# MEASURING SOCIO-ECONOMIC IMPACT OF CORRUPTION AND LACK OF GOOD GOVERNANCE IN THE PHARMACEUTICAL SECTOR

REPORT





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# ACRONYM

ACAL	Association des Companies d'Assurances au Liban	Mol
AIDS	Acquired Immune Deficiency Syndrome	Mol
AUBMC	American University of Beirut Medical Center	MoF
CAS	Central Administration of Statistics	Mos
CHE	Current Health Expenditure	MP
CIF	Cost, Insurance and Freight	NA
COVID-19	Coronavirus Disease 2019	NCD
СРР	Certificate of Pharmaceutical Product	NGC
CSC	Civil Servant Cooperative	NHA
DALY	Disability Adjusted Life Years	NS
DOTS	Directly Observed Treatment, Short-Course	NSS
DTP	Diphtheria-Tetanus-Pertussis vaccine	NTP
EML	Essential Medicines List	OEC
EPI	Expanded Program for Immunization	
FCA	Free Carrier	OOP
FOB	Free On Board	OPV
GDP	Gross Domestic Product	РНС
GGM	Good Governance for Medicine	PRL
GMP	Good Manufacturing Practice	PRS
GoL	Government of Lebanon	SHI
GSDP	Good Storage and Distribution Practices	SOP
GSF	General Security Forces	SPIL
HCS	Health Care System	
HIV	Human Immunodeficiency Virus	SSF
HMPD	Health Management and Policy Department	ТВ
ICU	Intensive Care Unit	THE
IMF	International Monetary Fund	TRIF
IMS	International Medical Statistics	UN
INGO	International Non-Governmental Organizations	UNH
INN	International Nonproprietary Name	UNI
ISF	Internal Security Forces	UNR
LOP	Lebanese Order of Physicians	
LPIA	Lebanese Pharmaceutical Importers Association	WB
MDG	Millennium Development Goal	WFF
MEHE	Ministry of Education and Higher Education	WH
MMR	Measles, Mumps and Rubella viruses	YMO
MoD	Ministry of Defense	Y-0-
MoET	Ministry of Economy and Trade	

MoPH MoSA NCD NGO NHA NSSF NTP OECD OOP OPV PHC SPIL THE TRIPS UNHCR UNICEF UNRWA WFP WHO YMCA Y-0-Y

SOP

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Ministry of Industry Ministry of Interior and Municipalities Ministry of Public Health Ministry of Social Affairs Member of Parliament National Accounts Non-Communicable Diseases Non-Governmental Organizations National Health Accounts Not Substitutable National Social Security Fund National Tuberculosis Program Organization for Economic Co-operation and Development **Out-of-Pocket** Oral Poliovirus Vaccines Primary Health Care Palestinian Refugees from Lebanon Palestinian Refugees from Syria Social Health Insurance Standard Operating Procedures Syndicate of the Pharmaceutical Industries in Lebanon State Security Forces Tuberculosis Total Health Expenditure Trade-Related Aspects of Intellectual Property Rights United Nations United Nations High Commissioner for Refugees United Nations Children's Fund United Nations Relief and Works Agency for Palestine Refugees in the Near East World Bank World Food Programme World Health Organization Young Men's Christian Association Year-on-Year

# **INTRODUCTION**

According to Transparency International's 2018 Corruption Perception Index, Lebanon ranks 138 out of 180 countries in terms of corruption<sup>1</sup>. Corruption is indeed a prevailing problem in the country and affects both public and private sectors. Local polls confirm that the Lebanese opinion considers the problem as endemic.

<sup>1</sup> Transparency International, "Corruption Perception Index 2018"

# **1.1. ABOUT THE ACT PROJECT**

The events that started on October 17, 2019, have proven that Lebanese citizens have a high level of awareness regarding corruption in public administrations and the widespread misconduct in almost all governing bodies. Activists have since voiced their concern regarding the lack of laws and/or their non-execution that can help prevent current corrupt behaviors and demanded clear steps towards drafting laws and/or develop implementing decrees to prevent and penalize any misconduct.

The association between the different layers of the current situation is becoming more visible, with corruption directly related to the worsening economic situation, and the economic situation undoubtedly causing the social conditions triggering recent events. The mentioned lack of good governance in the country has affected all major areas of a citizen's life and recent deterioration in public services have reached the pharmaceuticals sector in Lebanon, with a country wide shortage of medicine foreseen in the very near future.

However, in recent years, Lebanon has showed willingness to take action against this phenomenon and Anticorruption became a high priority. This echoes to the growing demand from the International partners. The CEDRE conference in Paris (April 2018) has provided an opportunity to recall the importance of a sound management of public finance for private and public investments, and the Lebanese government committed itself to take measures along these lines.

Funded by the European Union and implemented by Expertise France, ACT Anti-corruption and Transparency Project aims at supporting the national effort on combatting corruption. The specific objectives of the project are to strengthen public accountability and improve transparency at a national level. NGOs and CSOs dealing with corruption, transparency, or access to information can benefit from the information and know-how developed throughout this endeavour. The content created is meant to help formulate informed decisions when handling interrelated matters.

Continuous corruption combined with unceasing poor statesmanship and confessionalism, have taken a toll on public institutions in Lebanon, leading to indirect economic effects such as the lack of efficiency in the public domain, low foreign investments, uncertainty in conducting business, and other major economic implication. This has pushed the country into stagnation, and consequently affected the social conditions within the country.

Therefore, it is essential to define the sources of corruption, misconduct, and lack of good governance, in order to understand their effects on the current situation and the expected developments. Obtaining and analyzing this information is key to understanding the current tools available, and the efforts needed for the creation of additional instruments essential for future undertakings aimed to fighting it.

The expected results are the reinforcement of the National Authority in charge of combatting corruption, the enhancement of the technical capacities of control bodies (Court of Audit and Central Inspection Board), the implementation of operational tools for pilot administrations regarding the Access to Information Law, and an increased awareness among public service users.

These objectives will be achieved through technical assistance, equipment procurement and grants to Lebanese SCOs and NGOs.

## **1.2.** ASSIGNMENT GOAL

#### **1.2.1. OBJECTIVES**

This assignment aims to quantitatively measure the socio-economic impact of corruption on the health sector in Lebanon and more specifically on the pharmaceutical division, and especially drugs.

This research study is meant to tackle an influential subject that directly affects the quality of life of Lebanese citizens. The approach aims at forming a diagnosis of the effects of the lack of good governance on the existing situation and collect extensive information in order to be able to contribute to the formulation of future policies.

The research will be one of the tools used to better understand the economic and social cost of corruption in Lebanon, and to formulate interventions that induce large-scale change while helping in anticipating the results of targeting corruption in specific sectors.

#### **1.2.2. ASSIGNMENT OUTPUTS**

The following outputs are anticipated by the study results:

- Carry out a comprehensive research study using quantitative methods focused on the economic and/or social impact of corruption on the development of the pharmaceutical division of the Lebanese health sector.
- Focus on accessibility and price of medicinal products in Lebanon.
- Take the current economic situation in Lebanon into account.
- Provide recommendations based on the findings of the study.

# 1.3. METHODOLOGY

Initially, the study consisted of three phases: 1) literature review, 2) qualitative in-depth interviews, targeting main stakeholders of the pharmaceutical sector, and 3) analysis and report writing.

The focus on the pharmaceutical sector in Lebanon entails extensive data collection efforts regarding the structure of this sector, the pricing mechanisms, and key stakeholders, in order to determine the main sources and drivers of corruption and mal-practices within this sector. It also requires an overall overview of health care sector in Lebanon, besides the additional challenges and obstacles the HCS faced due to the outbreak of the COVID-19 in the country. Therefore, it was decided that the desk research would start with compiling previous literature; especially those related to strategic plans prepared by the Ministry of Public Health and the relevant international agencies, most importantly those of WHO, in addition to other analytical reports produced by specialized experts, concerned officials and global research firms. As a result, and with the information gathered, the team was able to choose the key individuals to be contacted and interviewed, in order to increase the amount and reliability of collected material and to bridge any existing information gaps concerning corruption and lack of good governance in the sector.

#### **1.3.1. LITERATURE REVIEW**

This phase comprises of a desk research on previous literature concerning the health sector in general, the pharmaceutical sector in particular and about the corruption within the latter sector. The desk research also covers the socioeconomic impact of corruption within the pharmaceutical sector, acquires quantitative data with regards to this sector, comprehends the legal and institutional frameworks' loopholes, determines the need for reforms and implementing good governance practices, etc.

#### **1.3.2. QUALITATIVE IN-DEPTH INTERVIEWS**

The fieldwork targeted gathering information from key informants and stakeholders within the pharmaceutical sector in Lebanon. At first, the in-depth interviews were intended to be conducted through face-to-face interviews. Unfortunately, due to the outbreak of the coronavirus (COVID-19) pandemic and the Governmental decisions dated on March 15, concerning the declaration of "health emergency" (including the closure of institutions); the initial plan was revised, and the in-depth interviews were conducted through phone calls with main stakeholders.

The interviews via phone conversations were carried-out utilizing semistructured and tailor-made discussion guides, directly addressing information gaps related to the interviewees' domain of expertise. The following stakeholders were selected and interviewed based on convenient sampling methods:

- Dr. Ismail Sukkarriyeh, former MP;
- Dr. Ahmad Sadeq, a former president of the "Secours Populaire Libanais";
- Ayham Al-Ahmar, Pharmacist;
- Sulaiman Jaber, Pharmacist;
- Khalil Majed, a previous General Manager of NSSF;
- · Jacques Kabanji, National expert and former NSSF high staff member;
- Dr. Rafic Badoura, Head, Rheumatology department, Hotel-Dieu Hospital at Universite Saint-Joseph;
- Rogeh Al-Haj, statistician and former expert at CAS;
- Dr. Omran Fouani, Physician.

#### **1.3.3. ANALYSIS AND REPORTING PHASE**

This phase of the study dedicated to the analysis of the information obtained and data collected from the literature review and desk research. The compilation of collected information and analysis of the outcomes and key findings were consolidated in this report.

This report consists of five main chapters. In addition to this introduction concerning the study objectives, methodology and limitations; chapter 2 is considered as an essential background and general overview of the overall health care sector. In light of the coronavirus COVID-19 outbreak in the country, chapter 3 covers the impact of this pandemic on Lebanon, and the challenges tackled by the health care system in response to the novel pandemic. Chapter 4 is directly concerned with defining the main sources of corruption and mal-practices in this sector, due to the lack of good governance. The next chapter 5 identifies the socio-economic impact and value of corruption and lack of good governance in the pharmaceutical sector.

The last chapter 6 contains the recommendations for interventions to reduce corruption and reform the sector. The Annexes, however, present additional details concerning the structure of the pharmaceutical sector in Lebanon. Annex 2 directly addresses the size of the health sector, the pharmaceutical sector in general and that of medical drugs in particular. It aims at determining the value of health expenditures and the distribution of the expenses and revenues. Annex 3 identifies the main stakeholders within the multi-faceted pharmaceutical sector, and the roles and domains of intervention of each stakeholder. Annex

<sup>2</sup> McKinsey & Company, "Lebanon Economic Vision", 2018. <sup>3</sup> WHO Regional Office for the Eastern Mediterranean (Cairo), "Country Cooperation Strategy 2019-2023: Lebanon", 2018.

4: tackles the exaggerated public prices of medicines and the price structure and pricing mechanisms, in order to comprehend the reasons behind the over-priced drugs in the pharmaceutical market. Annex 1 of this study presents a matrix that combines the main outcomes from the different chapters of this report.

# **1.4. STUDY LIMITATIONS**

It is well known that the healthcare sector in Lebanon lacks proper and accessible data base that is imperative to drive informed decision making. According to McKinsey & Company - the international management consulting firm - Lebanon does not even have "a centralized digital portal with a list of all hospitals (public and private) along with updated information on specialization, number of beds, surgeries, etc."<sup>2</sup> In the same sense, a recent report by WHO (Regional Office for the Eastern Mediterranean) stated: "There is wealth of information on health coverage and outcomes that are being collected within the system by the Central Administration of Statistics (CAS), the MoPH and other sector ministries, academic institutions, the private sector and NGOs. Much however is fragmented, unsystematic and lacking coherence; what exists focuses to a large extent on health care products that are being purchased by MoPH, from NGO health centres or private hospitals. However, even that is markedly incomplete, duplicated and of low quality. There is an urgent need for a master plan for health information system that engages all relevant institutions, strategizes and harmonizes data collection and analysis to prevent future waste of resources"<sup>3</sup>. This fact impedes any research or situation analysis of this vital sector, not to mention the gaps that might occur and hinder the outcomes of any study that aims at developing strategies and plans, in addition to policy making for the sector based on good governance practices.

Moreover, the study tackled serious challenges due to the outbreak of the coronavirus pandemic (COVID-19) in Lebanon. Fieldwork, which was initially intended to be conducted through face-to-face interviews with main stakeholders, was hindered by the announcement of a "medical state of emergency" and the lockdown of all non-essential public and private institutions, calling on citizens for a "self-imposed curfew". Hence, it rendered impossible to set appointments with the targeted stakeholders and meet them for in-depth interviews especially when it comes to health personnel. This measure might have reduced, to a certain extent, the outcomes of the study and made it difficult to directly demand for more updated data from the relevant entities.



# **BACKGROUND ON HEALTH CARE SYSTEM**

<sup>4</sup> World Bank (2017). GNI per capita, purchasing power parity. Available from: https://data.worldbank. org/indicator/NY.GNP.PCAP. PP.CD?locations=LB <sup>5</sup> World Bank (2017). GDP growth, annual. Available from: https://data. worldbank.org/indicator/NY.GDP. MKTP.KD.ZG?locations=LB <sup>6</sup> MoPH, "Health Strategic Plan Strategic Plan for the medium term (2016 to 2020)", December 2016. <sup>7</sup> Ibid. <sup>8</sup> Refer to: WHO, "The World Health Report - Health Systems Financing

- The Path to Universal Coverage"

2010.

# 2.1. ACHIEVEMENTS

In spite that, the MoPH medium term "Health Strategy Plan" for the years 2016-2020 marked that Lebanon achieved the MDGs related to maternal and child health in terms of key public health indicators. According to the document, the rates of immunization were found to be high, and they "have also increased between 2009 and 2015 in three key areas: polio (93 – 99.85%), measles (93 – 99%) and pentavalent vaccines (93 – 98%) ... maternal and child health indicators are also strong: the infant mortality rate is estimated at 9/1000 live births (2009)); the <5 mortality rate at 9/1000 live births (2009), and; the maternal mortality rate (/100,000 live births) reduced from 25 to 18 between 2011 and 2013 ... These indicators are all consistent with the levels and achievements of the bulk of high(est)-middle income countries, and are also strong in regional comparison"<sup>6</sup>.

The strategy plan added to the achievements within the health care sector, referring to "The World Health Report 2010", which documented "the case of Lebanon as a success story on how to decrease total health spending in terms of % of GDP by lowering mainly out of pocket while at the same time improving health indicators. This supports the sound health policy of strengthening PHC and rationalizing the cost of hospital services while promoting the MoPH regulatory capacity"7.

In fact, Lebanon spent 12.3% of its GDP on health in 1998 (the highest in the Eastern Mediterranean Region), while out-of-pocket payment was at 59.6% of total health spending (among the highest in the region); which is considered a significant obstacle to low-income people. Since then, a series of reforms has been implemented by the MoPH to improve equity and efficiency<sup>8</sup>; which reduced the share of the CHE out of the country's GDP to 7.75% and share of OOP expenditure out of total CHE to be eased substantially to 33.1% in 2017. The "key components of this reform have been: a revamping of the public-sector primary-care network; improving quality in public hospitals; and improving the rational use of medical technologies and medicines. The latter has included increasing the use of quality-assured generic medicines. The Ministry ... has also sought to strengthen its leadership and governance functions through a national regulatory authority for health and biomedical technology, an accreditation system for all hospitals, and contracting with private hospitals for

Lebanon is categorized as an upper-middle income country, as its gross national income was calculated at USD 14,690 per capita<sup>4</sup> in the year 2017, at a time the country's GDP growth rate was found to be deteriorating to a mere 2% in that same year<sup>5</sup>.

specific inpatient services at specified prices ... Improved quality of services in the public sector, at both the primary and tertiary levels, has resulted in increased utilization, particularly among the poor. Being a more significant provider of services, the Ministry ... is now better able to negotiate rates for the services it buys from private hospitals and can use the database to track the unit costs of various hospital services"9.

## 2.2. CHALLENGES

#### 2.2.1. DEMOGRAPHY:

The WHO conducted a country analysis in 2018, concerning Lebanon's health and development challenges and potential vulnerabilities. The report estimated the population residing in Lebanon to be at 6,093,509; comprising of approximately 4.4 million Lebanese and 1.7 million displaced people (refugees and migrants)<sup>10</sup>. The displaced people mostly include an estimated 1.5 million displaced Syrians among whom some 28,800 Palestinian refugees from Syria (PRS)<sup>11</sup>and some 174,422 enumerated Palestinian refugees from Lebanon (PRL) residing in the 12 official refugee camps and in 156 gatherings across Lebanon<sup>12</sup>.

<sup>9</sup> Ibid.

<sup>10</sup> WHO Regional Office (2018), op. cit. <sup>11</sup> Government of Lebanon (GoL) and the United Nations (UN), "Lebanon Crisis Response Plan 2017-2020 (2019 update)", January 2019.

<sup>12</sup> Central Administration of Statistics, the Palestinian Bureau of Statistics and the Lebanese Palestinian Dialogue Committee, "Population and Housing Census in the Palestinian Camps and Gatherings in Lebanon, 2017", 2019.

<sup>13</sup> WHO Regional Office (2018), op. cit. <sup>14</sup> World Bank, "Lebanon Economic Monitor: The Great Capture", Fall 2015. Refer to Chapter II "Lebanon's Health Sector: Modest Reforms despite the Challenges". <sup>15</sup> Institute of Health Metrics and Evaluation, "Global Burden of Diseases, Injuries, and Risk Factors Study 2010 - GBD Profile: Lebanon", 2013

<sup>16</sup> World Bank (Fall 2015), op. cit.

Moreover, the WHO report also stressed on the fact that "around 25% of the Lebanese population is under 15 years of age, and 10% is older than 65 years"<sup>13</sup>. These facts prove the arguments warning of the impact of a growing and aging population in Lebanon on the volatile health care system in the country, especially on the long term.

#### 2.2.2. EPIDEMIOLOGY:

The demographic changes are combined with a shift in the epidemiological trends from communicable diseases towards the rise in non-communicable diseases (NCDs), in addition to injuries, which "will carry significant implications for health care financing and service delivery in the future. The bulge of currently young and healthy people will transition into a middle-aged and older cohort by 2050 which will increase demand for health care<sup>"14</sup>. It was found that almost half of all deaths in Lebanon are due to cardiovascular diseases (45%), and one in five deaths are cancer related (20%)<sup>15</sup>. The WB report stated, that according to MoPH, "the top five causes of morbidity – measured by disability adjusted life years (DALYs) - are all NCDs, namely ischemic heart disease, low back pain, major depressive disorders, stroke and diabetes. These trends also suggest that Lebanon will have to reshape its health system to better address the prevention and treatment of NCDs"<sup>16</sup>.

<sup>17</sup> WHO Regional Office (2018), op. cit. <sup>18</sup> Refer to: WHO, Report of the Commission on Macroeconomics and Health, "Macroeconomics and Health: Investing in Health for Economic Development", 2001. <sup>19</sup> United Nations Agency of Funds

and Programmes, "United Nations Strategic Framework (UNSF) Lebanon 2017-2020".

<sup>20</sup> GoL and UN, (January 2019), op. cit. <sup>21</sup> These are estimates by the "National Poverty Reduction Program", refer to: UNHCR, WFP and UNICEF, "Vulnerability Assessment of Syrian Refugees in Lebanon 2015", 2018. <sup>22</sup> Refer to: WHO Regional Office (2018), op. cit.

Even before the outbreak of the Syrian crisis and the influx of displaced Syrians into Lebanon, the country health care system had "in the past performed poorly in controlling determinants and risk factors of NCDs. Two-thirds of the population suffer from overweight/obesity, half lack low physical activity and one-third smokes"<sup>17</sup>. Unfortunately, NCDs are the top causes of mortality and morbidity among adults in the country, and are increasingly affecting the poor segments of society. However, the influx of refugees with their triple burden of communicable diseases, NCDs and the social, economic and psychological effects of their displacement adds considerable complexity.

Indeed, the changing epidemiological profile of diseases is putting traditional health systems under stress, it is spiking its cost and financial burden and it is requiring additional resources and health services to adapt to the emerging needs.

#### 2.2.3. SOCIO-ECONOMIC:

Since the beginning of the Millennium, the WHO Commission on Macroeconomics and Health provided evidence that the link between poverty and ill-health functions in both directions. Hence, it stressed the importance of investing in health to promote economic development and reduce poverty<sup>18</sup>.

It is estimated that 28.5% of the Lebanese population are poor (living on less than USD 4 per day), of which 470,000 are children; and about 300,000 individuals are considered extremely poor (living on less than USD 2.4 per day) and unable to meet their most basic food needs. In addition, Lebanon hosts the highest ratio of refugees per capita, as around one-quarter of the population are refugees and displaced from neighboring countries, and the vast majority of the refugees are also poor (some 76% of displaced Syrians, 89% of PRS and 65% of PRL)<sup>19</sup>. Moreover, around 87% of those displaced from Syria reside in the same regions where the most deprived Lebanese (67%) are concentrated<sup>20</sup>. In 2015, it was estimated that 28% of the Lebanese and at least 70% of the displaced Syrians are vulnerable and may require subsidy for accessing timely and adequate health care<sup>21</sup>. Unfortunately, the situation is deteriorating and poverty is rising very fast among displaced Syrians, as a 2017 report noticed that more than three-quarters of displaced Syrians (76%) had slipped under the poverty line, whereas, the local host communities are strained by limited infrastructural capacity and increased competition for services and resources<sup>22</sup>.

It was found that the household OOP expenditure actually differs according to income levels and social strata. OOP expenditure's share

for the very poor is more than double that of the richest. Also, the share of the insured in the lowest income category is almost onethird that of those in the highest income category<sup>23</sup>. The Director General of the MoPH, Professor Walid Ammar, concluded that "a health financing system that relies so heavily on OOP payment has to face poverty and sustainability issues. Unfair financing is a threat to equitable accessibility and seriously jeopardizes the achievement of health goals"<sup>24</sup>.

Even before the current economic and financial crisis, the last UN Strategic Framework for Lebanon had acknowledged the deteriorating social situation in the country and the dire economic conditions; it stated that "Lebanon's development model has been characterized by striking inequalities, deep 'pockets' of persistent poverty, and weaknesses in the allocation and provision of services. Together with a significant debt burden and volatile macro-economic environment, these have resulted in productive sectors that are inefficient and under-performing, a difficult business and investment climate, and labor markets that cannot provide jobs in sufficient numbers"<sup>25</sup>. Since then, all socio-economic indicators in the country had worsened, social unrest escalated, political divisions peaked, and the whole economy was affected by the lock-down due to the outbreak of the COVID-19. These incidents had occurred simultaneously, severely impacting the health care system with an unprecedented sudden increase of demand and strain on it.

Currently, Lebanon is facing its worst economic turmoil, because of a prolonged economic slowdown and unprecedented sovereign debt burden. In fact, Lebanon has one of the largest public debts in the world, which is equivalent to 170% of its GDP. For the first time in its history, the country defaulted on its debt in March 9, 2020 and failed to pay the then matured USD 1.2 billion Eurobond (another USD 700 million payment matured in April 2020 and a USD 600 million in June of the same year). Since September 2019, the country has been hit by a severe financial crisis that steered a liquidity crunch, as foreign currency inflows had slowed and caused a dollar shortage in the market. The Lebanese pound has plunged in value and banks have imposed tough restrictions on dollar withdrawals and transfers. The Lebanese pound is officially pegged to the US dollar at a rate of 1,507, but it has devaluated to as low as 8,000 against the dollar on the parallel market (losing more than 80% of its value). With few sources of fresh dollar inflows and limited dollar reserves at the central bank, the country witnessed steep price inflation on almost all products and services. As a result, the banking sector imposed informal capital controls that have cut off depositors from their

hard foreign currency savings. This monetary and financial crisis has caused a scarcity of vital medical supplies, which is highly dependent on trade imports in foreign currency. In turn, the government halted reimbursement of hospitals for bills, which created a huge challenge for many hospitals that reached the verge of budget collapse and closures.

According to WB, "low public spending on health has negative implications on health outcomes especially among low income groups. The need to achieve fiscal consolidation, however, suggests that financial resources for healthcare are limited, and improving the efficiency of spending will thus be essential for improving health outcomes"<sup>26</sup>. However, with the escalation of cost of health services, the current level of MoPH health funding and the lack of universal health coverage, it should be alarming that the health system would be incapable to adequately meet the increasing needs of a growing and aging population.

#### 2.2.4. ENVIRONMENTAL HEALTH:

Lebanon faces numerous environmental challenges that widely vary across thematic areas, which add to all other challenges tackling PHS. The WHO has listed the most important environmental challenges impacting public health: "Lebanon is suffering from progressive environmental degradation, aggravated by a large number of informal refugees' settlements, an accelerated deforestation, lower precipitates and poor water resources management. Air pollution presents a serious health hazard, made worse with the poorly managed solid waste disposal topped by chaotic uncontrolled use of small local electricity generators. The MoPH has mainly a consultative role, and the Ministry of Environment has no executive role. This dissolves responsibility and accountability. However, the MoPH, with WHO support, has developed a national environmental health strategy in 2016, that could not go into a plan of action due to Government laxity and poorly defined mandates"27.

#### 2.2.5. SYSTEMIC GAPS:

<sup>26</sup> World Bank (Fall 2015), op. cit.

<sup>27</sup> WHO Regional Office (2018), op. cit.

The public health system suffers dearly from many systemic gaps on various levels and domains (on the political and economic levels, within the legal and institutional frameworks, market imbalances, etc.). The report will present and analyze the main ones that are directly related to the pharmaceutical sector. Nonetheless, it is important to mention some of the most prominent systemic gaps that impact PHS in general.

The confessional political regime in Lebanon and its direct influence on the public administration is one of the most important reasons for

<sup>23</sup> Refer to: Walid Ammar MD., PhD. (WHO & MoPH), "Health System and Reform in Lebanon", January 2003. <sup>24</sup> Walid Ammar MD., PhD. (WHO & MoPH), "Health Beyond Politics", 2009.

<sup>25</sup> Refer to United Nations Agency of Funds and Programmes, "United Nations Strategic Framework (UNSF) Lebanon 2017-2020".

corruption, red tape and lack of transparency and good governance in general and regarding improving efficiency and quality of the PHS.

The country's neo-liberal economic model is considered a key bottleneck to PHS reforms, because it encourages the domination of a private-for-profit health sector (private hospitals and clinics, heavy rely on imports of pharmaceuticals with no protection or subsidies for local manufacturers, the oligopoly of medical drugs merchants, the prevalence of expensive branded drugs, etc.).

Concerning the legal framework, unfortunately, "Lebanon does not have a modern medicine regulatory authority structure in place or a national medicine policy or policy document that lays out a vision for the future of the sector and that defines political, technical, economic and health related parameters that form the framework for pharmaceutical legislation. The only law in Lebanon that governs the pharmaceutical sector is the pharmacy law of 1994, which also includes the management of the practice and the profession"<sup>28</sup>.

Hence, the "mismanagement of the system and resources due to lack of effective laws and regulations, together with some degree of corruption or lack of transparency at one or more levels of the pharmaceutical system may also contribute to the high medicines bill and the lack of efficiency in providing affordable and accessible medicines to all"<sup>29</sup>. On the other hand, the government has limited regulatory capacity, its expenditure on public sector human resources is very limited, and its institutional capacity is feeble.

Other factors contribute to market failure, such as:

- The lack of competitiveness in services' provision,
- The separation between financing and provision of health care,
- The fragmentation and overlapping of public financing,
- The consumer perceptions in confusing quality with high technology and expensive pharmaceuticals,
- The imbalance between technology centered curative care and public health prevention and promotion,
- The large variations in quality of care.

Finally, the MoPH acting as an insurer-of-the-last-resort might fortify the clientalism base when providing public services, and reinforce the patronage practices by political parties of sectarian nature that influence the ministry's decisions.



<sup>28</sup> WHO Regional Office for the Eastern Mediterranean, "Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector - Lebanon", 2009. 29 Ibid.

To

# **CORONAVIRUS** (COVID-19) OUTBREAK **IN LEBANON**

In the midst of unprecedented economic, financial and monetary crises, which triggered political unrest and a historical uprising all over Lebanon, denouncing the sectarian political regime and the socioeconomic model of the post-civil war era; the country witnessed the outbreak of coronavirus (COVID-19) starting of the 21st of February, when the first case was diagnosed.

Since then, the Lebanese government has taken several precautionary steps, and initiated several measures to try to contain the progression of the coronavirus spread:

- were closed (March 6);

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· Lebanon introduced travel restrictions for non-residents from countries with large COVID-19 outbreaks, including China, Italy, South Korea, and Iran (February 28);

• The closure of all educational institutions (February 29);

• Public venues, such as gyms, cinemas, theaters, and nightclubs

• The Lebanese Parliament closed down and all people were instructed by the government to stay home (March 9);

• All restaurants in Lebanon were closed (March 11);

• Major malls announced their closure until further notice (March 12); • On March 15, the government announced a state of "general mobilization" until March 29, which has been extended several times since then, and President Michel Aoun declared a "medical state of emergency";

- The government announced the closure of Beirut Airport, seaports and land entrances (March 18);
- The Prime Minister Hassan Diab in a televised speech urged people in Lebanon to implement "self-curfew," (March 21);
- Lebanon imposed a partial curfew from 7 p.m. to 5 a.m. (March 26).

Eventually, the government ordered all non-essential public and private institutions to close, except those needed to fulfill vital needs, such as bakeries, pharmacies, supermarkets, and banks. Also an alternating traffic system was put in place, and MEHE implemented the distance-learning system.

Other measures were taken to mitigate the rapidly deteriorating socioeconomic conditions, trying to countering the effects of total lock-down of the economic establishments, the plunging value of the currency exchange rate, the rising inflation, the increasing numbers of lay-offs and unemployment and the wage cuts. In such dire situation, poverty has expanded dramatically with the World Bank<sup>30</sup> estimating that it will reach 50% of the population by the end of 2020. The Minister of Social Affairs Ramzi Moucharafieh announced the distribution of social assistance to the poorest families. The government allocated LBP 75 billion to be distributed by the Army to 200 thousand households in Lebanon (LBP 400 thousand per household).

Since the COVID-19 outbreak, the MoPH has published an emergency framework and presented its strategy of flattening the curve. The ministry identified four lines of hospitals (public and private) that will be activated as the need arises. The first concerns 12 hospitals, including the main governmental hospital (Rafic Hariri University Hospital); the other three lines should include another 58 public hospitals dedicated to Covid-19. According to the MoPH response scenario, 10 private hospitals can accommodate up to 381 COVID-19 patients under the first line preparedness scenario. Unfortunately, only private hospitals with independent wings will receive COVID-19 patients (i.e. the 10 hospitals listed under the MoPH response scenarios). In this regards, there are serious doubts that even the biggest private hospital will not be able to provide more than 20 beds to receive coronavirus cases.

The weak point of this emergency framework is that currently public hospitals have limited capacity (only 222 ventilators and 419 ICU beds) in contrast to private hospitals (1,242 ventilators and 2,391 ICU beds); whereas, it is not clear if private hospitals will accept to treat patients with Covid-19 for free. With this regards, the head of the Lebanese Syndicate of Hospitals reported that the NSSF rates are not applicable to COVID-19 cases, as significant additional costs are incurred by the hospitals such as expensive professional personal protective equipment.

Given the limited numbers of intensive care unit beds and ventilators, the MoPH has identified urgent needs: equipping 11 public hospitals with additional ICU beds, ventilators, personnel, and protective equipment. According to the MoPH, the maximum health capacity of the country would be reached with 5,000 infected patients, of which 20% would need hospital care (1,000 patients), 5% would require intensive care (250 patients), while 2-3% would need mechanical ventilation (150 patients).

Moreover, WHO has shipped personal protective gear to doctors in Beirut; and other international assistance to combat the virus started flowing to Lebanon, especially from China and France.

Indeed, Lebanon's financial strains have resulted in a scarcity of medical supplies necessary to deal with the COVID-19 outbreak. For instance, the dollar shortage has restricted the ability of medical supply importers to import vital medical supplies, ventilators and spare parts (private hospitals owe medical suppliers some USD 350 million accrued over the last two years). But the Central Bank issued a decision, on January 21, guaranteeing 85% of the dollars medical suppliers need for imports at the more favorable official rate, while some international companies have given Lebanese importers longer grace periods for payment.

Moreover, the government has also not reimbursed public and private hospitals for bills, including from the NSSF and military health funds (the government owes private hospitals an estimated USD 1.3 billion in unpaid bills since 2011).

There have also been concerns about the failure of the government and hospitals to adequately staff hospitals and protect staff from infection. Some hospitals laid off nurses causing an unsustainable workload other hospitals are not paying nurses or are slashing their salaries.

<sup>30</sup> World Bank, "Updated Poverty Numbers in Lebanon," 15 March 2020. The MoPH has an estimated budget of USD 461 million in 2020. It was forecasted that it requires an additional funding that varies between USD 43.01 million and USD 57.64 million. Nevertheless, the government was able to allocate the USD 39 million World Bank loan, which was awarded to Lebanon before the COVID-19 pandemic, to prepare and equip public hospitals to confront the outbreak.

# On another note, the cost of coronavirus patients' treatment is considered very high:

- The average cost of testing per patient is estimated to be USD 90;
- The weighted average cost of hospitalization amounts to USD 373.34 per patient per day;
- The weighted average cost of intensive care is estimated around USD 1,200 per patient per day<sup>31</sup>.

In fact, the cost of testing in public hospitals as published in the MoPH response plan is approximately of USD 40 per person; while, the cost of the test is set by the MoPH at USD 100 in private hospitals and laboratories (3 of the 17 hospitals and laboratories that can officially conduct the testing are public hospitals).

In Lebanon, three clinical diagnoses for COVID-19 are identified: (1) asymptomatic cases are sent automatically for home quarantine, (2) critical cases are admitted to intensive care units, and (3) mild / moderate cases are either sent to home quarantine or admitted to hospital quarantine depending on the severity of the symptoms.

Lebanon Coronavirus Cases, as of June 15, were set at 1,464 persons; Lebanon Coronavirus Deaths at 32 persons; while Lebanon Coronavirus Recovered at 875 persons. Lebanon has carried-out around 107,000 tests.

	Total	per 1 M Population	(%) of Total Cases
Tests	106,897	15,659	
Cases	1,464	214	100%
Active Cases	557	82	38%
- Serious (Critical) Cases	8	1	1%
Recovered	875	128	60%
Deaths	32	5	2%

<sup>31</sup> Institute of Finance Basil Fuleihan and Ministry of Finance, "The Economic Cost of Policy Action Against the Outbreak Scenarios of COVID-19 in Lebanon – Costing the Healthcare Interventions", 2020.

Table 1: Coronavirus(COVID-19) Cases inLebanon (as of June

15, 2020)

Even though the number of confirmed cases in Lebanon might be underestimated, mainly due to lack of massive testing, still, Lebanon seems to have been spared – so far – the worst of the pandemic. In fact, GoL has taken swift and broad measures to tackle the coronavirus challenges, and the country seems to have so far responded effectively to the pandemic and succeeded in slowing the pace of progression of the outbreak. Special concerns are raised regarding the refugee communities. Since the beginning of the outbreak, the UN agency and its partners have mobilized in raising awareness about COVID-19 and distributing soap and other hygienic and sanitation materials to refugees. UN agencies are also helping the government expand existing capacities for hospitalization, testing and intensive care.

Another serious concern related to the overcrowded prisons (10,000 inmates distributed among 25 prisons and 261 detention facilities). Lebanon has adopted preventive measures inside prisons, such as suspending all activities and reducing family visits. The United Nations Office on Drugs and Crime (UNODC) has provided mobile SIM cards for inmates to maintain contact with their families.

Nonetheless, there are lingering questions about the country's ability to test and treat a future outbreak. Can the country prepare itself for a possible second wave? Can it devise a socio-economic plan to mitigate the economic impact of the pandemic on an already marginalized population?





# • SOURCES AND **DRIVERS OF CORRUPTION AND MAL-PRACTICES**

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In a multi-faceted health care and pharmaceutical sector, a previous study conducted for MoPH had concluded that the "lack of coordination among health providers has to lead to an oversupply of services, false billing, and difficulties in admission to hospitals ... This has led to a tremendous increase in health care costs for the government, placing a heavy burden on the public as well as health providers"<sup>32</sup>.

Using a transparency tool developed by WHO, three staff doctors at MoPH prepared a report aiming at measuring transparency in the public pharmaceutical sector in Lebanon. The study noticed that "different stakeholders are involved in different stages of the medicines cycle", and concluded that "the pharmaceutical sector in Lebanon is complex and the high medicines bill could be due to many overlapping factors"<sup>33</sup>.

Indeed, corruption is one of the main driving factors of high expenditure on pharmaceuticals, over-consumption of medicine and the existence of poor quality drugs in the market. A former MP, Dr. Ismail Sukkarieh, mentioned in his book on medicine that it is considered a highly profitable commercial product in Lebanon, and stated that there exists a "coalition of tripartite mafia that consists of merchants, public administration and politicians"<sup>34</sup>.

Even though, the local pharmaceutical market is highly dependent on imports; one can add to the list of the "Big Ten" importers' oligopoly, who represent the interests of the global manufacturing firms of pharmaceutical products, a wide network of players and stakeholders, mainly those of officials, pharmacists, physicians and hospital management staffs. This allows the corruption network to prevail the import, registration, pricing, billing and marketing of pharmaceutical products in Lebanon.

This section of the report covers two topics: (1) the structural characteristics of the HCS and the pharmaceutical market - in particular - that are considered to be factors that encourage corruption; and (2) the mal-practices and corrupted behavior that nourishes within a corruptive environment and the lack of good governance in the public administration.

<sup>32</sup> Antoine ROMANOS (Medhealth BEIRUT & MoPH), "Ministry of Public Health – Vision, Planning and <sup>33</sup> WHO Regional Office (2009), op.cit. الدكتور اسماعيل سكرية، "<sup>34</sup> Refer to "الدواءً... مافياً أُم أزمةً نظام؟، 2010 (Dr. Ismail Sukkarriveh, "The Drugs ... Mafia or a System Crisis", 2010).

Legislation", 2012.

physicians and hospital in over-subscription of drugs, especially the branded drug names instead of generic medicines and antibiotics and psychiatric/psychotropic drugs.

# 4.1. STRUCTURAL FACTORS

The MoPH strategic plan for the period 2016-2020 had acknowledged some of the weaknesses related to the institutional framework of the ministry: "the basic organization of the MoPH pre-dates the civil war (1975-90). Since that time, also as a result of the war, it is clear that factors both in- and out-side the sector have changed radically and permanently ... There have been attempts to update the organization but did not materialize to date due to political issues"<sup>35</sup>.

The strategic plan highlighted the following issue: "the decline in the number of staff represents a serious threat to the sustainability of MoPH performance and reflects clearly the lack of political commitment to strengthen the public administration. This applies to all the consecutive governments for the past 2 decades. The current number of the MoPH staff barely exceeds one thousand employees. For comparison, the number of staff in one university hospital (AUBMC) is around 2,700"36.

More importantly, the "lack of control tools and inspection institutions of medicine", especially after the demolition of the "National Medicine Quality Control Laboratory" on one hand, and the halt of the "National Bureau of Medicine" on the other, had led to additional weakening of MoPH role in the pharmaceutical sector and the prevalence of private sector, which is driven by profits and market chaos.

## The MoPH Institutional framework:

Several recent health strategy documents have focused on the ministry's institutional framework, highlighting the achievements and progress accomplished with this regards, and recommending definite reforms taking into consideration the existing limitations.

A most recent country cooperation strategy report by WHO (Lebanon), for the years 2019-2023, stated that "improvements have been in health outcomes, in health care productivity and performance, and in health sector governance. Increasing access to the primary health care system, increasing the efficiency of hospital care and reducing out of pocket payments have been major objectives for the Ministry of Public Health (MoPH). In fact, between 2011 and 2017, access to services expanded in terms of both coverage and distribution of health facilities, as well as in types of services"<sup>37</sup>.

The Structural factors are concerned with the lack of a long term health strategy, and institutional and legal frameworks weaknesses, in addition to several health sector market imbalances (such as a predominant private sector with market centralization, the neglect of the national pharmaceutical industry and the over-supply of pharmacies). Also, this section will shed light on ten different drivers of mal-practices within the pharmaceutical sector in Lebanon, most importantly those of a multiplicity of health finance coverage, unfair competition and promotion practices, and the role of pharmacists,

<sup>35</sup> MoPH (December 2016), op. cit. 36 Ibid.

<sup>37</sup> WHO Regional Office (2018), op. cit.

#### 4.1.1 INSTITUTIONAL WEAKNESSES:

The "Health Strategic Plan" (2016-2020), for instance, has set "specific objectives" concerning the internal organization of the MoPH: "There are on-going attempts to modernize both the internal organization of the MoPH and wider sector governance arrangements. The wider sector governance arrangements are complicated as: not only because (human) health is affected by many factors and not just medical services; but also because the sector involves large numbers of selfregulatory bodies such as professional societies and orders. The first Specific Objective is therefore to strengthen and continuously improve both the internal ('executive') and external ('non-executive') regulatory bodies and agencies (Specific Objective 1.1.). Improving the internal organization of the MoPH also affects its sub-national administrative branches (Specific Objective 1.2)"38.

The report shed light on several improvements regarding the institutional framework; for example, it mentioned that "despite the institutional weakness of the MoPH devolved administrative units, which also reflects the political overlooking, the MoPH was able to make breakthroughs in several domains such as epidemiological surveillance and response, immunization, and food safety". The report added "MoPH took several initiatives to steer clear of conflict of interest. The Good Governance for Medicine (GGM) program; is only an example. The conflict of interest declaration form is currently a common practice in all concerned departments of the MoPH"<sup>39</sup>.

The WHO report notified that the ministry's "public authority over the health sector remains limited"; and addressed the following systemic gaps: "human resource for health imbalances and unregulated practice, the imbalance between technology-centred curative care and public health prevention and promotion, the large variations in quality of care with private care providers over whom MoPH has no authority". On the other hand, the report pointed-out some important achievements: "the MoPH has updated the national guidelines on good manufacturing practices and reinforced its inspection capacity.

Also, a review of pricing has been implemented, along with updating the list of essential and chronic medicines. A standardized system for eligibility criteria for support in terms of catastrophic illness medications (cancer, haemophilia, renal failure, rare diseases) has also been established. In addition, the MoPH has developed a national strategy for medical devices, with a short-term plan of action whereby regulations and standards are elaborated. Vaccines are provided free of charge in more than 500 primary health care centres and dispensaries. Reinforcing the regulatory role of the MoPH and ensuring financial sustainability for chronic disease medications, especially in light of the influx of Syrian refugees, are some of the challenges faced by the country"40.

<sup>38</sup> MoPH (December 2016), op. cit. 39 Ibid. <sup>40</sup> WHO Regional Office (2018), op. cit.

Another study concerning the strategy for National healthcare reform stated that "by law, the MoPH is the Planner, Supervisor, Regulator and Evaluator of health, and HCS", but it suffers due to institutional constraints; the study explains that "the scarcity of financial and human resources made it impossible for the MoPH to perform its role. More importantly, the proliferation of funds with different tutelage authorities has diversified their accountability with the MoPH has no legal authority on them"<sup>41</sup>.

The MoPH "Health Strategic Plan" for the medium term covering the period from 2016 to 2020 noticed that: "There have been numerous attempts to update the organizational structure of the Ministry but these have been severely hindered by the political log-jam that has affected all branches of the public administration over the last decade"42.

#### The halt of the "National Bureau of Medicine":

The idea of establishing a National Bureau for Medicine in Lebanon was triggered since the year 1960, with no success until the year 1983. The importance of the project rests in founding an official entity that represents the most prominent body in the pharmaceutical policy of the country, which is responsible of the procurement and provision of medical drugs at fair prices. The initial proposal was unsuccessful, and when the project was reinitiated in 1971, medicines disappeared from the local market, which led the Minister of Health to quit office at that time. The Law no. 5/83 was enacted by the parliament regulating the establishment of the National Bureau in 1983; but the actual procedures to make it operational did not start until 1994, and it was financed in 1996 through a Ministerial Decree (at that time GoL allocated LBP 10 billion from its budget to the National Bureau of Medicine, in order to launch the procurement procedures of medical drugs).

Unfortunately, the recruitment of staff for the National Bureau of Medicine was succumbed to the confessional system and political influences. As a result, this experience failed very quickly: the National Bureau was halted in 1998, and the Head of the bureau was dismissed, because of a corruption scandal.

In 1956 the law for establishing the National Laboratory was issued, and it was found during the next year (1957). It consisted of six different branches of specialties. The laboratory was not fully functional (only conducting chemical compound tests for drugs), accused of corruption and faced a problem with the lack of human resources (only 40 employees)<sup>43</sup>. It was closed and demolished in 2007.

<sup>41</sup> Roger Sfeir - MD, MBAIP, "Strategy for National Health Care Reform in Lebanon".

<sup>42</sup> MoPH (December 2016), op. cit. الدكتور اسماعيل سكرية، " Refer to: .Dr. "الصحة ... حق وكرامة، 2017 Ismail Sukkarriyeh, "Health ... Right

and Dignity", 2017).

#### The abolition of the "National Medicine Quality Control

The cessation of the "Central Laboratory" had created loopholes in examining imported and domestically produced medical drugs. The absence of a national central laboratory has left the registration process of imported medical drugs in Lebanon to mainly rely on site inspections performed by the drug regulation authority of the exporting country. In addition, drug analysis and tests are demanded by the importers (wholesalers) of medicine, and performed by "referenced" laboratories (mostly available in the producing countries).

On the other hand, the lack of updated Good Manufacturing Practices (GMP) and routine GMP audits for local manufacturers has made the local producers of medicines to count upon the outdated GMP guidelines that date back to the year 1985. It should be noted that GMP certificates are granted for local manufacturers at the approval of factory registration, whereby the "Inspection Department" at MOPH is not part of this procedure. Furthermore, following the issuance of certificates, GMP routine audits for local industry are inexistent.

In the year 2007, the national medicine quality control laboratory ceased being functional, due to security reasons related to its vicinity to the residence of the Speaker of the Parliament. The equipment was said to be removed before the destruction of the building, but suspicions had been raised that the laboratory equipment – granted by the Swedish Government in 1997 – were illegally sold.

Even when it was operational, drug samples were tested at the Chemistry Branch in the Central Laboratory prior to registration, however, it had limited resources in terms of equipment and trained staff to perform the necessary analysis of all drugs.

45 Ibid.

<sup>46</sup> MoPH, "National Household Health

Expenditure and Utilization Survey

1999". October 2001. Also. refer to:

Walid Ammar (2009), op. cit., who

... indicates that pharmaceuticals

represent on average 21% of the

drugs, and 6.5% medical supplies

on the following primary source:

2004 to 2007.

and consumables". This was based

International Medical Statistics (IMS).

"Health-Lebanon", for the years from

<sup>47</sup> According to the Director General of

the Ministry of Public Health, Walid Ammar MD., PhD.: "pharmaceuticals

hospital bill divided into 14.5% drugs,

consumables". Source: Walid Ammar

represent on average 21% of the

and 6.5% medical supplies and

(2009), op. cit. Page 96.

hospital bill divided into 14.5%

mentioned that "Aggregated data from

IMS, the Syndicate of Drugs Importers and the Syndicate of Private Hospitals

Dr. Walid Ammar commented on this issue, as follows: "Despite the closing of the Central Laboratory, the strict regulation of drug registration guarantees to some extent the quality of imported and domestic pharmaceuticals. Exceptions are related to parallel import and relatively small quantities of drugs donated to NGOs that bypass the system and reach dispensaries after obtaining a special permit from the Minister of Public Health". Nevertheless, he added that "there is an obvious and urgent need for a national reference laboratory for drug analysis, an issue that is currently subject to political wrangling"<sup>44</sup>.

#### Lack of control and inspection:

Lack of sufficient quality control and inspection tools and institutions, partially because of the lack of sufficient human recourses, led to the existence of forged, smuggled, faked, expired and worldwide prohibited (according to UN reports) medicines. The problem was extremely severe during the civil war era, and during late nineties, it was estimated that some 30% of pharmaceutical sector products

were either not authentic or smuggled products (according to the minister of health, Mr. Suleiman Frangieh, 1998).

Afterwards, regular inspection of pharmacies and warehouses was scaled-up and led to a significant number of confiscations of counterfeit and smuggled drugs, in addition to disciplinary measures and referral to court<sup>45</sup>.

#### MoPH Health F

In 2018, the LBP 728.8 billion MoPH budget – which was estimated to constitute a mere 0.88% of Lebanon's GDP – was mostly (85.5%) allocated for only two main items of spending: (1) hospitalization in both, public and private hospitals (63.8%); and, (2) drugs (21.7%).

The one-fifth of MoPH budget in 2018, which is classified under "drugs" item corresponds to procurement of: (a) essential medicines and vaccines for primary health centers, (b) distribution of drugs for chronic diseases (diabetes, hypertension and other diseases) through public health dispensaries, and (c) provision of special drugs to uninsured patients with severe and debilitating diseases through MoPH public medicine dispensing system.

Knowing from previous studies that pharmaceuticals represent around 20%-21% share of total hospitalization bill<sup>46</sup>; it is estimated that pharmaceutical items constituted approximately one-third of total MoPH budget for the years 2015-2018. And that pharmaceuticals' share of MoPH budget is roughly estimated to witness an increase from 33.4% in 2017 (equivalent to some LBP 237 billion) to 34.4% in 2018 (equivalent to some LBP 251 billion).

Therefore, change in the 2018 MoPH budget allocated for pharmaceutical goods, may be roughly calculated at a 5.9% increase on yearly basis at current prices. This increase was triggered by the expansion in MoPH budget directly allocated for drugs from LBP 144 billion in 2017 to LBP 158 billion in 2018 (USD 104.8 million).

More specifically, as drugs constitute only around 14.5% share of total hospitalization bill (whereas, the other 6.5% of the hospitalization bill is allocated for medical supplies and consumables)<sup>47</sup>; consequently, the share allocated for drugs in particular out of total MoPH budget in 2018 was estimated to reach 30.9%, which is equivalent to some LBP 225.5 billion (USD 149.6 million).

#### inancing:

#### Table 2: MoPH Itemized budget for the years 2015-2018 ('000 LBP)

	2015	2016	2017	2018
Hospitalization in Public and Private Hospitals	319,065,040	408,619,512	465,000,000	465,000,000
Public Hospitals	20,000,000	20,000,000	12,000,000	13,000,000
Drugs	104,976,000	130,892,800	144,000,000	158,025,000
Contributions to NGOs	12,487,816	15,975,035	30,221,701	27,222,760
Salaries and Other Employees' Benefits	27,820,432	28,256,620	27,139,500	37,194,500
Other Expenses	21,426,949	28,624,419	28,219,574	26,264,614
Part Two	10,174,000	10,339,900	1,968,750	2,142,200
Total MoPH Budget	515,950,237	642,708,286	708,549,525	728,849,074
Total Government Budget	20,643,785,487	24,355,781,060	23,906,048,924	23,891,224,583

Source: MoPH, Statistical Bulletin

#### lealthcare Expenditure:

<sup>48</sup> Note: the "Government" 60% share of Global health spending is measured out of "total health expenditures" worldwide. Whereas, the 46.6% share related to public health expenditure in Lebanon is accounted out of "current health expenditure" in the country. According to WB definitions the difference is as following: a) Total Health Expenditure: "the sum of public and private health expenditure. It covers the provision of health services (preventive and curative), family planning activities, nutrition activities, and emergency aid designated for health but does not include provision of water and sanitation"; b) *Current Health Expenditure: "include* healthcare goods and services consumed during each vear. This indicator does not include capital health expenditures such as buildings, machinery, IT and stocks of vaccines for emergency or outbreaks". Source: World Bank, "World Development Indicators 2013" Washington, D.C., 2013.

<sup>49</sup> WHO, "Global Spending on Health: A World in Transition", 2019.

MoPH expenditure out of the current health expenditure has decreased from 13.9% in 2012 to 12.4% in 2017. Whereas, health expenditure by public financing agents, such as MoPH, military schemes, social health insurance and public mutual funds, constituted around 46.6% of current health expenditure in 2017. According to WHO, the global pattern of rising health spending appears (as a world average) to be dominated by government sources, as Government spending<sup>48</sup> represented about 60% of global spending on health in 2017.

The WHO report mentioned that growth in the share of social health insurance (SHI) in current health spending varied from 16% to 20% in upper middle income countries<sup>49</sup>. In comparison, the share of NSSF and CSC (the SHIs in Lebanon) out of current health expenditure amounted to 23.4% in 2017, which exceeded the levels recorded by peer countries.

In 2017, the treasury contributed for 29.1% of current health expenditure in the country (i.e. LBP 1.8 trillion out of LBP 6.2 trillion). This should be added to a 3% of current health expenditure contributed by the "employer" (i.e. the Government) to CSC expenditure. Still, the overall Government spending on health is slightly more than half its global average.

Table 3: Distribution

of Current Healthcare

**Expenditure by Financing** 

Agent in 2017 ('000 LBP)

FINANCING	Households		Employer	Treasury	Extra budgetary	EXPENDITURES
	out of pocket	Contributions / Premiums	Contributions / Premiums		Donations / Loans	
Ministry of Public Health				767,356,763	4,449,392	771,806,155
National Social Security Fund		278,765,007	588,054,515	378,788,543		1,245,608,065
Mutuelle des Fonctionnaires de L'Etat (previously known as CSC)		26,863,183	186,915,465			213,778,648
Army				302,904,016		302,904,016
Internal Security Forces				198,012,518		198,012,518
State Security Forces				11,208,202		11,208,202
Customs				12,299,633		12,299,633
General Security Forces				39,138,527		39,138,527
Mutual Funds Public		40,600,000		69,126,280		109,726,280
Mutual Funds Private		185,476,291				185,476,291
Corporations			44,051,099			44,051,099
Private Insurances		850,85	51,000			850,851,000
NGOs				39,247,174	151,503,750	190,750,924
Households	2,062,801,153					2,062,801,153
TOTAL	2,062,801,153	2,201,5	576,560	1,818,081,656	155,953,142	6,238,412,511
%Total Health Expenditure	33.1	35	5.3	29.1	2.5	100

Source: National Health Accounts 2017 (based on the new System of Health Accounts SHA2011), MOPH.

#### The treasury's contribution was distributed as follows:

• 42.2% for MoPH, which covers 99.4% of its health expenditure; and constitutes 12.3% of current health expenditure;

• 31% for military schemes (Army, Internal Security Forces, State Security Forces, Customs and General Security Forces), which covers 100% of their health expenditures; and constitutes 9% of current health expenditure;

20.8% for NSSF, which covers 30.4% of its health expenditure; and constitutes 6.1% of current health expenditure;

• 3.8% for Public Mutual Funds, which covers 63% of its health expenditure; and constitutes 1.1% of current health expenditure; • 2.2% for NGOs, which covers 20.6% of their health expenditure; and constitutes 0.6% of current health expenditure.

#### Iousehold Out-of-Pocket Expenditure:

Indeed, the Government expenditure on health is crucial within the Lebanese social context, and it impacts the entire sector in addition to the socio-economic conditions at different layers, such as the quality of health services, accessibility to healthcare, universality of health coverage, poverty levels, etc.

One of the main goals of MoPH, since the outcomes of the NHA of 1998, is to decrease the out-of-pocket expenditure (OOP). Even though, most recent figures illustrate that OOP expenditure as a share of current health expenditure has slightly increased from 32.0% in 2016 to 33.1% in 2017; nonetheless, OOP expenditure numbers in Lebanon are still in line with levels recorded among the upper-middle income countries, and the global share of out-of-pocket expenditure out of overall health spending.

Furthermore, bearing into consideration the evolution of OOP expenditure's share over the past two decades, MoPH succeeded in lowering it significantly, from 59.6% in 1998, to 44.1% in 2005, and then to 37.3% in 2012, until it reached its current levels during the past few years, at around one-third of health expenditure.

It should be noticed, that figures related to household OOP expenditures are those directly paid by households for health services. Thus, OOP expenditure does not include contribution/ premiums paid by households to health financing intermediaries (such as, NSSF, CSC, mutual funds and private insurance companies). In case such contributions/premiums should be taken into account, an additional estimated sum of LBP 1.2 trillion (USD 804.2 million) would be added; escalating the household OOP expenditure to a total of LBP 3.275 trillion (USD 2.173 billion); which significantly raises the share of OOP expenditure to approximately 52.5% of total current health expenditure in 2017.

#### **Revenues of Providers of Pharmaceuticals:**

All in all, out of total/current health expenditure during the past two decades (in the years health accounts data are available), the health expenditure directly allocated to providers of "pharmaceutical and other medical goods" ranged between a minimum of around a quarter of THE (25.4%) in 1998, to a maximum about one-third of current health expenditure (34%) in 2012; and eventually flattened in the past few years slightly beneath the average, reaching a 27.2% share of CHE in the year 2017. The providers of pharmaceutical and other medical goods received around LBP 1.699 trillion (USD 1.126 billion) of direct revenues in 2017.

**Figure 1: Distribution of** Healthcare Expenditure by Type of Provider (in the years health accounts data are available)

Nonetheless, the health expenditure on pharmaceuticals exceeded the direct payments to the providers, as pharmaceutical items are embedded in hospital and ambulatory services bills. If this is taken into consideration; spending on pharmaceutical items mount to approximately 38.1% of current health expenditure in 2017, and is calculated at around LBP 2.377 trillion (USD 1.577 billion).



laboratory and imaging services.

Source: NHA 1998, 2005, 2012, 2015, 2016, and 2017 - MoPH.

It was found that in 2017 more than half (53.8%) of household outof-pocket expenditure on health were directly paid to providers of pharmaceuticals and other medical goods, estimated at around LBP 1,109.79 billion (USD 736.18 million).



\* Includes providers of all ambulatory services such as providers of medical consultations and dental practice and providers of ancillary services such as

\*\* Includes providers of preventive care, providers of health care administration and financing, the rest of the economy, providers outside Lebanon, un-classified expenditures, and some expenditures falling within the boundaries of health and not elsewhere classified.

Figure 2: Breakdown of

Health Expenditure by

Healthcare Provider in 2017

Financing Agent and

Other financing intermediaries also transferred payments to those providers in return for purchasing pharmaceutical items, as shown below:

- NSSF and CSC: allocated 22.9% of their health expenditure bill to pharmaceutical goods providers, an amount estimated at around LBP 334.2 billion (USD 221.69 million);
- Military schemes: 16.9% estimated at around LBP 95.24 billion (USD 63.18 million):
- MoPH: allocated 15% estimated at around LBP 115.77 billion (USD) 76.8 million);
- NGOs and INGOs: 3.7% estimated at LBP 7.06 billion (USD 4.68) million);
- Private insurance, mutual funds (both public and private) and cooperation: 3% estimated at LBP 35.7 billion (USD 23.68 million).

15% 16.9% 22.9% 14.9% 13.7% 1.5% 6.5% 53.8% 13.9% 2.7% 53.5% 73.3% 72.1% 15.4% 49.8% 79.9% 23% 7.8% 4.5% 13.4% 28.6 10.2% MoPH Military Social Health Household NGOs (4) Private Scheme (1) Insurances(2) Insurances(3) OOP Providers of pharmaceuticals and other medical goods Providers of ambulatory and ancillary services\* Hospitals (including residential long-term facilities) Others \*\* (1) Includes Army, Internal Security Forces, General Security, State Security, and Customs. (2) Includes National Social Security Fund and Mutuelle des Fonctionnaires de l'Etat (previously known as Civil Servant Cooperative). (3) Includes private insurances, mutual funds, and corporations.

(4) Includes local and international NGOs.

\* Includes providers of all ambulatory services such as providers of medical consultations and dental practice and providers of ancillary services such as providers laboratory and imaging services.

\*\* Others include providers of preventive care, providers of health care administration and financing, the rest of the economy, the rest of the world, un-classified expenditures, and some expenditures falling within the boundaries of health and not elsewhere classified.

Source: NHA 2017 - MoPH.

It is noteworthy, that household out-of-pocket payments constituted some two-third of the direct revenues of providers of pharmaceuticals and other medical goods. Hence, direct out-of-pocket payment is considered to be the largest portion of revenues (65.4%) within the pharmaceutical market. The remaining direct revenues for providers of pharmaceuticals are distributed among different financing agents: the NSSF and CSC contribute for 19.7% of the pharmaceutical providers' revenues; MoPH contribute some 6.8%; military schemes around 5.6%; private insurance, mutual funds (both public and private) and cooperation do contribute for 2.1%; and finally, the share of NGOs and INGOs constitute a mere 0.4% of the pharmaceutical market's direct revenues.

NSSF and CSC NGOs and INGOs Source: NHA 2017 - MoPH.

Figure 3: Breakdown of **Pharmaceutical and Other** 

Medical Goods Income by

Financing Agent in 2017

The National Health Accounts of Lebanon for the year 2015 reported the latest data available concerning the detailed breakdown of amounts paid by financing agents to providers. The data showed that the grand majority (96.5%) of the expenditures by the financing agents directly paid for pharmaceutical and other medical goods providers were allocated to pharmacies (i.e. in exchange for drugs in particular); while, the remaining 3.5% share went to retail sellers and other suppliers of durable medical goods and medical appliances.



If the same ratios are applied to current health expenditure in 2017, therefore - by deduction - the estimated amounts directly paid by financing agents to pharmacies in 2017 may be calculated at around LBP 1,070.94 billion (USD 710.41 million); against an estimated amount of approximately LBP 38.8 billion (USD 25.8 million) allocated to retail sellers and other suppliers of durable medical goods and medical appliances.

#### 4.1.2 WEAKENED LEGAL FRAMEWORK:

One of the main reasons behind corruption and lack of good governance is related to the weakened legal framework with regards to pharmaceutical sector. The 1994 Pharmacy Practice Law is considered as the main regulatory framework for the sector. As important as it is, the Pharmacy Practice Law needs to be updated and amended – in certain aspects – by new regulations.

There is a need to tackle some loopholes in the current legal framework, and to deal with the overlapping and contrasting regulations and decisions. For example, the public pricing of medical drugs should be revised and readjusted.

Furthermore, unapplied laws and regulations, and unexecuted governmental decisions, is another reason for corrupted practices. Lack of law enforcement with regards to certain issues, and the absence of proper executive decisions for implementing existing laws is another factor to be added to the weakened legal framework.

#### Pricing Mechanisms:

#### Decision No. 208/1 dated 3 May 1983:

Decision no. 208/1 dated 3 May 1983 reestablished the committee concerned in pricing of medical drugs and reasserted the following rules:

- Article 2: stated that public prices of imported medical drugs in Lebanon should not exceed their prices in the neighboring countries, especially those of Jordan and KSA;
- Article 10: reassured the revision of prices in accordance to currency exchange rates change of 3% on average rate for 3 consecutive months;
- Article 17: created the mechanism for producing the official guide for pharmaceuticals by MoPH;
- Article 18: delegated the inspection and control measures to be implemented by the "Inspection Department";

<sup>50</sup> FCA is an abbreviation for "Free Carrier", which implies that cost from the port of export does not include freight and insurance. <sup>51</sup> Ibid.

follows:

**Table 4: Medicine Pricing** 

Decision no. 208/1 – 1983

Structure According to

# Stage of Procurer Pricing Level Manufacturer price Freight and insurar

Price after freight a Custom clearing a Price after customs

Distribution margi

**Distributor Price** 

Pharmacists' margi

Price to public

Association (n/e/r/a),

This decision was criticized as it contained several flaws concerning pricing structure, which allowed increasing the importers' margin of profits. The most prominent criticism was marked by the Director General of the MoPH, Professor Walid Ammar, who pointed-out the following issues:

On another note, the implementation of the decision also raised several question marks. The former MP, Dr. Ismail Sukkarriyeh had raised a parliamentary question with this regards. The most important issues were the following:

#### Most importantly, the decision had revisited the pricing structure, as

nent	Price in USD
	FCA <sup>50</sup>
e (FOB)	100.00
nce expenses	7.50
and insurance	107.50
nd commission charges	12.36
S	119.86
n (profit margin of importer)	11.99
	131.85
n (profit margin of pharmacist)	39.55
	171.40

Source: Merck, Sharpe and Dohme (Secondary source: National Economic Research

"A Vision for Health Sector Reform in Lebanon", December 2003).

• The price-dependent profits, in fixed percent for all categories, encouraged importation and dispensing of expensive drugs.

• The margin allocated in the price structure for clearance and commission was exaggerated considering variable custom exemptions on imported drugs.

· Shipping and insurance expenses were uniformly calculated for both far and close countries. The freight percentage set as an average for USA, Canada, Australia, European and other countries, led obviously to over-pricing, as most of pharmaceuticals are imported from nearby European countries.

Freight was calculated as a percentage of the price, not in relation to shipment fees which are based on volume. This means that expensive drugs, with small volume and high price, generate more profit than less expensive ones.

• This phenomenon was further magnified by the cumulative margins of the price structure<sup>51</sup>.

- Article 2 was not implemented, and the ministry did not request the pricing lists of medicines applied in Jordan and KSA;
- Instead of acquiring the official prices from the "countries of origin", the committee accepted the price certificates provided by the importers/wholesalers of imported drugs;
- The revision of prices in accordance to currency exchange rates occurred frequently, almost on weekly basis, instead of every three months:
- Article 17 concerning the guide for pharmaceuticals was not executed, which resulted in importing counterfeited, smuggled and unregistered drugs.
- Inspection of pharmacies and drugstores was not implemented.

Moreover, Dr. Ismail Sukkariyeh strictly denounced the fact that the pricing committee that held responsible of executing decision 208/1 was formed from the same members whose mal practices, violations and involvement in corruptive behavior for the sake of importers/ wholesalers led, in the first place, to price manipulations. According to his estimation, the non-compliance with the decision had increased the profits of importers/wholesalers by a range that varied widely between a minimum of 15% and a maximum of 175% in certain cases<sup>52</sup>.

#### Decisions No. 301/1 and No. 306/1 dated June 2005:

Two "new" decisions issued in June 2005 had a direct impact on drugs prices:

Ministerial decision no. 301/1, which imposes adjustment of prices based on a price comparison with Jordan and KSA. The implementation of decision 301/1 led to price reductions on 872 drugs by an average of 20% (decreases reaching up to 40% for some medical drugs), with an expected total saving reaching USD 24 million per year.

Ministerial decision no. 306/1, which provides for a new pricing structure that lowers the mark-ups set in 1983 in a regressive way, whereas, "profit margins decrease as ex-factory prices increase. This scheme features four classes of products, where pharmacy mark-ups range from 24% to 30% and importer/wholesale mark-ups from 8% to 10%. This decision introduced for the first time a mechanism for periodic price revision. It widened the country basket for ex-factory price comparison to 14 countries besides the country of origin. Two other radical measures were also introduced: the first stated that public price in Lebanon must never be above the pharmacy retail price in any one of the reference countries, and the second stated that if any company abstains from delivering on time the requested documents for periodic re-pricing, the concerned drug would be subject to automatic price reduction with variable percentages depending on whether the drug is a patent, off-patent brand or generic, and on how long it has been put on the market".

<sup>52</sup> Refer to Dr. Ismail Sukkarriyeh's book in Arabic Language (2010), op. cit.

#### Table 5: Price Revisions by MoPH (2005-February 1, 2019)

Price Reductions	Decision # 301/1 (2005)	Decision # 51/1 (2006)	2013	2014	2015	2016	2017	2018	until 1st of February 2019
Number of Drugs that were subject for price reductions	872	700	167	253	441	279	187	308	332
Average percentage of price reduction	20%	3%-15%	17.4%	16.2%	21.8%	14.0%	21.5%	17.5%	21.2%

#### Source: MoPH

Lebanon lacks an overall health care strategy, which guides the development of the health care system for the long term. Nonetheless, the MoPH has lately introduced medium term strategic plans for the ministry, in order to direct its role and interventions within the health sector, which is still insufficient.

#### Size and growth of the Health Sector:

<sup>53</sup> The assessment of the two decisions (no. 301/1 and no. 306/1) was extracted from the following reference: Walid Ammar (2009), op. cit. p.p. 110-111.

<sup>54</sup> Central Administration of Statistics (CAS). "Lebanese National Account – Comments and Tables", 2018.

"The application of the revised decision no. 51/1 ... led to a price decrease per drug ranging from 3% to 15%, and cumulating to an approximate total of USD 27 million yearly ... In application of this decision, price revision of drugs registered between 2001 and 2006 was achieved as provided for, targeting 1,109 drugs in 2007, and resulting in lowering the public price of 360 drugs with a yearly saving exceeding USD 10 million".

"Unfortunately, under pressure exercised by multinationals and importers, the decision no. 306/1 was amended a few months later (Decision no. 51/1 dated 24 January 2006) to increase the freight and customs mark-ups, which nevertheless remained inferior to those of 1983. Most importantly the amendment decision, replaced the comparison with each European country by a comparison with the median price of European countries, which practically excludes extreme prices such as those of Portugal. This comparison is only applicable for drugs imported from Europe. The amendment decision canceled also the above mentioned "radical measures" of public price ceiling and automatic price decrease"53.

#### 4.1.3. LACK OF HEALTHCARE STRATEGY:

According to the CAS National Accounts, the country "GDP at current market prices was estimated at 82.9 trillion Lebanese Pounds (LBP) or 55 billion US dollars (USD), up by 2.7 trillion LBP from a 2017 estimate of 80.1 trillion LBP. However, in real terms, GDP at constant prices declined by 1.9% in 2018, following a slow positive growth of 0.9% in 2017. This reflects the tough conditions experienced by the Lebanese economy in 2018, driving real growth into negative territory. In terms of demand, whereas in the past, increases in households' final consumption led real GDP growth, it fell this year"54.

The NA report elaborated on this issue: "Following the exceptional growth rates of 8 to 10 per cent each year from 2008 to 2010, there was a pause in 2011 when the GDP grew by a further 1 per cent. Thereafter growth resumed at between of 2 to 4 per cent during the years 2012 to 2014. This was followed by a period (2015 to 2017) in which the GDP grew by less than 2 per cent each year. In 2018, for the first time in many years, the level of GDP declined by about 2 per cent in real terms"<sup>55</sup>. Moreover, the report announced that "inflation, as measured by the GDP deflator, surged to 5.5% in 2018, compared to 2.9% in 2017"56.

In a more updated data concerning Lebanon's GDP estimation for 2019, and according to the government's projection for the current year (2020), a recent memorandum stated that "Lebanon is faced with an unprecedented economic crisis. Economic indicators point to an acceleration of the contraction of the economy and the coronavirus crisis currently affecting Lebanon and the whole world will only add-up to the already deeply deteriorated economic environment. Output is estimated to have contracted by 6.9% in 2019 following a contraction of 1.9% in 2018. It could contract by an additional 9% to 14% in 2020 as dollar shortage is putting a massive drag on nonfuel imports and consumer demand while driving up consumer prices and squeezing businesses"57. Indeed, the most recent IMF estimates show around 12.4% decrease in the country GDP for the current year (2020).

The health and social care sector constitutes in terms of value-added around 3.67% of Lebanon's GDP for the year 2018. Despite the fact that the size of this sector had almost doubled during the period 2010-2018, from LBP 1,595 billion (USD 1.1 billion) to LBP 3,045 billion (USD 2.0 billion), the sector's real value at constant prices had only increased at around one-third: up to LBP 2,141 billion.

Knowing that the GDP cumulative growth in Lebanon (at constant prices of 2010) reached around 11% to 13% during the nine years' period (2010-2018); the 34% growth of the health and social care sector is considered to be substantial when compared to its global trend. WHO, in a recent global report, underlined the fact that "the health sector continues to expand faster than the economy. Between 2000 and 2017, global health spending in real terms grew by 3.9% a year while the economy grew 3.0% a year<sup>"58</sup>. The report also mentioned that the "middle income countries are rapidly converging towards higher levels of spending. In those countries, health spending rose 6.3% a year between 2000 and 2017 while the economy rose by 5.9% a year"<sup>59</sup>.

56 Ibid, p.4 <sup>57</sup> Government of Lebanon (GoL), "The Lebanese Government's Reform Program – Draft for Discussion", Version as of 6 April 2020. <sup>58</sup> WHO. "Global Spending on Health: A World in Transition". 2019. 59 Ibid.

<sup>55</sup> Ibid, p.3

Most importantly, even though the value of the health and social care sector had risen significantly during the past decade, there remain two issues of main concern:

income; and, economy.

GDP worth in half.

#### Table 6: GDP and Health & Social Sector Growth in 2010-2018

Gross Domestic Production	2010	2011	2012	2013	2014	2015	2016	2017	2018
At current prices (billions of Lebanese pounds)	57,954	60,190	66,384	70,716	72,563	75,284	77,192	80,110	82,854
overall % change at current prices	8.6	3.9	10.3	6.5	2.6	3.7	2.5	3.8	3.4
At constant prices of 2010 (chain-linked) in billions of Lebanese pounds	57,954	58,457	59,942	62,226	63,758	63,893	64,870	65,422	64,162
% real change (year to year)	8.0	0.9	2.5	3.8	2.5	0.2	1.5	0.9	-1.9
% change in prices (year to year)	0.6	3.0	7.6	2.6	0.1	3.5	1.0	2.9	5.5
Volume index (2010=100)	100	101	103	107	110	110	112	113	111
Implied deflator	100	103	111	114	114	118	119	122	129
GDP (in billions of US dollars)	38.4	39.9	44.0	46.9	48.1	49.9	51.2	53.1	55.0
Health & Social Care Sector	2010	2011	2012	2013	2014	2015	2016	2017	2018
"Health & social care" at current prices (billions of Lebanese pounds)	1,595	1,658	1,800	2,160	2,344	2,643	2,816	2,910	3,045
Share of "Health & social care" out of GDP at current prices	2.75%	2.75%	2.71%	3.05%	3.23%	3.51%	3.65%	3.63%	3.67%
"Health & social care" Volume chain-linked Index (numbers 2010 = 100)	100	108	111	129	126	125	129	135	134

First: the abovementioned increase in value of the health and social care sector barely contributed to a mere 1 percentage point growth of the share of this sector out of GDP during this period (from a 2.75% share in 2010 up to 3.67% share out of GDP at current prices in 2018). This issue points out to a couple of main characteristics of this sector:

**a)** that it still is too small in size as a share of GDP, especially, when compared to other peer countries in term of level of

**b)** that the current structure of the health sector – as a whole - has limited capacity to support any growth of the Lebanese

Second: the 2018 year-on-year change in real prices of 2010 recorded a slight decrease by 0.44%, and the sector's contribution to the change in GDP, for the same year, was found to record a barely negative result (-0.02%); even if the value of the health sector witnessed a yearly increase when calculated at nominal GDP. This result indicates that the health and social care sector would be heavily impacted by the projected deterioration of the Lebanese economy, in the coming few years, that might cut its

Health & Social Care Sector	2010	2011	2012	2013	2014	2015	2016	2017	2018
Y-o-Y percentage change of "Health & social care" Volume chain-linked Index (numbers 2010 = 100)	14.64%	8.25%	2.90%	16.14%	-2.80%	-0.24%	2.72%	4.63%	-0.44%
Health & social care at constant prices	1,595	1,727	1,777	2,063	2,006	2,001	2,055	2,150	2,141
"Health & social care" Contributions to the change in GDP	0.39%	0.23%	0.08%	0.44%	-0.09%	-0.01%	0.10%	0.17%	-0.02%
Implied deflators (chain-linked) of "Health & social care" (Index numbers 2010 = 100)	100	96	101	105	117	132	137	135	142
Y-o-Y percentage change of "Health & social care" Implied deflators	-1.73%	-3.97%	5.50%	3.33%	11.66%	13.00%	3.72%	-1.22%	5.10%
"Health & social care" (in billions of US dollars)	1.1	1.1	1.2	1.4	1.6	1.8	1.9	1.9	2.0

Source: Central Administration of Statistics.

The below graph illustrates that the health and social care sector growth was actually gradual during this time span, not without fluctuations and volatility, and that it might suffer severely at the event of the current economic, financial and monetary crisis, not to mention its negative effect on the socio-economic conditions of the Lebanese people.



<sup>60</sup> World Bank, (Fall 2015), op.cit. <sup>61</sup> Walid Ammar MD., PhD., "Universal Health Coverage: Bridging the Gaps", 2014.

The lack of such strategies has created several imbalances in the health sector, and led to the scaling in the cost of health services. For instance, a WB report emphasizing the importance of reforms in the health sector in Lebanon, mentioned that "disproportionate allocation of resources favors expensive curative over cheaper preventative care. As the main public health financing agency in Lebanon, the MoPH ... allocates the majority of its budget ... to reimburse contracted private hospitals for the care provided to the uninsured population, while contributions to non-governmental organizations (NGOs) that are the main providers of primary health care services have remained at a relatively low level ... As such, the system is skewed towards high cost curative care compared to lower, cost effective preventive and primary health care"60.

Affirming the existence of such imbalances, Dr. Walid Ammar stated that "there is no doubt that oversupply in addition to focusing on financing curative care, and the poor quality of preventive and primary health care at that time, have contributed to over consumption of expensive diagnostics and treatments provided by the private for profit sector". But he continues that "ambulatory services were mostly uncovered by MoPH, and therefore most OOP were spent on medication and outpatient services. The development of a wide network of PHC centers providing quality services that are accepted as an alternative for the private outpatient care, became the main goal of the MoPH to ensure universal accessibility to health care"61.

#### Predominant private sector:

It is estimated that around 90% of hospital beds are in the private sector, also ambulatory care is provided mostly by private physicians' clinics. The flourishing private sector and the weakening of public services left the government with no other alternative than contracting out with the private sector for a yearly widening range of services.

The predominance of private sector, especially within the hospitalization services, is considered to be of a great burden on middle and lower social strata. It is common that private hospitals (especially the wellknown ones) sometimes do not accept patients that are covered by MoPH, even if they are contracted with the ministry to reimburse for 85% of the hospital stays' bill. The private hospitals' excuse for such practices refers to the unavailability of beds or that the quota dedicated to the ministry was reached. Such incidents mostly occur in case of Government budget deficits or due to prolonged delays in payments by MoPH. This leaves the less fortunate social segments - the uninsured - with access to lower quality services within the private sector.

#### 4.1.4. IMBALANCES IN HEALTH SECTOR:

### Market centralization (oligopoly of importers):

The pharmaceutical market in Lebanon is highly dependent on import (93%). In turn, the import trade of medicine had – historically – been extremely centralized; as an oligopoly of the "Big Ten" importers/ wholesalers of pharmaceuticals is estimated to acquire some 90% of the local medical drugs market.

The traditional "Big Ten" pharmaceutical importers/wholesalers have dominated the market through its influence on public administration, by means of bribery and patronage of certain politicians. According to the former MP, Dr. Ismail Sukkarriyeh, they intervene in parliamentary elections through providing financial support to selected candidates' campaigns. Moreover, the Big Ten oligopoly is directly represented in the Lebanese parliament and, on many occasions, within the cabinet (Government) itself; it strongly influences legislation, policy and decision making in the country. In fact, the main stakeholders of the pharmaceutical sector are always ready to lobby alternative legislations and counter any suggestion to improve, amend and reform the prevailing legislative and institutional frameworks concerning pharmaceuticals.

Even though, the importers/wholesalers of medicines are not considered - by law - to be exclusive agents/dealers of the global manufacturing firms; unfortunately, any clear and direct anti-trust laws are inexistent in Lebanon. And despite the legislators' attempts to allow parallel import of medicaments, such regulations did not sincerely improve competition and had a limited impact on price reductions at the pharmaceutical market.

The marketed pharmaceutical items in Lebanon are supplied by 122 agents/dealers, from 829 manufacturers in 48 countries of origin all over the world. A guarter of the marketed pharmaceutical items in Lebanon are produced by the top 15 manufacturers.

Table 7: Top-15 Pharmaceutical **Products Manufacturers of** Marketed Drugs in Lebanon (March 2020)

#	Manufacturer	Amount of Marketed Dr <u>ugs</u>	(%) of Total Marketed Dr <u>ugs</u>
1	Benta SAL	213	3.8%
2	Mediphar Laboratories	163	2.9%
3	Alfa Laboratoires S.A.L.	134	2.4%
4	Algorithm S.A.L.	95	1.7%
5	Cipla Ltd	94	1.7%
6	Julphar	92	1.6%
7	Pharmaline SAL	90	1.6%
8	Pharmadex	87	1.5%
9	Serum Products	84	1.5%
10	Dar Al Dawa	68	1.2%
11	Tabuk Pharmaceutical Manufacturing Company	63	1.1%
12	Mephico SAL	60	1.1%
13	APL Swift Services (Malta) Limited	57	1.0%
14	Apotex Inc	54	1.0%
15	Boehringer Ingelheim Pharma GmbH & Co KG	53	0.9%

Source: MoPH.

the rest of the world.

#	Country of Origin	Amount of Marketed Drugs	(%) of Total Marketed Drugs
1	Lebanon	1,369	24.4%
2	Germany	548	9.8%
3	France	535	9.5%
4	Jordan	405	7.2%
5	Italy	273	4.9%
6	Spain	240	4.3%
7	USA	184	3.3%
8	Switzerland	175	3.1%
9	UK	174	3.1%
10	India	160	2.8%
11	Saudi Arabia	156	2.8%

 
 Table 8: Top-11"Countries of
 Origin" of Marketed Drugs in Lebanon (March 2020)

It was also found that almost a quarter of the marketed items are locally manufactured (1,369 pharmaceutical items); another 50% are being imported from 28 European "countries of Origin" (mainly from Germany); some 13.6% from other Arab countries (Jordan, KSA, UAE, Egypt and Tunisia); whereas, the remaining are being imported from

Table 9: Top-10 Suppliers of

Marketed Drugs in Lebanon

(March 2020)

The "Big Ten" agents/dealers of pharmaceuticals in Lebanon acquire slightly less than half of total amount of marketed drug items in the country (almost 46%).

#	Agent/Dealer	Amount of Marketed Drugs	(%) of Total Marketed Drugs
1	Mersaco	620	11.0%
2	Khalil Fattal & Fils S.A.L.	327	5.8%
3	Droguerie de l'Union	322	5.7%
4	Benta Trading Co s.a.l.	291	5.2%
5	Sadco	232	4.1%
6	Abela Frères S.A.L.	215	3.8%
7	UPO S.A.L.	162	2.9%
8	Omnipharma	155	2.8%
9	Alfa Laboratoires S.A.L.	134	2.4%
10	Codipha	122	2.2%
	Total	2,580	45.9%

Source: MoPH.

#### Neglect of National pharmaceutical industries:

The huge dependence on imports of pharmaceutical products has left the national pharmaceutical industry, which was first introduced in Lebanon during the fifties of the past century, neglected in Lebanon and lacking competitive advantages in general.

According to the survey on industrial sector in Lebanon conducted in 2007, all in all, there were 13 manufacturers of pharmaceuticals, medical chemicals and botanical products in Lebanon, which acquires a total workforce of 1,425 (including employers) and a production output of more than USD 52 million<sup>62</sup>.

Nowadays, there are only 11 local manufactures of pharmaceuticals (out of which 8 are specialized in producing medical drugs, 2 in serums and 1 produces food supplements), constituting around 7% of local market, with total investments of around USD 500 million, which provide around 1,800 job opportunities in Lebanon, according to latest data of SPIL (2018). Unfortunately, the local pharmaceutical industry has some 50% free production capacity untapped due to market limitations.

<sup>62</sup> Ministry of Industry, United Nations Industrial Development Organization and the Association of Lebanese Industrialists. "The Lebanese Industrial Sector – Facts and Findings – 2007", Report-2010.

The "Syndicate of the Pharmaceutical Industries in Lebanon" (SPIL) was founded in 2016. It comprises all the pharmaceutical manufacturers granted an authorization for exploitation of pharmaceutical plant according to the international good manufacturing practices by the

<sup>63</sup> MoPH, "MOPH Strategy 2025", March 2018. <sup>64</sup> WHO Regional Office (2009), op. cit.

**Table 10: National** 

Pharmaceutical Manufacturers and Number of Generics and Products Manufactured "Under License" (2017)

MoPH. These factories acquire "Under License" production permits for collaboration with global manufacturers of pharmaceuticals of Europe, USA, Canada, Korea and Japan.

	Local Manufacturer	# of Generics	# of Products Under License
1	Alfa Laboratories s.a.l.	90	0
2	Algorithm pharmaceutical manufacturers	134	39
3	Arwan Pharmaceutical Industries Lebanon s.a.l.	47	0
4	Benta Pharma Industries	298	110
5	CHAPHA s.a.l.	9	3
6	Mediphar Laboratories	153	4
7	MEPHICO s.a.l.	36	8
8	Pharma M	61	0
9	PHARMADEX s.a.l.	118	37
10	Pharmaline	259	181
11	Serum products a.s.a.l.	52	0
	Total	1,257	382

Source: SPIL.

The national pharmaceutical industry size is estimated at approximately USD 1.5 billion (equivalent to around 3% of GDP)63. The local manufacturers have only 7% share of the market value.

WHO conducted a study on the transparency and improvement of good governance in Lebanon, and the outcomes of the study, when addressing the assessment of the national pharmaceutical industry stated that "local manufacturing plants undergo inspection of their active ingredients and their finished products by sending samples for analysis. Yet local manufacturers have self-imposed standards that are beyond the Lebanese law requirements. The necessity to export pharmaceutical products to markets abroad or to obtain sub-licensing contracts from the international pharmaceutical industry is what led to these self-imposed standards"64.

#### Over-Supply of pharmacists/pharmacies

Pharmacists and hence pharmacies are rapidly increasing in Lebanon, and there seems to be an over-supply of pharmacists and pharmacies. This ensures a wide range of accessibility to medicines all over Lebanon, but it might also impose more pressure to keep pharmacy margins high, trying to maintain high income despite growing competition. Lebanon's large number of pharmacists and pharmacies, contribute to the escalating medicine costs.

The SPIL comprises of 11 pharmaceutical manufacturers, as follows:

In 2018, the number of registered pharmacists was 8,855, and licensed pharmacies by MoPH amounted to 3,198. The numbers of pharmacists and pharmacies have grown by 89.7% and 64.8% respectively between 2007 and 2018.

The vast majority of Lebanese pharmacists are actively working (91.3%) with a small proportion working outside Lebanon (8.1%) or unemployed (0.6%).

The average ratio of pharmacist to population was 20.3 per 10,000 population. The highest ratio was in Beirut (37.7) and the lowest ratio was in North Lebanon (10.7)65.

# 4.2. MAL-PRACTICES

The structural features within the fragmented pharmaceutical sector in Lebanon, such as weaknesses in legal and institutional framework, predominance of private sector, dependence on imported products, market centralization, etc.; act like driving factors for corruption. Other drivers of mal-practices, which affect the PHS, quality and price of pharmaceutical products (especially medical drugs) are detailed as follows:

#### 4.2.1 PLURALISM OF TUTELAGE:

There are six employment based social insurance funds publicly managed in Lebanon, including the NSSF, CSC, and the four military schemes: Army, ISF, GSF and SSF; in addition there exist private insurance firms, mutual funds, and not to forget the MoPH as a financing agent of the uninsured. The CSC is under the tutelage of the presidency of the Council of Ministers, while the other entities are under the tutelage of different ministries (in addition to MoPH), as follows:

#### **Table 11: Financing Agents and** their Supervisory Ministry

<sup>65</sup> The study estimated the total number of population in 2018 to reach around 4 million; refer to: Mohamad Alameddine, Karen Bou Karroum Mohamad Ali Hijazi (Human Resources for Health), "Upscaling the pharmacy profession in Lebanon: workforce distribution and key improvement opportunities", 2019.

Financing Agency	Supervising Ministry
МоРН	Ministry of Public Health
NSSF	Ministry of Labor
CSC	Presidency of the Council of Ministers
Army	Ministry of National Defense
IS	
GS	Ministry of Interior and Municipalities
SS	
Private Insurance	Ministry of Economy and Trade

Source: NHA - (2000)

The existence of six different public funds reporting to the Presidency of the Council of Ministers and to three different ministries other than the MoPH, is responsible for financing fragmentation. This multiplicity leads to the lack of inter-agency coordination, the adoption of different tariffs' systems and control mechanisms, weakens the purchasing power and control capabilities of these agencies, complicates the system and makes the MoPH monitoring and regulatory mission even more difficult<sup>66</sup>.

"Fragmentation of financing and service delivery systems is another challenge facing the health sector. Today, 20 percent of the insured population is covered by 70 private insurers, many of which are relatively small, while the other 80 percent are covered through multiple insurance schemes. On the public side, providers have different packages of subsidized services and varying reimbursement systems. From a governance perspective they fall under different ministries, making it politically difficult to obtain a coherent national policy framework. Fragmentation negatively impacts the health sector as it results in (i) adverse risk selection with the MoPH baring the burden of the sick population, (ii) higher administrative costs at both the fund (MoPH, NSSF) and the provider level, (iii) different groups getting different packages, and (iv) weak purchasing power"67.

The present system of multiple public funds is saddled with major defects. Of those, the overlapping of coverage and the shifting of eligible on the MoPH burden represent serious problems. A meaningful number of adherents to the NSSF or the CSC have been submitting yearly "certificates of ineligibility" signed by both agencies, enabling them to benefit fraudulently from MoPH's coverage. The MoPH coverage of 100% for some expensive interventions, like openheart surgery, was preferred over the 90% coverage by the NSSF. This problem was worsening with the extension of fully covered procedures. The extensions are decided at the discretion of the MoPH. Similarly, obtaining chemotherapy drugs for free from the Ministry's drugstore is a preferred option by an insured patient, instead of purchasing them from a private pharmacy, and getting 85% reimbursement by the NSSF and less by the CSC, several months later<sup>68</sup>.

On many occasions, there were some difficulties in confirming eligibility of citizens, due to limited coordination and lack of database sharing among the private sector and the MoPH<sup>69</sup>.

#### 4.2.3 PRIVATE HOSPITALS OVER-PRESCRIPTION OF DRUGS:

<sup>66</sup> Walid Ammar MD., PhD. (WHO & MoPH), "Health System and Reform in <sup>67</sup> World Bank (Fall 2015), op. cit. <sup>68</sup> Walid Ammar (January 2003), op.

<sup>69</sup> MoPH (March 2018), op. cit.

Lebanon", January 2003.

#### 4.2.2 OVERLAPPING OF FINANCIAL HEALTH COVERAGE:

Frequent delays in MoPH reimbursement of private hospitals for in-patient services provided for the uninsured makes hospital administrations adopt unethical technics to inflate hospitalization bills (including medical drugs that constitute, on average around 21% of the bill). Private hospitals tend to use fraud billing and registering of false patients during the weekends (when there is no inspection and control) affects the Government budget and household out-ofpocket expenditures.

On the other hand, private hospitals tend not to deliver the same quality of services to the rich and poor, and frequently impose extra fees on patients admitted under contracts with the MoPH. The tendency to overuse of hospital beds, and over-prescribing of diagnostic tests and drugs, is enhanced by the absence of practice guidelines<sup>70</sup>.

#### 4.2.4 INFLUENCE OF PHYSICIANS AND FIRMS ON THE DEMAND:

In the absence of any framework for medical prescription accountability, physicians have the freedom to prescribe medicaments to their patients; and hence, they play an important role affecting the demand side. This predominant role of medical professionals decreases the possibility of cost rationalization.

In Lebanon, the pharmaceutical firms have a determining influence over all forms of post-university medical education, through financing research and related publications, as well as through sponsoring medical conferences and seminars. Moreover, pharmaceutical firms spend large portions of money on marketing campaigns targeting physicians and luring them with a variety of incentives.

In fact, "the total pharmaceutical bill is sensitive to the marketing of new molecules, particularly when promotion goes beyond the approved indications for the patented drug, without necessarily showing solid evidence of added effectiveness"71.

Unfortunately, there is no regulator of medical practice in Lebanon, no checks over doctors' fees, nor control over doctors' prescriptions. "At the delivery arrangement level: irrational prescribing has been attributed to interactions of the pharmaceutical industry with health care professionals, weak institutional policies on conflict of interest, and poor consumer education on the proper use of medicine"72.

The widespread of mal-practices with regards to medicine prescriptions by physicians is one of the most important characteristics of the pharmaceutical market. A study conducted by the Health Management and Policy Department (HMPD) at AUB University on medical prescriptions in seven different hospitals revealed that around 40% of the prescriptions were found to contain some kind of faults.

#### 4.2.5 UNFAIR COMPETITION BY PHARMACEUTICAL FIRMS:

Unfair competition practiced by pharmaceutical firms contributes also to market failure. For example, upon patent expiry and registration of a less expensive generic drug, the originator company, instead of competing by reducing the price, floods physicians with free samples,

<sup>73</sup> Walid Ammar (2009), op. cit. <sup>74</sup> Fadlallah, R., El-Jardali F., (December 2016), op. cit. <sup>75</sup> Walid Ammar (2009), op. cit. and offers generous bonuses to pharmacists reaching sometimes 100%. This practice favors big pharmacies that are capable of purchasing bigger quantities with higher bonuses<sup>73</sup>.

#### 4.2.6 MEDICINE PROMOTION PRACTICES:

The law in Lebanon stipulates that all promotional materials, concerning pharmaceuticals, should be approved by the MoPH prior to their use for marketing.

However, there is no control over advertisement to professionals, including sending physicians to international conferences abroad, neither over published medical information. Also, there is no committee at MoPH for approving or monitoring such provisions of medicine promotion and advertisement.

#### 4.2.7 SUPERIORITY OF BRANDED NAMES DRUGS:

Over-prescribing branded drugs becomes a particularly serious issue with the incredibly exorbitant prices of innovative medicines witnessed lately. For instance, the "Orphan Drug Act" guarantees the developer of an orphan product seven years of market exclusivity. But patent protection should not be used as a means for merely extracting high rates of return on pharmaceutical investments, rather as a means to encourage the development of new medicines<sup>75</sup>.

#### 4.2.8 OVER-THE-COUNTER DRUGS PRESCRIPTIONS:

There is no official list of over-the-counter medicines issued and published by MoPH. There is a wide practice of over-prescribing and reliance on expensive injections rather than on lower-cost tablets or capsules. There is also considerable public demand for drugs, and until recently the public was able to buy almost all drugs over the counter without prescriptions (the exception was psychoactive medicines). Even nowadays, physicians may prescribe branded drugs and mention that these are "Not Substitutable" (NS); the fact that oblige the pharmacist not to offer a less expensive generic drug. The large number of physicians and pharmacists in the private sector contribute to the non-rational use of drugs and cost escalation.

#### 4.2.9 OVER-CONSUMPTION OF ANTIBIOTICS AND PSYCHIATRIC / PSYCHOTROPIC DRUGS:

There is an overconsumption of antibiotics and psychiatric and psychotropic drugs in Lebanon, if compared to the international limits of use of such drugs.

"The overall problem is the inappropriate prescribing of pharmaceutical

<sup>70</sup> Walid Ammar (January 2003), op. cit

<sup>71</sup> Walid Ammar (2009), op. cit. <sup>72</sup> Fadlallah, R., El-Jardali F., (Knowledge to Policy (K2P) Center), "K2P Dialogue Summary - Improving the Prescribing Pattern and Quality of Pharmaceutical Drugs in Lebanon", December 2016.

In Lebanon, most of the imported and locally procured drugs are highly priced brand-name drugs, rather than the cheaper generic equivalents affordable by everyone. Also, there are no proper incentive systems in place to encourage generic drug prescription<sup>74</sup>.

drugs in Lebanon which puts patients at risk of serious adverse effects, increases drug resistance, and leads to unnecessary increased costs on patients and the community at large. The current health system arrangements do not promote rational prescribing of drugs in Lebanon<sup>"76</sup>.

Analyzing the consumption of pharmaceuticals by therapeutic class shows that antibiotics lie in the second position (12%), and psychotropic medications represent 5.5% of the market, including 3.5% anti-depressive and 1% tranquilizers and sedatives<sup>77</sup>.

#### 4.2.10 ESSENTIAL MEDICINES LIST (EML):

Lebanon was the first country in the region to develop a limited list of medicines to be adopted and reimbursed in the country in the early 1960s. It was developed by the NSSF, while the first reference of WHO regarding this topic was in the mid-1970s. This first list contained 1.300 medicines.

Lebanon developed in 1987 its first essential medicines list (EML). It was subsequently updated in 1992 after an official committee was formed for this purpose. This list included 200 medicines, which were classified into three categories depending on the level of health care they are used in: (1) essential medicines for primary health care use, (2) for general hospital use, and (3) medicines used for specialized units in hospitals and dispensaries. It was developed based on WHO list taking into consideration the Lebanese health context.

The recommendation of the committee was to update the EML annually. However this was not applied and since then the EML has been updated every now and then by an unofficial committee that included relevant staff of MoPH and WHO.

It should be noticed that the committee did not rely on any SOP when developing the selection of the national essential medicines list. Moreover, there are no national standard treatment guidelines to guide the selection of medicines process by and for prescribers.

The last updated version was developed in 2002. This list is not distributed widely enough<sup>78</sup>.

#### 4.2.11 PARALLEL IMPORT:

According to the Ministerial Decision no. 90/1 dated 13 March 1992, the importation of medical and pharmaceutical products in Lebanon is allowed to any duly licensed entity, and hence – in principal – it is not restricted to a particular importer/wholesaler and should not be monopolized by a sole importer.

<sup>76</sup> Fadlallah, R., El-Jardali F., (December 2016), op. cit. <sup>77</sup> Walid Ammar (2009), op. cit. <sup>78</sup> WHO Regional Office (2009), op. cit.

The imported drugs through parallel channels are subject to the same inspection and control mechanisms as regularly imported drugs.

requirements:

- in Lebanon.

In 1998, the public price of any drug introduced through parallel import was conditioned to be at least 25% lower than the original product price already traded in the Lebanese market; but this condition was removed by Decision no. 96/1 dated 13 February 2002. Nowadays, the public price is based on the invoice price and would follow the price index variations.

process.



Nonetheless, parallel importation is conditioned by the following

• In case of importation from country/countries other than the country of origin, which is registered in Lebanon as the exporting country; then, the importer should present a "Free Sale Certificate", stating that the pharmaceutical product is: (a) registered and sold in the concerned country, and (b) registered and sold in the manufacturing country without restrictions.

Decision no. 539/1 dated 25 August 1998, added that both, the manufacturer and the manufacturing country, must be registered

After all, parallel imported drugs ended up being sold at a barely lower price than the original registered product, and could not profoundly improve anti-trust practices, due to legislative limitations.

Of course, narcotics and other restricted drugs, in addition to drugs similar to those produced locally cannot be imported through this

The health care system in Lebanon is highly privatized, and the pharmaceutical sector is largely dependent on profit-driven oligopoly of importers/dealers of medical drugs. Indeed, the pharmaceutical market is treated, unethically, as being a lucrative business. The fragmented sector rarely leads to improving market competitiveness and lowering pharmaceutical products' prices; instead it creates more loopholes for increasing levels of corruption, lack of good governance and spread of mal-practices.

There are several factors influencing the high cost of pharmaceuticals. These include the monopolization of the registered medicines, the corrupt practices in pricing of drugs, the reliance on public spending and the lack of inspection of fraudulent practices such as hospital billing of medical services to health coverage financing agencies.

power of the Lebanese Pound.

# 5.1. SOCIO-ECONOMIC IMPACT

Indeed, the study illustrated that the pharmaceutical sector is volatile, and that its current structure constrains its contribution in the development of the country and in stabilizing the deteriorating socio-economic situation and accumulating levels of poverty.

Corruption and lack of good governance within the sector may only lead to inflated health expenditure bill, which over-burdens government budget, private insurance firms and public health funds and financing agencies, in addition to OOP household expenditure on pharmaceuticals. This deeply affects the Lebanese society, which suffers from lack of proper social safety nets on one hand, and high levels of poverty, informal work, unemployment, and influx of refugees on the other hand.

In Lebanon, corruption in the pharmaceutical sector jeopardizes the quality of services, when compared to its high cost, and risks not to deliver best value for money. This represents a serious risk of driving more middle-class households below the poverty line; and would

# **ESTIMATING THE VALUE AND SOCIO-ECONOMIC IMPACT OF CORRUPTION**

Overpricing of pharmaceutical items has an overwhelming impact on socio-economic conditions in the country that is already suffering of high impoverishment and unemployment (lay-offs) rates, not to mention the effect of the recent financial and economic crisis on salary cuts, closure of small businesses and deteriorating purchase leave the lower social strata and marginalized segments of the society with two options: either, to seek after low quality health services, or – in worst case scenarios – to deprive themselves from the needed treatment.

In a situation lacking a universal health coverage and under-supply of public health facilities, even when the MoPH acts as an insurer-ofthe-last-resort, the confessional political system in Lebanon would only encourage "clientalism" and "nepotism", and hence, inequality and widening of impoverishment.

Nowadays, the socio-economic impact of corruption and lack of good governance within the pharmaceutical sector have intensified in light of several unfortunate incidents: (1) the current economic, financial and monetary crises, (2) the on-going social and political unrest, since last October the 17th, and (3) the outbreak of COVID-19 pandemic in the country.

However, it should be noticed that MoPH strategies, since the late nineties of the past century, had drastically improved the healthcare outcomes. In fact, health spending as a share of GDP has fallen from 12.3% in 1998 to 7.7% in 2017, and more specifically, out-of-pocket spending as a share of total health spending has dropped from almost 60% to some 33% respectively. This was the result of several factors, mainly those of utilizing preventive, promotion and curative services; the increasing role of the ministry as the insurer-of-last-resort; the direct procurement and dissemination of essential medicines and chronic illness drugs by the ministry; and the continuous revision of medicines' public prices.

## **5.2.** ESTIMATING THE VALUE OF CORRUPTION

In regards to prices of medical drugs, several documents emphasized the importance of public health services in effectively curbing medicines amplified prices. For instance, it was noted that "the cost born by the government for providing PHC and public secondary health services is equivalent to almost the third of the cost incurred by the individuals when purchasing themselves the services directly from the private sector"<sup>79</sup>. Of course, health services provided by public health centers are widely ranged, and are not limited to pharmaceuticals; although medical drugs – especially, essential and chronic illness drugs – is an important part of the public dispensing system, in addition to ambulatory care services, etc.

<sup>80</sup> Walid Ammar (2009), op. cit.
<sup>81</sup> Refer to: Dr. Ismail Sukkarriyeh (2010), op. cit.

In fact, the MoPH benefits from its purchasing power to get important discounts and bonuses through a highly competitive procurement procedure of pharmaceutical products (especially, medicines). Should the concerned patients have purchased the needed medicines on their own, they would have paid at least double the cost borne by the ministry<sup>80</sup>. Again, the MoPH procures mainly the extremely expensive drugs for the uninsured with severe and debilitating diseases. But an earlier experience, which dates back to the late nineties, was found to be a success story for MoPH; as the ministry, in collaboration with the Health Directorate in the Lebanese National Army, was able to save on average around 40% of the total cost of procured medicaments<sup>81</sup>. This was predicted earlier by the Speaker of the Parliament, Mr. Nabih Berri, in a parliamentary session dated on the 17th of December 1997; when he mentioned that the endorsement of certain policies concerning pharmaceuticals (establishing the "National Bureau of Medicine", and the direct procurement of medical drugs, etc.) might decrease the medicine bill in the country by around 40%.

An earlier very important experience was carried-out by the NSSF in the early Seventies of the last century (1970-1975), and was halted due to the chaos provoked by the civil war in Lebanon. The NSSF found that the cost endured by the fund to cover medical drugs constitute around 50% of its total health coverage bill; whereas, benchmarking with similar countries, medicine cost ranged from 8% to 19% only<sup>82</sup>. Therefore, the NSSF decided to intervene in the market and initiate its own attempt to directly procure medicine to the beneficiaries of its health coverage services. Its main objective was to provide the best efficacy drugs for the least price possible. Unfortunately due to lack of willingness to cooperate on the part of manufacturers and importers/ dealers of medical drugs, the NSSF was only able to provide 210 drug items out of an extensive medicine list comprising of 1,588 essential drug items. Even though this experience was not ideal, the NSSF was able to receive offers from manufacturers at a lower price (from 60% to 65% lower prices), and was able to reduce the share of medicine cost from 50% to 35% of its health coverage bill<sup>83</sup>.

Since 2005, several revisions of public prices of drugs had led, on several occasions, to certain reductions on prices based on benchmarking with neighboring countries (especially with Jordan and KSA). Hence, any further decreases in prices of pharmaceuticals might not reach the previously estimated 40%-50% average threshold for price reductions of medical drugs. But, additional requirements might add-up to price revisions, and substantially cut current medicine prices in Lebanon. Some of these arrangements might include: the founding of the "National Bureau of Medicine" responsible for procurement and setting the national policies for drugs; ratification of an anti-trust law for medicine providers; modifying the drug price structure; establishing universal health coverage and unification of patients' data; etc.

Indeed, modifying the price structure and pricing mechanism (expenses, profit margins and the incremental calculation method) is highly recommended, due to the following reasons:

- In general, the price-dependent profit margin encourages importation of expensive drugs.
- Knowing that imported drugs are customs exempted, the margin for clearance and commission (11.5%) is exaggerated.
- In the same sense, the percentage set for shipping and insurance (7.5%) might be over-estimated for most pharmaceuticals imported from some nearby European countries.
- Freight, being calculated as a percentage of the price and not based on volume, encourages the importation of expensive drugs with small volume.
- The cumulative price structure tends to magnify the pricing issue.

Moreover, it is highly important to increase inspection tools and activities, on several layers, most importantly concerning the following:

- Hospital in-patient billing, to control over-billing and false-billing of hospitalization services including pharmaceuticals. A universal health coverage system and the unification of patients' data would provide a crucial tool to control such mal-practices. Also, the timely payment and the commitment to reduce the frequency of payments (on monthly or quarterly basis) would encourage private hospital administrations to abide to good governance.
- Quality, prices and expiry of drugs. The re-establishment of the "National Medicine Laboratory" and the increase in inspection department staff is necessary.
- The medication prescribing habits and drug prescription errors and mal practices. Promoting the use of generic drugs (after making sure of their good quality), including licensed and labeled ones. Also, reconsidering medical curricula and training through a continuing education program (especially on pharmacy major), in collaboration with universities and Physicians Orders, is a must.

Even, at the governance arrangement level: challenges pertain to the regulation of physician-industry interactions; the implementation of clinical guidelines, clinical pharmacy services and systems for prescription audits and feedback; the integration of professional education about drug promotion and pharmacology in curricula; and the enforcement of systems for monitoring drug quality<sup>84</sup>.

#### <sup>84</sup> Fadlallah, R., El-Jardali F., (December 2016), op. cit.

# 5.3. CONCLUSION

In conclusion, the reduction of public price of medicine by 40% on average in Lebanon would have impact on the following domains: A reduction of the direct household OOP expenditure on medical drugs from LBP 1,1 trillion (USD 736.2 million) to LBP 665.9 billion (USD 441.7 million).

- hospitalization bills).
- 447.2 million).

In a country which is burdened by economic and financial crises, increasing levels of unemployment and expanding poverty levels; the reduction of medicines' prices and health care cost in general is crucial to slow down the deterioration of socio-economic conditions of the middle and lower income groups within the society. It would maintain a fair level of access to health care services, especially to medication and helps moderating the exclusion of more and more vulnerable social segments from the health care system in Lebanon.

It is noteworthy that corruption has another negative impact on the long run; it actually prevents better policies that could reduce the pharmaceutical bill of the country, but its extent is much deeper than that, reaching the over-billing in hospitals, exaggerated prescriptions, oligopolies, etc.

• A reduction of total current health expenditure by 10.9%, from LBP 6.2 trillion (USD 4.1 billion) to LBP 5.6 trillion (USD 3.7 billion). • A reduction of the share of OOP expenditure out of total current health expenditure from 33.1% to 29.1% (of course, this might be further reduced when implying the possible decreases on

• A reduction of the total MoPH expenditure by around 12.7%, from LBP 771.8 billion (USD 511.9 million) to LBP 674.2 billion (USD

• A reduction of the total health expenditure per capita from an estimated USD 936 to around USD 834.

OMMENDATI

Provision of medicine should ensure: (1) good quality, (2) accessibility, (3) fair prices, and (4) abidance to laws and regulations.

In order to reach this objective, first and foremost, the MoPH should take the stewardship role and be the regulatory body and policy maker overseeing the whole HCS. It will maintain its leading role in advocating and coordinating all public health policies and actions<sup>85</sup>.

The implementation of good governance in the pharmaceutical sector requires the implementation of the following set of recommendations:

## **1.** AT THE REGULATORY AND POLICY MAKING LEVEL

**1.1.** Develop a special policy for the pharmaceutical sector, in addition to producing relevant strategies and action plans.

**1.2.** Update the 1994 Pharmacy Practice Law, in accordance with the current level of globalization (the issue of "country of origin" as an example).

**1.3.** Introduce an anti-trust legislation with regards to the off-patent products importation.

1.4. Amendment of the Lebanese Patent Law, in accordance with "Doha Declaration on the TRIPS Agreement and Public Health" (November 2001), which reaffirmed the right of members to adopt an international principle of exhaustion of rights with respect to parallel importation under Article 6 of TRIPS.

**1.5.** Ease of parallel market regulation, in order to encourage competitiveness.

**1.6.** Promote measures to support rational drug prescribing, including policies to regulate health care professionals' interactions with the pharmaceutical industry and policies to ensure the quality of drugs, including generics, available in the market.

**1.7.** Revise and expand medicine promotion regulations, and the control over promotional activities and materials.

# 2. AT THE ORGANIZATIONAL LEVEL

branches.

necessary staff.

collection and analysis.

resources.

health.

# 3. AT THE HEALTH CARE PROFESSIONAL LEVEL

- 2.1. Re-establish the "National Bureau of Medicine".
- 2.2. Re-establish the "National Medicine Laboratory".
- 2.3. Modernize the internal organization of the MoPH, in order to strengthen and improve both the internal regulatory and executive bodies, in addition to the ministry's sub-national administrative
- 2.4. Provide the MoPH with sufficient recruitment of staff; and especially empower the Inspection Department at MoPH with
- **2.5.** Establish a unified health information system that engages all relevant institutions, in order to strategize and harmonize data
- **2.6.** Founding of a Universal Health Coverage system, based on the principles of justice, equity, poverty reduction and the rational use of
- **2.7.** Increase openness and transparency of MoPH activities in the pharmaceutical sector, through developing written procedures (SOPs).
- **2.8.** Enhance an intensive multi-sectoral cooperation, in order to address social and environmental risks and other determinants of
- 3.1. Promote education of health care professionals about rational prescribing and code of ethics, and the integration of professional education about drug promotion and pharmacology in curricula.
- 3.2. Introduce policies for monitoring physicians' prescriptions of medicines, limiting their freedom in prescribing branded names.
- **3.3.** Produce clinical guidelines and clinical pharmacy services and systems for prescription audits and feedback.

# **4.** AT THE LOCAL PHARMACEUTICAL INDUSTRY LEVEL

**4.1.** Upgrade manufacturing quality standards.

4.2. Acquiring priority in prescriptions through the MoPH Unified Prescription Form.

4.3. Create new foreign (export) markets for local production.

4.4. Support manufacturers to reduce costs.

# 5. AT THE MARKET LEVEL

**5.1.** Modifying the price structure and review pricing mechanisms.

**5.2.** Increase benchmarking of prices with more neighboring countries.

5.3. Encourage the widening of imports of the same drugs from countries with cheaper ex-factory prices.

**5.4.** Incentivize the importation of cheaper drugs.

**5.5.** Increase taxes on patented drugs.

**5.6.** Intensify inspection on prices, quality control and expiry date of pharmaceuticals.

**5.7.** Promote proper use of medication among consumers; especially generic drugs of good quality.

**5.8.** Renewal of registration of drugs periodically (every two or three years).

**5.9.** Provide the MoPH with the authority to revoke the registration of any drug that is not being marketed for any reason.

Corruption and Lack of Good Governance					
Sources an an	d Drivers of Corruption d Mal-Practices	Main Players	Social Impact	Recommendations	
Lack of Health Care Strategy	Lack of long-term vision, objectives and action plans	MoPH / WHO	«Market chaos; Limited access to high quality services; High prices & low quality; Fragmented health coverage system.»	«MoPH should take the stewardship role and be the regulatory body and policy maker overseeing the whole HCS. Develop a special policy for the pharmaceutical sector, and produce relevant strategies and action plans.»	
	The 1994 Pharmacy Practice Law is the main regulatory framework	MoPH / Parliamentary Health Committee	«Market chaos; Limited access to high		
Weakened Legal Framework	Lack of regulations is covered by Ministerial Decisions	/ LOP / Syndicate of Hospitals in	quality services; High prices & low quality:	in accordance with the current level of globalization (the issue of "country of	
	Lack of executive decisions for implementing existing laws	Lebanon / Order of Pharmacists of Lebanon / LPIA / SPIL	Fragmented health coverage system.»	origin" as an example).	
	Outdated institutional organization of MoPH	МоРН	«Restrictions in the role of MoPH; Market chaos.»	«Modernize the internal organization of the MoPH, in order to strengthen and improve both the internal regulatory and executive bodies, in addition to the ministry's sub-national administrative branches. Increase openness and transparency of MoPH activities in the pharmaceutical	
				sector, through developing written procedures (SOPs).»	
	Lack of sufficient human resources at MoPH	GoL / MoPH	Lack of sufficient control and inspection.	Provide the MoPH with sufficient recruitment of staff.	
Institutional Weaknesses	The halt of the "National Bureau of Medicine"	MoPH / Parliamentary Health Committee	«Poor medicine policies; Drug market oligopoly; High prices and low quality medicines.»	Re-establish the "National Bureau of Medicine".	
	The abolition of the "National Medicine Quality Control Laboratory"	MoPH / Parliamentary Health Committee	Poor medicine quality.	Re-establish the "National Medicine Laboratory".	
	Pluralism of tutelage	GoL / MoPH / MoL / Presidency of the Council of Ministers / MoD / MoIM / MoET	«Inequality in health financing schemes; Lack of a unified data	«Establish a unified health information system that engages all relevant institutions, in order to strategize and harmonize data collection and analysis.	
	Overlapping of financial health coverage	MoPH / NSSF / CSC / Army / IS / GS / SS / Private and Public Mutual Funds / ACAL	base for patients; Lack of a universal health coverage.»	Founding of a Universal Health Coverage system, based on the principles of justice, equity, poverty reduction and the rational use of resources.»	

# ANNEXES

## ANNEX 1: MATRIX OF STUDY OUTCOMES

## ANNEX 2: SIZE AND MAIN CHARACTERISTICS OF THE "PHARMACEUTICAL" SECTOR

#### National Health Accounts (Expenditures/Revenues)

The humble share of health sector out of GDP, which reached its peak in 2018, at 3.67%, has reflected on all the national health account figures. Despite the continuous rising of annual budget for MoPH in absolute amounts (a year-on-year increase by 2.8%, from LBP 709 billion in 2017 to LBP 729 billion in 2018); the share of the allocated budget to MoPH out of the total Government budget had slightly fallen from 2.96% in 2017 to 2.73% in 2018.

Yet, the ministry's annual budget per capita sustained its upward trend, reaching its maximum level in 2018 at USD 108, which doubled its amount recorded a decade and a half ago (USD 52.5 per capita in 2004)<sup>86</sup>. This increase was in line with the rise in current health expenditure per capita registered during almost the same period, which also doubled from a USD 456 in 2004 to USD 936 in 2017. Nevertheless, it should be noticed that the share of the current health expenditure out of the country's GDP has fallen from 8.8% in 2004 and from 7.91% in 2016 - to 7.75% in 2017.

According to WHO, the global spending (world average) on health continues to rise, and it constituted about 10% of GDP and USD 1,080 per capita in the year 2017; hence, health indicators in Lebanon are found to register below the world averages.

# (2015 - 2018)

<sup>86</sup> Note: the GDP per capita are calculated based on population

estimates declared by the Central

Administration of Statistics (CAS).

Unfortunately, in the absence of

population censuses in Lebanon since 1932, due to political and confessional reasons, these figures

should be dealt with precaution,

as the population size might be

the amount of GDP per capita.

underestimated, and thus, elevating

Allocated to MoPH from Tota
Annual Budget of MoPH*
Annual Budget of MoPH per
Total/Current Health Expend
THE as % GDP**
Out Of Pocket Expenditure a

\* Government Budget. \*\* National Health Accounts, MoPH. (Total Health Expenditure instead of Current Health Expenditure for the years 1998 and 2015).

Source: MoPH, Statistical Bulletin, 2018.

		i		
Institutional Weaknesses	Lack of sufficient control and inspection	МоРН	«Existence of forged, smuggled, faked, expired and worldwide prohibited (according to UN reports) medicines; Unfair pricing of medical drugs.»	Empower the Inspection Department at MoPH with necessary staff.
	Predominant private sector	MoPH / Administrations of Private Hospitals / Physicians / LPIA	«Private hospitals over- prescription of drugs; Unregulated medicine promotion practices; Influence of physicians and firms on demand increase.»	Promote measures to support rational drug prescribing, including policies to regulate health care professionals' interactions with the pharmaceutical industry and policies to ensure the quality of drugs, including generics, available in the market.
	Market centralization (oligopoly of importers)	LPIA / Physicians / Pharmacists / Universities (Medicine Curricula)	«Unfair competition by pharmaceutical firms; Superiority of branded names drugs.»	«Introduce an anti-trust legislation. Amendment of the Lebanese Patent Law. Ease of parallel market regulation.»
Imbalances in Health Sector				«Upgrade manufacturing quality standards.
	Neglect of National pharmaceutical industries	GoL / SPIL	Few manufacturers with a small share of the local pharmaceutical market.	Acquiring priority in prescriptions through the MoPH Unified Prescription Form. Create new foreign (export) markets for
				local production. Support manufacturers to reduce costs.»
	Over-Supply of pharmacists/pharmacies	Order of Pharmacists of Lebanon / Physicians / Pharmacists / LPIA	«Over-the-Counter drugs prescriptions; Over-Consumption of antibiotics and psychiatric / psychotropic drugs.»	«Promote education of health care professionals about rational prescribing and code of ethics.
				Revise and expand medicine promotion regulations, and the control over promotional activities and materials.»
	Inflated medicine prices			«Modify the price structure and review pricing mechanisms.
				Increase benchmarking of prices with more neighboring countries.
				Encourage the widening of imports of the same drugs from countries with cheaper ex-factory prices.
Inconsistent Drugs' Pricing	High OOP expenditure	MoPH /	«High prices; Extra costs on GoL and	Incentivize the importation of cheaper drugs.
Mechanisms		Parliamentary Health Committee /	MoPH budgets; Inequality;	Increase taxes on patented drugs.
and Complicated Price Structure	Increase in MoPH budget	MoET / MoI / Order of Pharmacists of Lebanon / LPIA / SPIL	Empoverishment of middle-classes; Increasing poverty	Intensify inspection on prices, quality control and expiry date of pharmaceuticals.
Structure			levels.»	Promote proper use of medication among consumers; especially generic drugs of good quality.
	High health expenditure per			Renewal of registration of drugs periodically (every two or three years).
	capita			Provide the MoPH with the authority to revoke the registration of any drug that is not being marketed.»

		2015	2016	2017	2018
al Gov. Budget*	percent	2.5	2.64	2.96	2.73
	Billion LBP	516	643	709	729
capita*	USD	77	98	106	108
liture per capita**	USD	863	930	936	n.a.
	percent	7.41	7.91	7.75	n.a.
s % THE**	percent	32.7	32.0	33.1	n.a.

#### Table 12: MoPH Budget and Health Expenditure in Lebanon

The below graph illustrates the constant growth in the amount of health expenditure in time (in the years health accounts data are available), against the downward trend of its share out of the country's GDP, which was stabilized throughout the period 2012-2017.

#### Figure 5: Current Health Expenditure as % GDP (in the years health accounts data are available)



#### Amount of Registered and Marketable Drugs

Finally, one of the most essential elements in determining the size of the pharmaceutical sector in Lebanon is to identify the amount of registered and marketable drugs in the local market.

According to MoPH drugs' public price lists, the amount of registered drugs in Lebanon reached over 8,900 during this year (2020). Almost 63% of these registered drugs are currently being marketed (over 5,600 pharmaceutical items), against a 37% share of drugs that are listed as being non-marketed (around 3,300 pharmaceutical items).

Figure 6: Graphs Illustrating the Change in Amount of "Registered", "Marketed" and "Non-Marketed" Pharmaceutical Items in Lebanon (Dec. 2019-Apr. 2020)

Source: https://www.moph. gov.lb/en/Pages/3/3010/ pharmaceuticals#/en/view/3101/ drugs-public-price-list-



The increasing amount of registered medicines in Lebanon was always regarded as an increase in "brand name variety" of available medicines in the market, which did not necessarily lead to substantial improvement in the quality of medical services. Most importantly, this increase in brand names of drugs did not favor fair competition in the pharmaceutical products market, and hence did not play a major role in decreasing the prices in the market.

According to the information on external trade available at the Customs Administration, Lebanon's import of pharmaceutical products in 2019 constituted 6.5% of total value of imports (USD 19.239 billion). This is considered a high share indicating that the country is highly dependent on imports of pharmaceuticals and medication, and faces high risks of lacking favorable conditions in terms of health security. On the other hand, such level of imports indicates the overconsumption of drugs that point out to existing mal practices in drug prescriptions, which may – in turn - affect the health conditions and increase drug resistance (such mal practices might cause early death in some cases, and eventually unnecessary rise in death rates).

During the past decade (2010-2019), Lebanon imported over 100 thousand tons of pharmaceutical products, at an average yearly value of LBP 1.69 trillion (USD 1.1 billion); which ranged from a minimum value of almost LBP 1.3 trillion (USD 859 million) in 2010, to a maximum value of around LBP 2.0 trillion (USD 1.33 billion) in 2018. In general, the yearly change in value of imported pharmaceutical products sustained its upward trend (with few exceptions), until the past year (2019) that recorded a significant decline in the value of imports by 6.5%, reaching LBP 1.87 trillion (USD 1.24 billion) worth of pharmaceuticals.

	Value			Weight	
Year	Million LBP	Thousand USD	Yearly Change (%)	Tons Net	Yearly Change (%)
2010	1,296,068	859,461	n.a.	8,331	n.a.
2011	1,467,086	972,869	13.2%	8,513	2.2%
2012	1,462,886	970,084	-0.3%	8,071	-5.2%
2013	1,645,586	1,091,238	12.5%	8,917	10.5%
2014	1,720,474	1,140,898	4.6%	9,827	10.2%
2015	1,696,549	1,125,033	-1.4%	11,135	13.3%
2016	1,830,636	1,213,949	7.9%	11,886	6.7%
2017	1,942,168	1,287,909	6.1%	11,748	-1.2%
2018	2,004,503	1,329,246	3.2%	11,467	-2.4%
2019	1,873,615	1,242,451	-6.5%	10,141	-11.6%

#### Source: Customs Administration.

Lebanon in 2019 imported pharmaceutical products from 65 different countries. Over 50% of the imported pharmaceuticals were produced in only four countries: Germany (LBP 321.4 billion) ranked first, followed by USA (LBP 221.6 billion), France (LBP 201.6 billion) and Switzerland (LBP 196.4 billion).

Table 14: Imports of **Pharmaceutical Products: Top 10 Countries by Value** and Share of Total (2019)

The top ten countries exporting pharmaceutical product to Lebanon were developed countries members of the OECD (mainly European countries, in addition to the United States of America). The share of these top 10 countries constituted three quarters of Lebanon's total imports of pharmaceuticals (75.5%).

		Value				
#	Countries	Million LBP	Thousand USD	%		
1	Germany	321,372	213,112	17.2%		
2	United States	221,628	146,968	11.8%		
3	France	201,644	133,716	10.8%		
4	Switzerland	196,393	130,234	10.5%		
5	Ireland	115,490	76,585	6.2%		
6	Italy	109,099	72,347	5.8%		
7	United Kingdom	70,410	46,691	3.8%		
8	Spain	65,812	43,642	3.5%		
9	Denmark	65,448	43,400	3.5%		
10	Belgium	46,521	30,850	2.5%		

#### Source: Customs Administration.

As for the imported "medicaments" items in particular for the same period (2010-2019); Lebanon imported almost 90 thousand tons, at an average yearly value of LBP 1.38 trillion (USD 912.7 million); which ranged from a minimum value of almost LBP 1.15 trillion (USD 759.8 million) in 2010, to a maximum value of around LBP 1.59 trillion (USD 1.05 billion) in 2017. Within the couple past years (2018 and 2019) the annual total value of imported medicaments witnessed significant decreases, by 8.5% and 17.5% respectively, reaching LBP 1.2 trillion (USD 795.8 million) in 2019.

It is worth mentioning that the percentage share of value of imported medicaments out of total imported pharmaceutical products were continuously shrinking on yearly basis during the past decade, from a maximum of an 88.4% share in 2010, to a minimum of 64.1% share of pharmaceuticals in 2019. Moreover, the average value of imported medicaments per Ton kept rising from LBP 150.3 million per Ton (USD 99.7 thousand per Ton) in 2010, until it peaked in 2013 at LBP 175.8 million per Ton (USD 116.6 thousand per Ton. Afterwards, it started decreasing until it reached its lows in 2019 at LBP 135.7 million per Ton (USD 89.9 thousand per Ton). There might be several factors behind this reduction, but it clearly indicates that the average unit price of imported medicaments fell down during the period 2014-2019, which might have influenced the ease in drug prices within the local market.

Table 13: Import of **Pharmaceutical Products** by Value and Weight (2010 - 2019)

#### Table 15: Import of Medicaments by Value and Weight (2010-2019)

Year	Value			w	eight
	Million LBP	Thousand USD	Yearly Change (%)	Tons Net	Yearly Change (%)
2010	1,145,745	759,778	n.a.	7,621	n.a.
2011	1,274,943	845,453	11.3%	7,523	-1.3%
2012	1,255,650	832,659	-1.5%	7,231	-3.9%
2013	1,412,455	936,641	12.5%	8,036	11.1%
2014	1,471,990	976,121	4.2%	8,821	9.8%
2015	1,441,795	956,098	-2.1%	10,117	14.7%
2016	1,516,802	1,005,837	5.2%	10,764	6.4%
2017	1,590,179	1,054,496	4.8%	10,723	-0.4%
2018	1,454,591	964,583	-8.5%	10,219	-4.7%
2019	1,200,062	795,797	-17.5%	8,845	-13.4%

Source: Customs Administration.

Assuming that all the imported "medicaments" are sold in the market at the highest permissible price; then the total public price of imported medicaments in 2019 (considering shipping and insurance costs, custom clearing and profits of importers and pharmacies, according to Decision no. 208/1 - 1983); would amount to around LBP 2.057 trillion (USD 1.364 billion). However, this estimation of total public price of imported medicaments is slightly overrated, as it should take into consideration the following curtailing factors:

- Drug merchants and pharmacies are not allowed to exceed the prices issued by the MoPH, but are expected to sell at lower prices (Law 480 issued in Dec. 2002, amending Article 80 of the 1994 Pharmacy Practice Law considers the price set by the MoPH as a ceiling not to be exceeded, but could be lowered).
- The MoPH, sporadically but continuously, produces public price lists that often contain price revision and contractions.
- Drugs procured by MoPH (purchased through pharmacies, public bids and hospitals) for distribution through various programs initiated by the ministry; especially the following programs:
  - Expanded program on immunization
  - Medication for Chronic Illnesses Program
  - Public Medicine Dispensing System.
- Drugs are also procured by Army insurance scheme at more favorable prices, due to their efficient procurement system.
- Imported drugs for non-commercial usage, which are not provisioned for market trade; such as medicines obtaining special permits from the Minister of Public Health:

 For scientific research in Medicine Academies, Laboratories and Research Centers.

- Those donated to certain Associations and NGOs for distribution at dispensaries.
- Waste drugs that eventually were not purchased by consumers.

It is essential, when determining the size of the pharmaceutical sector in Lebanon, to bear into consideration that the imported medicaments constitute around 94% share of the Lebanese market against a share of 6% accounted for national pharmaceutical industries in Lebanon.

In conclusion, the maximum total public price of drugs (both, imported and locally manufactured) in Lebanon is estimated at approximately LBP 2.188 trillion (USD 1.452 billion) in the year 2019.

## **ANNEX 3: MAIN PLAYERS OF THE PHARMACEUTICAL SECTOR IN LEBANON**

The "health care system" (HCS) in general and the pharmaceutical sector in particular are multi-dimensional and involve a variety of intertwined players. While HCS aims at improving the health security within the society and targets the well-being of the Lebanese people, it includes entities from the private, public and civil society sectors.

This section of the report covers the main players who are directly concerned in the pharmaceutical sector in Lebanon.

# THE MINISTRY OF PUBLIC HEALTH

The current organizational structure of the Ministry of Public Health (MoPH) was set out by the Decree no. 8377 dated on 30/12/1961. This decree regulated the ministry's general policy, function, vision and mission; and it stipulated that its main functions are public health, the health regulatory authority, and providing health care to the poor. The MoPH plays an important role in regulating, supervising, controlling and organizing the HCS. Through networking and in partnership with other stakeholders, it optimizes the use of resources to improve health conditions in the country and works on ensuring the provision of high quality services to all individuals, in order to protect and secure the health of citizens. Moreover, the MoPH is responsible for water and food sanitation, health education, school health, prevention and monitoring of communicable diseases, among other important accountabilities.

#### The MoPH mandate allows it to play several roles on different levels of intervention, as follows:

1. Regulatory role: where it drafts related health laws and regulations. The MOPH governs the opening of pharmacies and sets the prices of medical drugs and the mark-ups of importers and pharmacies (for imported medicines only). Also, the ministry authorizes and issues permits to practice medical and allied health professions; issues permits to establish health facilities (such as hospitals, medical labs,

#### **The Organizational Structure**

According to the organizational chart of MoPH, there are three directorates under the umbrella of MoPH "General Directorate": (1) the "Directorate of Preventive Health care", (2) the "Directorate of the Central Laboratory and Public Health", which is currently "SUSPENDED until further notice"88, and (3) the "Directorate of Medical Care". The latter consists of two services: (1) the "Service of Hospitals, Dispensaries and Medical Professions", and (2) the "Service of Pharmacy". At the regional level, the ministry acquires some subnational structures and administers HCS and programs through-out 6 Governorates (Mohafaza) referring to 25 district (Caza) health offices.

In turn, the "Service of Pharmacy" at the MoPH has three departments: (1) the "Department of Importation and Exportation of Medicines", (2) the "Inspection Department", and (3) the "Department of Narcotics". The "Service of Pharmacy" is the regulatory body for pharmaceuticals and drug dealers, and it is responsible of handling all medicine regulatory control matters, including licensing of premises and pharmacists. More specifically, the service is responsible for the following functions:

- Drug pricing;

The "Service of Pharmacy" at the MoPH is assisted by a "Technical Committee", which was created in accordance with the 1994 Pharmacy Practice Law, and is responsible for registration of new or imported drugs, and it consists of members from professional associations and universities.

## The MoPH Mandate

In reference to the MoPH mandate with regards to the pharmaceutical sector, especially drugs, the ministry acquires the authority to operate and intervene at the following levels:

#### **Registration of medical drugs:**

The "Technical Committee" is responsible of the registration of pharmaceutical products. According to the 1994 Pharmacy Practice Law, this committee comprises of three members representing MoPH, namely the head of the "Service of Pharmacy", head of the "Department of Importation and Exportation of Medicines", and head of "Inspection

dispensaries, etc.); deliver licenses to build and operate private and public hospitals. Moreover, MoPH has the legal authority to assess, classify and accredit private hospitals according to set criteria and conditions "within the framework of public interest".

**2. Insurer of the last resort:** through its interventions in medical markets the MoPH is considered a medical insurer/purchaser, as a "(third-party) financing agency". The ministry contracts private and autonomous public hospitals for services, ensuring the availability and access to comprehensive health services throughout the country. This function allows the MoPH to play an operational role in the sector, and an influential task with regards to service definitions, in addition to controlling prices and tariffs in hospital services, for both secondary and tertiary care.

3. Network facilitator: with respect to primary services, which mainly comprises of NGOs, MoPH provides in-kind supplies to this nationwide network of "affiliated" primary care providers. This goes back to the year 1991, when the MoPH, in collaboration with relevant stakeholders, developed a "National Strategy for Primary Health Care". This initiative identified 29 primary health care centers - at that time – to form the nucleus for the "National Network" of PHC centers. In 2016, and with funds from the WB, the MoPH initiated a pilot phase for implementing a performance based contracting with NGOs' operating PHC centers, whereby many services are delivered to the most vulnerable Lebanese population (based on the "national poverty targeting project")<sup>87</sup>. Currently (as of mid-2019) the network expanded to include 228 primary health care centers; mostly belonging to private non-profit enterprises (68%), ensuring close to national coverage of primary services, focusing on areas with vulnerable populations.

The MoPH initiates a number of "Primary Healthcare Projects and Programs", in collaboration with international organizations and a wide variety of local players. Some of these programs are related to certain diseases, while others concern with particular demographic groups. Examples of these programs include the following community based health services:

- the Expanded Program for Immunization (EPI);
- National AIDS Control Program;
- Medication for Chronic Illnesses Program;
- Tuberculosis Control Program;
- Reproductive Health Program;
- Non Communicable Disease Program.

Most importantly for the pharmaceutical sector, MoPH authorizes the registration of drugs introduced to the market ensuring their quality, determines the prices of medical drugs, and supervises control and inspection of goods at the pharmacies and drug warehouses.

<sup>88</sup> As stated at the MoPH official website: https://www.moph.gov.lb/ en/AdministrativeServices/index.

Issuing certificates related to pharmacies and pharmacists' practice;

- Drug industry management and control;
- Narcotic drugs' imports, distribution, and statistics;
- Medicinal imports/exports;
- Drug registration and control;
- Registration of non-medicinal health-related items;
- Pharmacies' and drugstores' inspection; and,
- Controlling fraud in the pharmaceutical industry.

Department"; in addition to two delegates from each of the Order of Pharmacists and Order of Physicians (LOP), who are replaced every time there are new elections in the Orders' administration, and finally, representatives from the academia.

Registration requirements were set in the Ministerial Decision no. 233, dated 9 March 2003; and then amended by the Ministerial Decision no. 212/1, dated 5 April 2004. Standard application forms for registration of imported and locally produced medicines are available to download from MoPH website. When the application is delivered, a regular staff member at the "Service of Pharmacy" checks if the file is complete and makes sure that all the requirements for registration are delivered, before submitting the application to the "Technical Committee"; and the application is granted a queue number for revision by the committee.

The committee uses a checklist to evaluate applications, which requires providing the following information:

- product name (both, the "trade name" and the "generic name" / brand and INN);
- a filled questionnaire by the manufacturing plant and the GMP certificate:
- a free sale certificate, certificate of pharmaceutical product (CPP);
- an attestation of origin of raw material;
- · a certificate of analysis issued from a recognized laboratory (quantity and purity of raw material and methods of analysis);
- pharmaceutical studies (disintegration, dissolution, pH) and stability data for three different batches;
- bioavailability studies of active ingredients;
- studies on drug efficacy (pharmacodynamic data);
- studies on toxicological effect of the drug (toxicological data); pharmacokinetic data;
- complete studies on toxicological effect of the drug (including: teratogenecity and carcinogenicity);
- summaries of toxicological, pharmacological and clinical information from published scientific literature;
- pharmacokinetic studies;
- patent certificate;
- six samples of the product;
- price certificates, etc.

As for the generic drugs, additional documents are required, such as the recognition of the manufacturing plant by other countries. On the other hand, local industry is required to conduct a bioequivalence study similar to imported generics.

Of course, exceptions to this registration process do exist in the system. They are mainly related to "parallel import and relatively small quantities of drugs donated to NGOs that bypass the system and

reach dispensaries after obtaining a special permit from the Minister of Public Health"89.

Afterwards, applications are studied by the committee, and a decision is made by the majority of vote (in case of a tie, the head of the committee makes the final decision). Then, registration fees are paid at the Ministry of Finance. Once granted, registration is for life; besides, there is no requirement for registration renewal.

For rejected applications, there exists an appeal process. But, it should be noted that all appeals are submitted to the same technical committee that made the original decision.

On another note, the registration committee at MoPH has no "standard operating procedures" (SOP) in the domain of medical drugs' registration.

The closure of the "Central Laboratory" for drug analysis, in January 2007, had created additional challenges concerning the set standards and quality control over imported and locally produced medical drugs. Since then, the technical committee at MoPH has decided on ensuring the quality of pharmaceutical products through imposing the following pre-requisites for registration:

marketing.

Local pharmaceutical industry: should conduct a bioequivalence study similar to imported generic brands.

Biopharmaceuticals and biosimilar products: are subjected to strict requirements and additional examination, as follows:

- use:
- efficacy and side effects.

<sup>89</sup> Walid Ammar (2009), op. cit.

**Imported drugs:** a certificate of analysis from an internationally recognized laboratory and batch analysis certificates are requested. Also, imported drugs are subject to direct inspection prior to

 Registration certificate of the manufacturing plant, GMP certificate, and official statement indicating the Inspecting Authority;

• Detailed information on the ability of the plant to manufacture biological material, including Genetic Chemistry, Animal Cell Culture, Protein Chemistry (Extraction, Purification, Analysis, Fixation, Dose Determination, and source of material used in production (Cells, Fixation material, etc.) with GMP for this source; Product Studies: Chemical Analysis, Clinical Studies, Comparative studies with the originator drug. Stability studies, Studies confirming compliance of different batches to unique standards, Study of side effects among which is secretion of antibodies after

Post-marketing study on therapeutic and side effects, comparative post-marketing clinical studies with the brand drug including Recently, changes modeled by the "Globalization" era had provoked the fragmentation of manufacturing processes amongst multiple industrial firms and commercial entities within a variety of countries, in a manner that complicated and dispersed responsibilities. It is currently common to find a drug sold in several countries (especially in the developing countries) with different names, sizes and forms.

The new norms introduced some inconsistencies to the concept of "country of origin", which was a key notion in the 1994 Pharmacy Practice Law. At that time, the legislator aimed at ensuring that manufacturers are not dedicating production lines with lower quality control requirements for export to the Lebanese market. Professor Walid Ammar, explains how the ministry tackled this issue through legislation amendment, as follows: "Law number 530, issued in 2003 to amend the 1994 law introduced new concepts, aside of the "country of origin", to be considered as a responsible party. These include the "manufacturer", "marketing authorization holder" and "applicant for certificate"; whereby the responsible country would be the country of residence of the responsible party. It is worth mentioning that five years of consultations with stakeholders were needed to reach a seeming agreement on an application decree for Law 530. The emphasis was put on the manufacturer of the pharmaceutical form (MPh.F), the responsible party for batch release and quality control, if different from MPh.F, and their related country (ies)"90.

#### Inspection of medical drugs:

The "Inspection Department" at MoPH is responsible for covering the inspection of medicine distributors according to the 1994 Pharmacy Practice Law. Also, the GSDP (Good Storage and Distribution Practices) committee was founded, based on the Ministerial decision no. 1/2124 dated 8 October 2015.

The "Inspection Department" aims at performing inspection of pharmacies and the detection of counterfeit medicines and checking imported medicines at the customs. It makes sure that imported drugs do not clear customs unless it verifies the existence of a duly legalized analysis certificate for each batch. It also ensures that pharmacies and dealers abide to the drugs pricing list issued by the MoPH.

Dr. Walid Ammar pointed out a preceding success story achieved by the "Inspection Department" when activated: "regular inspection of pharmacies and drugstores was scaled-up and led to a significant number of confiscations of counterfeit and smuggled drugs, in addition to disciplinary measures and referral to court. During the first 6 months of 2008, 65 ministerial decisions were issued for withdrawal of illicit drugs; of which 51 were smuggled including 3 narcotics and 14 counterfeit including one narcotic"91.

#### Hospitalization coverage:

The MoPH acts as the insurer of last resort, and covers hospital inpatient expenditures for all uninsured persons in Lebanon. The MoPH – based on the National Health Account results of the year 1998 - had adopted a clear strategic plan for rationalization of health expenditures, specifically targeting to ease the inflated share of households OOP expenses. One of the most important means to achieve this objective is the reimbursement of contracted hospitals for 85% of the hospital stays' bill for the uninsured.

A recent report concerning the "Country Cooperation Strategy" between Lebanon and WHO announced that those who do not benefit from any form of formal health insurance, amount to approximately half of the population; while the "the other 50% are covered through: (a) the Lebanese National Social Security Fund [20%]; Armed Forces [10-12%]; private insurance schemes [6-8%]; and by the government as civil servants [12%]"92.

The fact that makes the MoPH expenditure burden increases is that NSSF do not cover the adherents upon retirement, as they are excluded from health insurance after collecting their indemnities. Hence, while the population covered by the NSSF is relatively young, the MoPH welfare fund covers on average an older demographic segment of the population. This means that MoPH is responsible to cover higher hospitalization rates and larger average length of stay.

In 2018, some 64% of MoPH budget was allocated to cover hospitalization expenditures for the uninsured (in both public and private hospitals), through the "program of catastrophic illnesses" aiming at providing universal access to health services. It is obvious that MoPH budget increases are almost exclusively related to this program, especially to the part of hospitals' reimbursement and expensive drugs purchasing (medicines dispensed free-of-charge directly to the uninsured citizens suffering from cancer, mental illness, multiple sclerosis, and other financial duress diseases).

Ambulatory care:

The MoPH supports this network of PHC centers through the provision of essential drugs, vaccines and some medical consumable materials and some equipment. In addition, the MoPH tasks include the development of guidelines, health education materials, training activities, etc. In return, PHC centers provide a comprehensive package of services, such as immunization, essential drugs (including pediatrics, family medicine, oral health, reproductive health, cardiology, and vaccination), and play an important role in school health, health education, nutrition, environmental health, water control, etc. Beneficiaries also receive access to full medical services provided by physicians, nurses, and health workers through PHC facilities. Affiliated PHC centers charge equal nominal fees to both

insured and uninsured patients. This approach guarantees a primary medical safety net, which provides alternatives to secondary care to the uninsured, and access to affordable essential services.

In fact the MoPH developed options for provider payment reforms in ambulatory care, and initiated a system of accreditation for PHC centers including standard setting guidelines, requirements for physical facilities, and manpower, equipment and operational systems. The MoPH considered ensuring universal accessibility to primary health care, as an affordable alternative to the expensive private ambulatory care and out-patient services. The previous "Health Strategy Plan" assessed this role of the MoPH, as follows: "The wellrecognized achievements of the MoPH would not have been possible without a vision and an effective stewardship role to steer the system towards reaching goals agreed upon with major stakeholders"<sup>93</sup>.

#### **Procurement of drugs by MoPH:**

The "Tender Committee" at MoPH is responsible of procurement of a variety of medicines for those uninsured Lebanese who are in need of certain types of pharmaceutical products. It is formed on yearly basis by a Ministerial decree and has other responsibilities than the procurement office. The "Tender Committee" provides these medicines through tenders and bids, and acquires written procedures and follows written guidelines concerning the bid process. There is also a formal appeal process to be followed in case of rejection of bids. All procurement procedures are audited by the state's Central Audit Committee.

It is noteworthy that the tender list is not based on the essential medicines list (EML), and is listed by brand names instead of generic names. Nevertheless, the lists of medicines for procurement are developed based on the most prescribed ones for each disease treatment (usually following US Federal Drug Administration guidelines).

The "Inspection Department" at MoPH is responsible for port clearing of the procured medicines, through a designated staff member, who is responsible for checking receipts against the packing list when supplies arrive at the warehouse. The responsible person should prepare a receiving report specifying the types, quantities and conditions of the received supplies.

#### **Distribution of drugs by MoPH:**

Through a nationwide affiliation with a large network of PHC centers, the MoPH dispenses essential medicines and chronic illness drugs, provides vaccination, and runs various health programs. The MoPH uses several distribution channels depending on the type of medicine: **Vaccines:** the MoPH procures vaccines from UNICEF, for dispensing at all PHC centers and dispensaries in the country. The Expanded Immunization Program (EPI) provides vaccinations against poliomyelitis (OPV), diphtheria, tetanus, pertussis (DTP), measles, mumps, rubella (MMR) and hepatitis B. The program covers half of children with vaccinations (while, the rest are being vaccinated by private for-profit physicians' clinics). The total expenditure on immunization program amounted to USD 14.663 million in 2017, whereas, the expenditure on vaccines constituted some 82.3% of total expenditure, and comprised of USD 12 million for routine immunization and USD 72.5 thousand for vaccines dedicated for activities of a certain campaign<sup>94</sup>.

Essential Medicines: The MoPH procures from UNICEF essential drugs for dispensing free-of-charge through a huge public (MoPH and MoSA) and NGOs contracted PHC centers network.

Medication for Chronic Illnesses Program: the collaboration between MoPH and YMCA through a joint program funding is accountable of the procurement and distribution of 63 chronic medications for 15 different chronic illnesses; the program is being executed by more than 450 PHC centers in Lebanon for more than 150,000 Lebanese beneficiaries and around 15,000 Syrian refugees annually (in 2016, some 434 centers provided services to 154,261 beneficiaries). The well-known association (YMCA) is responsible of purchasing, storage, and distribution of drugs to chronically ill indigent patients.

Public Medicine Dispensing System: the MoPH provides individual patients with free of charge medicines for severe and debilitating diseases (such as HIV/AIDS, cancer, multiple sclerosis, mental illnesses, kidney dialysis, etc.), through the ministry's public medicine dispensing system, to approximately 15,000 patients annually. According to the 2017 NHA, cancer treatment or chemotherapy drugs are the most expensive, and constituted some 41.8% of the MoPH budget allocated for pharmacies.

National Tuberculosis Program: the MoPH takes full charge of tuberculosis patients who reside in Lebanon. The National Tuberculosis Program (NTP) operates through the PHC network and nine TB control centers across the country, and implements all WHO recommended TB strategies: DOTS, stop TB, and End TB strategy, providing services that include diagnostic, therapeutic, close followup and prevention activities. TB treatment should use standardized regimens that have proven their efficacy and use efficient-gualityassured anti-TB medicines, and adequately administered to patients. The full course of treatment should be given without interruption (Regular and steady anti-TB drugs intake by patient; TB drugs in fixed-dose combination, etc.)<sup>95</sup>.

#### Table 16: Share of MoPH **Expenditure on Drugs** According to Major Disease Categories (2017)

Disease Category	% of MoPH Exp. on Drugs
Cancer	42.32%
Rheumatology and osteoporosis	16.45%
Neurology	6.97%
Vaccines	3.75%
AIDS	2.78%
Immunosuppressants	2.31%
Mental Health	2.12%
Hemophilia	2.12%
Multiple Sclerosis	0.89%
Diabetes	0.67%
Growth Hormone	0.31%
Others	19.31%

Source: NHA 2017 - MoPH.

#### N.B.

In the year 2018 (the last year health accounts data are available), MoPH recorded providing medication for 668 individuals suffering from tuberculosis and 160 HIV/AIDS incidents. According to the 2012 edition of the "National Health Statistics Report in Lebanon", the provided medication monthly average cost amounted to USD 50 per tuberculosis patient and USD 250 per patient for HIV<sup>96</sup>.

#### HEALTH INSURANCE AGENCIES

The MoPH is considered the "largest" public sector financing and/ or purchasing agent, as it contracts health services for the Lebanese population who are uninsured, and thus, plays the role of the "insurerof-the-last-resort", covering around half of the Lebanese citizens (regardless of their ability to pay).

The MoPH covering the uninsured for the highly expensive hospital care is highly important for those who cannot afford it due to financial constraints, and to minimize the risk of more people falling beneath the poverty line because of hospitalization cost. This intervention by MoPH resulted in lowering the household OOP expenditure on hospitalization below the ambulatory care and medical drugs. A previous study revealed that during the period between 1998 and 2005, the cost of hospitalization on the Ministry's account had increased by only one-third of the increase of number of hospital admissions for the same period; which led to the conclusion that "the MoPH has not only been able to increase its services as an insurer of last resort, but also to manage more efficiently available resources"97.

The ministry, being also a regulator of the health care system, is able to enforce contracting and reimbursement arrangement and tariff

<sup>98</sup> It should be noted that there occur huge humanitarian risks among Palestinians (including the Palestinian refugees in Lebanon), due to political pressures and withholding of USA funds dedicated to UNRWA. 99 MoPH (December 2016), op. cit.

structures. Therefore, it was able to lower co-payments in the public hospitals (5%) when compared to private hospitals (15%).

**3.1** Army,

3.2 Internal Security Forces (ISF), **3.3** General Security Forces (GSF), and **3.4** State Security Forces (SSF), 4. Public mutual funds, 5. Private mutual funds. 6. Private insurance companies, and 7. Other insurers (including UNRWA for Palestinian refugees)<sup>98</sup>.

Most importantly, a unified "Beneficiaries Database" was created in 2003, including beneficiaries of MoPH, NSSF, CSC, and all four military schemes. The unification of beneficiary information, according to MoPH, has reduced double-coverage or double-billing by more than one (public) fund. This "also aimed at simplifying administrative procedures and reducing waiting time for getting the prior authorization of the MoPH for hospital admissions"99.

The law establishing the National Social Security Fund was issued in 1963 and partly enforced in 1964. Rules related to the "sickness and maternity fund" were only put in application in 1971.

The NSSF includes three separate branches: the "sickness and maternity" fund, the "family allowances" fund and the "end-of-service indemnities" fund. All three branches are under the management of the "Director General" and are overseen by 26 members of the "Board of Directors"; which includes ten representatives of employers, another ten representatives of employees, and the remaining six representatives of the state who are appointed by the GoL.

The NSSF mainly covers employees of the private formal sector; whereas those who are not registered at NSSF are considered to be informal employees within the private sector. In addition, the NSSF covers other categories such as: (1) contractual and wage earners of the public sector, (2) employees of autonomous public establishments (specifically, those who are not subject to civil service protection), (3) teachers in private schools, (4) taxi drivers, (5) physicians, (6) university students, (7) newspaper sellers, and (8) elected mayors. The coverage of NSSF expands to include adherents' dependents, including the spouse, children up to 25 years (if single and still in

<sup>96</sup> The Institute of Health Management and Social Protection, in collaboration with MoPH, WHO Lebanon and the Research Council of USJ, "National Health Statistics Report in Lebanon -2012 Edition".

<sup>97</sup> Refer to: Walid Ammar (2009), op. cit.; as the study illustrated that "The number of hospitalization on the Ministry's account has increased from 163,000 in 1998 to 183,000 in 2005 (+12.27%), while for the same period the cost has increased from 187 billion LBP to only 195 billion (+4.28%)".

Besides the MoPH, in Lebanon there are several public and private health care financing agencies: 1. The National Social Security Fund (NSSF), 2. Civil Servants Cooperative (CSC), **3.** Military schemes, including:

formal education), and parents over 60 years living in the same household. It should be noted, that after retirement or when the adherents lose their jobs, they have the right to collect their end-ofservice indemnities; but afterwards, they cannot benefit from the medical coverage (neither do their dependents).

The employer contributes a 21.5% share of the employee's salary, which is distributed among the three different funds, as follows: a 7% share for the "sickness and maternity" fund, 6% for the "family allowances" fund and 8.5% for the "end-of-service indemnities" fund. On the other hand, the employee contributes a 2% share of the salary to the medical scheme. Moreover, the GoL subsidies amount to 25% of the total expenditures of the "sickness and maternity" fund.

Based on article 11 of the 1963 NSSF Law, stating that a voluntary enrollment scheme is to be created in each of the three branches; Decree no. 7352 was issued in February 2002, establishing a "voluntary" section in the sickness and maternity branch. This scheme targets the following workforce segments: former adherents who lost their eligibility after retirement, employers and their relatives, employees excluded from the mandatory scheme, liberal professions and self-employed persons; whereas, the elderly are not eligible unless they had been previously enrolled in the NSSF (current private sector retirees, who retired before January 2017, are not covered by the NSSF). This voluntary scheme covers also family members living with the adherent including children till 18 years. However the spouse of a female adherent is not entitled to coverage unless he is handicapped or unemployed. The contribution is set at LBP 90 thousand per month for employees and self-employed and LBP 135 thousand for employers.

On August 17, 2010, the Lebanese Parliament promulgated law 128, amending the Social Security Law related to Palestinian workers residing in Lebanon who hold work permits benefit from the end-of-service indemnity and workmen compensation; but are excluded from the sickness, maternity and family allowances.

The NSSF directly pays 90% of hospital bills, and reimburses the beneficiaries 85% of costs for ambulatory care and medications; except for cancer drugs that reach a 95% reimbursement rate.

According to its strategic framework for Lebanon, the UN aims to strengthen the NSSF, so as to ensure adequate and sustainable benefits for those covered, in addition to the rest of the most vulnerable Lebanese population<sup>100</sup>.

As of the latest available data by the NSSF, dated on 30/9/2014, the total number of economic establishments registered at NSSF was 47,659 establishments, which constitutes approximately onequarter of the overall number of establishments in Lebanon. Also, the total number of NSSF adherents reached 620,656 (out of which three-quarters are salaried employees), while the total number of dependents amounted to 787,429 beneficiaries. Hence, the total number of beneficiaries covered by NSSF recorded over 1.4 million Lebanese citizens.

With the economic crisis at hand, it is essential to mention that the NSSF has not received the government's share of funding for several years now, and the debt it owns is marked as non-market debt, which means that they might not be handled as a priority or might even be scratched off by the government. Additionally, most of NSSF assets are in Lebanese Pound, raising the question of its sustainability on the long term.

### Civil Servants Cooperative (CSC)

The Civil Servants Cooperative was established by Decree no. 14273 issued in October 1963, as a public institution with administrative and financial autonomy. CSC covers the regular staff of the public sector and their dependents (the total number of CSC beneficiaries is approximately 350 thousand Lebanese citizens). Unlike the NSSF, the CSC covers male spouses, female children as long as they are single, adherent's parents (irrespective of their age), as well as brothers and sisters in certain conditions. And most importantly, eligibility of CSC beneficiaries extends after retirement.

The CSC medical scheme was – initially – set for a transitional period needed by the NSSF to expand its coverage to include the civil servants. In addition to medical coverage, the CSC provides educational and family allowances and marriage and birth assistance.

CSC adherent benefits are set at 90% of hospitalization costs and 75% for out-patient services (including dental care); as for the dependent family members, these healthcare services are only covered to the rates of 75% and 50% respectively. The CSC is the only public fund that imposes a fixed deductible payment upon admission and a progressive copayment ceiling for hospital care.

The greater share of CSC financing comes from GoL (87% of total CSC budget), while the civil servants contribute for the remaining 13% of the budget, which is resourced from a 3% share deduction from their monthly salaries.

## Military Schem

In Lebanon, there exist four military schemes that cover and finance health care services for the uniformed staff members and their dependents. The largest one is under the management of the "Army Medical Brigade", and the supervision of the "Ministry of Defense"

<sup>100</sup> Refer to "UNSF Lebanon 2017-2020", op. cit.

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(MoD), which covered 236,100 beneficiaries including retirees, in the year 2008.

The other three military schemes are under the jurisdiction of the Ministry of Interior and Municipalities (MoIM), are as follows:

- Internal Security Forces (ISF), which covers 126,677 beneficiaries (It is worth mentioning that the ISF scheme includes also 5,201 prisoners);
- General Security Forces (GSF), which covers 16,285 beneficiaries; and
- State Security Forces (SSF), which covers 5,645 beneficiaries<sup>101</sup>.

All military schemes are financed through the GoL budget and have the same coverage rules for hospital and ambulatory care, with 100% reimbursement for the uniformed members, 75% for the spouse and children, and 50% for dependent parents.

#### **Private Insurance**

There are 50 members of private insurance companies within the "Association des Companies d'Assurances au Liban" (ACAL), which represent around 98.9% of total medical private insurance sector. The insurance sector achieved written premiums of USD 1.636 billion in 2017, reflecting an increase by 3.45 percent from the previous year. The distribution of written premiums in 2017 was constant in comparison to the previous two years, and medical premiums accounted for 29% of the premiums total, with written premium volumes of USD 477.4 million in medical insurance. This overall positive performance was notably juxtaposed by negative profit performances in the medical business where profits contracted from USD 21 million in 2016 to USD 12.3 million in 2017<sup>102</sup>.

#### **Mutual Funds**

There are several "Mutual Funds" within both, private and public sectors in Lebanon in addition to self-funded schemes. Some of these funds are complementary to NSSF or MoPH, by covering only copayments; some others receive subsidies from the Government (more than 50% devoted to cover health services). Some are self-managed, while others are contracted-out to a Third Party Administrator. Mutuality Funds represent a small share of the market, covering a mere 2.3% of the population in 1999.

Some of the most well-known mutual funds are the following:

- Mutual Fund for Members of Parliament;
- Mutual Fund of the Parliament employees;
- Mutual Fund for judges;
- Mutual Fund for the Lebanese University professors.

<sup>103</sup> The Institute of Health Management and Social Protection (2012 Edition), op. cit. <sup>104</sup> MoPH (December 2016), op.cit. <sup>105</sup> Refer to: McKinsey & Company (2018), op. cit. The study noted that the calculation of number of beds per 1,000 habitants is "based on Lebanese population only". 106 Ibid.

The total number of adherents in mutual societies reaches 152,809. Among those, less than 25% benefits from NSSF and MoPH copayments.<sup>103</sup>

Hospitals

By the end of the civil war in 1990, only one third of the country's 24 public hospitals, were operational. At that time, they had an average of only 20 beds and very low occupancy rates. Since then, not only has there been considerable investment in public hospitals (28 hospital with 2,550 beds in 2016), but these public hospitals became autonomous enterprises under a 1996 law on public hospitals, which granted them autonomy with independent corporate governance and budgeting. There has also been a rapid and large scale investment in private hospitals. There are now 150 hospitals and (specialist) clinics in the country in total. Moreover, since May 2000, all hospitals have become subject to common external (quality) accreditation (contracted-out by MoPH)<sup>104</sup>.

Nowadays, there are more than 170 hospitals in Lebanon, out of which 85% are private hospitals and 15% belong to the public sectors. All in all, the Lebanese hospitals' capacity is around 16,500 beds or 3.4 hospital beds per 1,000 habitants<sup>105</sup> (which is in line with peer countries). However, according to McKinsey & Company, "Lebanon's healthcare system is highly fragmented and lacks specialization", in particular, the study stressed the following issues: (1) that 60% of private hospitals have less than 100 beds, (2) the majority of hospitals operate as standalone facilities with lack of consolidation into hospital chains across Lebanon, and (3) the majority of hospitals lack specialization, which potentially leads to higher costs, limiting the advantages of the economy of scale (a high value / high quality offerings)<sup>106</sup>.

Private hospitals depend heavily on public financing and a significant portion of private hospitals' financial resources are derived from the MoPH itself. The vast majority of Lebanese hospitals are contracting with MoPH (149 hospitals, out of which some 80% are private hospitals). In 2018, the MoPH subsidized more than 226 thousand hospital admissions and 168 thousand in-patients; almost two-third of them were provided healthcare in private hospitals. Unfortunately, MoPH reimbursement for private hospitals is being delayed, sometimes for a long period of time that extends to 2 or 3 years; which influences mal-practices by private hospital administrations, leading to providing unnecessary health services to patients, over-billing of services (including excess use of pharmaceuticals and medical drugs).

<sup>101</sup> It should be noted that the mentioned number of beneficiaries in each of these military schemes are collected as of May 2008. Refer to: Walid Ammar (2009), op. cit. <sup>102</sup> ACAL, "Market Annual Report", 2017.

#### **OTHER PLAYERS WITHIN THE PHARMACEUTICAL SECTOR**

#### **Table 17: Hospitals Contracting** with MoPH and MoPH Subsidized Admissions and In-Patients, According to Type of Hospitals (2018)

	Type of Hospital	#	%
	Private hospitals	119	79.9%
Hospitals contracting with MoPH	Public hospitals	30	20.1%
	Total	149	100%
	Private hospitals	148,579	65.7%
MoPH subsidized admissions	Public hospitals	77,694	34.3%
	Total	226,273	100%
	Private hospitals	110,118	65.4%
MoPH subsidized in-patients	Public hospitals	58,255	34.6%
	Total	168,373	100%

Source: MoPH.

#### Physicians

There are around 15 thousand physicians in Lebanon or a country ratio of 3.2 doctors per 1,000 capita (which is considered in line with OECD countries)<sup>107</sup>. In fact, many experts believe that there is an over-supply of physicians in Lebanon, leading to a fierce competition within the profession. It is noteworthy, that this "surplus" of physicians is affected by regional imbalances, with higher concentration of physician-to-population ratio in Beirut than other peripheral regions.

The multiplicity of physicians' graduating countries has an impact on guality of healthcare. It is particularly hard to reach a consensus on common medical standards, clinical protocols and drug prescribing preferences among physicians with wide educational background variations<sup>108</sup>.

More specifically, the problem lies in the fact that there is no regulator of medical practice in Lebanon, or checks over doctors' fees or control over physicians' prescriptions. Actually, physicians in Lebanon enjoy the freedom to market/promote any specific drug brand without restrictions, and the heavy promotion of brands by pharmaceutical firms to doctors has created trade name affinity and loyalty. As a result knowledge and use of generic names hardly exists.

The "Service of Pharmacy" at MoPH is responsible of medical drug pricing, according to the ministry's mandate. However, drugs public price lists are examined and determined through a relatively complicated procedure by a special committee that involves all stakeholders, including the head of the "Service of Pharmacy", the head of the "Department of Importation and Exportation of Medicines", and the head of the "Inspection Department" at the MoPH, in addition to representatives of other concerned ministries - the Ministry of Economy and Trade (MoET) and the Ministry of Industry (MoI) – as well as the "State Council" representative. Based on the committee's raised suggestions, the pharmaceutical prices are eventually set in application of a Ministerial Decision.

Article 80 of the 1994 Pharmacy Practice Law requires pharmacists to adhere to prices set by the MoPH. An amendment of this article was issued in Dec 2002 by Law 480 considering the price set by the MoPH as a ceiling not to be exceeded, but that could be lowered.

medicines:

- pharmacies;

Moreover, the pharmaceutical "Inspection Department" controls drug prices in the market, and imposes sanctions against pharmacies practicing over-pricing.

A Ministerial decision no. 361/1 issued in 1971 had re-defined the mechanism for pricing of imported medicines, in accordance with the following criteria:

- price or CIF price;
- set at 10%;

#### ANNEX 4: DRUGS' PRICING MECHANISMS AND PRICE STRUCTURE

The MoPH holds the following responsibilities with regards to pricing

• Setting a price structure that defines freight and mark-ups on landed costs of the imported drugs;

• Determining profit margins for importers/wholesalers and

• Providing for an updating mechanism, whereby a price index is issued regularly to take into account currency exchange rates; • Examining price decreases in the exporting countries, and comparing prices with neighboring importing countries in order to lower the market price accordingly;

• The basis for pricing are set to be, either on the cost price or selling price in the "country of origin"; and the lower price is considered whenever there are differences between the cost and selling prices; • The cost price of the wholesalers of imported medicines is set by adding a 5% tariff and clearance fee, either to the registered FOB

• The cost price of the wholesalers of imported medicines is multiplied by a 143% base;

• The margin of profit for the wholesalers of imported medicines is

<sup>109</sup> In comparison, the average gross

profit margin of retail pharmacy in the

in the year 2018 (refer to the "National

Community Pharmacists Association").

USA was calculated at around 21.8%

#### In English Language:

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- 2019.
- 2020.
- Lebanon", 2013.

- Report-2010.
- opportunities", 2019.
- 2017).

- The profit margin of the pharmacist is set at 30% (this margin of profit has been set in the year 1950, and remained fixed since then)<sup>109</sup>;
- Price conversion indexes are calculated based on foreign currencies exchange rates; the exchange rates are re-considered when a change of the average rate for 3 consecutive months of at least 3% occurs upward or downward.

In principle, the ministry had maintained the right to set a compulsory public price list for medicines, which pharmacies had to abide to. Exceptions to this rule first started in 1968 through the Ministerial decision no. 15/68, when the pharmacies were allowed to sell medicines at lower prices than that determined by the public price list. Later on, the decision no. 150/1 issued in 1978 allowed selling medicines in Lebanon at a lower price conditioned if it is imported and priced at a lower public price in a neighboring country. Afterwards, another decision issued in 1977 allowed any duly licensed entity to import medical drugs, in order to endorse competition.



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