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PROGRAMME DESCRIPTION

Towards a national pharmaceutical strategy in Lebanon: Ensuring access to quality and safe medications for all

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Abstract

Introduction: Lebanon is facing challenges affecting the whole health sector, including access to medications. Lebanon has only proposed very few short-term national pharmaceutical strategic solutions. Previous reform attempts targeting the pharmaceutical sector, could not protect it from the crises and their detrimental consequences on patient and population health. **Purpose:** This document unveils the critical elements that should be addressed in the planned National Pharmaceutical Sector Strategy (NPS) being developed by the Order of Pharmacists of Lebanon (OPL) in consultation with the concerned stakeholders. **Method:** Strategic goals were proposed for adoption and implementation by the competent authorities based on consultations, situational assessments, and gap analyses. The objectives and an implementation plan were developed based on the available resources and policy dialogue, respectively. **Conclusion:** The National Pharmaceutical Strategy would help the Lebanese authorities/policy-makers, aided by competent healthcare professionals, develop and implement a time-bound roadmap to attain a nation with access to quality and safe medications for the whole population. Implementing this strategy would require the commitment of decision-makers, the accountability of involved parties, innovation in finding solutions, close collaboration between stakeholders, and lengthy efforts to attain the stated vision.

Introduction

Definition of a drug/medicine/medication

According to the United States Food and Drug Administration (USFDA) (Research Center for Drug Evaluation and Research, 2017), a drug/ medicine/ medication is (a) a substance recognised by an official pharmacopoeia 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. It is important to mention that biological products are also included within this definition, and are generally covered by the same laws and regulations, but differences still exist regarding their manufacturing processes (chemical process versus biological process). In this document, the term "*medicines*" also includes vaccines. Generally, the words "*drugs*", "*medicines*", and "*medications*" are used interchangeably.

Rationale for a national pharmaceutical strategy

This National Pharmaceutical Strategy constitutes a "*Commitment to a goal and a guide for action*". It presents a "*formal record of the values, aspirations, aims, and medium to long-term government commitments*", as mentioned in the second edition of the World Health Organisation (WHO) guide on "*How to develop and implement a National Drug Policy*" (WHO, 2001). Furthermore, this strategy aims to address the main problems identified in the pharmaceutical sector of Lebanon at the national level. Although this document will tap into the different components of a National Drug Policy, as suggested by the WHO, it will also focus on those that significantly influence the 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 almost unaffordable for public health insurance entities, individuals, and households. Accordingly, this strategy highlights the critical components that would enable public health insurance entities to generate enough revenues, take efficient investment decisions, and enable access to healthcare in general, and quality medicines, 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 (PHCs) across Lebanon at a minimal cost to patients. It also aims to support Lebanon's aspiration to regain its position as the regional centre of excellence in healthcare, ensuring access to innovative and valuable treatments, and exporting healthcare to neighbouring 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 (McKinsey & Company, 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 development of pharmaceutical strategies and called upon countries to work on them (Panteli & Edwards, 2018). These strategies include:

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

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 unique systems. The WHO proposes an approach to strengthen 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). Reaching 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 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 only pose a particular problem in low- and middle-income countries (LMICs), with Lebanon having been recently downgraded to a lower-middle-income country after being an upper-middle-income country for 25 years (Hamadeh *et al*., 2022). 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.

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 implementation decrees (issued for laws to be implemented by the council of ministers and relevant ministries), which are 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, implementation decrees 106, 1983 & 9399, 2012), and ministerial decrees and memos issued by the Ministry of Public Health (MOPH). Ministerial decrees and memos have implementation power as long as they are valid.

Moreover, the Lebanese Drug Agency (LDA) law (253/2022) was enacted in January 2022 (Lebanese Parliament, 2002). Its implementation decrees should be issued by the Ministry of Public Health (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.

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 authorisation 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 sub-committees.

For branded products imported from reference countries, the registration goes only through the technical committee without a further review from sub-committees. Those sub-committees are made of experts from the academia to study specific modules of the registration files, mainly "*Module 3*" (for the knowledge of quality documents required for primary drug substances and finished product) and "*Module 5"* (which is related to bioequivalence studies, bioequivalence and clinical trials). Both sub-committees have set standard operating procedures (SOPs), standard applications, and checklists for file submission and review. The work of the sub-committees 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

The medication pricing committee

The pricing committee (PC) is responsible for setting the prices of pharmaceutical products after registration and before issuing a market authorisation. 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 (Ministry of Public Health, 2020). 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) and 14 neighbouring reference countries' prices. The pricing process follows these steps: i. submission of pricing documents by the applicant, electronic pricing and determination of authorised price in foreign currency, ii. evaluation by the Pricing Committee and, iii. the allocation of the products to one of the categories (from A to E; A includes all products with prices less than ten US dollars and E comprises all products with prices more than $300) depending on the price range, and conversion of authorised 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). The authors recommend that products with the same presentation but with different dosage forms should be repriced simultaneously. For imported products, the documents required for repricing are the same as those submitted for pricing upon registration. It is expected that upon registration, the price of a generic product should be lower than the branded version if imported from a reference country, 15% lower if manufactured locally, and 40% lower if imported from a non-reference country (Ministry of Public Health, 2020). When the repricing of a brand product leads to a drop in its price, the prices of all generic products will be automatically affected. If the public price of the branded 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 (Ministry of Public Health, 2020). Locally manufactured products must be lower than the brand by 25%. However, the public price of imported generics must always be ten per

cent 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 is also available on the MOPH website:
https://moph.gov.lb/en/publications

Parallel importation (pi) of medications

Parallel importation occurs when products placed into circulation in one market are imported into another market. Reference decrees 571 and 950/1-2013 regulate PI to ensure the quality of imported products. In this case, the Technical Committee's approval follows articles 14 & 15 of this decree (articles related to regulatory variations). Parallel import products should be analysed by one of the laboratories accredited by the MOPH, and the laboratory results should be confirmed by the inspection department.

The Lebanese context before 2019

In 2017, 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 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 (GBD 2016 Disease and Injury Incidence and Prevalence Collaborators, 2017). It was noted that the health system in Lebanon provided good value for money compared to other countries. When the HCAQ 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 the GDP ranked above it in the HCAQ index (GBD 2015 Healthcare Access and Quality Collaborators, 2017).

According to Human Development Reports (HDR) (Malik, 2013) 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 its GDP on healthcare in 2018 and 2019. Evidence from the MENA region suggests that investing in healthcare efficiently is crucial for improving health outcomes and the stability of health systems (Balkhi *et al*., 2021; Jebeli *et al*., 2019). 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 (IDAL, 2018).

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 subsidised medicines outside the country were disastrous elements to the sector. Consequently, the local currency lost around 95% of its value, and public health insurance entities and patients could no longer afford the actual cost of healthcare, including medicines (El-Harakeh & Haley, 2022). At the initial stage of the crisis, the Central Bank's subsidisation of medicines sustained the frequency of its purchase. 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 allocated by the Central bank (El-Harakeh & Haley, 2022).

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 led the government, in certain situations, to take quick actions not supported by any legal framework. Quality concerns will always remain an issue to be considered and tackled with new sources for medications being considered/adopted.

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 multi-dimensional poverty (ESCWA, 2021). 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 (ESCWA, 2021). 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.

In this challenging context, Lebanon lacks a long-term national pharmaceutical strategy, with very few short-term solutions proposed for the current catastrophe. Existing policies are scattered and might not be adapted to the country's needs, particularly in the current situation. Some regulations are also not enforced, and the central drug quality laboratory is not operational. Previous reform attempts targeted at the health sector, including the pharmaceutical sector, did not protect it from imminent concurrent crises and their negative consequences on patient and population health (such as shortages in oncology medications and most of the routine vaccinations, for example).

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. As medication experts, pharmacists should 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 (UHC) medication shortage responses, and rational and safe use of medications can expand the scope of pharmacy practice and improve patient care (Ammar *et al*., 2021). 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

This document is designed to unveil the critical elements that should be addressed in the planned National Pharmaceutical Sector Strategy (shortened to the National Pharmaceutical Strategy, (NPS)) developed by the Order of Pharmacists of Lebanon (OPL) in consultation with the concerned stakeholders. The document should be used to guide the public and private sectors in the coming years.

The focus is on rebuilding adequate, sustainable, and equitable funding mechanisms, as an essential building block for UHC (i.e. availability, accessibility, affordability, and quality), within the overall Sustainable Development Goals (SDGs) 2030 targets, developing the 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; it also coincides with that of the national health strategy, the ultimate aim being to integrate it into the national health strategy.

Development process

This document was developed on the initiative of the OPL. A policy dialogue was implemented with relevant stakeholders' official representatives, forming a steering committee that included the Ministry of Public Health, the World Health Organisation - Lebanon Country Office, the syndicate of Pharmaceutical Industries in Lebanon, and the Lebanese Pharma Group. A series of regular meetings permitted the actual reaching of a consensus regarding the document. This strategy was presented to the remaining national stakeholders, mainly the Lebanese Pharmaceutical Importers Association (LPIA) and third-party payer representatives (from the public and private sectors), who endorsed it. Moreover, the support of the International Pharmaceutical Federation was sought to facilitate the implementation.

Afterwards, the second series of technical meetings led to the establishment of the implementation plan: for every objective, a designated stakeholder representative was responsible for organising side meetings with other involved stakeholders, also reverting to the steering committee. A final round for consensus on the final document was conducted, and conflicting interests were resolved.

Mission and vision of the national pharmaceutical strategy

The mission of the NPS 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 NPS is to secure timely access for all patients (leaving no one behind) to quality, affordable, and safe medications without suffering financial hardship.

Strategic pillars

A comprehensive strategy was set with short-term objectives and a long-term vision to contribute to achieving UHC while keeping in mind the following pillars (see Figure 1):

Figure 1: Strategic pillars to ensure safe and quality medications in Lebanon

Principles and values

The strategies are ruled by the ten Good Governance Principles derived from the United Nations Development Program (UNDP) principles and suggested by the WHO (McKulka, n.d.). These principles are (Siddiqi *et al*., 2009):

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.

***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 should be accessible to those concerned. Enough information should also 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 all citizens' human rights and civil liberties, especially vulnerable populations.

***Information and intelligence*:** It refers 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: It 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 materialise 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, and the expectations of the community.

Gap analysis

Cross-cutting elements for regulatory health systems according to the WHO

Table I presents the necessary regulatory elements according to the WHO and the situation in Lebanon regarding these elements.

Table I: Elements for regulatory health systems according to WHO

What 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 is 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, and reimbursement of locally manufactured products according to MOPH price.	All activities should have legal bases and existing laws should be regularly updated by 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.
The 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 medication 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 specialisation 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 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.

What exists in Lebanon	What should happen
Lack of a national strategy for digitalising healthcare.	Develop a national strategy for digitalising healthcare. Determine the fields that should take priority to implement the information system and digital health.

Pharmaceutical sector context, needs, and challenges

This strategy covers several components to varying extents, based on the priorities and the current situation in Lebanon; these components span from drug development and clinical trials to manufacturing and registration, up to the point of use and disposal.

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 (Ministry of Public Health (nd)). Pre-marketing requirements exist but are not applied in all situations. A clinical trial registry with international recognition is in place, which will promote innovation and early access to Lebanese markets and patients. The authorities should encourage researchers and pharmaceutical companies to use the MOPH clinical trials registry and promote innovation in Lebanon (Appendix A). They should also establish a bioequivalence centre in Lebanon, recognised nationally, regionally, and internationally.

Local manufacture (including packaging)

There are 12 local manufacturers in Lebanon, three of which specialised 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 shallow, 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 ten in terms of units). However, there is still inconsistent enforcement of GMP in the country for manufacturers, and at manufacturing sites for imported medications. There is still a need to supervise foreign and local manufacturers by upgrading and enforcing GMP and joining the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The complete manufacturing of products and expansion of the production profile of local manufacturers are not incentivised (El-Harakeh & Haley, 2022; IDAL, 2018). Thus, the authorities should enact relevant regulations and mutual trade agreements to further develop the environment for local manufacturing diversity and promote the exportation of locally manufactured products.

Prescription habits are geared towards branded and originator products due to the perceived poor 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) price difference, leading to the stated brand preference (El-Jardali *et al*., 2017): price differences have always been safeguarded by price revision initiatives and decrees taken by the different health ministers. The prices of the local products are, on average, 30% lesser than the originators and, on average, 25% lesser than the imported generics. However, prescribers and patients know little about locally manufactured products. Therefore, the authorities should endeavour to enhance awareness through campaigns about quality as part of the comprehensive nationwide efforts to encourage prescription, dispensing, and use of locally produced medications whenever available, to ensure saving on the national pharmaceutical bill.

Regulations of medications: registration, selection, and pricing

Now that an independent LDA law has been approved (Lebanese Parliament, 2022), 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. Meanwhile, at the MOPH, the Department of Pharmacy handles all regulatory control measures, including licensing professionals and establishments (manufacturers, pharmacies, importers, etc.). The Department of Pharmacy has three subunits: inspection, importation and exportation, and narcotics.

The technical committee for registration works according to a set of standard operating procedures (SOPs); measures are taken to ensure the registration of quality drugs. For example, a certificate of analysis from an internationally recognised laboratory is required 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, thereby reducing political interference, and encouraging the re-establishment of the central laboratory (which is not functional at the moment). Although certificates from *"international"* laboratories are required for registration, there is still a need to reactivate the central drug quality laboratory and optimise pre-registration requirements to guarantee the quality of registered medications. This is possible by issuing a new and modernised registration law (for originators, local manufacturers, biosimilars, and generics), and adopting international regulations and guidelines. However, Lebanon remains committed to preserving intellectual property protection rights, evidenced by the removal of Lebanon from the watch list Special 301 Report (Office of the United States Trade Representative, 2022).

Moreover, in the current context of currency depreciation, the financing of healthcare and medications remains the main issue to ensure their affordability for patients. This process should be complemented by Health Technology Assessment (HTA) for effectiveness and cost-worth since pricing regulations are not based on long-term plans and strategies, thus affecting all stakeholders. There is a need to revise regulations and optimise 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. More transparent and evidence-based pricing should also be applied. Similar principles should apply to reimbursement and enlistment decisions, which should not be fragmented but established according to an explicit and consistent decision-making framework which relies on evidence to invest in interventions that hold relatively good value and are affordable, allowing to reach a strategic reserve of medications. Moreover, clear timelines for approving new products should be set as regulatory changes might impact the supply and, consequently, the access to medications.

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 institutionalised mechanism (Ministry of Public Health, 2014). The traceability of products was also decided through the barcode project at the MOPH but is only being applied newly. Maintaining the quality of health products by enforcing GSDP and traceability requirements helps to supervise the in-country supply chain.

Moreover, drug shortages should be addressed through the rationalisation of consumption (e-prescription is one of the suggested solutions, among others) (Hajj *et al*., 2020). Primary healthcare centres 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 importations in Lebanon and the enforcement of applicable regulations are needed. A tracking system is also 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 is 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 the 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 would involve the rapid operationalisation of the NBS at the national level and the implementation of it at the level of community and hospital pharmacies.

Moreover, the WHO has supported 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 optimise the control of MOPH stocks from the warehouse to the dispensing centres. 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 stock-outs. The LMS was tested successfully to be interoperable with existing MOPH patient record systems at PHCs, such as the primary healthcare network information and communication system (PHENICS). Most medicines

with 2D barcodes are registered in the MOPH MediTrack system. However, for non-registered ones (received as donations, for example), 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.

Access to medications and financing

Access to essential medications is part of UHC. 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 (El-Harakeh & Haley, 2022).

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 subsidise the importation of medications in part.

However, added to other factors, the currently adopted subsidisation 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-subsidised cost). Financing medications should be done efficiently and equitably; additional details are presented in Appendix B.

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 (Brown & Bussell, 2011). Medications could be inappropriately prescribed and dispensed in Lebanon; these patterns have already been reported in previous studies (Saleh *et al*., 2015; Zeenny *et al*., 2017; Hajj *et al*., 2021) and should be further monitored. The appropriate use of medications could be achieved by supervising in-country prescribing and dispensing and enforcing good clinical (standard treatment guidelines in primary, secondary, and tertiary care) and good dispensing practices. 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). An updated national formulary should also be in place. Efforts should be made to reduce antimicrobial resistance and other abuse-/misuse-related problems, and also to enhance medication adherence to regimens to improve treatment outcomes, and prevent prescribers from having a consequential responsibility in the absence of medical prescription accountability.

Moreover, medication misuse and non-compliance are common among patients; post-marketing studies are being conducted, thanks to the personal initiatives of some academics and some pharmaceutical companies but are not tailored to the country's needs. Also, the use of medications should be rationalised through electronic prescriptions and patient profiles; digital health should also be well-regulated.

Regarding generics, the MOPH has undertaken initiatives to contain the cost of pharmaceuticals and promote the use of generic drugs, especially locally manufactured ones. Most importantly, these generics are predominantly imported, while efforts should be deployed to have locally manufactured generics. The authorities should adopt a clear strategy for medication use, which includes the reinforcement of substitution of prescriptions and increase awareness of the local industry.

Furthermore, since the classification of medications is not clear to all stakeholders, a review of the guidelines for drug classifications is being suggested ("*prescription-only*", "*repeat prescription for chronic medications*", "*over-the-counter products*"), and a renewal of the recommendations for the use of narcotics (to promote palliative care), psychotropics, and other mental health medications.

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. So far, pharmacovigilance activities are limited to COVID-19 vaccine adverse events (Ministry of Public Health Lebanon, 2019). Their work can be expanded to all marketed products while optimising the collection, detection, assessment, monitoring, and prevention of adverse events of all medications and medical devices. The MOPH unit responsible for pharmacovigilance should initiate reporting at the facility, physician, pharmacist, and patient levels.

Market control for product quality

There is a need to ensure conformity of marketed health products with high-quality standards; withdrawing substandard and counterfeit products from the market is necessary, thus, the urgency for a central laboratory to evaluate the quality of marketed products, and ensure conformity with quality norms. A reporting portal which would be accessible to patients and healthcare professionals is also suggested. Moreover, the current recall drug system relies on memos issued by the regulatory bodies in other countries or the WHO; an active drug recall system should be put in place at the national level.

Human resource strategic development

Several studies have shown the need for training in many pharmacy practice sectors, and a mismatch between graduate competencies and actual job market needs. There are also perceived needs in many public and private institutions; some specialities are lacking, while others are surplus. This discrepancy is mainly due to the absence of a national workforce strategy. Furthermore, the professionals handling medications are not well-trained, and consumers report many perceived or expressed needs related to this lack (Iskandar *et al*., 2017). Developing a workforce strategy that would rely on education (initial and continuing) and professional development, and optimising human resources that handle drug registration and variations according to the pharmacy sector as well as market needs, is thus, of primary importance (Hajj *et al*., 2023).

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 (AbouAssi, 2015). It is important for all healthcare professionals, particularly pharmacists, to have a strengthened role in health promotion, which would allow them to contribute actively to achieving Universal Health Coverage (UHC).

Furthermore, recent studies have demonstrated that a high percentage of healthcare workers, including those in the pharmaceutical sector, are fleeing the country (Fleifel & Abi, 2022). This finding indicates the need to reverse the brain drain through innovative projects, highly valued specialities (such as in research and development, and industrial pharmacy), and appropriate policies and projects. Lastly, committees in the public sector should be optimised. It is suggested to expand the Technical committee and increase its resources to enable it to issue decisions faster within the legal framework (reduce parallel import).

Medication-related research

There is no national research agenda related to pharmacy and pharmaceutical products (Akel *et al*., 2022). Pharmaco-epidemiology studies are only being conducted by academics, or pharmaceutical companies, despite the conflicts of interest that should arise. Moreover, the very few clinical/interventional trials carried out in Lebanon are mainly driven by pharmaceutical companies (Ministry of Public Health, nd). Assessing post-marketing and long-term medication use is paramount, particularly in special populations. More generally, there is a need to develop a research strategy to organise and support research efforts in the pharmaceutical field; such a document was recently published as a suggestion that could be used to that end (Akel *et al*., 2022).

Control of promotion and advertising

As for marketing practices, while a Lebanese Code of Ethics is in place, enforcement by authorities and relevant professional orders are still needed (Appendix C). Marketing practices are still affecting prescribers' behaviours (Khazzaka, 2019). Monitoring pharmaceutical companies' marketing activities and prescribing physicians should be considered for discussion through an appropriate assessment system, and the enforcement of the code of ethics, as done in developed countries (Leonardo Alves *et al.*, 2019).

Handling of waste and expired products

Competent authorities should ensure the appropriate disposal of health product wastes. To date, there is no adequate system for medication disposal in Lebanon. Earlier on, an agreement was signed between the MOPH and the Lebanese Pharmaceutical Importers Association (LPIA) to export the waste and expired items, however, its application is not yet optimised, and it consists of an additional loss which is not compensated by any party, thus, increasing the burden on all involved stakeholders. Hence, it is advisable to establish a local *"incinerator"* or consider the use of existing incinerators used in other industries within the country while ensuring the environmental safety of such practices.

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 (Hajj *et al*., 2022). Some might also have an unknown fate, thereby constituting an environmental threat. A comprehensive strategy is thus necessary for Lebanon to take into account the following matters: mitigation of environmental hazards

relating to pharmaceutical wastes through an appropriate plan; exploring local solutions that are applicable and environmentally acceptable; and optimising the available agreement between LPIA, SPIL, and the MOPH.

Targeted levels and strategic goals

Based on the above points, several strategic goals are proposed to be adopted and implemented by the competent authorities (Figure 2). With the collaboration of all stakeholders, the objectives were subsequently prioritised and refined based on the feasibility and available resources and an implementation plan was developed. It included suggested initiatives/activities per strategic goal, the needed actions, the term (short, medium, or long), the involved stakeholders, the responsible entity, the priority level, and related indicators (Appendix D).

Figure 2: Targeted levels and strategic goals

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). Support from WHO and the International Pharmaceutical Federation (FIP) would also be necessary during the implementation process.

Expected outcomes of the national pharmaceutical strategy

- Ensure the accessibility and availability of all medication types in Lebanon at affordable prices (locally manufactured and imported quality products).
- 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.
- Ensure access to essential medications for all the people residing in Lebanon, particularly the most vulnerable, without experiencing financial hardship.
- Redesign sustainable, adequate, and equitable funding mechanisms, and enable public health insurance entities to provide beneficiaries with a comprehensive healthcare benefits package.
- Ensure an evidence-based, clear, and explicit decision process that public funds and insurance companies/third-party payers can rely on for the assessment of health technologies.
- 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 the regulations that need to be upgraded before being used by the LDA (e.g., registration, pricing) and other functions that still need to be carried out by the MOPH (e.g., licensing, controlled substances).
- Define the "*new*" role of the MOPH as a "*tutoring authority*" in relation to the role of the LDA, as set by the law, and the role of the OPL in implementing the proposed strategy.
- Develop a human resources strategy for pharmacists, and other specialities, needed for local manufacturers.
- Support the importation, distribution, and technical evaluation of innovative solutions through relevant training and education, proposing retention strategies.

Expected challenges in implementing this strategy

In general, challenges are expected when establishing effective and equitable access to medicines and vaccines in the Eastern Mediterranean region (World Health Organisation's Regional Office for the Eastern Mediterranean, 2020). These include the lack of good governance, weak regulatory mechanisms, medication shortages and stock-outs, inefficient procurement and supply management systems, low capacity to conduct health technology assessment of medical products, high out-of-pocket spending, and irrational use of medications, contributing to the increase in antimicrobial resistance, and limited collaborations. Additional challenges unique to Lebanon are also foreseen, such as the lack of political will, political instability, lack of domestic funding, lack of exit strategies for the government, and the current steep economic crisis with minimal external financial support.

Conclusion

The National Pharmaceutical Strategy would help the Lebanese authorities/policy-makers, aided by competent healthcare professionals, develop and implement a time-bound roadmap to reach a nation with access to quality and safe medications for the whole population. Implementing this strategy would require the commitment of decision-makers, the accountability of involved parties, innovation in finding solutions, close collaboration between stakeholders, and lengthy efforts to attain the stated vision.

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Conflict of Interest

The authors declare no conflict of interest

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