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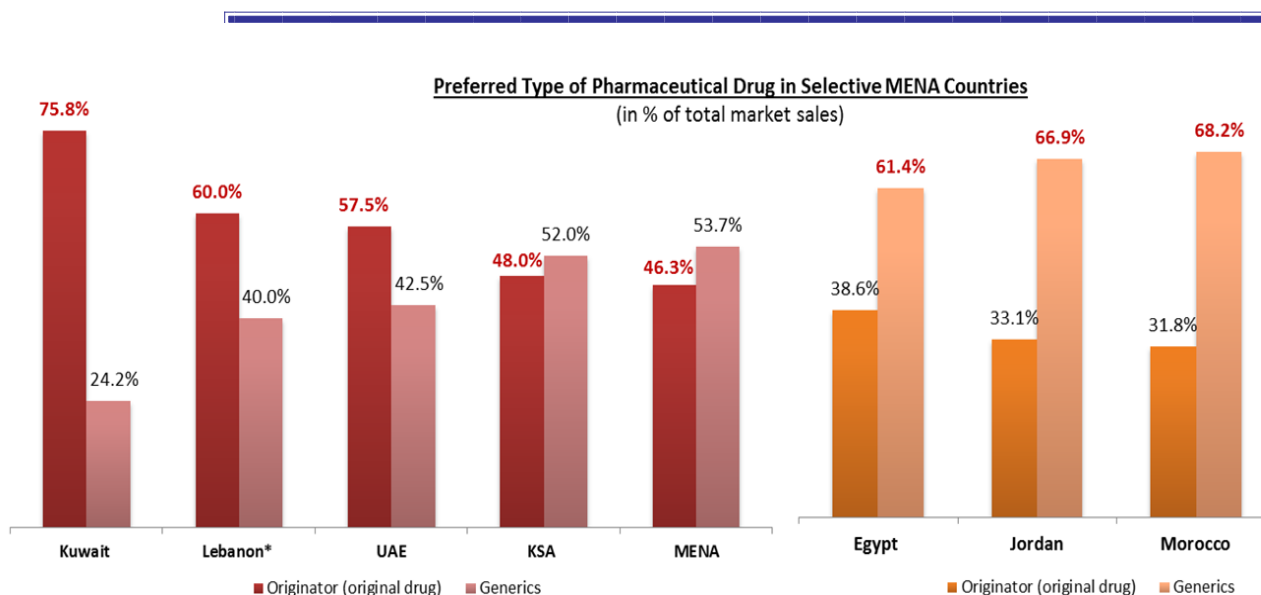
#### Abstract

The study explores the landscape and size of Lebanon's national pharmaceutical drugs industry, alongside its main national players who operate on regional and sometimes international dimensions. The report analyzes the developments in Lebanon's pharma drugs production and its promising potential. The main findings reveal the distinct business model per player and the unanimity regarding the lack of full-fledged government support, as opposed to governments of regional neighbours. The paper concludes that the industry is self-sufficient and self-equipped, possessing the human capital, means, technology, and technical know-how. Yet, it requires some national government protectionist - regulatory policies vis-a-vis existing importers in addition to a well-implemented legal framework to support the research & development (R&D) of "new drugs" and exploit the "export" business potential of pharma drugs.

Note: Information on the data collection and sample chosen for this study is found at the end of the paper.

#### Pharmaceutical Drugs in the MENA Region

**The MENA region is fertile soil for local manufacturers of pharmaceutical drugs.** According the 2016 study conducted by International Market Study (IMS Health), the MENA's pharmaceuticals market is projected to grow at the fastest rate to an estimated \$27.8B by 2020, registering a CAGR of 8.5% during 2015 – 2020. The rate is only surpassed by India's estimated 11.8% CAGR and it exceeds the highest international rates, including: the USA, the CIS (or ex-USSR countries), and China CAGRs, recording 7.6%, 7.3%, and 6.9%, respectively.



Sources: IMS data incl. retail & hospitals, 2016; BLOMInvest Bank Survey, 2018

(\*: updated input to reflect market payers' recent estimated input; IMS would have shown 52.7% for originator)

**The GCCs are dominated by imported drugs, but this paradigm may shift; Lebanon will need to jump on the bandwagon of supporting national production.** The market of pharma drugs consists of: the originator (or original molecule and drug) produced by the multinational companies (MNCs), like Merck, Sanofi, ABBOTT, GSK, MSD; the branded generics<sup>1</sup> (not produced by the MNCs but other laboratories, companies); the simple generics (not branded, usually locally produced). Citizens in the MENA region however trust “originator” drugs over the generics. Particularly in the GCCs, namely in the KSA, UAE, and Kuwait where patients are considered with higher purchasing power and a poor/negative perception towards generics, the share of originator drugs seem high. Yet the GCCs have been streamlining policies and updating the framework of operations as oil prices diminish and their economies are shifting to new models.

**Lebanon is among the top 9 fastest growing MENA pharma markets according to the IMS.** In fact, data from the IMS and the Business Monitor International coincide on Lebanon’s CAGR standing at 5% from 2017-2022. In addition, all 10 (out of 11) interviewed Lebanese pharma manufacturers corroborated the Lebanese market’s immense potential thanks to the internal know-how and means, but also to the international perception vis-à-vis the Lebanese pharma industry.

<sup>1</sup>A “generic” is the product produced using the same active ingredient as the original, but not manufactured by the original mother company (often the MNCs listed in-text) who created the active ingredient’s molecule. Therefore, a ‘generic’ is an imitation of the “originator” produced using the same active ingredient but after the original patent has already expired.

ATTN: It is not to be confounded with “a copy” which is the imitation of the same drug, based on the same active ingredient yet produced before the expiration of the (original) patent. Hence the name, a “copy”.

**The IMS discloses that the timeline to register a pharma drug in Lebanon is among the shortest i.e. most efficient in the region.** While drug registration takes approximately 6 months (M) to 12M in Lebanon, it can last up to 18-24 months in KSA and Morocco, and more than 24 months in Algeria and Egypt. For instance, Mr. Ayman Semaan, Health Industry Professional<sup>2</sup>, discussed the MNCs' preference of doing business in Lebanon in comparison to other regional states like Egypt, Jordan or even KSA, as Lebanon ranks well on several facets in the regional industry." In turn, General Manager of Pharmaline, Dr. Abi Karam, further elaborates, "*We were approached by our licensors, for instance, ABBOTT recently, who will begin exporting its products to Jordan via Pharmaline*".

**On the counterpart, it is now harder for Lebanon to penetrate the neighbouring markets of the Near East and North Africa who are already "generics"-oriented.** Egypt, Jordan, and Morocco as per the diagram above, consume more generics and have set the policies to support and protect local drug production and consumption. These home-protectionist measures are reducing the chances that Lebanon's products reach these markets as they do so too. Add to that, Lebanon also lacks the proper legal and regulatory frameworks setup that protects local manufacturing from foreign invasion – such is the case today.

**In Lebanon, 9 market players verify that the Lebanese present a cultural resistance to generics, while incentives to prescribe originator drugs are too high.** Patients in Lebanon still do not fully agree that larger volume in the market means greater patient confidence in the generics. Instead, they have greater affiliation to European or American-originated drugs. This can be attributed to the need for more awareness campaigns to support and explain the international standards by which national producers operate, but it is also linked to the trust between the patient and his/her doctor vs the pharmacist. Mr. Semaan added, "*The promotional capacities<sup>3</sup> of MNCs can give a preferential edge compared to those provided by the national producers operating on much smaller margins*".

### **Lebanon: Industry Scope & Players**

**The current market size of pharmaceutical drugs is worth \$1.3B excluding medical devices, and it is composed of 11 national manufacturers.** As per the President of the Syndicate of Pharmaceutical Industries in Lebanon (SPIL), Dr. Abi Karam clarifies that, "*Lebanon has a total of 1,100 local and foreign providers, of which 11 are national manufacturers of pharma drugs*". The 11 players are: Pharmaline, Benta Pharma Industries, Algorithm, Mediphar, Mephico, Pharmadex, Chalhoub Pharmaceuticals (Chapha), Arwan,

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<sup>2</sup> Mr. Semaan is also manager at Algorithm.

<sup>3</sup> Similar statements were shared by interviewed top management in each of Mephico, Mediphar, Pharmadex, Arwan, Chapha, and Benta Pharma.

as well as *Pharma M* (specialized in food supplements), in addition to *Alfa Laboratories & Serum Products* – noting these last 2 strictly produce IV solutions i.e. “serums”, destined mainly for hospitals.

**The manufacturers can produce their own generics, and/or produce under license.** All firms in Lebanon produce their own generics, and it has become a healthy competition among all these players to “add value” or an element of innovation within the production of the generic drug in their own labs, as they aim to enhance the efficiency of the end product for example by substituting a component with a healthier version but providing the same or even an enhanced efficiency to the patient.

**However, the players who have signed agreements with MNCs like Merck, GSK, MSD, NVR, ABBOTT, Triphar, or Sanofi can manufacture the foreign brands.** These licensees include: Benta Pharma, Algorithm, Pharmaline. In fact, producing under license depends on the contract signed between the licensor and licensee: the players either manufacture the originator drug in their own facilities in Lebanon via secondary packaging within their facilities, or alternately own market authorization over the originator product which makes them responsible to manufacture and market the product which is issued in the name of the national manufacturer and in reference to the originator.

**The 11 players altogether constitute 7% of Lebanon's total pharmaceutical drugs market, excluding the products produced “under license”.** The remaining 93% are composed of brands that are imported by almost 112 importing entities in the country. However, this market share climbs to around 11% when we include both: the generics and the products manufactured “under license” by these national players. The market thus includes the producers' portfolio of products (their own branded generics) in addition to the under license products for the 17 MNCs including European, American, and Japanese ones that were attracted by the players and potential of the Lebanese pharmaceutical market.

**Multiple market sources help quantify the shares of these players.** In terms of 2017 sales (including both, generics and under-license drugs), market sources estimate *Pharmaline* grasps a share of 38-40% of the total market, followed by 30-32% for *Benta Pharma*, and approximately 13-15% of market share for *Algorithm*. *Mediphar's* share is estimated at 10-12% of the market sales, and all other “pharma drugs” producers excluding serums and supplements, grasp the remainder shares.

**The drugs produced by domestic manufacturers (i.e. own generics) are trusted in the market and thus carry huge potential to grow.** Dr. Abi Karam clarifies that, “3 national Lebanese producers are among the ‘Top 15’ providers in terms of generic units sold. Also, in terms of dollar value, another 3 local players make it among the Top 15”. Accordingly, these facts reveal the confidence and volume of national generics in the market today and thus their potential. In details, *Pharmaline*, *Mediphar*, and *Algorithm* make it on the Top 15 list in terms of volume. Moreover, in terms of dollar value of sales, *Algorithm*, *Pharmaline*, and *Benta Pharma*, as per IMS, make it among the Top 15 list.

**The national manufacturers are specialized in producing certain lines of products.** The type of pharma drugs produced locally may be: a topical medication (including creams, ointments) or an oral dosage medication (like tablets, liquids, capsules). Moreover, only two producers: *Arwan* and *Benta* Pharma in Lebanon produce biosimilar products or biological drugs which namely require very advanced biotechnology and facilities. In turn, *Alfa Laboratories* and *Serum products* manufacture a more industrial product, known as "serum" (or IV solutions), while *Pharma M* strictly manufactures food supplements.

### Pricing in a Nutshell

**The law requires local pharma drugs to be less expensive vs the imported, so the MOPH requires a benchmark to set the final prices.** The nationally-produced drugs are priced, by law, on average around 30% lower than the foreign imported products, which is indeed reflected on the market's size. Moreover, Lebanon, in collaboration with the MOPH, prices its products based on a basket of similar drugs sold elsewhere. In details, to price any local drug, the MOPH uses the price of a similar drug sold in 14 different countries and this serves as a benchmark. The basket includes 7 European countries and 7 Arab countries (like KSA, Bahrain, Jordan, Qatar, Oman, UAE).

### Corporate Strategies: Evidence of the Players' Potential

**Every market player in Lebanon's pharmaceutical drugs production invests in high quality raw materials, advanced, specialized technologies and aims to "add value" to its produced generics.** Some firms may be more specialized than others in some product, technology, or innovation to treat particular diseases, but the 10 players interviewed seem passionate, optimistic, and full of plans for a bigger market locally and externally via exports. In terms of their portfolio of generics, the expert team of pharmacists and doctors, seems to add a certain technology, R&D innovation, or some added benefit to render the generic unique, not a mere copy of an originator drug.

**In a nutshell, every company has immense capacity to lift the national industry and economy.** For instance, *Algorithm* is the only pharma drug-manufacturing company in Lebanon with an export-oriented business model. It exports 50% of its production and is present in the Cypriot (i.e. EU) market, thus proving that Lebanese pharma drugs have what it takes to expand into European markets, especially when supported locally. Their new green factory in Zekrit promises bigger production and further specialization. *BENTA Pharma Industries* launched biotech drugs production in Lebanon, and produces specialized, advanced cancer treatment products.

They are to conduct leading clinical trials on a new way to eradicate Diabetes and are developing advanced diagnostic oncology machines with the USA and correspondents from Europe, France, and Spain, as per a key management figure. *Arwan Pharmaceutical Industries*, relatively new in the market, have state of the art technology in place. They are one of the two market players producing biotech specialized drugs. They

plan to up their production and diversify their portfolio of drug types by utilizing the remaining 60% capacity of their facilities. They will also support Lebanese exports with their plan to cover 24 countries, Arab and African, in the next 4 years.

**Other market players' growth can also create job opportunities for skilled nationals and build a brand name for Lebanese generic drugs.** *Pharmaline* as per Dr. Abi Karam, General Manager, has a rigorous R&D and "super generics" in its portfolio i.e. entirely developed in-house with own formulas, higher compliance, and more synergy of action. The company has the most licenses from multinationals in the country and will start being a national supply hub for the regional distribution of MNCs' products. Currently investing around \$17-18M in their facilities to double the capacity of production, they can create new jobs for the market. Also, *Pharmaline* is the only national firm that "exports its own generics" rather than the under license pharma drugs, which confirms the top-notch expertise and high caliber national production, in addition to the reputation of Lebanese pharma drug brands and their ability to go international.

**Efforts to boost international recognition of applied quality standards can assist manufacturers' national sales teams influencing physicians to prescribe generics.** Owners & managers at *Mediphar, Pharmadex, Mephico, and Chalhoub Pharmaceuticals* corroborate that being key players on a national level with local sales teams and branded generics can play a big role in influencing physicians, pharmacists, and hospitals in Lebanon, to push for preference of national pharma drugs. Moreover, Mr. Fadel, owner at Mediphar explains "*We are currently applying for the Good Manufacturing Practices (GMP) certificate which can give our Lebanese manufacturing an international footprint.*"

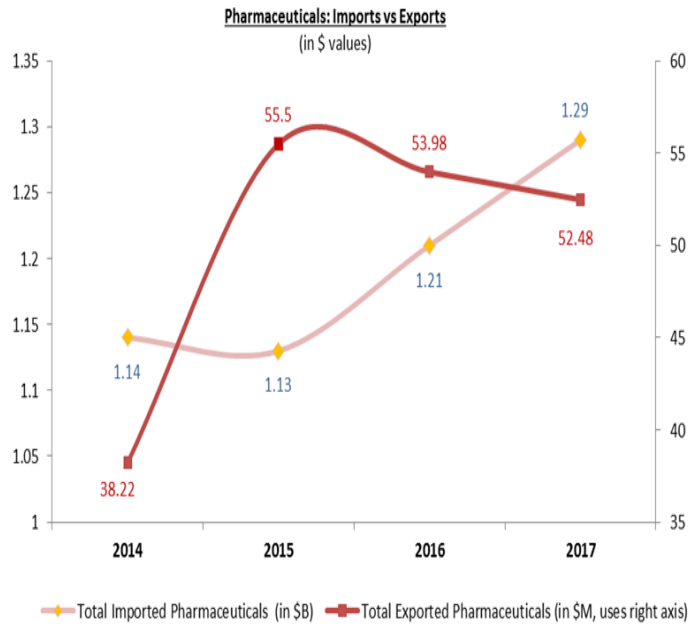
**Lastly, two players exclusively produce all hospital serums but innovation and diversification are key.** The supply of *Alfa Laboratories and Serum Products* alone satisfies the Lebanese market in terms of IV solutions (serums) of European quality standards. Yet, as Dr. Akl, General Manager at *Alfa Laboratories* explains, "*Despite the lack of government support to our high overhead costs, we invest in new combinations. We experiment to find innovative products, better ways to offer added value for our patients, physicians, and hospitals.*" Doing so can amplify Lebanon's exports to regional countries as well as build a regional and international brand name. In his turn, Mr. Tabbara, General Manager at Serum Products, highlights the recent threat of imported serums accessing the Lebanese market. He adds, "*We plan to diversify our operations by adding new lines of products to our portfolio and also expanding our exports to Africa, the Levant, and the Middle East where registration is already in progress.*"

**Key Challenges**

Despite this backdrop, the public remains skeptical towards the Lebanese pharma drugs. Multiple hurdles exist to the industry on the national front. According to 8/10 market players surveyed, the local market perception of national pharma drugs is a major hurdle. For instance, citizens tend to link the quality of drugs produced by national manufacturers to the low confidence the people have in the local government.

Thus, patients end up doubting the transparency of the local production processes because they don't trust that the government will rightly overlook local production, even though the players operate with top expertise, technology, know-how and prime quality standards and efficacy of drugs.

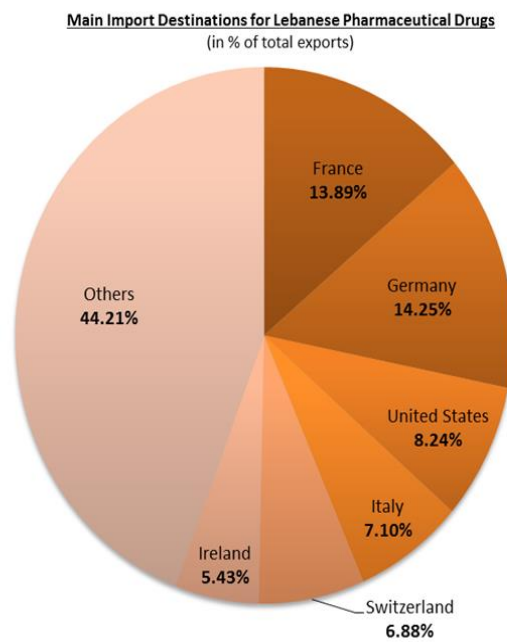
This leaves the patient with a higher medical bill and the government with a much-higher healthcare bill.



Source: Lebanese Customs; BLOMInvest Bank

The portion of imported drugs is significantly large, which dissolves local manufacturers' share of the pharma market. With more than 100 importer entities existent in the country, imports of pharmaceuticals have steadily increased since 2014 while exports remain subdued, valued at around \$48M on average, according to market sources complemented by the data from the Lebanese Customs.

A key management figure at *Benta Pharma* emphasizes, "The substantial amount of imports is huge and unsustainable", and this largely explains the low market share of 7% of total market for domestic pharma drugs today and the lack of full-fledged, frequent awareness campaigns on the quality of local Lebanese drugs and the



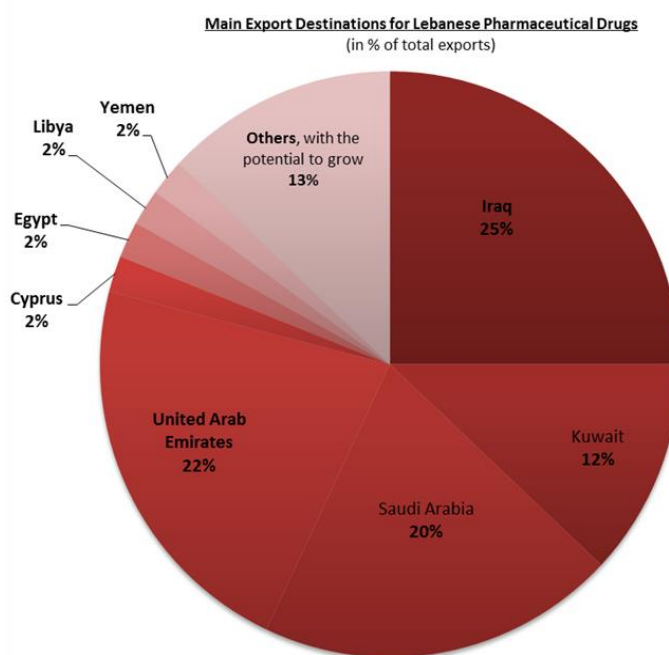
Source: Lebanese Customs; BLOMInvest Bank

international production standards followed by Lebanese manufacturers.

**Moreover, the local v/s foreign pharma drugs are not at the same level playing field.** MNCs, whether licensors or simply importing their final products to Lebanon and neighbouring markets, operate with large margins such that they benefit from economies of scale. They have a big, international market for their products and already have a brand name, market reputation, own or local distributors as well as their influence on physicians. Meanwhile, Lebanese manufacturers do not benefit from similar economies of scale, given they operate in a small local market whilst they also face difficulties exporting in large amounts. Moreover, a key management figure at *Benta Pharma* identifies the difficulty faced by all 11 national producers to be included in public tenders, in addition to complications in serving some local university hospitals which may require for example the US Food & Drug Administration's (FDA) expensive drug approval(s), knowing the market served remains not big enough to reap benefits of such an investment to meet the criteria.

**Overhead costs of manufacturing are high and they leave national production at a disadvantage vis-à-vis patients and regional peers as well.** While regional peers like Algeria, Iran, Tunisia and others have policies and a government alleviating production costs (reduced utilities costs, friendly raw material pricing) and supporting the market share of national products, the Lebanese players are entirely bearing the costs. According to Dr. Akl, General Manager at Alfa Laboratories, "*Water and electricity supply 24/7 are crucial to preserve the effectiveness of technologies used in production, as well to maintain the adequate temperatures and environment required to preserve the products in the factories and the warehouse.*"

In addition, penetrating these markets where national pharma industry has priority may become a greater challenge for Lebanon, even though some of its market players like *Pharmaline* and *Algorithm* already have positioned some of their under-license and generic products in Cyprus (i.e. EU trade potential), the GCCs, Levant, and Africa.



Source: Lebanese Customs; BLOMInvest Bank



## Ways Forward

**The growth of the pharma drugs industry in Lebanon during this critical slowdown can lift the economy and related industries.** The export of nationally-produced drugs can help reduce Lebanon's \$12.96B trade deficit (by Sept. 2018) via boosting national exports worth \$2.2B while total imports stand at highs of \$15.16B. The pharma drugs industry can therefore nurture medical tourism, cap the national healthcare bill, and slash costs for patients as well as the reimbursing entities if the authorities set some regulations giving local manufacturers preferential treatment, for instance in government tenders and in serving university hospitals. The pharma drugs industry can also improve access to medicine, ensure job opportunities for skilled nationals, and enhance expansion plans of local producers, albeit supporting the economy through the "manufacturing" channel - at a time where all other growth drivers remain either subdued or insufficient to reverse the latest slowdown.

**The capacity and potential of national manufacturers in Lebanon remains untapped with huge, promising potential.** BLOMInvest's primary research conducted with 10 key market players in the industry implied the potential in pharmaceutical drugs production is huge. The owners and managers emphasize Lebanon has the talent and human capital as well as the technologies and factories to meet local market demand but also to boost export, thereby contributing to the balance of trade improvement.

**The Syndicate of Pharmaceutical Industries in Lebanon (SPIL) has a rigorous agenda to fast-track the growth of the pharma drugs industry.** Dr. Carol Abi Karam, President of SPIL, explains "*The syndicate's priority is to resolve the internal challenge facing the Lebanese pharma drugs industry and then the external and regional challenges. In fact, growing our market share from 7% to 15% is an easily achievable short-term goal, given the current market activity and volume witnessed in the sector.*" The government can begin to include local players in government tenders, give them priority treatment locally at least, especially when local generics can compete with certain imported originator drugs in the market. Preferential treatment for national produce via a reduced utilities bill, exemption of customs tariffs can also go a long way in nurturing the sector and thus the economy as per all surveyed market players.

**Moreover, supporting the dynamic pharmaceutical industry can improve other sectors due to "production linkages".** Growth of the local pharma drugs market can create needed job opportunities to the skilled youth while it simultaneously nurtures parallel productions like packaging, printing and others. In fact, as per the UNIDO's in 2013 and 2018, manufacturing can go beyond productivity gains to create productivity growth as national production becomes the main vehicle for technology development and further innovation and jobs across parallel sectors.

***"Within 3 years, the Lebanese pharma drugs industry can create 1,000 jobs", as per the SPIL President.*** Currently, the Lebanese pharma drugs sector employs around 1,800 employees. The SPIL's vision and plan entails lifting the market share from 7 to 15% within a year only by working with the government on

“prioritizing” the industry on a national level first. With the government’s support as such, the SPIL can work to raise the market share of local producers to 30% of total pharma drugs market within 3 years while also boosting exports to \$300M, instead of 2017’s \$48.8M as per the Lebanese customs dataset for 2017. And within 5 years, national support to the industry can raise the local manufacturer’s market share to 50% of the total drugs market, albeit increasing exports to \$500M, also ensuring investments to further develop the sector.

**All market players unanimously expressed multiple propositions for new, more cost-efficient “reimbursement plans”.** Basically the NSSF for example in Lebanon covers 85% of all pharma drugs, imported same as generics. The SPIL for instance suggests, if the NSSF alone gives priority for local generics that fall among the 10 most sold drugs in Lebanon (namely cardiovascular and hypertension), the entity can save up to \$138M from its bill. If it goes further to change its model such that it covers 100% of local generics while covering 85% of imported drugs, then the NSSF can save an additional \$85M. Another key figure at Benta Pharma proposes an internationally used model that sets a fixed or set coverage for the molecule forming the drug in question. That way, even if the drug is administered in different forms on the local market, the NSSF fairly provides coverage, leaving the choice to the patient and physician. Such simple initiatives can support the industry, reduce public spending, and enhance access to medication to more patients.

**Note:**

**On Data Collection & Sample Chosen for this Study**

This research paper uses interviews and or surveys conducted with 10 out of Lebanon’s 11 pharmaceutical drugs producers of which one, Pharma M, is a food supplement producer, which renders the sample representative of the pharma drugs market. These are the players listed as official producers by the Lebanese Ministry of Public Health (MOPH). They are also members of the Syndicate of Pharmaceutical Industries in Lebanon (SPIL) formed in 2016 to support the national industry. Secondary data by the renowned International Market Study (IMS Health) is also used, alongside the Lebanese Customs database

among others, as the market for pharmaceutical drugs remains dominated by imported pharmaceutical drugs.

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