

QATAR UNIVERSITY

COLLEGE OF PHARMACY

EVALUATION OF PHARMACEUTICAL PRICING AND POLICY IN QATAR AND

LEBANON: A COMPARATIVE STUDY OF

CARDIOVASCULAR DISEASE MEDICINES

By

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## ABSTRACT

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Title: Evaluation of Pharmaceutical Pricing and Policy in Qatar and Lebanon: A Comparative Study of Cardiovascular Disease Medicines

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The study aimed to review the pharmaceutical pricing policies and to assess prices, availability, and affordability of essential cardiovascular disease medicines in Qatar and Lebanon across multiple sectors. A thorough review of applicable policies was undertaken and interviews with key informants were conducted, in addition to the use of a variant of the World Health Organization and Health Action International methodology as outlined in “Measuring medicine prices, availability, affordability and price components” (2008), second edition.

In conclusion, both countries are using multiple internationally recognized pricing policies simultaneously. Prices of medicines in the private sector are higher than the international reference prices. Nevertheless, and despite few exceptions, most medicines were affordable in all sectors surveyed. Of those surveyed, only the public sector in Qatar had a satisfying level of availability and affordability. Except for the public sector in Qatar, both countries fall short of the Sustainable Development Goals, and more efforts should be undertaken to achieve these goals.

## DEDICATION

*This thesis work is dedicated to my mom, Wafaa, for her endless devotion and continuous encouragement. I am also blessed for having my siblings, Samar, Rana and Houssam who are always ready to listen and would never leave my side. It is also dedicated to my supportive husband, Ali, without whom I wouldn't have earned this degree.*

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## ABBREVIATION

<b>CIF</b>	Cost-Insurance-Freight
<b>CPI</b>	Consumer Price Index
<b>CSR</b>	Corporate Social Service
<b>CVD</b>	Cardiovascular Diseases
<b>DALY</b>	Disability-Adjusted Life Years
<b>EDL</b>	Essential Drug List
<b>EML</b>	Essential Medicine List
<b>EMRO</b>	Eastern Mediterranean Regional Offices of the World Health Organization
<b>ERP</b>	External Reference Pricing
<b>FOB</b>	Free-On-Board
<b>GBD</b>	Global Disease Burden
<b>GCC</b>	Gulf Countries Council
<b>GDP</b>	Gross Domestic Product
<b>HAI</b>	Health Action International
<b>HMC</b>	Hamad Medical Corporation
<b>HIC</b>	High-Income Country
<b>HTA</b>	Health Technology Assessment
<b>IRP</b>	International Reference Price
<b>LIC</b>	Low-Income Country
<b>LMIC</b>	Low-Middle-Income Country

<b>LPGW</b>	Lowest-Paid Government Worker
<b>LPG</b>	Lowest Priced Generic
<b>MDG</b>	Millennium Development Goal
<b>MENA</b>	Middle East and North Africa
<b>MSH</b>	Management Science of Health
<b>MOPH/MoPH</b>	Ministry of Public Health (Qatar/Lebanon)
<b>MPR</b>	Median Price Ratio
<b>NCD</b>	Non-Communicable Diseases
<b>NGO</b>	Non-Governmental Organization
<b>NMP</b>	National Medicine Policy
<b>OB</b>	Originator Brand
<b>OECD</b>	Organization for Economic Co-Operation and Development
<b>OOP</b>	Out-Of-Pocket
<b>PDCD</b>	Pharmaceutical and Drug Control Department
<b>PHCC</b>	Primary Health Care Corporation
<b>UN</b>	United Nations
<b>UNDP</b>	United Nations Development Programme
<b>WHO</b>	World Health Organization
<b>YLD</b>	Years Lived with Disability
<b>YMCA</b>	Youth Men's Christian Association

## CHAPTER I: INTRODUCTION

### **Background**

Medication is a cornerstone in medical disease management and the timely presence and appropriate integration of medication in a treatment plan for short- and long-term ailments are crucial. Over time, experience has shown that opting for good-quality, safe and effective pharmacotherapy is a must to reverse avoidable medical consequences. This is quite evident in the treatment of non-communicable diseases such as cardiovascular diseases (CVD).

### ***Non-communicable disease in the Middle East and North Africa (MENA) region***

Diseases with long duration and slow progression are classified as non-communicable diseases (NCD) (1). Contracting a life-long disease is a burden in many respects. In addition to estimating and calculating the death rate, World Health Organization (WHO) in collaboration with UN agencies calculate the global burden of disease (GBD). This GBD is presented in a time-based unit expressed as disability-adjusted life year (DALY) which sums up: the life years lost due to premature mortality (2) and life years lost due to disability (YLD) (3). As mentioned above, CVD are classified as NCD. According to the latest WHO global disease burden report (2014), CVD are the leading cause of death (Tables 1 & 2). Within CVD, ischemic heart disease and stroke ranked highest according to the latest figures of leading causes of death globally with 13.2% and 11.9%, respectively.



**Table 1: Leading Causes of Death and their Projection**

<b>Region</b>	<b>Cause</b>	<b>Death by causes in 2012 according to Global Health Estimates (GHE)</b>	<b>Projected deaths by cause of 2030, baseline scenario</b>
<b>All WHO regions</b>	<b>All causes</b>	55,858,719	67,790,423
	<b>NCD (%)</b>	67.84	76.14
	<b>CVD (out of total NCD) (%)</b>	46.23	45.68
	<b>Diabetes (out of total NCD) (%)</b>	3.95	4.32
<b>EMRO</b>	<b>All causes</b>	3,997,132	5,434,124
	<b>NCD (out of total causes) (%)</b>	56.37	70.34
	<b>CVD (out of total NCD) (%)</b>	47.95	54.99
	<b>Malignant neoplasms (out of total NCD) (%)</b>	15.36	16.52
	<b>Diabetes mellitus (out of total NCD) (%)</b>	5.13	3.59

*Source:*

World Health Organization (WHO). Health statistics and information system - Global burden of disease (GBD) Geneva: World Health Organization; [Available from: [http://www.who.int/healthinfo/global\\_burden\\_disease/gbd/en/](http://www.who.int/healthinfo/global_burden_disease/gbd/en/)].

Cardiovascular diseases are the first leading causes of death in Lebanon and the second in Qatar after road injuries (1). Researchers in the region were able to detect similar figures (4) to what have been presented above (Tables 1 & 2) regionally and locally in both Lebanon and Qatar (5, 6). Risk factors for CVD and non-adherence to primary management guidelines are highly prevalent in the region (7-9). Some of these risk factors include: hypertension, dyslipidemia, diabetes, diet, abdominal obesity, and smoking (4-6, 8-10). In order to control risk factors and overturn their morbid effect, lifestyle modifications are the first line option (11, 12). When proven inappropriate and unsuccessful, medication is introduced and becomes an integral part of a life-long journey (11).

**Table 2:** Projected DALY (000s) by Cause of the Year 2030 according to WHO Regions and Income Level

Cause	EMRO	HIC	UMIC
<b>Total DALY</b>	144,469,201	122,206,629	97,331,558
<b>NCD (%)</b>	60.46	87.74	75.20
<b>CVD (of NCD) (%)</b>	23.28	16.70	22.92
<b>Malignant neoplasms (of NCD) (%)</b>	9.35	15.89	13.35
<b>Diabetes Mellitus (of NCD) (%)</b>	3.02	4.48	5.58

*Source:*

World Health Organization (WHO). Health statistics and information system - Global burden of disease (GBD) Geneva: World Health Organization; [Available from: [http://www.who.int/healthinfo/global\\_burden\\_disease/gbd/en/](http://www.who.int/healthinfo/global_burden_disease/gbd/en/)].

### *Value of medicine*

While medicines and drugs are being used interchangeably, some people may argue that they differ in meaning and action. By definition, the two terms are interchangeable, and in this document, are mostly referred to as a medicine based on the medicinal class or category described and surveyed in this thesis.

Any medicine whether traditional or modern has value, whether financial or non-financial, to different stakeholders. It is qualified as a product to manufacturers, a pharmaceutical product for prescribers and finally a therapeutic mean for consumers or patients. This last connotation confers an emotional and psychological value to pharmaceuticals in treating and alleviating pain or combating morbidity and mortality. Of the various values that patients look for in medicines, safety and efficacy are at the top of the list (13, 14). The healing value conferred to medicines is consistent with the literature where in most cases medicines have been proven to exert better efficacy than other non-pharmaceutical treatment or to no treatment at all (15, 16).

A medicine like any other commercial product is available in a market and is subject to supply and demand forces. The price for most goods is generally shaped by demand,

however this should not be the case for pharmaceuticals. Although patients have willingness-to-pay for an indispensable treatment, allowing market dynamics to set pharmaceutical prices could prove unethical. Given the maxim that “health is priceless”, controversy arises between manufacturers that aim at making the most benefit of their research and development and the highest return-on-investment (17, 18) and the patients who, whenever capable, would not spare any resource to access medicines that improve health, well-being and could be life-saving in cases such as chronic diseases treatment. Of interest are essential medicines that are deemed substantial for well-functioning health care systems. These medicines are those that "satisfy the priority health care needs of the population" (19). They encompass the most prevalent disease such as HIV, malaria, and chronic diseases (e.g. diabetes and cardiovascular diseases) (20). These medicines are selected for their efficacy, safety, quality and cost-effectiveness (21). Due to their relevance in treating fundamental illnesses they inherit the value of being essential and consequently their availability and affordability for communities and individuals are fundamental (19, 21, 22). In 1977, the WHO released the first model list of essential medicines that was entitled Essential Drug List (23, 24) then changed into Essential Medicine List (EML) in 2002 (25). The year 2017 marks the 40 years anniversary of the EML.

### ***Access to medicines***

Given the key role of medicines in the CVD management, ensuring a sustainable access to medicines is deemed indispensable. Access can be defined by the ability of citizens to reach and use pharmaceuticals that are of good quality and affordable, when needed (26).

Access to quality medicine is a basic human right, simply the right to health. Achieving and fulfilling this right enhances the quality of an individual's life and sustains an adequate standard of health. About one-third of the world's population lacks sustainable access to essentially needed medication. Poor access is not always related to technical issues. Others factors influencing access include social beliefs or values, economic interests, and political process (27). WHO identifies hindrances to access as being one or all of the following: medicine price, quality, availability, and affordability (28-30). This is most pronounced in poor countries where people face difficulties due to medicine price and availability whether in the public or private sector. While the right to be treated should be a basic right for people around the world, this is not the case in low- and middle-income countries (LMICs). In these countries, people are purchasing medicine out-of-pocket (OOP) because of the lack of a comprehensive health insurance system and inadequate publicly subsidized pharmaceutical services (26). Therefore, strategies to ameliorate access should take into account improving affordability (29). A close inspection of the disparity in access across the world sheds light on poor pharmaceutical policies and strategies. In LMICs, 20-60% of the total healthcare expenditure is on medicines in comparison to less than 18% in high-income countries (HICs) (31). To address this issue, an array of joint experts' efforts must be exploited on different levels worldwide, nationally, and locally.

As aforementioned, in the 1990s public organizations, such as WHO, Health Action International (HAI), Médecins Sans Frontières (29, 32), and others realized the need for reliable access to medication as an initial step to fight poverty and health inequity. At that time, this problem afflicted most developed and developing countries.

During the process of planning and implementing effective policies to address these issues, one common conclusion was drawn: the inexistence of a ‘magic bullet’ or a one-size-fits-all solution. This is due to discrepancy in medicine needs and challenges of each individual country.

Accordingly, each country should assess its own healthcare and pharmaceutical situation and consequently implement adequate policies and interventions.

By 2001, WHO and HAI had conducted several studies in countries with varying levels of income as well as studies targeting different therapeutic medicine classes. The “Project on Medicine Prices and Availability” produced valuable guidelines and methodology which have been adopted effectively in most industrialized and other middle-income countries (33).

Having all these tools to assist in shaping better pharmaceutical pricing policies does not exclude the major role played by national governments to enforce and regulate the pharmaceutical sector. Several nongovernmental organizations (NGO) and WHO acknowledge that in order to improve the availability and the affordability of essential medicines, evidence-based national policies and programs must be developed. In the same context, an editorial published in the British Medical Journal (BMJ) after the World Health Assembly in 2006, drew attention to existing problems discussed in the WHO/HAI report related to chronic disease management. According to BMJ: “the report’s findings make explicit what has long been recognized: that the cost of medical care impoverishes or is simply beyond the reach of many people in developing countries. Amid the gloom, however, there is some light. Simply collecting data and presenting it to governments can stimulate action” (27). Based on this statement, several neighboring

countries, e.g., Kuwait, Lebanon, and Syria, that were participating in the WHO/HAI project, undertook action towards medicine price' reduction and enhancement of availability (34).

Whether or not a government should intervene in product pricing is debatable in most cases, unless the product in question can determine quality of life and survival.

A key governmental intervention would be the establishment of an essential medicine list (EML) and promotion of affordable, quality generic medicines. These are two of the components required to establish a National Medicines Policy (NMP).

Governments can control different stages in the pharmaceutical supply chain. WHO has provided governments with the following effective methods to influence the prices set by the manufacturers (35):

- i. Price controls on the manufacturer;
- ii. Profit controls on the manufacturer;
- iii. Reference pricing and brand premiums;
- iv. Comparing pricing controls (international benchmarking);
- v. Eliminating tariffs and taxes;
- vi. Fixed margins;
- vii. Digressive mark-ups; and
- viii. Capitation systems.

Countries adopt varying strategies to manage the pharmaceutical market. Some have minimal interventions, allowing for an equilibrium based on health sectors, suppliers, and patient interactions. Other countries get fully engaged and intervene by either subsidizing

medicines or offering them for free to their population. The latter case is what is encountered in industrialized countries that are members of the Organization of Economic and Co-operation and Development (OECD) (36).

### ***Medicine pricing components***

To develop a suitable strategy for price control, it is imperative to comprehend the many factors involved in medicine price setting. These factors vary widely among countries, and they include (27):

- i. Basis for setting the original prices;
- ii. Shipping cost;
- iii. Distribution cost;
- iv. Import duties;
- v. Taxes;
- vi. Product registration cost; and
- vii. Transfer price.

Generally speaking, the ex-factory price or manufacturer selling price (MSP) of a medicine is only an initial starting component of the final retail price at which a patient purchases the medicine (27, 30). The MSP is thereafter subject to additive and cumulative price components that can increase the final price from 30% to more than 100% in some countries (35). While MSP is related to the procurement type and channels and the negotiation power and market volume of a nation, the price components added to

MSP are a good barometer for the effectiveness of a national pharmaceutical pricing policy, the pharmaceutical sector structure and regulation (27, 35, 37).

Different actions taken by stakeholders that are controlling the medicine supply chain result in a complex interplay whereby some governments may not be fully aware of the cumulative price components. The regulation of these components has a considerable impact on the public price (retail price) and improves access (38). While some of the incremental costs mentioned above are indispensable, others can be waived or should not be included in the final prices. Some governments decide to exempt essential medicines from taxes, and in general patients should not be charged for the drug registration fees (27). WHO/HAI separates the medicines price components in up to 5 stages (27). The comprehension of the price escalation at each stage helps understanding the pharmaceutical value chain and therefore empowers advocates and governments to take the appropriate actions towards supplying their populations with affordable drugs. So far, most of the studies evaluating these components are mainly focusing on the outpatient medicine prices (38); for instance the WHO/HAI methodology provides us with tools to evaluate this price only. These cumulative price increases throughout the supply chain are only a part of the pharmaceutical expenditure analysis. Other factors include the volume of medicine sales expressed in units (35) and rapid growth and OOP expenditure on medicines (4, 5, 10, 39-41).

Given the profile of CVD in Qatar and Lebanon as presented above (42), this study was developed to examine the state of essential cardiovascular disease medicines in terms of prices, availability and affordability. Moreover, it investigated the price component



schemes in both countries to understand the value added along the supply chains that culminated in the retail prices.

### ***Macroeconomics and demographic profiles***

Both Qatar and Lebanon are Arab countries in the MENA region and therefore fall under EMRO, the Eastern Mediterranean Regional Office of the WHO. They differ in terms of economic indicators due to the differences in income levels. While Qatar is a high-income country, Lebanon is an upper-middle income country. Table 3 illustrates these differences.

### **Problem Statement**

In comparing the pharmaceutical situation worldwide, scholars cannot ignore the existence of critical differences between developed and developing countries. In developed countries, the pharmaceutical sector is more organized and controlled with established local pharmaceutical production industries (7). Moreover, pharmaceutical prices are commonly benchmarked across developed countries of comparable economic status. Although the adoption of NMP is higher in developing countries, the rate of adoption and update of NMP is greater in developed countries (43). In developing countries, including the MENA region, the pharmaceutical sector is relatively unregulated and varies depending on the level of income, policies, and degree of inclusion of the healthcare system in the national vision (44). However, the rate of EML establishment is inversely proportional to the level of income (45). With budget

constraints, LMIC tend to limit their pharmaceutical procurement to mostly essential medicines (45).

**Table 3: Qatar and Lebanon Economic Indicators and Demographics**

	<b>Qatar</b>	<b>Lebanon</b>
<b>GDP (bn)</b>	\$164.64	\$47.08
<b>Population (mn)</b>	2.58*	6.24**
<i>Citizens (mn)</i>	0.313†	4.751**
<b>GDP Per Capita (35)</b>	\$73,653	\$8,047
<b>Health Expenditure (bn)</b>	\$4.82	\$3.34
<i>Public Health Expenditure (bn)</i>	\$4.10	\$1.59
<i>Private Health Expenditure (bn)</i>	\$0.72	\$1.75
<b>Pharmaceutical Sales (bn)</b>	\$0.52	\$1.64
<b>Pharmaceutical Sales, % of Health Expenditure</b>	10.90	49.00
<b>Per Capita Spending on Pharmaceuticals</b>	\$234	\$280
<b>Spending on Originator Pharmaceuticals (mn)</b>	\$360.0	\$800.0
<b>Spending on Generic Pharmaceuticals (mn)</b>	\$110.0	\$490.0

Source:

1- World Bank. Data, Indicators: The World Bank Group; 2016 [Available from:

<http://data.worldbank.org/indicator>].

2- Business Monitor International (BMI). Lebanon pharmaceuticals & healthcare report Q3 2016: BMI Research, FitchGroup; 2016 [Available from: [www.bmiresearch.com](http://www.bmiresearch.com)].

3- Business Monitor International. Qatar Pharmaceuticals & healthcare report Q3 2016: BMI Research, FitchGroup; 2016 [Available from: [www.bmiresearch.com](http://www.bmiresearch.com)].

(\*) Ministry of Development Planning and Statistics (mdps). Qatar population number: Ministry of Development Planning and Statistics; 2017 [Available from:

<http://www.mdps.gov.qa/en/Pages/default.aspx>].

(\*\*) Central Intelligence Agency (CIA). The World factbook - Library: Central Intelligence Agency; 2017 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/le.html>].

(†) Snoj J. Population of Qatar by nationality report 2017 [Available from:

<http://priyadsouza.com/population-of-qatar-by-nationality-in-2017/>].

A closer look into two middle eastern countries, Qatar and Lebanon, reveals the absence of an established national pharmaceutical policy (46). Both countries have put enormous efforts to control the pharmaceutical sector (28). An example of pharmaceutical market control is the pricing policies that both countries are applying and the measures that are being undertaken to implement them. In Qatar and Lebanon, prices of brand originators

are set by benchmarking against a basket of countries according to the respective government laws, and consequently generics if available are set to be priced lower than originators by different percentage in both countries (47, 48). This benchmarking is followed by the application of standardized mark-up schemes.

Over the years, both governments have made attempts at reducing prices. However, arbitrary price reduction without consideration to other factors resulted in some negative consequences. For instance, shortage of some medicines in Lebanon had been reported after government price containment strategies. That was due to importers and agents' decision to curb their financial losses by withholding the import of certain medicines.

Such deficit in the permanent procurement of affordable essential medicines is negatively impacting patients with NCD (49), notably the chronic pharmaceutical management of CVD highly prevalent in the MENA region especially the Gulf nations and to a similar extent in Lebanon (50, 51). The price of medicines and the overall cost of therapy are key factors of medication adherence, with lifelong payment for CVD medication coming at an impoverishing effect (52). So far, no research has been conducted in Qatar and Lebanon to investigate whether all essential CVD medicines are available or affordable in the private or public sector. The latest survey conducted in Lebanon by the WHO/HAI was published in 2013 and included only three CVD medicines. By the end of 2015, the new price control law was enacted, and no studies have been carried out since. Reports of these studies are available on <http://haiweb.org/what-we-do/price-availability-affordability/price-availability-data/>.

## **Study rationale**

With this alarming high prevalence of risk factors and prevalence of CVD among Qatari and Lebanese population, both countries included prevention strategies against chronic diseases generally and CVD especially in their national vision and had set future plans (53, 54). The management and control of the spread of CVD starts with a prevention plan, however, treatment is equally imperative and essential. While acknowledging the efforts of both countries to implement pricing guideline (e.g., benchmarking and mark-up), it is imperative to analyze the status of essential medicines aimed at treating CVD which are highly prevalent. Assessing access to these medicines is substantial in order to achieve optimal adherence to secondary prevention measures in treating early stages of CVD, to minimize complications, hospitalizations, and mortality, and to control the total cost of diseases management (29). Level of access to medication is determined through the evaluation of prices, availability and affordability of these medicines (47). Such studies have not been conducted in Qatar previously, and the most recent WHO/HAI survey in Lebanon in collaboration the MoPH was performed in 2013 (55) prior to the recent decreases in drug prices enacted by the ministerial decision number 796/1 of 2014 (46). Analysis of the components that comprise the final retail price enables the assessment of compliance with pharmaceutical pricing strategy at different stages of medicine supply chain, as well as comparison of how such policies are implemented in different countries.

Any evidence that the study would demonstrate could be utilized in the shaping of the measures undertaken in Qatar and Lebanon to reduce the high rates of CVD morbidity and mortality.

## **Objectives**

### ***General aims***

The study aimed generally at assessing the price, availability and affordability of CVD medicines in Qatar and Lebanon. It was conceptualized around the necessity for identifying factors hindering access to these disease-specific class of medications. The healthcare providers' duty is to ensure equitable access to healthcare services, including provision of pharmaceutical products (56). The cost of these medications is financially burdening the individuals, who when uninsured, must pay out-of-pocket. A financial burden on households is usually accompanied with social and psychological burdens. Such burdens can lead people to forgo their medical treatment in favor of other living expenses deemed by them to be more essential. Given the need for uninterrupted adherence to treatment in controlling and managing CVD, our study aimed at assessing the affordability and availability of CVD medicines and examining the effect of pharmaceutical pricing policies adopted in Qatar and Lebanon. By collecting data from different sectors and medicine selling outlets, our study will permit a better understanding of the current pharmaceutical situation in terms of pricing policies, price, availability, and affordability in both countries.

### ***Specific objectives***

The specific objectives are divided into primary and secondary objectives.

#### ***Primary objective***

Our purpose is to collect data about medicine prices, availability, and affordability from different outlets in the public and private sectors to allow us

to estimate their respective averages within a country. Additionally, we aim to investigate the adoption and implementation of external reference pricing and mark-up regulations as enacted by the official authorities in both Qatar and Lebanon. We present our primary objectives as follows:

#### Pharmaceutical pricing policy

- a. To investigate and review the latest pharmaceutical pricing strategies adopted in Qatar and Lebanon.

#### Prices

- a. To evaluate the median medicine prices, median price ratio (MPR) and the interquartile range (IQR) in each sector, across sectors, across areas, and nationwide.
- b. To measure the median price ratio of individual medicines in comparison to international reference prices.
- c. To calculate the brand premium between originator brand (OB) and lowest priced generic (LPG) of the same active ingredient.

#### Availability

- a. To calculate the availability of both medicine types i.e. originator and generic brands; within a single sector, across sectors, across areas, and nationwide.

#### Affordability

- a. To estimate the affordability of both medicine types within a single sector, across sectors, across areas, and nationwide.

### *Secondary objectives*

The same variables collected for the primary objectives would be compared across Qatar and Lebanon while taking into consideration the different income levels and others economic factors.

#### Pharmaceutical pricing policy

- a. To analyze and compare the distribution of mark-ups along the supply chain and to relate these margins to the pharmaceutical pricing strategies applied in each country.

#### Prices

- a. To compare adjusted MPR of both OB and LPG in both sectors in Lebanon and Qatar.
- b. To compare the brand premiums of medicines in the private sector.

#### Availability

- a. To compare the availability of medicines according to sectors in both countries.

#### Affordability

- a. To compare the affordability of a chosen basket of OB and LPG medicines in both countries.

### **Contribution of study findings**

Qatar and Lebanon are both developing countries but ranked differently according to income classification (57). Although they differ in GDP per capita, economic and health

profiles, they share the perception of steep pharmaceutical prices. The enormous efforts undertaken by both countries in line with their national health visions cannot be denied. They continuously endeavor to combat monopolism and unaffordability. Both countries also focus on controlling the spread and progression of non-communicable disease (e.g., CVD).

Embarking on projects towards eliminating the inequity in access to continuous preventive and curative treatments would fulfill the right to equitable health. Patients of different social and economic strata would be able to access affordable medicines.

Procuring medicines at reasonable prices in both sectors or even for free in the public sector could lessen the burden on society. The pressure of having to spend a significant portion of household income on medication imposes strain on patients (29). The lifelong consumption of chronic disease medicines comes at an impoverishing cost for people who are already close to the poverty line (34, 50). The availability of affordable medicines for patients is an initial step towards controlling and preventing the spread of diseases as many may sacrifice the costly medical treatment in favor of other essential living expenses.

Lack of adherence by patients, which in large part is due to the impoverishing cost of treatment, is a major hurdle for healthcare providers in the management of chronic diseases. Ensuring accessibility by reducing OB prices and procuring good quality affordable generics can facilitate the objectives of healthcare providers.

The pharmaceutical industry has been engaged in several corporate social responsibility (CSR) activities to embellish their image and reputation (52). Social activists and researchers often encounter cases of differential pricing especially for HIV/AIDS



medicines and malaria in afflicted countries due to such CSR initiatives by pharmaceutical companies (52).

The methodology adopted in this project has been widely used by different stakeholders such as health professionals, researchers, government authorities, international organizations, as it has proven to be a valuable monitoring and advocating tool. The information produced by this type of survey could be utilized for advocacy purposes.

This type of study is one of the enablers for the milestone project towards achieving equity and social justice by ameliorating the access to medicines. The study outcomes and findings would illustrate the status of the CVD medicines for the patients, society and prescribers. The results of this study could support an advocacy drive to pharmaceutical companies to expand their CSR activities in Qatar and Lebanon if deemed necessary.

As for the governments, any project that can assist in formulating a tailored pharmaceutical policy would be of high interest among stakeholders and the public. Such policy would reduce the fluctuation in prices, improve procurement processes and enhance availability of medicines. This could positively impact the management of the heavily burdening cardiovascular diseases.

### **Thesis layout**

This thesis will be structured as follows:

- i. Chapter II, a systematic review: the literature review that encompasses different strategies undertaken by developing countries to control medicine

prices and their effects whenever assessed. The different pharmaceutical pricing strategies identified in the reviewed studies will be mapped to the WHO pharmaceutical pricing guidelines (57).

- ii. Chapter III, methodology and methods: this chapter outlines the methodology and methods adopted in our study and describes how the research was conducted. That chapter will also detail how results will be analyzed.
- iii. Chapter IV, the results: we will present our research results by following the order of our specific objectives. These results will be reported by country and across the two targeted countries. We will start by analyzing the pricing strategies adopted in both countries and their effects on the pharmaceutical sector. Then we will evaluate the medicine prices expressed in different values, the availability of medicines under both types in both sectors, and the affordability of CVD treatments.
- iv. Chapter V, discussion and conclusion: we will interpret the study results and their significance in the context of our objectives and the countries surveyed. To conclude, we will start by disclosing the research limitation followed by a wrap up of the whole project starting with the planning phase and objectives to the conclusion and its advocative value.

## CHAPTER II: LITERATURE REVIEW

### **Introduction**

In developing countries, the majority of which are classified as low-income countries (LICs) and low-middle income countries (LMICs) (27), access to medicines comes at an impoverishing cost (50), where most people (90%) have to pay out-of-pocket for pharmaceutical products (Fig. 1) (56). This constitutes a key development challenge towards sustainable and strong health care systems reform and achievement of the Sustainable Development Goals by 2030 (SDGs).

In these countries, spending on medicines can reach up to 3 times the amount spent in Organization for Economic Co-operation and Development (OECD) countries, accounting for 60% of health expenditure (29). Increased public spending may have macro-economic repercussions while increased private spending would raise equity concerns (34). Various policies are available to address several issues present in individual national markets (29), however, one conclusion is always achieved: there is no “gold standard” pricing policy (29, 34). Numerous measures can be applied simultaneously in order to increase affordability and availability of medicines. Although many developing countries have pharmaceutical pricing policies, in many cases the evidence does not support their effectiveness in reducing prices and increasing availability.

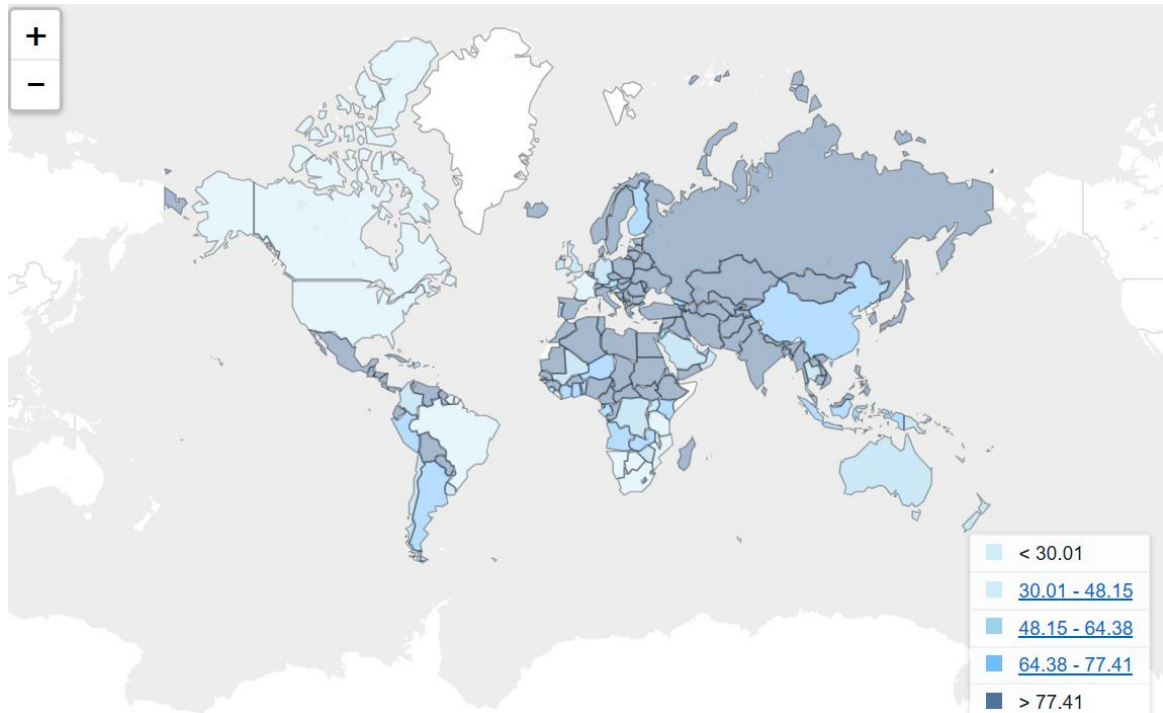


Figure 1. Out-of-pocket health expenditure (% of private expenditure on health).

*Source:*

World Bank. Out-of-pocket health expenditure (% of private expenditure on health): The World Bank Group; 2014 [Available from: <http://data.worldbank.org/indicator/SH.XPD.OOPC.ZS?view=map>].

In order to assess the general situation in the developing countries, we first conducted a systematic literature search to identify isolated government strategies or guidelines used to control the pharmaceutical pricing and to explore their consequent effects on the adopting nations as well as to map these strategies to the WHO pricing policy guidelines (29).

Secondly, studies with eligible designs were systematically reviewed to assess the policies' social and economic impact. A published scientific paper detailing the methodology and results of this systematic literature search was published in the Journal of Pharmaceutical Health Services Research under the title: "A systematic review of pharmaceutical pricing policies in developing countries" (2017) (58).

## **Systematic literature review**

### ***Search strategy***

We conducted a systematic review of papers, documents or studies published between January 2000 to March 2016 in English or Arabic that assessed and evaluated pharmaceutical pricing policies or strategies under the form of rule, law, initiative, administrative and financial instruction made by governmental authorities in the developing countries (57). A broad systematic search of electronic databases, grey literature and Google Scholar was conducted to locate relevant publications. The following databases were used to retrieve articles: PubMed, PQ Central, EconLit, ProQuest (for dissertations and theses), CINHALL, Scopus, Science Direct, Cochrane, WHO library database (WHOLIS), WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (WHOCC), and Web of Knowledge. Grey literature search was also conducted through government publications, WHO/HAI reports, Open Grey database in addition to using the search engine Google Scholar. References of retrieved articles and reports including reviews were screened to identify additional potential published and unpublished studies. All the databases and grey literature searches were conducted between the 7<sup>th</sup> and 23<sup>rd</sup> of March 2016 using several keywords in isolation or combined. An advanced search engine was utilized whenever available.

### ***Study selection and eligibility criteria***

To be eligible, studies needed to include a policy and an evaluation of its effects on at least one relevant outcome. For the qualitative synthesis in the systematic review, only studies

that quantify the impact of policies were included; e.g., pre-/post, longitudinal, and interrupted time series studies. Two reviewers assessed the quality of studies to be included in this synthesis.

## ***Results***

Only 21 articles fulfilled our objectives and were included in the explorative synthesis, of which 6 studies were qualitatively synthesized.

### *Explorative synthesis*

#### Study general characteristics

Some of the studies covered multiple countries. Sixteen studies covered Asian countries, three covered African countries, and four from Latin and South America. China had the highest coverage with eight studies addressing its policies. All studies were published in between 2004 and 2015.

The main characteristics of the included studies were summarized in Appendix A. The articles' objectives can be classified in three core categories: assessment of medicines availability and affordability (59-64); analysis of pharmaceutical and pricing policy (63, 65-70); and assessment of pharmaceutical expenditure and prices pre-/post policy reforms (61, 64, 67, 71-73).

#### Pricing policy, outcomes variables and their effects

The table in Appendix B illustrates the different pharmaceutical pricing policies identified in the studies.

While twelve of the studies addressed a single pricing policy adopted in the country/countries where the study was conducted (59, 61-67, 69, 70, 74, 75), nine covered countries where two or more policies were implemented (60, 68, 70, 72, 73, 76-79).

The effects of these different policies were assessed based on several outcome variables. With the exception for Oman (78) and Turkey (69), the use of single, dual or triple policies did not always result in an optimal control of the pharmaceutical prices.

Brazil and Thailand were successful in reducing prices and establishing generic production of antiretrovirals through price negotiations and compulsory licensing threats (74).

#### Policies mapping to WHO pricing policy guidelines and level of income

After accounting for multiple studies from the same country, two of the countries were classified as high-income countries (HICs), five were upper-middle income countries (UMICs), two were LMICs, and two were LICs (Appendix C). The WHO recommended pricing policies were identified in the reviewed studies as represented in Figure 2 below:

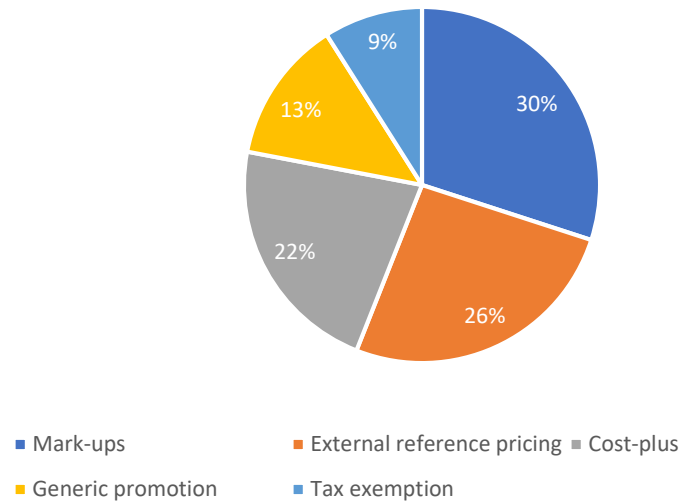


Figure 2. Identified WHO policies in reviewed articles.

### *Qualitative synthesis*

Of the six studies, which exhibited eligible study designs to be included in this analysis, five were pre-/post studies measuring impacts of a newly implemented pricing policies, and one was a longitudinal study (Appendix D). Although the studies measured the impact of price containment strategies, the outcomes measured varied by study, which made it difficult to quantitatively compare the results. Policies in China were effective in reducing prices (61, 67, 71, 72), however drug expenditure remained high due to irrational drug utilization (67, 71). In Indonesia, the prices were reduced for both drug types but did not reach the targeted maximum prices (73). Mali achieved its policy aims, although it took several years for the effects to be measurable (64).



## **Discussion**

Different countries employ varying theories on how to manage the pharmaceutical market. Some like Malaysia (80, 81) prefer minimal intervention, allowing for an equilibrium based on health sectors, suppliers, and patient interactions. Other countries get fully engaged and intervene by either subsidizing medicines or offering them for free to their population, which is the case in most industrialized countries that are members of the OECD (35, 82).

### ***General overview of pharmaceutical pricing policies in industrialized countries***

Both Qatar and Lebanon benchmark their medicine prices to a comparable basket of several European countries (members of OECD). A review of institutional reports and studies covering European and OECD countries was conducted to get an insight into the most commonly used pharmaceutical pricing policies. It is essential to emphasize the aggressive efforts undertaken by these countries to regulate the medicine prices in light of financial crisis (83, 84) as a main indicator of health equity and continuous access to health services (85, 86).

Most of the reviewed documents highlighted the widespread use of ERP in EU countries for on-patent medicines (86, 87) except in Germany where these medicines are freely priced (88). As of 2011, 24 out of the 27 EU countries covered in the RAND report used ERP with the exception of Sweden, UK, Denmark and to a certain degree Germany (88). As previously mentioned, ERP is a dynamic process to price on-patent and prescription only medicines including reimbursable medicines (86, 88). The size of the basket of countries included in the price benchmarking varies from as low as 4 (France, Netherlands) to as high as 20 (Spain) according to the statutory decrees implemented. Moreover, the

trend is towards including countries of similar income levels as the policy applying country (87). The overall impact of ERP in Europe is difficult to measure due to the various approaches utilized on a national level (88).

The supply chain remuneration is also relatively regulated in these countries through either a fixed fee, a fixed percentage or a fee-for-service (38, 86, 89). The margins added vary between linear or regressive mark-up schemes, with regressive scheme being applied more often recently (84). In order to curb the total drug expenditure for patients and third parties, regulators are focusing on the transparency and enforcement of the fixed profit margins for the different players in the distribution chain (87).

Another approach utilized to curb drug expenditure is the promotion of generic medicine use that is prevalent in most of the OECD countries (35, 38, 90-92). In addition to encouraging generics prescription and dispensing, different strategies are implemented to set generics prices at lower levels than on-patent medicines (84).

In recent years, the use of Health Technology Assessment policy (HTA) has been gaining ground in the OECD and European countries, and is reflected through different pricing and reimbursement strategies. Sweden has fully implemented HTA in the pricing decision-making while other countries such as UK are still at an early stage with the value-based pricing mechanism (93-97). HTA is being employed in addition to others economic, social, financial and humanitarian considerations under the value-based pricing and reimbursement mechanism as in Italy (98). HTA is a generic term and therefore each country applies it according to its needs. EUnetHTA (<http://www.eunetha.eu/>) is a database of HTA and other economic studies conducted in European countries which facilitates access to study results and promote efficiency (93).

Taxes are imposed on medicinal products at varying levels depending on medicine category and country (86). The taxes imposed on prescription medicines are relatively lower than non-prescription or over-the-counter (OTC) medicines. It is of note that taxes on medicine are generally lower than the standard taxes imposed on other products. Differences in retail price within a country can be attributed to the difference in taxes imposed among provinces (35). In the USA, where prices of medicines are higher than other OECD countries, no taxes are imposed on medicines (35).

Cost-plus pricing policy was not detected in the reports and articles reviewed.

#### ***In-depth discussion of pharmaceutical pricing policy identified in the systematic review***

Although developing countries are implementing policies as recommended by WHO guidelines, such policies have not always been successful as reported in China (67) and Indonesia (73). ERP which uses benchmarking against a basket of countries is one of the most widely used policies (99). However, it comes with some limitations which were evident in Mexico according to Moïse et al. (68) and in Egypt and Lebanon as per Kaló et al. (65). Optimal ERP should be benchmarked against countries with similar economic status. In many cases, countries with lower income such as Lebanon and Egypt are benchmarked against developed and high-income countries, resulting in higher medicine prices for local consumers (65).

Resistance to generic medicines use was observed and could be attributed to different reasons, some of which are patient and prescriber attitude and beliefs, financial incentive in selling higher-priced innovators and most importantly the lack of regulatory initiatives

to promote the use of generics (100, 101). Evidence supports that incorporating a pro-generic medicine policy in developing countries can immensely reduce the pharmaceutical expenditure and lessen the economic burden on consumers (102, 103).

While HTA has been implemented in several industrialized countries (86, 95), its use in developing countries is limited. This is mainly due to high level of skill required in design and implementation, as well as transparency in results assessment and decision-making (104-106).

Differential pricing, or “tiered pricing” adjusts the pharmaceutical prices to the purchasing power of the population and can result in an increase of market share and sales for the pharmaceutical industries (107). Despite its theoretical potential for reducing prices, tiered pricing is not commonly applied (108) as it requires confidential rebates, controlling of parallel trade and external referencing (109). Differential pricing has most commonly been used by NGOs such as UNICEF and Global Alliance for Vaccines and Immunization (GAVI) for vaccines, oral contraceptives and antiretrovirals in LMICs, particularly in Africa (53).

The data confirmed a scarcity of pharmaceutical pricing evaluative studies in developing countries as compared to developed countries (29, 92, 110). No significant relationship between income level and types of policies implemented was identified, although statistical confirmation was not possible due to the limited sample size (Appendix C).

After reviewing the impact of policies and the reality of the pharmaceutical sector status in developing countries to the extent permitted by the reviewed studies, more robust research targeting the analysis of pharmaceutical and pricing policy in the developing countries should be conducted, taking into consideration policy reform and adoption. With regards

to Qatar and Lebanon, a single study by Kaló *et al.* was identified (65). However, it did not reflect the actual pricing policies implemented nor measure the direct effect of these policies on the availability and affordability of medicines. The study only identified and assessed ERP by comparing the price corridor of pharmaceuticals that are subject to ERP versus non-pharmaceuticals. This scarcity of research regarding the pharmaceutical sector in the developing countries extended to Qatar where no such studies had been conducted, whereas Saudi Arabia, Kuwait and the United Arab Emirates (UAE) had been the subjects of WHO/HAI surveys. Lebanon was surveyed twice by WHO/HAI in collaboration with the MoPH in 2003 and 2013 (27, 55). However, these studies do not capture the impact of a recent amendment to the law concerning the evaluation of price depreciation by benchmarking the ex-factory price to the lowest price within the comparable basket of countries and the implementation of new regressive mark-up margins. Conducting regular studies is essential for decision makers to evaluate and take appropriate actions. Therefore, a systematic evaluation of the current state of CVD medicine prices, availability and affordability in these two countries and the effectiveness of pricing policies implemented is vital to the endeavors undertaken by the respective governments.

### **Research question**

Governments in developing countries are implementing several strategies to control medicine prices. The scope of policies used varies from disease-specific to essential and some countries extend it to all medicine classes. With the exception of a few success cases, policies have not been effective due to poor enforcement of regulations, inadequate monitoring, corruption, and non-compliance by stakeholders. Pricing policies adopted are

of international recognition, however, they are not optimally implemented and enforced.

Given the rarity of reporting in our region, our purpose is to be able to provide answers to the following questions:

- i. How are medicines priced? What actual pharmaceutical pricing policies are applied in each country and what price component has the highest contribution to the final retail price?
- ii. How do prices and pricing policies compare between Qatar and Lebanon?
- iii. Do the prices of CVD medicines in Qatar and Lebanon vary between sectors and how do the prices compare to international reference prices?
- iv. Are drugs priced higher in Qatar and Lebanon than in other countries in the region?
- v. What is the brand premium in each country?
- vi. Are CVD medicines available and affordable in Qatar and Lebanon?

## CHAPTER III: METHODOLOGY AND METHODS

### **Study methodology overview**

The World Health Organization and Health Action International (WHO/HAI) methodology is a standardized methodology that is publicly available on the HAI website (27). It is a reliable and valid tool to adopt in various settings. When used properly, it ascertains the situation of pharmaceuticals in terms of price and availability in the public and private sectors, price structure and composition, procurement prices efficiency, and their affordability to low-income patients (27). This study had two components: a policy analysis and a survey. The first component (Part I) was aimed at analyzing pharmaceutical pricing policies and regulations adopted in Qatar and Lebanon and investigating the pharmaceutical price components at a central level. The second component (Part II) was a cross-sectional systematic survey using a variant of the WHO/HAI methodology of the price, availability, and affordability of CVD medicines in public and private outpatient dispensing medicine outlets. For the latter part of this study, we utilized the following Price, Availability and Affordability survey and the data collection form provided by the WHO/HAI workbook.

### ***WHO/HAI methodology***

In the 1990s, several non-governmental organizations and governments realized that in order to fight poverty and inequity, a sustainable access to medicines is deemed essential. The price of medicines was one of the barriers to such consistent access. Furthermore, data from few small-scale studies had shown that prices in low-income countries were

higher than in richer countries. Sound information from systematic surveys of standard methodology to evaluate the price and availability of medicines was lacking. As a result, the WHO/HAI Project on Medicine Prices and Availability was established in 2001. After several provisional surveys, the methodology was launched in 2003, and has since been regularly reviewed to increase its efficiency and transparency. To further enhance the transparency and the universal applicability of the survey, a database of survey results was created on HAI website (<http://haiweb.org/what-we-do/price-availability-affordability/price-availability-data/>).

The main objective of the survey is to collect reliable data related to prices, availability, and affordability of a specific basket of medicines and price components added throughout the supply chain. Ideally, it is a national survey, or across a state or province in case of large countries. Data about the medicines' price, availability and affordability are collected from up to 4 different sectors. It is recommended to cover at least the capital plus 5 other areas within one-day drive from the capital. In each area, it is recommended to collect data from 5 outlets per sector. If possible, prices are collected from 1 or 2 central public procurement offices to measure the efficiency of the public procurement. For the price component survey, backward tracking of the add-on costs along the supply chain is undertaken for several medicines of different types, therapeutic classes and manufacturing origins. For the price, availability and affordability survey, the real retail price paid by the patient is collected in each sector in local currency. Surveyed outlets should have an outpatient pharmacy dispensing medicines directly to the patient. To calculate the affordability, the lowest-paid unskilled government worker (LPGW) salary is identified. Affordability is then estimated based the cost of a full treatment regimen for



either acute or chronic disease in terms of the number of the days' wages forgone by the LPGW to purchase the treatment. The outlet sampling is conducted in a systematic manner to ensure sufficient coverage. The list of surveyed medicines can include up to 50 medicines while the affordability can be calculated for up to 22. For each medicine, data about the originator brand (OB) and lowest-priced generic (LPG) available at the outlet are collected. The methodology standardizes the medicines surveyed to allow for international and global comparison of data. Medicines of national importance can be added to the list. The data collected are entered in the WHO/HAI Medicine Price and Availability Workbook – Part I and Part II, a customized Excel workbook (27).

### **Pharmaceutical pricing mechanism analysis**

#### ***Study design***

This part of the study was investigational, conducted at a central level (e.g. ministries) constituting meetings and discussions with key informants with knowledge of pharmaceutical pricing mechanisms, regulation and supply chain. The discussions covered the pricing mechanism of pharmaceuticals and delved into the various price components throughout the different stages of the medicine distribution chain. It was followed by official documents review and reporting (e.g., decrees, decisions, and laws).

#### ***Ethics***

Access to governmental authorities in both countries and meeting with respective personnel required the entities' approval. Therefore, a support letter issued by Qatar

University was utilized in Qatar (Appendix E), and an approval letter was issued from the MoPH in Lebanon for the same purpose (Appendix F).

### ***Study location, setting and timeline***

#### *Location*

The study is comparative and carried out in two different countries: Qatar and Lebanon. Both are developing middle eastern countries. The ministries of public health in both countries are located in the capitals: Doha and Beirut.

#### *Setting*

To collect central level data, public entities involved in the pharmaceutical pricing policies implementation and monitoring were visited. In Qatar, meetings were organized with the Pharmacy and Drug Control Department (PDCD) at the MOPH and the Drug Supply Department at Hamad Medical Corporation (HMC) to investigate the retail price composition. These departments regulate the private and public sectors medicine procurement processes, respectively. A similar process was followed in Lebanon, where meetings were conducted with the Import/Export & Drug Registration Department at the Lebanese MoPH to investigate the pricing mechanism. In addition, we also reviewed the results of the WHO/HAI study conducted in 2013 to ascertain compliance with pricing regulations.

Appendix G lists the departments visited in both countries per sector and the position of the key informants met.

### *Timeline*

In line with the WHO/HAI recommendation, the meetings with these entities were conducted simultaneously or directly after the price, availability, and affordability observational survey.

### ***Population and sampling***

#### *Geographical area sampling*

Based on the geographical and centralization of government bodies in the capitals of both countries, the investigational component of the survey was conducted centrally at the respective ministries of public health and related supply departments. The selection of key informants followed a snowball sampling approach.

#### *Operational definition and output measures*

Free-on-Board (FOB) and Cost Insurance Freight (CIF) are terms describing the international shipping agreement between sellers and buyers. They determine which party is liable for any damage occurring to the goods during shipping.

- i. FOB: The responsibility of the seller ends when the goods are at the port of shipping in the country of origin. The buyer assumes responsibility afterwards until it gets to the purchasing country.
- ii. CIF: The seller assumes responsibility until the goods are received by the purchasing party (111).
- iii. Mark-up: The additional costs to the MSP in the form of charges and costs to cover different stages of the distribution chain including profits, overheads

cost, and distribution fees. Regressive mark-up is the addition of lower mark-up for higher priced medicines. The mark-ups can be applied as fixed fees or percentage fees (27).

#### *Data management and analysis*

- i. Data collected from ministry meetings and publications: consolidation of the available information from the MoPH websites and publications with information gathered from individuals met at the MoPH, and detection of any exceptions or non-transparency.
- ii. The data gathered regarding the price components and the pharmaceutical pricing policies implemented in Qatar and Lebanon was compared. A further correlation between the regulations and the actual prices in terms of brand premium was conducted.

#### **Price, availability, and affordability survey**

##### *Study design*

A cross-sectional observational study using a data collection form in primary healthcare centers and community pharmacies. The data collection form was filled in by the researcher after observing the medicines listed in the form with the help of responsible persons in the surveyed facilities. The data collection was conducted during a specific period (27). Each outlet was visited once.

For each medicine, data about the originator brand and the lowest-priced equivalent generic available in the outlet at the time of the visit were collected.

### ***Ethics***

No QU IRB approval was required for the study as confirmed by the university (see Appendix H). Prior to surveying the “public sector”, ethics approval from the concerned entities were collected in both countries. The research study was approved by the Primary Health Care Corporation (PHCC) in Qatar (see Appendix I). A letter directed to the General Manager of the Ministry of Public Health in Lebanon seeking approval was accepted and signed (see Appendix J). As for the private sector, a letter of support from QU was issued and shared with the pharmacy managers prior to the survey in Qatar (Appendix K). In Lebanon, an endorsement phone call from the local study collaborator was made before the visits.

### ***Study location, setting and timeline***

#### ***Location***

The study is comparative and carried out in two different countries: Qatar and Lebanon. Both are developing middle eastern countries. The outlets visited were dispersed across the Qatari and Lebanese territories to grasp broader image of the medicines situation across different sectors, cities and/or areas.

#### ***Setting***

The study was carried out in public health care centers, private pharmacies and private hospitals or clinics:

- i. Public sector: public facilities where patients receive medicines either in primary health care centers or clinics as well as public hospitals. As per the manual, all included public facilities had an outpatient pharmacy. In

Qatar, PHCC network was established in 2012 with a vision of being the primary healthcare provider in the country. Since its foundation, the number of centers inaugurated across the country has been increasing (PHCC report 2013-2014). Likewise, the network of primary health care centers in Lebanon was expanding to provide services to eligible uninsured patients (112). In 2015, 225 centers were in operation, covering most of the Lebanese territory. All Lebanese public facilities visited were primary healthcare centers. However, in some instances these centers were located within a secondary healthcare facility as an outpatient unit for medical consultation and outpatient medicines dispensing units. The data was collected from outpatient pharmacies. In this study, the surveyed facilities were selected in advance and the level of care of each facility was determined and recorded as “1” to designate a primary level of care. All these designations were entered in the latest WHO/HAI workbook (latest version May 2015) available on the HAI website (<http://haiweb.org/what-we-do/price-availability-affordability/collecting-evidence-on-medicine-prices-availability/>).

- ii. Private sector: in our study, this sector covered private retail drug outlets e.g., community pharmacies. The ownership and management of private pharmacies differ between Qatar and Lebanon. In Qatar, most of the pharmacies are owned and operated by companies as a branded chain of pharmacies. Each pharmacy is typically managed by employees of the

company. On the other hand, community pharmacies in Lebanon are generally owned by individual pharmacists who also manage the facility.

- iii. Private hospitals or clinics: this sector covered the private hospitals or clinics that had at least internal medicine department and an outpatient pharmacy for medicine prescription' dispensing. Such outlets were only available in Qatar.

### *Timeline*

This study was conducted between August 2016 and April 2017. Data collection was carried out during different periods given the fact that two countries were surveyed.

Moreover, delays in receiving ethics approval to access some sectors resulted in varying data collection timeframes per sector.

### ***Population and sampling***

#### *Geographical area sampling*

The main areas surveyed were the capital cities in both countries (Doha and Beirut) in addition to other administrative areas within one-hour drive from each capital as per the table below. According to the WHO/HAI methodology, it is recommended to cover up to five areas besides the capital. Lebanon and Qatar have comparable areas, 10,452km<sup>2</sup> and 11,610km<sup>2</sup>, respectively (113). However, the populations vary significantly. Lebanon has a population of more than 5 million, almost double the population of Qatar with a much higher population density (113). According to WHO/HAI (27), the selection of the covered areas should be based on geographical districts around the country with a minimum

population density. In Lebanon, the population is dispersed across the country. However, Qatar has a centralized population density around fewer main cities or municipalities. As such, the availability and types of healthcare services and facilities in both countries are reflective of the demographic profiles. The 1+5 target was achievable in Lebanon due to its multiple population centers (27). However, the centralized population in Qatar limited our surveyed areas to 1+4 as per the Table 4 below.

**Table 4:** Surveyed Areas in Qatar and Lebanon

	<b>Qatar</b>	<b>Lebanon</b>
<b>Capital</b>	Doha (A1)	Beirut (B1)
<b>Other areas</b>	Al Khor (A2), Al Wakrah (A3), Umm Salal (A4), Mesaimmer (A5)	Tripoli (B2), Nabatiyeh (B3), El Shouf (B4), Baalback (B5), Tyre (B6)

### *Medicines list sampling*

The latest essential medicine list (EML) adopted and released in Lebanon was used as a reference. To note, the Lebanese EML (see Appendix L) is in line with the 18<sup>th</sup> edition of WHO list (114). Although Qatar has a formulary, it has not yet adopted an EML. In order to compile a common list of essential medicines to survey, the Lebanese EML containing the cardiovascular disease was first compared to the medicines available in Qatar. Validation visits to the Drug Supply Department in Hamad Medical Corporation and a primary health center in Qatar were conducted in July 2016 to compare the Lebanese EML to medicines available in Qatar. As a result of these visits, the list of Lebanese CVD



essential medicines was refined by excluding the medicines that were not available in Qatar. A previous pilot study (unpublished) covering the lipid-lowering drugs was conducted based on the same principle of compiled medicine list. Figure 3 illustrated further refinement stages where medicines were excluded if they were not available in level 1 healthcare facilities (community pharmacies and primary healthcare centers), and if they did not have an international reference price. The validated list was then compared to the WHO 2015 19<sup>th</sup> edition of essential medicines (115) (Figure 3). The twenty-seven cardiovascular disease medicines retained in the list to survey are the common essential and nationally important medicines in both countries (Table 5). The study covered the same active ingredients and strength. For each active ingredient, we reported the price and availability of two types: OB and a LPG available at the time of visit. The generic chosen was assumed to be of good quality and bioequivalent to the originator. For each originator or generic, the compared medicines of a specific active ingredient were of the same dosage form, strength and number of pills per package. For each medicine, a recommended pack size was determined. If this pack size was not available, the next larger pack size was reported.

#### *Medicine outlets sampling*

In each area, one facility per sector was covered. This resulted in one outlet per sector (total of two outlets) surveyed in each area in Lebanon and one outlet per sector out of a total of up to three sectors per area in Qatar as per Table 6. An exception was made in area number 5 (A5) in Qatar where no “other sector” facility existed. This decision was made to include this area based on the relatively large local population and the significance of its primary

healthcare center. In case of an outlet where less than 50% of the surveyed medicines were available, a back-up outlet from the same sector was visited where possible (Table 6). No verification visits were conducted.

**Table 5: List of Medicines Surveyed**

<b>Medicine Name</b>	<b>Dosage Strength</b>	<b>Dosage Form</b>	<b>Affordability</b>
Acetylsalicylic acid	100 mg	cap/tab	✓
Amiodarone	200 mg	cap/tab	✓
Amlodipine	5 mg	cap/tab	✓
Atenolol	50 mg	cap/tab	
Atenolol (2)	100 mg	cap/tab	
Atorvastatin	10 mg	cap/tab	
Atorvastatin (2)	20 mg	cap/tab	✓
Atorvastatin (3)	40 mg	cap/tab	
Bisoprolol	5 mg	cap/tab	✓
Captopril	25 mg	cap/tab	
Captopril (2)	50 mg	cap/tab	
Clopidogrel	75 mg	cap/tab	✓
Digoxin	0.25 mg	cap/tab	✓
Diltiazem	60 mg	cap/tab	
Enalapril	5 mg	cap/tab	✓
Furosemide	40 mg	cap/tab	✓
Gemfibrozil	600 mg	cap/tab	
Hydrochlorothiazide	25 mg	cap/tab	✓
Isosorbide dinitrate	5 mg	cap/tab	
Losartan	50 mg	cap/tab	
Methyldopa	250 mg	cap/tab	
Propranolol	10 mg	cap/tab	
Propranolol (2)	40 mg	cap/tab	
Simvastatin	10 mg	cap/tab	
Simvastatin (2)	20 mg	cap/tab	✓
Spirolactone	25 mg	cap/tab	✓
Verapamil	80 mg	cap/tab	✓

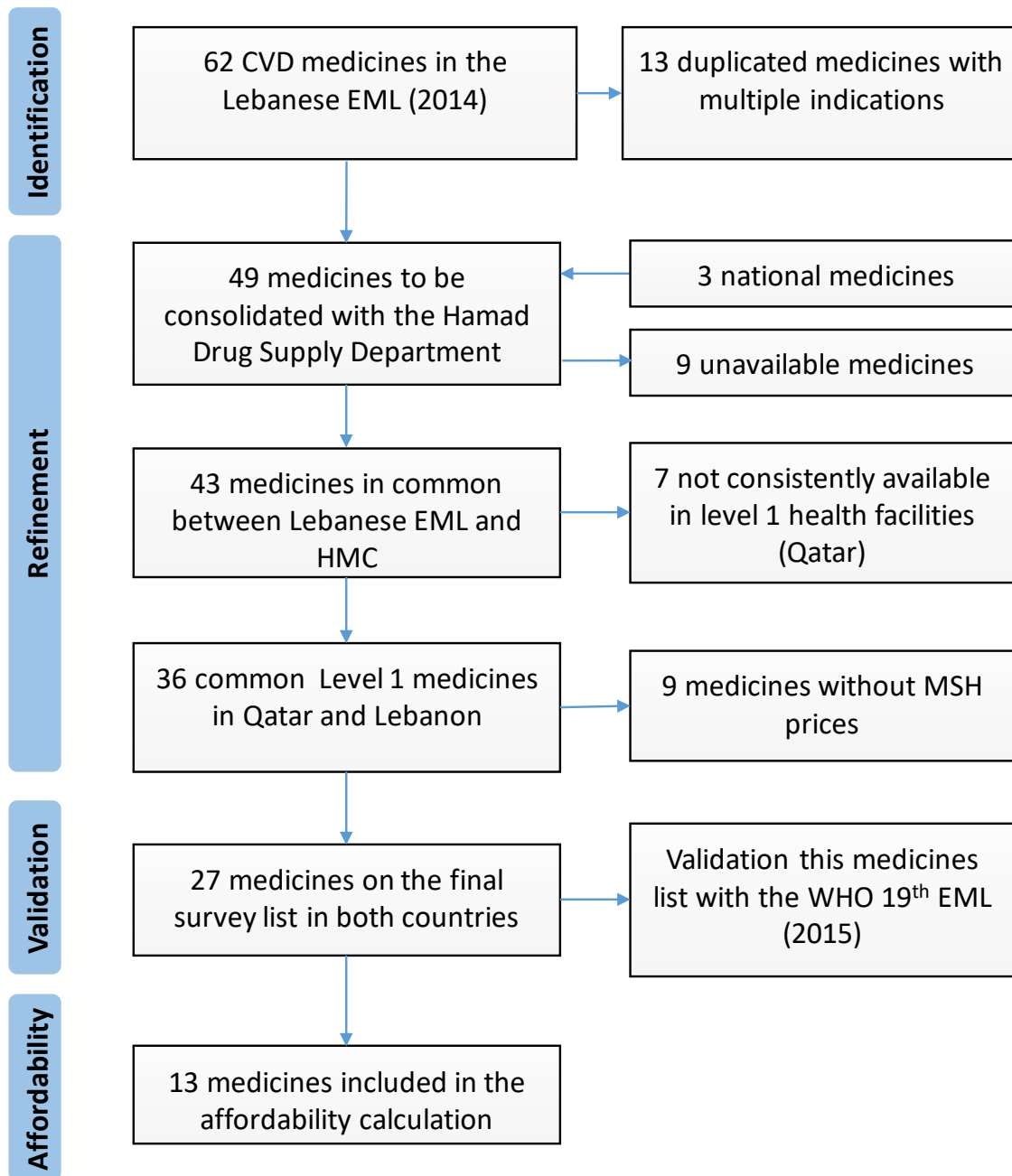


Figure 3. Refinement process of the surveyed list of medicines.

**Table 6:** Number of Facilities Covered by Country, Area and Sector

Sector	Qatar					Lebanon					
	A1	A2	A3	A4	A5	B1	B2	B3	B4	B5	B6
Public Sector Outlets (n)	1	1	1	1	1	2	2	2	2	1	1
Private Sector Outlets (n)	1	1	1	2	1	1	1	1	1	1	1
Other Sector Outlets (n)	1	1	1	1							

In each area surveyed, a public outpatient health care center was identified. A private sector facility was selected based on its proximity to that public health care facility. All outlets were identified and selected from publicly available lists of medical outlets.

In both countries, the managers of the pharmacies or medicine outlets were contacted ahead of time to brief them about the search strategy and purpose. In case of access denial, another outlet from the same sector and area was contacted. Upon request, managers were provided with a letter from the CPH.

A list of all selected outlets along with their contact details was compiled, and a schedule of visits was set. The medicine outlets listed were contacted and informed of the date and time of the visit in addition to the approximated duration of the visit.

### ***Tools***

The second edition of *Measuring medicine prices, availability, affordability, and price components* (2008) of WHO/HAI methodology that was developed in 2003 was adopted in the research with some variations due to the inherent characteristics of the countries surveyed and limited resources. As such, we reduced the numbers of sectors covered to

three instead of four and the number of facilities visited per sector and per area to one (27). The WHO/HAI workbook was the tool used to collect information regarding medicine prices.

### *Software*

The software available on the HAI website ([www.haiweb.org/medicineprices](http://www.haiweb.org/medicineprices)) was utilized for data entry and summary. The default set of essential medicines covering all essential medicines of the most common acute and chronic diseases in the workbook was replaced by the validated list of the essential medicines treating cardiovascular diseases in Qatar and Lebanon. Additionally, the manual provided the researchers with the tools to assess the price, availability and affordability of medicines and to conduct the appropriate analysis such as:

- i. Within sector analysis;
- ii. Across sector analysis; and
- iii. Nation-wide analysis.

### *Development and validation measures*

The best practice is to cover 6 areas in each selected country and to cover 5 facilities per sector. However, due to the nature of Qatar and its demographic uniqueness in addition to the financial and logistic constraints, we reduced the number of both parameters. This would not affect the validity of the tool used as it had been adopted in different settings and countries without compromising its validity. The WHO/HAI methodology does allow for variation as per the manual (27). Examples of surveys that varied from the standard are Tajikistan 2005 and Ukraine 2007, both found on the HAI website

(<http://haiweb.org/survey-related-reports/>). Similarly, the deviations from the standard WHO/HAI methodology in our study did not affect the tool, workbook or analysis.

Variances from the WHO/HAI methodology were limited to the setting and sample size.

### ***Data collection procedure***

The data collection form provided in the workbook was printed out after inputting the surveyed medicines. Visits to outlets were arranged by appointment. Two visits were conducted per day. The medicine price, manufacturer, availability, pack size and price were recorded. As mentioned before, in case of outlets where less than 50% of the medicines surveyed were available, a back-up visit was arranged to a same category facility. The data from the first facility was kept and reported. Such recommended back-up visits were not always conducted in this study given the unavailability of parallel outlets of the same qualification in some areas.

Daily management and review of collected data were conducted to minimize missing data and errors.

### ***Operational definition and output measures***

- i. According to WHO, National Drug (Pharmaceutical) Policy is defined as: “*a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field*” (116).

- ii. Essential Medicine List: is a list that includes all those medicines that satisfy the priority health care needs of the population (22).
- iii. International Reference Price: *“The practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country”* (117).
- iv. Availability: *“the availability of medicines is reported as the percentage of medicine outlets in which the medicine was found on the day of data collection”* (118).
- v. Affordability: *“the affordability is the cost of treatment in relation to peoples’ income”*. In other terms, *“the measure of days of work by the lowest-paid unskilled national government worker to purchase a defined course of treatment for a specific condition”* (27, 118).
- vi. MPR: is calculated as a *“ratio to an international reference price (IRP) expressed as Median Price Ratio”* (27).
- vii. Purchasing Power Parity: According to International Monetary Fund (IMF), purchasing power parity can be defined as: *“The rate at which the currency of one country would have to be converted into that of another country to buy the same amount of goods and services in each country”* (14).



## *Data management and analysis*

### *Data management*

The independent variables of this survey are the countries, sectors and the types of medicines (originator brand or generic). The outcomes are different medicine prices, affordability, and availability. The data collected was entered in the computerized workbook and analyzed by the researcher. This workbook allowed instant data entry, summarizing, and verification. The summary generates information about:

- i. Prices in different sectors, geographical areas, health facilities and pharmacies. The prices measured by the survey were the actual prices paid by patients in retail medicine outlets. In the public sector where medicines are dispensed for free or for a nominal fee regardless of the cost of medicine, prices were not reported or included in the analysis. The Letter “F” replaced the price in the workbook. This designation was also applied to public outlets where medicines are from donations. In both cases, the sector analysis was limited to the measurement of the medicine availability. The workbook output for medicine price consisted of the following:
  1. Individual medicine median price and MPR.
  2. A basket of medicine median price and MPR.
  3. Price variation represented by interquartile range.

All visits in both countries were conducted in 2016 except for the public sector (PHCC) in Qatar. Due to delays in issuing the approval, this specific sector was surveyed in 2017. For that reason, prices were deflated to 2016 by taking into consideration the health sector’ Consumer Price Index (CPI) of Qatar as reported

by the Ministry of Development Planning and Statistics (mdps) (119). The WHO/HAI manual details the steps followed to adjust prices (27).

- ii. Workbook output for medicine availability:
  - 1. The mean availability in percentage of individual and basket of medicines in each area and sector.
- iii. Workbook output for medicine affordability:
  - 1. Treatment affordability by medicine, and sector in relation to days' wages perspective.

### *Analysis*

The analysis was carried out to interpret the following:

- i. Price: The average price of medicines was generated as median prices within an interquartile range and as MPR as compared to the IRP as per the equation below:

$$MPR \text{ of a specific medicine} = \frac{\text{median local unit price}}{\text{international reference unit price}}$$

- ii. In order to measure the median price, medicine prices in local currency were converted to US Dollars based on the exchange rate at the time of the survey according to *Oanda* exchange rate (120). The IRP were based on the latest MSH reference prices of 2014 (121). IRP is utilized in WHO/HAI for a standardized mean to compare prices internationally across several surveys. The price of a

medicine in local currency in the two countries cannot be directly compared due to the difference in the purchasing power (27). Therefore, the estimation of the local currency in terms of purchasing power parity (PPP) was utilized for the international comparison of medicines price (122) whereas the availability and affordability were directly compared. The threshold of acceptable MPR was set at 4 in this study.

- iii. Availability: for each medicine, availability was calculated as per the following equation

$$\text{availability (\%)} = \frac{\text{number of outlets where the medicine was found in a specific sector}}{\text{total number of outlets visited in that sector}} \times 100$$

- iv. The affordability of medicines for chronic disease was determined by estimating the total quantity of units consumed per month. For the management of acute illness, the treatment regimen was based on the international standard treatment regimen as per WHO (27, 123) and the new national clinical guidelines launched by the Ministry of Public Health in Qatar (124). A further meeting was held with the clinical pharmacy department at the Heart Hospital in HMC to consolidate the information gathered from the guidelines. Treatment affordability is expressed in the number of days' wages forgone to purchase the complete treatment (month for chronic or else for acute). The workbook provided flexibility to determine the specific treatment regimen for each

medicine based on the indication. The salary of the lowest-paid unskilled government worker in each country was identified at the time of the study (27).

The following equation illustrates how affordability was calculated based on the WHO/HAI manual (WHO/HAI) (27):

$$\text{affordability (in days wage)} = \frac{(\text{number of unit per day} \times \text{unit price}) \times 30 \text{ days}}{\text{daily wage of LPGW}}$$

A treatment is considered affordable if it costs less than one day-wage.

All output summaries by WHO/HAI workbook were transferred to Excel for descriptive and pictorial analysis and illustration. This software was also utilized for international comparison of the summaries.

### ***Pilot study***

In early 2016, a pilot study was conducted using the same methodology. The main purpose of that pilot study was to familiarize the main researcher with the WHO/HAI methodology and workbook. The second objective was to investigate the feasibility of compiling a common list of medicines between Qatar and Lebanon by relying on the Lebanese EML. The medicines considered for that pilot study were limited to lipid-lowering agents. An extended list was developed after meeting with key informants in Hamad Medical Corporation's Drug Supply Department and Ministry of Public Health's Pharmacy & Drug Control Department. A validation of this issued list was conducted by visiting other pharmaceutical outlets. A workbook resembling to the WHO/HAI price,

availability and affordability model was developed. A cross-sectional systematic survey of prices in several medicines outlets was conducted. A total of four facilities in two different areas were surveyed:

- i. Public sector: PHCC- Mesaimeer
- ii. Private sector: Al Ahli Hospital, Khoulood Pharmacy (Al Markhiyya- Burger King roundabout); Care & Cure Pharmacy (Mesaimeer- near PHCC).
- iii. Date of visits: Al Ahli Hospital and Khulud Pharmacy were visited on May 2<sup>nd</sup>; Care & Cure and PHCC (Mesaimeer) on May 5<sup>th</sup>. To note that PHCC was revisited on May 17<sup>th</sup> for prices confirmation.

The visits to the private sector broadened our understanding of the medicines available in the Qatari market. At the first glance, it was evident that the public sector is procuring and dispensing only OB for the patients. Nevertheless, the medicines are dispensed for free for Qataris and at 20% of the total price for non-Qataris. The private sector was dispensing OB and generics but not all had the LPG. The prices of OB in the private sector could reach more than 2 folds those in the public. This can be explained by the bulk procurement prices that HMC can purchase at as reported by one of the key persons that we met in HMC. The private sector's MPR were significantly higher than the international reference prices. In the public sector, almost all medicines were affordable at less than 1-day wage for the lowest paid unskilled government worker. However, these medicines were not affordable in the private sector.

According to the methodology, we were calculating the price of one medication at a time. However, most chronic disease patients are being prescribed a full treatment

course formed of several medicines. Based on the observations made in this pilot study, the researchers decided on a plan to elaborate the list of medicines for our study. Medicines were to be included in the common list based on two main criteria: their availability in both markets in addition to their national clinical relevance.

## CHAPTER IV: RESULTS

### **Pharmaceutical pricing policy analysis**

The laws currently in effect in Qatar and Lebanon are based on the latest versions of decrees enacted in 2011 and 2005 respectively (125, 126). Over the years, the governments have been revising the regulations governing medicine prices either nationally as in Lebanon or regionally in Qatar in line with other members of the Gulf Cooperation Council (GCC) (127). Both Qatar and Lebanon have implemented similar pharmaceutical pricing policies. External reference pricing (ERP) is one of the pricing policies adopted by both countries, albeit with different baskets of reference countries. The basket of countries to which the prices in each country are benchmarked vary. In Lebanon, prices are benchmarked against three sets of prices with the lowest price adopted: ex-factory and patient selling price of medicines in the country of origin; basket 1 which is composed of 7 European countries; and basket 2 comprised of neighboring Arab countries including Qatar (128). To set a price for registration, Qatar and Saudi Arabia are mainly relying on the ex-factory and selling price of the medicines in the country of origin, as well as the cost-insurance-freight (CIF) price in up to 30 countries to which the medicines were exported and sold (126). In addition to ERP, mark-up regulations are applied with different schemes along the pharmaceutical supply chain. While a decree detailing all the different mark-up schemes is available to the public in Lebanon (46), such detailed scheme is not available in Qatar. In addition, Qatar may consider the economic evaluation of a medicine to set the price if such evaluation or Health Technology Assessment (HTA) is available at the time of registration (126). As such, relevant information was gathered directly from the public entities directly involved

in the process. The table 7 below summarizes the details pertinent to our study aim.



**Table 7:** Primary Features and Characteristics of the Pharmaceutical Pricing Policies and Regulation in Qatar and Lebanon

	<b>Qatar</b>	<b>Lebanon</b>
<b>National Decree and Law</b>	<ul style="list-style-type: none"> <li>• Decree number (1-10-1432) in 2011</li> </ul>	<ul style="list-style-type: none"> <li>• Decision 306/1 in 2005</li> <li>• Amendment decisions 1/51 in 2006; 1/796 in 2014; and 1/1151 in 2014</li> </ul>
<b>Pricing Mechanism</b>	<ul style="list-style-type: none"> <li>• Ex-factory price and retail price in the country of origin</li> <li>• Price in countries where the medicine is marketed</li> <li>• Proposed cost</li> <li>• Pharmacoeconomic considerations may be considered if available</li> <li>• Therapeutic significance</li> <li>• Price benchmarking to several countries: country of origin, and other importing countries</li> <li>• CIF price to KSA and thereafter Qatar imposes 44%</li> <li>• OB price is reduced by 20% upon registration of first generic</li> </ul>	<ul style="list-style-type: none"> <li>• Ex-factory price and retail price in the country of origin</li> <li>• Review of shipping certificate (CIF or FOB) to either: Jordan, KSA, Kuwait, Oman, UAE, Bahrain and Qatar or France, UK, Belgium, Switzerland, Italy, Spain, and Portugal</li> <li>• Adopt the lowest MSP, and the lowest FOB among neighboring and basket countries (796/1)</li> <li>• Repricing every 5 years</li> </ul>
<b>Generic Pricing Mechanism</b>	<ul style="list-style-type: none"> <li>• First generic is 35% less than OB</li> <li>• Second generic is 10% less than first generic</li> <li>• Third generic is 10% less than second generic</li> <li>• All subsequent generics are 10% less than third generic</li> </ul>	<ul style="list-style-type: none"> <li>• Generic is priced on the same mechanism as OB, and price to consumer is at least 30% less than OB (1/728 in 2013)</li> <li>• If no OB is registered, prices are reviewed 3 months after third generic is registered and average price is adopted</li> <li>• If the OB price was changed, the generics price should be changed in a rate that halves that of OB.</li> </ul>
<b>Locally Manufactured/Packed Pricing Mechanism</b>	<ul style="list-style-type: none"> <li>• Locally manufactured generic: same pricing mechanism as generic</li> <li>• If generics were already registered, then existing price applies</li> <li>• Generic package under-license: same pricing mechanism as generic</li> <li>• OB manufacturing and packaging under license: same pricing mechanism as OB</li> </ul>	<ul style="list-style-type: none"> <li>• Locally manufactured: adopt ex-factory price</li> <li>• Packaged under-license: adopt ex-factory price in country of origin</li> <li>• If generic, price must be at least 30% lower than OB</li> </ul>

<b>Basket of Countries</b>	<ul style="list-style-type: none"> <li>• Country of origin</li> <li>• Other GCC countries</li> <li>• All other countries where medicine is exported</li> </ul>	<ul style="list-style-type: none"> <li>• Country of origin</li> <li>• Neighboring countries</li> <li>• France, UK, Belgium, Switzerland, Italy, Spain, and Portugal</li> </ul>
<b>Pharmaceutical Pricing Policy</b>	<ul style="list-style-type: none"> <li>• ERP</li> <li>• Mark-ups regulation</li> <li>• HTA</li> </ul>	<ul style="list-style-type: none"> <li>• ERP</li> <li>• Mark-ups regulation</li> </ul>
<b>Importing Currency</b>	<ul style="list-style-type: none"> <li>• USD</li> </ul>	<ul style="list-style-type: none"> <li>• Several currencies according to exporting country and purchase currency</li> </ul>
<b>Price Adjustments for Exchange Rate Fluctuations</b>	<ul style="list-style-type: none"> <li>• Occasionally (QAR is pegged to USD)</li> </ul>	<ul style="list-style-type: none"> <li>• Updated every two weeks</li> </ul>
<b>Shipping Agreement</b>	<ul style="list-style-type: none"> <li>• Private: CIF</li> <li>• Public: various agreement</li> </ul>	<ul style="list-style-type: none"> <li>• Public and private: CIF or FOB</li> </ul>
<b>Mark-up</b>	<ul style="list-style-type: none"> <li>• Public: variable depending on the shipping agreement</li> <li>• Private: uniform</li> </ul>	<ul style="list-style-type: none"> <li>• Private: digressive mark-up</li> </ul>
<b>Price Tag in the Private Sector</b>	<ul style="list-style-type: none"> <li>• Set by the PDCD in MOPH</li> </ul>	<ul style="list-style-type: none"> <li>• Set by wholesaler, adjusted by pharmacist in case of variation in price indices (exchange rate)</li> </ul>

*Note: KSA: Saudi Arabia; USD: US dollar; QAR: Qatari riyal.*

In 2012, CIF was adopted as the landed price for pharmaceutical registration in the private sector in all GCC member states (127). Furthermore, the maximum mark-up allowed in the GCC was set at 45%. In Lebanon, the Ministry of Public Health (MoPH) decision 306/1 of 2005 was continuously reviewed with the latest update being decision 796/1 in 2014, adopting the lowest price out of any of the price comparisons considered for registration (Table 7). The different CIF and free-on-board (FOB) tranches were lately updated as well in decision 1131/1 in 2014 by the addition of a new tranche for expensive in-patient medicines. The pharmaceutical pricing policies in Lebanon apply to all sectors except for the primary health centers (PHC) whose medicines are procured through the Young Men's Christian Association (YMCA).

In Qatar, the public and private sectors have distinct procurement and pricing mechanisms. The public sector is massively subsidized. The medicines are procured through different channels, mostly through GCC bulk procurement, in addition to other agreements directly with manufacturers, local agents or from local manufacturing. The pricing mechanism in the public sector is not disclosed, however, the range of mark-up schemes varies from 2 to 10% on the purchased price. Not all medicines imported by Hamad Medical Corporation (HMC) are registered with the MOPH. Moreover, for the few generics found in the public sector, no price difference was detected compared to the OB. Based on discussions with HMC personnel, the HMC allocates a weighted average to the active ingredient price depending on the overall stock in use in various facilities with minimal impact to the end user price.

Table 8 demonstrates the various regressive and cumulative mark-up add-ons to medicines in Lebanon based on FOB and CIF price. Tranche E represents mainly in-patient formulation where specialized skills are required for the preparation. A new decision 1131/1 enacted in 2014 has allowed the addition of 8% as dispensing fees followed by \$86 as a fixed mark-up.

Some imported medicines are exempt from taxes. These include medicines imported and manufactured in Arab countries or medicines imported under EUR1 trade agreement. Such details are withheld within the Ministry of Finance. Table 9 shows some government encouragement of local manufacturer efforts.

**Table 8:** Different Pharmaceutical Mark-up Schemes Applied to Medicines in Lebanon

1	2	3		4	5	6
Tranche*	Cost of freight and Insurance (only if FOB)	Custom clearance, import tax, and others		Importer and wholesaler mark-up	Pharmacist mark-up	Base/100
		Without custom	With custom			
<b>A</b>	7.00%	6.00%	11.00%	10.00%	30.00%	143.00
<b>B</b>	5.00%	5.00%	10.00%	10.00%	30.00%	143.00
<b>C</b>	4.00%	3.00%	8.00%	9.00%	27.00%	138.43
<b>D</b>	3.00%	2.50\$	7.50%	8.00%	24.00%	133.92
<b>E</b>	1.50%	1.50%	6.50%	6.50%	\$86.00	86\$+106.50

*Source:*

Ministry of Public Health (MoPH). Decision 796/1 Beirut: Ministry of Public Health; 2014 [Available from: <http://www.moph.gov.lb/en/laws#/Laws/view/19>].

(\*): wider range for locally manufactured medicines

**Table 9:** Tranches Divisions per FOB and CIF Prices in Lebanon

Tranche	FOB price \$	CIF price \$	Local product price \$
<b>A</b>	0 - 10	0 - 10.70	0 - 11.34
<b>B</b>	10 - 50	10.70 - 52.50	11.34 - 55.13
<b>C</b>	50 -100	52.5 - 104	55.13 - 107.12
<b>D</b>	100 - 300	104 - 309	107.12 - 316.72
<b>E</b>	300 - and above	309 - and above	316.72 - and above

*Source:*

Ministry of Public Health (MoPH). Decision 796/1 Beirut: Ministry of Public Health; 2014 [Available from: <http://www.moph.gov.lb/en/laws#/Laws/view/19>].

*Note: Inclusion of a FOB/CIF to any tranche is related to the exchange indices.*

In Qatar, the add-on cost in the private sector is defined and uniform. All manufacturer selling price (MSP) prices are CIF based in USD. Figure 4 below illustrates these mark-up schemes.

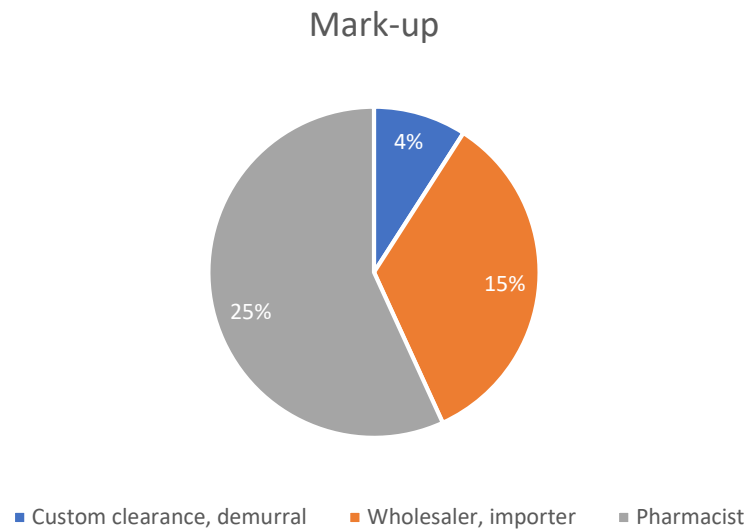


Figure 4. Different cumulative mark-up schemes applied uniformly to all medicines in the private sector in Qatar.

## Prices

### *Price variation in local currency*

Prices of all registered medicines in Qatar and Lebanon for the private sector are available online. It is routinely updated on the Lebanese MoPH ministry website, while less frequently updated in Qatar. Prices of the same medicine type (either OB or LPG) in Qatar and Lebanon varied slightly between different outlets within and across sectors.

The rate of price variation of LPG was higher than those of OB in line with the multitude

of generic brands for the same medicine found in the outlets. These incidences were more frequent in Lebanon than in Qatar. Table 10 demonstrates the few instances of these variations.

**Table 10:** MPR, 25<sup>th</sup>, and 75<sup>th</sup> Percentiles Variation in the Private Sectors for Both Medicine Types in Qatar and Lebanon

Country/sector	Medicine and product type	Median MPR	25 <sup>th</sup> percentile	75 <sup>th</sup> percentile
<b>Qatar/ Other Sector</b>	Acetylsalicylic acid- OB	12.07	11.91	12.07
	Atorvastatin 20mg- OB	24.11	24.11	24.11
	Atorvastatin 20mg- LPG	29.06	27.02	30.47
<b>Lebanon/ Private Sector</b>	Atorvastatin 20mg- LPG	15.34	9.96	18.51
	Hydrochlorothiazide 25mg- OB	14.25	13.43	15.07
	Captopril 50mg- OB	3.83	3.66	3.83

### ***Median price ratio (MPR)***

To compare the local price per unit of surveyed medicines to the international reference prices, the price per unit in local currency was converted to US dollars by using the exchange rate of each country according to *Oanda* (120). The exchange rate at the beginning of data collection was entered in the respective workbooks. The data collection in Qatar took place in two timeframes, second half of 2016 and the first half of 2017. The public primary healthcare centers survey was conducted in 2017, hence the median price ratios for this sector were adjusted based on the corresponding year's consumer price index (CPI). The median price ratio was calculated if a medicine was found in at least three outlets per sector. An MPR of maximum 4 was considered as a threshold in this

study given the costs at different stages along the supply chain. Therefore, MPR was not calculated for some medicines although they were available in one or two outlets (see Appendix M for all individual MPRs). For instance, of the 27 generic medicines on the list, only 10 had sufficient data to calculate median MPR across all sectors in Qatar. No MPR output for the lipid lowering gemfibrozil, although the OB type existed in two or less outlets per sector. Additionally, generic captopril was the only generic whose MPR was calculated in the public sector in Qatar as shown in Table 11. Atorvastatin 40mg and digoxin are the only medicines of considerable and comparable low median MPR in both countries (less than 1) (Appendices M and N).

Table 11 illustrates the median MPR for both medicine types across sectors in Qatar and Lebanon. Only the “Public Sector Patient Prices” in Qatar showed acceptable MPR with a median CPI-adjusted MPR of 1.44 (0.45-2.33) and 0.01 (0.01-0.01) for OBs and LPG, respectively. The LPG CPI-adjusted MPR is not representative of all generics in PHCC since sufficient data was only available to calculate the median MPR of captopril 50mg. The median MPR in the private sector and other sector patient prices were comparable for each medicine type. However, median MPRs for these two sectors were significantly higher than those of a comparative basket purchased from PHCC (see Table 12 below). Purchasing a comparable basket of medicines from community pharmacies or from outpatient pharmacies, patients would have to pay 13.6 and 14.2 times the price paid in PHCC. Amlodipine is the medicine of highest OB and LPG MPR in all three patient prices sectors in Qatar (see Appendix M) whereas atorvastatin 40mg had the lowest MPR.

**Table 11:** Median CPI-Adjusted MPR of Originator and Generic Brands in all Sectors Surveyed in Qatar and Lebanon

	Qatar						Lebanon	
	Public (n=5)		Private (n=6)		Other (n=4)		Private (n=6)	
	OB	LPG	OB	LPG	OB	LPG	OB	LPG
<b>Median</b>	1.44	0.01	21.60	26.50	26.71	29.52	12.37	5.82
<b>MPR (IQR*)</b>	(0.45-2.33)	(0.01-0.01)	(6.42-40.43)	(22.70-29.26)	(14.44-46.04)	(25.11-33.81)	(3.30-32.57)	(1.85-13.56)
<b>Min MPR</b>	0.09	0.01	0.72	0.40	0.72	13.28	0.52	0.32
<b>Max MPR</b>	9.68	0.01	67.73	44.10	67.73	44.10	59.73	41.13
<b>Medicines included</b>	23	1	19	9	14	4	20	17

Note: Min: minimum; Max: maximum.

(\*): Interquartile range

The median MPR of medicines dispensed in the community pharmacies in Lebanon is 12.37 (IQR = 3.30-32.57) for OB and 5.82 (IQR = 1.85-13.56) for LPG (Table 11).

Similar to the Qatari case, the generic atorvastatin 40mg and digoxin had the lowest MPR of 0.32 and 0.52 respectively. While losartan 50mg is the medicine that recorded the highest OB and LPG MPR of 59.73 and 41.13, respectively (see Appendix N).

**Table 12:** Comparison of the Median MPR between a Common Basket of Matched Pair of Medicines across Sectors in Qatar

	Public	Private	Public	Other	Private	Other
<b>Number of matched medicines</b>	17		14		14 (OB) 4 (LPG)	
<b>MPR - OB</b>	1.77	24.11	1.89	26.71	26.71	26.71
<b>MPR - LPG</b>					27.92	29.72
<b>% Difference</b>	1264.90%		1316.90%		0.00% OB/	6.40% LPG



### *International comparison*

After adjusting for purchasing power parity, the median MPR of individual medicines (both types) revealed higher price ratio to international reference prices in Qatar than in Lebanon. Table 13 demonstrates few examples of purchasing power parity (PPP) and consumer price index (CPI) adjusted-MPR.

**Table 13:** PPP and CPI-Adjusted MPR of Individual Medicines in Community Pharmacy

Medicine	Qatar		Lebanon	
	OB	LPG	OB	LPG
<b>Clopidogrel 75mg</b>	70.34	43.46	37.61	13.72
<b>Atorvastatin 20mg</b>	89.72	48.76	60.75	26.52
<b>Amlodipine 5mg</b>	129.71	84.45	54.55	44.37
<b>Acetylsalicylic acid 100mg</b>	23.12		18.15	12.94

This trend was also reflected in the overall PPP and CPI-adjusted median MPR per sector which is presented in Table 14, and showed results in line with what has been presented in Table 13.

### *Brand premium*

Table 15 illustrates the relative MPR of matched pairs of medicines found in each sector surveyed in Qatar and Lebanon. Across all four sectors, the MPR of lowest priced generics were lower than those of their respective originator brands. In Qatar, such comparison applies only to the Private Sector Patient Prices and Other Sector Patient Prices due to the near absence of generics in PHCC outlets visited. In the private sectors,

**Table 14:** PPP and CPI-Adjusted Median MPR of Originator and Generics in all Sectors Surveyed in Qatar and Lebanon

	Qatar						Lebanon	
	<i>Public (n=5)</i>		<i>Private (n=6)</i>		<i>Other (n=4)</i>		<i>Private (n=6)</i>	
	<b>OB</b>	<b>LPG</b>	<b>OB</b>	<b>LPG</b>	<b>OB</b>	<b>LPG</b>	<b>OB</b>	<b>LPG</b>
<b>Median MPR</b>	2.75	0.03	41.36	50.78	51.15	56.92	21.39	10.06
<b>(IQR*)</b>	(0.86- 4.46)	(0.03- 0.03)	(12.30- 77.43)	(43.46- 56.03)	(27.66- 88.17)	(48.09- 64.75)	(5.71- 56.29)	(3.20- 23.43)
<b>Min MPR</b>	0.18	0.03	1.38	0.76	1.38	25.43	0.90	0.55
<b>Max MPR</b>	18.53	0.03	129.71	84.45	129.71	84.45	103.23	71.09
<b>Medicines included</b>	23	1	19	9	14	4	20	17

*Note: Min: minimum; Max: maximum.*

*(\*): Interquartile range*

the prices of matched LPGs were almost 39% and 34% lower than their corresponding originators. In Lebanon, for the matched pairs of medicines found (13 medicines), the price of LPGs was 65% less than their respective OBs (Table 15).

As reported above in Table 7, generic medicines should be priced at least 35% and 30% less than the originator brands in Qatar and Lebanon, respectively. By referring to the brand premium observed in our survey (Table 15), prices of LPG are in line with the regulations in both countries.

**Table 15:** MPR of Comparable Basket of Matched OB and LPG Pair Medicines Found per Sector and the Relative Calculated Brand Premium

	Qatar						Lebanon		
	Private			Other			Private		
	OB 9	LPG 9	Brand prem.	OB 4	LPG 4	Brand prem.	OB 13	LPG 13	Brand prem.
<b>Median MPR</b>	43.61	26.52	1.64	45.23	29.72	1.52	21.76	7.64	2.85
<b>25%ile MPR</b>	36.73	22.70	1.62	38.73	25.11	1.54	4.81	2.15	2.24
<b>75%ile MPR</b>	48.28	29.26	1.65	52.07	33.81	1.54	35.15	15.34	2.29
<b>Min MPR</b>	0.72	0.40	1.80	24.11	13.28	1.82	0.68	0.32	2.13
<b>Max MPR</b>	67.73	44.10	1.54	67.73	44.10	1.54	59.73	41.13	1.45

Note: Min: minimum; Max: maximum; Prem.: premium.

### Availability

The availability of individual medicines of either type was variable across sectors in both countries. Table 16 illustrates the availability of medicines in Qatar and Lebanon. It is of note that the availability is measured for each medicine per sector regardless of the number of outlets in which they were found.

A high variability in the mean availability of originator brands and lowest priced generics were detected especially in the public primary health centers in both countries. The mean availability of generics in Qatar is low with its highest mean (SD) of 29.60% (37.10%) observed in the community pharmacies. In the same context, Qatar relies mainly on OB in its PHCC centers where mean availability (SD) of OB was 82.20% (27.90%) in the 5 outlets visited with a minimal supply of LPG 5.90% (15.50%). PHC in Lebanon are only dispensing generic essential medicines, nevertheless, the availability was critically low with only 46.90% (36.10%). The mean availability of OB and LPG medicines in the

community pharmacies in Lebanon was higher than the two private sectors in Qatar. In Lebanon, patients were more likely to face low availability of essential CVD medicines in the public sector in comparison to the private pharmacies.

**Table 16:** Mean Availability (in percent) of Cardiovascular Diseases Medicines in Sectors Surveyed in Qatar and Lebanon

	Qatar						Lebanon			
	Public (n=5)		Private (n=6)		Other (n=4)		Public (n=9)		Private (n=6)	
	OB	LPG	OB	LPG	OB	LPG	OB	LPG	OB	LPG
<b>Mean Avail.</b>	82.20	5.90	64.80	29.60	54.60	25.00	0.00	46.90	69.80	58.60
<b>SD</b>	27.90	15.50	37.90	37.10	40.50	34.70	0.00	36.10	32.70	39.90

*Note: Avail.: availability; SD: standard deviation.*

### **Affordability**

Affordability is calculated as the number in days' wages for the lowest paid government worker required to pay for a 30 days' standard treatment regimen for chronic disease management. According to the laws in Qatar and Lebanon, the daily wages for the lowest paid unskilled government workers were \$20 (129, 130). The affordability of medicines which were available in less than three outlets per sector was not calculated since a median MPR could not be derived as mentioned previously. These include generic forms of digoxin, verapamil, hydrochlorothiazide, furosemide, spironolactone in all four sectors in both countries in addition to generic forms of bisoprolol, amiodarone, and aspirin in all sectors in Qatar.

All medicines were affordable in the public primary healthcare centers in Qatar with the

antithrombotic agent clopidogrel 75mg being the most expensive among the cardiovascular diseases' essential medicines list at 0.4 days' wage as shown in Table 17. Most medicines were at 1 days' wage or less in all private sector outlets surveyed in both countries except for enalapril (antihypertensive medicine), clopidogrel (antithrombotic), and the simvastatin and atorvastatin (lipid-lowering agents). Originator brand of clopidogrel was the most burdening medicine in both countries as LPGWs have to forgo 4.2 and 2.5 days' wages in Qatar and Lebanon, respectively, in order to purchase their monthly dosage from the private sectors.

For originator brand medicines that impose high burden on LPGW, cheap affordable generics existed. If available in the pharmacies, LPGW could have saved 1.4 days' wages by purchasing the generic enalapril in Qatar. Likewise, by substituting originator branded clopidogrel by its generic equivalent, LPGW could have saved 1.6 days' wages in Qatar and Lebanon respectively. Affordable generic types of simvastatin and atorvastatin were available as well in the community pharmacies in both countries. 1.2 days' wages could have been saved by purchasing the generic simvastatin in the pharmacies in Lebanon.

**Table 17: Affordability in Number of Days' Wages Needed to Purchase Standard Treatment**

	Days' wages needed to purchase a 30 days' treatment			
	Qatar			Lebanon
	PHCC	Community pharmacies	Private clinics/hospitals	Community pharmacies
<b>Bisoprolol 5mg x 60</b>	0.1 OB	0.9 OB	0.9 OB	1 OB/ 0.4 LPG
<b>Digoxin 0.25mg x 30</b>	0 OB			0 OB
<b>Verapamil 80mg x 90</b>	0.2 OB			1 OB
<b>Amiodarone 200mg x 30</b>	0.1 OB			0.3 OB / 0.2 LPG
<b>Amlodipine 5mg x 30</b>	0.1 OB	0.9 OB / 0.6 LPG	0.9 OB / 0.6 LPG	0.4 OB / 0.4 LPG
<b>Enalapril 5mg x 120</b>	0.1 OB	3 OB / 1.6 LPG	3 OB	
<b>Hydrochlorothiazide 25mg x 30</b>	0 OB	0.3 OB	0.3 OB	0.2 OB
<b>Furosemide 40mg x 30</b>	0 OB	0.4 OB	0.4 OB	0.4 OB
<b>Spirolactone 25mg x 30</b>		0.4 OB		0.2 OB
<b>Acetylsalicylic acid 100mg x 30</b>	0 OB	0.1 OB	0.1 OB	0.1 OB / 0.1 LPG
<b>Clopidogrel 75mg x 30</b>	0.4 OB	4.2 OB / 2.6 LPG	4.2 OB	2.5 OB / 0.9 LPG
<b>Simvastatin 20mg x 30</b>	0.1 OB	1.4 OB / 1.1 LPG		1.4 OB / 0.2 LPG
<b>Atorvastatin 20mg x 30</b>	0.3 OB	3.1 OB / 1.7 LPG	3.1 OB / 1.9 LPG	2.3 OB / 1 LPG

## CHAPTER V: DISCUSSION AND CONCLUSION

The pharmaceutical sector is a major subset of the health sector especially with spending on pharmaceuticals constituting a high percentage of the total health expenditure (29, 83, 131). In Lebanon, almost half of the health expenditure is attributed to purchase of pharmaceuticals (132).

Unethical behaviors such as counterfeit medicines, price gouging, and medicines misuse along the supply chain and utilization can have a negative impact on patient health and well-being. It can also waste public resources and can be impoverishing for patients (49, 50, 133). Close monitoring, auditing and increased transparency of the pharmaceutical supply chain from the seller or manufacturer until it reaches the patients are necessary regardless of the pharmaceutical and economic status of the country (133).

### **Pharmaceutical pricing policy**

Qatar and Lebanon apply different pricing mechanisms for medicine registration. For medicines priced based on external reference pricing (ERP), three main approaches exist for allowed price setting. Lebanon is assigning the lowest prices available (46, 128) similar to Portugal and Iran (134), while Qatar and Ireland are using the average price (126), Italy is adopting the weighted average price (135).

Constant monitoring and review of the prices of pharmaceutical or health expenditure is a common practice worldwide (136). This periodic review and adjustment of the original regulations in both Qatar and Lebanon have generally resulted in beneficial effects for the patients. For instance, the WHO/HAI study was conducted twice in Lebanon in 2003 and 2013 after which several law adjustments took place (27, 125). One example of such

periodic reviews is China where the pharmaceutical pricing policy had been subject to several updates and adjustments between 2004 and 2015 (61, 67, 75, 137). Recently, studies were reporting that the Chinese government has been considering the use of ERP, and are seeking to identify a basket of reference countries that adhere to Chinese financial and social values (138). The pharmaceutical pricing in Qatar and Lebanon is mainly based on ERP and mark-up regulations. In addition, Qatar may consider the economic evaluation of a medicine to set the price if such evaluation is available at the time of registration (139).

The three pharmaceutical pricing policies identified in our study are among the six recommended by the WHO for developing countries. Furthermore, ERP and mark-up regulation were the most adopted in developing countries as per our systematic review (Figure 2, Chapter 2, page 25). For the mark-up regulation, it is recommended that once established, the government should progress to regressive mark-up schemes (29).

Lebanon and Saudi Arabia (55, 128, 140) are already applying it, while Qatar still has a uniform mark-up of 44% to all medicines registered and sold in the private sector regardless of the registered CIF price.

Most of the industrialized countries are endeavoring to apply aggressive strategies to control pharmaceutical expenditures (84). ERP is widely implemented for on-patent medicines (86, 87). As of 2011, 24 out of the 27 European Union countries (EU) covered in the RAND report used ERP with the exception of Sweden, the UK, and Denmark (88). As previously mentioned, ERP is a dynamic process to price on-patent and prescription only medicines including reimbursable medicines (86, 88). Moreover, the trend is towards including countries of similar income levels as the country applying the policy



(87). The supply chain remuneration (mark-ups) is also relatively regulated in these countries through either a fixed fee, a fixed percentage or a fee-for-service (38, 86, 89). Although some countries attempt to use Health Technology Assessment (HTA) to price medicines, its implementation is challenging for developing economies due to demanding human capital and financial needs (29, 105, 106). In some countries where HTA was being considered and implemented, economic evaluation studies revealed poor practice and few methodologic flaws in the low- and middle-income countries (LMICs) (141) as well as Saudi Arabia (142), Iran (143), and Thailand (106). South Korea, an OECD country, has switched from the use of cost-plus and ERP to implementing HTA since 2007 (144, 145) with no negative feedback reported due to technical issues. This may be due to South Korea having the required human capital and financial resources to best adopt HTA.

Although both Qatar and Lebanon use ERP, the basket of countries to which the prices in each country are benchmarked vary. In Lebanon, prices are benchmarked against three price points with the lowest price adopted: ex-factory and patient selling price of medicines in the country of origin; basket 1 which is composed of 7 European countries; and basket 2 comprised of neighboring Arab countries including Qatar.

To set a price for registration, Qatar and Saudi Arabia are mainly relying on the ex-factory and selling price of the medicines in the country of origin, as well as the cost-insurance-freight (CIF) price in up to 30 countries to which the medicines are exported and sold. In selecting a basket of countries, most common practice in Europe is usually to include up to 10 countries in the basket (87), and to use either the lowest price, the average price or the weighted average price as a reference (135).

Moreover, the mark-up schemes applied in both countries are also different. These different policy implementation mechanisms validate the conclusions of international organizations that: “there is no one-size solution” that fits all (29).

Our review of the price components as per national decrees and pricing guidelines was limited to the add-ons to the agreed-upon landed price for registration. The results of our study were compared to the results of similar WHO/HAI surveys conducted after 2010 in Lebanon, Saudi Arabia and Iran. The survey was conducted in 2015 in Saudi Arabia, a high-income GCC country (140). The survey in Iran, which is an upper middle-income country, was conducted in 2014 (146). Both Saudi Arabia and Iran are using ERP as one of their pricing policies. ERP is used for on-patent imported medicines in Iran with a mark-up reaching up to 100% for medicines with locally manufactured equivalent generics (134). These generics are subsidized with a maximum ceiling price (cost-plus formulae) (134, 147).

### **Price variation**

Typically, in a well-regulated pharmaceutical sector, prices of the same medicine brand, dosage form and strength should be uniform across a sector. Small variations are commonly encountered (80) even under strict regulation as in Saudi Arabia(140), Iran (146) and Lebanon in 2013 (55). The higher occurrence of the price variations observed in Lebanon could be due to the fact that the medicine price may change every two weeks. If the medicine was already in the pharmacy, it would be the pharmacist’s duty to adjust the price according to the bi-monthly index released by the MoPH to all warehouses and pharmaceutical outlets. These indices adjust prices based on foreign currency exchange

rates fluctuations (55). Human error could account for the minor price variations for those outlets not utilizing stock management and pricing software. Price variations observed for LPG could be attributed to the fact that several generic brands of the same active ingredient exist in the market as observed in Saudi Arabia in 2015 (140), Lebanon 2013 (55) and Iran 2014 (146).

The median price ratio is a mean comparison of local prices in a specific country to the international reference prices. The international prices retrieved from MSH are price per pill for bulk loose packs (121). Therefore, a ratio of 4 is acceptable to compensate for the cost of packaging (27). In general, compared to international reference prices, the prices in the private sector in Qatar were almost double the prices in Lebanon for the OB (originator brand), while the LPGs in Qatar were more than 5 times the Lebanese generic medicines for the basket of medicines available in each country. A more detailed analysis showed that although the overall median MPR in Qatar was higher, four medicines in Lebanon had a ratio to IRP greater than those found in the Qatari market. The scope of this study could not identify the reason behind this difference in individual prices to IRP, and may require tracking of price components to identify the cause of the variance. Atorvastatin 40mg demonstrated a ratio of less than 1 to IRP for both types in both countries. Such cases are difficult to explain especially that the OB is available in both countries. One possible explanation could be the composition of the MSH price per tablet. There is only one reference point for atorvastatin 40mg from Peru with a price of \$3.2494 per tablet whereby the atorvastatin 20mg in Peru is at \$0.0251 per tablet, and the median is \$0.0439. This leads us to conclude that more reference points from other countries are required to assess this dosage reference price internationally.

Medicines are free of charge in the public sector in Lebanon and only for the Qataris in Qatar. The median MPR of OB prices paid by the non-Qatari residents in the public sector were the lowest when compared to those in countries of any income level including Sri Lanka (148), Iran (146), and 11 other Asia Pacific countries (149). Although the patients' prices in the private sector in both countries were significantly higher than the threshold, the OB prices in community pharmacies and private clinics/hospitals in Qatar (21.50 and 26.71 times the IRP, respectively) were almost double the prices in the same sector in Lebanon (12.37 times the IRP), while the prices of LPG in Qatar were more than 4 times the LPG prices in Lebanon. The high ratios to IRP in community pharmacies in Qatar (21.6 for OB 26.52 times the IRP for LPG) were also significantly higher when compared to Saudi Arabia (6.66, 8.88 times the IRP) (140) and Iran (3.62, 1.21 times the IRP) (146). Despite the pharmaceutical price reduction in Lebanon by the end of 2015, the median MPR of OB increased in 2016 by 2.5% (12.36 vs. 12.06 times the IRP) while the prices of generics decreased by 18.2% (5.48 vs. 6.7 times the IRP). This can be due to the fact that the 2013 WHO/HAI survey included a wider basket of non-communicable diseases (NCD) essential medicines whose prices may have affected the overall median MPR (55). When focusing on individual medicines perceived to be expensive in Lebanon, the individual MPR showed significant decrease in prices between 2013 and 2016. Prices of clopidogrel almost halved from 41.00 in 2013 to 21.76 times the IRP in 2016. Similar cases were observed for acetylsalicylic acid, simvastatin 20mg, and furosemide 40mg. Overall, only the median MPR of generics price in Lebanon (5.48 times the IRP) were close to the threshold of 4 times the international prices, however still significantly higher than Iran (1.21 times the IRP) most

likely due to more developed domestic generic manufacturing in Iran (134, 147).

The significant difference in the prices paid by patients between the public and private sectors in Qatar demonstrated the Qatari vision for a subsidized public healthcare system that is of international standard and affordable to all.

Except for Schweitzer and Comanor where medicine prices in LMICs were demonstrated to be lower than similar medicines in industrialized countries (150), most studies have shown the absence of any link between the level of income and the prices of medicines in a country (58, 151, 152). The price difference between LMIC and developing countries on one hand and industrialized countries on the other hand could be due to differential pricing (53, 109).

In order to facilitate the comparison of countries with varying economic strength i.e., Qatar and Lebanon, prices of medicines were adjusted to account for purchasing power parity (PPP) (14, 122). After the adjustment, the prices in Qatar were still greater than in Lebanon. Hence, the price differences observed between Qatar and Lebanon may not be due to the level of income and the wealth of the country as proved by other studies (152). Given that the adjustments to prices applied in this study did not provide possible explanation for the gap in prices between Qatar and Lebanon, further investigation of the landed price and the pricing mechanisms is needed in the future to provide answers (27). With the significant price differences between the OB and its LPG in both countries, higher use of LPG can achieve major savings in pharmaceutical expenditure as per Dylst *et al.* (153). This must be incorporated in a sound national pharmaceutical policy to encourage the import, local manufacturing, and prescription of generics and the education of both the prescribers and patients to the value of quality generics (101, 103, 154, 155)

especially for chronic disease conditions (51, 152). Most industrialized countries are focusing on the procurement and prescription of generic medicines whenever available (156-159). Lebanon is taking steps to encourage the use of generics by decreasing their prices, allowing originator brands' substitution, and encouraging local manufacturing and packing of off-patent medicines.

### **Availability**

The selection of essential medicines on the WHO Model List covers the majority of contracted acute and chronic diseases (21). The list is reviewed every two years by a panel of international experts in line with the most recent standard guidelines (24, 160). The WHO target is to achieve more than 80% availability of affordable essential generic medicines in at least the public sector by 2025 (123). A sector is efficiently procuring medicines if it consistently procures generic medicines at competitive prices close to the IRP, ensures the availability of at least the essential medicines either core or supplementary (24, 160), and dispenses them free-of-charge or at affordable prices to the lowest paid population. In countries with scarce financial resources, governments direct their budget towards ensuring the availability of essential medicines under generic brands (45). Nevertheless, the availability of essential medicines is yet to be improved and more effort should be implemented to ensure the availability of chronic disease medicines (45). In our study, only Lebanon has an established EML based on the WHO EML (18<sup>th</sup> edition). The availability of generic essential cardiovascular diseases (CVD) medicines in the public sector, which slightly improved from 2012 (46.9% vs. 42% in 2013), is still low and comparable to the availability in the same sector and for the same medicine types

in Saudi Arabia (50.3%) (140). No OB of essential CVD medicines were found in the public sector in Lebanon. This is in line with what Ewen *et al.* (2017) demonstrated in their secondary study of WHO/HAI between 2008 and 2015 for UMICs surveyed in which Lebanon was included alongside Iran, Colombia, Ecuador, Mauritius, Mexico, and Brazil (123). According to that study, the median availability of generic essential NCD medicines in the public sector was 56.7% (123). The availability of generic CVD medicines in the private sector in Lebanon is lower than 2013 (59.3% vs. 77.9% in 2013) and lower than the UMIC average of 76.7%. The difference observed may be related to the addition of listed essential CVD medicines in our study as compared to the Ewen *et al.* study. Our surveyed list also included additional essential CVD medicines that did not have any generics in the Lebanese market at the time of the study (2016) including digoxin, enalapril, methyldopa, spironolactone and verapamil (161).

The public sector in Qatar is mainly procuring originator brand of CVD essential medicines with availability within the WHO target (82.2%) (123). This availability is significantly higher than the generic medicines availability in the public sector in Iran (75.2%) (146), where pharmaceutical pricing policies were enacted to control and challenge the OBs entry into the market while generics manufacturing is subsidized and their prices are controlled and competitive (134, 147). The availability of OB CVD medicines in the public sector in Qatar is higher than OB NCD medicines in the same sector in Saudi Arabia (82.2% vs. 22.3%) (140). The low availability of generic medicine in all sectors in Qatar may be related to consumer preferences for OBs (100, 101). The unavailability of any type of digoxin, diltiazem, amiodarone or isosorbide dinitrate in the private sector may be related to their usage restriction in community pharmacies. The

structure of the healthcare system in Qatar may have contributed to the lack of availability of CVD medicines in the private sector. Private cardiology medical services in Qatar are generally limited and mostly available in major hospitals in the capital city, potentially limiting the availability of CVD medicines to within proximity of these centers.

It is of note that pharmacists in Lebanon commonly substitute a brand medicine by its equivalent generic as allowed by the regulations (162), while this practice does not exist in Qatar.

In conclusion, the unavailability of medicines in the public sector in Lebanon has a direct impact on the pharmaceutical private sector. Patients resort to the private community pharmacies for prescription dispensing given the low availability of medicines in the public sector (50, 133). Such situations are commonly observed in LMIC (27, 131).

### **Affordability**

To calculate the affordability of medicines, WHO/HAI methodology recommends the usage of the lowest-paid unskilled governmental worker days' wages (27, 123). In Qatar, the lowest-paid unskilled government employee receives QAR 2,200 monthly in basic salary in addition to other benefits. As per Qatari law, a month is of 30 working days and thus the daily wage for this category is QAR 73.33 (approximately \$20.09) (129).

However, this official salary omits a substantial portion of the population in Qatar where out of a population of circa 2.58 million, around one million are blue-collar laborers employed in the private sector (Table 3, Chapter 1, page 11) that are paid significantly less. Although such laborers should be getting paid at least QAR 2,200 monthly as per



the law, much of the private sector construction workforce are paid salaries ranging between QAR 900-1,100 monthly, almost half of the LPGW salary adopted in our study. In order to calculate affordability for these workers, we would need to almost double the number of days' wages required to purchase a treatment course. Our results showed that medicines in the public sector were affordable to all residents of Qatar, even those at the lowest salary ranges in the private sectors. Generally, medicines in the private sector were affordable to the LPGW in Qatar, except for bisoprolol, amlodipine, enalapril, clopidogrel, simvastatin, and atorvastatin. Compared to the private sector in Saudi Arabia, purchasing of medicines by non-nationals in the private sector in Qatar is more affordable when comparing all types of amlodipine and clopidogrel (140).

As for Lebanon, the minimum days' wages adopted in our study was \$20 per day as per law (130). However, according the 2016 UNDP report, 27% of the population is living under the poverty line and earning less than \$4 per day (163). Moreover, the patients eligible for the free-of-charge medicines in the public primary healthcare centers are only a small portion of the population. Considering the low availability in the public sector, most of them are purchasing their medicines from the private sector and thus paying out-of-pocket for CVD medicines.

The reduction in medicine prices manifested in the increased affordability between the WHO/HAI survey 2013 and our study in 2016 (55). Almost all treatment courses became more affordable although still costing more than one days' wage in 2016 especially the OBs. For the few common essential CVD medicines surveyed (clopidogrel, amlodipine, amiodarone, hydrochlorothiazide, simvastatin and atorvastatin) in Saudi Arabia 2015, Iran 2014, and in Lebanon 2016, medicines were more affordable in Lebanon than in

Saudi Arabia for any type (140), and more affordable than the OBs in Iran (146). The pharmaceutical pricing policy of OBs in Iran may have resulted in more expensive medicines in comparison to Lebanon.

Data on the percentage of the population which is privately insured in Lebanon and Qatar were not incorporated into this study. However, patients with pre-existing conditions or chronic diseases can sometimes find it difficult to obtain private insurance as insurance companies can significantly increase premiums, increase deductibles or refuse coverage to such patients. As of 2011, there were 162,016 registered beneficiaries under the National Chronic Drug Program in Lebanon who are eligible to obtain free medicines in primary healthcare centers. Overall, roughly half of the Lebanese population has some form of health coverage (public and private) (55), while in Qatar all residents are eligible for subsidized healthcare services and medication through the Primary Health Center Corporation (PHCC) and Hamad Medical Center (HMC). It is important to note that most CVD cases require multidrug regimens (11), hence the affordability of a treatment plan would depend on the sum of prices of all drugs prescribed to a patient.

### **Access**

In 2016, CVD were the leading cause of death globally with 80% of the cases occurring in the LMICs, and are imposing the highest burden of disease (11). The rates of death due to CVD in Lebanon and Qatar are ranked first and second, respectively (1). Both governments are undertaking steps to combat such high prevalence of incidence and death (161, 164). To better understand the situation, we have to recognize that based on various studies and guidelines, eliminating bad lifestyle habits such as smoking,

unhealthy dietary intake and sedentary lifestyles are not sufficient to eradicate CVD (11, 12, 165). These lifestyles improvements can affect some modifiable risk factors; however, pharmacotherapy is an integral part in CVD control plans (11, 166, 167). For an equitable access to the right to health (168, 169), effective medicines (i.e., quality medicines) should continuously be available (availability) at affordable prices (affordability) at reasonably accessible health facilities (accessibility), and prescribed according to the latest guidelines (acceptability) (11, 27). To date, hindrance to access is common and is reported especially in the poor countries due to various factors. Wealthy countries are no exception since access can be hindered by any of the five dimensions cited above. In the presence of financial and technological resources in rich countries other obstacles can emerge, e.g., from an inefficient supply and distribution system as per Tran et al. (2017) (170). Countries of all economic status are endeavoring to overcome such issues, and the World Health Assembly assisted these efforts in 1977 with the issuing of the Essential Medicine List that contains the most cost-effective medicines to treat the major chronic and acute disease, which is regularly updated (160). As per the WHO, 95% of developing countries have established an EML and 86% regularly update it (133). Studies showed that with limited financial resources, LMICs tend to restrict the list of available medicines in the public sector to essential medicines (45). Some have taken this national responsibility a step further and included the access to medicines in their national constitutions (171-173). Access to medicines is a cornerstone in the management of health and a backbone to tackle the high incidence of CVD and comorbidities.

In our study, we evaluated two of the major healthcare system dimensions, availability

and affordability, as compared with the WHO 2025 target of affordable essential medicines for major chronic disease (174). The treatment of chronic disease is a life-long journey that requires early secondary management measures to slow down complications and avoid mortality (11).

### **Recommendations**

Based on the results of the current study, we recommend the following:

#### ***Qatar***

1. Publication of updated and detailed pharmaceutical policy and reforms documents and studies which are specific to Qatar
2. Switching to regressive mark-up on pharmaceuticals
3. Reviewing the private sector medicine prices and considering significant price reduction measures
4. Encouraging local manufacturing of generic medicines for local consumption and export
5. Increasing the supply of quality generic medicines in the public sector
6. Updating the pharmaceutical retail price more frequently
7. Promoting generic medicines as a substitute and educating physicians, pharmacists and patients about the benefits of generics
8. Legally enabling pharmacists to offer and provide generic substitutes.

#### ***Lebanon***

1. Rapidly updating of the Lebanese EML in accordance with WHO updates
2. Increasing public procurement of NCD medicines in PHC

3. Expanding coverage of NCD patients under the National Chronic Drugs Program
4. Testing and ensuring the quality of generics available in the private pharmaceutical market
5. Tax exemption of essential medicines
6. Utilizing the international reference price according to Management Sciences for Health (MSH) for medicine registration and price setting.

***Regionally***

1. Encouraging pharmaceutical companies to empathize with patients having limited resources and to consider practical solutions for supporting affordable medicines
2. Educating the public and prescribers on the economic benefits of quality generics
3. Undertaking such surveys more frequently given their ability to monitor policy effectiveness
4. Applying reference price for medicines based on the same therapeutic category rather than per type.

**Future works**

This study revealed several issues that need further analysis and review. The survey of more essential NCDs and cancer medicines is needed. Such studies would align Qatar on an international scale alongside all other surveyed countries by WHO/HAI. To better understand the pharmaceutical supply chain, a detailed analysis of the public procurement

system is also required.

The data on medicine price collected in our survey could be used by other methods that measure affordability such as impoverishing and catastrophic effects. This would require the collection of more aggregated data on prices, per capita income level, and income distribution available from several international sources. Such issues should be facilitated in Qatar especially given the availability of metadata in various national databases.

Once expanded to include all international surveyed medicines, the WHO/HAI standard survey should be conducted every other year until 2025 as per WHO target.

### **Strengths and limitations of the study**

This study relied on core elements that strengthen its outcomes. However, several limitations existed that may have impacted the findings.

#### ***Strengths***

First, the methodology used in this study is a variant of a validated standard WHO/HAI methodology that it is easy to apply and conduct. Moreover, the researchers involved in the study are from various backgrounds and two team members have a deep understanding and extensive experience in conducting the WHO/HAI survey in addition to an extensive body of scholarly work in the field of pharmaceutical policies. To the best of our knowledge this study is the first in Qatar and the fifth in a high-income country (HIC). Second, the medicines surveyed are of global and national imminent priority and are proven to be safe and cost-effective. The results of the study permit the ranking of the two countries on an international scale and allow for a simple medicine price comparison

to international reference prices. Our findings could also be used as indicators for the assessment of millennium development targets and other NCD indicators. Lastly, such studies provide valuable advocacy messages for policymakers, pharmaceutical industries, regulators, prescribers and patients if well shared and delivered in a timely manner.

### ***Limitations***

The use of WHO/HAI methodology is not innovative, and the adoption of a variant of the standard methodology may have affected the study findings. That choice was made based on several internal and external limitations. The healthcare system and demographics in Qatar limited our sample size and the limited funding and capital resources for the study affected the overall sample size in both countries. The design of the survey is cross-sectional while in countries where pharmaceutical policies and pricing are amended over time, changes may be better detected by longitudinal studies. Due to time limitations and lack of institutional support, the price components of medicines were not surveyed. This could have helped in providing answers to a few unexplained results in the study. That was also hindered by the lack of communication between the private and public regulatory entities in both countries. The limitations of the affordability calculation in both Qatar and Lebanon to the daily wage of the lowest-paid unskilled government worker may have overlooked a large population that is either unemployed or getting paid lower wages than what was considered in this study. Furthermore, the affordability calculation although easy to measure, may have overestimated the affordability of CVD medicines in both countries by not accounting for multidrug regimens or other healthcare expenses. Finally, the inclusion of only essential medicines in the surveyed list may have

been restrictive especially for the private sector where other strengths and pharmaceutical combinations are sold, and it may have underestimated the actual medicines availability in different sectors covered.

## **Conclusion**

The prevalence of NCDs and specifically CVD, which is the leading global cause of death, has motivated international organizations to act in order to curb these diseases. In 2010, a United Nations resolution placed NCD as a priority in the political and health agendas. Since then, the WHO has developed goals aimed at helping governments control the impact of NCD especially in LMICs. In developing these goals, the WHO benefited from similar successful efforts undertaken earlier in this century to prevent and treat HIV globally and CVD in industrialized countries. Although both Qatar and Lebanon are classified as HIC and UMIC respectively, the disease burden of CVD is on par with those found in LMICs. Both countries are aware of the threat of CVD and have taken big strides to improve the wellbeing of the populations and their healthcare systems. Considering the high prevalence of CVD risk factors and incidence in Qatar and Lebanon, the study was designed to provide a clear assessment of some components of the pharmaceutical sector and their impact on curbing these diseases. The aim was to review the pharmaceutical pricing policies in addition to assessing prices, availability, and affordability of essential cardiovascular disease medicines within sectors, across sectors, nationwide and across nations. By using a variant of the WHO/HAI methodology, reviewing governmental documents and interviewing stakeholders, our results provided a clearer understanding of the pharmaceutical situation in Qatar and



Lebanon. We quantitatively evaluated the medicine prices in comparison to international reference prices, as well as their availability and affordability and summarized the key pricing mechanisms in both nations.

Based on the research design and findings, this study demonstrated that both countries were using multiple internationally recommended pricing policies simultaneously.

Medicine price was more uniform across the same sector in Qatar than in Lebanon. In the public sector, medicines were free-of-charge in Lebanon and priced lower than the international reference prices in Qatar. However, the prices of medicines in the private sector were higher than the international reference prices in both countries. Moreover, the MPR of originator brands and lowest priced generics in Qatar were up to two and five times those in Lebanon, respectively. In terms of availability, only the public sector in Qatar met the WHO target for OB CVD medicines, while all other sectors fell short of this target. Despite a few exceptions, most medicines were affordable in all sectors surveyed. Even in cases where the OB was not affordable, a less expensive generic substitute was available.

The pharmaceutical pricing policies implemented in Qatar and Lebanon are reflective of both the advancements in the human capital and financial resources of the nations and are in line with the WHO recommended pricing policies for developing countries. However, more tailoring of these policies to the local environment is required for greater benefit to the populations given the substantially high prices of medicines especially in the private sectors, and their low availability in various sectors. Except for the public sector in Qatar, both countries fall short of the Sustainable Development Goals, and more efforts should be undertaken to achieve these goals.

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## APPENDIX A: GENERAL CHARACTERISTICS OF THE INCLUDED STUDIES

<b>Author</b>	<b>Country</b>	<b>Objectives</b>	<b>Target medicines</b>	<b>Target Sector</b>	<b>Settings</b>
Kaló et al. (2015) (65)	7 ME* countries: Egypt, Kuwait, Jordan, Lebanon, Qatar, Saudi Arabia, United Arab Emirates	<ul style="list-style-type: none"> <li>To document the use of ERP in the seven countries and assess whether it resulted in narrower price corridor for patented pharmaceuticals compared to non-pharmaceutical services not subjected to ERP</li> <li>To analyze factors influencing prices of original pharmaceuticals</li> </ul>	On-patent medicines	Public and private	Retail pharmacy and public, and private hospitals
Ahmed et al. (2012) (59)	Bangladesh	<ul style="list-style-type: none"> <li>To fulfill the knowledge gap by investigating the availability, affordability, and rational use of drugs in urban and rural areas</li> </ul>	Essential medicines	Public	Primary health clinics
Bertoldi et al. (2012) (60)	Brazil	<ul style="list-style-type: none"> <li>To investigate medicine prices, availability and affordability in the Brazilian state of Rio Grande Do Sul</li> </ul>	Essential medicines	Public and private and others	Public and private pharmacies in Southern Brazil
Nóbrega et al. (2007) (76)	Brazil	<ul style="list-style-type: none"> <li>To compare the retail prices of essential medicines in the private market in Brazil with that of two international pricing standards</li> </ul>	Essential medicines	Public and private	Brazil vs. Sweden and international bulk mean price-per-unit.
Ford et al. (2007) (74)	Brazil and Thailand	<ul style="list-style-type: none"> <li>To identify strategies employed to improve access to key antiretroviral drugs in both countries</li> <li>To reflect on the relative successes of each in order to identify factors for future success</li> </ul>	Antiretrovirals	NA	NA
Fang et al. (2013) (61)	China	<ul style="list-style-type: none"> <li>To assess medicine availability and price during the early years of the health reform in Shaanxi Province</li> </ul>	Essential medicines	Public and private	Public hospitals and retail pharmacy
Han et al.	China	<ul style="list-style-type: none"> <li>To investigate whether 1996 reform pricing policies of the</li> </ul>	60% of all	Public	State-owned

(2013) (71)		Chinese government have reduced pharmaceutical expenses on antibacterials	medicines including systemic antibacterial		facilities
Hu (2013) (66)	China	<ul style="list-style-type: none"> <li>To analyze the achievements, issues and policy recommendations for implementing essential medicine system in China after a 3-year effort</li> </ul>	Essential medicines	Public and private	Primary public hospitals
Zhou et al. (2015) (72)	China	<ul style="list-style-type: none"> <li>To assess whether the zero-markup policy for essential drugs reduces the medical expense for patients at county hospitals</li> </ul>	Essential medicines	Public	Public country hospitals
Meng et al. (2005) (67)	China	<ul style="list-style-type: none"> <li>To examine the impact of retail drug price control on the containment of hospital drug expenditure, and to analyze contributing factor such as rational drug use</li> </ul>	All medicines	Public	Public hospitals
Yang et al. (2010) (62)	China	<ul style="list-style-type: none"> <li>To investigate the availability of essential medicines and their prices in Hubei province</li> </ul>	Essential medicines	Public and private	Public hospital and private pharmacy
Ziyan (2007) (70)	China	<ul style="list-style-type: none"> <li>To describe China's pharmaceutical system, including overall health system, pharmaceutical industry and commerce, and drug pricing system</li> </ul>	All medicines	Public and private	NA
Geng et al. (2014) (75)	China & Taiwan	<ul style="list-style-type: none"> <li>To explore approaches to adjusting brand-name drug prices in Mainland China by comparing and analyzing prices between Mainland and Taiwan</li> </ul>	Brand-names medicines	Public and private	NA
Anggriani et al. (2013) (73)	Indonesia	<ul style="list-style-type: none"> <li>To evaluate the impact of the generic medicine pricing policy</li> <li>To measure the difference between the actual and maximum retail prices of unbranded generics</li> </ul>	Generic medicines	Public, private and NGO	Public hospitals, private pharmacies, NGO hospitals
Abbott et al. (2012) (79)	Jordan	<ul style="list-style-type: none"> <li>To assess the impact of Jordan's increased intellectual property protection after the WTO** and US-Jordan free trade agreement on medicines accessibility</li> </ul>	All medicines	Private	Private retail market
Ball et al. (2009) (63)	Kuwait	<ul style="list-style-type: none"> <li>To evaluate the efficiency of the public sector medicine procurement system</li> <li>To determine the relative availability of IB &amp; generic equivalents in public and private sectors</li> <li>To compare prices of IB and generics in the private sector</li> </ul>	All medicines	Public and private	Public and private retail pharmacies

		in/out of Kuwait			
		<ul style="list-style-type: none"> <li>• To identify pricing mechanisms and tariffs for medicines</li> </ul>			
Maïga et al. (2010) (64)	Mali	<ul style="list-style-type: none"> <li>• To assess the impact of government intervention on the evolution of market prices, availability and public access to essential medicines</li> </ul>	Essential medicines	Private	Wholesaler and private drug store in Bamako
Moïse et al. (2007) (68)	Mexico	<ul style="list-style-type: none"> <li>• To analyze Mexico's pharmaceutical sector policy</li> <li>• To assess the achievement of policy goals</li> <li>• To question the effectiveness of the maximum price regulation</li> </ul>	All medicines	Private	Outpatient sector
Russo and McPake (2010) (77)	Mozambique	<ul style="list-style-type: none"> <li>• To investigate medicine prices in urban Mozambique with the objective of understanding how prices are formed and their public implication</li> </ul>	All medicines	Public and private	Urban public, private and parastatal pharmacies
WHO (2004) (78)	Oman	<ul style="list-style-type: none"> <li>• To determine the achievement of key pharmaceutical objectives by monitoring and assessing various outcomes</li> </ul>	All medicines	Private and public	Private and public hospitals, pharmacies, and clinics
Tatar (2013) (69)	Turkey	<ul style="list-style-type: none"> <li>• Overview of Turkish Healthcare and Pharmaceutical Sector</li> </ul>	All medicines	Public and private	NA

Source: Abdel Rida N, Mohamed Ibrahim MI, Babar Z-U-D, Owusu Y. A systematic review of pharmaceutical pricing policies in developing countries. *J Pharm Health Serv Res.* 2017;8(4):213-26.

(\*): Middle Eastern; (\*\*): World Trade Organization; NA: Not applicable or not available

## APPENDIX B: PHARMACEUTICAL PRICING POLICIES USED IN DEVELOPING COUNTRIES AND THEIR EFFECTS

Author & Country	Policy	Outcome variables	Key Findings
Kaló et al. (2015) (65) 7 ME* countries: Egypt, Kuwait, Jordan, Lebanon, Qatar, Saudi Arabia, United Arab Emirates	<b>External reference pricing</b>	<ul style="list-style-type: none"> <li>• Average price corridors (based on min., max. and mean price)</li> <li>• Relative prices of originators compared to UK prices</li> <li>• Effects of influencing factors on the public pharmaceutical prices (GDP, population size, number of reference countries, lowest mandate for ERP)</li> </ul>	<ul style="list-style-type: none"> <li>• More stringent ERP in countries adopting the lowest price among <math>\geq 25</math> countries</li> <li>• Referencing higher income countries negatively affected the prices in Egypt and Lebanon</li> <li>• 27.5% of price variability (reduction) explained by larger population size, a basket of &gt;5 countries, and mandate of lowest price</li> </ul>
Ahmed et al. (2012) (59) Bangladesh	Implementation of NDP in 1982 with <b>price control of hundreds of essential medicines</b> and competitive procurement of raw material	<ul style="list-style-type: none"> <li>• Availability of medicines and EML</li> <li>• Number of drugs dispensed/prescription</li> <li>• Cost of treatment as percentage of min. weekly-income</li> <li>• Labeling of drugs in urban and rural clinics</li> </ul>	<ul style="list-style-type: none"> <li>• Poor availability of essential drugs</li> <li>• Higher number of dispensed drugs in rural clinics</li> <li>• 50% of the facilities presenting the EML</li> <li>• Frequent incorrect ATB prescription</li> <li>• Prices of branded &gt; 500% higher</li> </ul>
Bertoldi et al. (2012) (60) Brazil	<b>Annual adjustment of prices</b> defined by market competition and market share of generics. CMED† imposed <b>ceiling on manufacturer prices</b> , discounts when selling to government, and <b>maximum price to pharmacies and drug store including taxes</b>	<ul style="list-style-type: none"> <li>• MPR and availability of similar medicines, generics and originator brands in the public and private sector</li> </ul>	<ul style="list-style-type: none"> <li>• Variable availability of essential medicines in the public sector leading to OOP expenditure</li> <li>• All medicine types MPR <math>\geq 8</math></li> <li>• The launch of CMED started downward trend of prices</li> </ul>
Nóbrega et al.	<b>Regulatory mechanisms</b> to regulate	<ul style="list-style-type: none"> <li>• Retail price and ratios of essential drugs in</li> </ul>	<ul style="list-style-type: none"> <li>• Prices were 1.9 and 13.1 times</li> </ul>

(2007) (76) Brazil	<b>increases in pricing due to inflation rates</b> , exchange rates and cost of raw materials, as well as <b>limitations on retail markups and creating tax exemptions</b>	Brazil, Sweden and reference price from low cost international suppliers	more expensive than those in Sweden and international suppliers respectively
Ford et al. (2007) (74) Brazil & Thailand	<b>To reduce ART drugs price:</b> 1) Brazil used price negotiations backed by the threat of compulsory licensing and local generic production. 2) Thailand used patent challenges and compulsory licensing in the direct negotiations with pharmaceutical companies	<ul style="list-style-type: none"> <li>• Prices of ART in both countries</li> </ul>	<ul style="list-style-type: none"> <li>• Decrease in spending on some old ART but not on new ART which is problematic in case of drug resistance</li> <li>• Negotiations with drug companies insufficient to control prices</li> <li>• Compulsory licensing was more effective in reducing prices</li> </ul>
Fang et al. (2013) (61) China	<b>Zero mark-up on essential medicines</b> Provincial public bidding	<ul style="list-style-type: none"> <li>• Availability and inflation-adjusted MUP between 2010 and 2012</li> </ul>	<ul style="list-style-type: none"> <li>• Although inflation adjusted prices were lower, availability of LPG was decreased to lower than the poor availability in 2010</li> <li>• Decrease in prices of branded medicines was greater than that of LPG</li> </ul>
Han et al. (2013) (71) China	<b>Zero mark-up policy on essential medicines. Eradication of 15-20% drug margins</b> between wholesaler and retailers	<ul style="list-style-type: none"> <li>• Yearly expenditure on selected antibacterial drugs</li> </ul>	<ul style="list-style-type: none"> <li>• 2005 expenditure 205.7% higher than 1996' even though prices are almost halved</li> <li>• Prescriber behavior and limited government funding of hospitals are key determinants of drug expenditure</li> </ul>
Hu (2013) (66) China	<b>Zero-markup policy for Essential Drugs (ZPED)</b>	<ul style="list-style-type: none"> <li>• Prices of essential medicines</li> </ul>	<ul style="list-style-type: none"> <li>• 25% reduction in the average price of medicines and reduction in the average cost per visit/hospitalization</li> <li>• Expansion of EML by up to 455 medicines based on the</li> </ul>

			characteristics of clinical use and medical requirement, indicating the EML loss of authority
Zhou et al. (2015) (72) China	Setting of <b>maximum retail price and maximum margins</b>	<ul style="list-style-type: none"> <li>• Outpatient/inpatient per-visit cost and drug expense</li> <li>• Drug expense out of total cost</li> </ul>	<ul style="list-style-type: none"> <li>• Overall reduction of relative expenses by 11% for both outpatients and inpatients</li> </ul>
Meng et al. (2005) (67) China	<b>Direct control of retail prices</b> of selected pharmaceuticals believed <b>essential and cost-effective</b>	<ul style="list-style-type: none"> <li>• Prescribed daily dose PDD, rational use by analyzing top 15 prescribed per expenditure</li> </ul>	<ul style="list-style-type: none"> <li>• No positive impact on containment of hospital drug expenditure in the two hospitals</li> <li>• Drug expenditure affected by utilization more than price</li> </ul>
Yang et al. (2010) (62) China	<b>Drug price depreciation</b> (1996) and <b>drug public-bidding policy</b> (2000)	<ul style="list-style-type: none"> <li>• LPG and IB prices, affordability and availability</li> </ul>	<ul style="list-style-type: none"> <li>• Low availability of LPG in public and private sectors (38.9 and 44.4% respectively)</li> <li>• MPR of procurement prices for IB and LPG in public sector were 9.78 and 0.74 the IRP. Median MPR of LPG in retail public outlets was higher than that in the private (0.68)</li> <li>• Prices for general population are affordable, however not so for low income segment</li> </ul>
Ziyan (2007) (70) China	Set <b>maximum retail prices and margins</b> for different drug classes	<ul style="list-style-type: none"> <li>• Pricing, availability and affordability of IB and LPG, price components</li> </ul>	<ul style="list-style-type: none"> <li>• Poor access to essential drugs due to irrational supply and distribution systems</li> <li>• Ineffective pricing regulation</li> <li>• Lack of promotion of generics</li> </ul>
Geng et al. (2014) (75) China & Taiwan	<b>Cost-plus pricing</b> and <b>price-based adjustment</b>	<ul style="list-style-type: none"> <li>• Generic and brand medicines price difference between Mainland China and Thailand</li> </ul>	<ul style="list-style-type: none"> <li>• 54/70 medicines of same generic name and dose have a higher price in Mainland China</li> <li>• 47/54 that also have the same</li> </ul>

			manufacturing source besides names and dose have higher prices in Mainland China
Anggriani et al. (2013) (73) Indonesia	Setting a <b>maximum price for unbranded generic medicines</b> by MOH. <b>IRP for some branded medicines</b>	<ul style="list-style-type: none"> <li>• 2010 new prices of LPG and IB, and their comparison to the maximum retail price</li> </ul>	<ul style="list-style-type: none"> <li>• Price reduction of LPG by &gt;2000% for some and to a less extent for branded (5-35 times of IRP) due to the absence of policy regulating the price of IB</li> <li>• Unbranded prices are higher than the maximum retail price</li> <li>• The implementation of the pricing policy is not optimal</li> <li>• Local manufacturer of unbranded generic stopped their production</li> </ul>
Abbott et al. (2012) (79) Jordan	<b>Patent</b> and IP Protection of pharmaceuticals after joining the WTO and signing of FTA with US. <b>Fixed national retail prices in the private sector based on CIF</b> , price in the country of origin, export price to Saudi Arabia, and the <b>mean price in a basket of at least 3 out of 7 European countries</b>	<ul style="list-style-type: none"> <li>• Number of registered new chemical entities (NCE), total units of medicines, total medicines sales, average price of medicines/DDD, and pharmaceutical-based patent applications</li> </ul>	<ul style="list-style-type: none"> <li>• Increase of overall annual drug expenditure and the price of originator brands</li> <li>• Decline of the weighted average price of generics</li> <li>• Increased medications cost due to delayed generic entry</li> </ul>
Ball et al. (2009) (63) Kuwait	<b>Zero mark-up in addition to CIF for public retail pharmacy. Fixed markup for private retail of maximum 55% in 2005</b>	<ul style="list-style-type: none"> <li>• Availability in the public sector, availability and prices in the private sector, procurement price difference between the two sectors, MPR of IB and generics in the private sector, percentage of generics to IB, comparison of MPR of certain IBs between Kuwait and other countries, and affordability</li> </ul>	<ul style="list-style-type: none"> <li>• Public sector procurement is efficient</li> <li>• Medicine prices in the private sector two times more expensive with reference to MSH prices</li> <li>• Some medicines are unaffordable in the private sector, with limited penetration of generics whose prices are not efficiently regulated</li> </ul>
Mäiga et al. (2010)	<b>Setting maximum price for 107/426</b>	<ul style="list-style-type: none"> <li>• Availability and pricing of essential medicines</li> </ul>	<ul style="list-style-type: none"> <li>• Availability was unaffected by</li> </ul>

(64) Mali	<b>essential medicines</b>	pre/post enforcement	enforcement, however prices decreased significantly by 25.6%
Moïse et al. (2007) (68) Mexico	<b>Maximum price regulation scheme for patent-protected drugs</b> in the private sector The <b>price threshold is set by benchmarking with an international reference price</b> For new products with no comparators, the manufacturer sets the price. Generic and original products are exempt from price regulation	<ul style="list-style-type: none"> <li>• Pharmaceutical expenditure compared to total healthcare expenditure</li> <li>• Price of medicines in the private sector</li> <li>• Availability</li> </ul>	<ul style="list-style-type: none"> <li>• Drug price levels are higher compared to Latin American countries and others of the same economic level</li> <li>• Similar availability of medicines to that in developed countries</li> </ul>
Russo and McPake (2010) (77) Mozambique	<b>Fixed markup for each stage of distribution</b> based on FOB price and CIF (1990) <b>No government tax</b>	<ul style="list-style-type: none"> <li>• Availability, MPR, household affordability of drugs, and price determinants</li> </ul>	<ul style="list-style-type: none"> <li>• Market dominated by generics with availability varying significantly between the capital city and other areas</li> <li>• Controlled generic prices in the public sector</li> <li>• IB prices reach <math>\geq 23</math> times the IRP</li> <li>• Ineffective policy due to lack of enforcement and corruption</li> </ul>
WHO (2004) (78) Oman	<b>Benchmarking to the international prices of 2002</b> with the lowest median price A maximum of <b>30% mark-up in the private</b> sector	<ul style="list-style-type: none"> <li>• Drug prices, availability, and affordability, rational use of drugs</li> </ul>	<ul style="list-style-type: none"> <li>• Regulation of drug prices especially in the private sector</li> <li>• Prices of less than 50% of medicines are comparable to international prices, the remaining is 2 to 28 times higher</li> <li>• 100% availability across sectors</li> <li>• Affordable treatment in the private sector to lowest paid employees (especially for children)</li> </ul>



Tatar (2013) (69)  
Turkey

**External reference pricing with cheapest** ex-factory price of a medicine in a **basket of five countries** (usually France, Greece, Italy, Portugal and Spain)  
Other detailed policies for specific cases (i.e., no ex-factory price in a given country, or cheaper price from manufacturing country)

- Pharmaceutical expenditure as a percentage of total healthcare expenditure

- Decrease in pharmaceutical expenditure as percentage of total healthcare expenditure from 36% in 2004 to 27% in 2011

Source: Abdel Rida N, Mohamed Ibrahim MI, Babar Z-U-D, Owusu Y. A systematic review of pharmaceutical pricing policies in developing countries. *J Pharm Health Serv Res.* 2017;8(4):213-26.

(\*): Middle Eastern; (†): Câmara de Regulação do Mercado de Medicamentos; (‡): Individual Actual Transaction Price

## APPENDIX C: PHARMACEUTICAL PRICING POLICIES ACCORDING TO INCOME LEVEL OF COUNTRIES

Author & Country	Policy	Income Level	Target medicines	Year of adoption
Kaló et al. (2015) (65) 7 ME* countries: Egypt, Kuwait, Jordan, Lebanon, Qatar, Saudi Arabia, United Arab Emirates	<ul style="list-style-type: none"> <li>• Use of external reference pricing</li> </ul>	NA	Mainly branded patented medicines.	NA
Ahmed et al. (2012) (59) Bangladesh	<ul style="list-style-type: none"> <li>• Promotion of use of generic medicines</li> </ul>	LMIC	Essential medicines	1982
Bertoldi et al. (2012) (60) Brazil	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> </ul>	UMIC	Essential medicines	NA
Nóbrega et al. (2007) (76) Brazil	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Tax exemptions/reductions for pharmaceutical products</li> </ul>	UMIC	Essential medicines	2000
Ford et al. (2007) (74) Brazil & Thailand	<ul style="list-style-type: none"> <li>• Promotion of use of generic medicines</li> </ul>	UMIC	Antiretrovirals	2006-2007 Thailand. 2003 Brazil
Fang et al. (2013) (61) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	UMIC	Essential medicines	2009
Han et al. (2013) (71) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	UMIC	60% of all medicines of which systemic antibacterial	1996
Hu (2013) (66) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	UMIC	Essential medicines	2009-2011
Zhou et al. (2015) (72) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> </ul>	UMIC	Essential medicines	2009
Meng et al. (2005) (67) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	UMIC	All medicines	2000

	chain			
Yang et al. (2010) (62) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	UMIC	Essential medicines	2009
Ziyan (2007) (70) China	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> </ul>	UMIC	All medicines	2000/2001/2005
Geng et al. (2014) (75) China & Taiwan	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> </ul>	UMIC	Brand-names medicines	2009
Anggriani et al. (2013) (73) Indonesia	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> <li>• Use of external reference pricing</li> <li>• Promotion of use of generic medicines</li> </ul>	LMIC	Generic medicines	2010
Abbott et al. (2012) (79) Jordan	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Use of external reference pricing</li> </ul>	UMIC	All medicines	2000-2001
Ball et al. (2009) (63) Kuwait	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> </ul>	HIC	All medicines	NA
Maïga et al. (2010) (64) Mali	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> </ul>	LIC	Essential medicines	2006
Moïse et al. (2007) (68) Mexico	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> <li>• Use of external reference pricing</li> </ul>	UMIC	All medicines	2004
Russo and McPake (2010) (77) Mozambique	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Tax exemptions/reductions for pharmaceutical products</li> </ul>	LIC	All medicines	1990- 1998-2003
WHO (2004) (78) Oman	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Use of external reference pricing</li> </ul>	HIC	All medicines	1990
Tatar (2013) (69) Turkey	<ul style="list-style-type: none"> <li>• Use of external reference pricing</li> </ul>	UMIC	All medicines	2004 revised in 2011

Source: Abdel Rida N, Mohamed Ibrahim MI, Babar Z-U-D, Owusu Y. A systematic review of pharmaceutical pricing policies in developing countries. *J Pharm Health Serv Res.* 2017;8(4):213-26.

(\*): Middle Eastern; HIC: High income country; UMIC: Upper-middle-income country; LMIC: Low-middle-income country; LIC: Low-income-country

## APPENDIX D: QUALITATIVE SYNTHESIS OF ELIGIBLE STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

<b>Authors</b>	<b>Country</b>	<b>Study design</b>	<b>Policy/ Year of adoption</b>	<b>Policy effects</b>
Meng et al. (2005) (67)	China	Retrospective pre-/post case study	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain/ (2000)</li> </ul>	The overall drug revenue and expenditure increased in both hospitals. However, only one hospital had a decrease in the case-specific drug use by patient. The changes in drug expenditure were mainly impacted by changes in drug utilization (expressed by PDD) more than price. When drug utilization or quantity decreased, drug expenditure decreased and vice versa.
Han et al. (2013) (71)	China	Longitudinal study	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain/ (2000)</li> </ul>	The drug prices dropped dramatically after the implementation of the policy (expenditure due to price), however drug expenditure almost doubled between 1996 and 2005. This was mainly the result of significant increase in utilization of more expensive drugs (expenditure due to mixed-effect).
Fang et al. (2013) (61)	China	Cross-sectional pre-/post surveys	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain/ (2010)</li> </ul>	The low availability of generic forms of essential medicines decreased even further after the NEMP implementation especially in the public sector. A non-significant decrease was observed for the innovator brands. The median unit price of both IB and generics significantly decreased after implementation with a greater magnitude for IB. The patient' retail and procurement prices of IBs listed on NEMP decreased more than those of lowest priced generics (LPGs) which were the main target of NEMP.
Zhou et al. (2015) (72)	China	Quasi-experimental controlled pre-/post study	<ul style="list-style-type: none"> <li>• Regulation of mark-ups in the pharmaceutical supply and distribution chain</li> <li>• Application of cost-plus pricing</li> </ul>	Quantitatively speaking both the total expense per visit and the proportion of drug expense out of total expense per visit for inpatients and outpatients were reduced. In absolute terms, the reduction in inpatient

			formulae for pharmaceutical price setting/ (2010)	expenses were higher than the outpatient expenses. Whereas in relative terms, they had equal reduction in respective expenses.
Anggriani et al. (2013) (73)	Indonesia	Cross-sectional pre-/post surveys	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting</li> <li>• Use of external reference pricing</li> <li>• Promotion of use of generic medicines/ (2010)</li> </ul>	The price of LPG decreased significantly by up to 2000% in both public and private sectors, reaching an MPR of less than one. A significant decrease in IB was observed mainly in the private sector. The IBs' MPR ranged between 5 to 35. Despite the decrease in retail prices, they were still much higher than the maximum retail price set by government varying between 2% to 661% for both types in all sectors.
Maïga et al. (2010) (64)	Mali	Cross-sectional pre-/post surveys	<ul style="list-style-type: none"> <li>• Application of cost-plus pricing formulae for pharmaceutical price setting/ (2006)</li> </ul>	The new policy resulted in limiting the number of medicines monopolized by stakeholders in the private sector. The availability of medicines fluctuated between the three periods surveyed but it ended up increasing in long term (2009) with an overall decrease in the price of medicines below the maximum drug price fixed by the decree.

Source: Abdel Rida N, Mohamed Ibrahim MI, Babar Z-U-D, Owusu Y. A systematic review of pharmaceutical pricing policies in developing countries. *J Pharm Health Serv Res.* 2017;8(4):213-26.

APPENDIX E: PDCD SUPPORT LETTER ISSUED FROM QATAR UNIVERSITY.



Date: January 31, 2017

**To:**

Dr. Aisha Ibrahim Al Ansari  
Director of Pharmacy and Drug Control Department  
Supreme Council of Health, MOPH  
Qatar.

Dear Dr Aisha,

**Ref: Ms Nada Moustafa Abdel Rida, MSc Student at College of Pharmacy, Qatar University**

Ms Nada is a MSc student who is doing her MSc in Pharmacy Program at Qatar University.

She is conducting a research under my supervision. Her research topic is related to Pharmaceutical Policy and she is doing a comparative study of medicines prices in Qatar and Lebanon.

Your cooperation and support will definitely help in her MSc program and are very much appreciated.

Thank you.

Sincerely yours,

---

College of Pharmacy  
Qatar University  
P.O Box 2713  
Doha, Qatar.

APPENDIX F: SECOND APPROVAL LETTER ISSUED FROM THE MINISTRY OF  
PUBLIC HEALTH IN LEBANON FOR THE PRICING MECHANISM ASSESSMENT

28 كانون الاول 2016

معالي مدير عام وزارة الصحة العامة/ الدكتور وليد عمار

تحية طيبة وبعد،

أود أن اتقدم لسيادتكم بحزب الشكر لمنحي الإذن لزيارة مراكز الرعاية الأولية لاستطلاع نوافر أدوية أمراض القلب. يتضمن البحث أيضاً دراسة لكيفية تسعير الدواء ومكونات السعر (Price Components).

أفيدكم علماً بأنني راجعت المعلومات المتوفرة على موقع الوزارة، لكن بعد التفاصيل المهمة للبحث لم تكن متواجدة، على سبيل المثال، تصنيف الدواء بحسب طريقة الاستيراد (FOB / CIF)، كون الدواء مثيل أول أو ثاني، وتحديد نسب العلاوات على سعر الاستيراد (الضريبة الجمركية، علاوة الموزع، علاوة الصيدلي).

أرجو من معاليكم منحي الإذن للتواصل مع الإدارة المختصة في وزارة الصحة العامة للحصول على هذه المعلومات.

نقدر لكم دعمكم لتسهيل اجراء هذه الدراسة.

ولكم جزيل الشكر...

ندى عبد الرضا



مع المرفق -



APPENDIX G: LIST OF THE KEY INFORMANTS MET IN QATAR AND  
LEBANON PER DEPARTMENT AND SECTOR

Country	Entities/Sector	Key Informants position
<b>Qatar</b>	Hamad Medical Corporation (HMC)/public	<ul style="list-style-type: none"> <li>• Executive Director of Drug Supply Department</li> <li>• Assistant Executive Director - Drug Supply Department</li> <li>• Head of Pharmaceutical Procurement Supply Chain &amp; Expediting Pharmaceutical Supply Chain Management - SCM</li> </ul>
	Pharmaceutical Drug Control Department (PDCD)/private	<ul style="list-style-type: none"> <li>• Director of Pharmacy and Drug Control Department, Supreme Council of Health, MOPH</li> <li>• Drug Registration Section Supervisor</li> <li>• Registration &amp; Drugs Pricing Section Head</li> </ul>
<b>Lebanon</b>	Ministry of Public Health (MoPH)/public & private	<ul style="list-style-type: none"> <li>• Head of Pharmacy Department</li> </ul>



## APPENDIX H: QU-IRB WAIVER COMMUNICATION EMAIL

**From:** Mohamed Izham Mohamed Ibrahim  
**Sent:** Wednesday, February 15, 2017 8:57 AM  
**To:** Qatar University Review Board  
**Subject:** QU-IRB Ethics Application - MSc Study on Medicine Prices

To Whom It May Concern

Here I would like to request for waiver as our study will involve the prices of medicines and relevant policy, and no information related to human subject.

Thanks.

Regards,

---

Mohamed Izham B. Mohamed Ibrahim, PhD  
(محمد ايزهام محمد ابراهيم)  
Professor of Social & Administrative Pharmacy  
College of Pharmacy  
Qatar University, PO Box 2713, Doha, Qatar.  
Tel: (+974) 4403 5580 (GMT +3hrs)  
Fax: (+974) 4403 5551  
[www.qu.edu.qa/pharmacy](http://www.qu.edu.qa/pharmacy)

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----- Original message -----

**From:** Qatar University Review Board <[QU-IRB@qu.edu.qa](mailto:QU-IRB@qu.edu.qa)>  
**Date:** 3/13/17 8:12 AM (GMT+03:00)  
**To:** Mohamed Izham Mohamed Ibrahim <[mohamedizham@qu.edu.qa](mailto:mohamedizham@qu.edu.qa)>  
**Subject:** FW: IRB Confirmation- Dr. Mohamed Izham / MSc Study on Medicine Prices

Dear Dr. Mohamed Izham,

Please note that if there is no human subject involvement, then there is no need for IRB approval.  
Kindly confirm.

Regards  
QU-IRB

## APPENDIX I: PHCC ETHICS APPROVAL



Primary Health Care Corporation  
Clinical Affairs  
**Research Section**  
researchsection@phcc.gov.qa  
*Form RS/AE1*

### Research/Project/Study Approval Notice Form

<b>Title of the Project:</b>	Evaluation of Pharmaceutical Pricing and Policy in Qatar and Lebanon: A Comparative Study of Cardiovascular Disease Medicines		
<b>Reference No:</b>	PHCC/IEC/16/12/027	<b>Date:</b> 12/03/2017	
<b>Principal Investigator:</b>			
<b>Name</b>	Ms. Nada Abdel Rida		
<b>Title</b>	Master Student- PharmD		
<b>Department/Organization</b>	Clinical Pharmacy and Practice/ Qatar University		
<b>Contact details</b>	Email: <a href="mailto:Na14023S3@gu.edu.qa">Na14023S3@gu.edu.qa</a> ; Tell: 66840777		

Required Information Checklist	Ref. No	Yes	No	N/A	Date
Research Proposal Submission Form signed and Completed		✓			
Research Proposal Supplementary Form Completed				✓	
HMC /WCMCQ IRB Approval Obtained, (or Previously HMC Research Committee Approval)				✓	
PHCC Research Committee Approval Obtained		✓			
Investigator agreement Form Signed		✓			
Other Ethics Committee Approval ( Please specify) e.g. Qatar University		✓			
Informed Consent Form Copy Provided		✓			
Sponsors		none			

**Dear Ms. Nada,**

Having established that there is minimal risk relating to your request and having considered the logistical issues we have no objections to you carrying out this project. Therefore the departments of Clinical Affairs and Operations give **approval** for it to commence. Please see the accompanying letter which sets out the **specific terms and conditions** of this approval that must be adhered to in carrying out your data collection.

We wish you every success in this endeavor.

**Kind Regards,**

*Hanan*  
-----  
**Dr. Hanan Al Mujalli**  
Executive Director of Clinical Affairs



*Samya*  
-----  
**Dr. Samya Ahmad Al Abdulla**  
Executive Director of Operations

For more information: [Researchsection@phcc.gov.qa](mailto:Researchsection@phcc.gov.qa)

RS/IEC/FL/1/17/04

Our Ref: PHCC/IEC/16/12/027

Date: 12<sup>th</sup> March 2017

Dear Ms. Nada,

**Final Approval: Evaluation of Pharmaceutical Pricing and Policy in Qatar and Lebanon: A Comparative Study of Cardiovascular Disease Medicines**

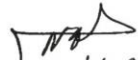
I write to confirm approval from the PHCC Research Committee for you to carry out the above student research project. This approval is granted under the terms for **expedited review** by the Committee which identifies that your request is a graduate student project with minimal risk. This **Final Approval** follows your completion of the necessary documents and revision of your application following initial reviewer feedback. Approval is valid for the period: From 12<sup>th</sup> March 2017 until 12<sup>th</sup> March 2018 subject to the following conditions: that

- You adhere to the principles of good research practice and ensure participants safety, privacy, confidentiality and data protection throughout the study
- You ensure the necessary logistical support is in place at the named Health Centres prior to commencement of the study.
- You ensure that participants are fully briefed on the nature and purpose of the study and what is expected of them, as part of the consent process
- You do not undertake other procedures and / or use participant materials or data outside of the scope of this present study, or for future use beyond this study.
- You agree to provide a progress report within **6 months** of the start and a final report at the end of the study or in the event that the study terminated early, an appropriate report.

This final approval requires no further review. However please note that this approval is applicable only in so far as you adhere to the above stated conditions and the Committee reserves the right to revise its approval should this become necessary.

On behalf of the Research Committee, I wish you success in the conduct of this study and look forward to receiving your final report following its completion.

Yours Sincerely,

  
16-03-2017

Dr Nagah Salim

Chair, PHCC Research Committee  
Consultant Community Medicine



APPENDIX J: PHC ACCESS APPROVAL LETTER FROM MOPH LEBANON

١٩ تشرين الثاني ٢٠١٦

سعادة مدير عام وزارة الصحة المحترم

تحية طيبة وبعد،

أنا خريجة الجامعة اللبنانية - كلية الصيدلة وأقوم حالياً بتحضير رسالة الماجستير في جامعة قطر. موضوع الدراسة هو "تقييم سياسات التسعير الدوائية في قطر ولبنان: دراسة مقارنة لأدوية أمراض القلب والأوعية الدموية".

يعتمد هذا البحث على دراسة وصفية مقطعية لأسعار وتوافر أدوية أمراض القلب والأوعية الدموية وقدرة المرضى على تحمل تكاليف العلاج، وهو مبني على المنهجية المعتمدة من منظمة الصحة العالمية ومنظمة العمل الصحي الدولية (WHO/HAI).

تهدف الدراسة لتقييم توافر الأدوية للأمراض غير المعدية وقدرة المرضى على تحمل تكاليف العلاج من أجل تسليط الضوء والتأكيد على أهمية تطبيق سياسات تسعير الدواء في كلا البلدين. من خلال جمع وتحليل البيانات في مختلف القطاعات ومنافذ بيع الأدوية، سيتكون لدينا فهم أفضل للوضع الحالي للقطاع الدوائي ككل في قطر ولبنان. ستعتمد الدراسة على قائمة الادوية الاساسية المعتمدة من وزارة الصحة اللبنانية ومقارنتها مع متيلاتها في قطر. الجدير بالذكر أنه سبق وأقيمت دراسة مماثلة مبنية على نفس المنهجية في لبنان عامي 2003 و 2013 للأمراض المزمنة.

بما أن هذا البحث يتطلب جمع بيانات من بعض المرافق الصحية التابعة لوزارة الصحة، ارجو من سعادتكم الموافقة على منحي الإذن لإجراء البحث في مراكز الرعاية الأولية في كل من الأفضية التالية: بيروت، الشوف، النبطية، صور، جبيل، وبعلبك. مع العلم بأن الدراسة لا تتطلب سوى زيارة مرافق واحد في كل قضاء، لمدة زمنية تقدر بحوالي الساعة.

نقدر لكم دعمكم لتسهيل اجراء هذه الدراسة.

ولكم جزيل الشكر...

ندى عبد الرضا



نقدم! بلدي! الى ب. اسلاش

رئيسة لجنة الديوان

هنادي بسناش

٢٨ تشرين الثاني ٢٠١٦



الجمهورية اللبنانية  
وزارة الصحة العامة  
مصلحة الديوان  
رقم التسجيل: ١٦/٧٤٨٠٠٢٩  
تاريخ الزور: ٢٠١٦

## APPENDIX K: SUPPORT LETTER FROM QU



Date: 24 October, 2016

### To Whom It May Concern

Dear Sir/Madam,

**Ref: Ms Nada Moustafa Abdel Rida, MSc Student at College of Pharmacy, Qatar University**

Ms Nada is a MSc student who is doing her MSc in Pharmacy Program at Qatar University.

She is conducting a research under my supervision. Her research topic is related to Pharmaceutical Policy and she is doing a comparative study of medicines prices in Qatar and Lebanon.

Your cooperation and support will definitely help in her MSc program and are very much appreciated.

Thank you.

Sincerely yours,

---

Mohamed Izham b. Mohamed Ibrahim, BPharm, PhD (PCPS, USA)  
Professor of Social & Administrative Pharmacy  
College of Pharmacy  
Qatar University  
P.O Box 2713  
Doha, Qatar.  
Tel: +974-44035580

## APPENDIX L: ESSENTIAL MEDICINES LIST OF LEBANON (2014)

Essential Medicines - Lebanon  
Based on WHO Model List – 18<sup>th</sup> edition

erythropoietine	injectable: 2000 UI.	R
erythropoietine	injectable: 4000 UI.	R
erythropoietine	injectable: 10000 UI.	R
ferrous salt	Oral liquid: equivalent to 25 mg iron (as sulfate)/ml.	R U
ferrous salt	Tablet: equivalent to 60 mg iron.	R U
ferrous salt + folic acid	Tablet equivalent to 60 mg iron + 400 micrograms folic acid (nutritional supplement for use during pregnancy).	R U
folic acid	tablet: 1 mg	R U
folic acid	tablet: 5 mg	R U
hydroxocobalamin	Injection: 10mg (as acetate, hydrochloride or as sulfate) in 1-ml ampoule.	R
<b>10.2 Medicines affecting coagulation</b>		
acenocoumarol	tablet: 4 mg	R Y
heparin sodium	injection: 25,000 IU (acetate)/ml in 1-ml ampoule	R
nadroparine	Injection: 0.3ml.	R
nadroparine	Injection: 0.4ml.	R
nadroparine	Injection: 0.6ml.	R
nadroparine	Injection: 0.8ml.	R
phytomenadione	Injection: 1 mg/ml	R
phytomenadione	Injection: 10 mg/ml in 5-ml ampoule.	R
protamine sulfate	Injection: 10 mg/ml in 5-ml ampoule.	R
tranexamic acid	Injection: 100 mg/ml in 10-ml ampoule.	R
<b>10.3 Other medicines for haemoglobinopathies</b>		
<i>Complementary List</i>		
deferoxamine	Powder for injection: 500 mg (mesilate) in vial.	R
hydroxycarbamide	Solid oral dosage form: 500 mg.	R
<b>11. BLOOD PRODUCTS AND PLASMA SUBSTITUTES</b>		
<b>11.1 Plasma substitutes</b>		
polygeline	injectable solution: 3.5%	R
<b>11.2 Plasma fractions for specific use</b>		
factor VIII concentrate	(dried)	R
factor IX complex concentrate (coagulation factors, II, VII, IX, X)	(dried)	R
albumin human normal	injectable solution: 25%	R
fibrinogen	(dried)	R
<b>12. CARDIOVASCULAR MEDICINES</b>		
<b>12.1 Antianginal medicines</b>		
bisoprolol	Tablet: 5 mg.	R Y
atenolol	tablet: 50 mg.	R
atenolol	tablet: 100 mg	R
glyceryl trinitrate	Paches: 10mg/24h	R
glyceryl trinitrate	Paches: 5mg/24h	R
isosorbide dinitrate	tablet (sublingual): 5 mg	R Y
molsidomine	tablet 2 mg	R Y

molsidomine	tablet 4 mg	R Y
propranolol	tablet: 10 mg (hydrochloride)	R Y
propranolol	tablet: 40 mg (hydrochloride)	R Y
verapamil	tablet: 80 mg (hydrochloride)	R Y
<b>12.2 Antiarrhythmic medicines</b>		
atenolol	tablet: 50 mg.	R Y
atenolol	tablet: 100 mg	R Y
digoxin	tablet: 250 micrograms	R Y
digoxin	oral solution 50 micrograms.	R
digoxin	injection 250 micrograms/ml in 2-ml ampoule.	R
epinephrine (adrenaline)	injection 1 mg (as hydrochloride) in 1-ml ampoule	R
lidocaine	injection: 20 mg (hydrochloride)/ml in 5-ml ampoule	R
propranolol	tablet: 10 mg (hydrochloride)	R Y
propranolol	tablet: 40 mg (hydrochloride)	R Y
verapamil	tablet: 80 mg (hydrochloride)	R Y
<b>Complementary List</b>		
amiodarone	Injection: 50 mg/ml in 3-ml ampoule (hydrochloride).	R
amiodarone	Tablet: 200 mg.	R Y
<b>12.3 Antihypertensive medicines</b>		
amlodipine	Tablet: 5 mg (as maleate: mesylate or besylate).	R Y
diltiazem	Tablet: 60 mg.	R Y
diltiazem	Tablet: 180 mg	R
bisoprolol	Tablet: 5 mg.	R Y
enalapril	Tablet: 5 mg (as hydrogen maleate).	R
atenolol	tablet: 50 mg.	R Y
atenolol	tablet: 100 mg	R Y
ramipril	tablet: 5 mg.	R Y
ramipril	tablet: 10 mg	R Y
hydrochlorothiazide	Solid oral dosage form: 25 mg.	R Y
valsartan	tablet: 80 mg	R Y
losartan	tablet: 50 mg	R
methyldopa	Tablet: 250 mg.	R Y
<b>12.4 Medicines used in heart failure</b>		
bisoprolol	Tablet: 5 mg.	R Y
captopril	Scored tablet: 25 mg.	R Y
captopril	Scored tablet: 50mg	R Y
digoxin	Tablet: 250 micrograms	R Y
digoxin	oral solution 50 micrograms.	R
digoxin	injection 250 micrograms/ml in 2-ml ampoule.	R
enalapril	Tablet: 5 mg (as hydrogen maleate).	R
furosemide	Injection: 10 mg/ml in 2-ml ampoule.	R
furosemide	Tablet: 40 mg.	R Y
hydrochlorothiazide	Solid oral dosage form: 25 mg.	R
spironolactone	Tablet: 25 mg.	R Y
<b>Complementary List</b>		
dopamine	Injection: 40 mg/ml (hydrochloride) in 5-ml vial.	R
<b>12.5 Antithrombotic medicines</b>		

Essential Medicines - Lebanon  
Based on WHO Model List – 18<sup>th</sup> edition

acetylsalicylic acid	tablet: 100 mg	R Y
clopidogrel	tablet: 75 mg	R Y
calcium dobesilate	tablet 500 mg	R Y
<b>Complementary List</b>		
streptokinase	powder for injection: 100,000 IU in vial	R
streptokinase	powder for injection: 750,000 IU in vial	R
<b>12.6 Lipid-lowering agents</b>		
fenofibrate	tablet: 200 mg	R Y
simvastatin	Tablet: 5 mg.	R
simvastatin	Tablet: 10 mg.	R
simvastatin	Tablet: 20 mg.	R Y
simvastatin	Tablet: 40 mg.	R
rosuvastatin	Tablet: 10 mg.	R Y
rosuvastatin	Tablet: 20 mg	R
gemfibrozil	tablet 600 mg	R



APPENDIX M: DETAILED INFORMATION PER MEDICINE IN QATAR

**Individual medicines availability, media price ration and local price per unit in Qatar**

Medicine	Product type	PHCC			Community pharmacies			Private hospitals		
		Availability	MPR	Median price in QAR	Availability	MPR	Median price in QAR	Availability	MPR	Median price in QAR
Acetylsalicylic acid	OB	100.0%	1.64	0.04	100.0%	12.07	0.33	100.0%	12.07	0.33
	LPG	0.0%			0.0%			0.0%		
Amiodarone	OB	60.0%	0.58	0.15	0.0%			0.0%		
	LPG	0.0%			0.0%			0.0%		
Amlodipine	OB	100.0%	9.68	0.33	100.0%	67.73	2.32	75.0%	67.73	2.32
	LPG	0.0%			100.0%	44.10	1.51	75.0%	44.10	1.51
Atenolol	OB	100.0%	1.72	0.04	100.0%	48.28	1.09	75.0%	48.28	1.09
	LPG	0.0%			50.0%	26.52	0.60	25.0%		
Atenolol (2)	OB	100.0%	0.49	0.04	100.0%	21.60	1.71	75.0%	21.60	1.71
	LPG	0.0%			33.3%			25.0%		
Atorvastatin	OB	100.0%	2.60	0.50	83.3%	24.11	4.68	100.0%	24.11	4.68
	LPG	0.0%			100.0%	13.28	2.58	100.0%	13.28	2.58
Atorvastatin (2)	OB	100.0%	4.95	0.79	100.0%	46.85	7.48	100.0%	46.85	7.48
	LPG	0.0%			100.0%	25.46	4.07	100.0%	29.06	4.64
Atorvastatin (3)	OB	100.0%	0.10	1.16	100.0%	0.72	8.55	75.0%	0.72	8.55
	LPG	0.0%			83.3%	0.40	4.70	25.0%		
Bisoprolol	OB	100.0%	0.61	0.15	100.0%	4.55	1.09	100.0%	4.55	1.09
	LPG	0.0%			33.3%			25.0%		
Captopril	OB	60.0%	0.13	0.00	33.3%			0.0%		
	LPG	40.0%			0.0%			0.0%		
Captopril (2)	OB	40.0%			50.0%	2.29	1.06	0.0%		
	LPG	60.0%	0.01	0.01	0.0%			0.0%		
Clopidogrel	OB	100.0%	3.10	0.87	83.3%	36.73	10.36	100.0%	36.73	10.36
	LPG	0.0%			50.0%	22.70	6.40	50.0%		

Digoxin	OB	100.0%	0.09	0.02	0.0%			0.0%		
	LPG	0.0%			0.0%			0.0%		
Diltiazem	OB	80.0%	0.16	0.03	0.0%			0.0%		
	LPG	0.0%			0.0%			0.0%		
Enalapril	OB	80.0%	1.77	0.06	83.3%	52.43	1.81	75.0%	52.43	1.81
	LPG	0.0%			66.7%	28.69	0.99	0.0%		
Furosemide	OB	80.0%	0.37	0.01	100.0%	29.32	0.89	75.0%	29.32	0.89
	LPG	20.0%			0.0%			0.0%		
Gemfibrozil	OB	40.0%			33.3%			25.0%		
	LPG	0.0%			16.7%			50.0%		
Hydrochlorothiazide	OB	100.0%	2.00	0.07	100.0%	21.56	0.74	100.0%	21.56	0.74
	LPG	0.0%			0.0%			0.0%		
Isosorbide dinitrate	OB	0.0%			0.0%			0.0%		
	LPG	40.0%			0.0%			0.0%		
Losartan	OB	100.0%	4.84	0.36	83.3%	43.61	3.21	100.0%	43.61	3.21
	LPG	0.0%			83.3%	30.38	2.23	100.0%	30.38	2.23
Methyldopa	OB	100.0%	0.41	0.06	83.3%	2.84	0.45	50.0%		
	LPG	0.0%			0.0%			0.0%		
Propranolol	OB	100.0%	0.62	0.06	0.0%			0.0%		
	LPG	0.0%			0.0%			0.0%		
Propranolol (2)	OB	100.0%	2.89	0.11	66.7%	8.30	0.32	100.0%	8.30	0.32
	LPG	0.0%			0.0%			0.0%		
Simvastatin	OB	80.0%	0.51	0.12	66.7%	11.80	2.83	50.0%		
	LPG	0.0%			33.3%			50.0%		
Simvastatin (2)	OB	100.0%	2.06	0.18	83.3%	37.26	3.32	50.0%		
	LPG	0.0%			50.0%	29.26	2.61	50.0%		
Spironolactone	OB	20.0%			66.7%	4.26	0.93	25.0%		
	LPG	0.0%			0.0%			0.0%		
Verapamil	OB	80.0%	1.44	0.13	33.3%			25.0%		
		0.0%			0.0%			0.0%		

APPENDIX N: DETAILED INFORMATION PER MEDICINE IN LEBANON

**Individual medicines availability, media price ration and local price per unit in Lebanon**

Medicine	Product type	PHC			Community pharmacies		
		Availability	MPR	Median price in LL	Availability	MPR	Median price in LL
Acetylsalicylic acid	OB	0.0%			100.0%	10.50	116.90
	LPG	0.0%			100.0%	7.49	83.33
Amiodarone	OB	0.0%			100.0%	3.23	345.65
	LPG	88.9%			50.0%	2.15	229.48
Amlodipine	OB	0.0%			100.0%	31.56	446.33
	LPG	88.9%			100.0%	25.67	363.09
Atenolol	OB	0.0%			100.0%	49.78	464.36
	LPG	66.7%			66.7%	17.90	167.00
Atenolol (2)	OB	0.0%			83.3%	23.35	762.21
	LPG	66.7%			50.0%	6.16	201.23
Atorvastatin	OB	0.0%			83.3%	17.65	1415.67
	LPG	0.0%			100.0%	8.19	656.82
Atorvastatin (2)	OB	0.0%			100.0%	35.15	2321.50
	LPG	0.0%			100.0%	15.34	1013.43
Atorvastatin (3)	OB	0.0%			66.7%	0.68	3311.90
	LPG	0.0%			83.3%	0.32	1566.67
Bisoprolol	OB	0.0%			83.3%	4.81	477.93
	LPG	88.9%			100.0%	1.79	177.33
Captopril	OB	0.0%			83.3%	32.91	440.63
	LPG	66.7%			66.7%	24.90	333.43
Captopril (2)	OB	0.0%			50.0%	3.83	736.13
	LPG	44.4%			33.3%		
Clopidogrel	OB	0.0%			100.0%	21.76	2537.59
	LPG	88.9%			100.0%	7.94	925.84
Digoxin	OB	0.0%			100.0%	0.52	37.66
	LPG	77.8%			0.0%		
Diltiazem	OB	0.0%			50.0%	2.47	222.73
	LPG	66.7%			66.7%	1.74	156.96
Enalapril	OB	0.0%			33.3%		
	LPG	0.0%			0.0%		
Furosemide	OB	0.0%			100.0%	34.35	428.95
	LPG	100.0%			33.3%		
Gemfibrozil	OB	0.0%			100.0%	2.12	319.03
	LPG	0.0%			16.7%		
Hydrochlorothiazide	OB	0.0%			66.7%	14.25	201.50
	LPG	22.2%			0.0%		
Isosorbide dinitrate	OB	0.0%			0.0%		
	LPG	33.3%			50.0%	0.50	58.11
Losartan	OB	0.0%			83.3%	59.73	1815.13
	LPG	0.0%			83.3%	41.13	1250.00

Methyldopa	OB	0.0%	66.7%	3.52	230.67
	LPG	33.3%	0.0%		
Propranolol	OB	0.0%	0.0%		
	LPG	77.8%	100.0%	0.81	30.00
Propranolol (2)	OB	0.0%	0.0%		
	LPG	55.6%	100.0%	3.45	55.09
Simvastatin	OB	0.0%	33.3%		
	LPG	0.0%	100.0%	2.04	202.00
Simvastatin (2)	OB	0.0%	50.0%	36.65	1350.93
	LPG	88.9%	83.3%	5.48	202.00
Spironolactone	OB	0.0%	66.7%	2.35	211.25
	LPG	55.6%	0.0%		
Verapamil	OB	0.0%	83.3%	8.58	318.85
		55.6%	0.0%		