To guarantee the progressive realization of the right to health, Mexico has made efforts to guarantee universal health coverage (UHC) and increase access to quality health services, including essential medicines. These efforts include the expanded healthcare coverage through the People’s Health Insurance (Seguro Popular de Salud – SPS), and other policy measures to improve and guarantee access to medicines in the public sector. In middle-income countries (MIC) in general, the epidemiologic transition leading to an increasing disease burden caused by non-communicable diseases (NCDs) has posed challenges to the health system. Among these challenges is the pharmaceutical expenditure, in particular for those innovative medicines that have become essential to treat NCDs, such as cancer medicines. There is little information about the availability and affordability of essential and innovative medicines in MICs. It is necessary to understand how such emerging markets could guarantee sustainable access to innovative medicines. This thesis reports on how a MIC deals with access to innovative medicines. We used Mexico as an example of a MIC and essential and patented cancer medicines as an example of innovative medicines.

Chapter 1 provides an overview of the importance of essential medicines in health systems towards reaching UHC. It expands on how health systems need to address challenges posed by NCDs and sustainable access to medicines, particularly high-cost innovative medicines for high-cost diseases such as cancer, which has become a leading cause of mortality worldwide. This chapter also introduces the context of Mexico, as the MIC of study. It provides an overview of the health system and the pharmaceutical market and describes the importance of how policies should address access to innovative medicines.

Chapter 2 presents a policy analysis of the different strategies and interventions used by the Mexican government to improve access to medicines. Mexico has not developed one single and comprehensive national pharmaceutical policy (NPP). Nevertheless, the government implemented the pooled procurement of medicines for public health institutions. The government also created the coordinating commission for price negotiations (CCNPMIS) to negotiate a single public procurement price of selected patented (single-source) medicines. In addition, the government created “CesMed” – a platform for sharing information between public health institutions on medicine prices and best procurement practices. These strategies intended to improve access to medicines, produce savings on the pharmaceutical expenditure
and promote the efficient use of resources. We conclude that their impact on access to medicines requires further assessment. As all these strategies have been developed in isolation, they should be included in one comprehensive NPP.

Chapter 3 analyzes the effect of a negotiating commission on the public procurement prices of patented medicines and their availability in the public sector from 2010 to 2016, focusing on eight selected innovative cancer medicines. In local currency, the prices of some medicines remained stable with minimal changes; only a few medicines like imatinib and rituximab had considerable price decreases. However, when converting to US dollars and adjusting for inflation, the prices of all medicines decreased in the period under study. There were rather large differences in actual prices paid by individual health institutions. We also found that the amounts of medicines procured in the public sector increased overall, suggesting better availability to patients. We conclude that, although a direct causal relation is difficult to prove, the CCNPMIS seems to have been able to prevent price increases in the public sector, despite currency devaluation and considerable price increases in the private sector for the same medicines. Furthermore, the price decreases may have contributed to better access to these medicines. However, the CCNPMIS has failed to monitor the compliance of the institutions to the negotiated prices. Our findings show that it is necessary to strengthen the CCNPMIS, develop performance indicators, and monitor its final impact on public procurement of innovative (negotiated) medicines.

In Chapter 4, we described the differences in use, as a proxy of access, of innovative essential cancer medicines between various health insurance institutions and geographical regions of Mexico. During a period of six years, the public sector procured more rituximab, imatinib, and trastuzumab than dasatinib, nilotinib, bevacizumab, sorafenib, and sunitinib. In general, the use of the selected cancer medicines was lower in IMSS (the main social health insurance scheme) and the Ministry of Health (MoH) facilities than in those of the other social health insurance institutions. We also found geographical differences, with greater use of these medicines in the central region of the country, where the capital is located, than in the rest of the country. The northern and western areas of the country have a high cancer burden and include a vast proportion of the population. In these regions, the use of these medicines did not increase much throughout the studied years. These differences between regions suggest that the government,
the social health insurance institutions and the public health institutions need to make the necessary investments to improve access to innovative medicines and promote equitable access to medicines.

Chapter 5 presents our findings on actual availability, prices, and affordability of essential cancer medicines in public and private health facilities in Mexico. The results show that the availability in neither the public nor the private sector reached the World Health Organization’s (WHO) target of 80%, with little difference between the two sectors. Prices in the public and private sectors were lower than in those in other Latin American countries and were comparable with international reference prices. Yet, in both sectors, most essential cancer medicines were unaffordable to patients. Innovative cancer medicines were less available and more unaffordable than other essential cancer medicines. We conclude that health facilities and institutions in Mexico should put various pricing policies in place to improve the availability and affordability of cancer medicines.

To obtain an overall perspective of access to essential cancer medicines in the public sector in Mexico, Chapter 6 reported on the perception of key stakeholders regarding the selection of medicines, procurement practices, and barriers on access to cancer medicines in public hospitals in Mexico. The selection of medicines follows the SPS treatment protocols, but most clinicians considered these protocols outdated and the range of cancer medicines procured too limited. Public hospitals that outsource pharmaceutical services seem to have achieved better availability and more efficient use of resources. Hospitals supplied through the central procurement carried out by the MoH encountered more stock-outs. Informants perceived the availability of cancer medicines as generally sufficient, but they encountered barriers such as shortages at the national market, lack of SPS coverage, lack of hospital accreditation for certain types of cancer, and lack of resources to cover all patients’ needs. Informants reported that hospitals took several ad-hoc actions to overcome such barriers. We conclude that expanding SPS coverage and increasing the number of accredited facilities is necessary to improve access to cancer medicines. Furthermore, sustainable financing of medicines and appropriate procurement mechanisms are necessary to prevent stock-outs and to guarantee timely and continued access to treatment.

Chapter 7 presents a summary of the main findings and reflects on these findings, following the WHO Access to Medicines Framework. The results of this thesis
show that the SPS has been an instrument that has helped to improve access to cancer medicines - medicines covered by SPS were more accessible than those without coverage. Furthermore, the government’s price negotiation strategy has been able to reduce prices and prevent price increases despite inflation and currency devaluation. However, the negotiating commission has not achieved price uniformity for patented medicines, as institutions continue to pay prices that differ from the negotiated prices. The results of this thesis also show barriers that prevent better and sustainable access to cancer medicines – particularly innovative medicines – and other challenges that the health system needs to address such as shortages, lack of coverage and inefficiencies in the procurement processes.

This chapter further discusses the implications of our findings and provides recommendations for policymakers regarding insurance systems such as SPS, for which the number of accredited health facilities should be increased in order to expand coverage. It also refers to the importance of strengthening the negotiating commission and of further implementing other pricing policies in the public and private sectors to improve the affordability of medicines. Other recommendations include the revision of procurement procedures and the compilation of all medicine’s policies into one single national pharmaceutical policy. This pharmaceutical policy should also be aligned with the National Cancer Control Plan to expand and improve cancer care and thus access to cancer medicines. These policies should also strengthen the health system, which in turn will address challenges posed by other NCDs.

This thesis also provides recommendations to other countries. These recommendations include the reform of health systems to implement public insurances (similar to SPS) to provide a package of interventions to reduce health inequities and reach UHC. Furthermore, other countries could implement other policies beyond pricing negotiating systems to improve the affordability of innovative medicines and thus their accessibility.

Future research should expand on access to comprehensive treatments per disease and analyze geographic and insurance scheme differences. In addition, research should study the accessibility of medicines for other prevalent cancers, as well as for other diseases with high-cost medicines (e.g. Hepatitis C). Addressing these issues can highly contribute to the improvement of the health systems for low- and middle-income countries.