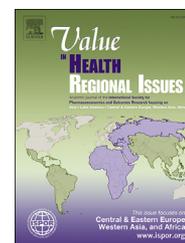


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Health Policy Analysis

Requirements for a Successful Drug Launch in Small Markets: A Pilot Study in Lebanon

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ABSTRACT

Objective: This study assesses the impact of an uncertain environment on pharmaceutical companies in Lebanon and investigates how they are launching new drugs despite Lebanon's economic instability, lack of data, low base salaries, and frequent drug repricing regulation adopted by Lebanese health authorities. **Methods:** A cross-sectional descriptive survey was conducted in a multinational pharmaceutical company in Lebanon. Employees were asked to complete a questionnaire between June and July 2017. Chi-square testing was used to check correlation. **Results:** Seventy-seven employees participated in this survey. Thirty-two (41.6%) emphasized the need for partnering with stakeholders. When asked about the activities to be improved, 17 (22.08%) stated that early stakeholder engagement was key to ensure launch success. Regarding the hurdles facing pharmaceutical companies, 35 (45.7%) indicated that patient access to the new medication was the key challenge, 19 (24.68%) agreed that tailored market access

programs should be planned before actual launch, and 30 (38.96%) realized the need to demonstrate clinical and economic value of the product using health economic data. Finally, 39 (50.64%) agreed that launch failure was linked to poor pricing strategy. **Conclusions:** Major challenges facing pharmaceutical companies under Lebanon's uncertain environment did not hinder companies from bringing innovative products. A partnership among decision makers, consumers, and pharmaceutical companies is the most efficient method to ensure future access to new and innovative drugs.

Keywords: launch, pharmacoeconomics, pharmaceutical companies, unstable environment, payers, market access

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Introduction

Lebanon is classified as an upper-middle income country. According to the latest statistics conducted by the Ministry of Public Health (MoPH) in 2016, the estimated population was around 4 356 000. The total gross domestic product (GDP) was 76 518 billion Lebanese pounds, equivalent to approximately \$51 012 million compared to an Organisation for Economic Co-operation and Development country such as Germany, which had a GDP equal to 3 699.97 billion during the same year. The GDP per capita accounted for around \$11 711. In 2012, the total health expenditure per capita was \$751 and the government allocated 2.6% of its budget for health. These numbers do not take into consideration the refugees and the undocumented residents because it is extremely difficult to gather any accurate data on this population.¹

In 2016, the pharmaceutical market in Lebanon was estimated to be worth \$1.75 billion, and it is projected to grow to reach a value of \$2.20 billion by 2020. Lebanon's pharmaceutical

sales are the largest among the Middle East and North Africa region and accounted for 3.22% of the national GDP in 2016. Patented drugs took a share of 61.6% of prescription sales and 49.5% of total sales in 2016, whereas spending on generics remains low at \$539 million and is expected to grow to reach \$734 million in 2020.²

All medicinal products must have marketing approval (registration) before being imported or sold. In 2017, 5833 drugs were registered and marketed, of which 78.5% were imported and 21.5% locally manufactured. The Lebanese pharmaceutical market comprises 164 importers and 11 manufacturing facilities and is regulated by the MoPH through a set of policies and regulations. According to the Lebanese Law #367/1994 regarding the Practice of the Profession of Pharmacist, all pharmaceutical products must be registered at the MoPH whether being manufactured locally or imported, and any production, importation, or distribution of drugs that is not controlled by the MoPH is considered illegal.³

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According to the World Health Organization, health systems are undergoing rapid change and the requirements for conforming to the new challenges of changing demographics, disease patterns, and emerging and reemerging diseases coupled with rising costs of healthcare delivery have forced a comprehensive review of health systems and their functioning.⁴

In Lebanon, the healthcare system is facing many challenges including economic instability, lack of healthcare data, a fragmented healthcare system, frequent repricing regulation, and an aging population associated with an increased demand for healthcare.

Lebanon is characterized by a highly fragmented healthcare system. Almost half of the population is financially covered by the National Social Security Fund, an autonomous public establishment, and other governmental bodies like the Civil Servants Cooperative, military schemes, or private insurance. These bodies provide financial coverage with variable patient copayment schemes. The MoPH covers the rest of the population.⁵

Economic Instability

Affected by the Syrian crisis, the plunging economic growth in 2011 highly influenced the Lebanese purchasing power. The ability to consume declined in almost all sectors including healthcare. This affected Lebanon's total health expenditure, which declined from 10.7% in 1995 to 6.6% in 2011.⁶ Therefore, the percentage of budget spent on total health expenditures decreased significantly during this decade in all health-related sectors.

The Lebanese MoPH has developed a strategy to decrease the GDP share of total health expenditures accounting for 12.4% in 1998 by specifically targeting out-of-pocket spending estimated at 60% of total health expenditures.⁷ It succeeded in significantly reducing health spending while improving health indicators through strengthening primary healthcare and relying particularly on essential generic drugs.⁸ Total health expenditures reached 7.2% of GDP and out-of-pocket spending declined to 37% of total health expenditure in 2012.⁹ In comparison, 18% of the GDP in the United States is spent on healthcare¹⁰ versus an average of 9% in Europe.¹¹

Despite efforts to periodically revisit the price structure of all drugs, spending on pharmaceuticals remains as high as 43% of total health expenditures and represents a high burden on households, exceeding 50% of their expenditures on health.¹² Therefore, the Lebanese MoPH started new initiatives to optimize budget allocation, cover hospital inpatient expenditures of uninsured patients, and provide eligible patients with drugs for free for severe diseases through a public drug-dispensing system. The MoPH has also developed an important line of work for rationalizing the pharmaceutical circuit: improved procurement and drugs registration, pricing, marketing authorization, goods storage, and distribution practices; unified prescription promotion of the local production and generic drugs; and introduced barcoding.¹³

According to the MoPH, once the drug has been approved, its export price must be lower than its cost upon leaving the factory where it was made. The export price must also be lower than a group of reference countries in the Middle East and North Africa region and certain European countries. The drugs are divided into 5 classes according to their price range based on an ascending range of prices between \$10 and \$300. Each category is subjected to 4 groups of markups: freight insurance, customs and clearing expenses, importer's and distributor's profit margins, and the pharmacist's margin. The markup percentage increases with the increase in the base price. These prices are

subject to a 5-year routine revision. If the international price of a drug is slashed for whatever reason abroad, the distributor is responsible for alerting the MoPH so the price in the Lebanese market is adjusted accordingly. Failing to do so could lead to legal consequences.

In 2014, the MoPH released a revised version of the methods and requirements for drug registration and pricing. The impact of these measures meant a decline in the revenues of multinational companies (MNCs) and a drop in their investment in Lebanon, which is enough to render the country's market a non-attractive market for investment. This has consequently discouraged the introduction of new medicines.

Besides, Lebanon lacks information on disease prevalence, outcomes, costs, and the social determinants of health in general.¹⁴

Lebanon's Healthcare System and Drug Pricing Strategy

Lebanon has a fragmented healthcare system characterized by multiple sources of funding and channels of delivery.⁵ Pharmaceutical companies have the obligation to approach each payer independently and to offer unique solutions for each, a process that is costly and often time-consuming. The pricing system is changing as well. The old price system (1983) established a fixed percent of profit margin for all price brackets, encouraging the importation and dispensing of expensive drugs and overpricing to maximize profit. Two ministerial decisions issued by the MoPH in 2005 had a considerable impact on the pricing structure. Decision 301/1 adjusted prices based on comparison with neighboring countries (Jordan, Saudi Arabia).¹⁵ This reduced the prices of 872 drugs an average of 20%, saving \$24 million per year. Decision 306/1 established a new stratified pricing structure, with lower and descending markups.¹⁶ This decreased prices by 3% to 15% per product, an estimated saving of \$27 million per year. It also introduced a mechanism for periodic price revision. The price revision targeted 1109 drugs by 2007 and lowered the public price of 360 drugs with a yearly savings exceeding \$10 million. More recently, decision 728/1 in 2013 targeting the decrease in generic drugs prices has led to the reduction in prices of 629 drugs by 21%.¹⁷ The introduction of a new category E in addition to the repricing mechanisms by decision 796/1 in 2014 has led to an automatic decrease in the prices of 261 drugs by 17%.¹⁸ Price decreases will continue to take place automatically in parallel with the periodic repricing mechanism. Exporting governments justify these price reductions as means of increasing medication affordability and promoting a sustainable healthcare system. Nevertheless, pharmaceutical companies fear that decisions on price cut will lead to more price revisions and will eventually affect their yearly profits.¹⁹

The objective of this study is to understand how the employees in an MNC view and deal with an uncertain environment in a small market like Lebanon and to describe how these MNCs are still able to launch therapeutically innovative products (products that provide clinically significant benefits not provided by medications currently on the market) despite the challenges of gaining authorization and Lebanon's economic challenges.

Methodology

Study Design

A cross-sectional design using a relevant sample and a well-structured questionnaire was adopted to address the objective

Table 1 – Variables associated with launch excellence.

Variable	Total Participants N = 77 n (%)
What is the key success factor for drug launch?	
Internal readiness	23.4
Robust situational analysis	10.4
Differentiated product	15.6
Launch readiness preparation	9
Early key stakeholder engagement	41.6
What is the challenging external factor?	
Local registration and reimbursement	46.7
Building advocacy with healthcare professionals	26
Differentiation versus competition	19.5
Patient awareness	7.8
What is the most reliable source of data?	
Health economic data	38.9
Patient data	16.9
Primary market research	14.3
Clinical data	29.9
What factor mostly causes drug launch failure?	
Poor Launch readiness plan	15.6
Poor launch strategy	16.9
Limited resources	9.1
Poor pricing strategy	50.6
Inadequate positioning and patient targeting	7.8
What is the impact of company profile?	
The company that embraces quality and innovation	57.1
Multinational company	23.4
Local companies must exert extra efforts	11.7
Individuals' competencies not the company	7.8
What are the skills/activities to be improved?	
Proper training of available clinical trials	15.6
Market understanding	7.8
Well-tailored market access programs	24.7
Understanding patient journey and medical needs	11.7
Stakeholder early engagement	22.0
Cross-functional collaboration	18.2

of this study. Participants included employees in an MNC that had an announced product launch during summer 2017. The survey was conducted during June and July 2017, 1 month before the planned launch of said new drugs.

The study targeted all employees involved in the launching process at the specified company.

Data Collection Method

The questionnaire was sent by email to 100 employees from different departments, excluding those unrelated to the launch process such as human resources, receptionists, technologists, cleaners, and cooks. It also excluded 14 trainees, employees who were not present at the company during the study period, and 3 who claimed to have not witnessed a launch before. Eighty-three eligible participants were included, from which a total of 77 (92.8%) responses were collected.

Study Tools and Approvals

The questionnaire was designed based on a thorough review of the similar literature. A related survey done by IMS-Health in 2013²⁰ was the main source for setting the questions. A pilot test was conducted on a group of pharmacists not involved in the study.

The questionnaire was presented to the compliance department in the pharmaceutical company for approval. The company had already given its consent and was made aware of the aim and general results produced to ensure there was no conflict of interest. A written consent form was signed by the participants to indicate their agreement to participate in this study.

The questionnaire was designed to address the following:

- participants' sociodemographic characteristics and employees' profiles
- key success factors for drug launch
- reasons behind drug launch failure
- challenging factors facing pharmaceutical companies during drug launch
- the most important source of data used in the preparation for a drug launch

Data Analysis

Results obtained were analyzed using the Statistical Package for the Social Sciences, and the chi-square test was used to check the correlation between the level of experience and the choice of answers to questions related to the key success factors, challenging external factors, and the most important source of data used. A *P* value <.05 allows the rejection of the independence hypothesis that states that 2 compared variables are independent. Thus, the variables being compared are dependent. The analysis also used chi-square to test the link between the number of launches witnessed and the choice of answers provided by the employees.

Results

Participants' Sociodemographic Characteristics and Employees' Profiles

Of 83 eligible participants, 77 (93%) were included in the survey with sex proportions of 39 (50.65%) men and 38 (49.35%) women. Among the respondents, 19 (24.68%) had experience of 11 years or more, and 74 (96.1%) had previously launched at least 1 product. The participants were selected from different departments, including medical (30%), marketing (20%), market access (10%), commercial (25%), and quality (15%).

Variables Associated With a Good Launch

The company defined a successful drug launch in terms of meeting sales expectation for a newly launched drug. The variables affecting a good or successful launch as judged by the group are shown in [Table 1](#).

According to the respondents, the most frequent enabling factors are early key stakeholder engagement including engaging with bodies such as the MoPH, the National Social Security Fund, governmental bodies, private insurance companies, and patients (41.6%) with tailored market access programs. All of the preceding factors take into consideration setting a proper strategy for pricing, showing value for effectiveness and understanding of the target purchasers' needs (24.68%), and having a company that embraces quality and innovation within its culture (57.14%). The strongest obstacles facing MNCs and hindering their success included the complicated processes of drug registration and reimbursement (46.7%), the unavailability of reliable data to develop health economic evidence needed to demonstrate the cost-effectiveness, the return on investment a medication provides and therefore its unavailability to support a launch (38.96%), and the adoption of a poor pricing strategy that fails to meet the customers' perception of a drug's value and to take into consideration the stakeholders' capabilities (50.64%).

Correlation Between Successful Launch and Key Variables

Experienced employees (11 years or more) have noted that early key stakeholder engagement, local drug registration and reimbursement, and health economic data are important factors for a successful drug launch.

Thus, there was no correlation between the 2 variables ($P < .001$), and the choice of answers was independent of the number of launches witnessed.

Discussion

Launching of a new product is an expensive and risky stage in the process of its development. Nevertheless, until recently, few studies were conducted to address drug launch readiness processes in small emerging markets like Lebanon.

Previous literature²¹ aimed at setting a short checklist presenting the critical activities needed to be done during the launch. It explored the associations between sets of decisions taken during the launch. Benedetto²¹ focused on identifying which activities are associated with launch strategies and launch tactics. The results showed that early stakeholder engagement is considered a key to launch success. Our findings are in line with previous literature where according to Jones,²² pharmaceutical companies need to understand the insights of patients and local physicians regarding a certain medication and understand if it satisfies their unmet needs and whether it is worth introducing into the market or not. It is through early engagement with stakeholders that companies can identify the unmet medical needs as well as the key clinical, policy, and economic drivers.

Our results are also consistent with those of Moa,²³ indicating that the decision about a medication choice is no longer restricted to physicians. In many cases, there is an overlap between patients and clinical experts in making key decisions. Physicians are less likely to prescribe drugs not covered by an insurance system. Therefore, engaging and ensuring strong relations with consumers is necessary to identify and understand the performance measures that matter to them.

Local drug reimbursement ranked at the top of the challenging external factors faced. Study results are consistent with the survey done by IMS Health in 2013²⁰ where pricing, market access, and reimbursement ranked at the top of the 3 most challenging factors by most respondents (95%) during drug prelaunch. This result indicates that drug access remains the key to drug launch success. In conclusion, if a product fails to be registered, it is as if it never existed. If it is not being reimbursed, physicians will eventually stop prescribing it.

Results also showed that the most important source of data used by pharmaceutical companies while engaging key stakeholders during drug launch related to the availability of health economic data (38.96%). This was in line with a study conducted in 2013 by IMS Health²⁰ that showed 73% of respondents ranked health economic data as the major source of data during prelaunch. This was explained by the need to prepare robust market access arguments to be presented to the payers. According to Ofman,²⁴ the health economics is important, especially that manufacturers are increasingly required to demonstrate the economic and the clinical value of the products. There is an increased demand for data reflecting not only safety, efficacy, and quality, but also dollarizing the value of a medication especially through the use of quality-adjusted life-year that assesses the value for money of medical interventions.

According to Cornelisse,²⁵ setting a price is beyond simply calculating the cost of production and adding a markup. In fact, when trying to reach an adequate drug pricing, pharmaceutical companies need to identify the prices of available competitors and the capacities of reimbursement bodies. According to Hinterhuber,²⁶ a value-based pricing strategy that relies on the value of a product as perceived from the customer's perspective should be considered when companies want to set a suitable drug pricing.

In our study, the quality and innovation of the company affect the success of a launch, as stated by 57.5% of the respondents. According to previous literature, physicians agreed that the company's profile matters a lot while prescribing a drug. It is easier for companies with a reputable name in the market to promote their newly launched products because doctors are more likely to trust their brands.²⁷

The notion of market developments and the readiness to change ranked highest in the study, which concurs with the findings of Knight,²⁸ who believes that to ensure success within a challenging environment, companies need to remain alert to market developments and prepared for any change. They must be flexible and anticipate any environmental changes in advance.

When asked about the points for improvement, tailored market access programs ranked first. Companies need to think of innovative solutions to ensure drug access to patients, to work on establishing patient support programs (PSPs), and to propose managed entry agreements (MEAs) for payers. The literature demonstrates the importance of PSPs where Ganqli et al²⁹ demonstrated the positive impact of PSPs on adherence and clinical and humanistic outcomes.

In many cases, MEAs are conducted. According to Ferrario et al,³⁰ MEAs can enhance the adoption of a medication, especially in cases where there are uncertainties related to the efficacy of a medication or where expensive drugs are concerned.

The human factor played an important role in our study. In assessing the relationship among several factors, our findings reflect a correlation between the level of work experience and a number of areas that scored high, including the choice of early key stakeholder engagement as a key success factor for drug launch, the choice of local drug registration and reimbursement as the most challenging factor facing pharmaceutical companies, and the choice of health economic data as the most reliable source of data. Results also showed that most respondents providing answers consistent with the literature are those with a high level of experience (11 years and above). The answers are, therefore, driven by the experience of respondents, making our findings more valuable. In fact, respondents providing answers consistent with the literature are considered more knowledgeable people because they are actively engaged in the product launch process. Consequently, they can deliver the most accurate, reliable, and useful information related to the activities and to the revenue of the launched product.²² Other studies also

demonstrate that the quality of data provided by senior-level respondents highly knowledgeable and actively involved in the launch process is valid and is very similar to secondary data, which refers to data that may be previously collected by government departments or organizational records or originally collected for other research purposes.^{30–33} In addition, participants from different departments provided a short list of innovative solutions they were advocating to ensure drug access upon launching. Such solutions serve as answers to the main objective of the study.

All the asked departments agreed on the importance of collaborating with patients and consumers. They provided solutions such as MEAs, PSPs, and special access schemes. Collaboration with payers is emerging at present while previous literature emphasizes the great impact of collaboration on the success of and its promise to improve access, quality, and efficiency in healthcare.³⁴ Moreover, collaboration with the stakeholders builds trust and creates value-based rather than product-based discussions. The pharmaceutical companies have realized that it is time to go beyond pills and to partner with customers in a valuable way.³⁵

Although Lebanon is a small country, the pharmaceutical market is relatively sizable and the competition is extensive. Expectations and challenges are growing, and a launch is a challenging task.

Lebanon's uncertain environment, characterized by economic instability and low salaries, was reflected by the inability of clients in general, and of the reimbursement bodies in particular, to purchase expensive treatments. This identified local drug registration and reimbursement as the biggest challenges companies face and a poor pricing strategy as the main contributor to launch failure. Payers find it difficult to make decisions among medications within these budget constraints and often ask whether it is worth paying for a certain medication. This was significantly reflected by the growing need for health economic data. We are looking today for new concepts that would make it easier for all parties—the pharmaceutical companies, the patients, and the reimbursement bodies—to have access to these databases.

Lebanon is characterized by a diverse healthcare system. Companies are aware of the importance of engaging with different stakeholders. They become more willing to improve their engagement with stakeholders and establish tailored market access programs specific to each reimbursement body.

Knowing that the role of the market access department is growing at present, we recommend strengthening the individuals involved in this department and dedicating at least 1 personnel for each body or establishment. At the same time, clients should work on accurately identifying their medical needs in terms of documents, samples, and safety, efficacy, or quality requirements. They should dedicate qualified individuals to communicate with pharmaceutical companies to ensure drug access.

Limitations of the Study

The constraints of our study relate to the interpretation of the results. First, the sample used may not be representative of the whole pharmaceutical industry. Secondly, findings may not apply to all other pharmaceutical firms because employees in our sample may tend to perform better than average. In addition, bias is also a constraint because respondents gave the perfect answers rather than what they really believe, rendering a possible inaccurate perception of reality.

Conclusion

Despite the uncertain environment, multinational companies are still able to launch new drugs in the Lebanese market. In fact, they

are coping with the economic instability in a fragmented health-care system, by providing patient financial support programs and tailored managed entry agreements to share the financial risks with different payers.

Whenever they are internally ready, they engage key stakeholders early to collect medical and economic information so they counter the lack of data.

Nevertheless, to persist in the future, companies need to think outside the box and search for more innovative solutions to ensure long-term success.

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