1 EXECUTIVE SUMMARY

This document pursues the aim of assessing the impact of freedom of prescription in the Mexicans' health levels, while it describes how several different countries (Germany, Chile, Colombia, Korea, Singapore, United States, and 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. Table 1 provides a summarized description of key concepts for each country.

The concept of freedom of prescription that gives support to the document establishes 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 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*"[1].

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.

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?**

[1] 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

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)
Private sector health financing	Out of pocket, private insurance. Some companies provide private insurance to	Contribution Regimen (employees), salary contribution, out of pocket	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	Out of pocket, private insurance

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
	their employees	expenditure				citizens)	
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 and discretion by insurers	Negative list	Absolut freedom of prescription	Positive list system
Authority in charge	COFEPRIS	Medicines and	Pharmacy and	FDA	Federal Joint	Health Sciences	Health

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
of approving prescription drugs		Food Vigilance Institute (INVIMA)	Therapeutic Committee		Committee (GBA) Institute for quality and efficiency in health care (IQWIG)	Authority	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 prescribe drugs that are not	Doctors may adapt their prescription to patients' needs, patients have the information and can make a their own choices	Medicaid is essentially a free market economy: pharmaceutical companies enroll in each state program and all their products are	Negative list encompass only lifestyle and over the counter medications. All other therapeutic areas (and their medications) are part of the	-Patients' right to be informed and to make choices about their treatment options is guaranteed. -Access to first class medications	Patients have better access to medicines, due to: 1)drugs from the Positive List System are reimbursable, and 2)doctors are free to prescribe what

	Mexico	Colombia	Chile	United States of America	Germany	Singapore	Korea, Rep
		included in the Manual of Essential and Therapeutics Medicines		available for prescription and reimbursement / Medicare allows for copayment schemes and avoids catastrophic expenditure	public system and the reimbursement mechanism		they consider the most appropriate treatment even if it does not belong to the PLS.

1.1 MEXICO

- In private practice, doctors can prescribe all medications that have 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.
- 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.

1.2 UNITED STATES

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 was 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*"[2] 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

1.3 SINGAPORE

- 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

1.4 GERMANY

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.

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[2] *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).*

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.

1.5 CHILE

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.

1.6 COLOMBIA

- The Colombian healthcare system is behind the 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.

1.7 KOREA, REP.

- 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.

1.8 CONCLUSION

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.

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

Table 2. 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	In-creased 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

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**	
Patients rights	Asymmetric information, limited availability	More information, almost non restricted availability (only sanitary approval), but with possibly high out of pocket expenses	More information, almost non restricted availability (only sanitary approval and non inclusion in the negative list)	More information, almost non restricted availability (only sanitary approval)	Respect of patient's right to information 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	

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 2 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 patients' and doctors' 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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