

The Selection Process of the Mexican NEML: A Grounded Theory Approach

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Abstract

One of the biggest challenges that low- and middle-income governments like Mexico have in ensuring equitable access to medicines is to maximize the quantity of drugs they are able to procure with their limited resources. This maximization can be achieved by purchasing, at the lowest possible prices, those drugs that are essential for treating the most prevalent diseases in their population. The first step in addressing this challenge is to have a National Essential Medicines List (NEML) that allows for a rational selection of Essential Medicines (EM). However, considering that the 70% of pharmaceuticals on the world market are duplicative or non-essential, equitable access to EM will also depend on the knowledge and technical capability that governments have to select drugs that meet the safety, efficacy, cost, and quality standards that satisfy the priority health needs of their population. Even though Mexico has a NEML, up until now, there have not been studies that describe how the government selects this list. All that is known is described in the regulation that standardizes the selection process of this list. My grounded theory study allowed me to interview 12 out of the 31 government officials who participate in the selection of the NEML, and also of a group of 5 people familiar with the process to better understand how the NEML is selected. Through these interviews, I learned about unknown aspects of the process that helped me to formulate a theory about how the process functions in reality. This theory suggests that the government selects its NEML in a very political environment, surrounded by many contradictions that cannot be easily uncovered because power controls, via domination, the “discursive consciousness” of the government officials who select the list and the Mexican population. Discursive consciousness involves the knowledge which actors are able to express on the level of discourse. Even though it is expected that the Mexican government bases the selection of its NEML on rational decisions, my study concludes that the foundation upon which the selection of this list is being made is not rationality, but rather the reflection of many political and economic interests.

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The Selection Process of the Mexican National Essential Medicines List: A Grounded Theory

Approach

Chapter 1: Introduction

The prevention, treatment, control, and cure of illness for many people depend on safe, effective, and affordable medicines. Unfortunately, not all medicines meet these three requirements. According to Chetley (1995), the market has been flooded with medications that not only are unsafe, ineffective, and needlessly expensive, but also useless, and irrational because they do not meet the healthcare needs of the population. In fact, there is evidence that shows that 70% of pharmaceuticals on the world market are duplicative or non-essential (Olson, 2012), and that 85 to 90% of all new drugs provide few or no clinical advantages for patients (Prescrire, 2012). Unfortunately, the medicines that are supposed to be instruments to alleviate ill health have turned into commercial commodities (Antezana, 2008) that are not accessible for everybody. Although governments around the world have struggled with these markets full of non-essential, unsafe, ineffective, and expensive medicines, these markets have been a particularly significant challenge for low- and middle-income countries (LMIC) (Wang'ombe 1987; Lemmens, 2013) since they cannot afford to waste their limited resources, dedicated for health services, on expensive, non-Essential Medicines.

According to Klug (2008), one of the large challenges that these governments have in ensuring that their populations have equitable access to medicines is to maximize the quantity of drugs they are able to procure with their limited resources by buying, at the lowest possible prices, those drugs that are essential for treating the most prevalent diseases of their population. The first step in achieving this goal is to have a National Essential Medicines List (NEML) that allows for the rational selection of Essential Medicines (EM). According to the World Health Organization (WHO), a rational selection of EM means choosing efficacious, safe, and cost effective medicines that meet the priority health needs of the population (WHO, 2004). However, despite the efforts that LMIC governments have made toward implementing a NEML in their countries, many governments have not been able to supply their population with even the most Essential Medicines that meet their healthcare needs. In fact, in 2012 more than two billion people in LMICs lacked adequate access to even the most basic EM (Leisinger, 2012). Although this information has not been updated since then, there was a report published in 2015 by the WHO that showed that 400 million people around the

world do not have access to essential health services and 6% of people in LMICs are pushed further into extreme poverty because of health spending (WHO, 2015).

In Mexico, in 2011, “Fundacion Mexicana” published data that showed that for every \$100 Mexican pesos spent on medications, only \$21 came from public funds, the rest came from private resources in the form of out-of-pocket payments. (Fundacion Mexicana, 2011). This information has not been updated either. Although the OECD Health at a Glance 2015 edition includes data on the pharmaceutical spending trends of several countries, it does not mention any recent statistics about pharmaceutical out-of-pocket spending in Mexico. However, the indicators that were reported in this edition, state that, in general, private spending on drugs, has not declined to the same extent as public spending since 2009 (OECD, 2015). The reason for this pattern is that there has been a shift of some of the cost-burden from the state to households. In Mexico, this shift of the cost-burden for pharmaceuticals to households jeopardizes equitable access to medicines and the nation’s public health, since, if the high price of medicines make them unaffordable for the government, this is even more the case for the 46.2% of the Mexican population that lives below the poverty line, according to a report published in 2015 by the Mexican National Council for the Evaluation of Social Development Policy (CONEVAL).

Although it is well known that the amount of public funding that LMICs invest in healthcare is very small compared to developed economies, and that the economic level of a nation is considered one of the main factors that affect access to EM (WHO, 2004), equitable access to EM does not only depend on the government having a large budget available to purchase medicines. It also depends on the knowledge and technical capability that governments have to select drugs that meet the safety, efficacy, cost, and quality standards that satisfy the priority health needs of their population. In 2010, the WHO estimated that 20% to 40% of all health spending is currently wasted through inefficiency (WHO, 2010). This waste has meant that many governments continue shifting the cost-burden for pharmaceuticals to households, depending, in this way, on the out-of-pocket payments that their citizens make for the provision of even the most basic EM. According to Wang’ombre (1987), governments of LMICs lack not only the budget, but also the knowledge and technical capability to efficiently select their NEML. However, it is difficult to assess the capacity of these governments to select their lists, since majority of the research that has been conducted on NEMLs has

focused on counting the countries that have a NEML as well as on analyzing the content of these lists and discussing their rationality, but not on describing how these governments choose the EM for their NEMLs.

In Mexico there is very little information available about how the government performs this selection. Even though the process for updating its NEML is described in a normative regulation entitled “Reglamento Interior de la Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud”, there are no descriptive processes available that explain how decisions are actually made. Until now, the articles that have been published focus on discussing the rationality of the list (Rico-Alba & Figueras, 2012; Rico-Alba & Figueras, 2014). According to Rapoport (1994), governments share the majority of their decisions through normative regulations that describe how certain processes should be undertaken, but descriptive processes that explain how decisions are actually made and how real actors behave are generally not shared with their citizens. Descriptive processes are usually not shared because government decisions are always surrounded by competing political interests. Among these interests are those of industry, civil society, and the academic and scientific community. Although it is expected that government makes rational decisions, the foundation upon which government decisions are likely to be made is not rationality, but rather the reflection of many of these political interests (Friedman, 1996). According to Sidjansky (1973), even though government decisions might appear to be the output of parliaments or presidents, many of them are merely endorsements of decisions already made both inside and outside the country by groups that hold political and economic power. Rational behaviour often clashes with a normative approach to politics because what is morally good for the society is not economically rational for the self-interest of certain groups and individuals (Luke, 1985).

My research will attempt to bridge the gap in knowledge that exists about how the government of Mexico selects its NEML by conducting a grounded theory study that will allow me to develop a theory that answers my research question of “How do Mexican government officials select their National Essential Medicines List?” Although the grounded theory methodological approach that I adopted will be fully described in Chapter Two, it is important to note that this study, as grounded theory studies typically do, does not begin with a theory from which hypotheses are deduced, but with the research question mentioned above. The type of research that follows this methodology is not focused on testing a hypothesis taken from existing theoretical frameworks, but rather on developing a new theory grounded in my empirical data collected in the

field which is presented as part of my results in Chapter Three. One of the characteristics of grounded theory is its capacity to explore, in situations where there is not enough information about a process, new areas of knowledge that existing theories do not cover (Glaser and Strauss, 1967; Elys and Levy 2009), as is the case with the selection process of the Mexican NEML. The theory that I propose in Chapter Four and that is discussed in Chapter Five can be further tested by other researchers interested in continuing exploring this, up until now, uninvestigated selection process.

I have organized this First Chapter into eight sections that will introduce the reader to the phenomenon that I am studying. The First Section will describe how the Concept of Essential Medicines emerged. The Second one will explain the role that a National Drug Policy plays in the selection of an effective NEML. The Third Section will discuss the WHO recommendations for the development of a NEML. The Fourth Section will describe the economic and political environment that triggered the development of the first NDP in Mexico. The context in which the first Mexican NEML emerged will be described in the Fifth Section. The Sixth Section will describe the NEML throughout the different presidential periods. The Seventh Section will explain the compulsory nature of the NEML. The Eight Section will discuss how current drug regulations either promote or interfere with the selection of an effective NEML, and last but not least, the Ninth Section will briefly describe the current situation of the Mexican NDP and the last version of the NEML.

The Essential Medicines Concept

The EM concept emerged as a response to a market full of unsafe, ineffective, and expensive non-essential medicines. This type of market dates all the way back to the “golden age” of innovation (Light & Lexchin, 2012). The “golden age” of drug development took place during the postwar era from 1945 to 1968. During this time, many “miracle” cures such as penicillin, cortisone, and streptomycin reached the market to meet the needs of the population. All these miracle drugs were accompanied by less-than-miracle cures that soon flooded the market (Greene, 2011). Inevitably, the health of many people in developed and developing nations and the economy of LMICs started suffering the consequences of a market full of unsafe, ineffective and unnecessary products. On the one hand, LMICs were purchasing drug innovations at prices which they could hardly afford. On the other hand, the inadequate knowledge about all those new drugs, as well as the aggressive sales policy of pharmaceutical companies, turned the people in developed and developing

countries into consumers of dangerous and unsafe drugs (Wang'ombe, 1987). In order to protect their populations from unsafe and dangerous drugs, developed countries implemented regulatory measures to restrict the approval process for these medicines. Unfortunately, the medicines that were not approved in these developed countries, often ended up in the developing world because their regulatory agencies did not have a strong infrastructure to allow them to determine the quality, safety and effectiveness of all the commercial variations of existing active ingredients. Hence, many developing countries suddenly had up to 50,000 brand drugs on their markets. These numbers were very high compared with some developed countries that only had 1000 drug brands (Kanji, 1992).

Governments of LMICs have been trying to improve their access to high quality, safe, effective, and affordable Essential Medicines (EM) for many years by implementing policies that rationalize medicine expenditures (Antezana, 2008). One example is Sri Lanka that in 1952 began selecting drugs to satisfy priority health needs in hospitals. By 1959, Sri Lanka had created a medicines list for purchase by the state health care system (Tucker, 1990). Cuba in the 1960s adopted a national formulary that reduced the number of registered medicinal products from about 20,000 to just over 600 (Capo, 1981). Countries such as Papua New Guinea, Peru, and Mozambique also created a formulary to limit their pharmaceutical purchases (Antezana, 2008). Mexico has been aiming to improve access to EM since 1950, the year when the Instituto Mexicano del Seguro Social (IMSS), the largest social security provider in the country that covers the formal private sector workers, retirees, and their dependents, created its first list of EM. However, it was not until 1984 that Mexico created its NEML (Gomez-Dantes et al., 2001; Rico-Alba & Figueras, 2013).

All these initial government attempts gained global visibility in 1975 when the World Health Organization (WHO) got involved in assisting developing countries to implement national policies that helped them to control their overspending on useless, non-essential, and dangerous medicines. Director-General Halfdan Mahler warned the 1975 World Health Assembly (WHA) of an “urgent need to ensure that most essential drugs are available at a reasonable price and to stimulate research and development to produce new drugs adapted to the real health requirements of developing countries” (Mahler, 1975). In 1977, the WHO introduced the concept of EM and created the 1st model list to assist countries in formulating their own NEML (WHO, 2002). Despite all these efforts, currently, more than two billion people in LMICs lack adequate access to EM (Lesinger, 2012).

The introduction of the concept of EM made clear that not all medicines can be categorized as “essential”. In fact the WHO model list bases its selection of EM on three important factors: 1) the disease prevalence/public health relevance, 2) evidence of efficacy, safety, and quality and 3) comparative cost-effectiveness (WHO, 2002). These three factors are basic to promoting both a rational selection and use of medicines. However, the implementation of a rational approach to medicines selection that truly distinguishes “Essential Medicines” from “Non-Essential” ones, as well as the introduction of the WHO EM concept, have not been easy tasks. According to Green (2010), pharmaceutical companies initially opposed the introduction of the WHO EM concept. They insisted that there was no such thing as an “inessential” medicine. For them, all their drug products were, and continue to be “essential”. After initially opposing the idea of a NEML, pharmaceutical companies agreed to cooperate with the program only if the concept would be limited to the public sector of developing countries. The WHO took some additional steps, during the Alma Ata Conference held in 1978 in the Soviet Union, to ensure that the implementation of the EM concept could lead to equitable access to medicines not only for developing countries, but for people around the world. Its “Health for All by the Year 2000 Report” recognized the need for urgent action by all governments to protect and promote the health of people, and invited governments to act individually in formulating national strategies and plans of action for attaining the “health for all by the year 2000” goal (WHO, 1978). One of these recommended strategies was the formulation of a National Drug Policy (NDP) that promotes equitable access to EM by controlling the import, local production, sale, and distribution of drugs and biologicals. The implementation of this drug policy will be discussed in the following section.

The Implementation of a National Drug Policy

The formulation of a NDP became an important tool for achieving the “health for all by the year 2000” goal. Even though, by 1981 all regions of the world had formulated national strategies to improve health for all (WHO, 1981), the development of a NDP represented a real challenge for many LMIC governments. For this reason, during the rational use of drugs conference held in Nairobi in 1985, many developing nations asked the WHO to prepare a guideline to help them to create their own NDP. Two years later, in 1987, a working group of experts met in Geneva to draft the guideline. The guideline was finalized and published in 1988 (WHO, 1988). By 1999, 66 countries had either formulated or updated their NDP

(WHO, 2001), and 156 had a NEML (WHO, 2002). Twelve years later, in 2011, the number of countries with a NDP doubled to 133 (WHO, 2011).

According to the WHO, a NDP is a document where governments can set out and prioritize medium- and long-term goals for the pharmaceutical sector. The development and implementation of this policy has three main objectives: 1) to ensure equitable access to essential medicines, 2) to assure good quality medicines, and 3) to promote a rational use of medicines. In addition to these three health-related goals, governments may also consider economic goals such as increasing the national pharmaceutical production capacity. A strong national production capacity is crucial, since pharmaceuticals are part of the international flow of capital and commerce. This industry does not only produce the medicines that a country needs, it also provides many other advantages such as more revenue, jobs, and spin-off effects for the economy. In capitalist societies, industry in general has two important powers: 1) the power of control over investment; and 2) the power to direct and supervise the labour process itself (Isaac, 1987). These two powers have been used by the pharmaceutical industry to control markets worldwide. However, the government can balance those powers through the implementation of effective regulations. According to the WHO (1988), the objectives of a NDP do not only depend on the level of economic development and resources of a country, but also on the capacity of the state to regulate its industry and enforce quality assurance. Cultural and historical factors as well as governments' political values and choices are also two critical factors that affect the establishment of the objectives of a NDP (WHO, 2001; WHO, 1988). For example, the political values of conservative governments have a tendency to lean towards the interest of the upper class and the business sector (Cawson, 1986; Read, 2002). This preference is reflected in the development of policies that support the deregulation of industry (Harding, 1986).

As for cultural factors, according to Lilja (2008), the lack of national solidarity has become a major challenge for setting policy objectives that benefit the most vulnerable sector of the population in developing countries. The government and urban elite of these countries usually have more interests in common with the elite in developed countries than with the rural masses of their own countries. This lack of connection and national solidarity is a huge barrier for the establishment of common national goals and objectives that really protect the interests of a nation. Another cultural factor that may affect the establishment of the objectives of a NDP is the level of participation and involvement of other actors outside the government circle.

Unfortunately, as mentioned before, in many developed and developing democratic countries like Mexico, citizen participation is still not a reality. On many occasions, the political groups involved in the development of health policies are not interested in introducing policies that redistribute health care resources among the poorer sectors of the population (Bossert, 1979; WHO, 2001). For this reason, the inclusion in the development of a NDP of all sectors of the population is crucial in order to set NDP objectives that truly promote equity among all Mexicans. Unfortunately, the existing normative regulation that describes the selection process of the NEML does not consider civil society as one of the stakeholders that participates in the selection process of this list. Therefore the voice and vote of the Mexican society is not required in this process. Citizen participation is important because it enables the development of a civic awareness of the responsibility that everyone, including government and private sector, has to preserve and guarantee health for all (PAHO, 1989). According to the WHO (1988), despite the contradictory interests that some of the stakeholders might have, the goals of a NDP should be consistent with the country's health objectives, and should promote equity and sustainability of the pharmaceutical sector. However, on many occasions NDP objectives also contradict each other. For example, while the health objectives of a NDP promote strict regulations to guarantee the safety and efficacy of pharmaceutical products, the economic objectives of this policy try to avoid them because regulations decrease pharmaceutical companies' production capacity.

A drug policy is the result of a complex process of development, implementation, and monitoring. Once the objectives have been established and the policy has been developed, the implementation plan should describe what needs to be done and who is responsible for its achievement. It should also provide an estimate of the budget and propose a time frame for doing so. If the implementation phase is not properly planned, the NDP can face strong opposition. For this reason, it is crucial to have an implementation plan that allows the government to identify political allies that can maintain their support throughout the process (WHO, 1988). A NDP without an implementation plan remains a dead document (WHO, 1988). Unfortunately, many NDPs never reach the implementation phase. For example, from the 133 countries that had a NDP in 2011, only 97 had a NDP implementation plan (WHO, 2011). Since one of the goals of a NDP is to achieve equitable access to medicines through the redistribution of goods and power, both the development and implementation phases have turned into highly political processes. A strong political will is vital for the successful development and

implementation of a NDP. Drug policies that are developed just to comply with international health commitments will not be able to achieve any objectives that improve equitable access to health and EM.

According to the WHO (1988), a NDP has 9 key components: 1) the selection of EM, 2) affordability, 3) drug financing, 4) supply systems, 5) regulation and quality assurance, 6) rational use, 7) research, 8) human resources, and 9) monitoring and evaluation. Of these 9 components, only the selection of EM is being discussed in this dissertation. The other eight components are outside the area of my research.

An appropriate selection of EM is central to a NDP because it promotes equity and helps to set priorities for the health care system (WHO, 1988). In fact, in many LMICs, the creation of a national EM program that regulates not only the selection, but also the procurement, distribution, and use of pharmaceuticals in the public health sector was the motivation for establishing a NDP (Hoebert, 2013). The selection of EM is directly linked to two of the three main objectives of a NDP: 1) ensuring access, and 2) rational use of medicines. It is also indirectly linked to the third objective, which is ensuring the quality of drugs. Since the EM concept focuses on a careful selection of a limited number of medicines, it is believed that an efficient selection of the EM that are included in the NEML will lead to a better drug supply, more rational prescribing, better drug quality, lower costs, and better health outcomes (WHO, 2000). The development of a NEML that truly includes EM is central for any NDP, and particularly for the NDPs that are developed by LMICs. In order to help the governments of LMICs to develop their NEML, the WHO proposed a set of recommendations that will be described in the following section.

The WHO Recommendations for the Development of a NEML

As mentioned before, the development of a NEML is intended to assist LMICs to maximize the quantity of drugs they are able to procure with their limited budgets by buying, at the lowest possible prices, only those drugs that are truly essential (Klug, 2008). It can also help developed countries which face problems with rising costs of medicines (Van de Ham, 2009). Currently 160 countries have a NEML. Interestingly, more than 90% of the LMICs have such lists compared to 60% of high-income countries (WHO, 2004). Some of these high income countries have been protecting their national pharmaceutical industry from the restrictions imposed by national drug lists, such as the loss of revenue associated with cost-control mechanisms (Tan, 1988). This protection is justified by the fact that pharmaceuticals are part of the international flow of capital and commerce, and the economy of many of these developed countries is

strengthened by the financial health of the pharmaceutical industry. These developed nations have been facing the dilemma of encouraging the pharmaceutical industry while attempting to contain the costs of medicines (Vandergrift & Kanavos, 1997).

Since the national adoption of the EM model list proposed by the WHO is not mandatory, each government has the power and the freedom to decide whether to follow this model or not when developing its own NEML or even whether to develop a NEML. If the government elects to develop a NEML, the WHO recommends that the selection of drugs on the NEML should be the result of a consultative and transparent process where EM are selected rationally (WHO, 2002). In order to guarantee a rational selection of medicines, the WHO suggests appointing a committee to give technical advice on the selection of EM. This committee may include people from different fields such as medicine, nursing, pharmacology, pharmacy, public health and consumer affairs. Even though it is clear that the committee should include a diverse group of people who can contribute from their different backgrounds to the selection of the NEML, neither the person in charge of selecting the committee members, nor the skills, the level of education, and the work experience that each member should have are specified by the WHO. According to the WHO guideline, since the selection of EM is a consultative process, it is expected that the committee should organize consultations on scientific and technical advice with interest groups such as consumer organizations, the government finance ministry, and the pharmaceutical industry. However, according to these guidelines, the responsibility for making the final decision should lie with the committee members and not with any of the interest groups.

The WHO (2002), suggests that the following five criteria should be considered by the expert committees when selecting EM for the NEML: first, only medicines with adequate evidence of safety and efficacy should be selected. This evidence should be determined by consulting relevant, up-to-date and unbiased information sources, such as clinical guidelines, systematic literature reviews, national pharmacopeias, the WHO model list of EM, and data available from clinical trials. This means that personal observations should not be used as justifications for selecting a medication, nor should the selection be based on a medicine's popularity on the market (Olson, 2012). Second, cost-effectiveness is another important point to consider when choosing medicines within the same therapeutic category. When comparing medicines, the total cost of the treatments must be considered, and must be compared with their efficacy. Third, the drug's

pharmacokinetic properties as well as the availability of facilities for manufacture or storage should also be considered. Fourth, each selected medicine must be available in a form in which adequate quality can be assured; and finally, only single compounds should be considered as EM. Fixed combinations are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single compounds. Besides these five selection criteria, another recommendation is that the list should be developed for different levels of care and also on the basis of standard treatment guidelines for common diseases and conditions treated at each level. A standard treatment guideline is defined by the WHO (2007) as “a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances”. A standard treatment guideline together with the NEML helps to rationalize medical practice. Last, but not least, the list should be regularly reviewed and updated at least every two years (WHO, 2002).

Even though both the guideline on how to develop a NDP and the WHO recommendations for the selection of EM became two important tools to assist developing countries with the selection of their NEMLs, not all governments have adopted them as a guide. According to the WHO, during the late 1980s, 29% of countries were either considering implementing some kind of EM policies or not interested in a NDP (WHO, 1988). Mexico developed both its first NDP and first NEML in 1984. The development of both documents occurred during a very interesting economic and political environment which will be described in the following section.

The Economic and Political Environment that Triggered the Development of the First NDP in Mexico

According to the WHO World Drug Situation Report that was published in 1988, many of the NDP that were implemented prior to 1988 originated from important political changes that created a “window of opportunity” to start the policy formulation process. For some countries the trigger for the formulation of the NDP was a change to a government committed to reform, but for others, it was the result of important economic and political changes. As will be discussed in the following paragraph, in Mexico, the actual drug policy change was driven by the World Bank and the International Monetary Fund (IMF). These two institutions have the ability to exert either positive or negative influence over the health of nations (Lee, 2002). Both institutions lend money to Less Developed Countries (LDCs) at very high interest rates. The

World Bank only provides loans to developing nations for the purpose of encouraging development projects, whereas the IMF grants loans, and oversees monetary and exchange rate policies in all nations (Hoy, 1998). As soon as a loan is made by the IMF, the debtor nation has to agree to Structural Adjustment Policies (SAPs). These structural policies impose conditions on the country to ensure that its economy can maintain the repayments. A common SAP requirement is that the debtor nation should drastically reduce expenditures for government services such as health and education. This tactic forces the debtor nation to privatize such services as far as possible (MacDonald, 2007; Lee, 2002). SAPs also promote deregulation of foreign trade, investment and production; a reduction in the budget deficit through cuts in public spending; rationalization of public sector employment; cost recovery in public services; and devaluation of the local currency (Lee, 2002). The negative impact of SAPs on social indicators such as health and education of many developing nations became widely recognized. This forced the World Bank and the IMF to leave SAPs behind and initiate a Poverty Reduction Strategy (PRS) in 1999 (IMF, 2016; UN, 2010). However, these poverty reduction strategies have been criticized for being reintroduced SAPs in disguise (UN, 2010; Petithomme, 2012). The 1982 devaluation of the Mexican currency promoted by the SAPs triggered the development of both the first NDP and NEML in Mexico.

In order to understand the political environment that surrounded this policy implementation, it is necessary to go back in time to 1976, the year when Mexico had another devaluation of its currency during the last months of the regime of President Luis Echeverria Alvarez (1970-1976). The economic chaos left by Echeverria's administration was faced by his successor, Jose Lopez Portillo who assumed office as the new president of Mexico in December 1976. In his swearing-in ceremony, the new president made the nation aware of the economic crisis that Mexico was facing and, in a very emotional and encouraging speech, promised an economic recovery during his presidential term. In the course of his first year in power, he was able to reduce the fiscal deficit and inflation (Thomas et. al, 1991). By the end of 1977, the economic landscape of Mexico seemed promising, especially after the official announcement of the discovery of major oil deposits in some areas of Mexico. However, since the country did not have the infrastructure to exploit all of these new oil reserves, the government decided to ask for foreign bank loans to finance the oil boom (Landman, 1986). With the new infrastructure, oil production rose from 202,100 barrels per day in 1977 to 1.098,000 barrels in 1981 (Hamnett, 1999). It was evident that Mexico was on its way to an economic

recovery. However, things changed in 1981 when oil prices dropped considerably. Since the reduction in oil prices was accompanied by an increase in interest rates, the interest that Mexico had to pay to foreign banks increased from \$2000 million in 1977 to \$9500 million in 1981 (Heckert, 1999). Unfortunately, Mexico relied heavily upon oil revenues for financing its debts and the government could not continue to pay these high interest rates. Despite the president's promise of economic recovery, the total national debt had tripled by the end of his presidential term, and the Mexican peso had been devaluated more than 50%.

By 1982, Mexico was facing a severe external debt crisis which forced the government to request emergency financing from the IMF (Copelovitch, 2010). Hence, in November 1982, Mexico entered into negotiations with the IMF and foreign commercial banks. The negotiations were finalized with a loan and an agreement that forced Mexico to implement SAPs. The SAPs obliged the government of Mexico to reduce public spending in order to keep the debt under \$5,000 million a year after the loan negotiations concluded. In addition, the incoming government of Miguel de la Madrid had to eliminate the protectionist measurements established by the outgoing government of Lopez Portillo (Aguilar-Mendez, 2006). The outgoing government was characterized by its use of trade barriers as tools for protecting national industries and for owning a large number of them. In fact, in 1982, the national pharmaceutical industry produced 98% of the drugs consumed in the country (Gasman, 1995). However, this production heavily depended on the raw materials manufactured by Transnational Corporations (TNC). During the 1982 economic crisis, TNCs requested price increases for their products to compensate for the peso devaluation. Since Lopez Portillo did not approve the price increases, TNCs stopped the importation of raw materials causing a serious shortage of medicines in the country.

The big challenge of economic recovery, including dealing with the medicines crisis, was assumed by the incoming President Miguel de la Madrid who came to office in December 1982. This new administration started implementing all the structural reforms required by the IMF as the condition for receiving the loan. Hence, the protectionist discourse from the previous administration got transformed into a laissez-faire neoliberal one. The number of companies owned by the government of Mexico went from 1155 in 1983 to only 399 in 1989 (Suarez, 1989). In the pharmaceutical sector, the drug shortage triggered by the 1982 devaluation of the Mexican peso, made the government aware of the serious structural weaknesses in its pharmaceutical industry, including its overdependence on raw material imports and the control by

multinationals (WHO, 1988-b). This awareness created the window of opportunity for the development of the first Mexican NDP in 1984. The objectives of this policy were: 1) to support the development of the national pharmaceutical industry in order to decrease dependence on the transnationals, 2) to promote the rational use of drugs, and 3) to make good quality EM available to the population at a reasonable price (WHO, 2001). The implementation of this policy faced strong external opposition from 40 transnational companies and their respective governments who filed suit against the Ministry of Health (Essential Drugs Monitor, 1986). According to Dr. Mario Liebermann, Director-General of the Control of Inputs for Health during Miguel de la Madrid's Administration, one of the reasons for this opposition was that the NDP promoted the use of generic products in the health sector and not the use of commercial brands. The WHO (1988-b) explains that opposition to the Mexican NDP was mainly directed at four points: 1) the use of generic names without registered trademarks on all products sold to the public health sector; 2) the addition of generic names to registered trademarks in the private sector; 3) the elimination of certain drugs from the trademark register; and 4) the ban on irrational combinations of drugs. In order to stop the legal action, the government of Mexico had to negotiate with those companies and redefine its NDP. In 1984, the Mexican government decided to change these regulations. A new set of rules that replaced the previous policy was released in 1985 (WHO, 1988-b). After the release of this new document, 35 companies withdrew legal action. However, the opposition of the pharmaceutical industry to the four points mentioned above delayed by five months the agreement on bilateral subsidies and countervailing duties that Mexico was signing with the United States. However, this bilateral agreement was finally signed in April 1985 (Gasman, 1995) as the first comprehensive trade agreement between Mexico and the United States. This agreement set the tone for other international commercial agreements including the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA) which will be discussed later (Dominguez & Fernandez de Castro, 2009).

According to Abraham (2002), the pharmaceutical industry has been quick to ward off regulations it perceives to be contrary to its interests by threatening governments and regulatory agencies that those regulations will have damaging results for the nation's economic prosperity and employment. The Mexican government and its regulatory agency accepted these threats uncritically, adjusting their regulations to the needs of the pharmaceutical industry, even when those modifications jeopardized the public health of the

whole nation by denying it access to truly safe, effective, and affordable EM. Despite the modifications made to the original version of the NDP, the NEML remained an important part of this policy.

The First Mexican NEML

Mexico had been aiming to improve access to EM since 1947, the year when the “Instituto Mexicano del Seguro Social” (IMSS), the largest social security provider in the country, published its first list of EM (IMSS, 2016). This list was selected by the commission that coordinated public health activities. An EM list became obligatory for all public health institutions almost 25 years later when the President of Mexico, Luis Echeverria Alvarez, published a presidential agreement on April 1975 which specified the need for having an EM list in each public health institution (DOF, 1975). Two years later, in 1977 President Jose Lopez Portillo established the commission in charge of developing the first sectoral EM list that harmonized all the public health institutions (Gomez-Dantes, 2001). Details about the composition of this commission are not provided in the literature. All that is known is that its members were government officials from some of the main public health institutions who received advice from renowned physicians in the country. According to the government official gazette of that year, this commission selected a list that included 432 generic drugs in 622 pharmaceutical forms (DOF, 1977). However, information published later in the same gazette indicates that this list included 444 generics in 636 pharmaceutical forms (DOF, 1982; DOF, 1984). This list was reviewed two years later by a new commission that decided to keep the same medicines in the list (DOF, 1984). The first regulation governing the commission in charge of selecting the public sector EM list was published on July 5, 1981 under the administration of President Miguel de la Madrid. This regulation specified the objectives of the commission as well as its composition, and the responsibilities of its members. Two years later, on June 9, 1983, his administration introduced the requirement for a comprehensive NEML that included not only medicines, but biological products, laboratory reagents, medical devices, and healing materials. The government administration assigned the “Comisión Interinstitucional del Cuadro Básico de Insumos” (CI-CIBSS) the responsibility of developing, updating, publishing, and disseminating the first Mexican NEML (DOF, 1983). This commission was made up of the General Health Council Secretary who led the commission, members representing three public health institutions: 1) “Instituto Mexicano del Seguro Social” (IMSS), 2) “Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado” (ISSSTE), and 3) “Sistema Nacional para el Desarrollo Integral de la Familia” (DIF), and their respective replacements

(DOF, 1984). This newly created commission developed the first NEML which was published on November 1, 1984 under the title of “Cuadro Basico de Insumos del Sector Salud” (CBISS). The General Health Law made the NEML obligatory for all the public health institutions on February 7, 1984, (DOF, 1984-b). This law regulates the right to health protection granted by the Mexican constitution and establishes the basis for ensuring access to healthcare services including the access to EM. In article 27, this law established that medicines are considered a basic health service. Article 28 specifies that the “Cuadro Basico de Medicamentos” applies to the first level of care, and that the “Catalogo de Insumos” is for the secondary and tertiary levels of care. It also states that public health institutions must conform to these two lists. Article 29 confirms that the Health Secretariat will determine the drugs on the list of EM and will guarantee their permanent supply and availability to the sector of the population that needs those medicines (CESOP, 2015).

The development of the first NEML was a laborious work that originated from the previous sectoral EM list. That list was reviewed over a period of six months by a group of 120 medical experts who collaborated with the commission and studied the various therapeutic groups on the previous list. Once the review was completed, a total of 148 drugs were removed from the list, and 19 new ones were added. The resulting final NEML included 329 generic drugs in 483 pharmaceutical forms (Essential Drugs Monitor, 1986). The selection criteria for this list considered the following four points: 1) medicines were chosen based on their risk-benefit ratio, 2) medicines whose quality had been surpassed by new drug products were withdrawn from the list while new products with a higher therapeutic value were added, 3) medicines with the same pharmacological action as those already on the list were not considered, and 4) the list excluded any combination medicines. In addition, following the pattern of the previous sectoral list, this new list included only generic drugs and single compounds (DOF, 1984). The list was accompanied by the “Catalogo de Insumos”, a separate list created only for the second and third levels of care which included biologics, laboratory reagents, instruments, and equipment, as well as essential medical devices. Both the “Cuadro Basico” and the “Catalogo de Insumos” are considered part of the NEML; the “Catalogo de Insumos” is outside of the scope of this paper.

Only the list that contains medicines for the first level of care will be discussed in this paper. The first-level of care is considered primary care where doctors diagnose, issue prescriptions, and perform simple tests and procedures. Medical treatment involving hospitalization and specialized ambulatory services for

patients referred from the first level of care or from the emergency room is considered the second-level of care. The third level of care involves more sophisticated procedures such as cancer treatment or organ transplants (Levy, 2008; DOF 1996).

Besides developing the first NEML, the government of Mexico had to face another important challenge in order to ensure that the NEML included good quality, safe and effective medicines. It was necessary to strengthen the regulatory capacity and efficiency with which the health regulatory agency approved the drugs that were on the Mexican market (Gutierrez, 1990; Gasman, 1995). According to the Mexican government, there were 24,215 drugs registered in the country in 1984 of which only 5000 were commercialized (DOF, 1984). The strengthening of the regulatory agency contributed to decreasing these more than 20,000 drugs to 7,500 over a period of four years, from 1984 to 1988 (Lieberman, 1988). According to the WHO, there were 7,000 and not 7,500 drugs registered in the Mexican private market in 1988, of which 1800 were classified as irrational (WHO, 1988-b). This rationalization of products on the market complemented the selection process of the NEML. However, as it will be shown in the following section, not only has this first NEML been subjected to many changes through the different presidential periods, but also has the regulatory framework that supports the implementation of this list.

The NEML through the Different Presidential Periods

The legislative and regulatory framework implemented by President Miguel de la Madrid not only tried to strengthen the capacity of Mexico's regulatory agency, it also attempted to rationalize the drug market. His administration was characterized by the implementation of measures that promoted economic efficiency. The development of the first NEML is an example of one of these measures. However, his successor, President Carlos Salinas de Gortari, focused more on the negotiation and implementation of the NAFTA rather than on implementing and monitoring the NDP developed by the previous administration. According to Gasman (1995), Salinas' neoliberal administration neglected health, education, and social development. During his period in office, there were no modifications or amendments that affected the NEML regulation.

Following Salinas' government, President Ernesto Zedillo on June 11, 1996, continuing with the work left by President Miguel de la Madrid, published a decree that emphasized the difference between the two lists that are included in the NEML. According to this decree, public health institutions will apply the

“Cuadro Basico de Medicamentos” to the first level of care and the “Catalogo de Insumos” to the second and third levels. The decree defined “insumos” as medicines, raw materials that are used to make medicines, biologics, lab reagents, medical devices, healing materials, and scientific information from electronic sources. It also established that the NEML, including both the “Cuadro Basico de Medicamentos” and the “Catalogo de Insumos”, was going to be permanently reviewed by the “Comision Interinstitucional del Cuadro Basico”. The following administration of President Vicente Fox, introduced another decree on December 24, 2002 that modified the previous decree from Zedillo that clarified the applicability of the two lists. However, President Fox changed the “will apply” used by Zedillo to “must use only” to specify that public health institutions “must use only” the products that are listed in the “Cuadro Basico de Medicamentos” for the first level of care, and “the Catalogo de Insumos” for the second and third levels of care (DOF, 2002). On May 27, 2003, President Vicente Fox also established the “Reglamento de la Comisión Interinstitucional del Cuadro Básico de Insumos del Sector Salud”, a regulation for the commission in charge of selecting the NEML. According to this regulation, the commission was made up of the General Health Council Secretary who acted as the president of the commission, as well as five titular members from SSA, IMSS, ISSSTE, DIF, and the Secretary of Defense (SEDENA) respectively. Each of these members also had to choose a substitute.

Contrary to the previous administrations, the new administration of President Felipe Calderon focused on the prices of medicines. On February 26, 2008, he established the “Comision Coordinadora para la Negociacion de Precios de Medicamentos y otros Insumos para la Salud” as the commission in charge of carrying out the annual price negotiations for products that have a valid patent and are included in NEML. This commission does not negotiate prices for patented drugs that are not considered EM, and therefore are not included in the NEML (Gaceta Parlamentaria, 2012). As will be discussed later in another section of this chapter, patented medicines that are not part of the NEML are regulated by the Ministry of Economy. Also, during Calderon’s period, on June 22, 2011, the “Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos Sector Salud” developed a new regulation with the intention of standardizing the review and update process of the NEML. This regulation invalidated the previous regulation that was introduced by President Fox on May 27, 2003 (DOF, 2011). The goal of this new regulation was to guarantee an efficient and transparent evidence-based assessment of the safety and efficacy of all the drug applications filed by pharmaceutical companies with the intent of being considered for the NEML (DOF, 2011). According to it,

the commission in charge of selecting the NEML is composed of the General Health Council Secretary who acts as the president of the commission, a technical secretary, and titular institutional representatives from the following public health institutions: SSA, IMSS, ISSSTE, DIF, SEDENA, the Secretary of the Navy (SEMAR), and the Secretary of Health of the Federal District (SSDF). The details about the education and expertise required for the committee members are not described in the regulation; it only mentions that the committee members should have clinical or health economics work experience. According to this regulation, the technical, secretary will lead a technical committee composed of a coordinator and institutional representatives assigned by the titular institutional representatives that are part of the commission. The technical committee can request the participation of experts who will act as their advisors. According to the regulation, representatives from the National Commission for the Social Protection in Health (CNPSS), the National Centre for Health Technology Excellence (CENETEC), the National Chamber of the pharmaceutical industry (CANIFARMA), a citizen representative from the Council of Ethics and Transparency of the Mexican pharmaceutical industry (CETIFARMA), the High Specialty Regional Hospitals Coordinating Commission (CCINSHA), and the National Chamber of Industry (CANACINTRA) will be permanently invited to the plenary sessions of the commission. Permanent guests have a voice but no vote. The final decision about which medicines to include lies with the members of the commission. The technical committee meetings could also accept representatives from other administrative units within the Mexican government, if all the members of the commission agree. The commission can also listen to the opinion of representatives from the social and private sectors. However, the regulation does not specify how these other administrative units and the social and private sectors can become aware of the meetings. Even though this is a consultative selection process, advisers like permanent guests are not allowed to vote.

Under the current administration of President Enrique Peña Nieto, this regulation has been amended twice, Once on January 16th, 2014, and the second time on February 23, 2016 while I was conducting my study. Even though my intention is not to analyze these two reforms, I will describe one important change made in the second reform of this presidential period because this change modifies the team that is assigned to conduct the selection of the NEML in 2011 under the administration of President Calderon. According to the amended regulation, six public health institutions will participate in the selection of this list: 1) SSA, 2) IMSS,

3) ISSSTE, 4) SEDENA, 5) SEMAR, and 6) PEMEX, which leaves DIF and SSDF out of the selection of this list. Although this reform includes more changes, these changes are outside the scope of my research.

Before finalizing this section, I would like to highlight the centralized decision-making power that characterizes the Mexican government, since, according to Arredondo (2001), Valdez (2000), and Cozio (1998), the Mexican constitution gives the president the sole ability and authority to amend and reform the constitution. This power, according to these authors, makes the president of Mexico not only the principal legislator, but also the person who can fire governors, municipal presidents as well as state and federal legislators and other government officials, since the president has unrestricted authority over legislative and judiciary powers. The constitutional authority that the Mexican president enjoys has made him one of the most powerful leaders of any democracy (Arredondo, 2001; Abrantes, 1997). Even though according to Arredondo (2001), the political constitution states that the power structure of the Mexican government is based on three branches (executive, legislative, and judicial), in practice this balance of power does not really exist. Rather, the power has been channeled to the office of the president and his main collaborators. Prior to the recent presidential election, both Houses of Congress were overwhelmingly dominated by members of the PRI and PAN (conservative parties). There has not been a real opposition that could have an impact on the legislation, although this situation has changed with the recent election (El Sol de Mexico, 2018).

The Compulsory Nature of the NEML and its Use in Public Healthcare Institutions

As mentioned before, the General Health Law made the NEML obligatory for all the public health institutions. Based on the compulsory nature of this list, physicians who work for public health institutions should not prescribe medicines that are not listed in the NEML. However, a study conducted by Duran et al. (1990), shows that out of 691 medicines that were prescribed by 310 physicians, 59% were not listed in the NEML. According to this study, the NEML was working well for the secondary and tertiary levels of care, but not for the first level. For the first level of care, the NEML assumed a voluntary nature instead of a compulsory one. Most of the medical centres did not have a pharmacy or if they had one, it was not properly stocked. Since their patients were going to purchase their medicines out-of-pocket in a private pharmacy, physicians felt free to prescribe any medicine available on the market. According to Gasman (1995), the use of the NEML varied among public health institutions, and depended on both the availability of medicines in each health facility, and the physicians' knowledge and level of acceptance of this list. In order to better

understand this variation in the use of the NEML prescriptions, it is important to know how the Mexican healthcare system is structured.

Mexico's health system is fragmented into three different subsystems that provide health care to different segments of the Mexican population: IMSS, SSA and ISSSTE. The IMSS and SSA were established in 1943 with two different missions. The IMSS insured employees in the formal economic sector and their dependents, while SSA provided healthcare services to the uninsured sector of the population. Years later, in 1959, the government created the ISSSTE. This institution was in charge of insuring civil servants, including local, state, and federal government employees and their dependents (Arredondo, 2001). These three institutions are partially funded by the government. However, the corresponding sources of financing vary among them. The IMSS is financed by the federal government, employers and employees, the ISSSTE by the government as employer and by government employees (Gasman, 1995), and SSA, was financed by the federal government if the states were not decentralized or by local government if they were, and by patients' co-payments (Gomez-Dantes, 2011). This difference between decentralized and centralized states emerged when the central government decided to transfer the responsibility for the provision of health services to the 31 states of the Mexican Republic. This transfer of responsibilities was part of a decentralization process which was done in two stages. During the first stage that started in 1983, with President Miguel de la Madrid, only 14 states accepted the transfer of this responsibility. These states were considered to be decentralized states. The second stage started in 1993, during the administration of President Ernesto Zedillo, and included the decentralization of the remaining 31 states and the Federal District. (Jaramillo, 2007; Homenades & Ugalde, 2011).

In 2003, during the administration of President Vicente Fox, the Mexican congress approved a health reform that gave rise to "Seguro Popular (SP)" a very basic public insurance coverage for the sector of the population that does not have any type of health insurance. This health program is co-financed by the federal government, state governments, and people who do not have public health insurance coverage because they are either self-employed or not insured by their employers and can pay for the services that SP provides. The funding that states receive from the federal government is conditional on the number of families that are register in the SP program which, according to Homenades and Ugalde (2009), can be considered a re-centralization of decision-making power. Even though SP was implemented in January 2004 with the

intention of reducing health inequities among Mexicans, by 2008 more than 30 million Mexicans still did not have any type of health coverage (Gomez-Dantes, 2011). According to a former director of the medical school of the “Universidad Nacional Autonoma de Mexico (UNAM), the SP goes against both the obligation of the state and the Mexican constitution because it tries to impose a pre-payment charge for healthcare services. These charges promote the privatization and commodification of healthcare, jeopardizing the principle of universality that the Mexican Constitution proclaims (Mendez, 2005). A recent report published by the IMSS and the National Institute of Statistics and Geography (INEGI), states that out of every 100 Mexicans, 45 are affiliated with SP, 44 with the IMSS, 7 with ISSSTE, and the last 4 with other public or private institutions (INEGI, 2013). These statistics purport to show that every single Mexican is covered by at least one type of health insurance. The World Bank (2015) has also confirmed the government’s statement that SP provides healthcare coverage for the entire uninsured sector of the population. According to the Bank, healthcare universality in Mexico was reached in 2009 during the time when another economic crisis led to a deep contraction of over 6 % of GDP. This crisis increased poverty and put pressure on the finances of vulnerable families who did not have health insurance coverage, or who had lost their health insurance when they lost their jobs due to this economic crisis. In order to protect the health and finances of all of these families, the government expanded SP. Hence, according to the World Bank, the number of individual beneficiaries of SP grew from 31.1 million in 2009 to 55.6 million in 2013. These numbers indicate that SP insures almost 50% of the Mexican population who do not have any type of health coverage. However, the reality differs from these statistics. Unfortunately, there are no independent evaluations that can challenge the idea that Mexico has achieved universal healthcare coverage. All the existing evaluations have been done by government officials from SSA or by research groups close to the Health Minister who implemented SP (Berguer and Ugalde, 2008). Many people without a formal job still do not have access to free quality healthcare services. SP does not cover all the services and medicines that the most vulnerable sector of the population needs.

In addition to IMSS, ISSSTE, and SSA, there are also three more social security institutions that make healthcare available to a more specialized sector of the population: 1) Petróleos Mexicanos (PEMEX) that provides health care services to employees from the national oil industry, 2) SEDENA, which offers healthcare services to the Mexican armed forces, and 3) SEMAR which insures the naval forces (Gomez-

Dantes, 2011). The number of Mexicans affiliated with PEMEX, SEDENA and SEMAR represents approximately 1% of the population. Health care may also be obtained via private insurance entities by those who can afford it. However, private insurance in Mexico is very limited. Only 3% of the population, mostly individuals with high incomes, has private insurance with employers' subsidized group plans accounting for half of private health insurance coverage (Moise & Docteur, 2007). This segmentation of healthcare services that characterizes the Mexican health system and the lack of a single entity that provides universal healthcare coverage is a big obstacle in ensuring equitable access to EM.

Even though the expert committee in charge of selecting the NEML includes representatives from the IMSS, SSA, ISSSTE, PEMEX, and SEDENA, the IMSS is the only institution responsible for the purchase of EM for all the other public health institutions, including ISSSTE, PEMEX, SEDENA, 17 federal entities, and 21 institutions and hospitals affiliated to the SSA (IMSS, 2014). According to the IMSS, it has traditionally purchased 70% of the drugs that are used in the public sector from the national market, and only 30% from TNCs. These rates differ in the private sector where TNCs supply about 80% of the whole pharmaceutical market (IMSS, 2014). Even though the IMSS purchases the medicines that are available under the NEML for all public health institutions, these institutions also use direct purchasing mechanisms to obtain drugs not included in the NEML, but requested by physicians. According to Gasman (1995), the amount spent on these items has never been disclosed, but it could account for up to 40% of the drug budget. The purchasing power of public health institutions has always reflected the interest of pharmaceutical companies. According to Abrantes-Pego (1997), the IMSS, ISSSTE, and SSA have turned into captive markets for both the national and transnational pharmaceutical industry. The procurement process that these public institutions follow has been linked to suspicions of corruption. One of these cases of corruption was made public in 2010. This case had to do with a purchasing contract between Novartis and the IMSS. The two parties (Novartis/IMMS) involved in the negotiation of this contract were going to receive a commission of 4 to 5 % on a medicine purchase of \$80 million pesos (Esquivel, 2013), approximately \$5,725,000 CAD.

It is important to know that despite the existence of a NEML in Mexico, physicians in public health institutions do not prescribe from this list, but from the EML that each institution puts together, taking as a model the NEML (Gasman, 1995). Even though the selection of these lists is based on the NEML, the type and number of EM selected by each institution differ. This difference promotes inequitable access to

medicines among the Mexican population. SSA through SP is the institution that covers the fewest medicines. Many of the drugs that physicians who work for this institution prescribe are purchased out-of-pocket in the private market (Gasman, 1995). Unfortunately, the sector of the population insured by SP is the most vulnerable, whose members cannot afford to pay the high prices of medicines in the private market. Drug out-of-pocket expenses are high even for patients that have a formal job and are insured by the IMSS or ISSSTE. In 2012, health-related expenditures in Mexican households with any of these two types of social security coverage were 72% of all out-of-pocket expenses, of which 66% was spent on medicines (Wirtz et al., 2012). Governments need to consider that relying on the supply of medications through the private sector and paying for them through out-of-pocket payments excludes the poor and vulnerable from obtaining even the most basic EM (Hogerzeil & Mirza, 2011). The partial implementation of universal coverage in Mexico interferes not only with the compulsory nature of the NEML, but also with equitable access to EM.

How Drug Regulations Interfere with the Selection of the NEML

Regulations are fundamental to guarantee an appropriate selection of high quality, safe, and effective EM. The lack of efficient regulations that control the pharmaceutical industry in Mexico, represent an obstacle to the development not only of the NEML, but also of its NDP. As the WHO (2001) suggests, a strong regulatory framework can contribute to enforcing the components of a NDP, while a weak one will allow the circulation of poor quality, unsafe, ineffective, and unnecessarily expensive medicines that will have a negative impact not only on the population's health, but also on the national economy. Countries with a regulatory environment that does not jeopardize the profits of the pharmaceutical industry are considered "attractive markets" for this industry. The more relaxed and unregulated the environment, the more attractive the location is. However, in a country where 46.2% of Mexicans live below the poverty line (CONEVAL, 2015), government officials need to be transparent and careful not only with the use of scarce resources available for improving and maintaining the nation's health, but also with the type of regulations that they enact for the pharmaceutical industry. There are two particular types of regulations that have had an important impact worldwide in guaranteeing equitable access to medicines and an efficient selection of a NEML: 1) regulations on drug prices, and 2) Intellectual Property (IP) rights regulations. These two regulations along with the regulations that cover generic medicines will be discussed in the following subsections.

1) Regulations for Drug Prices

Mexico has regulated product prices, including the price of drugs, since 1951. However, it was not until 1984 that a separate regulation for pharmaceutical prices was established in article 31 of the General Health Law. Based on this article, the president of Mexico conferred responsibility on the Secretary of Commerce and Industrial Development to establish maximum retail prices for drugs in the private market. These maximum prices were set based on the manufacturer's cost and operating expenditures with predetermined margins for manufacturers, wholesalers and retailers (OECD, 2007). According to Gasman (1995), the original version of the first Mexican NDP that was rejected by transnational companies in 1984, established a policy of equal prices for products of equal therapeutic value. However, as mentioned before, the original version of Mexico's first NDP was revised to eliminate all the provisions that were inconvenient for the pharmaceutical industry. According to the Ministry of Economy (2007), during the late 1980s and the early 1990s, Mexico had a strict price control policy that was based on the National Index Price of Medicines (INPC). This changed in 1992 when the neoliberal government of President Salinas oriented his price control policy toward the deregulation of prices. In 1996, the government established a self-regulation policy where the pharmaceutical industry became responsible for setting the maximum retail price of its products. In 2002 the Ministry of Health found out that in more than 43% of the cases, the retail sale prices were higher than the maximum permitted retail prices established by the industry (Gonzales-Pier and Gonzalez, 2004). In order to control this problem, the pharmaceutical industry entered into negotiations with the newly created Ministry of the Economy that had replaced the Secretary of Commerce and Industrial Development. These negotiations ended up with a new scheme of maximum retail prices that was adopted in 2004. This scheme loosened even further the maximum retail price policy. Since then, price regulation in Mexico includes only patented medicines that are sold in the private market. Generic drugs and original products with expired patents that are also for sale in the private market are exempt from price regulation. In contrast with the private market, in the public system, each health institution had to individually negotiate the price of its medicines based on the maximum retail price. These individual negotiations prevented institutions from sharing the negotiated prices amongst themselves. It was not rare to find out that one institution had paid significantly higher prices than others for the same medicine (CESOP, 2010). Unfortunately, as Moise and Docteur suggest (2006), strict price controls became a feature of past regulations. New regulations in general have been supporting

neoliberal markets by opening up pharmaceutical pricing in the public sector. As will be described next, there is a significant difference between the prices that pharmaceutical companies set for the public sector and those that are established for the private sector.

a) Drug Prices in the Public Sector

The government purchases all the medicines that are for public use at prices that are 83% lower than the retail prices in the private market (CESOP, 2010). The negotiation of drug prices in the public sector has been evolving. In 2008, President Calderon created the “Comision Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud”. The mission of this commission was to negotiate the prices of patented medicines included in the NEML with the pharmaceutical industry (DOF, 2008; Gomez-Dantes et al., 2012). The government also developed a public bidding system where different health institutions participate to negotiate better drug prices. This unified procurement system has decreased the prices of both generics and patented drugs for the government (Gasman, 1995). In 2013, the IMSS, ISSSTE, SSA, SEDENA, SEMAR, PEMEX, and five states of Mexico participated in the first biggest unified price negotiation that allowed the government to save \$3,700 million pesos, approximately \$263,799,484 CAD, compared with the previous year. The purchase of medicines for 2015 was done in December, 2014 also under this unified procurement system. The savings for 2015 were \$4,600 million pesos, approximately \$327,820,584 CAD (IMSS, 2014-b). According to a government official who was interviewed by the Mexican newspaper “El Economista” (2014), the savings that the government made on medicines in 2014 were going to be used in infrastructure, such as the improvement of emergency departments and waiting rooms. The allocation of these resources might explain why the government of Mexico cannot guarantee access to EM for all its population, since savings are not put back into purchasing EM. However, it is difficult to understand how the Mexican government expects the 46.2% of Mexicans living below the poverty line to be able to afford medicines at the exorbitant prices at which they are sold in the private market. Considering that private sector consumers are not any wealthier than the government, access to medicines and to health services will not be achieved by transferring responsibilities to the most vulnerable ones.

b) Drug Prices in the Private Sector

In contrast to all the savings that have been achieved in the public sector, the government has not been successful in controlling drug prices in the private sector. As mentioned before, generic drugs and

original products whose patents have expired that are sold in the private market are exempt from price regulation. According to Moise and Docteur (2006), even though the Ministry of the Economy is responsible for administering the price regulation scheme for the private market, the “Procuraduría Federal del Consumidor” (PROFECO), is the office responsible for enforcing compliance with the maximum prices by ensuring that pharmacies do not sell products at a price higher than the price approved by the government. However, PROFECO has no authority over how the pharmaceutical industry sets the maximum prices of their products. The Ministry of Economy does not have this authority either; its responsibility is restricted to receiving, on a yearly basis, information from pharmaceutical companies about its price increments (Moise and Docteur, 2006). In 2015, PROFECO published on its website a price report with the intention of “providing consumers with information that allows them to purchase their medicines at the best prices”. The report showed a comparison of the minimum and maximum prices of generic medicines, as well as the minimum and maximum prices of brand medicines. According to this report, a box with 30 tablets of 850 mg of metformin was found to have the highest price variation in the generics market, i.e., the greatest difference in prescription drug prices. The minimum retail price for this particular medicine was \$13.30 pesos (\$0.95 CAD) and the maximum \$65.00 pesos (\$4.65 CAD). There is a difference of \$51.70 pesos (\$3.70 CAD) in the price of this medicine which is 389% greater than the lowest price. Considering that the minimum wage in Mexico is equivalent to \$4.95 CAD (\$3.79 USD) a day, this price difference is meaningful. The percentage differences for brand drugs were much lower. They went from 48% to 102% of the lowest cost (PROFECO, 2015). However, brand drug prices are significantly higher than those for generics. Molina-Salazar (2008) suggested that high income countries face the challenge of price variation through price regulations and cost controls, but that this does not happen in low- and middle-income economies like Mexico. Some of the underlying causes of price variation include international exchange rates, differences in patient demand, national income, and government regulations (Danzon and Chao, 2000).

2) Regulations for Generic Drugs

One of the reasons why the wide variation in generic prices is possible in the Mexican market might be because the quality of generics is not uniform. In contrast to the U.S. where all generics must be bioequivalent, in Mexico there are two types of generics: 1) generics that contain the same active substance at the same concentration as their patented counterparts, but are not considered bioequivalent, and 2)

“interchangeable generics” that are not only pharmaceutically equivalent to the branded original, but also bioequivalent. This lack of uniformity has created a certain level of distrust among the consumers of these products which has caused price variability. According to Danzon et al. (2015), in countries with heterogeneous product quality, drug manufacturers’ pricing strategy depends of the distribution of consumers’ perception of and willingness to pay for drug quality. Danzon believes that the originator firms raise the price to target consumers who look for the highest quality, while multinational generic producers (that at least meet WHO standards of quality) use a high-quality/high-price generic brands strategy. As for the domestic generics industry with an established reputation, it may choose to invest in reputation for brand quality and charge higher prices than the domestic generics of unknown quality who usually charge lower prices to attract the most price-sensitive customers.

People in Mexico prefer brand name medicines rather than generics, even though they cannot always afford them in the private market. In fact, according to Hayden (2007) prior to 1998, pharmaceuticals were known, prescribed and purchased in pharmacies primarily by brand names. The alternatives to brand name medicines that people knew, were what they considered “the cheap medicines that IMSS/ISSSTE gives you when you go to the doctor”. However, generics became very popular in the private market in the late 1990s when Mexico was recovering from another devaluation of its currency in 1994, even when the population did not completely trust them. During this time, Mexico experienced another drug shortage, similar to the one experienced during the 1980s. Annual drug prices increased enormously, for example the price of all analgesics increased by 231% (Espicom, 2013). These high prices meant that public health institutions, such as the IMSS were regularly out of many medicines included in the NEML (Cruz, 1997). The government’s response to this shortage of medicines and to the exorbitant increase in drug prices was to facilitate the manufacture and consumption of generic drugs, but this time not only for the public sector, but also for the private one. Since then, many Mexicans have been buying generics in the private market not as their first choice, but more as way to compensate for the poverty inherited from the economic crisis. Generics are not even welcomed in the public sector. Despite the government’s efforts to create a “culture of generics in Mexico”, the fact that not all of them can be considered bioequivalent has hindered the popularity and acceptability of these products both in the private and public sector. According to Cortes-Cervantes (2007),

60.5 million Mexicans receive generic drugs through public health institutions and use them because they do not have a choice of buying the more expensive brand name products.

The generic policy that the government implemented during the late 1990s has been controversial not only in Mexico, but also internationally. Since the emergence of generics that cannot prove their bioequivalence created opposition from the U.S. and European drug companies, in 2005, the Mexican government reformed article 376 of the General Health Law to establish that all generics must be bioequivalent by 2010 (Hayden, 2007). However, neither the previous administration that ended in 2012, nor the current one have made public any information as to whether the deadline was met. On September 20, 2013, the current administration published Norm “NOM-177-SSA1-2013” which established the tests and procedures to demonstrate that a drug is interchangeable. Despite government efforts to ensure that all generics are bioequivalent, people in the private market continue to prefer patented medicines. This preference is shown in a report published in 2013 by the Ministry of the Economy of Mexico. According to it, 74.7% of medicines sold in pharmacies in Mexico were patented medicines, 12.1% generics and 13.2% OTC.

According to the WHO (2015-b), many health policies in general are unsuccessful because they do not address how the private and public sectors could complement each other. The current generic policy does not integrate the public and the private sector. For the last three years, public health institutions have been able to negotiate good generic prices with companies that meet high quality standards, through the unified procurement system that was implemented in 2013. However, also during the last three years, the government has been aggressively promoting the sale of generics in the private sector through a generic policy that claims to promote social inclusion. Unfortunately, this policy has not been able to guarantee, for the private sector, the same price of medicines that the government negotiates for its public sector. It is difficult to believe that the current generic policy promotes social inclusion, as the government (at the time this thesis was written) has been claiming for the last five years, when Mexicans have to pay more for EM out-of-pocket than what their government pays with public resources for the same products.

3) Regulations for Patent Drugs

Developing countries like Mexico face many difficulties in paying for medicines that have a valid patent. These difficulties have raised concerns about the effects of the 1994 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which established

standards for the protection of intellectual property (IP) (t'Hoen, 2009). According to Elliot (2003), this international trade agreement is keeping medicines priced out of reach for the majority of the world's population. Current patent law discourages drug companies from developing new drugs that offer significant new therapeutic value by allowing them to make excessive profits through minor changes to existing pharmaceuticals. The majority of newly developed medicines are considered "me-too" drugs which are minor variations of existing drugs (Light and Lexchin, 2012).

Pharmaceutical companies have always argued that each pharmaceutical innovation requires a lot of time and money to materialize. According to Parvis (2002), the core feature of the pharmaceutical industry is the intellectual prowess and creativity of its scientists. Since the majority of this intellectual work is done by U.S. pharmaceutical companies, this country has traditionally protected intellectual property by granting patents to reward the innovator. However, other countries like Mexico did not have this type of protection. In 1987, the Mexican government had to review its "Ley de Invenciones y Marcas", the patents and trademarks law that was established in 1976. According to article 10 fractions VII and XI of this law, pharmaceutical products and their production processes were not patentable (DOF, 1976). After this law was revised, pharmaceutical products were granted patents for 10 years (Zuniga, 2002). However, since Mexico was preparing for NAFTA, these changes were not sufficient. In June 1991, despite the unified opposition of the Mexican-own industry, Mexico signed the Law on the Promotion and Protection of Industrial Property (LEPPI). This law provided for the standard patent protection for pharmaceuticals of 20 years from the date when the application was filed in Mexico (OECD, 2007). With the implementation of this law, patent applications in the pharmaceutical area increased from 239 applications in 1990 to 3,164 in 2006. Mexico granted a total of 11,936 pharmaceutical patents from 1980 to 2006 of which 98.4% were granted to foreign companies and only 1.6% to Mexican ones (Shadlen et. al., 2011). The Mexican-own industry believed that U.S. pressure led Mexico to give too much away without gaining any real concessions for domestic companies (Gasman, 1995). Before TRIPS, Mexican firms used reverse-engineering to reproduce patented drugs. According to Moise and Docteur (2006), the country's weak patent protection contributed to fostering a domestic generic pharmaceutical industry in which many local firms specialized in producing copies of drugs that were still under patent in other countries. The speed of these firms' imitation capabilities was an issue of concern for U.S. pharmaceutical companies (Shadlen et. al, 2011) because it represented a financial

loss for them. This concern faded away when the new patent law started to increase the importation of medicines from the U.S. Imports into Mexico went from \$81 million in 1990 to \$613 million USD in 1998. More than a quarter of these imports were coming from the U.S. (Guzman and Zuniga, 2004).

During the 2001 WTO Ministerial meeting in Doha, TRIPS critics pointed out that the trade agreement was being interpreted and applied in a manner aimed at discouraging governments from pursuing policies to decrease the price of medicines (Elliot, 2003). Because of these criticisms, the Doha Declaration resulted, with WTO members agreeing that the TRIPS agreement does not and should not prevent members from taking measures to protect public health, and in particular, should not prevent members from promoting access to EM for all. The WTO created new rights for less developed countries by allowing them to postpone pharmaceutical product patenting. During the meeting, WTO members also clarified the rights that all countries have to take measures such as compulsory licensing to protect the health of their nations. Compulsory licensing allows for the production of generic versions of a medication even while the product is still protected by patents (Lexchin, 2013). Under this type of licensing the consent of the patent holder is not needed. Even though some developing countries have been able to use compulsory licensing for the purchase of antiretroviral drugs for their AIDS programs, Mexico has made several unsuccessful attempts to obtain a license for HIV/AIDS drugs under article 70 of the Law of Industrial Property (OECD, 2007). This article states that a compulsory license may be granted if a patented product has not been produced in Mexico within 3 years from the granting of the patent or 4 years from the patent application date. However, it also specifies that no compulsory license can be granted if the product is being imported by the patent holder or another company is licensed to import the drug. Even though compulsory rights were supported by the Doha Declaration, Western industrialized countries have been trying to attempt to limit the scope and use of these rights by pursuing stricter IP requirements ('t Hoen, 2009). In fact, trade agreements with the United States, such as NAFTA, have set stricter levels of IP protection than existed in the past. Property rights allow companies to veto many forms of government regulation, such as the regulation of prices and regulations that allow the disclosure of information generated during their clinical trials. The TRIPS agreement also represents an obstacle to the selection of safe, effective EM in the NEML because patented medicines are not affordable for LMICs. Worryingly, health regulatory agencies like COFEPRIS are no longer a protector of public health,

but faithful supporters of economic growth and innovation. This lack of support is reflected in the absence of a NDP.

Mexico's Current Edition of the NEML and NDP Situation

Mexico's constant reforms not only of the regulation that standardizes the selection process of its NEML, but also of its constitution, general health law, official norms and other regulations, have been an important obstacle to the development of a NDP that promotes a rational selection of its NEML. Despite several proposals submitted during the last two decades, Mexico has not been able to develop another NDP that replaces the failed version that was published in 1984. According to Wirtz (2013), the elements of a NDP are scattered in a fragmented legal framework as well as in the sectoral programs that are implemented by each federal government administration. According to the WHO (2012), for many decades, pharmaceutical policies both in LMICs and High Income Countries (HICs) have been developed in a piecemeal fashion. However, gradually, people came to realize that medicines and their proper place in society needed to be looked as a whole. Even though Mexico is aware of the need for a comprehensive NDP, the government continues to develop its pharmaceutical policies in a piecemeal fashion. It is more difficult to select Essential Medicines for a NEML when policies and regulations do not support each other. For example, despite the efforts of the Mexican government to standardize the selection process of its NEML, there is no standardization of the number of medicines that can be included in its NEML. According to the WHO (2006), a careful selection of a limited range of EM is important because it leads to a higher quality of care, better drug management and a more cost-effective use of health resources. However, the Mexican NEML keeps constantly growing. In 1996, the list included 454 drugs. This number went up to 771 drugs in 2010 and over 811 medicines in 2013 (Rico Alba & Figueras, 2014). The 2014 edition registered 911 drugs (Consejo de Salubridad General, 2014). However, while I was conducting my research in 2016, this number increased to 969 drugs. This number is the most recent information posted on the General Health Council website.

As mentioned before, the purpose of this grounded theory study is to bridge the gap in knowledge that exists about how the government of Mexico actually selects its NEML. I hope to learn the challenges, and obstacles, this government faces while selecting the EM that are included in this list. As mentioned before, in addition to this introductory chapter, this dissertation includes four more chapters that will fully describe the methodology used to conduct my research, my findings, the discussion of my findings, and my conclusion.

Chapter 2: Methodology

This chapter introduces the qualitative research methodology used to conduct my study and explains how this methodology guided my methods of data collection and analysis. From the five different approaches to qualitative inquiry, I adopted the systematic grounded theory approach, proposed by Strauss and Corbin (1998), to answer the research question: “How do Mexican government officials select their National Essential Medicines List?” According to Strauss and Corbin, grounded theory is of great utility in studies such as this one when the researcher wants to generate a general explanation of a process through the views of people who are directly experiencing it. This systematic approach allowed me to get closer to people who are experiencing or have experienced the selection process of the NEML, to find out how they perceive the selection process of this list, “why” things are the way they are, and “why” they behave and make decisions the way they do during the selection process. Their descriptions were crucial for the conduct of my research because they helped me to understand not how the selection process of the NEML is supposed to happen according to the regulation, but how this process actually takes place, according to the people involved in the selection process. Very often, actual processes are ignored or replaced by regulations that explain how things are supposed to be and not how they actually are.

As mentioned in my introduction, in Mexico, the selection process of the Mexican NEML is described in the “Reglamento Interior de la Comisión Interinstitucional del Cuadro Básico y Catalogo de Insumos del Sector Salud”, the regulation that standardizes the selection and update process of the Mexican NEML. Up until now, besides the information described in this regulation, there have not been any studies that explained how the people who participate in the selection process actually act, interact, and decide. However, the information that study participants shared during their interviews will contribute to bridging that knowledge gap that exists in the selection process. In order to be able to understand the actual selection process of the Mexican NEML, I adopted a relativist-pragmatist ontological position and a subjective epistemology as the philosophical perspectives of my study. My relativist-pragmatist position suggests that the world consists of multiple individual realities that are not static, but continually changing in response to evolving conditions. Pragmatism accepts the differences between the way things are supposed to happen and the way things actually happen.-Theories developed under a pragmatic perspective, according to Corbin and Strauss (2008), are usually embedded in a historical and cultural context in which different epochs, eras, and

moments influence their creation. In grounded theory, historical changes are not just interesting background material, but important incidents that define broader contextual and structural factors that contribute to the formulation of theories. As will be shown in Chapter 3, there were several historical and cultural events that occurred in Mexico while I was conducting my study which impacted the NEML selection process and also helped me to understand how particular historical structural factors were an important piece in the development of the theory that explains my findings.

I would like to mention the two points that made the Strauss and Corbin grounded theory approach the best choice for this study, over other grounded theory approaches. One of them was the inductive and deductive combination that they inserted to their methodology. Unfortunately, qualitative research has historically been depreciated for being a deductive method, to the extent that it has been considered to be “anecdotal, unsystematic, and biased” (Charmaz, 2006). However, the inductive approach that Corbin and Strauss have inserted into their methodology gives a qualitative approach, such as grounded theory, a sense of rigor and structure without denying the role of the researcher, and the study participants in the construction of a theory. As a person who has conducted only quantitative studies, I not only identified with this inductive/deductive balance, but also with the epistemological and ontological neutrality that these two authors associate their theory with. In fact, the second point that made the Strauss and Corbin grounded theory approach the best choice for my study was that these two authors do not link their approach to any predetermined theoretical perspectives. Their neutrality gives researchers the opportunity to assume any philosophical perspective that helps them to understand the social phenomena under study. In my case, as mentioned above, I was not only able to adopt a relativist-pragmatist ontological position and a subjective epistemology as the philosophical perspectives of my study, but also to apply both a deductive approach to explore the selection process with the study participants, and an inductive one to identify several patterns in the process that helped me to outline a theory grounded in my data.

My motivation to conduct a grounded theory study came from the desire to enter into the world of the people involved in the selection process of the NEML to understand the selection process from their perspectives, since the type of social question that I am trying to answer aims at understanding the motivations that lie behind human behaviour. Using surveys to describe, on a scale ranging from 1 to 10, how the people involved in the selection process of the NEML make decisions would not fully explain their

challenges, obstacles, behaviours, decisions and even feelings and emotions because they are difficult to obtain by quantitative research methods. According to Strauss and Corbin (1998), by entering into the world of the people involved in the process under study, the researcher can make discoveries that move us away from the unknown. This unknown world that affects access to medicines in Mexico was something that I witnessed as a Mexican child who once experienced the provision of medicines in the public healthcare system. Although I have lived half of my life outside of Mexico, six years ago, I had the opportunity to work in a project that reconnected me not only to the public healthcare system and the regulatory health agency, but also to cases and stories from patients who did not have access to healthcare and Essential Medicines. These stories became an inspiration for me to go back to school to pursue my PhD and write this dissertation paper. I have organized this chapter in two main sections. The first one describes my data collection including: a) my sampling methods, b) the recruitment process of the study participants, and c) the methods of data collection that I used to conduct this study. The second section explains the methods that I used to analyze my data.

Data Collection

a) Sampling

The theoretical sampling method of data collection characteristic of grounded theory allowed me to conduct purposeful sampling to identify thirty-one persons who participate in the selection process of the NEML, and six more who, although not directly involved in the selection process, are knowledgeable and very familiar with the NEML because they have been somehow involved in this process in the past. This second group was included in my study with the intention of having an outsider's point of view about the selection process. In order to differentiate these two groups in this chapter, I will refer to the first group of thirty-one as "insiders" and to the second group of six as "outsiders". The people who represent the thirty-one insiders have been classified into four different categories that can be identified in the organogram that is in Appendix C. The first one includes nine members of the "Comisión Interinstitucional del Cuadro Básico", the commission in charge of selecting the NEML. These nine members represent the General Health Council, an organ of the Mexican state established by article 73 of the Mexican Constitution that depends directly on the President of the Republic and is chaired by the Minister of Health with the purpose of issuing general health provisions. It is important to note that the Secretary of the General Health Council acts as the President of the commission in charge of selecting the NEML. The other eight members of the Commission are leaders of the

public health institutions that are part of the National Health Care System. Even though the General Health Council also includes some other important political actors such as the Director of the Mexican National University, the General Director of the National Council of Science and Technology, and the President of the National Academy of Medicine, none of them are part of the Commission in charge of selecting the NEML.

The second group referred as “Institutional Representatives’ Substitutes” includes four substitutes for these nine members who represent them, when needed, in the plenary sessions of the Commission. The third group comprises twelve members of the medicines committee who are in charge of evaluating the safety and efficacy of the medicines that are being proposed to be included in the NEML. From these twelve members, eight of them represent the same public health institutions as the Titular Representatives, and the other four, the General Health Council. The fourth and last group includes six permanent guests that are invited to the plenary sessions of the commission in charge of selecting the NEML. According to Chapter IV, Articles 9 and 10 of the regulation that standardizes the selection process of the Mexican NEML, the plenary is the supreme decision-making organ of the commission made up by the nine Titular Representatives which meets at least once a year.

As for the six outsiders, they initially included one academic from one of the top three public universities located in Mexico City, and five ex-Mexican health ministers who occupied that position since the creation of the first NEML in 1984. However, three more participants were added after I identified one more academic and two ex-members of the medicines committee when I implemented snowball sampling as an additional strategy to help me to recruit the participants that were initially purposefully identified. These nine outsiders and the thirty-one insiders are the forty participants that make up my initial sample. Table 1 shows these forty participants organized in categories along with the institutions that they represent. It is important to mention that even though the names of the institutions that participate in the selection process have been made public in the existing regulation, I will not associate these institutions with any of the study participants, since doing so would automatically reveal their identity. The names of these institutions are shown in Table 1 only with the intention of orienting the reader to the context in which the selection of the NEML takes place. The acronyms of these institutions and the sector of the population that they cover are listed in Table 2, also for the same purpose. It is also important to mention that even though the names of

some of these institutions are mentioned in the descriptions that the study participants offered about the process, none of these names are associated with any study participants.

The protection of the identity of all the study participants meets the requirements of the York University Office of Research Ethics, the ethics board that approved both my study and my informed consent form prior to me making contact with my initial sample. The approved informed consent form, which is included in Appendix D, clearly states the rights of the study participants, including their right to protect their confidentiality and anonymity. With the exception of one study participant, PG-5, who had his/her lawyer review the form prior to signing it, this form was freely discussed and signed by all the participants. Once this form was reviewed by this participant's lawyer, PG-5 also signed it and was recruited for the study.

Table 1: Initial Sample

Initial Sample (n = 40)		
Group	Participants' Category	Institutions that the Study Participants Represent
Insiders	Nine Institutional Titular Representatives	1) IMSS 2) PEMEX 3) SEMAR 4) DIF 5) COFEPRIS 6) ISSSTE 7) SEDENA 8) SSDF 9) General Health Council
	Four Institutional Representatives' Substitutes	1) COFEPRIS 2) IMSS 3) SEDENA 4) DIF
	Twelve Medicines Committee Members	1) IMSS 2) PEMEX 3) SEMAR 4) DIF 5) COFEPRIS 6) ISSSTE 7) SEDENA 8) SSDF 9) The General Health Council* *This last institution is represented by four members
	Six Permanent Guests	1) The National Commission for the Social Protection in Health 2) The National Centre for Health Technology Excellence. 3) National Institutes of Health and High-Specialty Hospitals 4) The National Chamber of the Pharmaceutical Industry 5) The National Chamber of the Transformation Industry 6) A citizen representative from the Council of Ethics and Transparency of the Mexican pharmaceutical industry
Outsiders	Five Ex-Health Ministers	1) Presidential Period 1982-1988 2) Presidential Period 1994-2000 3) Presidential Period 2000-2006 4) Presidential Period 2006-2012 5) Presidential Period 2012-2018
	Two University Professors	1) "Universidad Nacional Autónoma de México (UNAM)" 2) "Universidad Autónoma Metropolitana (UAM)"
	Two Ex-Medicines Committee Members	ExCom-A ExCom-B

Table 2: Public Health Institutions Involved in the Selection Process of the NEML

Public Health Institutions that Participate in the Selection of the Mexican NEML		
Acronym	Institution's Name	Population Covered
IMSS	"Instituto Mexicano del Seguro Social"	The largest social security provider in the country that covers the formal private sector workers, retirees, and their dependents.
ISSSTE	"Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado"	Insures civil servants, including local, state, and federal government employees and their dependents
PEMEX	"Petróleos Mexicanos"	Provides health care services to employees from the national oil industry.
SEDENA	"Secretaría de la Defensa"	Provides healthcare services to the armed forces.
SEMAR	"Secretaría de Marina"	Provides health coverage to the navy forces.
SSDF	"Secretaria de Salud del Distrito Federal"	Provides health coverage to the public sector in the Federal District.
DIF	"Desarrollo Integral de la Familia"	Provides health coverage to vulnerable families, especially to children and pregnant women.
COFEPRIS	"Comisión Federal para la Protección de Riesgos Sanitarios"	The Mexican health regulatory agency in charge of evaluating the safety and efficacy of the drugs that are approved for sale in the market.
CSG	"Consejo de Salubridad General"	The General Health Council is in charge of leading the selection process of the NEML.

Table 3 shows the codes that were assigned to each member of my initial sample in order to protect their identity and guarantee their confidentiality and anonymity in this study.

Even though I had no problems identifying the six outsiders who made up my initial sample, the identification of the 31 insiders was not an easy task because none of the three governmental sources that provide information about the NEML clearly identify the actors who are part of the selection process of the Mexican NEML. These governmental sources include: 1) the 2014 edition of the NEML, 2) the Website of the Commission in Charge of Selection the NEML, and 3) the regulation that standardizes the selection process of the NEML. The first and the second sources list the names of 63 persons including thirty-five members of the General Health Council who, although they are important political figures in the country such as those in charge of the Ministry of Health, the Ministry of Finance and Public Credit, the Ministry of Environment and Natural Resources, the Ministry of Transportation, the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food, and the Ministry of Education, are not recognized by the third source as the people who participate in the selection process.

Table 3: Study Participants' Codes

Study Participants' Codes		
Group	Participants' Category	Study Participant's Code
Insiders	Nine Institutional Titular Representatives	T1 T2 T3 T4 T5 T6 T7 T8 T9
	Four Institutional Representatives' Substitutes	S1 S2 S3 S4
	Twelve Medicines Committee Members	MedCom-1 MedCom-2 MedCom-3 MedCom-4 MedCom-5 MedCom-6 MedCom-7 MedCom-8 MedCom-9 MedCom-10 MedCom-11 MedCom-12
	Six Permanent Guests	PG-1 PG-2 PG-3 PG-4 PG-5 PG-6
Outsiders	Five Ex-Health Ministers	ExMin-1 ExMin-2 ExMin-3 ExMin-4 ExMin-5
	Two University Professors	Academic-1 Academic-2
	Two Ex-Medicines Committee Members	ExCom-A ExCom-B

This third source only recognizes nine institutional Titular Representatives, who are the leaders of eight public health institutions that make up the National Health Care System, as being part of the commission in charge of selecting the NEML. Although this third source also makes reference to the participation of the

Institutional Representatives Substitutes, the medicines committee, and the permanent guests who attend the plenary sessions of the commission, it does not recognize them as members of the commission in charge of selecting the NEML. Fortunately, with the help of the people who are involved in the selection process, I was able to identify my initial sample, overcoming the ambiguity and inconsistency found in these three public sources that make it difficult to identify who is really involved in the decision-making process and accountable for the selection of this list.

However, if the identification of these 31 persons who are involved in the selection process of the Mexican NEML was not easy, establishing contact with them was even more complicated. Even though their names are listed in the 2014 edition of the NEML and on the website of the Commission, none of these sources provide the email, telephone number, office address, or any type of information about where or how these persons can be contacted, if needed. I started searching online for a way to get in touch with them, and found a website called “Portal de Obligaciones de Transparencia” (Transparency Obligations Portal). This website is a directory that the Mexican government created with the objective of locating public servants and promoting the transparency of their work. On this website, I was able to locate the contact information for 13 of the 31 insiders. These 13 members included 8 of the 9 “Titular Institutional Representatives” (T-1, T-2, T-4, T-5, T-6, T-7, T-8 and T-9), two of the four “institutional representative’s substitutes” (S-1 and S-4), and three of the six permanent guests who represent a public institution (PG-3, PG-5, and PG-6). As will be explained later, the other three permanent guests who represented the private sector were more difficult to locate since the institutions that they represent are not governmental institutions listed in the portal. This portal did not include either the contact information of any of the 12 members who are part of the “medicines committee”, despite the fact that these 12 members are, in theory, considered public servants. I next reviewed the institutional websites of the remaining 18 persons who I could not find in the portal. Even though through these websites I was able to identify the contact information of T-3, I could not find any information that helped me to make contact with any of the 12 members of the medicines committee and the 2 institutional representatives’ substitutes. As for the three remaining permanent guests, their institutional websites did not make reference to the person who represents them in the plenary sessions of the commission. However, I was able to locate each of these institutions’ general phone numbers. After I called these numbers and my call was transferred to several departments within each institution. I was able to identify two of the other three

permanent guests who attend the plenary sessions of the commission. After spending a considerable amount of time searching online for the twelve medicines committee members and the two substitutes that I was still missing, I realized that the contact information for these fourteen persons was not available online. In an effort to validate my search, I asked for the assistance of an academic from Mexico City who was able to corroborate my finding that the contact information of these fourteen potential participants was not on the internet.

b) The Recruitment Process

Once I found the online contact information of seventeen of the thirty-one insiders and the six outsiders, I tried to establish a first contact with them via email with the intention of recruiting them and also with the hope that these twenty-three persons could help me to establish contact with the rest of my initial sample. As Table 4 shows, from these twenty-three potential participants who received my email invitation to participate in my study, only ten replied to my message. These ten participants included: two of the six “Titular Institutional Representatives” (T-4 and T-6), one of the two “institutional representatives’ substitutes” (S-1), three of the five ex-health ministers (ExMinister-1, ExMinister-3 and ExMinister-4), three “permanent guests” (PG-1, PG-5, and PG-6), and Academic-1. As is also shown in Table 4, from these ten subjects, only six (T-4, ExMinister-4, PG-1, PG-5, PG-6, Academic-1) accepted my invitation to participate in my study prior to implementing snowball sampling. Although the other four of the ten participants who replied to my initial email (T-6, S-1, M-1, and ExMinister-3) did not openly reject my invitation, I lost contact with T-6 and S-1 after S-1 replied to the initial invitation and recommended that I contact the General Health Council and not his/her institution, since according to S-1, the topic that I was investigating was the responsibility of the Council. I replied back letting S-1 know that my study included all the government officials who participate in the selection of the NEML. However, S-1 never responded to my second message. Something similar happened with T-6, who replied saying that his/her institution was no longer part of the selection process of the NEML due to some internal changes that I will discuss later and therefore could not participate in my study. I also replied back to T-6 letting him/her know that despite these internal changes, I was interested in interviewing both him/her and also MedCom-6, the medicines committee member who represents the same institution as T-6, but T-6 never replied to this second message.

Table 4: Initial email Response and Recruitment Rates Prior to Snowball Sampling

Participant	Participants who Received an email Invitation Letter	Participants who Replied to the email Invitation	Participants who Agreed to Participate in the Study
T1	Yes	No	No
T2	Yes	No	No
T3	Yes	No	No
T4	Yes	Yes	Yes
T5	Yes	No	No
T6	Yes	Yes	No
T7	Yes	No	No
T8	Yes	No	No
T9	Yes	No	No
S1	Yes	Yes	No
S2	No	No	No
S3	No	No	No
S4	Yes	No	No
MedCom-1 MedCom-2 MedCom-3 MedCom-4 MedCom-5 MedCom-6 MedCom-7 MedCom-8 MedCom-9 MedCom-10 MedCom-11 MedCom-12	No No No No No No No No No No No No	Since the contact information of these 12 members is not available online, they received an invitation to participate in my study once I arrived in Mexico and was able to implement snowball sampling	
PG-1 PG-2 PG-3 PG-4 PG-5 PG-6	Yes Yes Yes Yes Yes Yes	Yes No No No Yes Yes	Yes No No No Yes Yes
ExMinister-1 ExMinister-2 ExMinister-3 ExMinister-4 ExMinister-5	Yes Yes Yes Yes Yes	Yes No Yes Yes No	Yes No No No No
Academic-1 Academic-2	Yes Snowball Sampling	Yes Snowball Sampling	Yes Snowball Sampling
Ex-MedCom-A Ex-MedCom-B	Snowball Sampling Snowball Sampling	Snowball Sampling Snowball Sampling	Snowball Sampling Snowball Sampling
Total	23	10	6

As for ExMinister-1 and ExMinister-3, even though their assistants replied to all my emails on their behalf, these two participants could never find the time to meet with me. However, even though ExMinister-3 could not participate in my study, he/she helped me to recruit one of the Institutional Titular Representatives,

T-8, who is considered a key participant as the leader of the selection process of the NEML. The intervention of ExMinister-3 in my recruitment process inspired me to implement snowball sampling at this stage of my study to recruit participants who were unapproachable or difficult to reach like T-8.

However, even with the implementation of snowball sampling, it was difficult to get in touch with the people involved in the selection process who hold positions of power or with the ones who represented the more powerful institutions. As part of my snowball strategy, I visited the institution that leads the selection process of the NEML with the hope of locating the 12 medicines committee members and the two substitutes whose contact information I never found online, as well as the eleven insiders who did not answer my initial email invitation. The day of my visit, I brought with me an invitation letter for each of the people who belonged to that particular institution. However, even though I was granted access to the building and was able to speak with the person who is responsible for updating the introductory pages of the 2014 edition of the NEML, and the website of the commission in charge of selecting the NEML (two of the three governmental sources that I consulted to identify my initial sample), this institution did not accept any of my letters. I was told by one of the persons who I initially identified as an important participant for my study, through purposeful sampling, that nobody in that office could talk to me because the information that they handle is completely confidential. I asked for the contact information of the twelve members of the medicines committee and the two substitutes that I was still missing. However, this person told me that the contact information of those members was part of the information that they considered confidential and advised me to contact each of the institutions that these members represent to see if somebody there was willing to share the contact information of these members with me. After questioning the transparency policy that the current administration claims exists, this person granted me 15 minutes for an interview that was scheduled the following week. During these 15 minutes, this person agreed to participate in my study and was assigned the pseudonym of MedCom-8. As will be shown in Table 7, the interview with this participant ended up lasting more than two hours.

This interview helped me, in an indirect way, to continue snowball sampling because even though this institution did not provide me the contact information of the people involved in the selection process, MedCom-8 invited me to attend a meeting organized by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in conjunction with the General Health Council. This meeting took place in the

facilities of an international pharmaceutical company located in Mexico City. In this meeting, the General Health Council met with representatives of the industry, who are in charge of submitting the applications for inclusion of their products in the NEML, to give them an update report that included some statistics about the rejection and approval rates of their applications. During this meeting, I was able to recruit ExMedCom-B and get the contact information of ExMedCom-A and MedCom-1. After contacting and interviewing this last participant, he/she helped me to get in touch with MedCom-7. In this meeting, MedCom-8 introduced me to his/her supervisor, MedCom-9, who expressed no interest in participating in my study. However, when I interviewed T-8, this participant voluntarily referred me to MedCom-9 who at that time did agree to grant me an interview. In addition to the people who I was able to recruit by attending this meeting, I continued delivering my invitation letters, in each of the eight public health institutions, for the members of my initial sample who I was still missing. Each of the eight institutions where I delivered my invitation letters gave me a copy of a receipt that I kept for my records. Only the institution that T-4 and MedCom-4 represented replied to my invitation letter, contacting me separately over the phone to arrange an interview. While delivering these letters, I was able to get in touch with MedCom-3 through the referral of Academic-1 who also invited me to attend the “XI Meeting of Sanitary Regulation” where academics, the industry, and the government meet every year to discuss issues related to the Mexican health regulatory framework, and additionally recommended me to Academic-2. After I interviewed MedCom-3, this participant helped me to get in touch with MedCom-5. As Table 5 shows, snowball sampling had a great impact on my recruitment process. Prior to implementing this technique, I was able to recruit 6 participants which represented 15% of my initial sample. However, after snowball sampling, my recruitment rate more than doubled, since I was able to recruit 11 more participants. These 11 participants represent 28% of the people who I initially identified as important participants through purposeful sampling. Combining both groups, I recruited a total of 17 participants which represented 43% of my initial sample. Table 6 shows the participants who were recruited prior to and after the implementation of snowball sampling.

Table 5: Recruitment Rates Prior to and After Snowball Sampling.

Participants Category	Communicated with the Researcher During the Recruitment Process	Agreed to Participate in the Study Prior to Snowball Sampling	Agreed to Participate in the Study After Snowball Sampling	Total Participants Recruited
Insiders				
Nine Institutional Titular Representatives	5	1	1	2
Four Institutional Titular Substitutes	1	0	0	0
Twelve Medicines Committee Members	10	Recruited during snowball sampling	7	7
Six Permanent Guests	5	3	0	3
Outsiders				
Five Ex-Health Ministers	3	1	0	1
Two University Professors	2	1	1	2
Two Ex-Medicines Committee Members	2	Recruited during snowball sampling	2	2
Total of Participants = 40	28	6	11	17

Table 6: Participants Recruitment Prior to and After Snowball Sampling.

Participants Recruitment Prior to and After Snowball Sampling				
Group	Participants' Category	Initial Sample Identified	Participants Recruited Prior to Snowball Sampling	Participants Recruited After Snowball Sampling
Insiders	Nine Institutional Titular Representatives	T1 T2 T3 T4 T5 T6 T7 T8 T9	T4	T8
	Four Institutional Representatives' Substitutes	S1 S2 S3 S4	—	—
	Twelve Medicines Committee Members	MedCom-1 MedCom-2 MedCom-3 MedCom-4 MedCom-5 MedCom-6 MedCom-7 MedCom-8 MedCom-9 MedCom-10 MedCom-11 MedCom-12	—	MedCom-1 MedCom-3 MedCom-4 MedCom-5 MedCom-7 MedCom-8 MedCom-9
	Six Permanent Guests	PG-1 PG-2 PG-3 PG-4 PG-5 PG-6	PG-1 PG-5 PG-6	—
Outsiders	Five Ex-Health Ministers	ExMin-1 ExMin-2 ExMin-3 ExMin-4 ExMin-5	ExMin-1	—
	Two University Professors	Academic-1 Academic-2	Academic-1	Academic-2
	Two Ex-Medicines Committee Members	ExCom-A ExCom-B	—	ExCom-A ExCom-B
	Total of Participants	40	6	11

c) **Methods of Data Collection**

Even though the most common method of data collection in qualitative research is interviews (Ploeg, 1999; Strauss and Corbin, 1998), according to Corbin and Strauss (2008), the researcher can use more than one data source as a method of data collection in grounded theory. They believe that the use of triangulation to engage multiple methods such as interviews, observations, and field notes will lead to a more valid, reliable and diverse construction of reality. My primary method of data collection was face to face, in depth, open-ended, unstructured interviews combined with observations, field notes, literature, and document analysis. It is expected that when the researcher samples theoretically, he/she does not only interview people, but also observe places and situations that provide information about the concepts that he/she wants to learn more about (Corbin & Strauss, 2008). The interviews gave me an opportunity to obtain participants' opinions, views, and experiences in more detail, since the study participants had the opportunity to elaborate on their answers and explain what is important to them. The open-ended question that I asked the study participants gave them the freedom to give any answer they wished. This question for the insiders was: "How do you select the NEML?" And for the outsiders it was: "How do you see the selection of the NEML?" These initial questions were followed by more questions to prompt or encourage participants to elaborate more on the subject. However, after the first interview, I began to focus on the key issues that emerged during each interview and started asking more questions in the following ones. By the end of the study, the initial unstructured interviews had turned into semi-structure ones. Considering that the starting point of a grounded theory study is a question on how or why things happen in a specific "process", these face-to face, in depth, open-ended, unstructured interviews were the best option for collecting the data that I needed to answer my research question. It is important to mention that all the interviews were conducted in Spanish, since it is my first language, and that all the interviews were face to face with the exception of one that took place over the phone.

Prior to starting the interviews, I discussed the informed consent form with all the study participants and asked their permission to record the interview. The only participant who was not asked for permission was ExMin-1 because his/her interview was the one that took place over the phone and I did not have my tape recorder available on that day. Of the seventeen study participants, nine allowed me to record the interview and the other eight let me take notes. After each of these eight interviews, once I arrived at the place where I

was staying in Mexico, I read my notes aloud and recorded them in the same tape recorder that I used in the other interviews where participants allowed me to record the interview. All the interviews saved in that tape recorder were later transcribed during my data analysis. During the recruitment process, I asked each interviewee for an hour of his/her time. However, the majority of the interviews exceeded this time, lasting as long as two and three hours. The duration of each interview as well as the list of the participants who let me record the interview are shown in Table 7.

Table 7: Interview Duration

Interview Duration		
Participant	Interviews Recorded	Duration of the interview
T-4's Substitute T-8	Yes	1:20
	No	1:35
MedCom-1	Yes	1:20
MedCom-3	Yes	1:00
MedCom-4	No	1:25
MedCom-5	No	2:00
MedCom-7	Yes	1:35
MedCom-8	No	2:15
MedCom-9	No	0:20
PG-4	Yes	3:15
PG-5	No	2:30
PG-6	Yes	1:30
Ex-Minister-1	N/A	00:30
Academic-1	Yes	2:20
Academic-2	Yes	2:45
ExMedCom-A	Yes	1:30
ExMedCom-B	No	2:30
Total	9	

In addition to the interviews, I also observed the environment and culture of each of the institutions that I visited, as well as the environment that surrounded the cultural and historical moment that the country was living through when I conducted the study. These observations were written in a journal during each interview. Once each interview was over, my observations were transferred to my tape recorder and transcribed, similarly to the interviews that were recorded. All the observations that I made were complemented with field notes that included, for example, the instructions that I was given on how to access each building, maps, or drawings that helped me to identify each location as well as detailed notes about the environment of each building where the interviews took place. As Bluff (2005) suggested, field notes usually include aspects of the context of the study that cannot be recorded on tape during the interview (Bluff, 2005).

Besides observations, and field notes, other sources that helped me to understand the context in which the selection of this list takes place, and in particular the political environment that the country was living through, were the local newspapers as well as television and internet news. As will be fully explained in my results, while I was conducting my research, the President of Mexico announced some changes to his cabinet that had an impact on my research. The day after the President of Mexico officially announced these changes on TV all the local newspapers reported this political change on their cover pages. I read five of these newspapers. However; none of them mentioned the reason for these changes. Five days after the announcement, I conducted an internet search, in Spanish and English, looking for articles that explained the reasons for the changes in the cabinet. As a result of this search, I found four articles, three in Spanish and one in English that I am using in the following chapter, as a source to situate the reader into the political context that frames my results.

Data Analysis

According to Corbin and Strauss (2008), in order to find out how things work, sometimes it is necessary to break things apart to examine their components and identify their properties and dimensions. The data analysis method that they propose includes a process called coding which allows an examination of these properties and dimensions. This coding process is divided into three phases: 1) open coding, 2) axial coding, and 3) selective coding. Prior to starting coding, I transcribed all my interviews, observations, and field notes. At this point I did not translate anything, since the translation could distort my data and have an impact on my analysis. Once I had all this information captured on paper, I started the open coding phase. This phase allowed me to interact with my data to identify concepts in terms of their properties and dimensions. During this phase, I read through my transcripts many times looking for segments of raw data that I could elevate to a conceptual level that best described what my data meant. I extracted 456 segments of raw data that were conceptualized into 70 codes that were later sorted, compared, contrasted, and grouped into 3 categories identified as: 1) power, 2) ambiguity, and 3) domination. Both, the table that includes a sample of 456 transcript segments that were part of the initial conceptualization process and the one that shows the distribution of the 70 identified codes into the three related categories are shown in Appendices A and B respectively.

I used the constant comparative method and theoretical questions such as “what is the relationship of one concept to another” or “what do two concepts have in common” to group the identified codes into categories according to their properties and dimensions. These two methods helped me to identify variations and to make connections among concepts. Once the 70 codes were analyzed in terms of their specific properties (e.g., size of the public health institutions) and dimensions (e.g., small, medium, and large), they were grouped together into 3 categories: 1) power, 2) ambiguity, and 3) domination. During the axial coding phase, I explored 5 subcategories that include: 1) causal conditions, 2) intervening conditions, 3) contextual conditions, 4) actions/interactions, and 5) consequences to understand the conditions that establish the structure in which the selection of the Mexican NEML occurs. In the last selective coding phase, my three identified categories were linked to a core category with the intention of facilitating the emergence of a conceptual framework/theory. This core category represented by the concept of “contradiction” is considered the central phenomenon of my study that appeared frequently in the data and is the one that all other major categories relate to. This central phenomenon helped me to integrate my findings into a story line and develop the theory that I propose in Chapter Four. It was not until I started writing the story line that I translated the data from my interviews, field notes, and observations.

Chapter 3: Results

This chapter presents the selection process of the Mexican NEML as it was described by the study participants during their interviews. Although their descriptions explain how the people involved in the process act, interact, and decide while selecting the Essential Medicines for this list, the rationales for these actions, interactions, and decisions could not be fully understood in isolation without making reference to the regulation in which the Mexican government explains how these people are supposed to act, interact, and decide. Initially, in my study, this regulation was only a reference point that I carefully reviewed prior to entering field research, not with the intention of imposing any existing frameworks or hypotheses upon the data that I was about to collect, but to become familiar with the selection process of the NEML to be able to appropriately focus and direct my research. In qualitative research, reference points such as this regulation are considered “sensitizing concepts” that give a general sense of reference and guidance in approaching empirical instances (Blumer, 1954). However, once I completed the analysis of my data, the procedures described in it stopped being simply a reference point and became deviations from what study participants say they do in practice.

Although I cite several passages of the regulation in this paper and even summarize three of its chapters that explain the objectives, the organizational structure, and the process, my results go beyond a comparison between the procedural steps described in the regulation and the ones explained by participants of this study. They integrate the rationales that study participants gave for how they act, interact, and decide with the structure that describes the circumstances in which these actions, interactions, and decisions occur, including the selection process itself. This integration is important because according to Strauss and Corbin (1998), in grounded theory the structure is usually unknown or ignored by the people who experience the process under study. They both believe that these active members of the process are usually more focused on learning how to produce and reproduce the process than on analyzing structural factors such as the regulation itself, the organization of their own institutions, the political agenda, cultural values, beliefs, or the historical context that surrounds the process in which they participate. As Corbin and Strauss suggest, if the researcher focuses only on understanding the process by analyzing the rationales that study participants give for how they act, then the conditions that form the structure, or the set of circumstances in which the problem under study is situated will be missed.

Despite the lack of familiarity with the structure that, according to Strauss and Corbin, is expected from the active members of the process, in my study, several of the study participants, who belonged to the group of “insiders” that are directly involved in the selection of this list, pointed out important aspects of the structure. These structural aspects emerged spontaneously in some cases and in others after I encouraged the study participants to elaborate more on the particular issues that they were discussing. Other aspects were hidden in their descriptions of the process and became evident after transcribing, codifying, categorizing, and comparing all the interviews many times. In addition to these structural factors, my study also includes broader structural, contextual, and historical factors that became evident during the three months that I was exposed not only to the environment and culture of each of the study participants and the different institutions that they represent, but also to the historical moment that the country lived through when the President of Mexico announced on February 9th, 2016, some changes in his cabinet. These changes included the replacement of the Health Minister and the change of the “Titular Representatives” of three of the eight institutions that participate in the selection process of the NEML: 1) IMSS, the institution that provides health care services to the formal private sector workers, retirees, and their dependents; 2) PEMEX, the institution that provides health care services to employees from the national oil industry; and 3) COFEPRIS, the Health Regulatory Agency. These changes consisted of the transfer of the Titular Representative of COFEPRIS to the IMSS, the transfer of the Titular of IMSS to PEMEX, and the dismissal of the Titular of PEMEX. The name of the person who covered the vacancy that was left in COFEPRIS was announced by the Mexican President several weeks later in an environment of much anxiety and expectation. Although these political changes are outside the scope of my research, I will briefly explain, in this introductory section, the context in which they took place, since this context will help the reader to understand the political environment that surrounds the selection process of the NEML that I am studying.

Even though the President of Mexico did not provide an explanation for any of these structural changes when he made his public announcement, the national press situated the change of the titular of PEMEX in a context of an international crisis in the price of oil (El Financiero, 2016). This change was also surrounded by some strong rumours in the country that the current administration had sold the public oil industry to foreign capital. As for the change of the Titular of the IMSS, this change was situated in a moment where the reform to the pension system that this institution provides to the sector of the population that it

insures was becoming a challenge for the government (Vanguardia, 2016). It is important to note that out of the eight institutions that participate in the selection of this list, the IMSS is considered the institution with the most economic and political power due to the fact that it does not only provide health services, but also the pension plans to more than half of the population who pay for both services through their employers. The transfer of the Titular of COFEPRIS to the IMSS was neither explained by the local press nor the Mexican government. Both sources focused only on explaining the responsibilities that the President of Mexico assigned to this Titular in his/her new position as the Titular of the IMSS. One of these responsibilities will be *“to maintain and speed up the simplification process of applications that are processed by this institution”* (Universal, 2016; Gobierno de Mexico, 2016). In an article published in English by “Salud Mexico”, Ibarra (2016) made reference to this change by saying that *“the Titular of COFEPRIS was praised by the healthcare industry after successfully improving and optimizing new drug approval times, implementing an efficacious pharmaceutical policy that supports innovation and generics, and gaining the recognition and certification of COFEPRIS as a National Regulatory Authority of Regional Reference of medicines and biological products”*. Due to the challenges that the IMSS faces with the pension system and health coverage of more than half of Mexicans, the healthcare industry, according to Ibarra, *“wants to see the Titular of COFEPRIS optimizing the policies and operations of IMSS”*.

As for the change of the health minister, this change was described by an anonymous Mexican researcher specialized in public health, who according to the press (El Pais, 2016) does not want to be identified, as a political change that brings a “very effective politician” on board. According to this researcher, prior to this change, there was a “tense dynamic” between the IMSS (that he describes as “a giant with a big budget”) and the Ministry of Health that should be the head of the public health sector. However, it is expected that this tension will end with this newly appointed health minister (El País, 2016). Since this new health minister is the former director of “Universidad Nacional Autónoma de Mexico”, the National University considered the largest one in Latin America with over 300,000 students currently enrolled, it is also expected that the new health minister can bridge the communication gap that the previous minister left between the academy and the public health sector (El País, 2016). During the time I was in Mexico, the General Health Council also announced on February 23, 2016, some reforms that were made to the regulation that standardizes the selection process of the NEML. Even though these reforms are also outside the scope of

my research, I will describe later in Section Two, a structural change that was brought up by the study participants in their interviews because this change had an impact on the structure of the medicines committee.

In addition to having witnessed these historical events, I also attended the two meetings that I mentioned in my previous chapter: 1) the “XI Meeting of Sanitary Regulation” and 2) the meeting organized by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the General Health Council. In these two meetings, I had the opportunity to observe some important interactions between the different institutional cultures and ideologies that participate in the selection process of this list, including the government and its different Public Health Institutions that have the legitimate power to regulate the selection process of the NEML, and the pharmaceutical industry that has the economic power to manufacture and commercialize the Essential Medicines that are included in this list. These interactions helped me to better understand the selection process described by the study participants during their interviews. In order to describe this process, I have organized this chapter into four sections. The first one provides a brief summary of the regulation with the intention of introducing the reader into the context in which, according to the Mexican government, the selection of the NEML is supposed to happen. This first section will also place the reader into the context that study participants, directly and indirectly, described as discrepant to what they do in practice. The second section includes the description that the study participants provided about the selection process of the NEML. The third section shows the influence that the system has on the resources that are part of this selection process. The fourth section will describe the transparency of the selection process, and the fifth and last section, the impact that the Mexican health care system has on ensuring equitable access to medicines for the entire Mexican population.

I. The Normative Process Described in the Regulation

According to the Mexican government, the regulation that standardizes the review and update process of the NEML was implemented by the “Comisión Interinstitucional del Cuadro Básico”, the commission in charge of selecting the NEML, on June 22, 2011. The purpose was to guarantee an efficient and transparent evidence-based assessment of the safety and efficacy of all the drug applications filed by pharmaceutical companies with the intent of being considered for the NEML (DOF, 2011). This regulation is organized into seven chapters that include: 1) “generalities” 2) “the organization and objective of the

commission”, 3) “the responsibilities of the commission”, 4) “the responsibilities of the members”, 5) “the procedures for the update of medicines”, 6) “the diffusion of the NEML”, and 7) “the procedure for the modification of the regulation”. In this first section, I will briefly describe the sections included in these seven chapters of the regulation that make reference to the objectives, the organizational structure, and the process that explains why, by whom, and how the Mexican NEML should be selected. By describing these sections and their articles, I will also reveal to the reader the ambiguity and disorganization with which this regulation has been written.

a) The Objectives Established in the Regulation

The commission in charge of selecting the NEML has clearly established four objectives in the regulation that standardizes the selection process: 1) the objective of the regulation itself, 2) the objective of the NEML, 3) the objective of the commission in charge of selecting the NEML, and 4) the objective of the “update process” of the list. The first two objectives are described in Chapter I, Articles 1 and 2 respectively. According to Article 1, *“the objective of the regulation is to regulate the way in which the NEML is elaborated, updated, and disseminated. This is done for the purpose of improving the quality, safety, and efficiency of the healthcare services provided by the public health institutions that are part of the National Health System. The regulation establishes the ethical principles and the deontological compromises of the commission which are intended to achieve transparent and efficient processes, based on scientific evidence that complements the activities and responsibilities of the Health General Council, with those of the Health Regulatory Agency and the Public Health Institutions to avoid duplications”*. For its part, according to Article 2, the objective of the NEML is *“to collaborate in the optimization of the public resources dedicated to treat the country’s health problems, through the use of medicines that have proven their safety and therapeutic efficiency and efficacy”*. As for the objective established for the commission in charge of selecting the NEML, Chapter II, Article 5 says: *“the commission has as an objective to elaborate, update, and propagate the NEML through a process grounded in criteria of transparency and efficiency, incorporating the evidence of scientific and technological advances in medicine to foster the quality and rational use of medicines in the public institutions that make up the National Healthcare System”*. The fourth objective described in the regulation is explained in Chapter VI, Article 26. According to this article, *“the update process of the NEML will have as an objective the optimization of the resources for the detection, prevention,*

and treatment of diseases that affect the population". This article also says that the list must be kept continually updated, based on advances in knowledge and technological developments.

Even though these four objectives make reference to important concepts such as transparency, safety, efficacy, efficiency, optimization of resources, and the country's health problems, the concept of "equity" shown in my introduction, as one of the most important components of the Essential Medicines concept proposed by the World Health Organization (WHO) to ensure equitable access to medicines in developing countries like Mexico, is not mentioned. Yet, this concept was an important element of the selection process that came to light during both my data collection and my data analysis phase and will be described in the last section of this chapter.

b) The Organizational Structure Established in the Regulation

Even though the Mexican government describes the organizational structure of the commission in charge of selecting the NEML in Chapter II of the regulation, the three articles that comprise this chapter do not clearly specify who really is involved in the selection process of this list, and what criteria are followed to select these people. According to Article 4, the government assigned the selection of the NEML to nine members that make up the commission in charge of selecting the NEML. These nine members include the president of the commission, who also acts as the secretary of the General Health Council, and the eight Titular Representatives who lead the eight public health institutions that make up the National Health System (IMSS, ISSSTE, PEMEX, SEDENA, SEMAR, SSA, SSDF and DIF), who are also part of the General Health Council along with many other members. Although Article 4 also mentions the presence of two more groups: 1) the substitutes for these nine members of the commission and 2) six permanent guest institutions that attend the plenary sessions of the commission, none of these actors are recognized as part of the commission that is in charge of selecting the NEML. These six permanent guests institutions include: 1) the National Commission for the Social Protection in Health, 2) the National Centre for Health Technology Excellence, 3) National Institutes of Health and High-Specialty Hospitals Commission, 4) the National Chamber of the Pharmaceutical Industry, 5) the National Chamber of the Transformation Industry, and 6) a citizen representative from the Council of Ethics and Transparency of the Mexican pharmaceutical industry. There are also two groups of actors who, despite the contribution that they make to the process, are not only not recognized as contributing to the selection of this list, but also not mentioned at all in Chapter II, but in

Chapter 3, Article 7, Section XI that describes the responsibilities of the commission. According to this section “*it is responsibility of the commission to establish the selection criteria for both the representatives that will make up the committees as well as the experts, who are referred to in this regulation, following ethical principles of confidentiality, no conflict of interests, and professional competency*”. The fact that the selection of the medicines committee and the experts is presented in the regulation as a “responsibility of the commission” and not as a “delegation of responsibility” from the commission in charge of selecting the list to the medicines committee, makes it difficult to understand, not only who participates in the process, but also who is accountable for what, and how the people who do participate are selected.

Although some of the information that describes these points is explained in other chapters, the ambiguity and the disorganized manner in which this information is presented does not allow one to fully understand the structure and the selection of members. For example, Chapter IV, Article 15, makes reference to the composition of the medicines committee and explains that it is made up of a technical secretary who acts as the leader of the committee, a coordinator who assist the technical secretary, and eight representatives from the public health institutions. However, this article does not specify the selection criteria that should be followed to choose any of these 10 members. In fact, none of the chapters of the regulation describe the selection criteria of the people involved in the selection process. Article 15 mentions that the eight members of the medicines committee who represent the public health institutions will be selected from among the candidates proposed by each of their institutions, but does not establish who will be in charge of proposing them and based on what qualifications. This article also mentions that experts and other guests can participate in the committee meetings upon request of the members of the committee. However, it does not specify how the committee members should go about requesting the participation of these experts. It also says that each member of the medicines committee is allowed to take an expert with them to the monthly committee meetings upon approval of the rest of the medicines committee members. Even though Article 15 does not mention anything about the selection criteria of these experts, their selection criteria are vaguely taken up again later in Chapter V that describes the procedures for updating this list. In this chapter, Article 37 states that the nine members of the commission will select experts, who have clinical experience or experience in health economics, from the eight public health institutions that make up the National Health Care System, as well as from the academic, social, and private sectors. Although this Article states that “*the selection of*

experts will be grounded in the following aspects: general data, work experience in the field that is being analyzed, and documents that prove the required experience”, it is not clear what dimensions are considered under “general data” (e.g., sex, age) or any of the other criteria, and if the general data has an influence on the selection of these experts. Unfortunately, the disorganized and ambiguous description of the organizational structure in the regulation does not allow for the full identification of what groups and interests are allowed to be part of the selection process and what groups are excluded. It also does not lend an understanding of how qualified these people are to participate in the selection of this important list and why only nine members are legitimately recognized as being in charge of selecting the NEML, despite the contribution that other actors make to the process. However, not only is the nature of the people who participate in this selection ambiguous and unclear in this regulation, but also, as it will be shown in the following section, the process.

c) The Update Process of the NEML Established in the Regulation

The process that must be followed not only to include Essential Medicines in the NEML, but also to exclude them, or modify the composition or presentation of any of the products already listed there, is described in the regulation as the “update process” of the list. This update process is explained in 31 Articles contained in Chapter V of the regulation. According to Article 26, the first of the 31 articles, the commission will approve the inclusions, modifications, and exclusions made as part of the update process of this list. According to Article 27, the applications to update this list can be submitted by the public health institutions, scientific organizations, the academy, “providers” (the term that refers to the industry), governmental institutions, the members of the commission, as well as the secretary and the president of the General Health Council. Article 28 establishes the requirement that the applicants should meet in their applications which include:

- 1) A current copy of the sanitary registration granted by the health regulatory agency.
- 2) Information that proves the safety and efficacy of the products that will be evaluated, when the sanitary registration is older than 1 year; if this registration was issued within a year, there is no need to include any information that proves the safety and efficacy of the product, since according to what Article 28 says, the health regulatory authority already reviewed the safety and efficacy in order to issue the registration number.

- 3) An evaluation of the product's safety profile performed by the National Centre of Pharmacovigilance that is part of the health regulatory agency.
- 4) A pharmacoeconomic study done based on the "Guía para la Conduccion de Estudios de Evaluación Económica" (Guideline for the Conduction of Economic Evaluation Studies) which was developed by the nine members of the commission.
- 5) The draft generic description of the medicine that is proposed for inclusion, according to the format that the commission published in the Official Gazette, along with clinical studies that support the therapeutic indication and any adverse events.
- 6) A letter that testifies under oath that the product does not infringe any patents or is the subject of litigation as well as that the information is reliable.

Articles 29, 30, and 31 describe the documents that will be submitted if the inclusion is a medical device, since this regulation also considers the products that are listed on the "Catalogo de Insumos", a separate list that includes medical devices and other healthcare products that are not considered medicines. This list is also selected by the commission, but with the assistance of other committees that specialize in those products.

Articles 32, 33, 34, and 35 describe the information required to request exclusions as well as how the approval of those exclusions are notified in writing to the applicant. According to these Articles, each application for exclusion must include the contact information of the people who are requesting it and a justification from a clinical, epidemiological, pharmacological, economical and/or technological point of view that considers:

- 1) Any communications issued by the National Center of Pharmacovigilance.
- 2) The existence and availability of another product with the same indication, but greater proven efficacy and lower risk.
- 3) Proven high quality in manufacturing operations or in the manufacturing materials.
- 4) The existence and availability of another product with the same therapeutic indication that demonstrates cost minimization and better cost-effectiveness, cost-utility, or cost-benefit.
- 5) Proven evidence of obsolescence or lack of effectiveness.
- 6) Shortages due to the lack of production, incapacity to meet the demand, or not being interested in participating in national supply programs.

According to Article 36, the commission will receive these applications on the first five working days of each of these three periods: January to April, May to August, and September to December. This article also mentions that after these applications are received, the Technical Secretary of the medicines committee will have 15 working days to perform the initial evaluation to decide if the application meets the basic requirements established in the regulation. If the applicant does not hear from anybody in 15 working days, he/she can assume that the application has been accepted. However, the regulation in this chapter or in any other one does not specify how these initial evaluations are conducted or by whom.

Article 37, which was already mentioned in my previous section, shows how disorganized the regulation is, since it describes the selection of experts under this chapter that explains the update process and not under Chapter II that describes the organizational structure, where it would be most likely that the reader would expect to find this information. The update process continues being described in Article 38. This article says that the applications that have been accepted by the Council will be analyzed by a group of experts, according to the steps described in the “Guía de Evaluación de Insumos para la Salud” (Guide for the Evaluation of Health Products), a second guide also produced by the nine members of the commission. According to Article 38, these experts will prepare an evaluation report of the medicines that are being analyzed by the commission which will be sent to the members of the medicines committee to help them in the decision-making process. Even though Article 39 mentions that the members of the medicines committee will analyze the applications within 90 days, this article does not provide any information about how this analysis will take place, nor make reference to any guide that the medicines committee should follow. Article 40 states that the medicines committee will arrive at, through a consensus process, the decision in a unanimous way, considering the evaluation that the experts provides it with. According to this article when no consensus is reached, the decision will be based on the concurring opinions of at least half plus one of the institutional representatives. In cases when there is a tie, the technical secretary will have the deciding vote.

According to Article 42 when an application is not approved, the reasons will be provided to the applicant in writing, so the applicant can submit a new application once he/she has resolved the deficiencies identified in the first review. In case the application is rejected a second time, the applicant will have to wait a year to re-apply. However, it is not clear if the two rejections take into consideration the first review or not. According to Article 43 the applicant will also receive a notification in writing when the application is

approved. Articles 44, 45, and 46 refer to medical devices and other products that are listed in the “Catalogo de Insumos”, the other list mentioned before. According to Article 47, the medicines that have been included, excluded, or modified are listed for 10 days on the Council’s website for public consultation, so “whoever is interested” can give their opinion. Article 48 explains that it will take the medicines committee 15 days to approve the unique identification code called “clave”, the number that is assigned to each of the products that are included in the NEML. According to Article 49, the commission will make public all the inclusions, exclusions and modifications in the Official Gazette. Article 50 establishes some very interesting points. This article says, *“All the inclusions, exclusions, and modifications made to the NEML express the decisions taken by the public health institutions that make up the commission. For this reason, it is not justified for these institutions to request information twice to determine the quality, efficiency, safety, and economic implications of the medicines”*. Since this article does not specify from whom this information should be requested, the reader cannot understand why the request of this information is considered an “unjustifiable petition for duplicate information” that should be avoided by the public health institutions that conduct the technical evaluations. Article 50 also mentions that the public health institutions that participate in the selection process of the NEML will be able to generate different Institutional Essential Medicines Lists, based on the NEML that they help to select, with the condition that the content of these institutional lists does not exceed the one in the NEML. Each public health institution will have the right to decide what medicines it buys from the ones that are listed in the NEML, *“according to their institutional policies, their impact, and financial availability”*. This Article also says that *“the fact that a medicine is included in the NEML or in the Catalog does not force the health institutions, in any way, to buy those products”*. Article 50, and in particular this last statement, invalidates the effort that the regulation makes to standardize the selection of the Essential Medicines that are included in this list. Article 51, the last of the 31 Articles of this chapter that describe the update process, guarantees that the approved inclusions, exclusions, and modifications will become effective the day after they are published in the Gazette. It is important to note that Chapter V also includes Articles 52, 53, 54, 55 and 56 that describe the transparency and accountability of the selection process. However, the description of these five articles will be part of Section IV of this chapter, the section that explains how the study participants described the transparency of the selection process. There are a few more articles from the regulation that will be cited in the section below that explains how the study participants described the

selection process of the NEML. However, the three chapters of the regulation described in this section explain the most important aspects of the process established by the Mexican government in the regulatory framework that standardizes the selection process of its NEML.

In contrast to describing this norm as a “standardizing tool”, the regulation was described during the interviews by PG-6 as *“a tool that originally was developed to break with the pressure of the pharmaceutical industry”*. While describing it, this participant also said, *“When the regulation was implemented, it established thresholds that determine which medicines could be included in the list and which could not. However, a moment arrived in which the regulation started to become obsolete because the industry found loopholes in it and started to look for the less strict side of the commission. This less strict side of the commission sometimes tells the industry: it is not cost-effective, but do not worry, we are going to analyze something else. Unfortunately these shortcuts are not formally written anywhere”*. In addition to PG-6, the other participants, although not as explicitly and directly as him/her, also made reference to this less strict aspect of the regulation that allows for “shortcuts”, by describing many discrepancies between what the regulation says and what they do in practice. The description of how the selection process of this list is actually carried out, according to the study participants, will be explained in the following subsection.

II. The Descriptive Process According to the Realities of Study Participants

a) Who Starts the Selection Process of the Mexican NEML

Article 7 subsection II states that *“it is the responsibility of the commission to periodically review the NEML with the purpose of updating the list”*, and subsection III that it is also the responsibility of this commission to *“receive, study, and rule that the applications are submitted according to what is established in this regulation”*. However, according to the study participants, since the pharmaceutical industry takes the initiative to voluntarily submit applications for the inclusion of its products in the NEML, the government does not see the need for a periodic review to update the list. MedCom-5 defined the update process of the NEML as *“a process that is triggered by all the applications that the industry voluntarily submits to the General Health Council, and not by a periodic review through which the commission identifies the health needs of the population”*. This participant said, *“In order for the medicines committee to have a reason to meet, there has to be an application submitted by the industry to the General Health Council that needs to be evaluated”*. Although the regulation states in Article 27 that the public health institutions, scientific

organizations, the academy, “providers”, governmental institutions, the members of the commission, as well as the secretary and the president of the General Health Council can submit an application to update the NEML, according to ExCom-A, 98% of the applications come from the pharmaceutical industry and only 2% from public health institutions.

This strong presence that the industry has during the stage where applications for inclusions, exclusions, and modifications are submitted is better understood with the description that T-8 gave of the application process. When T-8 described the submission process, this participant said, *“Anybody can submit an application, but all the applicants need to provide clinical studies and a pharmacoeconomic evaluation, as the industry does. The process is the same for everybody; there are no exceptions, all the applicants are considered equal”*. Although it is difficult to understand where the “equality” that this participant refers to resides, especially from the standpoint of civil society that does not have the same economic and information resources or the same health interests that the pharmaceutical industry does, his/her idea about fairness and equality in the submission process was also supported by another participant, ExMedCom-A. Initially ExMedCom-A said: *“the regulation does not prevent anybody from submitting an application for the inclusion, or exclusion of any medicine. I as a citizen, academic, industry, or governmental institution can submit an application to request that a medicine is included in the NEML. It could be a disadvantage that civil society does not have a place at the decision-making table, but they are allowed to submit an application”*. However, after I asked this participant about the disadvantages that the population faces by not having enough power to have a seat at the decision-table, this participant realized that there was a contradiction in the regulation and said *“you are right, the regulation mentions in Article 27 that everybody can apply, but when you see the requirements in Article 28, they are so specific that only the pharmaceutical industry will have access to the information that is necessary to submit an application”*. There was one more participant, PG-6 who was already aware of the contradiction that exists between Articles 27 and 28 of the regulation. This participant said, *“It does not matter that the regulation says that anybody can submit an application to the General Health Council to include, modify, or exclude a medicine from the NEML because, in practice, nobody has the resources to do it, but the pharmaceutical industry, If my institution wanted to submit an application to the General Health Council to include a medicine in the list, my institution would have to get in touch with the pharmaceutical company to be able to access the information needed to*

complete the application because we would not even have the most basic information to complete all the forms, such as the registration number that proves that the drug has been authorized for sale in Mexico, not to mention the clinical trials information. In order for an institution to be able to submit an application, the pharmaceutical company would have to agree to share its information with this institution. It is not easy to establish a relationship with the industry, especially if you want to exclude any of its products”.

According to the study participants, since the industry owns all the information needed to support the application, it does not matter that the regulation says that the public health institutions can submit an application, because when these institutions want a medicine to be included in the list, the public health institutions have to contact the industry and ask it to submit the application package for inclusion of that particular medicine. For example, T-4's substitute narrated that once, after his/her institution received some requests from physicians who wanted lactulose, a generic medicine used for patients with cirrhosis, to be included in the NEML, the institution looked for the company that manufactured this medicine and asked it to submit an application to the General Health Council to include lactulose in the NEML. MedCom-4 and T-8 mentioned an incident in which the institution that MedCom4 represents was sued by some of its patients who wanted ecolisumab to be prescribed by the doctors of this institution. However, according to these two participants, this medicine could not be prescribed in any public health institution because the doctors from public health institutions can only prescribe what is listed in the NEML and the manufacturer of ecolisumab never applied to have this medicine listed there. T-8 said that *“as a result of this lawsuit, the judge ordered the institution that MedCom-4 represents to submit an application to request the General Health Council to include ecolisumab in the NEML”*. However, even though previously this participant had said that *“anybody could submit an application to include a medicine in the NEML, including the population and the public health institutions”*, after describing this particular incident, T-8 said, *“It is not the public health institution, but the laboratory that manufactures it that should be the one that requests the inclusion in the NEML”*. According to MedCom-5 *“the manufacturing companies cannot be forced to submit an application for inclusion of a medicine that a patient or an institution needs. Sometimes they want to do it, but sometimes they are not interested”*. MedCom-8 said that *“medicines like ibuprofen and paracetamol for children were not on the list because their inclusion does not represent a large profit for the pharmaceutical industry, so the industry was not interested in applying for their inclusion”*. According to MedCom-7 *“ibuprofen was added*

to the list last year, after its inclusion was requested by one of the study participants whose institution provides healthcare for the uninsured” who, as it will be shown later, do not have a seat at the decision-making table where medicines are selected.

When MedCom-4 described how the selection of medicines starts, he/she said, *“The selection process of the NEML is very political. It is time to stop considering other interests and start paying attention to the real interests of the country. The regulation says that the Council will receive applications for the NEML, but how many applications and for what type of products? Well, whatever it is that the industry wants to submit”*. It is important to note that even though the regulation says that the applications will be received during the first five working days of each quarter (i.e., January to April; May to August; September to December), in practice, there is no deadline for submitting an application. According to the medicines committee members who participated in my study, the industry keeps constantly sending applications to include its products in the list, regardless of whether those products are “Essential” or not for the Mexican population. According to PG-6, *“up to 60% or 70% of the applications that have been reviewed from the industry since 2015, are new medicines, innovations that do not offer any therapeutic advantage”*. T-4’s substitute believes that the NEML includes not only doubtful innovations, but also many “me too” drugs. Me too drugs are considered products that largely duplicate the action of existing drugs (Hollis, 2004). For MedCom-4, *“the NEML should not list innovations. This list should be a tool where only medicines that can be afforded by the public health institutions are listed”*. MedCom-5 thinks that *“it is the system that allows not only the existence of 70% of ineffective medicines in the market, but also the presence of many medicines that should not be listed in the NEML”*. As mentioned in my introduction, according to the WHO (2015), Essential Medicines are defined as those that satisfy the priority health care needs of the population. Based on this definition, not all medicines can be categorized as “Essential”. As it will be shown in Subsection C, the fact that the selection process of the NEML does not start with the periodic review specified in the regulation that should identify the needs of the Mexican population, but as a response to the large volume of applications voluntarily submitted by the pharmaceutical industry, does not allow the government to clearly distinguish “Essential Medicines” from “Non-Essential” ones. However, before describing how the Essential Medicines are selected, I will explain, in the following subsection, who participates in the selection of these Medicines and how these people are selected, according to the study participants.

b) Who Participates in the Selection Process of the Mexican NEML?

Although Article 26 of the regulation legitimately recognizes the nine members of the commission as the people in charge of approving the applications for inclusions, exclusions, and modifications that the industry voluntarily submits to the General Health Council, according to the study participants, these nine members are not really involved in the selection process of the NEML. ExMedCom-A, described these nine members of the commission as *“politicians who do not know anything about the selection of the medicines that are included in the list”*. This participant said that the commission members only meet twice a year in the plenary sessions to discuss with the industry and the permanent guest institutions controversial issues that cannot be debated at the medicines committee level. According to him/her, *“it is the medicines committee that is not only in charge of the selection of the NEML, but also of keeping the nine Titular members of the commission updated about the selection process of the list through periodic reports”*. These reports allow these nine members of the commission to go to the plenary sessions well-informed, and aware of any problems that surround the selection of the specific medicines that will be discussed in those sessions. An example of how committee members update their respective institutional Titular member was shared by MedCom-1. This participant said: *“I say to my Titular representative that this decision was made because of this, this, and that. I have to keep the Titular informed. I can even accompany my Titular to the plenary sessions and stay behind him/her; sometimes we have to be there. The Titular most of the time approves everything, but if at any moment the Titular says no, that means no”*. According to this participant, there are some occasions when the plenary sessions are exclusively for the nine members of the commission and nobody else can attend, not even their substitutes who sometimes attend these meetings. This participant said *“when these meetings have restricted access it is because the commission is discussing critical issues and taking important decisions. The people who participate in these controversial meetings are the members of the commission, who are our bosses and directors”*. When MedCom-3 described the plenary sessions, he/she said, *“In the plenary sessions the Titular members decide if our opinion as the medicines committee is valid or if they need to change it. Some of the issues that are discussed in these meetings are complaints expressed by the pharmaceutical industry, especially in regard to their products that the medicines committee does not approve for the NEML, so the industry is present in these meetings”*. There was one participant, MedCom-5, who described the nine members of the commission as *“independent actors who meet to evaluate what the*

medicines committee does. They are practically only the façade that frames the selection process of this list”.

However, for this participant, *“regardless of the level of intervention of the nine members of the commission in the actual selection process, these nine members are responsible for the teams that support them in this selection process, including the members of the medicines committee”.*

It is important to mention that although the members of the medicines committee hold an administrative position in the public health institutions that they represent, they are at a management level where the discrepancy in power between them and their Titular Representatives, who are in charge of selecting the NEML, is very marked and perceptible. The discrepancy in power that exists between these “Titular Representatives” and the general population that, as it will be shown at the end of this subsection, is not invited to participate in this process, is even more perceptible. In one of the interviews, after I turned off the tape recorder, one of the study participants said that, *“he/she does not have contact with his/her Titular very often because his/her immediate superior acts as the bridge between him/her and the Titular Representative of his/her institution”.* The fact that the members of the committee cannot easily approach the “Titular Representatives” of their institutions, to discuss any concerns or disagreements, makes it difficult for any type of questioning, challenging, or confrontation to occur between the less and the most powerful public servants that are part of the selection process of the NEML. In fact, when I tried to approach T-8 for the first time, MedCom-8 who is under his/her supervision, told me that it was going to be impossible to meet with T-8. The same comment was made by MedCom-1, MedCom-3, MedCom-5, and MedCom-7, and Academic-1, when I mentioned that I wanted to interview the “Titular Representatives” who represent the public health institutions. Although, as mentioned in my methodology, in the end, I was able to recruit T-8, with the exception of T-4’s substitute, I could not interview the rest of these “Titular Representatives” who are part of the Commission in charge of selecting this list. However, as will be shown in the rest of this chapter, the fact that the authority of the people in power is accepted does not stop the less-powerful from noticing and sharing the irregularities and contradictions in the process that is discussed in this paper.

Considering that, according to the study participants, it is the medicines committee that actually performs the selection of Essential Medicines and not the Commission, the descriptions from the medicines committee members who participated in my study were crucial, since they were able to explain parts of the process that the regulation does not make clear such as who and how many people participate in this process.

According to these participants, prior to the reform that I described earlier, the medicines committee was made up of eight members who represent the same public health institutions as eight of the nine Titular Representatives that are part of the commission. In addition to these eight members, there were four more, including the technical secretary and the coordinator that the regulation mentions in Article 15, and two advisors, who although not described in the regulation, attend the medicines committee monthly meetings as support for the technical secretary and the coordinator. There is also one more member, PG-6 whose participation in the medicines committee meetings is also not described in the regulation. However, during the interviews, the study participants mentioned that the recent reform made to the regulation had changed the composition of this committee. Even though they described how this committee was constituted before and after the reform, in order to understand the impact of this change I will describe its new structure in a separate section.

T-4's substitute and MedCom-4 described the composition of the medicines committee before the reform as "hybrid" because its members represent two types of institutions: 1) institutions that only provide treatment such as the one that MedCom-6 and the regional institutions located in each state of Mexico represent, and 2) institutions that not only provide treatment, but are also payers for their medicines such as the institutions that MedCom-2, MedCom-3, MedCom-4, MedCom-5, MedCom-7 and MedCom-12 represent. However, there is also one institution, the one represented by MedCom-1 that does not provide treatment or finance any medicines. When PG-6 referred to the hybrid nature of the committee, this participant said:

"since the objective of the commission is to generate the NEML, and the NEML has the purpose of narrowing the range of the medicines that are going to be purchased with public funds, the institutions who participate in the medicines committee meetings in theory are the payers. However, in practice, it is a bit strange that the institution that provides healthcare services for the uninsured is not included in the discussion of the NEML".

PG-6 believes that the uninsured should be present at the decision-making table during the monthly meetings of the medicines committee, with a voice and vote, because they, like the other hybrids, also buy medicines. According to this participant, the two seats that the Ministry of Health has, both in the Commission and the medicines committee, can be assigned to either the Health Regulatory Agency, the institution that represents the uninsured, or the institution that PG-6 represents because these three institutions are considered decentralized bodies of the Ministry of Health that have technical, administrative and operational autonomy.

However, from these three institutions the one that officially represents the Ministry of Health both in the Commission and the medicines committee, is the Health Regulatory Agency, that does not provide treatment or finance medicines, and not the institution that represents the uninsured or the institution that PG-6 represents. Although the uninsured have representation through the Titular of the “Comisión Nacional de Protección Social en Salud” (The National Commission for the Social Protection in Health) in the plenary sessions of the Commission, this institution is not invited to participate either in the Commission or the medicines committee. Even though PG-6 is the only permanent guest whose institution, in addition to attending the plenary sessions of the Commission, has also been attending the monthly meetings of the medicines committee for over three years, his/her participation in these monthly meetings is limited, since his/her institution is only allowed to have a voice, but not vote at the decision-making table. The fact that the participation of PG-6 in these monthly meetings is not legitimately recognized in the regulation, limits his/her voice. From the twelve members who attend the monthly medicines committee meetings, only the eight members who represent the public health institutions have a voice and vote, the rest like PG-6 cannot vote. The vote that these eight members of the committee cast determines which Essential Medicines are included in the NEML.

It is important to mention that when the institution that PG-6 represents started to participate in the monthly meetings of the medicines committee, it was able to vote at the decision-making table. However, the right to vote of this institution was withdrawn, and currently, PG-6 is a passive participant who can be heard, but is not allowed to cast a vote and make decisions. I asked PG-6 the reason for attending these meetings if he/she cannot vote and he/she said *“the reason we attend these meetings is to inform. We summarize the clinical and economic evidence and try to present it in the best possible way in a monthly report. This means in a clear, concise and understandable way, to all the members of the committee. This evidence is commented on during the monthly meetings with the medicines committee. Therefore, what our institution does is to provide technical information to support the decision-making process”*. PG-6 also explained that when he/she used to have a vote, his/her votes did not always coincide with those of the other members of the medicines committee. He/she realized that each of the public health institutions had their own needs according to the population that they serve and that their votes were influenced by those needs. PG-6 said *“this does not mean that we are wrong, but that there are different needs, so now we only give an impartial report which means*

that we are not in favour or against anything". When I interviewed MedCom-8, this participant made reference to PG-6's participation in the medicines committee meetings. MedCom-8, said *"PG-6 wants to give recommendations as NICE does in the UK, but he/she does not understand the problem that surrounds the presence or absence of a medication in the list"*.

As for the participation of the public in this process, Article 4 of the regulation makes reference twice to the presence of the public in the selection process of this list. Once when it mentions that the nine members of the commission will listen to the opinion of the public and private sector, and a second time when it lists a "Citizen Representative of the Ethical Council and Transparency of the Pharmaceutical Industry", among the six Permanent Guests who attend the plenary sessions of the commission. However, the day when I got in contact with the permanent guest institution that is behind this citizen representative, I learned that, in practice, the public does not have representation in the selection process of the NEML. The person who attends the plenary sessions, as the "Citizen Representative" mentioned in the regulation is the director of an organization created by the pharmaceutical industry to self-regulate itself. The director of this self-regulatory body described his/her organization as, *"an institution that was created by the pharmaceutical industry to strengthen its development as a socially responsible, integral, and transparent industry"*. According to him/her, *"this self-regulatory body verifies that the industry is in compliance with its codes of ethics and other self-control instruments that were designed by his/her institution"*. When I asked the director of this organization who the person who attended the plenary sessions on behalf of his/her organization was, he/she said, *"I have not been asked to attend the plenary sessions of the commission since November 2015, the year when I became the director of this organization. Although the previous director used to attend, we do not have the minutes of these meetings in our files to share them with you"*. He also said, *"Since we have not been invited to attend these plenary sessions yet, I have not selected the citizen representative who will attend. However, it is most likely that it will be me who attends these meetings as the Citizen Representative when we are invited to participate"*. Despite the agreeable disposition of the director of this institution to attend these plenary sessions, it is difficult to see the connection between a citizen representative and a director of an organization who receives a salary from the pharmaceutical industry. This case shows how the public is represented only in theory in the regulation as a way to legitimize the selection process of the NEML as

“inclusive and representative”, but in practice, as it will be shown in the following section, the public has no voice and even less vote in the selection process of this list.

MedCom-4 and MedCom-7 mentioned that the opinion of the general public is not taken into consideration in the selection process of the NEML, nor in the selection of their own institutional Essential Medicines list. According to ExCom-A, *“The decisions are not unilateral because the General Council develops monthly reports for the industry about the update process of the list and keeps them informed throughout the decision-making process”*. PG-4, explained that when his/her institution reviewed its institutional EM list they invited the State Health Systems, the National Institutes, sub-specialty Regional Hospitals, Federal Hospitals, and the pharmaceutical industry. He said, *“I think that the bias was removed from the selection process of our list because after allowing both the pharmaceutical industry and the healthcare providers to participate in the process, the only thing that was not acceptable was that the director of our institution unilaterally decided what enters and what did not enter the list”*. According to their descriptions of the process, study participants can see the importance of including the industry in it, but they cannot see the need for the presence of the public. Contrary to what ExMedCom-A just mentioned above, decisions can still be considered unilateral when the population, including not only the uninsured, but also the insured who pay through their employers for their healthcare services, are not part of the discussion. There was one of the participants, MedCom-1, who self-reflects about the participation of the public when I asked about it during the interview. This participant said, *“You are right, the regulation specifies how many copies of the applications should be submitted and what information should be submitted by the pharmaceutical companies, but does not specify how the committee is going to know about the needs of the patients. We usually know about these needs through MedCom-4 and MedCom-12, since these institutions provide health care services for more than half of the country”*. PG-6 also made reference to the participation of the public in the selection of this list and said, *“Even though the medicines that are approved for inclusion on the NEML are published for public consultation, the only one who comments on this list is the manufacturer and perhaps its competitors because the General Public is not aware of these public consultations”*. This participant made reference to how the selection of the NEML is carried out in other countries saying *“In Brazil, during the public consultations, the academy, patients, and the general population give an opinion and those opinions are really taken into consideration. The selection process, there, is more transparent, but, here, we only take*

into consideration what is discussed in the medicines committee meeting. There is not an exchange of ideas with other people”. Before fully describing how the selection of the NEML is done in Mexico, according to the participants of this study, I would like to describe first, how the people who participate in this selection process are chosen, since their selection is as important as the selection of the medicines that are included, or perhaps even more.

c) How the People Who Select the NEML are Chosen

The fact that the government of Mexico does not establish in its regulation the selection criteria that it follows in choosing the nine members of the commission, the members of the committee, and the experts who participate in the selection of its NEML, means that it is not known what knowledge, skills, and expertise these members bring with them to the decision-making table where final decisions are taken. All that is available about the profile of the nine members of the commission are the credentials that are listed alongside their names in the introductory pages of the 2014 version of the NEML. According to this list, six of the nine members are physicians who hold a directorship or sub-directorship position in the public health institution that they represent. The other three are a military general, a rear admiral, and a lawyer with two master's degrees, one in law, and the other in public policy. Based on these credentials the nine members of the commission have the political, economic, military, and institutional power to be part of the selection process, but not the appropriate knowledge, skills, and experience to lead an appropriate selection of medicines. According to MedCom-5, “in the federal agencies, people do not deal with names but with designations”. In fact, the designation of “Titular” comes from the Latin “Title”, which along with what MedCom-5 just explained could suggest that it does not matter what qualifications the “Titular Representatives” have because they hold the “Title” granted by the President of Mexico that gives them the power to be in charge of the selection of this list. It is the “Title” and not their knowledge and capacity that makes them eligible for being in charge of selecting the Essential Medicines for this list. The fact that the people in charge of selecting this list are chosen based on their political power and not based on the skills, education, and experience that they have to be able to contribute to a good selection of medicines makes the selection process of this list very political. This political selection of the people involved in this process which extends to the members of the medicines committee and other bureaucrats became evident in the tense environment that existed in the eight public health institutions, the Regulatory Health Agency, the General Health Council, and the Health

Secretary that I visited after the change in Health Minister and the three Titular Representatives mentioned at the beginning of this chapter. This tension existed because, according to some of the study participants and other employees of these institutions, any of “the other bosses” could be replaced at any moment too and those replacements might have an impact on the positions of more people including themselves.

Although the regulation in its Article 7 says that “*the selection of the members of the medicines committee is based on ethical principles, confidentiality, conflict of interest, and professional competence*”, the study participants described the selection of these members as something far from what the regulation says. According to MedCom-7 each member of the medicines committee is selected, not according to their knowledge and expertise, but based on “compadrazgo”, a term in Spanish used to express a buddy-buddy relationship, camaraderie, and godfatherhood. This participant said, “*this way of choosing people for a job position in this country, based on ‘compadrazgo’ is something characteristic of the Mexican culture*”. During the interviews, two of the study participants made an allusion to the way they became a member of the medicines committee. One of them was MedCom-8 who mentioned that after working for two years for the institution that he/she currently represents, three years ago was invited by his/her current boss to occupy his/her current position that allows him/her to participate in the selection process of the NEML. The other participant who mentioned how he/she became a member of the medicines committee is MedCom-3. This participant said: “*it is the Titular of each institution who chooses the member of the medicines committee or sometimes the selection is done in conjunction with somebody else. Everything is an organogram; some are on the top and some on the bottom. In my case, I belonged to the department of acquisitions and new technologies in my institution, and was recommended for the medicines committee by the Titular of my institution who said, you guys are the technicians, you should go*”.

However, in practice, not only the selection of the medicines committee members, but also the selection of the experts is in contradiction to what the regulation says. Even though Articles 7 and 37 grant the commission the authority to choose experts from the academic, social, and private sector as well as from the public health institutions that make up the National Health Care System, PG-6 said, “*The few experts that participate in the committee meetings are physicians who work in the public health institutions and who have many years of clinical experience, but not from the academy or national research centres*”. PG-6, also mentioned that it is very rare to see experts during the medicines committee meetings and when an expert is

invited, it is usually to discuss some clinical aspects of the drug that the medicines committee is analyzing. This participant said, *“For example, now that we are analyzing antiviral drugs for hepatitis, the General Health Council invited a national expert to participate in the medicines committee meeting, but this is very rare. Each medicines committee member discusses the dossiers that they review with their own institutional experts who are usually physicians”*. MedCom-1 mentioned that on rare occasions when consensus cannot be reached among the members of the committee, T-8 attends the medicines committee meetings to help to solve any problems or controversies. However, according to this participant, there are times when T-8 goes alone to the few controversial meetings, and other times in which he/she takes a renowned national or even international expert with him/her. According to the regulation, the experts who provide evidence and support to the medicines committee should be chosen by the members of the medicines committee upon the approval of the other members. However, from the seven medicines committee members who participated in this study, only one claimed to have invited experts to the committee meetings. This participant is MedCom-7 who said, *“Although the regulation allows the eight members of the committee to invite experts to their monthly meetings, upon the approval of the other members, only my institution has invited experts to these meetings”*. The political selection of the nine members of the commission, the medicines committee members, and the few experts that participate in the selection process of this list does not only suggest a high degree of nepotism, imposition, and backscratching, but also a weak selection process.

Although the regulation does not include either the qualifications of the nine members of the commission and the medicines committee members, it does establish the qualifications for experts in Article 37. According to this Article, the experts who participate in the selection process of the NEML, providing advice to the members of the medicines committee, should have clinical expertise and also experience in health economics or pharmacoeconomics to be able to provide support for the clinical and pharmacoeconomic evaluations that are part of the selection process that will be explained in the following subsection. During the interviews, several study participants mentioned that Mexico does have experts with a strong clinical and pharmacological background, although they are not necessarily involved in the selection process of the NEML, but not real experts in health economics or pharmacoeconomics. Some of the participants recognized that their institutions do not have any staff members with a background in pharmacoeconomics who can conduct the pharmacoeconomic evaluations that the General Health Council has established as a requirement

to prove the cost-effectiveness of medicines that are being considered for inclusion in the NEML. For example, MedCom-4 said, *“In our institution, we have honorary advisers with clinical experience, but not with experience in pharmacoeconomics”*. PG-6 and Ex-Com-A also confirmed this lack of expertise. ExCom-A said, *“Although, you can find some people with masters or courses in health economics whose average experience in economic evaluation is approximately four years, the education in health economics in Mexico is not what we would desire. The majority of the public health institutions in Mexico do not have people trained in health economics which is an important limitation for the selection process”*. This lack of training suggests that even though the members of the commission, the experts, and the members of the medicines committee, who represent these public health institutions, might have some other relevant training, they lack the expertise that is needed to perform or understand the pharmacoeconomic evaluations that are a crucial component of the decision-making process. Academic-2 also brought up the lack of expertise in pharmacoeconomics. This participant said, *“The Mexican government has a procedure that describes that currently the medicines that are included in the NEML are selected based on pharmacoeconomic studies. However, 90% of the people who review these pharmacoeconomic studies are physicians who have not had any education whatsoever in pharmacoeconomics”*. Academic-1 confirmed this lack of knowledge and said that almost all the people who conduct pharmacoeconomic studies are either economists or physicians who do not have a background in pharmacology. This participant said, *“I cannot explain to myself how the commission in charge of electing the NEML is conducting the pharmacoeconomic evaluations, if the country does not have professionals who can truly conduct this type of evaluation. Somebody from the committee might have gone to the UK to get some training and come back with some ideas that he/she is using to perform the evaluations, but it does not mean that they are experts in pharmacoeconomics”*. As Academic-2 said *“one thing is that you feel that you are an expert and another one, completely different, is that you really are an expert because of the information that you can share with others”*.

MedCom-8 confirmed that there are not many experts in pharmacoeconomics in Mexico. He/she said that the country started offering some courses in pharmacoeconomics approximately 10 years ago. However, according to Academic-2, these courses are usually sponsored by pharmaceutical companies that invite the government members involved in the selection process to see how their own staff conducts their pharmacoeconomic studies. For MedCom-1 *“some members of the medicines committee have been trained in*

pharmacoeconomics through online courses, but also by attending courses outside of the country". In fact, MedCom-8 mentioned that his/her boss, MedCom-9, is one of the pioneers in pharmacoeconomics in the country because he/she did her master's in pharmacoeconomics 15 years ago outside of Mexico. According to this participant, all the experts in pharmacoeconomics that Mexico has are in their 40s. Considering that MedCom-9 is one of the pioneers in pharmacoeconomics in Mexico, there was important information that this participant could have shared about the country's expertise in conducting pharmacoeconomic evaluations during his/her interview, if this participant had not stopped the interview after talking with me for less than 20 minutes. Unfortunately, he/she started the interview by asking me to go and read the regulation first because according to him/her, the selection process that I was studying was described there. After I replied saying "*I had already read it, but I am not interested in studying the normative process, but the descriptive one that includes the different versions of the people who live the process*", this participant said, "*there are not different versions, but only one and that is in the regulation*". It was very unfortunate that MedCom-9 ended up asking me, not in a friendly way, to come back when he/she did not have his/her current position anymore, so we could have a coffee and chat about what I wanted to know about the process. Considering the position that he/she holds in the selection process, it would have been very interesting to be able to know and understand not only how the medicines committee members conduct the pharmacoeconomic studies, but also the challenges that this participant faces in his/her current role that makes him/her unwilling to share the selection process. It is important to mention that although MedCom-9 is a member of the medicines committee, who does not have the legitimate power that the Titular members of the commission do, he/she has political power as one of the leaders of the selection process. He/she is one of the few members of the medicines committee who works full-time exclusively on the selection process of the NEML. As will be shown later in Section III in the subsection that describes the jobs and benefits of some of the people involved in the selection of this list, the rest of the members of the medicines committee have to combine the work that they do for the Council with the responsibilities that each of them has in their own institution. Combining two jobs does not allow these members to really focus on a good selection of medicines or on working on the training they need to be able to perform the clinical and the pharmacoeconomic evaluations.

However, the lack of training and expertise in pharmacoeconomics does not only relate to the government officials involved in the selection process of the NEML, it also applies to the professionals in the

industry who are in charge of putting together the pharmacoeconomic studies that the government reviews. According to MedCom-8, the majority of the applications submitted by the industry cannot even pass the initial pharmacoeconomic evaluation because their pharmacoeconomic studies do not meet the basic criteria that the government specifies in the regulation. When I attended the meeting that was organized by the ISPOR, I observed the presence of many national consultants who, according to MedCom-8, are the ones who perform the pharmacoeconomic studies for the industry. It is a bit strange that even though the companies have access to experts in other international locations who could train their own employees in Mexico, they prefer to hire national consultants who do not have the command of the principles of pharmacoeconomics to perform their pharmacoeconomic studies. During this meeting, the General Health Council gave some statistics about the number of applications that do not pass the initial review. According to these statistics, 25% of the applications are rejected because the pharmacoeconomic evaluations are incomplete. According to the Council, the main problem with these pharmacoeconomic studies is that the electronic files are submitted in programs that the technical reviewers cannot open because the government does not have the same computer programs that the industry has, although according to MedCom-9 *“the reviewers do know how to use these programs”*. In fact, this participant described the medicines committee as *“a competent multidisciplinary team of physicians, economists, and biomedical scientists”*. A good selection of medicines will highly depend on the recognition of the existence or nonexistence of the necessary knowledge to carry out the activities involved in the selection process, as well as of the technical limitations such as the necessary software to perform the pharmacoeconomic evaluations. If these limitations are not recognized by the people with the power to improve and transform the process, the actors involved in the selection of this list who represent both the state and the pharmaceutical industry will keep pretending that they are doing their work with efficiency and transparency. On one side, the pharmaceutical industry will continue submitting poorly-done pharmacoeconomic studies just to comply with the requirements specified in the regulation, on the other side, the government will keep pretending that it has the knowledge to understand and evaluate those deficient studies prepared by the industry.

However, despite the deficiencies in pharmacoeconomics already mentioned, according to the study participants, there is a strong tendency in the country to pay more attention to the economic aspects of medicines than to the clinical ones. MedCom-7 said, *“Currently the medicines committee has more members*

who have an administrative background than a clinical one. The presence of a majority of members in the medicines committee with an administrative background means that the committee decisions very often lean toward the economic side". Although the regulation does not specify the balance of knowledge and expertise that should exist among the members of the medicines committee, for MedCom-7 *"the medicines committee members should have a strong clinical background and some education in administration"*. However, the academics who participated in this study described how people with a clinical background are not selected by the nine members of the commission who decide who can participate as medicines committee members or as experts in this selection process. Academic-2 said, *"The people with a pharmacy degree are not allowed to occupy positions in the selection process where decisions are taken. Only lawyers and people with a degree in business administration are the ones who are involved in the decision-making process for this list"*. Both Academic-1 and 2 mentioned that pharmacists are not even included in the *discussion* of the selection of the NEML, despite the fact that there are a few pharmacists in Mexico who have a good command of pharmacoconomics. As Academic-2 said before, it is difficult to understand how the members of the medicines committee who have an administrative background are conducting not only the clinical evaluations about safety and efficacy without the proper clinical background and/or the support of real experts, but also the evaluations of the pharmaco-economic studies. The following subsection shows how the NEML is selected, according to the study participants, despite all the weaknesses explained in this subsection.

d) How the Essential Medicines for the NEML are Selected

According to MedCom-4, the medicines committee reviews four types of applications: 1) inclusions, 2) minor modifications, 3) major modifications, and 4) exclusions. The review process of these applications is divided into two different stages, the first one, considered the initial evaluation is conducted by the technical secretary, the coordinator, and the two advisors mentioned in the section above. This evaluation is focused on ensuring that all the application forms that the General Health Council receives are complete and that they meet the requirements specified in Article 28 of the regulation. The applications that pass this initial evaluation are submitted to the eight members of the medicines committee who represent the public health institutions. In this second stage, these eight members perform the clinical and pharmaco-economic evaluations of each of the applications they receive. According to MedCom-4 each application is reviewed according to their type (i.e., inclusion, exclusion, major modification, minor modification). Only the inclusion

of medicines that have been approved by the health regulatory agency longer than one year previous to the meeting, as well as the major modifications, require an evaluation of their safety and efficacy. Minor modifications and inclusions that have received marketing approval from the health regulatory agency within the last 12 months do not need to be evaluated again, since according to this participant their safety and efficacy has already been reviewed by the health regulatory agency. Regardless of the fact that the applicants do or do not need to prove the safety and efficacy of their products in their applications, all the inclusions need to present a pharmacoeconomic study that, as mentioned before, is also evaluated by the medicines committee.

According to the study participants, both the clinical and pharmacoeconomic evaluations that the eight members of the medicines committee perform are not done as a team, but individually in their own institutions under different standards, guidelines, and with different levels of support and resources. Some of them perform the evaluations on their own, while others are surrounded by a team of experts who helped them to conduct the evaluations. For example, MedCom-1 said that his/her team does not perform any in-depth clinical evaluations nor does it have the advice of experts because the clinical evaluation has previously been carefully done by the health regulatory agency that grants the marketing authorization of the product. However, this participant does check with the pharmacovigilance department of his/her institution if there are any safety reports prior to making a decision. He/she also reviews additional scientific resources as well as the registration file of the drug he/she is evaluating. When this participant described the way he/she conducts the clinical evaluations as a committee member, he/she said *“I review the clinical information that the manufacturing company sent in its application without the participation of any experts and write a report with my decision. This report is reviewed by my coordinator. After his/her review, he/she tells me: ‘this is OK, this is not’. After this, the report is reviewed by my sub-director, and then by the Titular Representative of my institution who finally approves the decision. I am the initial contact between the General Health Council and my institution”*. These reports that MedCom-1 circulates in his/her institution for the approval of his/her superiors support the vote that MedCom-1 casts in the medicines committee meeting.

When MedCom-3 explained the clinical evaluations, this participant said, *“Prior to submitting an application to the General Health Council to include a medicine on the NEML, the pharmaceutical industry should have received marketing approval from the regulatory health agency to sell that particular medicine.*

In order to get that marketing approval, they had to provide evidence for their safety and efficacy, so for us, the registration number that the regulatory health agency issues when a drug has been approved for marketing is the proof of its safety and efficacy. Obviously, we also check other sources like the FDA, NICE, the regulatory agencies of other countries. We look sometimes at the Canadian and the Australian ones. We also read the articles that come in the application package that the industry submits because the industry includes the original studies. We do the evaluation based on this information; there is certainty in this information isn't there?" Contrary to MedCom-1 and MedCom-3, MedCom-4 mentioned that in his/her institution, the clinical evaluations are performed by the department of scientific evaluation and technological support. In this department, four physicians perform the clinical scientific evaluations. According to this participant, there are several factors that are taken into account in this evaluation, such as whether the medicine has been approved in some other countries, and how other regulatory agencies have evaluated the medicine that they are analyzing. His/her institution conducts a systematic search to evaluate the safety and efficacy of the medicines that are being analyzed and also consults the National Pharmacopeia and studies of comparative efficacy. According to MedCom-4 *"it would be good if the eight medicine committee members could follow the existing regulation so that everybody performs the same type of evaluations. It would be good that each evaluation could be documented to ensure that the different institutions involved in the selection process really respect the regulation"*. Although Article 38 of the regulation says that the experts who support the medicines committee should prepare a clinical report to help them with the evaluation of medicines following the "Guideline for the Evaluation of Health Products", with the exception of MedCom-4 who made reference to the regulation and MedCom-8 who specifically made reference to this guideline, this guideline was not mentioned by any of the other study participants in their descriptions of the process. Academic-2 said, *"The organization that MedCom-4 represents is, perhaps, the only one that conducts a good analysis out of all the institutions involved in the selection process"*. There was another participant, Academic-1, who concurred with the previous statement and added that the physicians who provide clinical advice in the institution that MedCom-4 represents have a strong background in pharmacology. However, according to MedCom-8, his/her team, which she/he describes as *"young experts who performed the initial evaluations"*, also conducts, during the initial stage of the review process, a systematic review of the clinical

studies that the industry publishes. They perform a search in PubMed looking for evidence that can help them to conduct their evaluations.

As for the pharmacoeconomic evaluations, MedCom-5 mentioned that in his/her institution, these evaluations are conducted by a pharmacist, although he/she did not give any more details of how these evaluations are conducted. According to this participant the clinical and the pharmacoeconomic evaluations are consolidated in a report that he/she takes to the monthly medicines committee meetings as a support for the vote that he/she casts on behalf of his/her institution. All the medicines committee members who participated in this study only mentioned that their institutions conduct a pharmacoeconomic evaluation, but did not expand on how this evaluation is conducted. They focused more on describing the clinical evaluations. However, there was also an important point that was raised by some study participants related to the pharmacoeconomic evaluation of medicines. According to them, the Health Regulatory Agency does not evaluate the cost of the medicines that are approved for sale in the private market where people pay out-of-pocket. Only the General Health Council requests pharmacoeconomic studies in order to include medicines in the NEML, since although these medicines are purchased with the money that the population pays through their employers for health services, these resources are controlled by the government. Academic-1, said that *“the industry should include the pharmacoeconomic studies in the application that they submit to the health regulatory agency to get the registration to market their products in the country. Unfortunately, there is not the political will to evaluate the cost of medicines during the marketing approval phase because let’s say that 80% of the medicines are purchased in the private sector, out-of- pocket. The industry rules this sector and is not going to accept that the government truly controls it.”* This difference that exists in the control of prices for the private and public sectors makes it difficult to guarantee equitable access to even the most Essential Medicines. MedCom-4, said that *“since the Health Regulatory Agency in its evaluations does not request pharmacoeconomic studies, it gave the designation of an orphan drug to the most expensive medicine in the world”*. Orphan drugs are medicines or vaccines intended to treat, prevent or diagnose a rare disease (Gammie, et al., 2015). This participant also said *“before we had the “Comisión Reguladora de Precios” [the commission that regulates the prices], the country was a paradise for the industry because their products could be sold at very high prices. However, it would be good if the prices of medicines were regulated better. We practically work for the pharmaceutical industry”*.

Although nobody described how the pharmacoeconomic evaluations are conducted, the medicines committee members mentioned that once their institutions have performed, according to their own standards and resources, both the clinical and the pharmacoeconomic evaluations, the eight members of the medicines committee meet to discuss the rationale for their decisions with the other four members of the Health General Council who perform the initial evaluations and also with PG-6 who provides the technical information to support the decision-making process. In these meetings that are usually held once a month, or more often if needed, the eight members of the committee who perform the technical evaluations cast their votes on behalf of their institutions and with that vote decide which medications are included in the list for that particular month. According to MedCom-7, it does not matter if one of the eight members of the medicines committee bases his/her evaluation and final decision on the opinion of several experts and the rest don't. In the end, according to this participant, the value of the vote is the same, regardless of the quality of the evaluation. When describing the vote process MedCom-4 said, *"It does not matter that my institution provides medicines for more than half of the Mexican population because, for the council, all the votes are worth the same"*. However, for MedCom-5, *"despite all the difficulties that the institutions face during the selection process, the vote is fair"*. As it has been shown in this section, although it may seem that the nine members of the Commission have delegated the power to vote and decide what medicines are included in the list to the medicines committee, this delegation of power is illusory, since, the nine members of the Commission have a louder voice and the final vote at the plenary sessions where they meet with the industry and the other permanent guests.

The study participants described the exclusion of medicines as a more complicated process than their inclusion because of the politics involved with this process. For example, for MedCom-1, *"there have been very few occasions on which the medicines committee has received a request for exclusion of a medicine. It is very rare that the industry submits applications to exclude its own products. During the year that I been a member of the committee, there has not been any exclusion"*. According to PG-6, *"The exclusion of medicines is not the result of a collegial and informed decision-making process as the inclusion of medicines is"*. Considering the political complexity that surrounds the exclusion of medicines from the NEML, this part of the process will be fully described in the next section.

e) The Exclusion of Medicines from the NEML

According to ExMinister-1, the Health Regulatory Agency had established very clear criteria for the safety and efficacy of the medicines they review before granting them marketing authorization. However, the selection of medicines for the NEML does not have the same clarity. In order to achieve this clarity, the law was modified to give the General Health Council's decisions enforcement powers. However, despite those powers granted by the state, as will be shown in this section, the Council cannot exclude any unsafe and ineffective medicines from the NEML without the approval of the Health Regulatory Agency. The Mexican Health Regulatory Agency plays an important role in the selection of the medicines for the NEML, not only because any medicine that is considered for inclusion in the NEML needs to have a sanitary registration number assigned by this agency, as proof that it is safe and effective and eligible to be sold in the Mexican market, but also because in order to withdraw a medicine from the list this agency, as will be shown, has to submit a safety alert. However, the fact that some of the members of the medicines committee, who on behalf of the Commission and the General Health Council select the medicines for the NEML, do not rely on the previous safety and efficacy of medicines evaluations from the Health Regulatory Agency makes the inclusion for and exclusion of medicines from the NEML an untrustworthy process.

According to T-4's substitute, even though there are medicines on the list that are not safe, it is very rare that a medicine can be excluded from the list when it has been commercialized. MedCom-7 said, *"There are many medicines that despite being garbage have been approved by the Health Regulatory Agency and have a sanitary registration number that makes them qualified for the NEML. I would like to know why the Health Regulatory Agency gives registration numbers to everybody, if many medicines are useless."*

According to MedCom-8, there is a medicine manufactured by a well-known pharmaceutical company that was not approved by the FDA because it had many cardiac adverse events; however, this medicine complied with the requirements established by the Mexican Health Regulatory Agency and was approved in Mexico.

ExCom-B explained how this Health Regulatory Agency was reluctant to withdraw a drug that was manufactured by a European company, despite the many alerts about it that were issued by the FDA.

According to this participant, it took the Mexican Regulatory Agency three months to withdraw that particular medicine from the Mexican market because *"the Health Regulatory Agency said that the FDA was not its dad"*. Since, as shown before, the safety and efficacy of many of the medicines that are included in the

NEML depends on the clinical evaluations made by the Health Regulatory Agency, there are unsafe and ineffective medicines that make it to the NEML, and once there, it is very difficult to exclude them. The exclusion of medicines from the NEML, according to the study participants, is a responsibility of the Health Regulatory Agency and not of the General Health Council, or the Commission, or the medicines committee that the Council leads. As ExCom-2 said, *“It is the role of the Health Regulatory Agency to withdraw medicines that are not safe and effective, not that of the Council”*.

According to MedCom-7, in theory, a medicine is excluded when there is a safety alert, when there are other therapies that are more cost-effective, or when the medicine is not manufactured anymore. However, he/she said, *“There is a medicine that the FDA withdrew from the US market called dextropropoxyphene that has an alert from our Health Regulatory Agency and it is still on the NEML”*. This participant also mentioned that, on the list, there is a synergistic treatment that combines salmeterol with fluticasone. He/she said that according to the clinical guidelines, it is more cost-effective if they are taken together than separately and that despite knowing this, these two medicines are listed separately on the NEML because they cannot be removed to be replaced by the combination. This participant also said that, *“in order to exclude something from the list, there has to be some damage to health that is reported”*, otherwise, the Health Regulatory Agency will continue maintaining that the medicine is safe and effective. However, according to Academic-2, *“Mexico does not have a culture of safety in which health care providers report adverse events, so it will be very difficult for a medicine that is not safe to be withdrawn from the market based on safety reports”*. MedCom-8 said, *“There are occasions when medicines are excluded because of a safety alert like in the case of sibutramine. The Mexican Health Regulatory Agency has many areas where it can improve; they approve products left and right. Medicines that are not safe are still on the list because there have not been any deaths reported”*. According to MedCom-5, *“If the Health Regulatory Agency sends a safety alert, the exclusion would be done immediately without the need of a committee”*. However, PG-6 said, *“Medicines are never excluded based on their adverse events because the reporting of adverse events is not a reality in Mexico yet. There is a glucose-lowering drug that has had many adverse events and has not been removed”*. According to T-8, *“medicines are excluded from the NEML when they become obsolete, or when there are adverse reactions reported that have not been noted before”*.

The people involved in the selection process of the NEML are aware that the NEML needs to be cleaned up. However, they are conscious that it is not an easy task and that the Health Regulatory Agency and other powerful actors play an important role in this pruning process. For example, ExCom-B said, *“on several occasions when we wanted to exclude medicines from our institutional EM list, the U.S. embassy contacted my boss and the director of my institution to ask what was happening”*. MedCom-8 mentioned that the institutions that participate in the selection are aware that they need to start excluding medicines from the NEML, but he/she said, *“if we take them out we will hit the industry where it hurts the most”*. According to this participant, since they cannot exclude medicines, they do make some adjustments to the doses. He/she said *“we reduced the doses for kids, or we only keep the dose for adults. For example, with dextropropoxyphene, we have made several adjustments and discussed several things, but again, the responsibility for the safety of all the medicines listed is from the Health Regulatory Agency. We cannot remove medicines from the list if they have an authorization from the Health Regulatory Agency to be sold in the country”*. ExCom-A said, *“There are many medicines that are not being produced anymore and are still listed there because we do not have the productive capacitive to sit down to analyze them”*. By “productive capacity”, this participant was referring to the manpower that the General Health Council needs to clean up the list. MedCom-4 concurred with the previous participant saying that there are medicines that nobody buys, but that are still on the list. This participant mentioned that these types of medicines are only withdrawn from the list if somebody says that they need to be removed. MedCom-1 said that *“since, in practice, the exclusions have to be requested by the manufacturer, they are very rare. The industry only submits an application for exclusion when it is going to stop manufacturing a certain product because there is a new drug coming onto the market”*. When this happens, he/she said, *“We tell them no! Please do not take it out because we need it. You can get a patent for your new product, but do not take the other out from the market”*. During the year that this participant has been on the committee, there has not been any exclusion. MedCom-3 also mentioned that it is only the company itself that excludes products from the NEML when the exclusion is convenient for its economic goals. This participant said *“All of a sudden, the company says I am going to apply for the exclusion of this product because I am going to stop manufacturing it. They give different reasons for the exclusion such the existence of other similar drugs on the market with more efficacy, so they send the application and we exclude it”*. MedCom-8 also mentioned that sometimes the company requests the

exclusion because it wants to stop making the drug. This participant said, *“They make a lot of money, then when the generic comes out, the acquisition laws becomes effective and they have to compete, so they think it is better to stop making it”*.

Even though the regulation says that anybody can apply to exclude a medicine, including the public health institutions that participate in the selection process of the list, MedCom-3 said, *“During the time that I have been a member of the committee, only the institution that MedCom-7 represents has applied for exclusion of one medicine that was withdrawn because it was considered obsolete”*. MedCom-7 also mentioned this withdrawal during his/her interview and said, *“The medicine excluded was a medicine that contained phenylalanine that was no longer used”*. However, based on the requirements that the regulation established for the exclusion of medicines, to be able to exclude this medicine from the NEML, the pharmaceutical company that manufactures this drug had to agree to provide MedCom-7 with the information that was needed to complete the application for exclusion. This permission to access the information needed to exclude this medicine suggests that was in the best interest of the manufacturer. Last, but not least, the next subsection will describe who will continue to participate in the selection process of this list after the reform in 2016 and how this change was communicated to the people involved in the selection process.

f) The Structural Changes that are Part of the Recent Reform

As mentioned in my introduction, the regulation that standardizes the selection process of the Mexican NEML has been amended two times since the Commission in charge of selecting the NEML implemented the regulation on June 22, 2011. The first amendment took place on January 16th, 2014, and the second two years later on February 23, 2016. Among the recent changes made to the regulation, there was a structural change in the organization of the medicines committee that included the exclusion of two out of its eight members, MedCom-6 and MedCom-3, and the withdrawal of the right to vote from MedCom-1. It is important to note that unlike the other topics discussed by the study participants in which the majority of them were consistent in their descriptions, and complemented and reaffirmed each other with their stories, their versions that described the exclusion of these two members showed some inconsistencies. Perhaps these inconsistencies were because the changes were recent, and the medicines committee members who participated in my study had not yet had the opportunity to discuss the reasons for these exclusions with the General Health Council’s Technical Secretary who leads their meetings.

Each of the members of the medicines committee who participated in the study gave his/her opinion about the reason for these three changes. MedCom-7 said that MedCom-3 was excluded because his/her institution does not depend on the government of the federal district anymore because the federal district recently became another state of the Mexican Republic. According to this participant, since states do not participate in the selection process of the list, this institution cannot continue participating. As for the exclusion of MedCom-6, this participant said: *“MedCom-6 was excluded because his/her institution provides rehabilitation and physical therapy services and does not have hospitals”*. This participant did not mention anything about the withdrawal of the vote from MedCom-1; for him/her, the selection process of the Mexican NEML will now depend on only 6 votes. In contrast to this participant, MedCom-8 did mention the withdrawal of the right to vote of MedCom-1 and said *“MedCom-1 was excluded because his/her institution does not buy medicines, so it shouldn’t vote”*. As for the exclusion of MedCom-6, this participant said, *“MedCom-6 was excluded because his/her institution does not buy medicines either”*. In addition to this comment, MedCom-8 also mentioned that MedCom-6 on many occasions did not agree with many things such as the use of oral contraceptives. It is important to clarify that the institution that MedCom-6 represents cannot support the use of oral contraceptives because they go against its mission and the type of population it serves. Neither the mission of each institution, nor the type of population that they serve should be an obstacle to allowing institutions to have a voice and vote at the decision-making table. ExMinister-1 explained that there are medicines that can be a good choice for many reasons including their cost-effectiveness, but they might not be included in the list because they are not compatible with the “social values” of the population that are important to consider. This participant gave as an example of these medicines, the oral contraceptive pill. However, with the recent reform of the regulation, the institutions that uphold some of these social values for vulnerable sectors of the population, such as the institution that MedCom-6 represents, are being left out from the selection process of this list.

Even though I interviewed MedCom-1 one week after the regulation changed, he/she did not mention during the interview that his/her institution had lost the right to vote. However, he/she did mention the exclusion of the two members of the medicines committee and said, *“out of all the changes that were made to the regulation, their exclusion was the one that impacted us the most”*. According to this participant, MedCom-6 was excluded because the type of population that his/her institution serves is very small and this

institution does not have hospitals. As for the exclusion of MedCom-3, he/she said, *“I really do not know the reason. Sometimes there are things that one ignores, things that have to do with decisions that come from above”*. When MedCom-4 referred to the withdrawal of the vote from MedCom-1, this participant said that the institution that MedCom-1 represents always voted in favour of including medicines in the NEML. This participant said, *“we cannot start the selection process with a positive vote”*. T-8 explained the reasons for the exclusion of MedCom-3 and MedCom-6 and said, *“MedCom-6 was excluded because his/her institution is a social development secretariat that provides social assistance and MedCom-3 cannot be invited anymore because his/her institution became another state of the Mexican Republic and if we invite MedCom-3, we will have to invite other states like Zacatecas”*.

Since I had interviewed MedCom-3 before his/her exclusion was announced, I contacted him again to collect his/her impressions about his/her exclusion after these changes were made public. According to this participant his/her exclusion was not communicated to him/her in advance. MedCom-3 said *“I do not know if my boss anticipated this, but I did not know anything until now. Nobody told me anything in advance or asked for my opinion. Everything was decided from the top. We have to accept whatever it is that they decide”*. The study participants could not reach agreement on the time when these structural changes were decided. I interviewed one of the study participants, two days before the announcement who told me that MedCom-3 and MedCom-6 were not going to continue to participate in the selection process of the list. However, he/she added, *“even though nobody knows it yet, this change is going to be announced soon”*. According to PG-6, the decision to exclude these participants was made by the Commission, during the plenary sessions in December 2015 and that people involved in the selection process had known about this potential change since then. MedCom-1 also mentioned that the institutions that were excluded knew about their exclusion in advance. During the interviews, I asked some participants if the members who were excluded showed any opposition. According to PG-6, during the last committee meeting where these two participants were still present, there were not any problems or incidents with the participants who were excluded. However, according to MedCom-1, during this last meeting the two salient committee members showed some opposition to their exclusion, especially one of them. Unfortunately, I could not make contact with MedCom-6, the other member excluded, either before or after his/her exclusion to ask for his/her impressions. According to MedCom-1, the medicines committee was going to have the first meeting without these two

members the following month in April 2016, after I had left Mexico. Even though I submitted a request in February to the General Health Council to be invited to the next meeting that the medicines committee was going to have in March, the Council never replied to my petition.

These recent structural changes that were made to the regulation made the medicines committee lose the hybrid nature that MedCom-4 mentioned before, since the committee now includes only institutions that have purchasing power. It will be difficult to meet the needs of the population if not all the voices that can express their needs, including the voice of children, the uninsured, and the public in general are heard. Unfortunately, there are louder voices that control who can participate in this process and what voices are heard, to the point that the regulation has to be modified. When Medcom-9 explained the recent changed to the regulation, he/she said, *“There are many challenges in our administrative processes that led us to modify the regulation”*. The power that the Commission has to modify the regulation is established in Chapter III, Article 7, Subsection XIV. According to this section, the Commission has the right to form new committees that support the selection process of the NEML, as well as the right to modify the existing one. In addition, Subsection XVI gives the nine members of the Commission the right to perform *“any other activities that might be required for fulfilling their responsibilities”*. Based on these two sections, the nine members of the Commission on the one hand are bound to be in compliance with the existing regulation, but on the other hand, are allowed to impose changes to it, not only to legitimize their own participation and authority in this process, but also the selection process itself. It is important to note that the procedure that these nine members follow to modify the regulation does not include any type of consultation, but is solely based on the opinion of the nine members of the Commission. The steps that this Commission should follow to undertake a change to the regulation are described in four rows in Article 60 of the regulation. According to this article, a change to the regulation can be requested by the President of the Commission or at least two Titular Representatives during the plenary sessions. In order for a reform to the regulation to be approved, it only requires a unanimous vote from the nine Titular Representatives that are part of the Commission. Although, there is not any other public consultation involved in these approvals, just the opinion of these nine members, the pharmaceutical industry is present in the plenary sessions where these nine members of the Commission vote to approve a possible reform to the regulation.

The third section of this chapter will describe how the system that supports the selection process of this list influences some of the resources that are involved in this process, including the human resources.

The Influence of the System on the Resources that are involved in the Selection Process

a) Training and Knowledge

According to MedCom-4, the biggest challenge that he/she faces, as a member of the medicines committee, is to educate himself/herself to be able to see what the population really needs and how patients are treated in the institution that he/she represents. When MedCom-5 discussed the training of the medicines committee members, he/she said, *“The government needs to show some interest in ensuring that all the people involved in the selection process are well trained, and that the pharmaceutical industry is not involved in this training. It would be good if the federal government and not the industry pays for the training and education of the persons who conduct the evaluations”*. According to ExCom-B, one of the challenges that the people involved in the selection process of this list have to face is *“not to succumb to the temptations of the gifts that the pharmaceutical industry constantly offers. In the selection process of the NEML, we need honest people who can endure temptations of trips to Paris. The Titular members of the different public health institutions do not do their job with total honesty”*. According to this participant some of these gifts that the industry offers are usually in the form of training trips. After the tape recorder was turned off at the end of one of the interviews, one of the participants mentioned that during Christmas time, he/she sees a parade of gifts turning up at the office of the Titular Representative of his/her institution. These gifts do not only indicate that there might be conflict of interest in this process, but also that the process itself might be biased. The fact that the government lets the industry intervene in the training of the people who reviews its applications can have an impact on the type and level of skills that the reviewers develop with this potentially biased training, since the less skillful they are, the better for the industry.

There was another participant, MedCom-7, who said that the government does train all the members involved in the selection process and sends them to courses and seminars through the General Health Council. However, MedCom-8, one of the members of the medicines committee who is part of the team that provides this training said, *“It is very difficult in Mexico to train the people involved in the selection process because is not easy for them to understand the problems and consequences of listing or not listing a medicine without hurting the interests of any type of institution, at the same time that the population is protected”*. According to

this participant, *“it is easier to train young people who do have not preconceived ideas”*. In fact, the initial evaluation that this participant coordinates is conducted with the help of advisers who are between 26 and 32 years old and have recently graduated from a master’s program in biomedical engineering, a B.Sc. in nutrition, and a master’s in health economics. These advisers received training for 6 months, through online courses, in health economics and clinical research methodology. ExCom-A describes this group of young advisers, who are part of the initial review process, as *“people with experience whose productive capacity to evaluate the applications that are received from the industry is good”*.

During the “XI Meeting of Sanitary Regulation” that I was invited to attend where representatives of the industry, the academy, and the government, who can afford approximately CAN\$700 for the registration fee, meet every year to receive some training, the discussion revolved around issues such as regulatory harmonization, good manufacturing practices, biotechnological products, the national clinical trials registry, orphan drugs, and biosimilar interchangeability. Although there was one speaker who kept repeatedly making reference to the “National Pharmaceutical Policy”, that according to him/her Mexico currently has, the fact that Mexico has not had a National Pharmaceutical Policy since the 1980s and the importance of having one was not included in the meeting agenda. This agenda did not include either topics such as Essential Medicines, or the NEML. In fact, there was no presence at all of the people involved in the selection of the NEML. However, later, when I interviewed Academic-2, this participant said, *“The academy proposed that the government and the industry discuss both the NEML and the topic of pharmacoeconomics in this meeting, but neither of them showed any interest in including these two themes in the agenda”*. According to this participant, *“the excuse that both the government and the industry gave for not bringing pharmacoeconomics up in the discussion was that neither of them had command of the topic at that time”*. According to this academic, *“since the industry and the government do not want to talk about these topics, the academy has to take this discussion to other forums”* where, unfortunately, these stakeholders are not present. It is contradictory that the government refuses to discuss issues related to the NEML with experts that are outside the boundaries of the eight public health institutions that make up the National Health Care System that it leads. However, according to this participant, things were not like this before. He/she recalled how *“with previous administrations, the government not only used to get into good debates and heated discussions with the academy, but also accepted being questioned and challenged about its work”*. For this participant, *“the*

current regulation is in tatters. There is an open window through which the pharmaceutical industry continuously pressures and pressures a lot to all the experts in general". The pressure explains why the academics whose knowledge is not being considered in the discussion of the NEML take their concerns to other forums where neither the industry nor the government are present to avoid any type of conflict, or even threats from the ones with power.

However, not only has the political will of the government to discuss its work with knowledgeable people who challenge its decisions changed over the years, according to Academic-2, the education system has also changed over the years. During the interview, this participant made reference to the evolution that the B.Sc. in Chemistry has gone through, after pharmacists became very dependent and attached to the industry. This dependency forced the curricula to focus on developing skills in the students that accommodated the industry's needs. For example, according to this participant, in the specific "Pharmaceutical Chemist" program, topics related to public safety or even to the Mexican National Health Care System were not being taught to the students because the program was creating professionals who could work for the industry and not in social or clinical pharmacy. Currently, the presence of pharmacists in these two areas is non-existent because the majority of them work for the industry in the manufacturing area. Academic-1 mentioned that there are very few people in the country who can discuss topics such as equitable access to essential medicines or the NEML. In fact, during my interviews, within the group of "insiders" only T-8 and T-4'substitute mentioned the WHO model of Essential Medicines, perhaps because their political power exposes them to a different base of knowledge that the rest of the people who participate in the process are not familiar with. According to Academic-1, it was only recently that some universities have started to cover these topics.

There was also an important issue that was pointed out during the interviews about the difference that exists between the public and private education systems. According to ExCom-1, private universities focus their programs on shaping the minds of entrepreneurs who will contribute to enhancing the private market, while the public system focuses on waking up the social consciousness of their students. This participant said that despite this difference that exists between the public and private education system in Mexico, it does not mean that all the professionals, once they are out in practice, follow the pattern mentioned above. According to him/her, there are a lot of people in the government who come from private universities and who are defending public interests. Another important point that has to do with the education system in

Mexico was also discussed in the “XI Meeting of Sanitary Regulation” that I attended. According to one of the speakers who participated in these meetings, *“for the majority of health professionals in Mexico it is easier to go to Spain to get training, because in English speaking countries the language barrier inhibits people from fully understanding the training”*. The fact that training has to be received in Spanish speaking countries might mean that doors are being closed on the trainees to other types of discourse and levels of knowledge that are only available in English, the universal language of science. Despite the fact that Mexico shares a border with the U.S., the public education system is not bilingual. A strong education system that does not control knowledge and training, but on the contrary that supports a robust and well-trained national group of experts can make a difference between having a group that simply legitimizes the selection process with its presence and having a group of experts that with their experience, knowledge, and skills work together in the selection of an effective list. The following subsection will describe how the political system influences the jobs and salaries of the people involved in the selection process of this list.

b) Jobs and Salaries

The lack of good job opportunities for people with clinical training within the government makes the few jobs available with the pharmaceutical industry very appealing to many health professionals. According to ExMedCom-A, out of the twelve persons who attend the medicines committee, the two technical advisors who conduct the initial technical evaluations are hired under precarious conditions. This participant said, *“These advisors only receive a payment for their services called “pago por honorarios”, and not a permanent salary with benefits”*, despite the fact that they work full-time and according to ExMedCom-A, *“even overtime with no extra payment in the building where the Commission has its office”*. This participant explained that *“these two advisors are offered an initial contract for six months. This initial contract is usually renewed an average of 5 times because, after this period of time, the majority of the people who hold this position end up moving to the pharmaceutical industry”*. However, ExMedCom-A said, *“This transition for some of them is even faster. On some occasions, they move after barely having worked for the council for a couple of months. The people who work for the General Health Council are very appealing to the pharmaceutical industry because the industry sees them as an airplane’s black box that can show them the things that happen in the Council. These advisors who perform the initial technical evaluation, one day can be working for the Council, and the following day can be hired by the industry that submits the applications*

for the NEML that they used to evaluate as members of the committee, or they might be working in access to medicines as managers, or as managers of the pharmacoeconomics department, with better salaries”.

MedCom-8, confirmed that the advisors who perform the initial technical evaluations are not considered full-time employees with benefits. Even the position of MedCom-8 is temporary, despite him/her being considered a trusted employee. According to this participant, only his/her bosses have a full-time job with benefits. It is important to mention that both the bosses of MedCom-8 and the two technical advisors are the same. When ExMedCom-A was describing the precarious jobs of the two technical advisors, he/she said, *“The payment for these temporary workers as well as the salaries of their two bosses, who are also part of the selection process of this list, comes from the budget of the General Health Council. In practice, the General Health Council does not depend on the Health Secretary, but on the office of the President of Mexico. In fact, the chief of the General Health Council and the head who leads the selection process of the NEML is the President of Mexico. Seen this way, it should be the President of Mexico who pays the salary of the people involved in the initial evaluations. However, there is something very strange because at a decision-making level, the council depends on the President, but the payroll for the council comes from the Secretary of Health. This is strange because in the hierarchy, at the decision-making level, the General Health Council depends on the President, but at the payroll level the Council depends on the Secretary of Health”.* MedCom-8 also made reference to these salaries and said, *“The salaries of the staff that participate in the selection of the NEML representing the General Health Council depend on the office of the President of Mexico, although the salaries are from a payroll that comes from the Health Secretary”.*

As for the employment, benefits, and salaries of the other eight members of the medicines committee who perform the clinical and pharmacoeconomic evaluations, according to MedCom-7, these eight members have their full-time jobs at the institutions that each of them represents. The selection of the NEML is an additional project for them for which they do not receive any additional payment. When the medicines committee members who participated in this study described their participation in the committee, MedCom-7 said *“being a medicine committee member is an honorary position that implies 4-5 sleepless nights a month”.* Each month, this participant reviews an average of 5-8 dossiers overnight, at the same time that he/she is also working during the day on his/her other projects in his/her institution. However, this participant did not show any open conflict towards the system that is not compensating his/her work fairly. On the contrary, he/she

showed how proud he/she is when he/she opened the interview saying: *“It is very gratifying to be able to vote as a medicines committee member and to be one of the decision-makers who participate in this selection process. Instead of watching TV, I review the dossiers”*. In fact, none of the members of the medicines committee that I interviewed showed any discomfort about work exploitation. Although one of the medicines committee members was able to recognize the precariousness of the job that the government offers him/her, this participant did not exhibit any type of conflict, opposition, or disagreement. On the contrary, he/she was grateful for the opportunity that his/her boss gave him/her to participate in the selection process of this list. This gratefulness and loyalty can also prevent the people who participate in this selection process from making impartial decisions or challenging the system.

According to ExCom-A, considering the number of applications that the General Health Council consistently receives from the pharmaceutical industry, there should be more people conducting the initial evaluations. However, this participant said, *“The General Health Council cannot hire more people to review the high number of applications that it receives in the initial stage of the selection process because the budget is not large enough”*. One of the reasons for the budget shortfall to hire more staff is because the General Health Council does not charge the industry any money for reviewing the applications that it voluntarily submits with the hope of selling its products through the NEML. Despite the economic benefits that it represents for the industry to have its products listed in the NEML, it is not the industry that pays for the work that is involved with the selection of the NEML, or even the government, but the staff members who participate in the selection process of this list, either conducting the evaluations for free, or performing them under precarious work conditions. As will be shown in the following section, the system also allows the presence of threats and coercion in this process of carrying out the evaluations.

c) The Use of Threats, Intimidation, and Coercion

Even though both the industry and the government have power over the resources involved in the selection of the NEML, the economic superiority of the industry makes this power imbalanced, not only between this industry and the government, but also between these two stakeholders and the rest of the people who participate in this process. Although some of the participants had something to share about this power imbalance, sharing this information was uncomfortable for them. For T-8, the study participants with more political and legitimate power in this process, it was not easy to recognize the power that the industry exerts

over the state. Some of these participant's statements were not consistent. For example, at the beginning of the interview, he/she said: *"Nobody pressures us, anybody can say whatever they want; we know the decisions are well grounded. We say to the industry blatantly that their applications did not proceed"*. However, minutes later, this participant made evident the pressure that exists from the pharmaceutical industry when he/she said, *"the pressure from the laboratories and manufacturers is not a matter of one tablet, but of millions of tablets"*, perhaps recognizing that some pressure from the industry would delegitimize the role that this participant has in the process. When he/she talked about the efficiency of his/her institution this participant said, *"When I accepted this charge, I knew that my institution was very strict and it was not going to stop being strict because of me. We are forced to maintain the prestige of an institution that is second in authority after the President"*. Something similar happened with T-4's substitute. When I asked if it was the industry that controls the selection process of the NEML, this participant said, *"The industry and the government collaborate with each other"*. Other participants like MedCom-8 and MedCom-9, did make evident the pressure and the fact that the industry on occasion has sued the government, but they were not willing to talk about it because according to them *"only their lawyers are familiar with that information"*.

However, for other participants it was easier to talk about this pressure that the industry exerts on the government, although they were careful not only with the tone of voice they used, but also with the volume of their voices. PG-6 said, *"The pressure from the industry, on some occasions, takes the form of an inducement to favour their products for inclusion in the NEML. Yes, the issue is a bit sensitive; some of the institutions create their own demand to be able to favour some of their products"*. This participant explained how the industry visits some of the people involved in the selection process to convince them to vote in its favour during the monthly medicines committee meetings where they cast their votes. MedCom-4, mentioned that the industry is very powerful and sometimes uses its power to influence patients and pressure the government through these patients. According to T-8, some public health institutions have been the subject of lawsuits and judgments that patients initiate on behalf of the industry. Academic-1 also commented on the pressure from the industry and said, *"the fact that the government buys medicines that are listed in the NEML in large quantities has created a lot of pressure in the selection process. This pressure has distorted what can be considered a list of only essential, Essential Medicines"*. According to Academic-2, the NEML is not a list of Essential Medicines anymore because of this pressure. This participant said, *"The government does not make*

an effort to select only Essential Medicines. Some people think that the medicines included in the list are old and cheap and they want innovations that the industry promotes. However, these old and cheap medicines can be the best option for the population". The pressure to include the innovations that Academic-2 refers to became evident during the meeting that was organized by ISPOR and the General Health Council in which the government provided the industry with an update about the selection process of the NEML. The speaker representing the Council, who is one of the participants in this study, looked uncomfortable and anxious about answering all the questions from the industry representatives that attended the meeting, perhaps because the meeting was in one of the manufacturing plants that one big international pharmaceutical company has in Mexico City and not in a governmental institution. Accessing this facility was not easy, people needed an invitation and their names had to be included on the list held by the entrance security guard. The location where the meeting takes place can make a big difference in the power with which a message is being delivered as well as on the content of the message. In this meeting, the Council shared with the industry some statistics that reflected the efficiency of the selection process of medicines, including that 40% of the industry applications do not pass the initial evaluation. After this rate was released, the speaker immediately started to justify it, emphasizing that this high rejection rate was not the Council's fault, but the industry's because its applications do not meet the basic requirements. There was a certain desire in this meeting to please the industry and collaborate with it, rather than emphasize the need to enforce the regulation. During the meeting, the speaker also said, *"We have in the list medicines that are from the 70s and the 80s, isn't that true? So, we are looking for a way to help you [referring to the industry], through the different social programs that we offer to the different communities in the country. For example, like we did with the dental varnish for caries prevention that was included in the NEML and that we used a lot for our dental campaigns in the province, and other things like that"*. Even though it is difficult to understand what this person refers to with the term *"other things like that"*, his/her statement suggests that the government strives to find a use for the innovations that the industry wants to include in the NEML in its different social programs that it offers to the Mexican population, regardless of whether they are considered Essential Medicines, innovations, or even cosmetics.

According to the study participants, the industry usually saves its threats for occasions when it cannot reach agreement with the government during the plenary sessions of the Commission. ExMedCom-1

gave an example of a controversy that he/she witnessed between the industry and the government in these plenary sessions, one time when this participant had the opportunity to attend this meeting. According to him/her, at the end of this plenary session, there was an interesting discussion about an orphan drug that was extremely expensive and that had not been originally approved by the medicines committee. This drug was not authorized in other countries and the company wanted Mexico to include it in its NEML. Mexico did not authorize this drug either and the industry ended up suing the government. According to MedCom-1, *“the industry sues the government when their products are not approved. Sometimes the government wins and some other times the industry does”*. This participant wonders *“why the industry fights with the Mexican government for a drug that is very expensive and that was not authorized in any other part of the world, and why they don’t fight because there is not enough insulin, antibiotics, or Tamiflu right now?”* MedCom-1 said, *“I have heard on some occasions that some of my coworkers have been intimidated and threatened by the industry with losing their jobs”*. This participant also explained that when the industry sues the General Health Council, the people involved in the selection process of this list are advised not to travel because they can be called anytime to testify in court.

g) Transparency in the Selection Process

As mentioned in my Section II, the Mexican regulation was established in Chapter V, Section IV, Articles 52 through 56 regarding the government’s practices of accountability and transparency. According to Article 52 in order to ensure transparency in the process, the status of all the applications that are accepted by the General Health Council can be tracked on the Council’s electronic website. Article 53 focus on assuring the industry that its information will be handled as confidential, according to the Federal Law on Transparency and Access to Public Information, the Industrial Property Law, the Federal Law of the Workers at the Service of the State, and the Federal Law of the Administrative Responsibilities of Public Servants. Article 54 mentions that the experts that participate in the selection process, the members of the committee, the guests, bureaucrats, and the staff that work for the government institutions that have access to the industry’s information must sign a confidentiality agreement and refrain from disclosing this information. Article 55 mentions that the experts that participate in the selection process should sign a conflict of interest form, although it does not specify if the rest of the staff involved in the process, such as the members of the medicines committee and the Commission should also sign one. According to Article 56, in case the

confidentiality agreement is violated or if the conflict of interest form does not declare all the interests, those responsible of these violations will be withdrawn from the process and all his/her opinions and evaluations will be discarded. In addition, the case will be made public on the website of the General Health Council. As will be shown in this section, these national and international confidentiality agreements that protect the industry's clinical information do not allow the Mexican government to truly regulate the selection process of its NEML to the point that only "safe and effective medicines" can be included in this list.

During the interviews, several study participants made reference the fact that the pharmaceutical industry's clinical information, that proves the safety and efficacy of its products, is protected as confidential under national and international laws, limits their selection of medicines when they conduct the technical evaluations. For example, MedCom-4 said, *"When we do the evaluations, we try to look for as much information as possible. However, there is a lot of information that is confidential that we cannot have access to"*. Another participant, PG-6, said *"When we conduct our evaluations, we do a systematic search to identify the best available evidence. We look for meta-analyses, systematic reviews, clinical studies, and also technological evaluations. However, there are times when we find a lot of information and many other times when we find the same information that the manufacturer sent. It is not easy to have access to information from the manufacturer"*. There was one more participant, ExCom-B, who used to work for the same institution as MedCom-4 who said, *"When we performed the evaluations, we reviewed the international evidence about medicines available in the National Library of Medicine, looking for adverse events because the industry did not say in its applications what was published in other countries about their products"*. T-4's substitute explained that there have been cases when the industry wants to include its products on the list at an early phase when their safety has not been fully proven and there is not enough clinical data. PG-6 concurred with T-4's substitute and said that *"for the last two years many innovations have entered the market prematurely before they have completed their development phase. Many of these innovations do not have enough studies that can fully prove their safety and efficacy and even less their cost-effectiveness and some have sneaked through onto the NEML"*. The fact that the clinical information of the pharmaceutical industry is protected as confidential does not allow the government to systematically evaluate the safety and efficacy of their products. The protection that the regulation gives to the industry's information is in contradiction with its Article 27 that says that anybody can submit an application for inclusion, modification, or exclusion of a

medicine to the General Health Council, as long as they provide the clinical and pharmacoeconomic information about the product that Articles 52 through 56 protect as confidential.

Is also important to note that none of the articles in the regulation mention how the government is going to guarantee the population the transparency of the selection process of its NEML. According to ExMinister-1, there are three areas related to medicines where there is a risk of corruption: 1) when the safety and efficacy of the drug is demonstrated, 2) during the selection of the NEML, and 3) during the medicines purchasing phase. According to him/her there is confidence that in the two first areas there is no corruption, since the fact that the government was able to define the selection process of the NEML increased the transparency of process and with this transparency, he/she said, that also increased the investment of the pharmaceutical industry in the country. In fact, this participant said that he/she did not even know about a single case where somebody had said that the Council received bribes. However, he/she believes that there is space for improvement and for stricter controls in the third area where medicines are purchased. The corruption that seems to exist in this third area explains why, when I interviewed T-8, this participant said on several occasions during the interview that it was important that I mention that the General Health Council is only in charge of selecting the medicines, but not of buying them. For ExCom-B, the transparency of the process starts with the values that each of the Titular Representatives bring to the table. This participant said that *“the Titular Representatives of the different public health institutions do not do their job with total honesty”*. Contrary to ExMinister-1, ExCom-B thinks that the government has many conflicts of interest in the area of health, especially when safety and efficacy of medicines are documented by the pharmaceutical industry. This participant said, *“there is nothing specified by the Health Regulatory Agency, either for the industry or for its employees, that can prevent conflicts of interest. The Mexican regulatory agency is not like EMEA that has on its website 1100 links that take you to something related to conflict of interest”*. For PG-6 *“even though corruption and transparency have improved in the selection process of the NEML, the decision-making process is not transparent”*.

One of the points that suggests a lack of transparency is that the strong presence that the industry has in the selection process of the NEML is in contradiction to the lack of involvement of the public in this process shown in Section II of this chapter. However, despite the exclusion of the public from the selection process of this list, some participants insisted on defining the process as transparent because, as mentioned

before, they associate transparency with the presence of the pharmaceutical industry, but not with the presence of the public. For example, T-4's substitute made reference to the fact that the process is becoming more and more transparent to the point that the pharmaceutical industry gets recommendations and feedback on their applications from the General Health Council. The participants were concerned about proving that the process was transparent because the government does not hide anything from the industry. PG-6 said, *"the industry is not going to stay quiet if we tell them: you are going to do what we say. There is all this about transparency that says that government has to be fair and facilitate the selection process for the industry"*.

The openness to the public is one dimension of transparency that is ignored in the selection process of this list. In order to extend transparency to the public, the information has to be communicated to them. However, communication is also something that participants did not relate to transparency. For example, when PG-1 was explaining to me how the pharmaceutical industry is trying to change its image as a "corrupt entity", as he/she defined it, he/she made reference to the internal regulation of his/her institution that was created to self-regulate the interactions with the pharmaceutical industry. According to this participant this internal regulation establishes the steps that health professionals and the consumers should follow in submitting a complaint about ethical issues related to the pharmaceutical industry. When I asked how this information is communicated to these two groups, this participant said that it was through the internet. I asked him/her if the processes were transparent because they release the information through the internet and this participant said, *"Yes, we made them transparent by publishing them on the internet... but, wait a minute, transparency is not communication. I agree with what you said before that we need to reinforce the communication of our information, but this does not mean that we are not transparent"*. When I was discussing the communication of his/her internal regulation with this participant, his/her administrative assistant entered the room with a message written in a notebook for PG-1. After PG1- read the message the secretary left with the notebook and five minutes later, PG-1 told me that he/she had to go. The topic of communication also emerged during the interview with PG-5. This participant showed me several booklets that his/her institution has published to inform patients about their rights. However, when I asked how these booklets are distributed, this participant mentioned that the budget ran out for the distribution phase of this material. This participant said that they had some money left, but they had to use it to conduct patient satisfaction surveys.

It will be difficult to include the public in the selection process of this list if the stakeholders involved, including the state and the industry, do not understand what transparency means. The lack of clarity with which the government defines “transparency” in the glossary of terms in its regulation does not allow people who participate in this selection process to fully understand this term. Since the version in Spanish that defines this term is very confusing, I have included both versions, the original in Spanish and its translation, so the version in English cannot be interpreted as a bad translation that does not make sense. The original version in Spanish says: “*Transparencia, los procedimientos aplicados a los procesos y a los integrantes de la Comisión para garantizar prácticas exentas de conflictos de interés, apegadas a principios éticos y acordes con las políticas de salud*”. The translation in English would be: “*Transparency, the procedures that apply to the processes and members of the Commission to ensure practices are free of conflicts of interest, respect ethical principles and in line with health policies*”. It will be very difficult for the Mexican government to put together a list of Essential Medicines that meets the priority healthcare needs of the population, if the population is not invited to participate in this process. Last, but not least, I will describe in the following section the role that the Mexican health care system plays in ensuring equitable access to Essential Medicines.

V. Equitable Access to Essential Medicines

As mentioned in my introduction, Mexico has a fragmented health care system in which the eight public health institutions that made up the National Health Care System that participate in the selection of the NEML, serve different sectors of the population (i.e., the military and their families, public servants, oil industry workers, the uninsured), and therefore have different budgets and degrees of power. Unfortunately, not all their budgets can cover the medications that their different populations of patients need. There are some that can provide more medicines for their patients than others. According to T-8 “*the economic capacity of each institution determines the type of its medicines*”. MedCom-7 said, “*Each institution has a different budget. However, in small systems medicine can be personalized, since it is believed that small families have a better quality of life*”, making reference to the small sector of the population his/her institution serves. The difference in population coverage between institutions is significant. While the institution that MedCom-4 represents provides healthcare for almost half of the Mexican population, according to T-8, the institutions of MedCom-5 and MedCom-2 together provide healthcare for only 3 million Mexicans, approximately 2.5% of

the Mexican population. Even though T-8 recognized that not everybody has access to the same medicines, this participant said proudly that the NEML includes all the Essential Medicines that the population needs, and even a variety of medicines to treat breast cancer. According to him/her, it is important to cover the individual needs of patients in order to really meet the needs of the country. Even though MedCom-8 agreed with T-8 that the NEML has included many medicines to treat cancer, MedCom-8 said that not all the institutions can afford these cancer treatments. According to this participant, there are institutions like the one that MedCom-7 represents that very often say, *“We already have this medicine”* because they have the budget to buy all the medicines they want, while the one that MedCom-4 acts for cannot afford to buy the same type of medicines for its population because it lacks the economic resources to do it. MedCom-4 said, *“From this enormous NEML, each institution buys only what it can afford”*. According to this participant, once a medicine is listed in the NEML, his/her institution needs to see if it can afford that particular medicine for the 56 million patients that it provides healthcare for.

According to PG-6, and ExCom-2, a medication can be listed in the NEML, but this does not necessarily mean that this medicine is available in each of the eight public health institutions that participate in the selection process. PG-6 said, *“These eight institutions perform the clinical and pharmacoeconomic evaluations to select the NEML. They go to the monthly meetings and cast their votes to decide what medicines are included on the list. However, once a medicine is included in the NEML, some of them might decide not to add certain medicines to their institutional essential medicines list because they are very expensive, or perhaps because only a very small part of the population served by their institutions needs that particular medication, or for many other reasons”*. There is a significant difference in the number of medicines that each public health institution includes in its Institutional Essential Medicines List. For example, according to MedCom-5, his/her institutional list includes 700 medicines, a third of the medicines included in the NEML. While according to MedCom-3, his/her list includes only 490 medicines. For MedCom-3, the NEML is the menu for all the institutions, from that menu each institution takes what it needs according to its budget.

Although all the participants were conscious about having a fragmented healthcare system, many of them were not conscious of the inequities involved with this fragmentation. For example, when PG-6 commented that many health technologies that are very expensive can only be bought by the institutions that

MedCom-7, MedCom-5, and MedCom-2 represent because these institutions have money to pay for them, this participant did not show any feelings of discomfort. For him/her, these differences in access were perceived as natural. In fact, when I asked this participant if somebody from the medicines committee has questioned, or discussed these differences in access to medicines, PG-6 answered, *“No, we all are conscious that everybody buys according to their population’s needs. We all understand that MedCom-7 has different needs than MedCom-4. How can we not support the different needs of each institution? We cannot say that we are not going to support MedCom-7 just because the other institutions cannot afford to buy the same medications”*. However, in the institutions that cover majority of the Mexican population, MedCom-8 said, *“Six million pesos [approximately CAN\$400,000] are spent on eculizumab. A lot of money is spent on diseases of poverty and the poor do not even know how much his/her medicines cost”*. The difference in political power of each of the eight public health institutions, as well as the social status and economic and political power of the affiliates to whom these institutions provide healthcare services for, seems to be the reason why the inequity involved in access to the Essential Medicines listed in the NEML goes unnoticed for some people.

However, there are some participants that were more aware than others about the “inequity” involved with the access to the Essential Medicines listed in the NEML. For example, ExCom-2 said, *“I believe that this fragmentation is what creates ‘inequity’ in resources. The institution that MedCom-4 represents does not provide the same healthcare service, with its scarce resources, as the one that the institution of MedCom-7 provides. The healthcare service in this last institution is very similar to the healthcare provided in other countries that have good healthcare systems, while the services provided by the first one are similar to the ones offered in a deficient health care system. There is a huge income distribution gap in the healthcare sector and it is difficult to fight against it. How can we unify the healthcare system if there are many inefficiencies and inequities?”* For MedCom-7, *“a universal healthcare system that would not discriminate among oil workers, state workers, or the uninsured would be what would improve equitable access to essential medicines in Mexico”*. However, T-8 did not associate inequitable access to medicines with the fragmented healthcare system. According to him/her, in order to achieve equitable access in medicines, the commission should include medicines covered by the catastrophic health insurance plan offered by the government through the institution that provides health services for the uninsured. There were other

participants who described the differential access to Essential Medicines as an “inequality”. For example, MedCom-8, who said, *“It is an inequality that MedCom-7 can afford drugs for ovarian cancer, and MedCom-4 cannot”*. According to MedCom-7, *“the fragmentation of the healthcare system is a huge problem in Mexico because it promotes inequality. The inequality that this fragmentation generates is promoted by the Health Secretariat itself”*. According to this participant, the fact that, as mentioned in one of the previous sections, the Health Regulatory Agency does not require the industry to prove that the medicines that are sold in the private sector are cost-effective contributes to this inequality because these medicines are paid for by the general population out-of-pocket. The industry only has to prove that its products are cost-effective if they want to include them in the NEML that the government uses as a menu to decide what medicines it should purchase with its limited resources. According to this participant, it is very rare that the government buys medicines that are for sale in the private sector.

Despite the differences in access to medicines, PG-6 said, *“Patients do not complain about the lack of some medicines, especially the uninsured ones because they are not aware of their rights. And even if they were aware of them, who are they going to demand their medicines from? If the institution that provides medicines for the uninsured covers very few medications, you cannot demand anything from this institution because its budget is very low. In this fragmented healthcare system all the voices get diluted. In Mexico you cannot sue the government. It is very difficult for patient organizations to do it, especially if five of their members are insured by the institution that MedCom-4 represents, another five by the one represented by MedCom-12, and some others get healthcare coverage from the institution that provides services for the uninsured.”* It is unfortunate that the fragmented healthcare system divides the public health institutions and takes their power away by diluting their voices.

VI. Anecdote

In this section, I also would like to share a very uncomfortable experience that I had during one of my visits to the public health institution that MedCom-7 represents that showed me how power works to intimidate and threaten people. Once I arrived in Mexico, some of the study participants as well as some academics that I spoke with during the events that I attended warned me that it was going to be almost impossible to be able to interview any of the Titular Representatives because according to them, these people were on a high pedestal, sitting in a lordly posture, dizzy with power, and very unapproachable. The academics

that I met, including the two that participated in this study, also mentioned how difficult it has been for them to approach Titular Representatives to ask for authorization to conduct research at the institutions that they lead, especially at the institutions that T2, MedCom-2, T5, MedCom-5, T7, and MedCom-7 represent. However, it was not until I was trying to deliver a letter in person for T7, and MedCom-7, inviting them to participate in my study, that I was able to understand this difficulty in approaching them. My experience trying to make contact with them showed me how power can use violence and intimidation, to distance itself from anybody who wants to question it. The day before I delivered the invitation letters for T-7 and MedCom-7, I called their institution to check if I needed some type of authorization to enter the building, since this institution is one of the two most guarded ones I visited. During this phone call, I was told where to find MedCom-7 and how I could get into the area where this person works. According to the instructions that I received, all that I needed to do to access this area was to register at the entrance door. I expressed some concerns to the person who answered my phone call about how easy he/she said it was to access the building. However, this person, assuming that my research was part of a clinical trial conducted by the pharmaceutical industry, tried to diffuse my concerns by telling me that I should not be worried about access because every day many pharmaceutical representatives go up and down the building without any complications. I clarified to him/her that I was not a pharmaceutical representative, but a PhD student conducting the research for my dissertation, and he/she told me that the same freedom of access applied for me.

The next day, after I followed the instructions that this person gave me, I was able to access the building where I was supposed to be able to find MedCom-7. However, once in the building, I was mistaken for a reporter by one of the nurses who, in a very threatening way, asked me to go with her to the director's office. When we arrived at the office of the director of that specific area that I was visiting, the director questioned my presence in the building and asked one of his/her colleagues to "investigate my case". I noticed that the person who was assigned to do this had some level of authority within the institution because of the way people referred to him/her. Using this authority, he/she started screaming at me in a very threatening, intimidating, and violent way, using a military tone, and repeating over and over: "Shut up, do not respond to me" every time when I tried to justify my presence there. Fortunately, I had written down the name of the person who I had spoken to over the phone the day before, so I was able to prove that I was not trespassing any boundaries. However, the violent behaviour of this person continued and now it was also against the

person who gave me the instructions about how to access the building. In order to make sure that I understood his/her power, the director of this area gave instructions to look for that person saying “punish him/her for the offence that this person made by granting her access into the building”. This person was even questioning why my tone of voice was at the same level as his/hers. However, things started to change when I told him/her that since my university in Canada was aware that I was visiting his/her institution to conduct my research, I was going to call the director of my PhD program so he/she could be informed of the violation that I had made, if there was any. Even though this person was aware that I was a PhD student conducting my research for my dissertation, because that was all that he/she allowed me to say when he/she initially questioned my presence in his/her institution, he/she did not know that I was not a student from one of the universities in Mexico. Once I asked for the intervention of the director of my program at York University in Canada, this person started treating me differently. His/her violent behaviour changed to a more relaxed one, although still sarcastic. Using this sarcastic attitude, he/she walked me not only out of the building, but of the institution. Once he/she kindly walked me outside, on the sidewalk of the street, he/she extended his/her hand to shake mine and told me “Welcome to Mexico”. Although I was able to recruit MedCom-7 through MedCom-3 when I conducted snowball sampling, unfortunately, I could never get in touch with T-7. The level of intimidation that I experienced might also be suppressing dissent by some of the people involved in the selection process of the NEML who might be uncomfortable with the decisions that their superiors make with respect to the drugs included in this list.

This is the last section of my results; my discussion will start in the following chapter.

Chapter 4: Discussion

Up until now the regulation that standardizes the selection process of the Mexican National Essential Medicines List (NEML) was the only source available that described how the Mexican government selects the Essential Medicines (EM) that are included in this list. My grounded theory study allowed me to apply both a deductive approach to explore the selection process with the study participants, and an inductive one to identify several patterns in the process that helped me to outline a theory grounded in my data. As shown in my previous chapters, I entered into the world of both the government officials who choose this list and a group of knowledgeable people familiar with it, to better understand how the Mexican NEML is constructed. By entering into their worlds, I was able to learn unknown aspects of the process, not specified in the regulation, that explain how this list is selected in practice. These unknown aspects of the process became an important piece in the development of the theory that answers my research question of “how do Mexican government officials select their National Essential Medicines List?” This theory emerged during my coding phase when, after a deep and thorough analysis of my interviews, observations, and field notes, I was able to identify the recurrent presence of three main concepts: 1) power, 2) domination, and 3) ambiguity.

The concept of power became evident in my transcripts, field notes, and observations when codes such as economic power, political power, knowledge power, lack of power, soft power, hard power, legitimate power, institutional power, power asymmetries, and judicial power, among others shown in Appendix B, recurrently appeared in my data. These codes ultimately collapsed in two types of power that summarize the forms of power present in the selection of this list: 1) hard power, and 2) soft power. Hard power was linked to a pattern of “domination” that also became visible in my transcripts, field notes, and observations when codes such as “salaries” “job opportunities”, “high turnover rate”, “exploitation”, “precarious jobs”, “threats”, “repression”, “control of information”, “lack of freedom of the press”, “lack of training”, “coercion”, among other codes also specified in Appendix B, recurrently appeared during my coding phase. As for soft power, it was connected to the legitimacy claimed in the regulation that the Mexican government has established to standardize the selection process of its NEML. As shown in my results, this regulation legitimizes the selection of this list as inclusive, representative, and based on rational scientific evidence, when, in practice, the selection of this list is a very political process that is far from being inclusive, representative, and rational. This regulation plays an important role in establishing not only who has the

power, granted by the state, to participate in the selection of this list and who does not, but also how people will use that power to conduct their actions and interactions while participating in this process. Unfortunately, as shown in my results, the ambiguity with which the regulation was written does not allow the reader to clearly understand who really is involved in this process and how the EM are selected. In fact, the concept of “ambiguity” became the third main concept identified during my coding phase when several procedural steps that the study participants cited from the regulation were codified as “ambiguous”.

The three concepts discussed above made evident several discrepancies between what the regulation says about the process and what the study participants described. These discrepancies exposed several contradictions between the resources that the government specifies in its regulation and the actual resources available to select this list. It is important to note that none of these contradictions could have been identified only by reading the regulation because they are hidden not only in the ambiguity of the regulation, but also in the environment of power and domination in which the NEML is selected. The three concepts of power, domination, and ambiguity helped me to identify the theme of “contradiction” as the central phenomenon of my study.

Even though there is a tendency to link “contradiction” to something that is discrepant, inconsistent, or in opposition, the discussion of my results will go beyond a simple identification of the inconsistencies found in the selection of this list or even of the opposing statements identified among study participants. The pattern of contradictions found in my data is consistent with a more sociological meaning of contradiction that includes a praxis approach to social action, suggested in Giddens’ structuration theory (1979). This praxis approach connects contradiction, power, and domination, with human agency or “action”, as Giddens also calls it. According to Giddens, human agency is what gives people the capacity not only to act independently and make choices, but also to identify contradictions and resolve them. The theme of contradiction is considered by Giddens a source of dynamism where actors involved can either stabilize a situation or transform it. Giddens argues that when contradiction emerges to the surface and meets with conflict it acquires a “transformative capacity” that can convert passive “actors”, involved in the contradiction, into mobilized change “agents” who can act to resolve such a contradiction and transform the world. However, despite the capacity that people have to identify contradictions, Giddens believes that contradictions cannot easily be uncovered because power tries to dissipate them, via domination, by controlling rules and resources

that restrict human agency. In fact, he defines contradiction as “an opposition or disjunction of structural principles (rules and resources) of social systems, where those principles operate in terms of each other but at the same time contravene one another” (Giddens, 1979, p. 141).

Giddens’ theory, as the technical framework that supports my theory, became one of those sensitizing concepts that in qualitative research give the researcher a general sense of reference and guidance in approaching empirical cases. The connection that Giddens makes between contradiction, power, domination, and human agency helped me to become sensitized to the three main concepts that emerged in my data. By becoming sensitized to these concepts, I was able to outline the theory that answers my research question of “how do Mexican government officials select their National Essential Medicines List?” As will be discussed in this chapter, the theory that I propose suggests that the Mexican government selects the NEML in a very political environment, surrounded by many contradictions that power prevents from becoming evident because it controls the “discursive consciousness” of the government officials who select the list and the Mexican population, through the regulation that standardizes the process and the allocation of material and human resources. As will be fully explained in the following section, discursive consciousness involves the knowledge which actors are able to express on the level of discourse.

I organized this chapter into two sections that will allow me to further explain this theory that frames my results. The first one will discuss the power that the regulation has as a tool of domination that hides the contradictions that surround the selection of this list. The second section will relate my results to three structures of domination through which power dissipates contradictions. These three mechanisms are: 1) opacity of action, 2) regionalization, and 3) direct repression.

I. The Power of the Regulation

Even though, as mentioned before, my intention has never been to analyze the regulation that standardizes the selection process of this list, this regulation, although with a different connotation, keeps appearing in majority of my chapters. In my first chapter, I referred to it as a “reference point” or “sensitizing concept” that helped me to become sensitized to the main concepts involved in the selection of this list. In the third chapter, I described it as a document that included many deviations from what study participants say and do in practice. In this fourth chapter, in which I am outlining a theory that integrates my results, this regulation has acquired a sociological meaning, as a tool that “power” is using to restrict human agency and

prevent contradictions from coming to the surface and become noticeable. As shown in my results, the regulation legitimizes the selection process of the NEML as inclusive and representative when, in fact, there are power asymmetries that restrict representation and do not allow full participation. For example, even though it lists the names of the public health institutions that participate in the selection process of the NEML, it does not specify that these institutions have been chosen based on their economic power to purchase medicines. This regulation does not mention either that the interests of the vulnerable sectors of the population (such as women, children, people from different regions of the country, and the poor) whose institutions cannot buy medicines are not included at the decision-making table. It also fails to mention that although it lists “Secretaria de Salud”, the institution that represents the uninsured, as one of the institutions that participates in the selection of the NEML, this institution is represented by the health regulatory agency in all the meetings, despite the fact that the regulatory agency is not listed in the regulation as one of the participants. Even though the regulation also mentions the presence of a citizens’ representative, as my results showed, in practice, this citizen representative turned out to be an employee of the pharmaceutical industry. Unfortunately, the ambiguity and lack of clarity with which the regulation describes who is in charge of selecting the NEML does not allow the reader to clearly identify who has been granted the power to be part of this process and on what basis. It is interesting that even though “Essential Medicines” are defined as those that satisfy the priority health care needs of the population (WHO, 2015), the Mexican population has not been granted the power, by the state, to participate and decide what Essential Medicines should be included in the NEML.

According to Giddens, human agency can only exist when people have the capability of intervening or not intervening in events or situations to influence their course. He argues that when people have absolutely no power to intervene, such as is the case of the Mexican population, they cease to be human agents who cannot influence decisions, act independently, and make free choices, but also cannot identify and resolve contradictions. The case that I described in my results about the dental varnish that was included in the NEML shows how power interferes with the human agency of the population and its capacity to identify contradictions. The fact that the government did not consult about the inclusion of this dental varnish with the rural population where it was distributed, meant that these regions were not given an opportunity to decide if this dental varnish was essential for them. In an ideal world, the intervention by the population may have

helped the government to construct a stronger list and optimize its use of economic resources by only listing medicines that meet the priority health needs of its population. However, in practice, as my results showed, the intervention of the population seems to be a barrier that potentially interferes with the apparent promise that the government made to the industry about looking for ways to distribute its products through social programs and therefore the general population is not allowed to participate.

Unfortunately, the interest of the pharmaceutical industry in economic profit has turned the selection of the NEML into a very political process that ignores the real purpose of meeting the health needs of the population through the medicines that are included in this list. As my results showed, the power involved in the selection process of this list has ignored the inclusion of truly “Essential Medicines” as well as the opinions of the entire population, especially of those who cannot afford to buy them. It also has ignored the voice of the people who, by paying an insurance premium to receive healthcare services from the public health system, give the five public health institutions that participate in the selection process of this list the economic power to buy medicines. It is important to note that both the population that is insured by the public health system and the uninsured represent 97% of the population who depend on the NEML. Out of this 97%, 46.2% live below the poverty line and therefore do not have money to buy even the most Essential Medicines. Only the remaining 3% of Mexicans have access to private insurance and therefore, do not depend on the NEML. As mentioned in my introduction, a NEML is intended to assist low-and middle-income countries to maximize the quantity of drugs they are able to procure with their limited budgets by buying, at the lowest possible prices, only those drugs that are truly essential (Klug, 2008). However, the fact that the uninsured do not have representation at the decision-making table means that they cannot remind the government that it should not waste its resources on inefficiencies or through corruption that, according to ExMinister-1, exists in the medicines purchasing phase. The distinction at the decision making table between the insured who can buy medicines and the uninsured who cannot afford them, turns the NEML into a formulary list that is not concerned with achieving equitable access to medicines, as a NEML should be, but with the economic profits generated from the insurance premiums that the insured pay for their coverage.

The power asymmetries that exist in the selection process of this list and that are not clearly identified in the regulation also include the presence of a weak selection team that lacks the power that comes from knowledge to conduct both the clinical and pharmacoeconomic evaluations. My results showed that the

current selection team has enough skills, knowledge, and experience to help the government to legitimize the selection process of its NEML as rational and scientific-based, but not enough knowledge “power” to interfere, through their human agency, with the many political and economic interests that are behind the Mexican NEML. The objectives established by the Mexican government in its regulation, in theory, support a rational selection of medicines that guarantee that only efficacious, safe, and cost-effective medicines that meet the priority health needs of the population are included in its NEML. However, in practice, not only are the health needs of the population not being heard, but also the inclusion of safe, effective, and cost-effective medicines in this list is in doubt because the Mexican government does not allocate the appropriate human and material resources that can support a rational selection of medicines.

It is important to mention that the World Health Organization (WHO) has written a set of recommendations to help low- and middle-income governments to appoint a committee to give technical advice on the selection of EM so these governments can guarantee a rational selection of medicines (WHO, 2002). However, although these recommendations suggest that this committee may include people from different fields such as medicine, nursing, pharmacology, pharmacy, public health and consumer affairs who can contribute from their different backgrounds to the selection of the NEML, neither the person in charge of selecting the committee members, nor the skills, the level of education, and the work experience that each member should have are specified by the WHO. As my results showed, this lack of precise information about the backgrounds that the people who select this list should have is also not clear in the regulation either. It would be of great help for somebody to establish the minimum requirements for the people who participate in the selection of this type of list.

As my results showed, in addition to the unclear backgrounds of the people who participate in the selection of Essential Medicines, the regulation fails to specify several aspects of the process that can guarantee a rational selection of medicines. For example, even though it mentions that the cost-effectiveness of drugs will be determined by the evaluation of pharmacoeconomic studies conducted by experts, it does not say that the industry and the government should have people qualified enough in pharmacoeconomics to conduct the pharmacoeconomic studies or evaluate them. It does not mention either that the technical reviewers should have the power to access the clinical information that they need to conduct the clinical evaluations even though access to this information is protected by national agreements such as the Federal

Law on Transparency and Access to Public Information, the Industrial Property Law, the Federal Law of the Workers at the Service of the State, and the Federal Law of the Administrative Responsibilities of Public Servants. The regulation does not specify either the role that the health regulatory agency plays in deciding what can be included and excluded from this list. In fact, as mentioned before, the name of this agency is not even mentioned in the regulation. One further area not dealt with by the regulation, which has to do with the disempowerment of the reviewers, is that the pharmaceutical industry should not be able to force government officials to constantly re-evaluate their applications. As my results show, the updating process of the NEML is triggered not by the health needs of the population, or by the government, but by the economic needs of the pharmaceutical industry that wants its products to be included in this list. One final thing absent from the regulation is that the human agency of the reviewers should be respected through the allocation of sufficient material resources, such as the time needed to perform the evaluations within a regular work schedule, and with adequate salaries, as well as the appropriate training to conduct the technical evaluations. As my results showed, currently the evaluations are being performed during the free time that the reviewers have outside their full-time jobs without providing them with any additional compensation. As for the training of the technical reviewers, since the training that they require is not specified in any of the articles of this regulation, on many occasions, it is provided by the industry. All these aspects not stipulated in the regulation are contradictions between the resources that the government establishes in its regulation and the actual resources available that emerged in my study.

As mentioned before, it is difficult for people like me, who are not part of the selection process of this list, to illuminate the contradictions through reading this ambiguous regulation that fails to reflect the actual process that the people who select the NEML follow. In fact, this is why MedCom-9, instead of describing the actual process, asked me to go and read the regulation. As it will be shown in the following sections, the reaction of MedCom-9 is very normal for people in power, since they try to avoid letting other people uncover the contradictions removing the possibility that they can eventually get resolved. People should not just cite norms or appeal to them to justify actions as a way to avoid the responsibility and accountability for their actions. However, as my theory suggests, it is not easy for the government officials to uncover contradictions because people in power do not only control the process described in the regulation, but also the resources that prevent them from sharing what they know through their discursive consciousness.

In the following section, I will discuss three mechanisms of domination that dissipate contradictions so they cannot emerge to the surface, become noticeable, and get resolved: 1) opacity of action, and 2) dispersion of contradictions through regionalization, and 3) direct repression.

II. Mechanisms of Domination that Dissipate Contradictions

1) Opacity of Action and the Capacity of Actors to Uncover Contradictions

Giddens argues that it is not easy to penetrate into contradictions because power tries to dissipate them via domination by controlling rules and resources that restrict human agency. According to Giddens, since action is constituted via the accountability of practices, there is no way in which the conditions of action can be wholly opaque to actors because they know the rules and resources within which their conduct is carried out. He refers to the term “opacity” as “the low degree of penetration by actors of the conditions of their actions and its involvement in the reproduction of social systems” (Giddens, 1979, p. 144). Giddens thinks that even though actors, if asked, can give accounts of the circumstances of their action, their accounts will not exhaust what they know about why they act as they do, because not all the tacit knowledge, (the knowledge they have gained by routinely producing and reproducing the process) can be articulated in discourse. He makes reference to several elements that interfere with the low degree of penetration into contradictions that he relates to opacity of action. These elements include tacit knowledge, reflexivity, practical consciousness, unconsciousness, and repression. According to him, tacit knowledge is not always articulated in discourse because, since it is learned daily through our actions and interactions, we usually take it for granted and do not verbalize it when somebody asks us to express our routinized rational actions.

Polanyi (1966) thinks that actors who know something tacitly are not always aware of the knowledge they possess or how it can be valuable to others, usually leaving important aspects of what they know out of what they say. I was able to see how tacit knowledge limits the capacity of actors to uncover contradictions when I asked MedCom-3 to explain the selection process of the NEML and this participant initially entirely described it in five minutes. His/her short description did not have anything to do with a lack of willingness, or a lack of transparency, but more with the fact that it was the first time that somebody had asked him/her to describe “what he/she knew” about the process that he/she routinely produces and reproduces, and “why he/she acts as he/she does” during this process. Based on Giddens’ theory, this participant was not aware of the knowledge that he/she possesses and how it could be of value to others and considered many of his/her

actions and interactions irrelevant. However, after I asked him/her to expand on specific aspects of the process that he/she had initially described, he/she was able to share his/her tacit knowledge. Although MedCom-1 was the only participant who mentioned that it was the first time that somebody asked him/her about what he/she does, contrary to MedCom-3, he/she was able to identify how his/her knowledge was valuable to others and started explaining the process in detail from the beginning.

Giddens uses the term “practical consciousness” to refer to all the things that actors know tacitly about social conditions, especially about the conditions of their own actions that are not articulated in discourse because they are not being asked to explain them. Consciousness, according to Giddens, is described as the capacity to give a coherent account of one’s activities and reasons. He thinks that actors can achieve consciousness through reflexive monitoring of their conduct. As my results showed, based on the capacity that actors have to reflect, there are actors who are more conscious than others. Giddens believes that it is the actor’s awareness of the structure (rules and resources), expressed in their practical consciousness, what is considered the core of their “knowledgeability”, that connects them to their capacity to transform things, and not their theoretical knowledge per se. This means, for example, that the theoretical knowledge in pharmacoeconomics, that people who are involved with the pharmacoeconomic evaluations claim to have, is not what will improve the selection process of this list, but the practical consciousness of this people that makes them aware of the limitations of their knowledge. Giddens also introduces the concept of discursive consciousness and explains that while practical consciousness involves what actors know tacitly about the conditions of their own actions, discursive consciousness includes what actors are able to share about these conditions with other people. It is important to note that being discursively conscious does not mean that actors will say what they know in public, since their practical consciousness is what sets the limits of what is appropriate for public disclosure. As my results showed, there were cases where participants did not feel comfortable sharing what they know in front of a tape recorder or inside their own institutions and had to look for zones where they felt more comfortable. These zones will be later discussed in the section that describes the concept of regionalization.

However, according to Giddens, not all reasons for action are found at a conscious level. He also makes reference to “unconscious” conditions of action. For Giddens being “unconsciously aware” does not mean to have lost consciousness, but being able to articulate in discourse only a fragment of what the actor

knows. He thinks that the “unconscious” refers to modes of recall to which the agent does not have direct access to because there is a negative bar, centred in repression, inhibiting not only discursive formulation, but also reflective monitoring of his/her conduct. Repression inhibits people’s rational understanding of their own conduct and thereby the capability of communicating with others. This repression, according to Giddens, is what separates or muddles the reasons that explain why people act as they do, as well as what they are inclined to or able to say about those reasons to other people. This bar of repression does not exist between practical consciousness and discursive consciousness. For Giddens, practical consciousness involves recall to which the agent has access during action without being able to express what he or she thereby knows. However, while in practical consciousness an actor, if asked, will be capable of transforming his or her practical consciousness into discursive consciousness, in the unconscious, this actor will not be able to verbalize what he/she knows, unless he/she distorts it to the point that it is no longer completely true and accurate in order to be able to share it.

According to Giddens, “opacity of action” varies between the ruling class and the rest of the population. The ruling class for Giddens is the class which has the means of material production at its disposal and at the same time has control over the means of mental production. He thinks that the ideas of the ruling class are the ruling ideas in every epoch. While the ruling class will attempt to stabilize contradictions, by denying them, the rest of the population who do not belong to this class might try to resolve contradictions by bringing them to the surface in discursive consciousness. In my study, I was able to identify a pattern that shows that the participants with a higher degree of authority and power were not able to uncover contradictions that exist in the selection process of the Mexican NEML, while the ones with less authority power were. These two patterns will be described in the following two subsections.

a) The Degree in which Participants in Higher Authority Positions were able to Uncover Contradictions.

Giddens considers human beings “purposive agents” who have reasons for their activities, and are able, if asked, to elaborate discursively upon those reasons. The rationalization of action, which includes the capabilities of human agents to explain why they act the way they do by giving reasons for their conduct, is, according to Giddens, a normal characteristic of the behaviour of competent social agents and the main basis upon which their competence can be considered by others. However, in my study, the people in high authority

positions did not show any interest in, or disposition to show their competency or share how they act and interact during the selection process of the NEML. Based on Giddens's theory, it is expected that when people who belong to the ruling class are asked how they act, they explain their actions and interactions either by sharing fragments of what they know, or distorting what they know in order to be able to share it; this did not happen in my study. However, in my study, since the majority of the Titular Representatives in charge of selecting the list, who could be considered members of the ruling class, did not reply to my invitation, I was not able to ask them how they act and interact while selecting the list, and therefore they did not have to find themselves in need of explaining or justifying their actions and interactions. It was interesting that the majority of the Titular Representatives did not even provide a written response in answer to my invitation and say that they refused to participate in my study.

However, it is important to note that of the two Titular Representatives who accepted to participate in my study (T-4 and T-8), T-8 initially had ignored my invitation, and only reconsidered it, after somebody with a higher political power than him/her asked him/her to grant me the interview. As for T-4, even though he/she was the only Titular who voluntarily accepted my invitation, he/she not only assigned a substitute for the interview who was accompanied by a minute taker, but also was the only participant who requested the questions in advance. Although the substitute was very knowledgeable about the selection process, this person will never be able to explain how T-4 acts and interacts in this process because the substitute is only accountable for his/her own actions. He/she might have been able to convey the message that T-4 entrusted him/her to communicate, with statements such as: *"As T-4 says, without innovations, we cannot have generics"*. However, when I asked this substitute why, if T-4's concern was to make generics available to the population, they granted those innovations patents for 20 years, this participant answered that he/she was not aware of this time-frame. As for T-8, as my results show, his/her message was characterized by denying contradictions; this participant shared distorted fragments of what he/she knows about the selection process of this list. In fact, his/her struggle to deny things made him/her the only study participant who contradicted himself/herself during the interview, which affected the credibility of his/her statements. For example, at the beginning of the interview, he/she said: *"Nobody pressures us, anybody can say whatever they want; we know the decisions are well grounded. We say to the industry blatantly that their applications did not proceed"*. However, minutes later, this participant made evident the pressure that exists from the pharmaceutical

industry when he/she said *“the pressure from the laboratories and manufacturers is not a matter of one tablet, but of millions of tablets”*.

It is important to note that the Titular Representatives, in addition of being in charge of selecting the NEML, are leaders of the public health institutions they represent. Their role as leaders of state agencies, according to Giddens, is to be in charge of monitoring the way processes are reproduced with the intention of minimizing any type of conflict that might otherwise break out without their intervention. Taking this responsibility into consideration, the nine Titular Representatives, who are in charge of selecting the NEML, will never be able to share what they know and reveal the deficiencies of the process as well as the challenges, and the obstacles they face while selecting this list. Because, if they share what they know, the system could be disrupted and they have not been put in charge of state agencies to disrupt the system, but to maintain the working of the system even in the presence of contradictions. Although they might be aware of all the contradictions that surround the system, it is more convenient for them to ignore them because if they admit them, they will have to do something about them. According to Giddens, the routines that actors follow to perform their actions give them a sense of “ontological security” which can be understood as a sense of order and continuity in regard to ordinary day to day life. Ontological security is maintained by the predictability of routine, since routine is psychologically linked to the minimization of unconscious sources of activity. Radical disruption of routine practices is associated with anxiety and fear. Therefore, actors prefer to follow activities routinely rather than face anxiety by reflecting on their actions and interactions. The Titular Representatives are strategic actors who follow the rules established by the person who granted them the power they hold, the President of Mexico. As mentioned in my Introduction, according to Abrantes (1997), Valdez (2000), and Arredondo (2001), the Mexican president has unrestricted authority over legislative and judiciary powers. This power makes him not only the principal legislator, but also the person who can fire governors, municipal presidents as well as state and federal legislators, and leaders of state agencies such as the Titular Representatives. According to them, the constitutional authority that the Mexican president enjoys has made him one of the most powerful leaders of any democracy. However, Sidjansky (1973) believes that even though government decisions might appear to be the output of parliaments or presidents, many are merely endorsements of decisions already made both inside and outside the country by groups that hold political and economic power.

The interview with MedCom-9 is another example of how the participants in higher authority positions try to avoid disrupting the system and bringing contradictions to the surface. Although this participant is not a Titular Representative, he/she has a lot of political power, as the person who leads the Medicines Committee. As shown in my results, in addition to his/her political power, MedCom-9 has a reputation as an expert in pharmacoeconomics. Both his/her political power and reputation put him/her in the position of being able to penetrate the structure in ways that the others members of the Medicines Committee cannot. Although, as described in my results, this participant did not want to continue with the interview, the message that he/she was able to articulate during the 20 minutes that his/her interview lasted, was similar to that of T-8, also characterized by a tendency to cover things up and deny contradictions. For example, he/she described the people who participate in the selection of the NEML as “*a competent multidisciplinary team of physicians, economists, and biomedical scientists*”, while several members of the Medicines Committee said the opposite. The fact that after asking him/her to describe the process, he/she told me to go and read the regulation because according to him/her, “*there are not different versions, but only one and that is in the regulation*”, clearly shows not only his/her effort to avoid allowing me to identify contradictions, but also that he/she was not willing to share publicly what he/she knows. MedCom-9’s responses to my questions and requests were also characterized by saying a lot without revealing very much. Based on Giddens theory, his/her reactions to the interview can be interpreted in several ways. One is that although this participant may be discursively conscious of the contradictions that surround the selection of this list, he/she rationally decided not to directly disclose any information that might disrupt his/her routine and jeopardize his/her job and ontological security. The negative bar, centred in repression that Giddens relates to the unconsciousness may be preventing MedCom-9 from sharing what he/she knows about the selection of the NEML. Another theoretical possibility is that this participant may have entered into the reflective monitoring of his/her actions during the interview and decided to stop it because reflexivity could have interfered with three important things: 1) the prestige of his/her institution, 2) the image of the competence of the team that he/she described, and 3) the reputation that he/she has as a national expert in pharmacoeconomics. It may be more convenient for this participant to repress contradictions that he/she might be aware off, and pretend that the group he/she leads is doing a good job with the selection of medicines, than to uncover the contradictions that might show the opposite.

In addition to MedCom-9, T-4's substitute, T-8, I also interviewed one more participant who also had higher political power, but belonged to the group of "outsiders", ExMin-1. During the 30 minutes that this participant granted me for the interview, he/she was able to explain structural aspects related to the selection of Essential Medicines that were not discussed by any of the other participants. Among these structural aspects was the concept of "social values" that he/she related to the approval of oral contraceptives. However, despite the fact that none of the other participants mentioned this concept in their interviews, the concept emerged during my coding phase as something that currently is being ignored in the production and reproduction of the selection process of this list. As mentioned before, the recent reform of the regulation left the institutions that protect the "social values" of the most vulnerable sectors of the population, out of the selection process, especially those who are opposed to things such as the use of oral contraceptives. According to Giddens, a feature of political discourse includes the need to sustain legitimacy through the claim that the interests of the community are being represented. It is a bit difficult to understand how the interests and "social values" of the population have been taken into consideration, if the population has always been ignored in the selection of this list. Although ExMin-1 was able to deliver a message in the 30 minutes that he/she granted me for the interview, there was no time for asking questions, since when I was about to start asking them, we ran out of time and the interview had to be concluded. The fact that the people in higher authority positions refused to talk, either by stopping the interviews, sending substitutes, or by not granting the time for the interview that is requested, follows the pattern described by Giddens that shows that people who lead state agencies have a tendency to deny and dissipate contradictions. However, as will be shown in the following section, the study participants who have less authority power followed a different pattern. Although there were some who denied contradictions, there were others who brought them to the surface and attempted to rationalize them.

b) The Degree to which Participants with Less Authority Power were able to Identify Contradictions

Contrary to the lack of interest and willingness that the participants in higher authority positions showed in sharing how they select the NEML and explaining their actions and interactions during the selection process of this list, the study participants with less power were not only interested, but also willing to explain how they participate in this process. This group of participants with less power included the

members of the Medicines Committee and the Permanent Guests, who are active members of the process, as well as the Ex-members of this Committee and the Academics who are part of the group of outsiders. With the exception of MedCom-9, none of these participants was encouraged to participate by their bosses or by people with higher political power, as was the case with T-8 and the Titular Representative's substitute who participated in my study. The interest of these members was manifested not only in their positive responses to my invitation, but also in the effort that some of them made to facilitate the recruitment of more participants by helping me to get in touch with some of their colleagues. However, it is important to note that despite their positive disposition, I could not have recruited any of these members of the Medicines Committee if it had not been for the snowball sampling technique that I implemented after I realized that the contact information for these members was not available on any of the governmental websites or on the internet. As will be discussed in the following section, the absence of their contact information makes it difficult to get in touch with them and learn about what they do. As explained in Chapter Two, I could not get in touch with two of these members, not even through the snowball sampling technique. I even tried to recruit them through their Titular Representatives, but, since these Titular Representatives were not interested in participating in my study, they might have not extended my interview request to these two members of the Medicines Committee who represent their institutions.

The interest of these members with less authority power was also shown in their flexibility to accommodate the interviews and find a place to meet. Although as mentioned in Chapter Two, the majority of the interviews were in a conference room, in their offices, or workstations, there was one that took place in a cafeteria due to the difficulty for me to get a permit to access the building where the participant had his/her office. There was also one study participant, MedCom-7, who granted me an interview despite being overwhelmed by the full-time job that he/she has in the public health institution that he/she represents. The interview took place in a common area where this participant had his/her desk full of piles of documents that he/she was reviewing, at the same time that he/she was answering my questions. By common area, I refer to an area not separated by cubicles or offices where several desks are located. Contrary to what I expected, despite MedCom-7's visible excessive work load, this participant did not show any type of opposition or discomfort about having to work for free for the Council and the industry as the technical reviewer of their applications, in addition to his/her demanding full-time job. On the contrary, this participant was the only one

who expressed that it was very gratifying to be able to vote as a Medicines Committee member and to be one of the decision-makers who participate in the selection of the NEML. The other members of the Medicines Committee did also not express any discomfort with having to do the technical evaluations in addition to their full-time jobs and with no additional salary.

According to Giddens, the capacity that actors have to reflect on their actions and interactions plays an important role in the identification of contradictions. However, the fact that majority of the members of the Medicines Committee combine the selection of the NEML with their full-time jobs, does not leave them much time for reflection. According to Giddens, the reflective monitoring of actions is usually carried out at the conscious level when actors transform their tacit knowledge into practical consciousness, and only partly at the discursive level. As my results show, several study participants with less authority power found space to reflect on their actions and interactions during the interviews while they were sharing what they know about the process. These reflections allowed them to uncover some contradictions that exist in the selection of this list which they had not noticed before. For example, ExMedCom-A initially could not see the contradiction that exists between Article 27 that specifies who can submit an application for inclusion, exclusion, and modification of a product in the NEML, and Article 28 that establishes the requirements for the submission of those applications. However, after reflecting on the content of these two articles, he/she was able to identify a contradiction that shows that even though Article 27 says that anybody can submit an application, only the pharmaceutical industry can meet the requirements established in Article 28. It is important to note that while this participant identified this contradiction during the interview, PG-6 was already aware of the contradiction that existed between these two articles. *“It does not matter that the regulation says that anybody can submit an application to the General Health Council to include, modify, or exclude a medicine from the NEML because, in practice, nobody has the resources to do it, but the pharmaceutical industry”*. My results show more examples that illustrate the different consciousness levels of the study participants and how some of them shared and rationalized more contradictions than others.

Although the majority of the government officials, with lower authority power, were able to rationalize and uncover contradictions that were related to their lack of training, the biased selection of the people who participate in the selection of this list, the biased backgrounds of their bosses and colleagues, and the lack of salaries, there were some who could not uncover these contradictions. There were also some other

contradictions, such as the ones involved with the inequitable access to medicines, that the fragmented health care system and the NEML itself promote that were not uncovered by the majority of these members. There are several theoretical interpretations that can explain why some of the participants with lower authority power did not comment on topics such as their lack of proper training, the lack of competency of the members who participate in this process, or the inequity involved with this list. One of these interpretations is related to the participants' ontological security, since some of these participants, similar to the group of participants with higher authority power, may be repressing themselves for fear of losing their jobs or their credibility and not being able to uncover contradictions. Another reason why the participants with lower authority power may not have shared all they know about this process may be related to their opacity of action, or the degree to which they are able to penetrate into contradictions. According to Giddens, there is no way in which the conditions of action can be wholly opaque to actors who produce and reproduce a process. However, the fact that in Mexico's fragmented health care system, the technical evaluations are performed individually by each public health institution that participates in this process, may be interfering with what each of the members of the Medicines Committee know about the selection of this list. In the next section that explains the concept of regionalization, I will expand more on how the fragmentation of the health care system contributes to the dissipation of contradictions.

According to Giddens, opacity of action depends on the access that actors have to knowledge by virtue of their social location. Social location is considered the place that individuals occupy within the community based on their position (i.e., technical reviewers, directors of public health institutions, academics, etc.) and on other different features such as gender, race, education, socio-economic status, etc. As my results showed, the social location of each of the study participants with less authority power determines what they know about the selection of this list. Some of these participants are granted access to circles of power where they can have access to restricted information, while others are excluded from these circles. For example, the study participant, who knew about the withdrawal of MedCom-3 and MedCom-6 days before their withdrawal was publicly announced, was granted access to information that other participants did not know about, including MedCom-3 and MedCom-6. These two participants only learned about their withdrawal the day when the Council announced it.

However, the majority of the members of the Medicines Committee do not have access to information that is only discussed in the circles of power where the Titular Representatives, who are not willing to talk, meet. In fact, there was one participant, MedCom-1, who answered one of my question saying: *“I really do not know the reason. Sometimes there are things that one ignores, things that have to do with decisions that come from above”*. Unfortunately, the social location of the study participants with less authority power does not allow them to be in contact with the Titular Representatives of their institutions who are in charge of selecting this list. This lack of communication between them limits even more their access to knowledge and therefore the degree in which these actors can identify, uncover, and resolve contradictions.

Another example of how social location influences access to knowledge and the capacity to uncover contradictions can be seen with the two academics who participated in my study. The social location of these two participants does not only expose them to knowledge that the other participants may ignore, but also allows them to say things that other participants might not be able to say because of their social location, even if they had the knowledge. For example, while the two academics recognized that there are not experts in pharmacoeconomics involved in selecting this list, a couple of members of the Medicines Committee claimed that some of their colleagues are experts in pharmacoeconomics. Although these members of the Medicines Committee may be aware that there are no experts, it is not their job to reveal this information, according to the social location they occupy. The revelation of this information could jeopardize their ontological security, so it may be more convenient to ignore this type of information and continue performing their routines in the presence of many contradictions. As my results show, the members of the Medicines Committee have been performing the pharmacoeconomic evaluations for many years in their own institutions without the appropriate training in pharmacoeconomics.

However, despite the difference that exists between the social location of academics and government officials, my study shows how difficult it is not only for the academics, but also for the general population to get access to the circles of power that control the selection of this list. For example, in my previous chapter, it was shown how the academics have restricted access to certain forums because apparently the government does not want to touch topics that may be controversial for it, such as the topic of pharmacoeconomics. Several times, I also experienced restricted access to places that have the potential for revealing contradictions. One time was when I was threatened and removed from one of the public health institutions

that I visited. Another time was when the participants with positions of higher power that I interviewed decided to end the interviews perhaps to avoid me identifying contradictions. The Titular Representatives also automatically denied me access to their circles of power by ignoring my invitation to participate in my study. However, not only were the Titular Representatives careful about opening the doors to those circles, but this also occurred with the General Health Council that did not reply to my request to attend one of the monthly meetings where the members of the Medicines Committee meet. Giddens makes reference to a process called “regionalization” to explain how power establishes boundaries and walls to disperse contradictions and avoid people identifying, uncovering, and resolving them. This process will be discussed next.

1) The Dispersal of Contradictions through Regionalization

The dispersal of contradictions is closely related to opacity of action, since the greater the dispersal of contradictions the less the tendency for any people who have identified contradictions to become a mobilized change agent who can share and resolve them. According to Giddens (1984), when there is a fusion or overlap of contradictions, contradictions have a greater probability of coinciding with conflict and therefore of being noticed and getting resolved. He thinks that the possibility of conflict is weakened to the degree to which contradictions are kept separate from one another. Giddens links the dispersal, diffusion, or segmentation of contradictions to the concept of regionalization which he defines as the establishment of boundaries that define a region either physically or symbolically. As it will be shown in this section, there are three ways of regionalization that contribute to the dispersal of contradictions; a) regionalization by social class and territorial divisions, b) regionalization by positioning the actor in zones, c) regionalization through walls.

a) Regionalizing by Social Class and Territorial Divisions

According to Giddens there are three basic divisions that are regionalized in time and space: class, ethnic differentiation, and territorial claims. For him, regions within societies have cultural significance that can either cut across or can act to further class divisions. When regions further class divisions, such as what the regionalized fragmented Mexican healthcare system does, there is a greater probability that contradictions will meet with conflict, if contradictions are not dissipated. As my results show, the selection process of the NEML has been regionalized by including only the capital of the country and ignoring the remaining 32

States in which the country is divided. This process has been regionalized even more by including only the voice of five public health institutions from this region and leaving the voices of the rest of the population out of the decision-making table.

In this system of representation, there is no way that the government officials who are assigned as representatives of these five public health institutions can defend the interest of the population, as the population itself would do through public consultation. For example, as my results showed, even though all the study participants who represent these public health institutions were conscious of having a fragmented healthcare system, many did not see the inequities involved with this fragmentation. For them, the differences in access to medicines that exist between the institutions who have more money to buy expensive medicines and even innovations and the ones that do not have these resources were described as natural and legitimate. One of the participants even said in my previous chapter, “...*We all understand that MedCom-7 has different needs than MedCom-4. How can we not support the different needs of each institution? We cannot say that we are not going to support MedCom-7 just because the other institutions cannot afford to buy the same medications*”. By allowing only five government officials to decide what medicines are included in the list, the government avoids the direct intervention of the population who could bring not only contradictions to the surface, but also create conflict in order to defend their own interests. Giddens believes that when regions have developed unevenly, there is more probability that the population that lives in those regions will identify the differences that exist between their regions and uncover many contradictions that could eventually overlap. The different ways in which the selection process of this list has been regionalized contribute to avoiding the overlapping of contradictions.

As my results show, since the government distributes the resources needed for the selection of this list and decides who gets what, there is a huge gap in budgetary distribution in the health sector that relates to the concept of uneven development suggested by Giddens. While institutions that represent the military, the navy, and the oil workers get more resources from the government and have a lower patient population, the institutions that provide services for the civil workers, formal private sector workers, retirees, and their dependents, and the uninsured get a more restricted budget and provide services for more patients. Although the distinctions that the fragmented health care system makes between classes are in contradiction to the purpose of the NEML of achieving equitable access to Essential Medicines for all, the contradiction of having

a NEML in a healthcare system that promotes class division, social exclusion, and health inequities will never be identified by an absent population. As mentioned before, this contradiction is not being identified by the members of the Medicines Committee, since each of them represent the different interests of this fragmented system. The fact that the members of this Committee perform their technical evaluations not as a team, but individually in their own institutions, is another way in which the selection of this list has been regionalized to avoid contradictions overlapping. This regionalization does not allow the members of the Medicines Committee to know how their colleagues perform the technical evaluations, and what guidelines, supports, and resources they have to perform the selection of this list. If the members of the Medicines Committee knew all these details, many contradictions that may be related to the uneven development of their institutions may come to the surface. This could create an overlapping of contradictions that regionalization is trying to avoid by isolating the members of the Committee. Giddens makes reference to the “positioning of actors” in zones as another form of regionalizing the process and dispersing contradictions. This form of regionalization will be discussed next, including the relationship that exists between regionalization and the back zone.

b) The Positioning of the Actors in Front and Back Zones

According to Giddens, actors, who participate in social encounters, such as the ones involved in the selection of the NEML, are usually positioned in two different zones: the front and the back. While in the front zone there is a tendency to cover up information, in the back zone information is more prone to be disclosed. The front zone includes frontal aspects of regionalization that are inherently inauthentic because what is real or substantial is hidden. However, the back zone, according to Giddens, is a place that gives actors the opportunity for reflection that both the powerful and less powerful actors can use to keep a distance between their own interpretations of social processes and those mandated by official norms. Giddens believes that back regions are zones within which agents can recover forms of autonomy which are compromised or treated in frontal contexts where information cannot be disclosed. However, since as mentioned before, the members of the Medicines Committee are isolated from one another when they perform the technical evaluations, due to the regionalization of the selection process, they have no back zone where they can informally meet with their colleagues to share and exchange information, or reflect on their actions and interactions. In fact, the reason I could not get in touch with two of the Medicines Committee members, during my snowball recruitment process, was because none of the other members of this committee had a

close relationship with them so as to be able to refer me to these two Committee members. However, despite the differences between the front and the back zones, according to Giddens, both zones are under surveillance and controlled through sanctions imposed upon actors whose commitment to the norm is marginal or nonexistent.

As for the Titular Representatives, as my results suggest, as the leaders of the public health institutions that they represent, they maintained themselves at all times in the front zone during their interactions with me. These participants seemed to be more concerned about maintaining their prestige by keeping conflict away of their institutions, rather than on reflecting upon their actions, interactions, and decisions. According to Giddens, even though actors in the front zone have a tendency to cover up and hide contradictions from their audience, they are motivated by it and want to impress it. As my results showed, the Titular Representatives only followed this pattern of impressing their audience when it came to the industry. However, as an “outsider” who should not know the hidden secrets, I also was part of their audience. Unfortunately, they did not show any interest in impressing a population that is absent from this process, or the members of the Medicines Committee and academics who these Titular Representatives conveniently ignore.

The fact that the government equates transparency with dialogue with the industry and not with civilian society or their subordinates makes it easier for these Titular Representatives to hide information from the population and to be disconnected from their own staff and real experts who could provide good technical advice. If the Titular Representatives did not just visit the facilities of the pharmaceutical industry to dialogue with them and keep them updated about the selection process of the NEML, as was shown in my results, but also visited the offices or workstations of their subordinates who are involved in the technical reviews, and were open to a dialogue with the population, including the academics, these representatives would be aware of other needs, rather than just the profit needs of the industry. However, being aware of other needs could disrupt the ontological security of the Titular Representatives and, for this reason, these Representatives may prefer to ignore them.

Although as mentioned before, the Medicines Committee members cannot not go to the back zone with their colleagues to informally talk with them and share secrets and reflections, some of the members of this Committee were able to go to the back region with me. In this region, they reflected on their own actions

as well as on the actions of the people they interact with. From this zone, they were able to recover their autonomy, that Giddens believes is compromised or treated in front regions where information cannot be disclosed, and share information behind the scenes. As shown in my results, there were different ways in which the Medicines Committee members took me backstage. One of them was by telling me things that only a few people knew, such as the withdrawal of MedCom-3 and MedCom-6. Another way was when participants knew it was inappropriate to share certain things with me, but they did it anyway either whispering, waiting until the tape recorder was off, or using phrases such as “*here among us*”. There were also some participants such as PG-6, who may have shared what they knew about the process with me with the hope that this information would create some change in the system. As for the Titular Representatives, since they considered me part of the audience whom secrets should be hidden from, the majority of them, by not granting me an interview, chose not to share any information with me. As shown in my results, the participants in higher authority positions also preferred to stop the interviews rather than going to the back region where they could reflect on their actions, identify contradictions and recover their autonomy to be able to connect with the real purpose of this list. The fact that the Titular Representatives keep themselves, at all times, in the front zone is taking away from them the opportunity to connect with the real needs of the population. As Wei Cheng, quoted by Tse Tung (1967 p.p. 344) says, “Listen to both sides and you will be enlightened, heed only one side and you will be benighted.” A rational selection of medicines that guarantees that the medicines included in this list meet the healthcare needs of the population will not be a reality until both sides can be heard. As will be shown in the following section, there are several walls that demarcate regionalization which contribute to the positioning of actors into these two zones. These walls are another way to dissipate contradictions.

c) Walls that Demarcate Regionalization

According to Giddens, walls between rooms are another way to demarcate regions. These walls in my study were represented in many different ways, from closed doors that prevented anyone from seeing what was behind them to figurative walls that prevent people from seeing through. However, although many of these walls have already been discussed in the previous sections such as the closed doors of the Titular Representatives’ offices; the walls that the government established between the public and the members of the Medicines Committee by not listing their contact information anywhere online; and the walls that promote

class divisions and inequity, there is one invisible wall represented by the absence of a National Drug Policy (NDP) that I will discuss in this section. As mentioned in my introduction, a NDP could allow the Mexican government to set and prioritize medium and long-term goals for the pharmaceutical sector that promote equitable access to EM by controlling the import, local production, sale, and distribution of drugs and biologicals. Through this type of policy, governments can also consider economic goals such as increasing the national pharmaceutical production capacity that allows the government to be more independent from the medicines that the pharmaceutical industry produces, at the same time as offering some other advantages such jobs and the spin-off effects for the economy of the nation. A strong NDP could help the government to balance the two powers that the industry has: 1) the power of control over investment; and 2) the power to direct and supervise the labour process itself (Isaac, 1987). The lack of this policy seems to be contributing to the generation of more contradictions.

The establishment of a NDP depends on the capacity of the state to regulate the private for-profit pharmaceutical industry and enforce quality assurance. However, as mentioned in my Introduction, there are cultural and historical factors as well as government political values and choices that affect the establishment of this policy and that act, in turn, as a wall to the development of a good NEML. As my results showed, the political values of the current conservative administration have a tendency to lean towards the interest of the upper class and the business sector. This preference is reflected in all the reforms that this administration has been making, not only to the regulation that standardizes the selection process, but also to the Mexican Constitution. These reformed policies and regulations support the interests of the industry in deregulation. This support explains why the NDP has not moved beyond the negotiations described in my results by Academic-2 and ExMin-1, the two participants who identified the contradictions involved in selecting a NEML in the absence of a NDP. It is very unfortunate that the power of the current administration has to be understood in terms of domination, conflict, and contradictions to explain the selection of a NEML whose objective is to achieve health equity. Rather, it would be much more preferable to view the power of the current administration as the capacity that the Mexican government has to use both its material and human resources towards the construction of policies that guarantee a rational selection of its NEML. I will explain in the following section, the role that direct repression, threats, and coercion play in Giddens' theory and how they connect to my results.

1) Direct Repression

As mentioned before, Giddens makes reference to a negative bar, centred in repression that inhibits people's understanding of their own conduct and thereby the ability to communicate with others. This inhibition involved with repression is linked to anxiety and fear. Giddens (1984) makes reference to the concept of "direct repression" and explains that it involves the use of force or the threat of its use to prevent active struggle from emerging. He believes that the use of force is normally taken as a way to express that a conflict is occurring, while the threat of its use may serve to prevent sources of opposition from emerging. In my study some participants described how the pharmaceutical industry has threatened not only the government, but also experts and patients to prevent opposition and conflict from emerging. According to the study participants, the industry usually saves its threats for occasions when it cannot reach agreement with the government during the plenary sessions of the Commission. Although neither T-8 nor MedCom-9 wanted to talk about law suits, some of the participants said that the industry on several occasions has sued the General Health Council. According to the two academics who participated in my study, the pressure from this industry gets extended to experts, who despite their knowledge are not granted a voice and vote in this selection process. Considering Giddens' definition of direct repression, since there is no conflict involved in the selection of this list, either between the people who select the list or between the government and the industry, there has not been a need to use force to prevent active struggle from emerging. However, as my results suggests, repression seems to be used to block the consciousness of actors, inhibiting their capacity to talk and share what they know. Giddens believes that since repression blocks the consciousness of actors, there is little to say about direct repression.

Even though the study participants did not want to expand on this topic, there were some signs of possible repression that were identified in my field notes. According to these notes, there were participants who lowered the volume of their voice while they were talking about controversial issues such as the pressure that the pharmaceutical industry exerts on the government or that during Christmas time, there is a parade of gifts turning up in the office of the Titular Representative of his/her institution. There were also cases when participants had to look for alternative ways to explain important aspects of the process that they could have explained more directly if they were not fearful of being punished for sharing what they know. One more sign of possible repression was identified when participants made clear that they could not share specific

information because only their lawyers were familiar with it. It is unfortunate that repression not only prevents government officials involved in the selection of this list from sharing what they know about this list, but also a whole nation from truly enjoying the social benefits of a well-selected NEML. The following and last chapter includes the conclusion of my study.

Chapter 5: Conclusion

This grounded theory study allowed me to bridge the gap in knowledge that existed between the normative process outlined by the Mexican government in the regulation that standardizes the selection process of its NEML and the process described by the government officials who participate in the selection of this list. In the process of bridging this gap, I was able to outline a theory that, grounded in my empirical data, answers my research question of “How do Mexican government officials select their National Essential Medicines List (NEML)?” According to this theory the Mexican government selects its NEML in a very political environment, surrounded by many contradictions that cannot be easily uncovered either by the government officials who select this list or the Mexican population because power controls, via domination, the “discursive consciousness” of these two actors. As mentioned before, discursive consciousness involves the knowledge which actors are able to express on the level of discourse (Giddens, 1979, p. 5). This theory emerged from the analysis of the data that I collected in the field. As described in my methodology, I conducted 17 interviews with 12 out of the 31 government officials who participate in the selection of this list, and a group of 5 people knowledgeable and familiar with this process. These interviews are complemented with the information that I learned by being physically present in Mexico interviewing the study participants, during a very particular historical moment in which the Mexican government announced the most recent reform made to the regulation that standardizes the selection of this list, and other important political changes described in Chapter 3. The theory that I propose has several implications for theory as well as implications for practice that I will describe in this chapter along with some recommendations and the limitations of my study. These sections will be described after I briefly summarize my findings in the following section.

Summary of Findings

As described in my previous chapters, the regulation became an important piece of my study despite the fact that my intention was not to compare the process described in it with the one shared by the study participants, but to explain how the Mexican government officials select their country’s NEML. My findings showed how this regulation, as well as the human and material resources that the Mexican government has assigned for this process, instead of being used to increase the government’s capacity to select a strong NEML, are being used as tools of domination that help to dissipate and hide the contradictions that surround the selection of this list. For example, instead of assigning a strong selection team whose members can apply

their knowledge, skills, and experience to uncover and resolve the contradictions that do not allow a rational selection of medicines that guarantee the inclusion only of safe, effective, and cost-effective medicines that meet the priority health needs of the population, the government has chosen people with no real knowledge power to perform the selection of medicines.

As shown in my Chapter 3, the selection of the people who are in charge of putting together this list, including the nine members of the Commission, the Medicines Committee members, and the few experts that participate in the selection of this list is very political, based not on their competency, but, according to one participant, on “compadrazgo”, a term in Spanish used to express a buddy-buddy relationship, camaraderie, and godfatherhood. My study showed that the Titular Representatives who are part of the Commission, as leaders of the public health institutions that participate in this process, are not only assigned to be in charge of selecting the NEML, but also of monitoring the way the process is reproduced. For this reason, these Titular Representatives will never be able to share what they know about the selection of this list with other people, including the Members of the Medicines Committee who are their subordinates, the population, and people like me who are interested in learning how they act and interact while selecting the list. Their unwillingness to share what they know was reflected in their unwillingness to participate in my study.

I would like to emphasize that since the contact information of the Medicines Committee members is not available in any of the governmental websites or the internet, it is difficult to get in touch with them without passing the filter of the General Health Council or the Titular Representatives who are in charge of keeping conflict away from this process. As my study showed, the General Health Council refused to share their contact information with me or to deliver my invitations to these members, arguing that this information was confidential information. Since the Titular Representatives were willing to participate in my study, they may not have extended my invitation to the members of the Medicines Committee. If it was not for the snowball sampling technique that I implemented to recruit these participants, I would never have had the opportunity of getting in touch with them and learning about the contradictions they experience, as the technical reviewers who cast their votes and, in theory, decide what medicines are included in the NEML. However, even though the members of the Medicines Committee were more willing to share what they know about this process than the participants with higher authority power, they will never be able to uncover all the

contradictions that surround the selection of the NEML because they may not have access to information that is only known by the participants with more power.

However, according to my study, power does not only control what people who participate in the selection of this list can share about the process, but also what the population could say about this list if they were allowed to participate in this process. The absence of the population in the selection of this list denies it the opportunity of becoming aware of the decisions that are being made by the government and influencing them, as the pharmaceutical industry does. By being present, the population would not only be able to identify, and uncover contradictions as some of the government officials do, but also to create conflict until these contradictions get resolved. However, although the selection of the NEML should be based on the health needs of the population, my study showed that it is the industry that triggers the update process of the NEML through all the applications that it voluntarily submits to the General Health Council and not the health needs of the population. Considering that Essential Medicines are defined as those that meet the priority health needs of the population (WHO, 2002), the medicines that the government of Mexico selects, by ignoring the health needs of the population and listening only to the economic needs of the industry, cannot be considered “Essential”. Unfortunately when policy-making intersects with politics, decisions are always surrounded by competing political interests. These interests may be interfering with the normative goal that the Mexican government has of protecting the right to health of its population through the selection of a strong and effective NEML. Even though it is expected that the Mexican government should base the selection of its NEML on rational decisions, as my results showed, the foundation upon which its decisions is being made is not rationality, but rather the reflection of many political and economic interests. As mentioned in my Introduction, the WHO (2002) believes that “lists that are imposed from above will never be able to meet the needs of the population”.

However, my study shows how power is interfering with a good selection of this list, by controlling both the people who can participate in the process and the material resources that are necessary for the selection of this list, such as salaries, jobs, time, knowledge, and training. The fact that the government does not provide appropriate training and does not invest in increasing the skills and knowledge of the government officials who select this list, also interferes with the capacity to identify, uncover, resolve contradictions, and undertake a good selection of medicines. The time that these government officials have to perform the

evaluations also interferes with their capacity. As my results showed, currently the evaluations are being performed during the free time that the reviewers have outside their full-time jobs. Their required work schedule does not give them enough time to reflect on their actions and interactions and gain the practical consciousness that allows them to share what they know about the selection of this list. My study also showed that although the Medicines Committee members were able to uncover some contradictions, power does not permit them to resolve them. In fact, the contradictions that they shared were followed by a feeling of powerlessness and resignation. Unfortunately, despite the effort that the members of the Medicines Committee, who perform the technical evaluations, make in selecting a strong and effective NEML, the rules and resources assigned by the Mexican government for the selection of this list, including the training of these members, cannot guarantee the selection of safe, effective, and cost-effective medicines that meet the priority health needs of the Mexican population.

Implications for Theory

While looking for the theory that was congruent with my results and explained why both the government officials who select the NEML and the population, who should be one of the main stakeholders in this selection process, cannot uncover contradictions, I reviewed Mao Tse-tung's theory of contradiction (1937). In this theory Tse-tung, makes reference to the conflictive side of contradictions that suggests that antagonistic/conflictive contradictions cannot be resolved unless they assume the form of open antagonism and develop into revolution. However, my results did not show any type of conflict that could lead to revolution because power does not allow the government officials involved in this process and the population to act in their own interests and create conflict. There is no need to use violence or force to prevent active struggle from emerging because hard power is being used, via domination, to dissipate any type of contradictions that could create conflict, by controlling salaries, job opportunities, information, freedom of the press, knowledge, training, and by exploiting people through precarious jobs, via domination. The regulation is also a way in which soft power is exerted to avoid active struggle and conflict.

I also reviewed regulatory capture theory (Carpenter, 2013). However, even though this theory offers an alternative explanation for the behaviour of the government officials who participate in the selection of this list, it is not fully congruent with my results. This theory focuses on how health regulatory agencies can be captured by the industry, but does not explain the behaviour of leaders of state agencies who can modify

regulations without being part of the health regulatory agency. Regulatory capture theory does not describe either the behaviour of those who are not in charge of enacting rules, such as the technical members of the Medicines Committee or the Mexican population.

I also considered the ideas of some of the authors that I mentioned in my Introduction such as Rapoport (1994) and Wang'ombre (1987). However, my interest was not in testing a hypothesis taken from existing research, but to develop a theory grounded in both my empirical data and a theoretical framework. Wang'ombre suggests that low- and middle-income countries do not have the knowledge or the technical capability to select drugs that meet the safety, efficacy, and quality standards that satisfy the priority health needs of their population. However, as shown in my previous chapters, my findings do not coincide with his idea, since the theory that I propose suggests that it is not that a middle-income country like Mexico lacks people with the knowledge or the technical capability to perform a rational selection of medicines, but that power may be controlling the knowledge of these people and other resources that are needed to carry out a good selection of medicines. This control of knowledge is, according to my theory, one of the ways in which power may be interfering with the capacity that the government officials who select this list have to uncover contradictions. As for Rapoport (1994), he suggests that governments share the majority of their decisions through normative regulations that describe how certain processes should be undertaken. However, he believes that processes that describe how decisions are actually made and how real actors behave are not shared with the population. In the case of the Mexican government, my study allowed me to bridge the gap of knowledge that exists between the process that the government specifies in its regulation and the actual process described by the government officials who participated in my study. By bridging this gap, I learned that the government only shares the selection process of its NEML with industry and not with the population because it equates transparency with dialogue with the industry and not with civilian society.

However, Giddens' structuration theory (1979) proposes concepts that are consistent with my empirical data. These concepts offer new ways of explaining why NEMLs do not reflect and satisfy the needs of the population, without presuming that actors are always acting in fully rational ways. It is difficult for actors to act rationally in a system that does not support a rational selection of medicines. Giddens' theoretical framework, allowed me to show how rational actors can produce irrational outcomes and sustain legitimacy through the claim that the interests of the community are being represented, and how an irrational system can

be resilient in resolving contradictions and making changes. The connection that Giddens makes between power and human agency or action, and the notion of discursive consciousness that he describes in his concept of opacity of action, helped me to identify a connection between the “authority power” of the study participants and their capacity to reveal contradictions. This connection, which has not been discussed in the existing literature, became a fundamental part of my theory.

In the process of finding this theoretical framework that identified with my empirical data and helped me to outline my theory, I realized that it is very unfortunate that the concept of power, repetitively present in my data, has to be understood in terms of domination, conflict, revolutions, and contradictions. The selection of a NEML that is intended to achieve health equity should not have to be explained in these terms, but as the capacity that the Mexican government has to use both its material and human resources towards a good selection of its NEML. However, since the majority of the research done in relationship to the theme of Essential Medicines has been focused on the rational use of these medicines or on comparing the content of NEMLs, the relationships between these lists and power has not been considered. I will show in the following section the implications that my theory has for practice.

Implications for Practice

The implications that my theory has for practice involve not only the Mexican population, but also the government officials who select this list, the academics, the state and the WHO. For the Mexican population my study bridges the gap in knowledge that existed between the normative process described in the regulation and the descriptive one usually not shared with them. The theory that I propose shows the important role that the population plays in ensuring that Mexico really has a NEML that meets its priority health needs, and not a list that is imposed from above. While the population continues to be ignored, the Mexican government will not be able to claim that its NEML is being selected rationally based on the health needs of its population.

The implications that my study has for the Titular Representatives in charge of selecting this list are several. My findings will show these Representatives how the walls that they have created, not only between them and the population, but also between them and the members of the Medicines Committee, interfere with a rational selection of medicines. They will be able to see that these walls are not letting them become aware of both the health needs of the population and the training needs and concerns of the members of the

Medicines Committee who try hard to put together a list with the limited resources that they have. These Representatives might also be able to realize two features of the current process. First, that the regulation that they develop and reform continues to deny the contradictions that show that some of the people who perform the clinical and pharmacoeconomic evaluations do not have the appropriate background to conduct the safety, efficacy and cost-effectiveness evaluations of drugs. Second, the Mexican government will not be able to guarantee a rational selection of medicines. My findings might help create some awareness of the important role that the reflective monitoring of their actions and interaction plays in the selection of a strong and effective NEML that can ensure equitable access to medicines. They might also see that they have the potential for transforming from actors who dissipate contradictions to agents who can identify, uncover and, resolve them. My study might also help them to realize that, as shown in my previous chapter, there are more audiences beyond the pharmaceutical industry that are waiting to be impressed by their work, who will certainly appreciate and recognize their willingness to protect the health needs of the population, including the population itself.

As for the implications that my study has for the Medicines Committee, their members might also become aware of how important it is to reflect on their actions and interactions in order to be able to identify, uncover, and resolve the contradictions that are interfering with a good selection of medicines, especially the contradictions that have to do with their training. They could become aware that while the lack of knowledge in pharmacoeconomics is not recognized by the government and the pharmaceutical industry, not only they themselves, but also the industry will keep pretending that the selection of this list is being done rationally, based on the cost-effectiveness of medicines. My study might encourage these members to demand appropriate training, since this training will empower them so they can not only cast their votes, but also defend their decisions according to the technical evaluations that they will make with more conviction. My findings might also help these members to exert some pressure on the government so it can start charging the industry for the evaluations that the members of the Medicines Committee make so the government can have a larger budget for fair salaries and training of the members of the Medicines Committee.

For the academics, since they are not being heard by the government, my study might help them to remind the government that it has competent people whose skills, knowledge, and experience should not be wasted and replaced by less qualified people. It might also remind the government that in order to avoid

policy and politics intersecting, the knowledge and expertise that the academics have could replace that of the politicians who currently are in charge of selecting this list. My study will show the academics how the list is currently selected which might encourage them to find a place in the selection process of this list. My findings might also show the government that the academics are important players that can contribute to improving the training of the people involved in the selection of this list and that the academics should not be ignored in discussion forums. Last, but not least, my findings will also remind both the academics and the government that they need to work together in order for the government to be able to claim that its NEML is being selected by a team of experts.

For the state, my study might remind it of the responsibility that it has to protect and meet the health of its population through a good selection of its NEML. It might also remind it of the option that it has to develop a national pharmaceutical production capacity so it does not have to directly depend on the industry to meet the health needs of its population. My study might also remind the state that poor quality, unsafe, ineffective, and unnecessarily expensive medicines have a negative impact not only on the health of the population, but also on the national economy, since the selection of these types of drugs will never be able to help it to maximize its resources. My study might also remind the state that it is not enough to comply with international agreements and pretend that Mexico has a NEML that represents a rational selection of medicines as recommended by the WHO. Again, as the WHO suggests, lists that are imposed from above will not help it to protect the health needs of its population. Another important implication for the state includes the possibility that it can reflect on its actions and realize that it is wasting its human and material resources in inefficiencies. My study might also help the state to realize that, considering the social nature of this list, it is very unfortunate that its government officials have to select “Essential Medicines” in an environment of contradictions and domination that might not be intentional.

Last, but not least, my study also has some implications for the WHO, since, as mentioned in my Introduction, this organization makes some recommendations to help low- and middle-income governments to select their NEML (WHO, 2002). These recommendations include: 1) the appointment of a committee that gives technical advice on the selection of Essential Medicines, 2) that this committee organize consultations on scientific and technical advice with interests groups such as consumer organizations, the government finance ministry, and the pharmaceutical industry, and 3) that the selection of drugs on the NEML should be

the result of a consultative and transparent process where EMs are selected rationally. Similar to what the Mexican government describes in its regulation, the WHO suggest including people from different fields such as medicine, nursing, pharmacology, and pharmacy, public health, and consumer affairs. However, as my study showed, the lack of precise information about the backgrounds that the people who select this list should have, as well as who will be in charge of selecting them, are interfering with a rational selection of Essential Medicines. My study might help the WHO realize that it is important to establish the minimum requirements for the people who participate in the selection of this type of list to guarantee that countries will be able to undertake a rational selection of medicines. My study will also show the WHO how important it is for countries to understand the concept of transparency to be able to include in the selection process of the list not only the pharmaceutical industry, but the also the Mexican population. Last, but not least, my theory might make the WHO aware of how power is controlling the selection of Essential Medicines in a middle-income country like Mexico and might set the tone for more research in other low-and middle-income countries. The theory that I propose can also be tested by other researchers in Mexico.

Recommendations

Considering the possibility that the environment of domination that surrounds the selection of this list is not intentionally, but accidentally created by the lack of time that the Mexican government has for the reflective monitoring of its actions, I suggest the following points that can help, not only to ensure that the government officials who participate in the selection of this list can identify and uncover contradictions through their discursive consciousness, but also to avoid this list being selected in an environment of domination and contradiction.

- 1) As mentioned in my Introduction, in order to achieve a proper selection of Essential Medicines, the selection process of the NEML needs to be, as the WHO recommends, a transparent and consultative process that involves all the stakeholders, including the Mexican population.
- 2) The presence of the population needs to be real and not disguised as it turned out that the Citizen Representative mentioned in the regulation ended up being a representative of the pharmaceutical industry.
- 3) Both the members of the Commission in charge of selecting this list and the members of the Medicines Committee should be selected based on their knowledge, skills, and experience. A

strong team will help to ensure a rational selection of medicines that truly distinguishes “Essential Medicines” from “Non-Essential” ones.

- 4) The government officials who select the list should be empowered by the Mexican government with the appropriate training needed to perform the clinical and pharmacoeconomic evaluations.
- 5) In addition to the members of the Commission and the Committee, the government should select a group of experts, who should also attend the monthly meetings where the Medicines Committee members cast their votes and select the medicines that are included in the NEML. These experts should be national experts in their fields.
- 6) The updating process of the NEML should be triggered by the health needs of the population and not by the economic needs of the pharmaceutical industry. The government should not review the applications of the industry on a monthly basis, but only when its list needs to be updated to meet the health needs of its population.
- 7) The human agency of the reviewers should be respected through the allocation of sufficient material resources, such as the time needed to perform the evaluations within a regular work schedule, and adequate salaries and training.
- 8) The government should create some space for reflexivity, so the reviewers can reflect on their actions and interactions and constantly provide feedback to the General Health Council that leads the selection of the NEML, so the Council can resolve any possible contradictions that may emerge.
- 9) The technical reviewers should have the power to access the clinical information that they need to conduct the clinical evaluations even though this information is protected by the national agreements described in Article 53 of the regulation which includes: the Federal Law on Transparency and Access to Public Information, the Industrial Property Law, the Federal Law of the Workers at the Service of the State, and the Federal Law of the Administrative Responsibilities of Public Servants.
- 10) The regulation should clearly specify the role that each of the government officials involved in the selection of this list play, including the role that the health regulatory agency has in deciding what can be included and excluded from this list.

- 11) The regulation should be written in a very clear and concise way, avoiding jargon and the unclear definition of important concepts such as the definition of transparency discussed in Chapter 3.
- 12) The government should describe in more clearly the concept of transparency in its regulation, so that the government officials can understand the concept and be transparent not only with the industry, but also with the population.
- 13) The government should work on the formulation of a National Drug Policy (NDP) that promotes equitable access to Essential Medicines and the selection of good quality medicines by controlling the importation, local production, sale, and distribution of drugs and biologicals.
- 14) It is important that the government builds laboratories that support the national production capacity for medicines, so it does not have to depend on the industry and can have more room to regulate it.
- 15) In order to ensure equitable access to medicines, the government should also work on achieving a Universal Health Care system that does not regionalize the population by social classes.

It is important to consider that a rational selection of Essential Medicines will only be achieved when the Mexican government uses its power in a transformative capacity that lets it make good use of its resources and not as a tool of domination that makes its resources go to waste in inefficiencies. Last, but not least, I will describe in this chapter the limitations of my study and some recommendations for future research.

Limitations of the study

Considering that what people know varies according to their social location or what is the same, the place that an individual occupies within the community based on different features such as gender, race, education, socio-economic status, it was very unfortunate that I could not reach saturation with the group of Titular Representatives and the Ex-Health Ministers. As described in Chapter Two, the people who belong to these two groups were not willing or disposed to participate in my study. Even though, according to the concept of opacity of action discussed in my previous chapter, the Titular Representatives might have only shared fragments of what they know during their interviews, their participation was important, since they are the members in charge of selecting this list. However, it would be interesting to see if, with the recently elected liberal government, the recruitment rate of these two groups improves to the point of reaching saturation. Even though, I was able to reach saturation only with the group of people who belonged to the

technical members of the Medicines Committee when the conservative government was in power, recruiting the majority of these technical members was not easy, since the conservative government did not make the contact information of the technical members of the Medicines Committee available on any of the governmental websites or on the internet. This lack of information represents a significant limitation for anybody who would like to get in touch with them. Last, but not least, considering the qualitative and academic nature of my study, and the fact that the interviews were done in Spanish, another limitation was that I was the only person who read the transcripts and codified the information. The classification of my codes may include unconscious biases that may have affected the interpretation of my data.

Recommendations for Future Research

The majority of the studies that have been done about NEMs have focused on analyzing the content of the list and the rational use of the medicines, but not on how governments select these lists and make their decisions. It would be interesting to compare how various governments select their lists and see if there is a difference in their content, based on the processes that governments follow to select them. It would be also interesting to see if the selection process of these lists varies according to the economic power to purchase medicines of other countries and their government ideologies.

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Appendix A: Sample of Extracted Segments

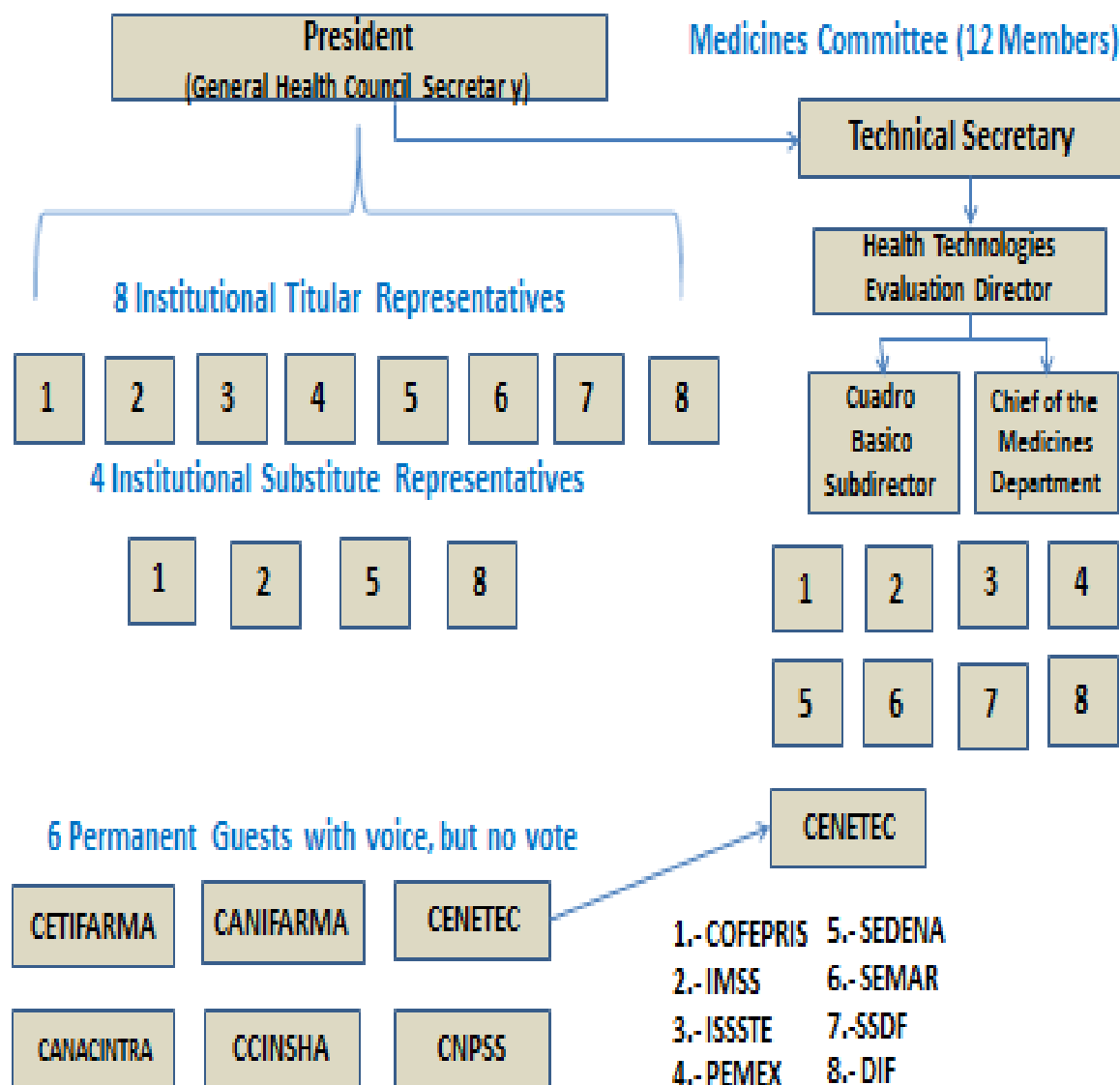
Codes	Extracted Segments
Fragmentation, Inequity, Inequality, Different Budgets	MedCom-5: El sistema de salud está fragmentado, cada institución tiene diferente presupuesto. En sistemas chiquitos se puede hacer medicina personalizada. "la familia pequeña vive mejor". En este tipo de instituciones hay indiferencia a que se vote a favor porque la toma de decisiones es en base económica y se politiza en lugar de verse el beneficio a la salud.
	T8: La población del IMSS es una población joven, El ISSSTE tiene una población de burócratas más viejos. Esta variación complica un poco la unificación del cuadro básico.
	MedCom-5: La fragmentación es un problema, eta en la misma propia secretaria. El registro sanitario es para la gente que no está asegurada y lo puede adquirir en una farmacia. Solo las instituciones deben comprar medicamentos con clave. El tener clave abarata los medicamentos. Una clave indica que son costo efectivo. Con algunas excepciones e pueden comprar medicamentos que no tengan clave. Al Ibuprofeno apenas el año pasado se le dio la clave. El ibuprofeno fue una inclusión del seguro popular.
	MedCom-4: Los medicamentos de patente se negocian desde el 2008 a través de la comisión coordinadora. La mayoría de las compañías han sostenido el precio de medicamentos.
	MedCom-4: Los estados compran variado y muchos más caro....(las compras consolidadas ayudan).
	MedCom-4: Se crea un menú de medicamentos con el cuadro básico de donde las instituciones pueden escoger.
	T8: Quien más compra es el IMSS, se hace una compra consolidada, también participan 24 gobiernos estatales. Esto ha ayudado a abatir los precios. Las cantidades que cada quien compra varían.
	MedCom-8: De acuerdo al artículo 50 del reglamento 2014, las instituciones públicas no pueden adquirir algo que este fuera del cuadro básico, pero cada institución decide que compra.
	MedCom-8: Se gastan 6 millones mensuales en Ecolizumab. En enfermedades de pobres que no saben lo que cuesta su medicamento.
Training, Skills, Profiles, Human Resources, Nepotism, Exploitation.	MedCom-5: El reglamento no incluye perfiles del puesto de los miembros del comité. A estos representantes los nombre cada institución y no hay perfiles de puesto. Se da mucho el compadrazgo y lo que implica la cultura mexicana.
	MedCom5: Cuando se cambian miembros, los nuevos que llegan no saben que es un análisis de costo-utilidad y quieren hacer estudios de calidad de vida. No saben que son los DALYS y QALYS.
	MedCom5: El mejor perfil seria que ya haya trabajado en clínica con formación administrativa. En el comité hay más administrativos que clínicos y se van más por lo económico. Es una frustración que todo esto está politizado.
	MedCom-5: Los miembros del comité no estamos solo enfocados a la selección, tenemos que trabajar en el consejo y trabajar en las instituciones a las que representamos en otras cosas. Entonces la revisión se hace en las noches y madrugadas. Este es un cargo honorifico. Cada dossier implica 4-5 desveladas.
	MedCom-5: Primero que nada, es muy gratificante ser un voto como tomador de decisiones. En lugar de ver una novela, me pongo a revisar los dossiers.

Appendix B: Initial Codes

Power	Domination	Ambiguity
Economic power	Control of Information	Disperse information
Legitimate power	Threats	Vagueness
Obedience	Coercion	Hidden Information
Institutional power	Repression	Incompatible practices and procedures
Hard power	Precarious jobs	Inconsistencies
Soft power	Labor exploitation	
Legal power	Lack of freedom of press	
Power asymmetries	Lack of training	
Knowledge power	High turnover rates	
Expert power	Low salaries	
Political power	Lack of monetary compensation	
The power of no taking action	Fragmentation	
Authority	Inequity	
The power of the population	Social stratification	
The power of innovation	Political struggle	
Prestige	Opposition	
Lack of power	Gatekeepers	
Divergent interests	Allies	
Delegated power	Subordination	
Constitutional power	Inaction	
Power of norms	Weak education system	
Decision-making power	Struggle for transparency	
The power of information	Class division	
Unilateral decisions	Uneven development	
Political struggle	Lawsuits	
Hierarchies	Imposition	
Judicial power	Lack of communication	
Military power	Constitutional reforms	
Nepotism	Job insecurity	
Power of the State		
Power of the Industry		
The power of pretending		
Conflict of interest		
The power of the regulation		

“Comisión Interinstitucional del Cuadro Básico”

(Commission in charge of the development, update and diffusion of the NEML)



Informed Consent Form

Study Name: The Selection Process of the Mexican National Essential Medicines List and the Views of Key Stakeholders on this Process.

Researchers: Mirna Romero, PhD Candidate in Health Policy and Equity, York University 4700 Keele St. Toronto, ON, M3J 1P3, Canada, mirna@yorku.ca

Purpose of the Research: The purpose of this study is to describe both the selection process that the Mexican government follows to select its National Essential Medicines Lists, and the views that Mexican physicians, pharmacists, ex-ministers of health, and some experts have about this list and its selection process.

What You Will Be Asked to Do in the Research: Each participant will be invited to participate in a one-hour open-ended interview. During this hour each participant will be asked to answer seven open-ended questions. The interviews will be conducted either in person, by telephone, or via Skype.

Risks and Discomforts: We do not foresee any risks or discomfort from your participation in the research.

Benefits of the Research and Benefits to You: There are no specific benefits that will be generated to you through your participation in this study.

Voluntary Participation: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the nature of your relationship with York University either now, or in the future.

Withdrawal from the Study: You can stop participating in the study at any time, for any reason, if you so decide. Your decision to stop participating, or to refuse to answer particular questions, will not affect your relationship with the researcher, or York University. In the event you withdraw from the study, all associated data collected will be immediately destroyed wherever possible.

Confidentiality: All information you supply during the research will be held in confidence. No names will appear in any report or publication of the research. You have the option of having your interview recorded or not. Your data will be safely stored in an encrypted format in a locked filing cabinet at York University Faculty of Health for seven years upon completion of the study. Only the researcher and faculty members of her supervisory committee will have access to this data. Any information that could identify any individual will be changed to ensure the anonymity of the participants. Confidentiality will be provided to the fullest extent possible by law.

Questions about the Research: If you have questions about the research in general or about your role in the study, please feel free to contact Mirna Romero by e-mail (mirna@yorku.ca) or Dr. Joel Lexchin (jlexchin@yorku.ca). This research has been reviewed and approved by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process or about your rights as a participant in the study, please contact the Sr. Manager & Policy Advisor for the Office of Research Ethics, 5th Floor, York Research Tower, York University (telephone 416-736-5914 or e-mail ore@yorku.ca).

Legal Rights and Signatures:

I (fill in your name here), consent to participate in the study entitled "The Selection Process of the Mexican National Essential Medicines List and the Views of Key Stakeholders on this Process" conducted by *Mirna Romero*. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form. My signature below indicates my consent.

Signature
Participant

Date

Signature

Date