreme poverty**. While the NHI covered 96.6% of the population in 2012, the Medical Aid Program covered 3.4%.[96]

The sources of income described above are unable to cover all the expenses incurred by the NHI, which is why **Koreans are also subject to copayments and out of pocket expenses**.

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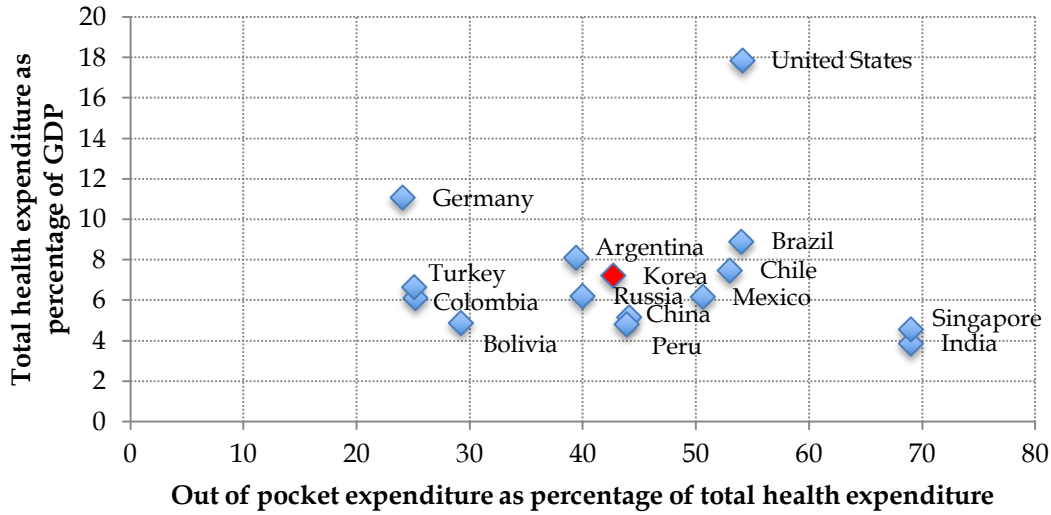
[93] WHO, MohW, Health Service Delivery Profile: Republic of Korea, 2012
[94] Jones S. Randall, Health Care Reform in Korea, OECD, Paris, 2010
[95] Idem
[96] WHO, MohW, Health Service Delivery Profile: Republic of Korea, 2012

Graph 31.Percentage of health expenditure in GDP over out of pocket expenditure in health, 2011



Note: Out of pocket expenditure as a percentage of health expenditure
Source: Source: Health expenditure from World Bank data 2011 http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS and Out-of-pocket expenditure from WHO interactive maps 2011http://gamapserver.who.int/gho/interactive_charts/health_financing/atlas.html?indicator=i2&date=2011

Regarding an international comparison, Korea's out of pocket expenditure of 42.7% is closer to Russia's 40% and China's 44.1%, than to Germany's 24.1% or Singapore's 69%. These results are confirmed when total health expenditure is considered as Korea spends 7.2%, which is closer to China 5.2% and Russia 6.2%, and further from Singapore 4.6% or Germany 11.1%.

9.5.1 Improvements in the system

Recently, the Korean government has instituted a number of measures aimed at improving the efficiency of the national health system including an expansion of the NHI's coverage of medical costs and a capping of annual per capita health expenditures.

However, these mechanisms have been shown to upset the relationship between the government and health care providers as the government's expansion of medical coverage implies that more services and medications are regulated resulting in smaller profits for health providers. **This provides an incentive for health providers to prescribe medications and services not covered by the NHI,** weakening the government's efforts to curb down individual costs for Koreans and placing Korea amongst the OECD countries with highest out of pocket expenses.

Currently, the NHI is preparing itself to deal with an ageing population (as is the case in Mexico), something that will require significant alterations in the scheme that

delineates how the system works today. According to statistics from the OECD, the population growth rate in 2011 was 0.7% while 11.4% of the population was aged over 65.[97] Something that favors the outlook in Korea as compared to other ageing populations is that traditional culture places a lot of value on family and many times elders are adopted by their younger family members and cared for, therefore reducing the necessity of the state to intervene. In 2007 only 0.2% of the government's spending was allocated for care of the elderly population, an amount much lower than the average for OECD European countries (1.5%).[98]

Nevertheless, traditional Korean culture and lifestyles have been affected by the country's economic development and families are not structured the way they were thirty years ago. For example, today the proportion of women in the labor force is much higher than it was back in 1980. These and other factors have made it harder for families to care for their older members and have reduced the number of elders living with their families (in 1981 approximately 80% of the elder population lived with family members and by 2008 this amount dropped to 29%).[99]

This is partly the reason that prompted the NHI to introduce its long-term health insurance program (LTHI) in 2008 and assist the needs of a growing elder population. Persons can sign up for the program and if their profile is approved (i.e. they meet the age requirements, economic necessities, etc) they can receive benefits in the form of services or care, rather than cash. As a consequence, the program has detonated growth in the long-term care and service industry for people of the third age.

9.6 HEALTHCARE PERFORMANCE

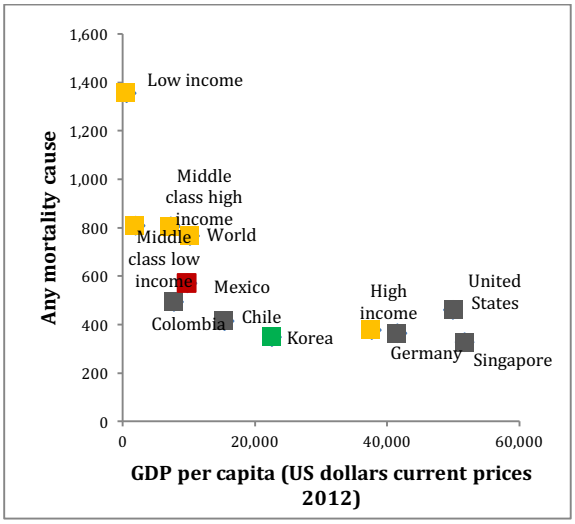
9.6.1 Main indicators

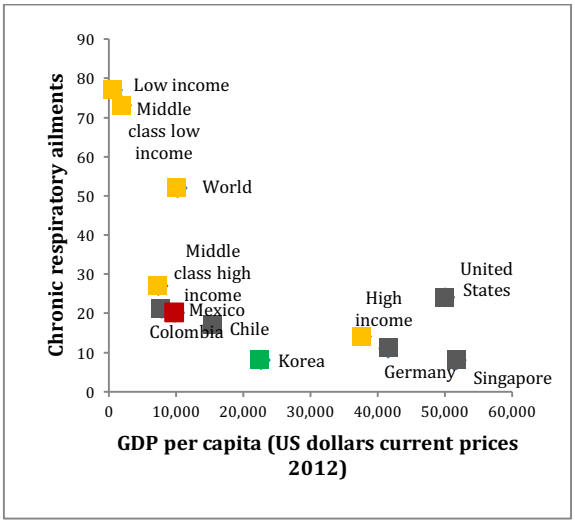
Healthcare system in Korea is very efficient, especially when government's health expenditure is taking into account as the percentage of total government expenditure represented only 13.7% in 2011, slightly more than Singapore, but less than UK (15.9%), Japan (18.2%) or United States (19.8%). Moreover according to WHO the obesity, as an adult risk factor, is one of the lowest in the world. It represents 7% of the population who is older than 20 years old, whereas it's 15% in France, 17% in Sweden, 20% in Germany and 32% in Mexico. This is an indicator quite important because, as a recent study showed[100], obesity has a negative impact on economy. Indeed, obesity might generate medical, productivity and transportation costs which are harmful for the economic wealth of a country.

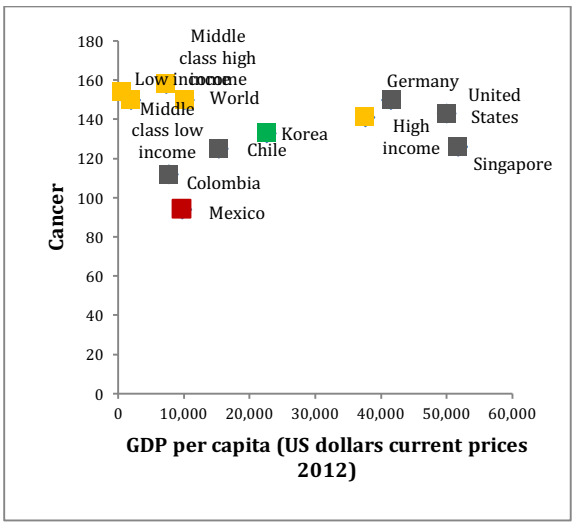
[97] OECD, Statistical Profiles of Countries: Republic of Korea. Paris, 2013
[98] Jones S. Randall, Health Care Reform in Korea, OECD, Paris, 2010
[99] Idem
[100] Ross A Hamond and Ruth Levine, The economic impact of obesity in the United-States, 2010, Brooking institutions, Washington, USA

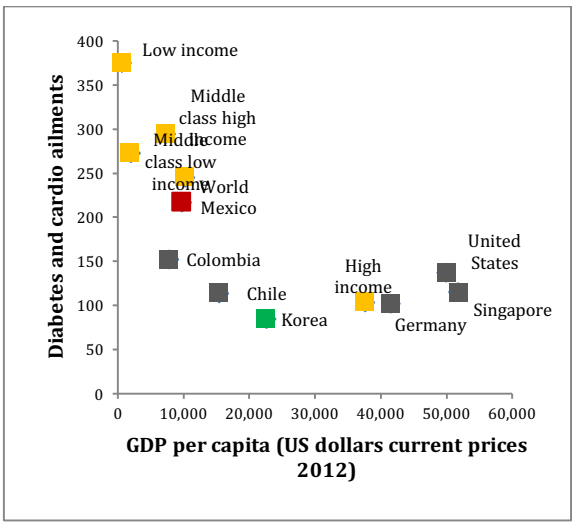
Graphs below show Korea's health performance considering the GDP per capita. Although Korea has a lower GDP per capita than Germany, Singapore and high income countries, it has similar results to these countries.

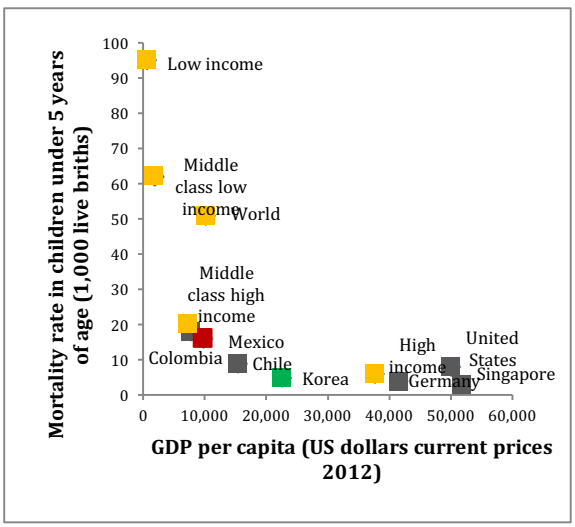
Graph 32.Key performance indicators for the Korean health system: Mortality rate in the adult population between 30 and 70 years normalized according to each group for the following causes (per 100,000 inhabitants) Diabetes, Cancer, Respiratory diseases, Life Expectancy and Infant Mortality Rate (over 5 years of age) and GDP per capita (2011)

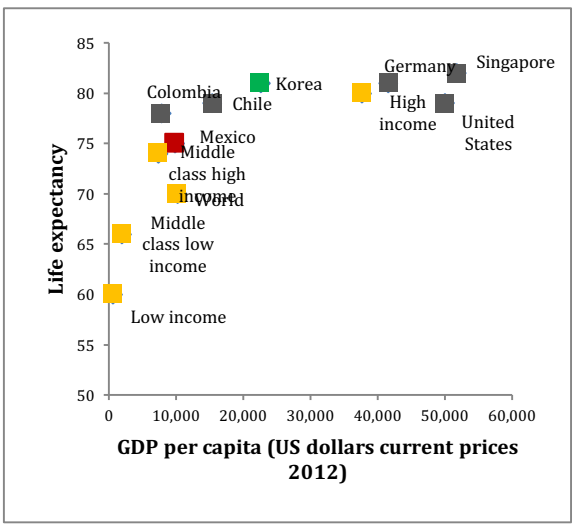












Source: World Health Statistics 2013

As it is shown, the Korean healthcare system proved to have outstanding results: life expectancy at birth is 81 years, the same as Norway and Germany; mortality rate under 5 is 5/1000 live births whereas the regional average is 16 and 51 for global average. Maternal mortality rate is 16 for 100,000 whereas the global one is 210.

9.6.2 Competitiveness

According to IMCO's competitiveness index, Korea is positioned in the 8th place in the healthcare pillar. In the general ranking, its performance descends to the 19th place mainly due to environmental issues. Indeed, regarding the sustainable environment indicator, Korea faces challenges in the use of non polluting energy, carbon emissions, water treatment, and ecological balance.

In spite of the environmental problems, Korea is still one of the most competitive countries in Asia. Considering that is a young democratic country, its general positions in IMCO and WEF ranks are high. After Singapore, Taiwan, and Hong Kong, Korea is the 4th Asian country in the top 20 in the WEF's global competitiveness index 2012-2013. Although it is a non-petroleum and non-European economy, Korea performs similarly to Norway, France, Australia, Austria, and Saudi Arabia. It shows the success of a liberal and low-regulated country, in terms of healthcare and its financing mechanism.

Graph 33. Korea's rep, position in competitiveness indexes

Korea, rep general position	
World Economic Forum	IMCO
19th/144	19th/46
Korea, rep position in the healthcare pillar	
World Economic Forum	IMCO
11th/144	8th/46

Source: World Economic Forum, Global Report on Competitiveness, 2013 and Instituto Mexicano para la Competitividad, International Competitiveness Index 2013.

Freedom of prescription in Korea contributes to consolidate the link between a healthy population and its productivity. Given the fact that Koreans are informed about appropriate treatments for their specific needs and have access to first class drugs, among other factors, they have a high probability of being healthy and productive. Moreover when doctors have freedom of prescription they are able to prescribe new drugs and technologies. This provides incentives to innovation which is also a necessary step to a productive economy.

10 CONCLUSIONS

Freedom of prescription affects people's lives. In the individual sphere it influences patients' access to medicines and treatments appropriate for specific ailments, while form a wider perspective it has a direct impact in a population's health level and quality of life and, therefore, in a nation's competitiveness and productivity performance.

Freedom of prescription is a very important component of healthcare systems. It addresses the doctors' right to prescribe what they consider best and the patients' rights to receive appropriate information about their specific therapeutic needs and to make their own choices about their treatments. Moreover it allows developing more equitable societies, as aims to achieve a balance between patients' and doctors' rights in a context of limited resources.

In this regard, Mexico has one challenge: **how the Mexican government can improve its framework to better address the concurrence of patients' and doctors' rights within the context of an environment with limited resources?**

In Mexico the balance between patients' and doctors' rights in a context of limited resources leans mainly upon financial considerations. Patients' right to be informed and to make their own choices about their treatments is the opportunity cost and it is seldom addressed by health practitioners.

Countries with outstanding healthcare indicators address freedom of prescription successfully through different regulations. Singapore has no lists apart from the drugs that are legally accepted in the country. Citizens have a yearly monetary allocation after which they pay out of pocket. Singaporean's system, although with the highest out of pocket expenditures, has resulted in high health standards and full freedom of prescription.

Korea and Germany, in contrast, have low out of pocket expenditures. Germany has a negative list that excludes lifestyle drugs and treatments, and over the counter medications; while Korea has a broad positive list that is not restrictive at all, as doctors are allowed to prescribe other medicines. These models (Singapore, Germany and Korea) have common feature: doctors in the public healthcare system are able to prescribe all registered drugs in and patients can have access to the most appropriate treatments according to their needs. These three countries are highly competitive and are in the top 10 of IMCO's index, and top 20 of WEF index.

Table 14. Proposals to improve Mexican framework on freedom of prescription

Elements	Current Mexican public health system	Proposals			Advantages of other alternatives over Mexican system
		Positive List with freedom to prescribe other drugs	Negative List	Absolute freedom of prescription	
Financing tools of medicines in public healthcare system	*Cuadros basicos* vary depending on the institution of enrollment, but government pays for the costs of medicines (no copayment, no reimbursement)	Copayment and partial reimbursement	Copayment and partial reimbursement	Copayment and partial reimbursement	Patients more responsible due to co-payments
Accessibility of medicines	Limited to (i) *cuadro basico* (ii) availability in public pharmacies (iii) supply (iv) corruption and theft	Highly innovative drugs are more affordable (and, thus, accessible) due to copayment	All medicines are automatically included save exceptions (normally life style medications)	Complete access to medicines	Increased accessibility for everyone, more equality
Role of private insurance in public healthcare	None. Zero portability	Complementary plan to public one. Completing the partial reimbursement	Complementary plan to public one. Completing the partial reimbursement	Complementary plan to public one. Completing the partial reimbursement	Private companies share costs and individuals, by paying companies, also share costs and reduce catastrophic expenditure
National healthcare profile	Mortality and morbidity from chronic illness higher than other systems	Mortality and morbidity from chronic illness lower than Mexico	Mortality and morbidity from chronic illness lower than Mexico	Mortality and morbidity from chronic illness lower than Mexico	More possibilities to provide adequate and innovative treatment to chronic and highly disabling illnesses
Patients rights	Asymmetric information, limited	More information, almost non restricted	More information, almost non restricted	More information, almost non restricted	Respect of patient's right to information

Elements	Current Mexican public health system	Proposals			Advantages of other alternatives over Mexican system
		Positive List with freedom to prescribe other drugs	**Negative List**	**Absolute freedom of prescription**	
	availability	availability (only sanitary approval), but with possibly high out of pocket expenses	availability (only sanitary approval and non inclusion in the negative list)	availability (only sanitary approval)	and better access of drugs
Role of pharmacies in access to medicines in the public healthcare system	Public pharmacies are the only ones that may supply prescriptions from doctors in the public system. This implies scarcity in supply and favors corruption (pilot program in some states for private pharmacies supply of public prescriptions)	Commercial pharmacies supply prescription from doctors both in the private and the public sector (the only restriction is the sanitary approval of a given medicine)	Commercial pharmacies supply prescription from doctors both in the private and the public sector (the only restriction is the sanitary approval of a given medicine and **its exclusion from the negative list**)	Commercial pharmacies supply prescription from doctors both in the private and the public sector (the only restriction is the sanitary approval of a given medicine)	Wider distribution mechanisms by reducing the distance patients have to travel to have access to drugs and treatments
Competitiveness	Population more vulnerable to chronic illnesses and the disability that characterizes then	More treatment alternatives for chronic illnesses	More treatment alternatives for chronic illnesses	More treatment alternatives for chronic illnesses	More development, healthier population… virtuous circle
Reference country		Korea, Colombia, Chile	Germany	Singapore	

Meanwhile, in Chile and Colombia, doctors and patients have the final word in the prescription mechanism. If they judge that a treatment is more appropriate than another one, they can both ask for it. Even if both countries still face challenges in terms of health, they both have a healthcare system that respects patients' and doctors' rights. Freedom of prescription contributes in these countries to improve equality problems, as everyone can have access to the same treatments. In Colombia, the out of pocket expenditure, which is an indicator of equity, is one of the lowest (25.2% of the total health expenditure) of the sample, it comes just after Germany with 24.1%.

The United States has a decentralized healthcare system and a composite framework with specific mechanisms in each state. In this context, the United States produced a wider freedom of prescription mechanism. The high level of out of pocket expenditure can be mainly explained by the wide access to medicines provided by their system which supports mostly patients' rights to be informed and have access to first class drugs.

All these countries have better health indicators than Mexico in almost all of the areas analyzed by the WHO regarding chronic illnesses, except for cancer. Partly this can be explained because Mexico has a highly regulated freedom of prescription mechanism which restricts patients' rights. The country has high out of pocket expenditure, which cannot be explained (as is the case in the USA and Singapore) through the lack of a universal public healthcare system.

The Mexican public healthcare system claims to be able to provide, without any cost, medicines to all the population that is covered through Imss, Issste or Seguro Popular, **and spends public resources accordingly.** But, in reality, out of pocket expenditure (many times, catastrophic) is the rule and not an exception for patients that use the public health care system.

Thus, freedom of prescription is restricted by the argument that medicines in the public system are free and the government must choose how to better distribute limited resources by privileging *cuadro basico* medications that address more recurrent illness, over medicines that address ailments experienced by low percentages of the population, or generics over patented and innovative medications that might have positive impact in efficiency and patient's quality of life.

The system's objective could be logical and strong arguments made in its favor, but if and only if, it proved to be efficient and effective to deliver on time the medications of *cuadro basico* free of cost to those who required it. Since this is not so, the system efficiency is widely questioned and challenged.

The countries in the sample do not claim to provide the patients in their public health system medicines completely out of charge. They contemplate all of them, either copayments or reimbursement mechanisms and are able to address through them the following challenges:

- Reducing out of pocket expenditure
- Reducing catastrophic expenditure
- Patients have wider access to innovative medications

It is worth mentioning that all of the countries analyzed in this document do not burden the lowest income percentiles of its population with copayments. They have specific mechanisms so that the impoverished sectors do not incur in any expenses, not even copayment. Nevertheless, this is only for those sectors that are, indeed, impoverished. Middle classes (high and low) do face copayment schemes that help allocate resources more efficiently and facilitate access to a wider set of drugs and treatments with positive impacts on welfare and competitiveness.

Mexico could analyze the possibility of modifying its existent legal framework on freedom of prescription. In the table 14 three options are conveyed, each of them would have a positive impact on the current healthcare system. The improvement of healthcare in Mexico, in terms of medicine availability in the public healthcare system, also would need a change in its financing system (copayment and reimbursement). Combining freedom of prescription and an adequate financing system would permit patients' not only to receive better and wider information about their treatments, but also a more effective access to drugs. This would increase the equality and the country's competitiveness levels.

In order to make patients more responsible for their health expenses, as well as to give financial viability to the public healthcare system, copayment and reimbursement mechanisms could be useful as public healthcare system might contribute in a higher proportion to pay specialized treatments (usually highly cost medicines), and in a lower proportion to cover over the counter medicines. Patients could have the possibility of having complementary plans with private insurance to complete the government copayment.

Finally, it is worth mentioning the need to establish a clear legal framework regarding the freedom of prescription and its interlocking doctors' and patients' rights, and budget restrictions in Mexico. In addition, as a temporary measure, public health institutions should create and promote efficient and fair mechanisms to allow patients and doctors access to treatments outside the *cuadro basico* and supplementary institutional lists of drugs.

To achieve so, some legislative changes are called for in the articles mentioned in the Mexican chapter in the General Health Law, the IMSS law, and their bylaws.

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