LEBANESE PHARMACEUTICALS AND HEALTHCARE INDUSTRY: INVESTING IN THE PHARMACEUTICAL INDUSTRY TO PROMOTE EXPORTS

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ABSTRACT

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Compared to importation, the pharmaceutical production in Lebanon is still weak. The generics prescription is neglected according to the medicines of origin as only big brands dominate the Lebanese market. Despite the agreements between Lebanon and other Arab countries, the nature of the regulatory environment in the latter is likely to be a substantial obstacle that prevents the access of the Lebanese medicines to the markets of the Arab countries. On the other hand, the development of a new market access remains a necessity for increasing the volume of pharmaceutical exports. This paper aims to demonstrate, based on the Lebanese market analysis the significance of supporting local pharmaceutical manufacturing since it contributes as a primary factor in reducing the cost of the medical bill for citizens, public institutions, and payers. The paper concludes with a set of recommendations to strengthen the pharmaceutical sector as well as to stimulate and develop the local production of pharmaceutical medications.

Keywords: Lebanon, Pharmaceutical Manufacturing, Pharmaceutical Sector.

INTRODUCTION

The pharmaceutical industry is in a constant rise in the Arab world as most Arab countries have been able to build their regulatory capacities in the fields of registration and control in this market. Lebanon realized several achievements over the last years in strengthening the capacity of the Ministry of Health in the registration of medicine, the adoption of full transparency in administrative work, and the development of tools to ensure the quality of pharmaceuticals.

A recent achievement was the development of regulatory capabilities for Good Manufacturing Practice (GMP) assets and the issuance of Good Storage and Distribution Practice (GSDP) guidelines. “In the coming years, the pharmaceutical market in Lebanon will grow slightly, pushed on by rising household’s incomes and enhancing access to healthcare”

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(Business Monitor International, 2018). High per capita spending, public's preference for originator medicines and increasing chronic disease burden, are the triad to ensure and enforce the demand for patented medicines. Though, the small Lebanese population size, the rigid pharmaceutical pricing regulations and the high level of political risks continue to be high constraints for the market.

Despite the several achievements in the healthcare industry, Lebanon has limited local pharmaceutical production capabilities and will, in this way remain intensely dependent on imported medicines. Due to its dependency on imported pharmaceuticals, the Lebanese medicine market will continue to be overwhelmed by multinational and foreign manufactures which lead to an increase in the cost of the medical bill. Hence, Lebanon's status as a destination for inventive pharmaceutical unveilings in the Middle East and North Africa (MENA) region is dominated by the bigger regional players with higher pharmaceutical consumption, as reflected in the nation's score of "49.5 out of 100 in Innovative Pharmaceuticals Risk/Reward Index" (Lebanon Pharmaceuticals & Healthcare Report, 2018).

Accordingly, it is a vital concern to encourage the local pharmaceutical manufacturing industry by pointing the importance of reducing the cost of the medical bill on the citizens, public institutions, and payers through giving preference to the local pharmaceutical industry.

As reported in the Business Monitor International Report (2018), Lebanon's pharmaceutical sales represented 3.5% of GDP and 49.3% of healthcare expenditure in 2016. Pharmaceutical sales increased from LBP2.60trn (USD1.73bn) in 2016 to LBP2.75trn (USD1.82bn) in 2017, representing local currency y-o-y growth of 5.7%.

It was projected that by 2022 the healthcare spending would reach $5.10 billion, experiencing a compounded annual growth rate (CAGR) of 4.2%, and the total pharmaceutical sales to amount to $2.32 billion which would correspond to a compound annual growth rate (CAGR) of 5.0% and 3.5% of GDP. Moreover, the spending on pharmaceuticals was expected to increment to LBP4.74trn (USD2.84bn) over the 2016-2026 period (Business Monitor International, 2018). However, the escalating financial crisis in Lebanon along with the recent incapability of Lebanon's central bank, Banque Du Liban, to subsidize all drug imports has led to a series of market weaknesses accompanied with high reliance on overhead spending. This ambiguous environment of the pharmaceutical market and fears of an intensifying financial crisis discouraged drug export to Lebanon and resulted in supply complications (Baggili, 2021).

Hence, a tourough analysis of the Lebanese pharmaceutical sector is a key pillar for understanding the potential and the limitation of the industry as well as providing the corresponding recommendations to be implemented by the Lebanese governments in order to stimulate the local pharmaceutical production and its export. This study contributes as well to the pharmaceutical research by partially filling the gap that exist from lack of pharmaceutical evaluative studies in developing countries versus developed countries (Nguyen et al., 2015).

Literature Review

The Lebanese pharmaceutical industry possesses several success factors which contribute to its competitive advantage. According to the Global Competitiveness Report 2016, Lebanon is ranked 18th worldwide in quality of the education system and sixth worldwide in quality of math and science education (WEF, 2016). Every year, Lebanon supplies local, regional, and international markets with approximately 3,000 graduates in the field of pharmacy. Moreover, Lebanon is a donor country of medical doctors and physicians and with the highest immigration factor in the Middle East and North Africa (Akl et al., 2008). Prior to the war in Syria, there has been an oversupply of physicians in the Lebanese market which continued to fluctuate even after the influx of refugees from Syria to Lebanon (Ammar et al., 2016).

Lebanon is considered a health hub in the Middle East with a robust healthcare sector. It was ranked 34^{th} with a score of 6.8 out of 7 in the Global Competitiveness Report 2016-2017 published by World Economic Forum. Lebanon was also ranked the healthiest country in the Arab world by Bloomberg 2017 Healthiest Country Index which also confirms the good performance of its healthcare system (Ministry of Public Health [MOPH], 2018a). The hospital beds density in Lebanon is 3.5 beds per 1,000 individuals. Likewise, the medical doctor to population ratio is 3.5 physicians available per 1,000 individuals. Both figures are the highest in the Arab world making Lebanon a primary performer in the field of healthcare both regionally and worldwide (Bank Bemo, 2013).

The pharmaceutical market is characterized by its fast-growing nature. The pharmaceutical industry in the MENA region witnessed a continuous growth in the last years and is expected to grow exponentially in the coming years and be valued at circa. $60B by 2025 (Burton, 2019).

Moreover, the strategic geographic location of Lebanon adds a logistic advantage to the Lebanese pharmaceutical market by allowing a feasible and timely access to the Middle East, Europe, and Africa.

On the other hand, there are several barriers that hinder the development of the Lebanese pharmaceutical manufacturing, dominance in the local market and expansion in the regional and international markets.

While the Lebanese pharmaceutical market consists of 175 players, only 11 are manufacturing companies and the rest are importing companies. Thus, imported products satisfies 95% of domestic demand while local products satisfy only 5% (Bank Med, 2014). This imbalance between importing and manufacturing companies creates a heavy barrier to the development of the Lebanese medicament and its potential share in the local market. The main importing countries of pharmaceutical products are France, Germany, Switzerland, and USA. This fact makes foreign drug producers the primary beneficiaries of any increase in the Lebanese pharmaceutical expenditure, noting that until recently Lebanon has been an important export market and one of the largest spenders on pharmaceuticals in the MENA region as GDP percentage (Yan, 2017).

Limited production efficiency and high production cost are other restraints which add to the total bill. According to Carol Abi Karam, President of the Syndicate of Pharmaceutical Plants, "*Quality costs. If we do not grow our market, how can we decrease our prices further and further*?" (Yan, 2017).

The nature of the Lebanese pharmaceutical producing industry, as it is a generic industry, is another factor that draws a barrier to its ability to compete in foreign markets. As per Raymond Sayegh, president of the Order of Physicians *"The Lebanese industry is a generic industry, which means we reproduce drugs five years after they launch, when we have the rights"* (Yan, 2017). Accordingly, the Lebanese drug manufacturing market is lagging and not entering a parallel competition with other drug manufacturing countries.

The legal structure that governs the Lebanese pharmaceutical market and the lack of government protection make the prospective growth and development of the Lebanese drug in the local market and its export potential limited. One of the purposes of the recently founded Syndicate of the Pharmaceutical Manufacturers in Lebanon comes as a reply to this lack of protection. The syndicate first purpose is "protection, promotion and enhancement of the profession, safeguarding of its interests, representation of the pharmaceutical manufacturing business before all public authorities and contribution to its advancement at all legal, regulatory, economic, industrial, commercial and social levels" (MOPH, 2018b).

Moreover, the registration of the Lebanese medicament in potential importing countries adds another constraint to the ability of exporting Lebanese pharmaceutical products. According to the former Industry Minister Hussein Hajj Hasan in the National Campaign to Support Lebanese-made Pharmaceuticals, *"regrettably, many Arab and foreign countries make it very difficult to register Lebanese-made medications and drugs. That makes it nearly impossible to export them to these states"* (Yan, 2017). Noting that the Arab countries constitute around 80% of the demand for Lebanese pharmaceutical exports. The main importing countries of the Lebanese drugs are Saudi Arabia, UAE, Iraq, Jordan, Kuwait, France, Egypt, and Yemen.

Another reason that weakens the credibility of the Lebanese pharmaceutical product and its potential export is the existence of counterfeit medications. The Lebanese Ministry of Public Health (MOPH) has established quality standards to guarantee the delivery of a safe, efficient, and acceptable drug to the consumer (Al Rahbany, 2018). The Good Manufacturing Practices tackles storage and distribution practices of pharmaceutical products, laboratory practices for pharmaceutical quality control as well as other regulations (MOPH, 2018c). Despite the efforts executed by the Ministry of Public Health, the counterfeit medication continues to be an existing problem in the market. 10 out of 23 ministerial decrees issued by the Minister of Public Health in the three-month period of August, September and October 2018 were related to counterfeit and smuggled medications (MOPH, 2018d).

In addition to the restraints in the local market, regional competition contributes to the impediment of exporting the Lebanese drug regionally and internationally.

MATERIALS AND METHODS

The study combines qualitative primary research and secondary research. The sampling approach for the qualitative method was purposive as respondents were selected based on their roles and experience in the Lebanese pharmaceutical field and related fields including academics as well as managers of pharmacies, medical centers, and pharmaceutical distributors (Saunders et al; 2019). Semi-structured interviews were conducted to guide the interviewees in their talk (Saunders et al., 2019) while open-ended questions allowed for obtaining in-depth information (Berg, 2004), as shown in Table 1. Of the eight individuals who were contacted, five were interviewed as shown in table 1. As for secondary data research, data were collected, summarized, and collated following Saunders et al. (2019). Since the qualitative analysis and desk research we conducted on the pharmaceutical industry led us to use interpretivist methods, we implemented an inductive approach in our analysis and recommendations with a focus on weaknesses, challenges, and barriers. Note that implications of the coronavirus and Beirut Harbor blast on the Lebanese pharmaceutical sector are considered in (El-Bacha, 2020a; Gerges, 2020). Furthermore, the origins of the pandemic are discussed by Huang et al. (2020). Regionally and globally, impediments caused by the virus and the Beirut Harbor blast on the sector were discussed by El-Bacha (2020a), Gerges (2020), and Rogoff (2020).

Table 1. Profiles of respondents

Respondent	Title/Position	Length of interview
Respondent 1	Associate professor	33 minutes
Respondent 2	Associate professor	40 minutes
Respondent 3	Owner and manager of a pharmacy	25 minutes
Respondent 4	Manager at a drug distributing firm	23 minutes
Respondent 5	Purchasing manager at a medical center	28 minutes

RESULTS

Therefore, our findings point out the weaknesses, challenges, and barriers that the Lebanese pharmaceutical sector is facing.

Weaknesses and challenges

Lebanon is characterized with economic instability and low salaries. In addition to severe flaws in the national health coverage as the national payers are gradually eroded under debt. According to Drug Importers' Syndicate, Karim Jabara, Lebanon is facing shortage in supply due to mounting news on the state's bankruptcy and inability to pay its accumulating bills, a condition that deters drug exporters from supplying the Lebanese market (Baggili, 2021).

Moreover, the Lebanese healthcare system is diverse in terms of delivery channels, almost half of the population is financially covered by the National Social Security Fund, an autonomous public establishment, and other governmental bodies such as military schemes, the Civil Servants Cooperative, or private insurance companies (Ramadan et al., 2019). Over the years, the Lebanese healthcare system and has faced a series of challenges, including civil and regional wars and ongoing geopolitical conflicts and changes which impacted its infrastructure (Mathers and Deonandan, 2018). The escalation of the war in Syria resulted in a tremendous influx of refugees which reached more than 1.5 million, representing a 30% increase in the Lebanese population by the end of 2015. Such sudden increase burdened the capacity of the health system. By 2014, the Syrian nationals comprised around 35% of the beneficiaries for primary national healthcare (Ammar et al., 2016).

Another major weakness that prevents the pharmaceutical sector from being efficient and from reaching its full potential is the shortcomings of the domestic intellectual property (De George, 2005). The failure of the Lebanese government to develop a domestic patent law constitute a prominent weakness and obstacle. MOPH suggested an amendment to the Lebanese Patent Law. According to International Trade Administration (2021), the sale and distribution of pirated, counterfeit, and copycat products which includes pharmaceuticals remain existing throughout Lebanon.

We identify as well that several multinational companies often are unwilling to launch the latest drug in the Lebanese market due to lack of market restrictions wherein some Lebanese companies register and market unauthorized copies of original innovative products (El-Jamal et al., 2020).

Counterfeit medicine remains a major problem in the pharmaceutical sector. According to one respondent *"several practices are tied to the classification of counterfeit medicine in Lebanon. Of which is the importation of generic medicine. In some cases, the counterfeited medicine does not contain the same active material or the same pharmaceutical composition as in the original medicine. Other practices include expired medicine, medicines that are not registered by the MOPH, smuggled medicine, drugs prohibited from trading, or fraud in pharmaceutical ingredients".*

Another weakness in the system is the purchase of medicines by the Ministry of Health which is in favor of some distribution companies. One respondent highlighted the fact that the drug approval process by the MOPH is more facilitated for certain distribution companies which can be attributed to gaps and ambiguity in the system and lack of accountability.

Alongside, the country remains almost fully dependent on imported pharmaceuticals (Ramadan et al., 2019). The Lebanese market is dominated by 164 importing agencies represented by Lebanese Pharmaceutical Importers Association (LPIA). Meanwhile, only 10 manufacturing companies (Alfa labs, Algorithm, Arwan, Benta Pharma, Chapha, Medipharm, Mephico, Pharmadex, Pharmaline, Pharma M) exist in the market and are recently represented by the Syndicate of the Pharmaceutical Manufactures in Lebanon (founded in 2016). Parallel importation weakens the local Production. Moreover, the reliance on foreign assistance in the pharmaceutical industry hinders the accuracy of evaluating the performance of this sector and contributes to the lack of retrieving accurate industry data (Ramadan et al., 2019). Hence, despite the strengths and opportunities of the health sector in general, the imbalance between drug importers and local producers in terms of market dominance significantly hinders the prosperity of domestic production. It is worth mentioning that the MOPH contributed toward supporting local production by promoting the use of generic medications and providing higher profit margins to local manufactured and packaged generics (Abdel Rida et al., 2019).

Moreover, and after extended desk research, a critical weakness is a defunct bureaucratic procedure that experts in the medical sector believe to paralyze this sector similar to other sectors. The consequences of this bureaucratic procedure were paramount in the past few months (Massoud, 2021). Coupled together, these factors seriously impinge the pharmaceutical sector.

Barriers

The pricing in Lebanon discourages foreign direct investment. For medicines priced based on external reference pricing (ERF), Lebanon adopts the lowest price available among neighboring and basket countries; basket one is composed of seven European countries (France, UK, Belgium, Switzerland, Italy, Spain, and Portugal), basket two is compose of neighboring countries, in addition to country of origin (Abdel Rida et al., 2019). In 2014, the MOPH revised its methods and requirements for drug pricing and distribution. The revised measures caused a deduction in the revenues of multinational companies (MNCs) which resulted in a downsize in their investment and a discouragement of introducing a new medicine (Ramadan et al., 2019).

Moreover, the overall market value is affected by the price reduction on particular pharmaceutical medications (Baggili, 2021). The escalating financial crisis, spearheaded by the exchange rate that caused a loss of around 85% of the value of the LBP against the USD since 2019 accompanied with the absence of an established national pharmaceutical policy and the rise in black market medicine trade all contribute to additional mounting challenges (Abdel Rida et al., 2019). On the lack of national pharmaceutical policy, one respondent stated "

Uncertain political situations remain the primary obstacle of foreign investments (Hjeij, 2021; Massoud, 2021; Zreik, 2021) and impedes most economic development projects. The turbulence in Lebanon and the Middle Eastern region negatively affects revenues generated from medical tourism as well (Noaman & Chapuis, 2021; Hassan, 2017; Chatterjee, 2022) Finally, Covid 19 and other diseases also constitute major challenges to the pharmaceutical industry in Lebanon. (Huang et al., 2020; Chatterjee, 2022). Finally, a major impediment is the one discussed by Baggili (2021) which pertains to the Lebanese Central Bank's lack of vision in maintaining its policies regarding the procurement of medicines, as it is doing so at an unsustainable rate whilst severely eroding its reserves.

DISCUSSION

The Lebanese pharmaceutical market is 95% dependent on imported pharmaceuticals (Bank Med, 2014), noting that the most significant regional drug makers are located in Jordan, Palestine, and Syria.

It is assumed that Lebanon will keep spending a vast extent of GDP (3.4% in 2021) on pharmaceuticals over the medium term (cf. Chaaban, 2019; Hobeika, 2019). This is the highest level in the Gulf, Levant, and the seventh highest globally. The following four major reasons explain Lebanon's healthcare and pharmaceutical expenditure and characterize its industry vis-à-vis other countries in the region:

1- The private healthcare care sector composes 90% of Lebanon's hospitals and pharmacies. This leads to the prescription of high-priced medicines, as fixed mark-ups on drugs often promote irrational patterns and prescriptions.

2- The absence of consolidation among the Lebanese pharmaceutical distributors, combined with fixed mark-ups imposed by the government eliminating the possibility of competition and economies of scale by keeping the drug price relatively high.

3- Medical tourism has become an increasing element of tourism in Lebanon and its contribution to the Lebanese economy. As reported in the BMI (2018), 1.5 million plastic surgery interventions are conducted each year in Lebanon.

4- The country remains almost fully dependent on imported pharmaceuticals in terms of value. Key drivers of overall market growth showing explicitly an increase in healthcare disbursement, joint with population and rejuvenation of the health care industry (OECD, 2020; UNWTO, 2020). Economic recovery can boost private sector coverage, leading to rise in pharmaceutical expenditure. Over the longer term, the economy is expected to reach a recovery period boosting the private sector coverage. In such scenario, it would positively affect the spending capacity of private and public sectors as well as attracting more medical tourists (UNWTO, 2020).

On the other hand, aside from funding difficulties and the low purchasing power of most of the Lebanese citizens, the nature of the regulatory environment is probably going to be another vital parameter that limits the growth level in the short term.

At present, inadequate legislation and negligent implementation of the existing regulatory system have a negative impact on world's direct investment, with numerous international operators' content to negotiate licensing agreements with local drug makers, instead of investing in direct production (Hjeij, 2021).

As for generic medications, which constitute the most important inducement to stimulate the local production of the pharmaceutical industry, the production is still limited due to the lack of consumer confidence in the generic medication as well as the trend of doctors to prescribe the principal drug for personal and commercial interests (Al Rahbany, 2018). Currently, the government continues its attempts to control the cost of the healthcare bill, seek achieving a number of goals in pricing strategy, and promote generic (substitute for the branded) medication through supporting providers and educating patients, especially on Covid 19 matters (see: OECD, 2020).

To stimulate and strengthen the pharmaceutical sector, Lebanon has signed several partnership agreements that aim to bring economic bilateral benefits to Lebanon and the corresponding countries (Ramadan et al., 2019). Some of the bilateral agreements are:

1. FTA (Free Trade Agreement) with Iceland, Switzerland, Norway and Liechtenstein which took place in 2004 and became effective in 2007.
2. GAFTA (Greater Arab Free Trade Area) with Egypt, Iraq, Jordan, Kuwait, Libya, Morocco, Oman, Qatar, Saudi Arabia, Sudan, Syria, Tunisia, Yemen, UAE and Palestine.
3. GCC and Iraq (The Gulf Cooperation Council) approved in 2000.
4. EU (European Union) which became effective in April 2006.

Despite the enormous efforts put by the government to control the pharmaceutical sector, there remains an absence of national pharmaceutical policy. Furthermore, in view of the bankruptcy of the state of Lebanon and the inability to continue subsidizing the imported drug, the wholesale removal of medicine subsidies further complicates an already existing crisis in healthcare provision. On the other hand, such consequences highlight the importance of developing a nation-wide strategy that aims to support local pharmaceutical production in an effort to contain the chaotic environment and decrease the burden of subsidizing imported drugs.

Contributions and recommendations

This evaluative study contributes to the pharmaceutical literature in developing countries which until this date remains scarce. The findings were consistent with previous research that investigated the Lebanese pharmaceutical sector. More precisely, they confirm the outcomes of Ramadan et al. (2019) on the ambiguous pricing strategy and the high need for health economic data. They are consistent with Abdel Rida et al. (2019) with respect to absence of an established national pharmaceutical policy.

After the detailed analysis of the health sector in general and medications in specific, following are the proposals and recommendations that would help flourish the Lebanese pharmaceutical market and stimulate and develop the local production of the pharmaceutical medications:

Communicating the value of the local medication to a wide range of customers who lead access. Promoting the local pharmaceutical manufacturing by pointing out to all involved stakeholders the importance of reducing the cost of the medical bill on the citizens, public institutions, and payers and by giving preference to the local pharmaceutical industry in MOPH approval processes. Furthermore, encouraging local production of the pharmaceutical product by the MOPH via subsidizing the infrastructure and the cost of production as well as supporting innovation and research. On product level, research can be encouraged by supporting clinical trials for a better identification of new potential drugs. Academic-corporate collaborations can be established between the Lebanese University (and other private universities) and local manufacturers to satisfy the market needs more effectively.

Developing a new market access system that provides a comprehensive engagement by understanding the needs of all stakeholders in the acquisition (consistent with Ramadan et al., (2019)), ranking, and funding of the Lebanese products.

Regionally, striving through negotiations, agreements, and reciprocity to remove the obstacles imposed on the registration and importation of Lebanese manufactured medicines by the health authorities of regional countries (ex: Iraq, Jordan, and other regional countries). Such initiatives can be commenced by practical collaborations with the League of Arab States as well as Health Departments in Arab countries to enforce receiving and registering the Lebanese drugs in their respective countries. Parallel efforts can be projected to provide accessibility to European markets.

Encouraging NGOs, such as the UNICEF and other associations that help refugees to acquire Lebanese medicine through tendering processes and decrease reliance on imported medicines.

Finally, reforming the healthcare industry on the level of pricing, reimbursement, and safety which would support the acceptance of the Lebanese production and facilitate a healthy and pharmaceutical marketplace.

CONCLUSION

Despite possessing several success factors represented by its human resources, logistical advantage, and fast-growing market, it was indeed found that the Lebanese pharmaceutical industry suffers from weakness and faces many challenges and barriers that mounted since the country’s financial crisis in October 2019 and during the pandemic. A major challenge noted in this study is the abundance of overpriced original medications, a lack of the generic substitutes, and absence of national sector policy.

Foreign direct investment in Lebanon is obstructed by the concern of counterfeiting, the culture of corruption, and the ambiguity of information and pricing systems (El-Hajj, 2020; Hjeij, 2021; Massoud, 2021; Chaaban, 2019). Moreover, the recent incapability of subsidizing imported medicine and sustaining a steady pharmaceutical supply increase the national burden and further deprive citizens from their right to be treated. Overall, such circumstances necessitate a shift away from reliance on imported medicine and a focus on supporting local production.

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