نقابة صيادلة لبنان
Order of Pharmacists of Lebanon

Towards a National Pharmaceutical Strategy in Lebanon

A project by:
The Order of Pharmacists of Lebanon

In collaboration with:
The Ministry of Public Health
The World Health Organization, Lebanon Office
The Syndicate of Pharmaceutical Industries in Lebanon
The Lebanese Pharma Group

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A commitment and a call to action to ensure access to quality and safe medications in Lebanon for all.

"Quality means doing it right when no one is looking".

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Disclaimer

The Order of Pharmacists of Lebanon aimed to develop a nationally acceptable strategy that gets the buy-in of all stakeholders for smooth implementation and concrete collaboration to achieve the set objectives. This first version of this strategy represents a consensus between the involved stakeholders, although the related implementation plan remains a live dynamic document that would be updated based on further discussions and consultations with relevant stakeholders. Its suggested actions would be discussed in small groups among the involved stakeholders.

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FOREWORD

At the beginning of the twentieth century, and before the fall of the Ottoman Empire, the Lebanese tried to give meaning and justification to the existence of their Lebanon.

After the declaration of the state of Greater Lebanon, this emerging entity stood firm, and the identity triumphed despite all wars, tragedies, abolition attempts, occupation, and subjugation.

Lebanon preserved its identity thanks to its prominent clinging and commitment to playing its role as the Message, the meeting place of civilizations and religions, and the link between East and West. Lebanon's civilization (dating back to thousands of years and represented by the distinguished and leading universities, schools, hospitals, press and print media, and the intellectual, literary, and cultural freedoms) is its true identity, the source of its strength, and the more profound meaning and justification for its continued existence.

Today, instead of lamenting over the ruins, while Lebanon's history and civilization are collapsing before our eyes and the Lebanese patient is suffering, we, at the Order of Pharmacists of Lebanon, have decided that the rescue process begins by having all sectors endeavor to preserve their existence, each from their perspective and specialization.

In this regard, our goal is the healthcare sector, particularly the pharmaceutical sector; therefore, we are determined to propose a sustainable and realistic pharmaceutical strategy while collaborating with all key stakeholders and partners to secure good quality medications for the Lebanese patient by facing all challenges and creating innovative solutions related to the pharmaceutical supply chain.

As a consequence, medications will remain one of the most prominent features of civilization in Lebanon, and the pharmacist will remain the guardian of identity and entity...

Joe Salloum,
President, Order of Pharmacists of Lebanon.

مطلع القرن العشرين، وقبيل سقوط السلطنة العثمانيّة، تساءل اللبنانيون من نحن؟ وحاولوا الإجابة عن هذا السؤال لإعطاء لبنان الذين يحلمون به، معناً، ومبرّراً لوجوده.

وبعد إعلان دولة لبنان الكبير، إتّخذت الإجابات عن هذا السؤال وجهة تبرير الكيان الناشىء، وضرورته الوجودية فصمد الكيان وانتصرت الهويّة بالرغم من كل الحروب والمآسي ومحاولات الإلغاء والإحتلال والضمّ والتطويع.

ولعلّ أبرز ما أنقذ لبنان من الزوال، تشبّثه بلعب دوره الرسالة، من ملتقى الحضارات والأديان، وصلة الوصل بين الشرق والغرب، وما حضارته التي تعود إلى آلاف السنين، والمتمثّلة بالجامعة والمدرسة والمستشفى والمطبعة، صناعة الإرساليّات، والحريّات الفكريّة والأدبيّة والثقافيّة، إلاّ هويّة لبنان الحقيقية ومصدر قوّته، والمعنى الأعمق والمبرّر لاستمراريّة وجوده.

واليوم وعوض التباكي على الأطلال، ولبنان التاريخ والحضارة ينهار أمامنا، والمريض اللبناني يقاسي ما يقاسيه، رأينا في نقابة صيادلة لبنان، أنّ مسيرة الإنقاذ تبدأ في الحفاظ على معالم الهويّة ومبرّرات الوجود كلّ من موقعه واختصاصه، فإذا بقطاع الإستشفاء وجهتنا سيّما الدوائي منه، فعقدنا العزيمة على اقتراح استراتجيّة دوائيّة ثابتة واقعيّة، مع كل المعنيّين والشركاء في القطاع، إستراتجيّة مستدامة تؤمّن للمريض اللبناني الدواء الجيّد، وتجترح وتبتكر الحلول لتمكين المريض من الحصول عليه، فيبقى الدواء من أبرز معالم الحضارة والإنسان في لبنان، ويبقى الصيدلي حارس الهوية والكيان...

جو سلوم،
نقيب صيادلة لبنان.

BACKGROUND

1. Definition of a Drug/Medicine/Medication

According to the U.S Food and Drug Administration (FDA)[1], a drug/medicine/medication is: **a)** A substance recognized by an official pharmacopeia or formulary; **b)** A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; **c)** A substance (other than food) intended to affect the structure or any function of the body; **d)** A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device; **e)** Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process).

In this document, whenever medicines are mentioned, it also includes vaccines. The words drugs, medicines, and medications are used interchangeably.

2. Rationale for a National Pharmaceutical Strategy

This National Pharmaceutical Strategy constitutes a "Commitment to a goal and a guide for an action". It presents a "formal record of the values, aspirations, aims, and the medium to long-term government commitments", as mentioned in the second edition of the World Health Organization (WHO) guide on "How to develop and implement a National Drug Policy".[2]

Furthermore, this strategy aims to address the identified main problems in the pharmaceutical sector in Lebanon at the national level. Thus, although this document will tap into the different components of a National Drug Policy, as suggested by the WHO, it will focus on those that influence significantly pharmaceutical and health sectors in Lebanon and, subsequently, patients.

As Lebanon is going through an unprecedented economic depression, the local currency has lost around 95% of its value, rendering healthcare unaffordable for public health insurance entities, individuals, and households. Accordingly, this strategy highlights the critical components that would enable public health insurance entities to collect enough revenues, strike efficient investment decisions, and enable access to healthcare in general, and quality medicines in particular, without patients experiencing financial hardship.

Aiming to cater to the Lebanese population's needs at large, this strategy discusses the importance of having the essential medicines available at all the Primary Healthcare centers across Lebanon at a minimal cost to patients. It also aims to support Lebanon's aspiration to regain its position as the regional center of excellence in healthcare, ensuring access to innovative and valuable treatments and exporting healthcare to neighboring countries. This matter is of primary importance from a national perspective, as medical tourism constitutes an essential source of foreign exchange earnings. The latter has been supported in the McKinsey report[3], published in 2018, mentioning tourism (including medical tourism) as one of five sectors that would present the highest economic potential for Lebanon.

The WHO has issued policy briefs related to the matter, and stated countries should work on[4]:

- Ensuring access: making sure that patients have timely and affordable access to safe and effective medications;

[1] US Food and Drug Administration. Drugs@ FDA glossary of terms. Silver Spring, MD: US Food and Drug Administration. June 2017. https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

[2] World Health Organization. How to develop and implement a national drug policy. World Health Organization, 2001. https://www.who.int/publications/i/item/924154547X

[3] Lebanon Economic Vision. https://www.economy.gov.lb/media/11893/20181022-1228full-report-en.pdf

[4] Panteli D, Edwards S. Ensuring access to medicines: How to stimulate innovation to meet patients' needs? [Internet]. Richardson E, Palm W, Mossialos E, editors. Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2018. https://pubmed.ncbi.nlm.nih.gov/30272894

- Stimulating innovation: providing incentives for research that will lead to innovative medications that effectively target real therapeutic needs;
- Safeguarding sustainability: developing the mechanisms to purchase these medications at affordable prices to protect the sustainability of pharmaceutical budgets.

Regulatory systems are thus critical for ensuring the safety, efficacy, and quality of medications and other health technologies. Countries with small populations and gross domestic products face challenges in developing their systems, which are unique. The WHO proposes an approach to strengthening the regulatory system in these small states to help them accomplish the most vital functions and do so more efficiently.

Access for all to safe, effective, quality, and affordable essential medications and vaccines is one of the targets of the Sustainable Development Goals (SDGs) (target 3.8). Achieving this target is central to achieving universal health coverage (UHC), as medicines and vaccines are considered common goods. Improving access requires a comprehensive health systems approach, strong partnerships, reliable funding mechanisms, and the presence of national policies/strategies supported by legal and regulatory frameworks that address all stages of the medicines and vaccines life-cycle and value chain. Substandard and falsified medical products represent a threat to public health worldwide but pose a particular problem in low- and middle-income countries (LMICs). An efficient and effective national regulatory system is an essential component of any resilient health system, seen as a critical enabler and an assurance mechanism for health products.

3. Laws and Regulations Related to the Pharmaceutical Sector in Lebanon

The main legal framework to regulate the pharmaceutical sector consists of laws (issued by parliament) and implementing decrees (issued to implement laws by the council of ministers with relevant ministries) related but not limited to: the pharmacy profession (law 367, 1994), registration of pharmaceutical products (implementation decree 571, 2008), licensing for local pharmaceutical manufacturers (law 12063, 1963, implementing decrees 106, 1983 & 9399, 2012), and ministerial decrees and memos issued by the Ministry of Public Health (MOPH). Ministerial decrees and memos have the implementation power as long as they are valid.

Moreover, the Lebanese Drug Agency (LDA) law (253/2022) was enacted in January 2022. Its implementation decrees should be issued by the MOPH and submitted to the council of ministers for approval. The LDA would act as the highest authority in the pharmaceutical sector in coordination with the MOPH and other stakeholders. A transitional period would be necessary to organize the efforts and manage the move.

4. Technical Committees for Medication Registration in Lebanon

The committees for licensing local manufacturers (Industrial Committee) and registration of pharmaceutical products (Technical Committee) are mentioned in the relevant laws and composed of senior ministry staff and experts representing academia and professional Orders. Their final decisions are sent to the minister of health to issue the market authorization certificate (Technical Committee) and relevant licenses for local manufacturers (Industrial Committee).

Registration of pharmaceutical products is subject to the Common Technical Dossier (CTD) requirements and goes through two subcommittees. For brand products imported from reference countries, the registration goes only through the technical committee without a further review from subcommittees.

Those subcommittees are made of eminent experts from academia to study specific modules of the registration files, mainly Module 3 (for quality documents for primary drug substances and finished product) and Module 5 (related to bioequivalence studies BE and clinical trials). Both subcommittees have set standard operating procedures (SOPs) and standard applications as well as checklists for file submission and review.

The work of the subcommittees is framed by ministerial decrees no. 1634 in 2013 and no. 344 in 2017. The list of all registered products in Lebanon can be found on the MOPH website: https://www.moph.gov.lb/userfiles/files/HealthCareSystem/Pharmaceuticals/LNDI/LNDI-2015.pdf

5. The Medication Pricing Committee

The Pricing Committee is responsible for setting the prices of pharmaceutical products after being registered and before issuing a market authorization. The pricing mechanisms follow Law 367 "Practice of the Profession of Pharmacy in Lebanon" and other memorandums and decisions issued by the MOPH concerning the pricing of pharmaceuticals, the most recent being Decision 119-1/2020 and its amendments.

For brand imported products, the CIF (Cost, Insurance, and Freight)/FOB (Free on Board) price to be adopted is the lowest price between the COO (Country of Origin), 14 neighboring, and reference countries prices. The pricing process follows these steps: submission of pricing documents by the applicant, electronic pricing and determination of authorized price in foreign currency, evaluation by the Pricing Committee, allocation of the product to one of the categories (from A to E; A includes all products with prices less than 10$ and E comprises all products with prices more than 300$) depending on the price range, and conversion of authorized price to public price in Lebanese Pounds.

Repricing is a continuous process that affects all registered pharmaceutical products. It is done periodically, every five years (documents shall be submitted in September of the fourth year, and the pricing decision is issued in January of the fifth year and is effective immediately). Products with the same presentation and a different dosage form should be repriced simultaneously. For imported products, the documents required for repricing are the same as those submitted for pricing upon registration. Upon registration, the price of a generic product should be 30% lower than the brand if imported from a reference country, 15% lower if manufactured locally, and 40% lower if imported from a non-reference country. When the repricing of a brand product leads to a reduction in its price, prices of all generic products will be affected automatically. If the public price of the brand decreases by a certain percentage (by more than 40%, voluntarily by the company), the prices of imported generics must decrease by half the percentage of the brand. Locally manufactured products must be lower than the brand by 25%. However, the public price of imported generics must always be 10% lower than that of the brand, and the maximum allowed public price of locally manufactured generics is that of the brand.

Public prices are regularly published on the MOPH website and easily accessible to the public (website and mobile application). https://www.moph.gov.lb/en/Pages/3/3010/pharmaceuticals#/en/view/3101/drugs-public-price-list. The Manual for Drug Pricing in Lebanon (دليل إجراءات تسعير الأدوية في لبنان) is published on the MOPH website: https://moph.gov.lb/en/publications

6. Parallel Import (PI) of Medications

The parallel importation of products happens when products placed into circulation in one market are then imported into another market. Reference decrees 571 and 950/1-2013 regulate PI to ensure the quality of imported products:

- There should be no change in the marketing authorization holder (MAH) or mother company.
- The approval of the Technical Committee is in accordance with articles 14 & 15 of this decree (articles related to regulatory variations).
- Importation is performed based on the MAH or mother company approval.
- The invoice should be coupled with the original certificate of analysis.
- Parallel imported products should be analyzed by one of the laboratories accredited by the MOPH, and the results should be confirmed by the inspection department.

7. The Lebanese Context Before 2019

In 2018, the Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016) was used to assess personal healthcare access, and the Healthcare Access and Quality (HCAQ) Index was used to evaluate quality. Lebanon ranked in the 33rd place with 86 points (in a previous HCAQ edition, Lebanon was ranked 31st with the same score), rubbing shoulders with European nations like Estonia and Portugal. It was noted that the health system in Lebanon provided good value for money compared to other countries. When the HCAP score was related to the total health expenditure as a percentage of GDP (in dollars at constant purchasing power parity), the score of 86 put Lebanon below some countries with higher health expenditure. However, none of the countries with inferior healthcare spent less than Lebanon, as the share of GDP ranked above it in the HCAQ index.[5]

According to Human Development Reports (HDR)[6] by the United Nations Development Program in 2013, low-income countries early in this decade spent on average 5.7% of GDP on financing healthcare, compared to 12.3% in high-income countries. Lebanon spent around 8% of the GDP on healthcare in 2018 and 2019. Reports generally show that higher levels of healthcare spending are reflected in higher life expectancy and are very visible in data points such as the number of physicians and hospital beds per country inhabitants.

While the Investment and Development Authority (IDAL) highlighted Lebanon's pharmaceutical industry for its investment opportunities and reported that pharma sales reached $1.63 billion in 2015, the bulk of pharmaceutical trade was inbound. The pharmaceutical market in Lebanon was estimated at around 1.93 billion USD in 2018.[7]

8. The Lebanese Context After 2019

With the occurrence of the political turmoil, the COVID-19 pandemic, and the Beirut port blast in August 2020, severe socioeconomic and health crises started to affect Lebanon. The depreciation of the local currency, the medication stockpiling, and the smuggling of subsidized medicines outside the country were disastrous elements to the sector.

Consequently, with the local currency losing around 95% of its value, public health insurance entities and patients could no longer afford the actual cost of healthcare, including medicines. At the start, the Central Bank's subsidization of medicines kept its purchasing possible. However, as the reserve in foreign currency was limited, the Central Bank allocated a capped value for the subsidy of medications, medical devices, and infant formula. Subsequently, the MOPH found itself forced to remove the subsidy gradually on many medications to meet the capped budget that was allocated by the Central Bank.

Moreover, the pharmaceutical market in Lebanon reached 1.7 billion USD in 2020 and was reduced by 25% in volume in 2021 (IQVia data), driven by the cap on the subsidy of importation imposed by the Central Bank and the complexity of the approval process. Throughout the crisis, severe budget restrictions and medication shortages have led the government, in certain situations, to take quick actions not supported by a legal framework. Quality concerns will always remain an issue to be considered and tackled with new sources for medications being considered/adopted.

In this challenging context, Lebanon lacks a national strategy for medications, with very few solutions proposed for the current catastrophe. Policies that might be present are scattered and may not be adapted to the country's needs, particularly in the current situation. Some regulations are also not enforced, and there

[5] GBD 2015 Healthcare Access and Quality Collaborators. Electronic address: cjlm@uw.edu; GBD 2015 Healthcare Access and Quality Collaborators. Healthcare Access and Quality Index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990-2015: a novel analysis from the Global Burden of Disease Study 2015. Lancet. 2017 Jul 15;390(10091):231-266. doi: 10.1016/S0140-6736(17)30818-8.

[6] UNDP. Human Development Reports. https://bit.ly/3sqPJ4b

[7] IDAL. Pharmaceutical Sector in Lebanon, 2018 Factbook. https://bit.ly/3KuksDn

is no active central laboratory. Previous reform attempts targeting the health sector in general and the pharmaceutical sector, in particular, did not protect the sector from imminent concurrent crises and their negative consequences on patient health. Nevertheless, as medication experts, pharmacists play an active and dynamic role in the health system in general and in times of crises and medication shortage response. Supplementing existing guidelines with an actionable framework of activities to support effectual universal health coverage, medication shortage responses, and rational and safe use of medications can expand the scope of pharmacy practice and improve patient care.[8]

9. Crisis Management and the Right to Health

A policy paper published by the Economic and Social Commission for Western Asia (ESCWA) in September 2021 estimated that 82% of the Lebanese population lives in multidimensional poverty. Access to medicines, health insurance, and medical services are the three most vital factors used to determine poverty levels. According to the ESCWA report, 55% of the Lebanese population does not have any health coverage.[9]

Although States bear the primary human rights responsibility for ensuring access to medicines, pharmaceutical companies (including innovator, generic, and biotechnology companies), and healthcare professionals (physicians and pharmacists), share joint human rights responsibilities concerning access to medicines, particularly in low-income countries.

The need for constructive cooperation and coordination across all pharmaceutical stakeholders has emerged as a matter of importance and urgency to put in place actions that would enable the country to achieve national self-sufficiency. The improvement of access to medicines has a significant position in the societal purpose of pharmaceutical corporations. Working together, experts representing these firms must establish as much common ground as feasible and good faith agreements that would suit the goal.

PURPOSE OF THIS DOCUMENT

This document aims to suggest the critical elements that need to be addressed in the planned National Pharmaceutical Sector Strategy that the Order of Pharmacists of Lebanon (OPL) intends to develop in consultation with the main concerned stakeholders. It is to be considered a general framework that will initiate policy dialogue and culminate into a concrete 5-10 years National Pharmaceutical Sector Development Strategy (shortened to National Pharmaceutical Strategy) that will be used to guide the public and the private sectors.

The focus is on rebuilding adequate, sustainable, and equitable funding mechanisms, as an essential building block for UHC (availability, accessibility, affordability, and quality), within the overall SDG 2030 targets, developing self-sustainability of the sector, and promoting innovation/development. Developing the national pharmaceutical strategy at this time of multiple crises in Lebanon is considered a window of opportunity.

The development of this strategy coincides with that of the national health strategy, the ultimate aim for this strategy being to be integrated into the national health strategy.

[8] Ammar MA, Tran LJ, McGill B, Ammar AA, Huynh P, Amin N, Guerra M, Rouse GE, Lemieux D, McManus D, Topal JE, Davis MW, Miller L, Yazdi M, Leber MB, Pulk RA. Pharmacists leadership in a medication shortage response: Illustrative examples from a health system response to the COVID-19 crisis. J Am Coll Clin Pharm. 2021 Apr 28:10.1002/jac5.1443. doi: 10.1002/jac5.1443.

[9] Economic and Social Commission for Western Asia (ESCWA). Multidimensional poverty in Lebanon (2019-2021): Painful reality and uncertain prospects. https://www.unescwa.org/sites/default/files/pubs/pdf/multidimensional-poverty-lebanon-2019-2021-english.pdf

MISSION AND VISION OF THE NATIONAL PHARMACEUTICAL STRATEGY

The mission of the National Pharmaceutical Strategy is to contribute effectively to UHC through universal and sustainable access to quality medications and secure their rational use while ensuring that the pharmaceutical sector develops steadily in line with national health requirements and context.

The vision of the National Pharmaceutical Strategy is to ensure timely access for all patients ("leaving no one behind") to quality, affordable, and safe medications without suffering financial hardship.

STRATEGIC PILLARS

A comprehensive strategy is proposed with short term objectives and a long-term vision, aiming to contribute to achieving UHC ensuring the following pillars that need to be kept in mind:

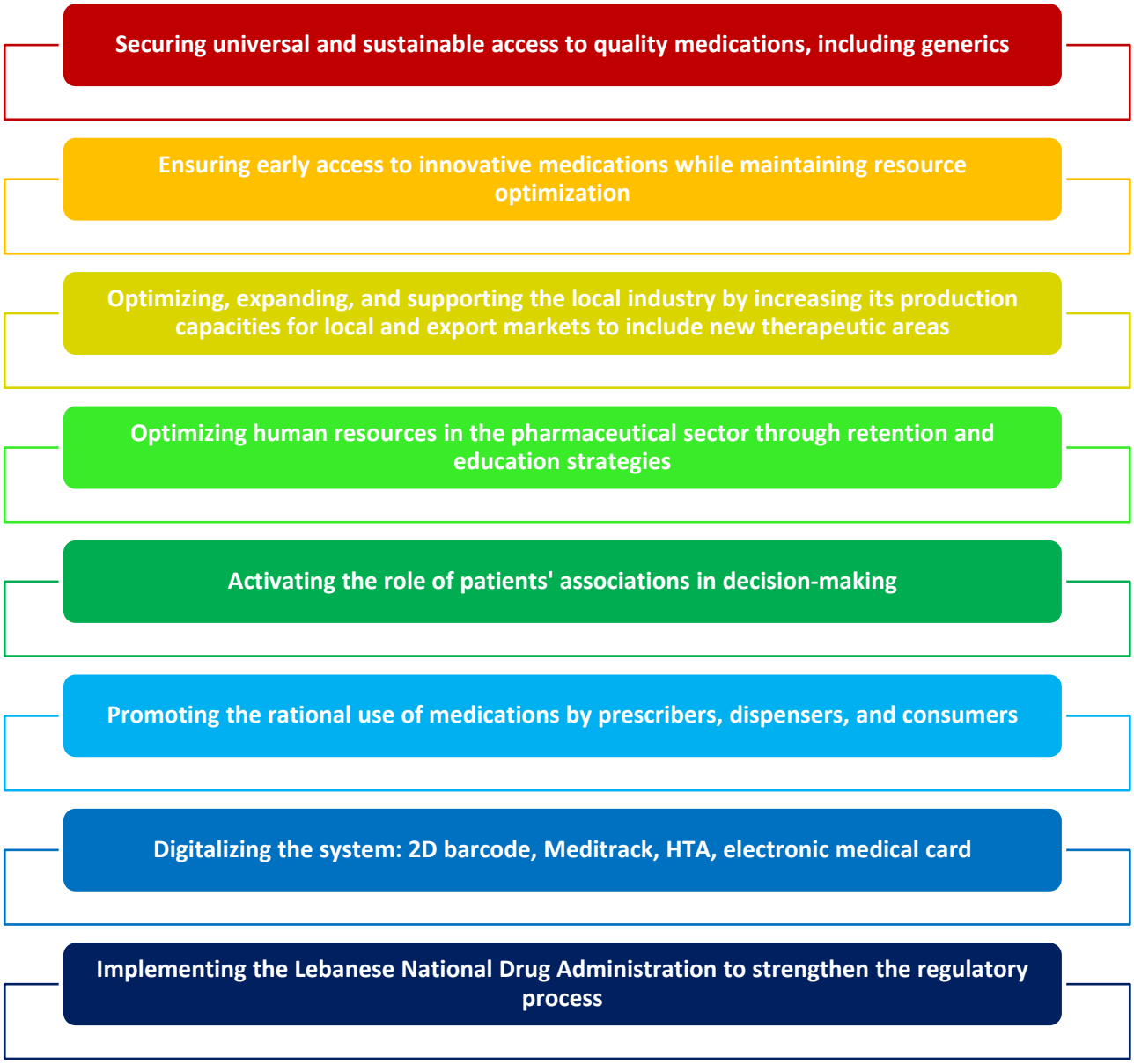

Figure 1. Strategic pillars to ensure safe and quality medications in Lebanon: What to keep in mind during the strategy development

PRINCIPLES AND VALUES

The strategy should abide by the ten Good Governance Principles suggested by the WHO that were derived from the United Nations Development Program (UNDP) principles[10]:

Figure 2. Principles of good governance

These principles are[11]:

- **A strategic vision:** To have a broad and long-term perspective for the pharmaceutical sector in Lebanon.
- **Participation:** Participation and inclusion include empowerment through representation in government and administrative and local mechanisms facilitating free, active, and meaningful participation in decision-

[10] UNDP. 8 Governance Principles, Institutional Capacity and Quality. 2011. https://bit.ly/3s9TWsO
[11] Siddiqi S, Masud TI, Nishtar S, Peters DH, Sabri B, Bile KM, Jama MA. Framework for assessing governance of the health system in developing countries: gateway to good governance. Health Policy. 2009 Apr;90(1):13-25. doi: 10.1016/j.healthpol.2008.08.005.

making processes. The OPL is keen to mediate divergent perspectives to reach a broad consensus on the strategy for what is in the best interest of the population and other stakeholders.

- **Transparency:** It means that all stakeholders (citizens, professionals, and others) understand and have access to the means and how decisions are made, particularly if they are directly affected by such decisions. Transparency should be built on a free flow of information for all health matters and accessible to those concerned. Enough information should be available to monitor the strategy implementation.
- **Accountability:** It refers to institutions being ultimately accountable to the people and one another. These include government agencies, civil society, and the private sector.
- **Rule of law:** It refers to the respect for current impartial legal systems in Lebanon that protect the human rights and civil liberties of all citizens, especially vulnerable populations.
- **Information and intelligence:** Refer to using data and digital technologies for evidence-based decisions and monitoring through indicators. They are essential for a good understanding of the pharmaceutical sector, without which it is not possible to provide evidence for informed decisions.
- **Responsiveness:** This is when institutions respond to their stakeholders within a reasonable time frame.
- **Equity:** Addresses power inequalities (be they political, economic, legal, or cultural) and requires the extension of development gains to the most excluded groups and individuals.
- **Efficiency and effectiveness:** They are developed through the sustainable use of resources to meet the needs of society. Sustainability refers to ensuring social investments materialize and that natural resources are maintained for future generations.
- **Ethics:** It means to follow various codes of ethics related to the pharmaceutical sector, e.g., the code of conduct for pharmacists, the code of conduct for civil servants, and the code of ethics for drug promotions.

The implementation of this strategy should follow the good governance approach, i.e., it should be developed to be consensus-oriented, demonstrated by an agenda that seeks to mediate between the many different needs, perspectives, and expectations of a diverse citizenry. Decisions should reflect a deep understanding of the historical, cultural, and social context of the community.

POTENTIAL STAKEHOLDERS

Potential stakeholders include the MOPH, pharmaceutical companies (Lebanon Pharma Group and Lebanese Pharmaceutical Importers Association-LPIA), local manufacturers (Syndicate of the Pharmaceutical Industries in Lebanon-SPIL), health professionals (physicians, pharmacists, dentists, nurses, and others), academia, third-party payers (private insurance companies, and the seven different public funds in Lebanon), parliament, media, and patient representatives (NGOs). The support of the WHO and the International Pharmaceutical Federation (FIP) would also be necessary.

EXPECTED OUTCOMES OF THE NATIONAL PHARMACEUTICAL STRATEGY

- To ensure the accessibility and availability of all types of medications in Lebanon, at affordable prices (locally manufactured quality products and imported quality products).
- To ensure the local production and importation of quality-assured pharmaceutical products, thus avoiding the circulation of any sub-standard medical products in the Lebanese market.
- To ensure access to the essential medications by all people residing in Lebanon, particularly the most vulnerable, without experiencing financial hardship.
- To redesign sustainable, adequate and equitable funding mechanisms, enabling public health insurance entities to provide beneficiaries with a comprehensive healthcare benefit package.

- Public funds and insurance companies/third party payers, to rely on an evidence-based, clear, and explicit decision process for the assessment of health technologies.
- To assist the Lebanese government/regulatory authority in developing and implementing a time-bound roadmap for transition between the MOPH and the newly established Lebanese Drug Administration (LDA) by the law issued in 2022. This roadmap/implementation plan would include what regulations need to be upgraded and used by LDA (e.g., registration, pricing) and what other functions still need to be carried out by the MOPH (e.g., licensing, controlled substances).
- To define the "new" role of MOPH as a "tutoring authority" in relation to the role of LDA, as set by the law, and the role of OPL in implementing the strategy to be proposed.
- To develop a human resources strategy for pharmacists, and other specialties, needed for local manufacturers. Furthermore, to support the importation, distribution and technical evaluation of innovative solutions through relevant training and education, proposing retention strategies.

GAP ANALYSIS

1. Cross-Cutting Elements for Regulatory Health Systems According to WHO

What actually exists in Lebanon	What should happen
Low trust in the government due to the lack of transparent decisions in the absence of long-term healthcare strategies, especially after the collapse of the health sector and the crisis of shortage of medications. A collapsing state unable to find sustainable solutions related to the availability of medications and other health services.	Leadership and governance: increase confidence in the health system and medications.
Laws exist but are not fully implemented, i.e., LDA, Good Manufacturing Practice (GMP) inspection of importing manufacturers, reimbursement of locally manufactured products according to MOPH price.	All activities should have legal bases and existing laws should be regularly updated in accordance with the requirements of due process.
Lack of implementation decrees for the LDA and lack of premises, staffing, and budget.	Develop a structure that puts plans and strategies.
Suboptimal assessment process for health technologies by some budget holders in Lebanon.	Plan an explicit decision-making process for assessing and investing in health technologies, ensuring efficient and equitable access to innovative treatments and quality care.
Standard guides, specifications, and procedures are not fully developed. There is a need for several types of strategies and clinical guidance documents related to medications treatment modalities and priorities.	Develop standard guides, specifications, and procedures.
Funding healthcare in general, and medications in particular, has been compromised by the economic crisis and the sharp depreciation of the local currency. No new funding sources have been identified yet.	Establish adequate and equitable funding mechanisms for healthcare in general and medications in particular.
No structured national quality assurance system for the health system or products.	Establish a quality assurance system for the health system and products.
Lack of needs assessment to inform decision-makers about the size and specialization of the needed health workforce.	Capacity building to have competent and sufficient human resources to manage the system.

The adequacy of the health workforce has not been assessed systematically yet, except for some personal initiatives, especially in the light of the significant brain drain generated by the economic depression.	Assess the workforce competencies and prompt appropriate changes through education. Maintain the health workforce for optimal service delivery and develop policies aiming to retain the health workforce and reverse the brain drain. Provide incentives for pharmacists to stay.
Lack of a national strategy for digitalizing healthcare.	Develop a national strategy for digitalizing healthcare. Determine the fields that should take the priority to implement the information system and digital health.

2. Pharmaceutical Sector: From Clinical Trials to Manufacture/Registration and Use/Disposal

The strategy will cover the following components/functions but to varying extent based on the priorities and the current situation in Lebanon.

2.1. Medication Development and Clinical Trials

Regarding drug development and trials, some regulations about clinical trials already exist in Lebanon and are in line with international requirements. A clinical trial registry with international recognition is in place, which will promote innovation and early access to Lebanese markets and patients.

What actually exists in Lebanon	What should happen
Some regulations about clinical trials already exist, but the registry is not promoted enough.	Promote the use of the MOPH clinical trials registry by researchers and pharmaceutical companies. Promote and enhance innovation in Lebanon. Establish a bioequivalence center in Lebanon, recognized nationally, regionally, and internationally.
Pre-marketing requirements exist, but are not applied in all situations.	Ensure adequate pre-marketing requirements for products. Review legislations related to registration. Develop transparent and evidence-based criteria for fast-track registration.

2.2. Local Manufacture (Including Packaging)

There are 12 local manufactures in Lebanon, of which three are specialized in serum products that are self-sufficient for the Lebanese market needs.

Several local manufacturers with Good Manufacturing Practice (GMP) certification and high-quality standards operate in the market. However, their contribution to the pharmaceutical sector remains shy, despite many positive points: Local manufacturers implement a stringent local and regional GMP; they are trusted partners and licensees of some multinationals, who moved their production to the Lebanese facilities and used them for exports of some products. As per IQVIA 2021 report, the local pharmaceutical industries are among the key players in the market (top 10 in terms of units).

The prescription habits are geared towards branded and originator products and to the insufficient perceived quality of some generics in the absence of a central laboratory (this concept also applies to imported generics). Another interpretation would consider the historically limited (if existing) difference in price, leading to the stated brand preference[12]: Price differences have always been safeguarded by price revision

[12] El-Jardali F, Fadlallah R, Morsi RZ, Hemadi N, Al-Gibbawi M, Haj M, Khalil S, Saklawi Y, Jamal D, Akl EA. Pharmacists' views and reported practices in relation to a new generic drug substitution policy in Lebanon: a mixed methods study. Implement Sci. 2017 Feb 17;12(1):23. doi: 10.1186/s13012-017-0556-1.

initiatives and decrees taken by the different health ministers. The prices of the local products are on average 30% less than the originators and on average 25% less than the imported generics.

What actually exists in Lebanon	What should happen
Limited awareness about locally manufactured medications by prescribers and patients.	Enhance awareness through campaigns about quality as part of comprehensive nationwide efforts to encourage prescription, dispensing, and use of locally produced medications whenever available to ensure saving on the national pharmaceutical bill.
Inconsistent enforcement of GMP in the country for manufacturers and manufacturing sites for imported medications.	Supervise foreign and local manufacturers by upgrading and enforcing GMP and joining the Pharmaceutical Inspection Co-operation Scheme (PIC/S).
No incentive to manufacturers for full manufacturing of products.	Ensure the manufacturing of quality-assured products by providing incentives to expand the production profile of local manufacturers. Develop the environment for local manufacturing diversity.
Only a few locally manufactured products are exported.	Increase export opportunities for locally manufactured products by setting relevant regulations, i.e., mutual trade agreements: Apply the principle of reciprocity تطبيق مبدأ المعاملة بالمثل

2.3. Regulations of Medications: Registration, Selection, and Pricing

At the MOPH, the Department of Pharmacy handles all regulatory control measures, including licensing professionals and establishments (manufacturers, pharmacies, importers, etc.). It has three subunits: inspection, importation and exportation, and narcotics.

The Technical Committee for registration works according to SOPs; measures were taken to ensure the registration of quality drugs, e.g., requiring a certificate of analysis from an internationally recognized laboratory as a prerequisite for registration or a bioequivalence study in the case of generic drug registration. Nevertheless, quality control tests are an essential tool to ascertain compliance with the specifications, hence the need for a Technical Committee involving more specialists allowing for less political interference and the re-establishment of the central laboratory. In the current context of currency depreciation, the financing of healthcare and medications remains the main issue to ensure affordability for patients. This process should be complemented by Health Technology Assessment (HTA) for effectiveness and cost-worth.

Now that an independent LDA law has been approved, efforts should be conducted to activate it, and collaboration modalities with the MOPH should be defined. In all cases, competent authorities should ensure adequate manufacturing requirements are met and secure the procurement of quality products related to specifications and compliance with quality assurance standards.

Finally, Lebanon remains committed to preserve intellectual property protection rights, evidenced by the removal of Lebanon from the watch list Special 301 Report.[13]

What actually exists in Lebanon	What should happen
Certificates from “international” laboratories are required for registration.	Optimize pre-registration requirements to guarantee the quality of registered medications by issuing a new modernized registration law (for originators, local manufacturers, biosimilars, and generics), adopting international regulations and guidelines.

[13] USTR Releases 2022 Special 301 Report on Intellectual Property Protection and Enforcement. https://bit.ly/3s9TWsO

Pricing regulations are not based on long-term plans and strategies, thus affecting all stakeholders.	Revise regulations. Optimize the consideration of affordability and profitability based on a long-term planned strategy to maintain the sustainability of the pharmaceutical sector, including multinational companies and local industries.
There is no central laboratory to assess medication quality.	Establish and activate the central laboratory and secure the needed funding.
The Pricing Committee at the MOPH works based on the decisions of subsequent ministers.	A more transparent and evidence-based pricing should be applied.
Reimbursement decisions are fragmented at the level of the public and private funding bodies.	Establish an explicit and consistent decision-making framework relying on evidence to invest in interventions that hold relatively good value and are affordable.
Enlistment principles are not clear.	Enlistment principles should be clarified, allowing for a strategic reserve of medicines to be secured.
No clear timelines for approving new products, and some regulatory changes might impact the supply.	Define clear timelines for approvals.

2.4. Import, Storage, and Distribution

Although Good Storage and Distribution Practices of Pharmaceutical Products (GSDP) guidelines exist and are implemented, it needs to be included in an appropriate, clear, and institutionalized mechanism. The traceability of products was also decided through the barcode project at the MOPH but is newly being applied. Maintaining the quality of health products by enforcing GSDP and traceability requirements helps supervise the in-country supply chain.

Moreover, drug shortages should be addressed through the rationalization of consumption (e-prescription is one of the suggested solutions, among others). Primary Healthcare centers should have plans for minimum stock of at least six months of essential medicines and vaccines and an alarm system when stock is near a certain threshold with set mechanisms for stockpiling when needed.

Better control of the parallel import in Lebanon and enforcement of applicable regulations are needed. A tracking system is a must to ensure quality and lower prices. These components should be articulated within an effective national supply system for emergencies and disasters.

The MOPH has been working to establish a “track and trace system” for imported and locally manufactured pharmaceuticals to guarantee their quality, safety, and efficacy. For this purpose, the MOPH, with the support of WHO, facilitated the development of the National Barcode System (NBS) for Pharmaceuticals in Lebanon using a GS1 two-dimensional (2D) barcode printed on all packages and linking all stakeholders through a shared information system. The use of the data matrix 2D barcode will allow traceability of products while moving from one location to another until it reaches the patient.

Adjusting the software based on the pilot phase findings has also been completed. The basic regulations and guidelines needed have been published. The next phase will be to rapidly operationalize the NBS at the national level and implement it at the level of community and hospital pharmacies.

Moreover, the WHO supported the MOPH in developing a fully automated logistics and management system (LMS) for the medications and medical devices distributed at the MOPH Central Drug Warehouse. The LMS would optimize the control of MOPH stocks from the warehouse to the dispensing centers. It would also provide real-time data on medication availability at the central and peripheral levels and facilitate ordering and replenishing stocks on time, thereby reducing medicine stockouts. The LMS was tested successfully to be interoperable with existing MOPH patient record systems at PHCs such as PHENICS. Most medicines with 2D barcodes are registered in the MOPH Meditrack system. However, for non-registered ones, the WHO

developed a temporary code to include them in the system and ensure proper tracking of medicines across the LMS. Regarding data integrity, the LMS will be linked to other MOPH systems to unify beneficiary identity and avoid duplication.

What actually exists in Lebanon	What should happen
GSDP exists but without a clear and sustainable implementation mechanism.	Enforce GSDP to become a requirement rather than an option.
The Barcode project and Meditrack are being slowly applied. No traceability of medications beyond distribution.	Enhance the traceability of medications and expand it to reach the patients by applying the patient profile in community pharmacies.

2.5. Access to Medications and Financing

Access to essential medications is part of universal health coverage. Although ensuring equitable access to quality care is a primary objective of the National Pharmaceutical Strategy, this objective is highly dependent on an essential element of the strategy, namely financing. The economic decline and the local currency depreciation have led to a sharp decrease in the purchasing power of the revenues collected domestically for healthcare. Consequently, public risk pooling entities, in addition to individuals and households, are no longer able to afford the actual cost of healthcare. In an attempt to contain the situation, the Central Bank issued an interim measure to subsidize the importation of medications in part. However, added to other factors, the currently adopted subsidization mechanism has led to frequent stock ruptures and suboptimal patient care. Hence, financing represents a priority that should be addressed through this strategic plan, aiming to restore the ability of risk pooling entities to afford the actual cost of healthcare (non-subsidized cost).

2.5.1. Funding healthcare, including medications

The current healthcare funding mechanisms have been compromised by the steep depreciation of the local currency, thus the need to ensure adequate and equitable funding that would balance the collected revenues with healthcare expenditures.

- Government transfers

Several public risk pooling entities are funded wholly or partially by government transfers. Accordingly, the government collects tax and non-tax revenues and decides on yearly budgets to allocate to each of the relevant risk-pooling entities, such as the Ministry of Public Health, the Armed Forces, the Civil Servants Cooperative, and other relevant bodies. In addition, the government subsidizes 25% of the healthcare expenditures of the maternity and sickness fund at the National Social Security Fund (NSSF).

Firstly, the government has defaulted on several yearly payments to the NSSF. Accordingly, and in an attempt to restore the fund's ability to afford the actual cost of the healthcare provided to their beneficiaries, the government should aim to settle, the soonest, NSSF's dues, which should happen in an agreement on the further relevant details among the concerned parties.

Secondly, the government has to allocate adequate funding, in the local currency, for the concerned public risk-pooling entities, considering the depreciation of the local currency. This allocation should account for the purchasing power of the local currency, the evidence generated from a thorough needs assessment, and previous years' expenditures reports. Conversely, this brings forward the questionable ability of the government to allocate adequate funds; thus, the importance of finding new funding mechanisms hypothecated directly for healthcare, contrary to the current model where funding healthcare relies mainly on general taxation. Furthermore, whereas the local tax system relies on regressive taxation mostly, bringing additional funds should consider an equitable funding approach, not through the addition of non-equitable taxes.

Thirdly, the government should rely on global evidence to generate additional and sustainable funding for healthcare and medications. The taxation of harmful behaviors, for example, has compiled a significant load of evidence globally, with a clear double impact on health and healthcare, i.e., reducing harmful behaviors at the population level (which is considered a paramount input for health production) and generating adequate funding earmarked for healthcare and medications.

- National health insurance contributions through the NSSF

The steep depreciation of the local currency has diminished, in general, the purchasing power of the salaries of the employees in the private sector. In addition, the correction of the salaries' real value is expected to happen at a relatively slow pace. While this significantly affects individuals and households, it does also affect the ability of the Maternity and Sickness Fund at the NSSF to afford the actual cost of the healthcare benefit package they offer to their beneficiaries. Accordingly, the NSSF has to revisit its current contribution model to ensure equitable and adequate funding for the Maternity and Sickness Fund, restoring the trust of its beneficiaries and re-gaining its role of financial protection against illness.

Firstly, the design of the contribution system should be revisited to minimize contribution evasion, a problem currently plaguing the NSSF.

Secondly, the NSSF should look at ways to increase funding in a progressive manner, e.g., revisiting the upper-ceiling for contributions or rendering the contribution system progressive rather than proportional. However, any decision should factor-in potential impact on the labor market.

Thirdly, co-payments also play a funding role, though it also holds other purposes, i.e., addressing the moral hazard of patients and prescribers. The current co-payment system at the NSSF is regressive by nature; it depends on the medical condition, and the payable amount by the patient is proportional to the price of the intervention while completely disregarding the individual or household's income. Moving forward, reforms should consider three points taken from a regional report by the European WHO regional office. First, poor people or people with chronic conditions should be exempted from co-pay. Second, annual caps should be set to keep co-pays under an affordable ceiling and avoid catastrophic spending on healthcare. Third, co-payments should be absolute and not a percentage from treatment cost. An alternative for this third payment, is to make the co-pay depend on salaries rather than treatment cost. Experts should be consulted on that matter.

Finally, NSSF beneficiaries are currently paying additional charges, which are not officially part of the co-payment, because of the difference between the price fixed in the local currency by the NSSF and the higher price charged by the providers. This additional amount is caused by the depreciation of the local currency that could represent an affordability obstacle from the patient's perspective, thus the need for the NSSF to secure additional revenues and rationalize some interventions (i.e., lab tests, MRI, etc.) to afford the actual cost of healthcare and medications (digitalization is a must).

- Out-of-pocket payments

It is of primary importance for the government to ensure that public risk-pooling entities will not lose their role of financial protection against illness. Otherwise, the rate of catastrophic spending on healthcare and the impoverishment rates due to healthcare expenses will considerably rise.

- Foreign aid

While the government strives to build sustainable funding mechanisms, foreign aid could play a prominent role in bridging the gap while ensuring that no patients are left behind. This matter should not push the government to displace or reduce the allocated budget of healthcare and medications; instead, the foreign aid should be added on-top to the locally allocated budget.

In addition, the government should encourage and facilitate fundraising or donations for drug financing, especially for the disease areas where frequent stock ruptures of critical medications is witnessed. Donations of medicines should be accepted based on WHO guidelines.[14]

2.5.2. Management of scarce resources with efficiency and equity

It is more important than ever, at this stage, for the risk-pooling entities to seek efficient investment decisions while ensuring equitable access to healthcare. Thus, the need for the development of an explicit decision-making framework for assessing health technologies. The process should rely on evidence, reward value, and ensure a multi-stakeholder involvement. Optimizing the efficiency of investments in health technologies would enable risk-pooling entities to treat more patients better. Additionally, patients with equal needs should be treated equally (horizontal equity). Thus, the government should strive for more equitable access to healthcare across the fragmented healthcare system. In addition, the government and the health system should seek to provide people with higher health needs more healthcare than those with lesser needs (vertical equity).

What actually exists in Lebanon	**What should happen**
Public risk-pooling entities are losing their role of financial protection against illness because of compromised funding mechanisms. Principles of enlistment by public funds for reimbursement are unclear.	Establish sustainable and equitable funding for healthcare at public risk-pooling entities. Standardize enlistment principles. Unify and centralize the bidding process for all public funds while prioritizing local production if available. Supply PHCs with locally produced medications if available and less expensive.
Funding for healthcare is not hypothecated (earmarked/dedicated). There is a shortage of many acute, chronic, and medications used for catastrophic conditions like cancer and dialysis.	Develop laws related to the taxation of harmful behaviors earmarked for healthcare. Secure the availability of medications.
There is no clear, explicit, consistent, and evidence-based approach for deciding on investments in health technologies.	Develop feasible and fair decision-making processes for the evaluation of health technologies.
Foreign aid is prevalent.	Facilitate development loans for drug financing while ensuring that investments are not displacing a domestic allocation of budget for healthcare and that the foreign aid is invested in a priority area. Regulate the drug donation part while ensuring quality and reducing waste.
Access to healthcare and medications is inequitable.	Issue and implement policies that would enhance horizontal and vertical equity in healthcare. Ensure adequate and equitable funding to balance collected revenues and healthcare expenditures. Promote public-private partnerships. Involve international support agencies (WHO, other UN agencies...).

[14] World Health Organization. Guidelines for Medicine Donations Revised 2010, vol. 2020. WHO, Geneva, Switzerland. 2011. https://www.who.int/publications/i/item/978924150198-9

2.6. Rational Use of Medications: Prescribing, Dispensing, and Using

As per the global figures of the WHO, more than 50% of all medications are prescribed, dispensed, or sold inappropriately, and 50% of patients fail to take their prescribed medications correctly. Medications can be inappropriately prescribed and dispensed in Lebanon; these patterns should be monitored. The appropriate use of medications could be achieved by supervising in-country prescribing and dispensing and enforcing good clinical practices (standard treatment guidelines in primary, secondary, and tertiary care) and good dispensing practices. An updated national formulary should be in place. Efforts should be made to reduce antimicrobial resistance and other abuse/misuse-related problems and enhance medication adherence to regimens to improve treatment outcomes. Furthermore, post-marketing studies are conducted thanks to the personal initiatives of some academics and some pharmaceutical companies.

Regarding generics, the MOPH has undertaken initiatives to contain the cost related to pharmaceuticals and promote the use of generic drugs. Also, prescribers have a prominent role in the absence of medical prescription accountability. Most importantly, these generics are predominantly imported, while efforts should be deployed to have locally manufactured generics.

What actually exists in Lebanon	What should happen
Prescription errors and inappropriateness have been reported in studies.	Diffuse treatment protocols according to national and international guidelines. Monitor and optimize prescribing and dispensing practices.
Medication misuse and non-compliance are common among patients.	Rationalize the use of medications through electronic prescriptions and patient profiles. Rational therapeutic protocols should be promoted in the media through awareness campaigns and patient education, using tailored and targeted interventions at all levels (prescribers and pharmacists). Digital Health should be well regulated.
The use of locally manufactured generics is low overall, although it increased during the current crisis.	Adopt a clear strategy for medication use that includes reinforcement of substitution of prescriptions and increases awareness of the local industry.
The classification of medications is not clear to all stakeholders.	Review the guidelines for drug classifications: prescription-only, repeat prescription for chronic medications, Over-the-Counter products, and renewal guidelines for the use of narcotics (to promote palliative care), psychotropics, and other mental health medications.

2.7. Pharmacovigilance

Competent authorities should ensure the collection, detection, assessment, monitoring, and prevention of adverse events and guarantee that initial risk/benefit information is updated and risk mitigation implemented.

The pharmacovigilance system is newly established by the MOPH for this purpose. It should assess medication use post-marketing in special populations and long-term use. Currently, the pharmacovigilance system activities are limited so far to COVID-19 vaccine adverse events.[15] Their work can be expanded to all marketed products.

[15] Ministry of Public Health. The Pharmacovigilance System in Lebanon. https://www.moph.gov.lb/ar/Pages/4/44742/pharmacovigilance-system-lebanon

What actually exists in Lebanon	What should happen
The national pharmacovigilance system is still in its infancy.	Optimize the collection, detection, assessment, monitoring, and prevention of adverse events of all medications and medical devices. Initiate reporting at the facility, physician, pharmacist, and patient levels.

2.8. Market Control for Product Quality

There is a need to ensure conformity of marketed health products with high-quality standards: withdrawal of substandard and counterfeit products from the market is necessary, thus the urgency for a central laboratory to evaluate the quality of marketed products, ensuring conformity with-quality norms.

What actually exists in Lebanon	What should happen
There is a lack of post-marketing surveillance of product quality to avoid substandard and counterfeit medications.	Ensure the conformity of marketed health products with high-quality standards by enhancing a reporting system portal and making it available to patients and healthcare professionals.
The current recall drug system relies on memos issued by regulatory bodies in other countries or WHO.	Put in place an active drug recall system.

2.9. Human Resource Strategic Development

Several studies have shown the need for training in many sectors of pharmacy practice and a mismatch between the competencies of graduates and the job market needs. There are also perceived needs in many institutions, ranging from public to private; some specialties are lacking, while there is an overflow for others. This discrepancy is mainly related to the absence of a national workforce strategy. Moreover, committees in the public sector should be optimized.

Furthermore, recent studies could demonstrate that a high percentage of healthcare workers, including those in the pharmaceutical sector, are leaving the country. This finding indicates the need to reverse the brain drain through innovative projects and appropriate policies and projects.

What actually exists in Lebanon	What should happen
Professionals handling medications are not well-trained, with many needs being expressed or perceived by consumers related to this lack.	Develop a workforce strategy relying on education (initial and continuing) and professional development and following the pharmacy sector and market needs.
The Technical Committee responsible for registration is limited in the number of members and lacks some specific expertise (e.g., in biosimilars). It also lacks sufficient resources leading to delays in approvals.	Optimize human resources that handle drug registration and variations: expand the Technical Committee to issue decisions faster within the legal framework (reduce parallel import).
The Fast-Track Committee has been recently formed to respond to the current crisis.	Integrate the Fast-Track Committee into the Technical Committee for a faster and better workflow.
Most health professionals in Lebanon are geared toward disease treatment, while disease prevention and health promotion activities are uncommon and mainly conducted by health authorities.	All healthcare professionals, particularly pharmacists, should have a strengthened role in health promotion, allowing them to contribute actively to achieving Universal Health Coverage.
Industry-related specialty degrees are limited.	Develop/update some majors to meet the industry needs and retain talents.

2.10. Medication-Related Research

There is no national research strategy related to pharmacy and pharmaceutical products. Pharmaco-epidemiology studies are conducted by academics only or pharmaceutical companies, despite conflicts of interest. Moreover, very few clinical/interventional trials are conducted in Lebanon; these are mainly driven by pharmaceutical companies.

What actually exists in Lebanon	What should happen
Pharmaco-epidemiology studies are conducted on individual initiatives (academia and some pharmaceutical companies).	Assess medication use post-marketing in special populations and long-term use.
Clinical/interventional studies are mainly driven by pharmaceutical companies.	Develop a research strategy to organize and support research efforts in the field.

2.11. Control of Promotion and Advertising

As for marketing practices, while a Lebanese Code of Ethics is in place, enforcement by authorities and the relevant professional orders is still needed. Marketing practices are still affecting prescribers' behaviors.[16] Monitoring pharmaceutical companies marketing activities and prescribing physicians should be considered for discussion through an appropriate assessment system, similar to developed countries.[17]

What actually exists in Lebanon	What should happen
There is no reliable system to monitor marketing methods and no proper enforcement of the code of ethics for drug promotion.	The marketing procedures of pharmaceutical companies should be standardized.

2.12. Handling of Waste and Expired Products

Although competent authorities should ensure the appropriate disposal of health product wastes, there is no adequate system for medication disposal in Lebanon. An agreement was signed between the MOPH and drug importers to export the waste and expired items, but its application is not yet optimized and consists of an additional loss that is not compensated by any party, thus increasing the burden on all involved stakeholders. Establishing a local "incinerator" remains a must, considering the use of existing incinerators in the country used in other industries and ensuring the environmental safety of such practices. It can serve to reduce the burden while keeping the foreign currency in Lebanon.

As for the general population and healthcare professionals, pharmaceutical wastes are generally dumped through domestic sewage pipelines or stored in warehouses for years until they can be exported to other countries. Some might also have an unknown fate, constituting an environmental hazard. A complete strategy is thus necessary to take into account these matters in Lebanon.

What actually exists in Lebanon	What should happen
There is no appropriate system for medication disposal in the community and healthcare settings.	Mitigate environmental hazards related to pharmaceutical wastes through an appropriate plan. Explore local solutions that might be applicable and environmentally acceptable.
The disposal system by pharmaceutical companies and industries is not optimal.	Optimize the agreement between LPIA, SPIL, and the MOPH.

[16] Khazzaka M. Pharmaceutical marketing strategies' influence on physicians' prescribing pattern in Lebanon: ethics, gifts, and samples. BMC Health Serv Res. 2019 Jan 30;19(1):80. doi: 10.1186/s12913-019-3887-6.

[17] Leonardo Alves T, Lexchin J, Mintzes B. Medicines Information and the Regulation of the Promotion of Pharmaceuticals. Sci Eng Ethics. 2019 Aug;25(4):1167-1192. doi: 10.1007/s11948-018-0041-5.

TARGETED LEVELS AND STRATEGIC GOALS

Based on the above points, many strategic goals and elements/initiatives can be proposed to be adopted and implemented by the competent authorities. It is suggested to prioritize the objectives and refine them based on the available resources. Next, more practical steps about the implementation of this strategy should be discussed and agreed upon.

1. Product	•Enhance the quality of medications on the Lebanese market to increase trust in generics and available brands.
2. Funding	•Improve and ensure adequate, sustainable, and equitable funding for healthcare in general and medications in particular.
3. Access	•Improve universal and sustainable access by patients to medications (essential and innovative ones).
4. Workforce	•Optimize the competencies of administrators and healthcare professionals related to medication development, manufacturing, handling, and use.
5. Rational Use	•Promote the rational use of medications by prescribers, dispensers, and patients. •Empower patients through awareness campaigns and communication with patient associations.
6. Policy-Makers	•Involve policy-makers in all activities, including innovative projects and new models. •Activate the Lebanese Drug Administration (LDA).
7. Digital Reform	•Digitalize all the steps related to the strategy, from development to waste management.

Figure 3. Targeted levels and strategic goals

EXPECTED CHALLENGES IN IMPLEMENTING THIS STRATEGY

Many challenges are expected when establishing effective and equitable access to medicines and vaccines in the Eastern Mediterranean region[18]:

- Lack of good governance;
- Weak regulatory mechanisms;
- Medication shortages and stockouts;
- inefficient procurement and supply management systems;
- Low capacity to conduct health technology assessment of medical products;
- High-out of pocket spending;
- Irrational use of medications, contributing to the increase in antimicrobial resistance;
- Limited collaborations.

Lebanon has additional challenges to the above:

- Lack of political will;
- Political instability;
- Lack of domestic funding;
- Lack of exit strategies for the government;
- Steep economic crisis.

THE WAY FORWARD

There is a need to establish a national Technical Committee to follow up on the implementation of this strategy, identify priorities based on the strategic goals and expected challenges, and monitor the implementation progress.

Suggested activities and their application modalities are to be discussed within small groups of involved stakeholders.

[18] World Health Organization. Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean, 2020–2030, including lessons from the COVID-19 pandemic. World Health Organization. Regional Office for the Eastern Mediterranean; 2020. https://apps.who.int/iris/handle/10665/335952

STRATEGIC GOALS AND IMPLEMENTATION SUGGESTIONS

Each of the below initiatives/activities are related to needed actions, terms (short, medium, and long), involved stakeholders, responsible entity, priority level, and indicators.

All the below are suggestions to be discussed in small groups.

1. Product: Enhance the quality of medications available on the Lebanese market.
Define a clear framework for medications quality assurance (standards for manufacturing, registration, distribution, storage, use, and disposal). - Suggest updates to the related legal framework (e.g., laws, decrees, decisions, policies). - Optimize the registration requirements to guarantee registered medication quality. - Adopt a transparent and scientific registration system, including more elaborated pre-marketing requirements that incorporate the fast-track process for products out of the market that have no alternative and criteria of approval to ensure early access to innovative products (Reliance model), a priority to be taken into consideration. - Establish a modern life cycle management system to allow proper review of the upcoming regulatory changes, a priority to be taken into consideration. - Ensure the conformity of marketed health products with high-quality standards, even after marketing. - Establish the central laboratory and secure the needed funding. - Create a monitoring system for GSDP with clear policies; enforce GSDP practices. - Ensure supervision of manufacturers through upgrading and enforcing GMP.
Develop the environment for local manufacturing diversity. - Determine the pharmaceutical industries that Lebanon needs to have manufactured locally for the country to attain pharmaceutical security. - Pharmaceutical security can also be attained by establishing strong agreements for importing medications at affordable prices. - Ensure the local manufacturing of quality-assured products by providing incentives to local industries to expand their production lines that are entirely produced in Lebanon or under licensing with international pharmaceutical companies. - Encourage the national industry through expertise exchange and close collaboration with international pharmaceutical companies in Lebanon. - Expand the production profile of local manufacturers. - Ensure that the government approach attracts licensors and partnerships with international pharmaceutical companies to produce their products in Lebanon. - Encourage the collaboration between local manufacturers and scientific offices of international pharmaceutical companies in Lebanon to ensure the availability and affordability of all medications. - Increase export opportunities for locally manufactured products by authorities.
Monitor marketing methods to respect ethical principles and the Lebanese code of ethics. - Control marketing practices of pharmaceutical companies (e.g., gifts and honorarium). - Set motivational plans on the importance of promoting prescription, dispensing, and use of locally produced medications as part of improving the economic cycle in the country by decreasing the flow of foreign currency and creating more working opportunities with local manufacturers as well as with scientific offices of international pharmaceutical companies, in case of collaboration.
Implement plans for environment-friendly disposal of medications. - Mitigate environmental hazards related to pharmaceutical wastes through an appropriate plan. - Optimize the agreement between drug importers syndicate and the MOPH. - Explore locally applicable and environmentally acceptable waste management solutions.
Promote and enhance innovation in Lebanon. - Promote the use of the MOPH clinical trials registry by researchers and pharmaceutical companies. - Establish a pharmaceutical research strategy for Lebanon.

- Emphasize the role of academics as impartial experts in the development and implementation of the national pharmaceutical strategy.
- Consider establishing a bioequivalence center in Lebanon if found to be cost-effective.

2. Funding: Manage scarce resources with efficiency and equity.

Improve and ensure adequate, sustainable, and equitable funding for healthcare and medications.

- Promote long-term sustainable pricing, prioritization, and financing models for medications that could also reflect in improved drug coverage, pricing, and purchasing strategies.
- Prioritize healthcare and medications at the national level, reflected by government allocating adequate budgets.
- Consult with experts to find sustainable funding mechanisms for healthcare and medications.
- Build sustainable funding mechanisms, relying on the allocation of earmarked revenues (tax-related or non-tax related) for healthcare to ensure continuous funding regardless of political dynamics.
- Advance in the implementation of taxing harmful behaviors and earmarking it to healthcare with the double purpose of improving population health and funding healthcare.
- Optimize the funding mechanism at the NSSF by addressing the contribution evasion and optimizing regressive funding barriers (e.g., upper ceiling for contributions, regressive copays).
- Support and sustain public risk pooling entities in their role of financial protection against illness.
- Strengthen the pricing schemes to allow fair pricing and sustainable access to innovation.
- Establish an explicit, consistent decision-making framework relying on evidence to invest in interventions that hold relatively good value and are affordable.
- Promote development loans for drug financing while not displacing local healthcare investments.
- Regulate the donations of medications to Lebanon.

3. Access: Improve universal and sustainable access to medications (essential and innovative ones) by patients.

Secure the availability of essential and innovative medications and vaccines.

- Put in place clear agreements to secure access to essential medications at affordable prices at PHCs.
- Adopt a clear strategy for medication use based on priorities and standard clinical protocols.
- Address the shortage issue through appropriate means.
- Improve and ensure adequate, sustainable, and equitable funding for healthcare in general and medications in particular.
- Promote non-exclusive voluntary licenses to enable Lebanese manufacturers to develop lower-cost generic of patented pharmaceuticals under the terms of the agreements contracted with multinationals, which might be either commercial or non-profit and would include the necessary technology transfer. Under the terms of these licenses, Lebanese manufacturers would be allowed to manufacture and commercialize the generic versions in a tentative to increase patient access to affordable drugs.
- Forbid stockpiling and smuggling by enforcing laws.

Secure a strategic reserve for medicines to prioritize national drug security.

- Establish a task force to work on developing the Strategic Reserve system for medicine.
- The task force will propose agreements to contributing pharmaceutical companies for the provision of emergency and disaster stock, with quantities sufficient to cover the needs of the local market for at least six months.
- Promote generic use through awareness campaigns on quality medications.

Promote public-private partnerships.

- Centralize governmental purchases.
- Tenders should consider a price premium and priority to the local industry (full manufacturing in particular) to support the local sector and reinforce its contribution to public health.

Build a Health Technology Assessment (HTA) framework, enabling budget-holders to make evidence-informed decisions, investing in valuable technologies at a fair and affordable price.

- Propose a concrete and transparent mechanism for public funds and insurance companies/third-party payers to cover advanced treatments based on HTA methods.
- Initialize collaborations and coordinate between different public funds.
- Standardize enlistment principles on public funds lists.

4. Workforce: Optimize competencies of administrators and healthcare professionals.
Optimize human resources handling medications. - Endeavor for human resources retention and education by creating new fields, e.g., clinical pharmacy, industrial pharmacy. - Implement Good Pharmacy Practice principles in the community and promote pharmacy accreditation. - Optimize the existing hospital pharmacy accreditation system. - Diffuse treatment protocols according to national/international guidelines. - Ensure continuing education for health professionals about medications and medication therapy management. - Assess healthcare and administrative Professional Practice Evaluation and suggest guidelines nationally adapted. - Monitor and optimize prescribing and dispensing practices. - Develop continuing education programs related to critical public issues, e.g., antimicrobial resistance prevention and control, unified automated prescription, clinical trials, and the code of ethics for drug promotion. - Develop higher education degrees related to medication manufacturing and promotion to produce graduates with competencies that meet local needs. - Develop and implement strategies related to human resources education according to workforce needs and future vision.
5. Rational use of medications: Promote the rational use of medications and empower patients.
Promote the rational use of medications. - Promote the rational use of medications through awareness campaigns in media and patient education through tailored and targeted interventions at the pharmacy level. - Improve communication with patients about their medications. - Involve patient associations and groups in any activity, as appropriate; empower patients through awareness campaigns and communication with patient associations - Update the guideline related to media promotion and Patient Support Programs (PSP), a priority to be taken into consideration.
Optimize the functioning of the national pharmacovigilance system. - Optimize the collection, detection, assessment, monitoring, and prevention of adverse events of all medications and medical devices.
Promote pharmacy and pharmaco-epidemiology research. - Promote pharmaco-epidemiological studies through access to available medication databases. - Assess post-marketing medication use in special populations and long-term use. - Develop a pharmaceutical sciences research-related strategy.
6. Policy-makers: Activate the LDA and involve policy-makers in innovative projects and new models.
Involve policy-makers in all activities, including innovative projects and new models.
Implement the Lebanese Drug Administration as soon as possible, according to international standards and country needs. - Assist government/regulatory authorities in developing and implementing a time-bound roadmap for the transition between MOPH and the newly established LDA (law issued in 2022). - Include which regulations need to be upgraded and used by the LDA in this roadmap/implementation plan. - Set a clear roadmap for Lebanon to join the PIC/S (Pharmaceutical Inspection Co-operation Scheme). - Define the "new" role of the MOPH in relation to the role of LDA as set by the law and the role of OPL in implementing the strategy to be proposed. - Map the laws related to the pharmaceutical sector to be canceled or updated, according to the new LDA law.
Update and enforce medication-related legal frameworks (laws, decrees, decisions, and policies). - Activate the Central Laboratory as a primary priority. - Structure appropriate legal frameworks for the suggested activities. - Implement/update/develop laws and regulations to facilitate and encourage the export of locally manufactured drugs. - Separate the decision-making from purchasing medications.

- Regulate digital health technology and solutions as part of a general master plan and well-defined governance structure. - Enforce current legislation at all levels, such as the unified prescription, the non-prescription list, and pharmacy laws, as appropriate.
7. Digital reform: Digitalize all the steps of the strategy.
Develop a national strategy for the digitalization of the healthcare system in Lebanon.
Implement the appropriate information system to monitor and assess the whole process (digitalization from registration/manufacturing to use by patient/disposal). - Enhance traceability of medications and expand it to reach the patients. - Optimize the MOPH official site.
Promote the rational use of medications through electronic prescriptions and patient profiles. - Use the unified prescription electronically and link it to clinics, hospitals, and pharmacies. - Use electronic records at all levels of the health sector, including clinics and pharmacies. These should be compatible with existing systems in medical institutions (hospitals). - Adopt a unique identity number to be used in the health sector at all levels and be compatible with other unique IDs used by other initiatives, for example, the Ministry of Social Affairs (MOSA). - Consider the Medication Card as a complement to the electronic prescription program. - Regulate Digital Health.


QUALITY
PHARMACY
PATIENTS