Chapter 1
Chapter 1

Access to innovative and essential medicines has become a challenge to achieve comprehensive health coverage in both developed and developing countries, while at the same time maintaining the financial sustainability of the healthcare system. Universal Health Coverage (UHC) is defined as access to comprehensive health services. We use the concept of UHC as the main framework for access to healthcare, and thus medicines, for non-communicable diseases (NCDs), including cancer. Access to medicines, including innovative essential medicines, is not possible without a functioning health system. Ensuring access to innovative essential medicines, such as those for cancer, provides an additional challenge considering how complex cancer treatment and care is. In this thesis, we present the case of Mexico as an example of how a middle-income country addresses the challenges of providing access to innovative essential medicines, using cancer medicines as an example.

1.1. Universal health coverage and access to healthcare for non-communicable diseases – the case of cancer in low- and middle-income countries

Dr. Tedros Adhanom Ghebreyesus, Director General of the World Health Organization (WHO), once said: “Universal Health Coverage is a powerful tool not only for better health but for sustainable development”.1 UHC is defined as “access of all people to comprehensive health services at affordable cost and without financial hardship through protection against catastrophic health expenditures”.2 UHC seeks to ensure that governments provide access to healthcare and financial protection to their populations as part of the progressive realization of the right to health.2,3 UHC should be embedded within a functioning health system to provide a set of service packages that meet the basic healthcare needs of the population. Reaching UHC requires that governments, particularly in low- and middle-income countries (LMICs), strengthen their health systems to create the necessary infrastructure to ensure access to basic healthcare to all people and to prevent catastrophic expenditure.4

UHC can provide the basis of a health system through policies that promote quality, equality, and equity in access to healthcare, particularly for vulnerable groups.3 Under the principles of UHC, the health system should provide access
for all people to promotive, preventive, curative, rehabilitative and palliative health services.\textsuperscript{3,5} To achieve universal access to healthcare, health service packages and sustainable financing, adequate human resources and infrastructure, and affordable and accessible medicines and health technologies\textsuperscript{3} must be in place.

Through UHC, countries seek to provide their populations with a comprehensive package of services for all healthcare needs, from acute and infectious diseases to NCDs. While most LMICs still face health challenges related to infectious diseases, they also have to manage the increasing burden of NCDs.\textsuperscript{6} NCDs are now the primary burden of disease worldwide\textsuperscript{7} with the main diseases being cardiovascular diseases, respiratory diseases, diabetes, and cancers.\textsuperscript{8} The characteristics of NCDs pose a high burden on health systems because these diseases require control programs that include screening, prevention and lengthy, if not life-long, treatments. Therefore, it is important that health systems provide prevention and care for patients with NCDs, within the basic healthcare package.\textsuperscript{7} According to the WHO “the implementation of universal health coverage is a key to tackle the burden of NCDs.”\textsuperscript{9} UHC provides the fundamental platform to expand healthcare for NCDs, but NCDs also pose challenges such as expanded expenditure and more complex administrative demands.\textsuperscript{10}

Many middle-income countries (MICs) in Latin America (LATAM) and Asia have initiated structural and political health system reforms to increase health coverage to include NCDs.\textsuperscript{10-12} Asian countries such as Sri Lanka, Thailand, Vietnam, and China have made progress towards developing UHC systems.\textsuperscript{3,4,13,14} Many LATAM countries, such as Colombia, Brazil, Costa Rica, and Mexico,\textsuperscript{15-19} have implemented new public insurance schemes, have strengthened their health system financing, and have implemented decentralization and other mechanisms to provide comprehensive health coverage to vulnerable populations. Despite these achievements, these countries continue to face challenges to provide NCD care to the whole population while maintaining the financial sustainability of the system.\textsuperscript{16}

The increasing burden of NCDs in LMICs includes a rising burden of cancer.\textsuperscript{20} Globally, all types of cancer cause more deaths per year than HIV, TB, and malaria combined. In addition, cancer is the main cause of productivity loss.\textsuperscript{21} In LMICs, cancer incidence and mortality are rising due to poor prevention, late diagnosis, and poor treatment.\textsuperscript{20} Cancer exemplifies the complexities, inequalities,
and inequities in timely access to healthcare, and often causes catastrophic expenditures, particularly to households in LMICs with weak health systems.7,22

Even though LMICs bear almost 80% of the global burden of cancer, only 5% of global expenditure on cancer occurs in these countries.20 The challenges posed by cancer care and other NCDs in a low-resource setting are multifaceted: from preventive measures, changes in lifestyle and behavior, and programs for early detection, to the use of specialized technologies and personnel for early and accurate diagnoses, timely and comprehensive treatment and palliation. Strengthening the health system can lead to the improvement of access to healthcare and treatments for cancer. This could be achieved through national cancer programmes designed to support the health system in responding to cancer and other NCDs within the context and framework of UHC.20 National cancer programs should address all aspects of cancer care: prevention, detection, diagnosis, treatment, survivorship, and palliation.20,23,24 In addition, health systems must address general barriers to cancer care, such as limited infrastructure for detection, diagnosis, and treatment.25

A range of treatment options exists for the appropriate care and control of cancer: surgery, radiotherapy, and pharmaceutical treatment.20 The primary objectives of effective cancer treatment are “to cure, prolonging life, and improving the quality of life”, and they are linked to early diagnosis and standard clinical guidelines. Surgery, which is essential for the control and cure of solid tumors, requires clinical professionals and hospital infrastructure to guarantee favorable outcomes.27 Radiotherapy has become essential for the curative and palliative treatment of cancer.20 It is provided through specialized equipment (cobalt machines or linear accelerators), infrastructure, medical and nonmedical personnel (e.g. physics and technicians), and validated clinical protocols. LMICs face limitations in providing access to these types of treatment as these countries have few trained surgeons and limited capacity for radiotherapy.20,24 For effective care and control of cancer, surgery and radiotherapy must be available and included in any program and health coverage package to guarantee optimum health outcomes. However, this is currently far from reality in many LMICs.

Several essential medicines exist for effective pharmaceutical cancer treatment; these include chemotherapeutic agents, hormones and palliative care medicines.
Cancer medicines account for more than half of the total of cancer treatment costs, and even more for cancers mainly treated with chemotherapy. Most basic cancer medicines are off-patent and available in their generic form, which should facilitate their availability and affordability in LMICs. Nevertheless, barriers persist regarding their effective and timely access in LMICs, often leading to abandoned treatments and poor health outcomes. One such barrier is the high price of some essential cancer medicines as reported in LMICs in Africa, Asia, and LATAM. Besides resolving the issue of high prices, health systems and national cancer control programs need a comprehensive pharmaceutical system approach that includes standard treatment guidelines, a list of essential medicines and other health technologies for cancer, medicine price information, medicine price reduction strategies, reliable supply and procurement systems, as well as quality assurance.

It is possible to meet the challenges of cancer care in LMICs without undermining the investments in the control of other high burden diseases. In view of the rising prevalence of cancer and increasing popular demand for cancer care, it is necessary for governments to include basic cancer care in their health service packages, together with strengthened cancer control programs. Including basic cancer care and control in UHC should lead to better health systems, which in turn will support the control of other diseases.

1.2. Access to essential medicines and the case of innovative essential medicines

Safe, effective, quality and affordable essential medicines are critical tools for providing UHC. According to WHO, essential medicines are those that satisfy the priority health needs of the population. Within a health system, medicines are an essential component of adequate and comprehensive healthcare. Alongside lifestyle adjustments and vaccines, medicines represent tools for the prevention, treatment, decrease of mortality, increase in quality of life, and eradication of many diseases and health problems. Therefore, a well-functioning health system must ensure equitable access to essential medicines.
To realize UHC, health systems should achieve sustainable universal pharmaceutical coverage, balancing the quality of care, efficient resource allocation, and sustainable financing.\textsuperscript{31} In LMICs, pharmaceutical expenditure accounts for 20-60\% of the total health expenditure.\textsuperscript{33} Therefore, effective policies for essential medicines are central to the financial sustainability of any health system and the provision of timely access to care.

In order to optimize the use of resources and guarantee access to essential medicines, WHO recommends the implementation of a national Essential Medicines List (EML), using the global WHO Model List of Essential Medicines as a model.\textsuperscript{35,36} The WHO also recommends the development and implementation of a national pharmaceutical policy (NPP).\textsuperscript{30,31} An NPP is a governmental commitment to a goal and provides a framework to address all aspects related to the pharmaceutical sector. An NPP is necessary to deal with the various barriers that limit effective and timely access to essential medicines.\textsuperscript{31} Barriers may include out-of-pocket payments on medicines that induce catastrophic spending,\textsuperscript{34} irrational use of medicines, high costs, poor availability at supply facilities, inappropriate health systems, and substandard and falsified medicines.\textsuperscript{37,38} Policies should, therefore, include all key components to address these barriers\textsuperscript{30} and support health systems towards becoming more reliable and sustainable.

The universe of innovative medicines is dominated by patented medicines provided by research-based pharmaceutical companies.\textsuperscript{39} The research and development of new medicines represent 10-15\% of the budget of research-based pharmaceutical companies.\textsuperscript{40,41} Some new medicines offer safer, more acceptable and less invasive interventions\textsuperscript{3} that can improve patients’ health outcomes and quality of life.\textsuperscript{22} Such advances also include medicines to treat cancer.\textsuperscript{30,41,42} Some of these innovations have been designated as “breakthrough therapies” as they have demonstrated substantial improvement over standard treatment.\textsuperscript{44} Most of these breakthrough medicines are targeted therapies and biological agents. Some of these are more effective, provide better health outcomes and present fewer side effects than existing chemotherapeutic agents.\textsuperscript{40} Some innovative cancer medicines have become cornerstones for the treatment of advanced stages of cancer, and others have expanding indications.\textsuperscript{45} Some newer cancer medicines have recently been listed as essential medicines by WHO, which implies that they should become available and affordable to all who need them.\textsuperscript{46}
Little data exist on the prevalence and accessibility of innovative cancer medicines in emerging markets. Most innovative medicines are very highly priced, which is possible through the market monopoly provided by the patent system. In addition, in most cases, more than one medicine and therapeutic intervention are necessary to provide comprehensive cancer treatment, which further increases the costs of care. In LMICs and even in high-income countries, the high prices of innovative medicines now jeopardize the financial sustainability of health systems since limited resources need to be used efficiently to finance and guarantee access to essential medicines to all patients. Furthermore, the prices of innovative medicines are unaffordable for a large proportion of the world’s population, which contributes to and highlights inequities in access.

Affordability is a challenge to any health system striving to provide UHC. This is particularly relevant for MICs excluded from voluntary licensing agreements and other special pricing agreements (e.g. differential and tiered pricing, etc.) which are usually restricted to low-income countries (LIC). Therefore, a comprehensive NPP should include provisions to guarantee access to innovative and high-cost essential medicines, to improve their accessibility while protecting the financial sustainability of the health system and to improve the efficiency of healthcare delivery.

1.3. The health system and access to essential medicines in Mexico

Mexico has made progress to reach UHC and provide access to healthcare and services to progressively fulfill the right to health of all people. In 2004, these reforms led to the implementation of the People’s Health Insurance (Seguro Popular de Salud – SPS). The SPS has improved health conditions in the country, and citizens without social health insurance (SHI) have been able to access healthcare and medicines without incurring in catastrophic expenditures.

Despite the reforms in the national health system, access to health services in the country continues to be different for the public and private health sectors. Figure 1.1 presents an overview of the health system in Mexico. The public sector, covering close to 90% of the population, has several SHI (social security) schemes that provide comprehensive healthcare to their affiliates and their families. These
public schemes cover workers of the private sector (National Institute of Social Security – IMSS) and state workers (Institute of Social Security and Social Services of State Workers - ISSSTE). In addition, there are public SHI systems for the army (SEDENA), the navy (SEMAR) and the public national oil company (PEMEX). Each SHI scheme has its own management, health facilities and financing mechanism. These public SHI schemes are financed by contributions from the government, the employers and the employees (directly deducted from their salary). At the point of service, healthcare is provided at the SHI’s own facilities, and free of charge for those covered by the scheme.

The national Ministry of Health (MoH) and the state health services (state’s MoHs), through their health facilities, provide direct health services to the population without SHI and to the affiliates of SPS, which are mainly poor and vulnerable populations. SPS is a government insurance that reimburses health services to health institutions based on its “Universal Health Services Catalogue” (Catálogo Universal de Servicios de Salud – CAUSES), which covers 285 health interventions and 522 medicines; and through the Fund against Catastrophic Expenditure (Fondo the Protección contra Gastos Catastróficos – FPGC), which covers 59 health interventions. Particularly, the goal of the FPGC is the care of “catastrophic” diseases to prevent personal or family impoverishment caused by excessive out of pocket medical expenditure. This system covers a range of diseases with high treatment costs (e.g. HIV/AIDS, cancer, hepatitis C, etc.). In order to be reimbursed for the healthcare provided to SPS patients, health institutions must be accredited (i.e. guaranteeing that they have the resources and infrastructure to provide care according to SPS’s CAUSES and FPGC protocols and standards). The SPS is financed by federal and state government contributions and personal contributions from affiliates (based on their income level). Healthcare services are free of charge at the point of care for SPS patients. Patients without SPS coverage pay “recovery fees” or personal contributions, which is a type of co-payment based on their income level.

The private sector comprises several for-profit institutions and healthcare units with their own resources that provide health services directly to patients. This sector provides healthcare to less than 25% of the population who have the ability to pay for private insurances (less than 10% of the population) or pay for services out of pocket. Some of those covered by SHI institutions also use the private sector to get healthcare against direct payment or private insurances.
However, in recent years several private health facilities have been accredited by the SPS (now representing 17% of accredited units for healthcare provision, mainly for diseases covered by FPGC).\textsuperscript{59} SPS now reimburses these private institutions for treatments based on SPS protocols, guidelines, reference prices, and disease-based tabulators.\textsuperscript{59}

The differences between the private and public sector and the existence of different health institutions (SHI, MoH, and SPS) reflect the fragmentation of the health system in Mexico. This fragmentation has led to inequalities on access to healthcare, inefficiencies in the use of resources, and catastrophic expenditures for patients (particularly in the private sector).\textsuperscript{60-63}

Mexico is the second largest pharmaceutical market in LATAM. In 2012, pharmaceutical expenditure represented 1.7% of the gross domestic product (GDP), representing 28% of overall health expenditure.\textsuperscript{65} The Mexican pharmaceutical market is divided into the generic medicines market (including branded generic medicines), and the patented medicines market (usually labeled as “innovative”). Generic medicines represent 79.6% of the market volume, while patented medicines represent 20.4%.\textsuperscript{39}

Access to medicines is divided between the public and the private markets. The public market includes the procurement of medicines by the state and federal governments and the SHI institutions. Medicines are financed and procured like any other health service and are provided at no additional cost at the point of delivery to those covered by the public scheme. The private market responds to the demand of homes, hospitals, private insurances,\textsuperscript{39} and patients that did not get their medicines as part of the health services in the public sector. The private sector consists mainly of for-profit health facilities with their own institutional and retail pharmacies. In the private sector, medicines are financed directly by out-of-pocket payments and in some cases reimbursed and covered by private insurances according to their own policies.

In the public market, the government uses the national formulary, which is equivalent to a national EML. The national formulary defines the range of medical products for the public sector, from which the different public institutions select the medicines to be procured and made accessible at their health facilities.


**Figure 1.1. The Health System in Mexico**

<table>
<thead>
<tr>
<th>Sector</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Health Insurance (formal sector)</td>
<td>MoH (informal sector, unemployed)</td>
</tr>
<tr>
<td>Government, employee, employer</td>
<td>Government + personal contributions*</td>
</tr>
<tr>
<td>IMSS (private employees) ISSSTE (public employees) PEMEX, SEDENA, SEMAR</td>
<td>Personal contributions*</td>
</tr>
<tr>
<td>Institution’s hospitals, clinics, doctors, pharmacies</td>
<td>Seguro Popular (SPS)</td>
</tr>
<tr>
<td>Institutional lists (based on national formulary)</td>
<td>Non-SPS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Users</th>
<th>Informal sector employees, self-employed, unemployed, poor populations (43% popl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formal sector employees + their families (56% popl.)</td>
<td></td>
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<table>
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<tr>
<th>Providers</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoH hospitals, clinics, doctors, pharmacies</td>
<td>Private providers (for-profit hospitals, clinics and pharmacies)</td>
</tr>
<tr>
<td>SPS – according to CAUSES and FPGC coverage based on national formulary</td>
<td>All medicines with market authorization</td>
</tr>
<tr>
<td>Non-SPS – according to national formulary and each facility’s lists</td>
<td>Private insurances – own policies</td>
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<tr>
<th>Medicines</th>
<th>Population with ability to pay (approx. &lt;10% popl.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional lists (based on national formulary)</td>
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IMSS – Mexican Social Security Institute; ISSSTE - Civil Service Social Security and Services Institute; MoH – Ministry of Health; PEMEX – Mexican oil Company (Petróleos Mexicanos); SEDENA – Defense Ministry (army); SEMAR –Navy Ministry; SPS – People’s Health Insurance; CAUSES - Universal Health Services Catalogue; FPGC - Fund against Catastrophic Expenditure; popl. – Population; approx. - approximately.

* Personal contributions – a type of co-payment according to the level of income.
** The sum of the percentages is higher than the 100% of the population, because users may enjoy/use more than one health coverage scheme (e.g. IMSS + private sector user (paying out of pocket or through private insurance)).

Source: author’s based on Gomez-Dantes, González-Block, and INEGI.
The national formulary includes approximately 770 medicines (1300 products), of which approximately 95% are generic medicines (usually produced by several manufacturers) and the rest are patented products (usually produced by a single manufacturer or the patent holder). The term “generic medicines” includes pure generics, branded generics, and branded originator products for which generic alternatives exist. To guarantee access to essential medicines, the government aims to optimize expenditure and rational use of resources through decisions on the inclusion in the national formulary and the subsequent procurement of these medicines through public financing.

The fact that a medicine is listed in the national formulary does not guarantee its financing and availability in all public facilities. SHI schemes provide medicines to their members free of charge, but each scheme has its own medicines list within the range of the national formulary. Likewise, the SPS, through MoH facilities, provides medicines free of charge to its members, based on its coverage package as listed in CAUSES and the FPGC, which is again a subset of the national formulary.

Despite the reforms of the national health system to expand health coverage through SPS, the availability and accessibility of (all types of) medicines are low in the public sector. The problems of availability in Mexico are related to budget cuts, the high prices of medicines, as well as challenges in procurement, distribution, and supply at the health institutions. To improve access to medicines, Mexico has implemented several policy tools, such as regulatory aspects that guarantee the safety and efficacy of medicines, the medicines’ timely entry into the Mexican market, the rational use of medicines, etc.

Private health services have thrived due to the lack of investment in public health institutions and the fragmentation of the health system in Mexico. This phenomenon is attributed to the lack of availability of medicines and the lack of capacity in the public sector despite the reforms of the national health system. Even when medicines are provided free of charge at the point of delivery in the public sector, patients continue to get medicines in private pharmacies, e.g. when they are out of stock in the public facility or when they are not included in the patient’s insurance scheme. The private market is constituted of medicines purchased in private pharmacies and medicines procured by private institutions and hospitals. Half of all medicines consumed at the national level are purchased in the private market, and
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represents approximately 80% of national pharmaceutical expenditure as prices are much higher than in the public market. The procurement by hospitals and private insurers represents only 3% of the value and 2% of the volume of medicines consumed in the private market. Thus, most of the expenditure on medicines in the private sector is by people with the means to afford these costs via private pharmacies, where medicines are delivered at the point of service, and where medicines are mainly financed through out-of-pocket payments.

The availability of medicines in the private sector is – for those who are willing and able to pay out of pocket - generally satisfactory. Access to medicines is strongly related to their affordability. The stock of medicines is based on the operation of specialized distributors that supply to more than 25,000 private pharmacies in the country. The distribution system is based on the reposition of inventories allowing for high availability of medicines, resulting in higher efficiency and lower process costs due to efficient management of stocks. However, the unavailability and medicines stock-outs in the private sector are related to some extent to the shortages in the private market.

In the public sector, cancer care is available only in tertiary specialized hospitals, located mainly in urban areas – both the MoH and SHI hospitals. However, there are differences in the availability of resources and the quality of services at the health facilities. Access to healthcare services is suboptimal and access to treatment is irregular for patients covered by SPS and for patients with SHI. In addition, the fragmentation of the Mexican health system promotes financing restrictions that contribute to the inefficient use of resources. These financing restrictions also contribute to differences in access to cancer care for insured (SPS and SHI members) and uninsured populations.

The national formulary list of cancer medicines aims to address most cancers and is largely consistent with the WHO model of Essential Medicines List (WHO-EML). All innovative medicines represent 4.4% of the volume of all procured medicines and 20.4% of the pharmaceutical expenditure at a national level. In the past years, the use of patented medicines in the public sector has further increased. Currently, 56% of cancer medicine expenditure corresponds to patented cancer medicines, even when they represent only 5.5% of the total volume of cancer medicines procured – providing clear proof of the high prices for innovative
cancer medicines. Many chemotherapeutic interventions, in particular innovative medicines that have become an essential part of chemotherapeutic treatment for cancer, continue to be unaffordable for the national health system and thus limiting their accessibility. The high prices of innovative medicines in Mexico are a consequence of the lack of regulation in prices, procurement, and consumption of medicines. Furthermore, Mexico does not employ preferential pricing or other mechanisms to improve the accessibility of high-cost medicines, as practiced in other LIC. Only by addressing the challenge of high prices of medicines the government can guarantee that the health system can provide access to innovative medicines and improve health outcomes of patients.

Little research has explored the factors that affect access to innovative medicines in Mexico, which can lead to inefficiency in the delivery of cancer treatment. The evidence is limited about the availability, affordability, and accessibility of innovative and essential cancer medicines. Several types of cancer, like prostate cancer, lung cancer, breast cancer, and cervical cancer, have become leading causes of mortality in Mexico. Considering that in Mexico cancer accounts for approximately 13% of the total mortality, it is important to assess aspects that influence access to cancer care and find gaps and barriers that prevent equitable access to innovative essential medicines. Only then, proposals to tackle such barriers and to strengthen the health system can be developed.

1.4. Objective and research questions

On a global scale, cancer has become a leading cause of mortality and productivity loss. Health systems in LMICs continue to address the challenges posed by the complexity of cancer as a disease. Many of these countries, particularly MICs, provide health coverage to prevalent types of cancer in their pursuit to achieve UHC. To improve pharmaceutical cancer treatment, innovative medicines have been introduced to the market and some of those have been listed as essential medicines. These medicines have contributed to improved health outcomes, better life expectancy and improved quality of life of cancer patients. However, innovative essential medicines are high-cost and often unaffordable for LMICs. Thus, it is important to analyze how emerging economies – such as Mexico - intend to address the growing problem on access to innovative and essential medicines for cancer.
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The overall research question of this thesis is, therefore: How does a middle-income country such as Mexico improve access to innovative and essential cancer medicines, as part of universal health coverage? This thesis focuses on the following aspects to address this question: policies used to improve access to innovative medicines and their impact, the use and availability of innovative medicines, the prices and affordability of medicines, and other barriers that limit the access to innovative medicines.

To address our research question, we applied the WHO Framework on access to medicines. This framework describes four main components of access: rational use, affordable prices, sustainable financing and reliable health systems (Figure 1.2). We have used a mixed methods approach (Figure 1.3), consisting of various quantitative and qualitative research methods. The data used for this research include peer-reviewed and grey literature in addition to government reports and other documents; procurement data that included the amount of medicines procured, prices of medicines procured and expenditure; availability and price data of cancer medicines gathered through a national assessment derived from the standard WHO/HAI survey methodology; and qualitative data gathered through interviews.

Figure 1.2. WHO Framework on access to medicines.

Source: WHO
To fulfill the main objective of this research, this thesis answers the following more detailed research questions:

**RQ1.** Which policy strategies and approaches has the Mexican government taken to improve access to (innovative) medicines, within the National Pharmaceutical Policy (NPP) context?

**RQ2.** What is the effect of a price negotiating commission on public procurement prices and the accessibility of innovative cancer medicines?

**RQ3.** What is the utilization rate and access to innovative cancer medicines in the public sector in Mexico?

**RQ4.** What is the actual availability, price, and affordability of essential cancer medicines in Mexico?

**RQ5.** How do health professionals perceive the accessibility of cancer medicines in the public sector in Mexico?

Figure 1.3. Research model

Chapter 1 presents an overall introduction to the concept of access to innovative essential medicines within the context of UHC and the Mexican health system.
Chapter 2 answers the question: **Which policy strategies and approaches has the Mexican government taken to improve access to (innovative) medicines, within the National Pharmaceutical Policy (NPP) context?** The WHO recommends the development and implementation of an NPP to address all issues related to access to medicines, from R&D, production, and quality assurance, to rational use, procurement, and final access. It is important to analyze how governments deal with all aspects related to access to medicines according to the country’s context and priorities to assess their impact and progress towards improving access to medicines. Chapter 2 describes the Mexican approach and the policies aimed at improving access to (innovative) essential medicines.

Chapter 3 deals with the question: **What is the effect of a price negotiating commission on public procurement prices and the accessibility of innovative cancer medicines?** One main barrier to effective access to medicines is high prices, particularly for innovative medicines under patent protection. Research has looked at several strategies to mitigate the effect of prices on access to medicines. One strategy used by the Mexican government is price negotiations. Looking at public procurement prices of medicines and their accessibility can provide information on the impact of price negotiations on access to innovative medicines. Chapter 3 explores the effect of price negotiations on public procurement prices and access to innovative medicines.

After considering price negotiations, Chapter 4 assesses the question: **What is the utilization rate and access to innovative cancer medicines in the public sector in Mexico?** Access to essential medicines includes access to innovative medicines that improve health outcomes and treat complex diseases like cancer. Looking at the utilization of medicines provides information on differences in access to medicines. This information is relevant to inform policymakers on the actual use and access to medicines by patients in need. Looking at differences in use can show inequities in access to medicines, and further look into options to tackle such inequities. Chapter 4 analyzes the use of innovative cancer medicines and differences in use between different insurance schemes and geographical regions in Mexico.

In Chapter 5, this thesis addresses the following question: **What is the actual availability, price, and affordability of essential cancer medicines in Mexico?**
Studying the availability, prices, and affordability of essential cancer medicines can provide a diagnosis of actual access to cancer medicines from the patient perspective. This information provides insights on barriers to access to medicines and the performance of the health system to provide medicines and cancer care. Chapter 5 reports on availability, prices, and affordability of medicines to assess the accessibility of essential cancer medicines.

Chapter 6 tackles the following question: How do health professionals perceive the accessibility of cancer medicines in the public sector in Mexico? Perceptions and experiences of health professionals are important. Health professionals are in the front line of healthcare and intimately know the problems and barriers that affect the health system in providing timely and effective access to medicines to patients. Beyond the use of purely quantitative and statistical data, it is important to document personal experiences and perceptions about access to medicines to improve the quality of care. Chapter 6 explores the insights, experiences, and perceptions of health professionals on aspects that hinder and promote access to essential cancer medicines in public hospitals.

In Chapter 7, the general discussion, all findings from the previous chapters are summarized and discussed to address the overall research question of the thesis. The chapter also includes a section on policy implications of the findings, limitations and methodological considerations, and a final conclusion.
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