



نقابة صيادلة لبنان
Order of Pharmacists of Lebanon

Towards a National Pharmaceutical Strategy in Lebanon

Appendix D – Implementation Plan

A project by:
The Order of Pharmacists of Lebanon

2022



LIST OF ABBREVIATIONS

- BD: Business Development
CAPA: Corrective And Preventive Actions
L: Long term (3 to 5 years)
LDA: Lebanese Drug Agency
LPIA: Lebanese Pharmaceutical Importers Association
LPG: Lebanon Pharma Group
M: Medium term (2-3 years)
MOPH: Ministry of Public Health
OOP: Out-of-pocket
OPL: Order of Pharmacists of Lebanon
GSDP: Good Storage and Distribution Practices of Pharmaceutical Products
GMP: Good Manufacturing Practice
IMF: International Monetary Fund
LOP: Lebanese Order of Physicians
NSSF: National Social Security Fund
NGO: Non-governmental organization
PAGs: Patients Advocacy Groups
PHC: Primary Healthcare Center
PPE: Professional Practice Evaluation
PV: Pharmacovigilance
S: Short term (1-2years)
SPIL: Syndicate of the Pharmaceutical Industries in Lebanon
WHO: World Health Organization



STRATEGIC GOALS AND SUGGESTED INITIATIVES/ACTIVITIES

Term: short (2-3years), medium (4-5 years), long (more than 5 years)

Priority: 1 (High), 2 (Medium), 3 (Low)

Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
1.Product: Enhance the quality of medications available on the Lebanese market						
Pillars:						
1. Securing universal and sustainable access to quality medications, including generics						
2. Optimizing, expanding, and supporting the local industry by increasing its production capacities for local and export markets and adding new therapeutic areas						
3. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
1.1 Define a clear framework for medication quality assurance (standards for manufacturing, registration, distribution, storage, use, and disposal).						
1.1.1 Suggest updates to the related legal framework (e.g., laws, decrees, decisions, policies).	Review current laws and regulations and propose necessary updates related to quality assurance (1)	S	SPIL, LPG, WHO, OPL	MOPH	1	Number of updates required
1.1.2 Optimize the registration requirements to guarantee the quality of registered medications.	Review the current registration guidelines to keep abreast of the international guidelines, including the protection of intellectual property (2)	M	SPIL, LPG, WHO, OPL	MOPH	2	Number of updates required
1.1.3 Adopt a scientific and transparent registration system that includes an exhaustive list of pre-marketing requirements	Propose requirements to adopt the Reliance Model	S	SPIL, LPG, WHO, OPL	MOPH	1	Draft/Approval of the guidelines and model



<p>incorporating the fast-track process for products that are no longer on the market and that have no alternatives. The system should also prioritize the Reliance Model by determining the criteria for approval and early access to innovative products.</p>					
<p>1.1.4 Establish a modern life cycle management system to allow proper review of the upcoming regulatory changes, a priority to be taken into consideration.</p>	<p>Review of the variation guidelines (online submission, annual reports...)</p>	<p>S</p>	<p>SPIL, LPG, LPIA, WHO, OPL</p>	<p>MOPH</p>	<p>1</p> <ul style="list-style-type: none"> - Issuance of variation guidelines - Implementation of automation for submission
<p>1.1.5 Ensure the conformity of marketed health products with high-quality standards, even after marketing.</p>	<ul style="list-style-type: none"> - Implement the 2D bar code system (3) - Enforce a higher frequency of inspections - Follow up on the execution of corrective actions (published...) - Drive further the implementation of pharmacovigilance (PV) regulations - Report PV cases to MOPH 	<p>M S S S M</p>	<p>MOPH, SPIL, LPG, LPIA, WHO, OPL</p>	<p>MOPH</p>	<p>1</p> <ul style="list-style-type: none"> - Number of stakeholders implementing the 2D bar code - Number of inspections performed on a monthly basis by OPL and MOPH - Number of corrective and preventive action (CAPA) reports/month following inspection - % of increase in the number of stakeholders reporting PV cases - Number of reported cases



<p>1.1.6 Establish the central laboratory and secure the needed funding.</p>	<ul style="list-style-type: none"> - Update the cost study for the central laboratory activation - Seek alternative funding (WHO, international bodies...) - Build on the expertise available in university labs to train the staff - Alternatively, establish a legal framework for private /public partnership with university laboratories 	<p>L L L S</p>	<p>MOPH, Academia, SPIL, LPG, WHO</p>	<p>MOPH</p>	<p>1</p>	<ul style="list-style-type: none"> - Determination of the funding requirement - Creation of the legal framework
<p>1.1.7 Create a monitoring system for GSDP with clear policies; enforce GSDP practices.</p>	<ul style="list-style-type: none"> - Establish a digitalized dashboard for GSDP (4) accreditation (stakeholder mapping, accreditation status, frequency, CAPA, CAPA closure...) - Seek funding to ensure implementation and sustainability 	<p>M</p>	<p>MOPH, LPIA, SPIL, WHO, OPL</p>	<p>MOPH</p>	<p>2</p>	<ul style="list-style-type: none"> - Creation of the digital dashboard - Number of GSDP inspections - % accredited stakeholders
<p>1.1.8 Ensure the supervision of manufacturers through upgrading and enforcing GMP.</p>	<ul style="list-style-type: none"> - Train the MOPH staff on GMP guidelines and audit (5) - Establish a digitalized dashboard for GMP accreditation (stakeholder mapping, accreditation status, frequency, CAPA, CAPA closure...) - Seek funding to ensure implementation and sustainability - Ensure regular inspection by MOPH on local manufacturers - Enforce inspection on international manufacturers from non-reference countries; alternatively, enforce product testing as a minimum requirement for manufacturers from non-reference countries 	<p>S M M S M</p>	<p>MOPH, LPIA, SPIL, WHO, OPL, LPG</p>	<p>MOPH</p>	<p>1</p>	<ul style="list-style-type: none"> - Certification for MOPH staff on GMP guidelines and audit - Creation of the digital dashboard - Number of GMP inspections - % of GMP certified local manufacturers - <i>All drugs from non-reference countries should be tested locally at the Central laboratory</i>
<p>1.2 Develop the environment for local manufacturing diversity.</p>						



1.2.1 Determine the needed local pharmaceutical production lines to attain national pharmaceutical security.	Setup the list of existing and missing production lines	S	WHO, OPL, SPIL, LPG	SPIL	1	Gap analysis report on production lines
1.2.2 Establish strong agreements for importing medications at affordable prices to attain national pharmaceutical security.	Define the regulatory framework to allow for special importation and innovative access agreements	S	WHO, OPL, SPIL, LPG	MOPH	1	Published special importation policy
1.2.3 Guarantee local manufacturing of quality products by providing strong incentives to local industries to expand their production lines for drugs entirely produced in Lebanon and those produced under license from international pharmaceutical companies.	Setup local industry incentives framework	S	WHO, OPL, SPIL, LPG	MOPH MOI	1	Published local industry incentives decree / law
1.2.4 Strengthen the national industry through expertise exchange and close collaboration with international pharmaceutical companies in Lebanon.	Explore possible cooperation framework on selected medicines / therapeutic classes	M	WHO, OPL, SPIL, LPG	WHO	1	Cooperation framework report
1.2.5 Expand the production profile of local manufacturers.	Setup business development (BD) workshops with EU/US consultants to train on BD best practices covering the country's needs for the next 5-10 years.	M	WHO, OPL, SPIL, LPG	SPIL	1	Number of workshops enrolled



1.2.6 Ensure that the government's approach attracts international pharmaceutical companies for partnership and licensed production in Lebanon.	Develop incentives for international pharmaceutical companies to locate manufacturing in Lebanon and use Lebanon as a regional hub.	S	WHO, OPL, SPIL, LPG	LPG	3	Number of incentives published
1.2.8 Increase export opportunities for locally manufactured products by authorities.	<ul style="list-style-type: none"> - Develop a clear execution plan - Establish Healthcare exchange agreements with foreign/neighboring Health agencies and corresponding ministries. 	S	WHO, OPL, SPIL, LPG	MOPH	3	Published MOH plan Increased number of exports
1.3 Monitor marketing methods to respect ethical principles and the Lebanese code of ethics.						
1.3.1 Control marketing practices of pharmaceutical companies (e.g., gifts and honoraria).	<p>1. Guidelines for Implementation of code of ethics for the pharmaceutical industry (6) to be adopted by MOPH and enforced including [Appendix 4 – Code of Ethics Implementation Plan].</p> <ul style="list-style-type: none"> - Establish a professional supervision committee (composed of members listed in the code of ethics) - Establish a review board included in the code of ethics - Enforce the three levels of reporting and follow-up - Develop standard forms and checklists for reporting and finalize the information needed for reporting - Set reporting mechanisms from the pharma industry - Set reporting mechanisms for complaints - Set follow-up mechanisms for complaints 	S	MOPH, OPL, LOP, LDA, LPG, SPIL	MOPH, relevant Orders	1	<ul style="list-style-type: none"> - Relevant committee and board established - Three levels of reporting enforced - Development of standard form for reporting all relevant activities - Development of reporting mechanisms from pharma - Development of reporting mechanisms for complaints - Current code of ethics updated to include new components



	<ul style="list-style-type: none"> - Develop a new component to regulate interaction with media, social media and others as needed - Develop a new component to include regulation of Websites, mobile apps, SMS, emails, and other channels of communication - Develop a new component related to communication with non-health professionals to talk about health issues, mainly diseases and treatments. <p>2. Recommend to MOPH and the relevant committee responsible for Food Supplements to develop a similar code of ethics or to adopt the OPL's suggested code of ethics and be in line with the law.</p> <p>3. Sign/re-sign the pledge of the Code with every new head and board of relevant professional orders</p> <p>4. Inform all registered and newly joined members about the Code appropriately to be part of the oath and bylaws of Orders</p> <p>5. Sign/re-sign the pledge of the Code on yearly basis for all pharma industry members</p> <p>6. Update the Lebanese Code of ethics, when possible, without delaying the enforcement of the current one that is endorsed by all relevant parties.</p>	<p>S</p> <p>Ongoing Process</p> <p>Ongoing process</p> <p>Ongoing Process</p> <p>M</p>	<p>OPL, LPG, SPIL</p> <p>OPL, LOP, LDA</p> <p>OPL, LOP, LDA</p> <p>LPG, SPIL, LPIA</p> <p>MOPH, OPL, LOP, LDA, LPG, SPIL, LPIA</p>	<p>MOPH, relevant committee</p> <p>Relevant Orders</p> <p>Relevant Orders</p> <p>All Pharma Industry</p> <p>MOPH to lead</p>	<p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>2</p>	<ul style="list-style-type: none"> - Recommendation made to Food supplement committee at MOPH - Pledge signed on a regular basis as advised - Signature on Code of ethics to be part of oath process - Pledge signed on a regular basis as advised - Current code of ethics to be updated
<p>1.4 Implement plans for environment-friendly disposal of medications.</p>						



1.4.1	Mitigate environmental hazards related to pharmaceutical waste through an appropriate plan.	Set up pharmaceutical environmental hazards and waste management framework and plan based on LPIA initial study (7, 8)	S	WHO, OPL SPIL, LPG, LPIA	LPIA MOPH	2	Published pharma environmental hazards and waste management plan
1.4.2	Optimize the agreement between the LPIA and MOPH.	Revise and update the agreement between the LPIA and the MOPH (7)	S	LPIA	LPIA MOPH	2	Revised and enrolled agreement
1.4.3	Explore locally applicable and environmentally acceptable waste management solutions.	Revise current applicable laws and practices for waste management solutions and update where required	S	LPIA, SPIL, OPL	LPIA MOPH	3	- Revised laws - Published updated practice framework
1.5 Promote and enhance innovation in Lebanon							
1.5.1	Promote the use of the MOPH clinical trials registry by researchers and pharmaceutical companies.	MOPH and Pharma Industry to further promote the already existing clinical trials' registry (9) among researchers and internally [Appendix 1. Promoting the Lebanese Clinical Trial Registry]. [Note that research-driven pharma companies would not compromise on intellectual property rights related to innovation].	M	MOPH, LPG, SPIL, Academia, university hospitals, others	MOPH	1	Number of registered trials
1.5.2	Establish a pharmaceutical research strategy for Lebanon, emphasizing the role of academics as impartial experts in the development and implementation of the national pharmaceutical strategy.	- Form a steering committee for a network of pharmaceutical/clinical trials researchers in Lebanon - Approve and implement the suggested pharmaceutical research strategy in Lebanon (10)	S M	MOPH, OPL, LPG, SPIL, Academia, university hospitals, others	OPL	1	Steering committee activities Pharmaceutical research strategy document and implementation plan (with specific indicators)



1.5.3 Consider establishing a bioequivalence center in Lebanon if found to be cost-effective.	The MOPH to appoint a special committee to conduct a cost-effectiveness analysis to study the feasibility of establishing a bioequivalence center in Lebanon	L	MOPH, OPL, academia, SPIL, LPG	MOPH	2	Specific indicators to be developed by the committee
Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
2. Funding: Manage scarce resources with efficiency and equity.						
Pillars						
1. Ensuring early access to innovative medications while maintaining resource optimization						
2. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
2.1 Improve and ensure adequate, sustainable, and equitable funding for healthcare and medications.						
2.1.1 Prioritize healthcare and access to medications at the national level, reflected by the government allocating adequate budgets from foreign aid/loans, SDRs etc.	<ul style="list-style-type: none"> - Run the exercise to accurately evaluate the funding needed for the currently subsidized medications - Align Pharma sector stakeholders on one Funding Position Paper (Foreign Funding to cover old dues & future shipments) - Consider prioritizing development loans over donations, general loans, and other sources. - Put in place an Advocacy Plan, which includes meeting with MOPH representatives/Members of Government/Members of the Parliament 	S	<ul style="list-style-type: none"> - LPG, SPIL, LPIA - OPL, LOP? <p><i>Target Audience: Ministers of Health and Finance, Prime Minister</i></p>	The whole Group.	1	Government commitment to an allocated budget for a period of 1 year
2.1.2 Support and sustain public risk pooling entities (MOPH, Armed Forces, COOP, NSSF) in their role of financial protection against illness through adjusted Domestic Funding taking into consideration the real	<ul style="list-style-type: none"> - Align Pharma sector stakeholders on one Funding Position Paper tackling Domestic Funding - Put in place an Advocacy Plan that involves meeting with MOPH representatives/Members of Government/ Members of the Parliament 	M	<ul style="list-style-type: none"> - LPG, SPIL, LPIA - OPL, LOP? <p><i>Target Audience: Ministers of Health and Finance, Prime Minister, MPs</i></p>	The whole Group.	1	The budget allocated to Public risk pooling entities is aligned with the devaluation %



value of the USD needed to purchase medications.						
2.1.3 Build sustainable funding mechanisms for healthcare and medications.	<ul style="list-style-type: none"> - Consult local and international experts to support in conducting an analysis of the current situation at the NSSF and MOPH aiming at identifying new and sustainable funding mechanisms, i.e., instate taxing on harmful behaviors and earmarking taxes 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). 	M-L	<ul style="list-style-type: none"> - WHO - LPG, SPIL - Policy Experts - Consider including NGOs & PAGs, i.e., Tobacco Alliance - Academia - OPL & LOP - Members of the Parliament - MOPH - NSSF 	An Alliance should be in place to lead this project.	2	<ul style="list-style-type: none"> - Taxation on harmful behaviors laws are passed - NSSF Maternity and Sickness Fund is able to collect enough revenues, equitably, to reduce the imbalance vs Healthcare expenditures
2.1.4. Engage in the IMF Plan	<ul style="list-style-type: none"> - Form a group of experts, representative of all Healthcare stakeholders to participate in the IMF negotiations for Healthcare. (Consider all vital sectors to be represented) - This group will align on a clear position prior to entering into the negotiations 	S	LPG, SPIL, LPIA OPL/LOP, MOPH IMF Taskforce Team, including MPs, MoF, MoE&T WHO to support	MOPH	2	Healthcare is prioritized on the IMF agenda ensuring the protection of the most vulnerable patients from catastrophic spending related to HC
Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
3. Access: Improve universal and sustainable access to medications (essential and innovative ones) by patients.						
Pillars:						
1. <i>Securing universal and sustainable access to quality medications, including generics</i>						
2. <i>Ensuring early access to innovative medications while maintaining resource optimization</i>						



3. Optimizing, expanding, and supporting the local industry by increasing its production capacities for local and export markets to include new therapeutic areas						
4. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
3.1 Secure the availability of essential and innovative medications and vaccines.						
3.1.1. Ensure the availability of essential medications and National Immunization Program (NIP) vaccines at the PHCs	<ul style="list-style-type: none"> - Revise and update the local list of essential medications (11) - Establish a clear framework for the procurement of essential medications and NIP vaccines at the PHCs 	S	MOPH Medical Societies/LOP	MOPH	3	Essential medications (as defined locally) and NIP vaccines lists are available at the PHCs
3.1.2. Essential and innovative medications and vaccines are available in the private market	The MOPH and NSSF to establish an official framework to enable affordability solutions (i.e., PSP framework, etc.)	S-M	MOPH NSSF LPG, SPIL, LPIA OPL (Community & Hospital pharmacists)	MOPH	2	An official framework (s) is established and announced
3.1.3 Address the medications shortage issue through appropriate means.	Medical societies to establish standard clinical protocols to promote the effective and safe use of medications, protecting the standards of the clinical practice in Lebanon. Examples include CAP (12) and UTI (13).	M	Medical Societies	Medical Societies	1	Clinical Protocols are updated and published by the Medical Societies
3.1.4. Overcome the out-of-pocket payment/reimbursement at the purchase point for NSSF/COOP patients	<ul style="list-style-type: none"> - Establish a solution to allow patients to settle the copay percentage only at the purchase point - Secure the copayment process through a complete national digital solution (Section 7) - Implement a transparent process to assess and accelerate reimbursement (see HTA) 	M-L	MOPH OPL Hospitals LPIA NSSF/ COOP	NSSF	2	Patients pay only their share when buying medications
3.1.5. Establish a Track and Trace system for medications	Initiate the Track and Trace System with a pilot test involving a specific range of products before scaling up to all products	L	MOPH, LPIA, SPIL, LPG, OPL, Hospitals	MOPH	3	All Medications are tracked from the source to the end user
3.1.6. Private Insurance & out-of-pocket (OOP)	Align with MOPH on an importation scheme to ensure sustainable access to medications at their	S	MOPH LPG, LPIA, SPIL OPL, Hospitals	MOPH	1	Patients who can afford the actual cost of



patients continue to have access to their treatments	actual cost (Appendix 2 – Access to medications and financing)					medications are able to access them
3.1.7 Promote non-exclusive voluntary licenses enabling Lebanese manufacturers to develop lower-cost generics of patented pharmaceuticals under the terms of the agreements contracted with multinationals, which might be either commercial or non-profit and would include the transfer of the necessary technology. 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.	Organize bi-annual talks with LPG to discuss international Health initiatives to enroll Lebanon in the voluntary license program as a Low / Medium income country, with the objective to make innovative medicines available to the Lebanese patient at affordable price.	S	SPIL LPG WHO	SPIL	2	Voluntary licenses signed
3.2 Secure a strategic reserve for medicines to prioritize national drug security.						
3.2.1 Establish a task force to work on developing the Strategic Reserve system for medicines.	Set up the task force and develop the framework and implementation clauses	S	WHO, OPL SPIL, LPG	MOPH	1	Published Strategic Reserve policy
3.2.2 The task force will propose agreements to contributing	Set up the task force and develop the framework and implementation clauses	S	WHO, OPL SPIL, LPG	MOPH	1	Published Strategic Reserve policy



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.						
3.3 Promote public-private partnerships.						
3.3.1 Centralize governmental purchases.	Recommend the best practices for centralized purchase: Assign a Committee of neutral experts to assess the current purchase model and recommend ways to improve efficiency and quality.	S	WHO, OPL SPIL, LPG	LPG	1	Issue Best practice document
3.3.2 Prioritize the local industry in the tendering strategy and processes (full manufacturing in particular) to support the local sector and reinforce its contribution to public health.	Develop decrees/law drafts for local industry incentives: Assign the Committee of neutral experts to analyze and evaluate the best practices in several countries and recommend the best system to incentivize local manufacturing without putting trade barriers on imports.	S	WHO, OPL SPIL, LPG	SPIL	1	Published Local industry Incentives decree / law
3.4 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.						
3.4.1 Base the investment decisions in Health technologies on explicit criteria, relying on evidence, and acknowledging the value of the technology rather than the price only	Consult with International Experts to develop a framework by reimbursement body for the reimbursement/procurement of medicines/medical interventions, that guarantees an explicit, consistent, equitable, efficient decision process (while establishing HTA)	M-L	International Experts/ Academia; Payers/ Reimbursement bodies; PAGs; Medical Societies; Procurement Specialists	MOPH/ NSSF/ Armed Forces/ COOP	2	An explicit, consistent, equitable, efficient HTA framework is in place in every institution (not necessarily the same)



Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
4. Workforce: Optimize the competencies of administrators and healthcare professionals.						
Pillars:						
1. Optimizing human resources in the pharmaceutical sector through retention and education strategies						
2. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
4.1 Optimize human resources handling medications.						
4.1.1 Endeavor for human resources retention	<ul style="list-style-type: none"> - MOPH to recognize credentials (14, 15) - Remunerate according to recognized credentials 	Short Medium	OPL, MEHE, Academia, MOPH	OPL	2	Credentials decision
4.1.3 Implement Good Pharmacy Practice principles in the community and promote pharmacy accreditation.	<ul style="list-style-type: none"> - Diffuse the GPP concept among pharmacists (mandatory & elective sessions) (16, 17) - Implement GPP decision (elective) 	Short Medium	OPL, MOPH	OPL	1	<ul style="list-style-type: none"> - CE regarding the GPP training sessions for pharmacists - Number of pharmacies with GPP
4.1.4 Optimize the existing hospital pharmacy accreditation system.	<ul style="list-style-type: none"> - Implement current official standards (18) (controlled by MOPH). - Assess hospital pharmacy standards and update them as needed. 	Medium	OPL, MOPH	OPL	2	Application of updated standards
4.1.5 Diffuse treatment protocols according to national/international guidelines.	Gather guidelines related to the most important diseases (chronic and acute)	Long	OPL, OLP, MOPH, academia, University Hospitals	OPL	1	Number of diffused guidelines
4.1.6 Ensure continuing education for health professionals about medications and medication therapy management.	<ul style="list-style-type: none"> - Put a CE program about medications for healthcare professionals, in collaboration with all orders and MOPH (19-22) - Explore collaborators willing to provide the venue (academia mainly) - Involve physicians who are used to work with pharmacists 	Medium	OPL, LOP, MOPH, academia, other Orders	OPL	1	Number of health professionals adhering to the program



<p>4.1.7 Develop continuing education programs related to critical public health issues, e.g., antimicrobial resistance prevention and control, unified automated prescription, clinical trials, and the code of ethics for drug promotion...</p>	<ul style="list-style-type: none"> - Involve scientific societies of the LOP 					
<p>4.1.8 Implement Healthcare and administrative Professional Practice Evaluation and suggest nationally adapted guidelines. 4.1.9 Monitor and optimize prescribing and dispensing.</p>	<p>Approve the National Pharmaceutical Sciences Research Strategy and develop its implementation plan;</p> <ul style="list-style-type: none"> - Include an objective assessment of prescribing and dispensing, and other professional practice evaluations (PPE) as pillars of the Strategy (decrease prescription errors, improve medication adherence, etc.). - Promote interprofessional collaboration (23-25). 	<p>Long</p>	<p>OPL, OLP, MOPH, academia</p>	<p>OPL</p>	<p>1</p>	<ul style="list-style-type: none"> - The National Pharmaceutical Sciences Research Strategy Report - The number of assessment studies
<p>4.1.10 Develop and implement strategies related to human resources education according to workforce needs and future vision. 4.1.2 Optimize education by creating new fields, e.g., clinical pharmacy, industrial pharmacy. Develop higher education degrees related to medication manufacturing</p>	<ul style="list-style-type: none"> - Develop a national health workforce and education strategy [Appendix 3 – Suggested Strategy for Pharmacy Education and Workforce], taking into account market needs, educational offerings (master’s and other postgraduate programs), postgraduate, early career, and specialized training to improve the value and ensure the quality of the profession (14, 15, 26-36) - Create new master’s programs according to the market needs 	<p>Long</p>	<p>OPL, OLP, MOPH, academia</p>	<p>OPL</p>	<p>1</p>	<ul style="list-style-type: none"> - National health workforce and education strategy; implementation indicators - Number of graduates per specialty per year



and promotion to produce graduates with competencies that meet the local needs.						
Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
5. Rational use of medications: Promote the rational use of medications and empower patients.						
Pillars:						
1. Activating the role of patients' associations in decision-making						
2. Promoting the rational use of medications by prescribers, dispensers, and consumers						
3. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
5.1 Promote the rational use of medications.						
5.1.1 Promote the rational use of medications through awareness campaigns in media and patient education through tailored and targeted interventions at the pharmacy level.	<ul style="list-style-type: none"> - Prepare a communication program for patients: involve primary healthcare centers, community pharmacists and patients' associations; educate inpatients about primary healthcare centers and medications (37, 38) - Use media, focus group sessions, ... - Home visits by the pharmacist (medication review using modern techniques), taking the current laws into account and suggesting new ones - Include communication skills in pharmacist CE programs and award certifications for pharmacists (quality label) (20-22) 	Short	OPL, patients' associations, LPG, SPIL	OPL	1	<ul style="list-style-type: none"> - Number of awareness campaigns / year - Primacy healthcare centers and community pharmacies involved - Number of attendees at communication skills sessions - Pharmacists with communication certificate
5.1.2 Involve primary health care centers, and patient associations and groups in any activity, as appropriate; empower patients through awareness campaigns and communication with patient associations.						
5.1.3 Promote the use of generics through						



awareness campaigns on quality medications 5.1.4 Foster and improve communication with patients about their medications.						
5.1.5 Update the guidelines related to media promotion and Patient Support Programs (PSP) [a priority to be taken into consideration].	<ul style="list-style-type: none"> - Update the related guidelines (39). OPL to be actively involved. - Disseminate guidelines to pharmacists to guide patients. 	Medium	LPG, OPL, MOPH, NGOs	LPG, MOPH	2	<ul style="list-style-type: none"> - Updated guidelines - Awareness sessions attended by pharmacists regarding the guidelines
5.2 Optimize the functioning of the national pharmacovigilance system.						
5.2.1 Optimize the collection, detection, assessment, monitoring, and prevention of adverse events of all medications and medical devices.	<ul style="list-style-type: none"> - Collaborate with the national pharmacovigilance team to optimize the system (40) - Conduct awareness sessions for students (co-curricular activity? create a pharmacovigilance module?) - Conduct awareness sessions for pharmacists about pharmacovigilance 	Medium	OPL, MOPH PV team, LPG, and SPIL	MOPH	2	<ul style="list-style-type: none"> - PV activities - Awareness session for students and pharmacists
5.3 Promote pharmacy and pharmaco-epidemiology research.						
5.3.1 Promote pharmaco-epidemiological studies through access to available medication databases.	Implement the suggested National Pharmaceutical Research Strategy that includes both pillars (10) (see 1.5.2 & 4.1.8)	Medium	OPL, academia, LPG, SPIL, MOPH	OPL	2	Document of the Strategy; Number of conducted studies
5.3.2 Assess post-marketing medication use in special populations and long-term use.						



Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
6. Policy-makers: Activate the LDA and involve policy-makers in innovative projects and new models.						
Pillars:						
1. Implementing the Lebanese National Drug Administration to strengthen the regulatory process						
2. Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card						
6.1 Involve policy-makers in all activities, including innovative projects and new models.						
6.2 Implement the Lebanese Drug Administration as soon as possible, according to international standards and country needs.						
6.2.1 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).	Draft a proposal for the clauses of implementation of the LDA law (41)	S	LPG, SPIL, OPL, MOPH, LPIA, WHO	LPG, SPIL	1	Issuance of the proposal of implementation clauses
6.2.2 Select regulations that need to be upgraded and used by the LDA in this roadmap/implementation plan.	Draft a proposal for the clauses of implementation of the LDA law	S	LPG, SPIL, OPL, MOPH, LPIA, WHO	LPG, SPIL	1	Issuance of the proposal of implementation clauses
6.2.3 Set a clear roadmap for Lebanon to join the PIC/S (Pharmaceutical Inspection Co-operation Scheme).	Identify the PIC/S requirements and needed procedures	S	SPIL, LPG	SPIL	1	Requirements to be included in the implementation clauses of LDA
6.2.4 Define the “new” role of the MOPH in relation with the role of LDA as set by the law and	<ul style="list-style-type: none"> - Propose a draft to reshape the role of MOPH towards a focus on public health - OPL to endorse and drive the implementation strategy 	S	LPG, SPIL, OPL, MOPH, LPIA	SPIL, LPG, MOPH	1	Issuance of the proposal draft



the role of OPL in implementing the strategy to be proposed.						
6.2.5 Map the laws related to the pharmaceutical sector to be canceled or updated, according to the new LDA law.	Map and update necessary MOPH laws and regulations that fall under LDA	S	LPG, SPIL, OPL, MOPH, LPIA, WHO	SPIL, LPG, MOPH	1	Issuance of the list of laws and regulations requiring an update
6.3 Update and enforce medication-related legal frameworks (laws, decrees, decisions, and policies).						
6.3.1 Activate the Central Laboratory as a top priority.	Refer to the Central laboratory section (1.1.6)					
6.3.2 Structure appropriate legal frameworks for the suggested activities.	Refer to the LDA section (6.2)					
6.3.3 Implement, update, and develop laws and regulations to facilitate and encourage the export of locally manufactured drugs.	Refer to 1.2.8					
6.3.4 Separate the decision-making from purchasing medications.	Assign scientific committees per specialties allocated exclusively for medication enlistment with no intervention on the procurement personnel to guarantee the objective selection of the most suitable medications according to the nation's priorities	S	LPG, SPIL, OPL, MOPH, LPIA, WHO, academia	MOPH	1	Scientific committees' decision for medication enlistment
6.3.5 Enforce current legislation at all levels, such as the unified prescription, the non-prescription list, and	<ul style="list-style-type: none"> - Check and review the current related laws (42) - OPL and LOP to enforce the implementation of legislation 	M	OPL, LOP	OPL	2	Issuance of OPL decision on enforcing related laws



pharmacy laws, as appropriate.						
Strategic Goals and Suggested Initiatives/Activities	Needed Actions	Term (S, M, L)	Involved Stakeholders	Responsible Entity	Priority Level	Indicator
7. Digital reform: Digitalize all the steps of the strategy.						
Pillar:						
<i>Digitalizing the system: 2D barcode, MediTrack, HTA, electronic medical card</i>						
7.1 Develop a national strategy for the digitalization of the healthcare system in Lebanon.						
7.2 Implement the appropriate information system to monitor and assess the whole process (digitalization from registration/manufacturing to use by patient/disposal).						
7.2.1 Regulate digital health technology and solutions as part of a general master plan and well-defined governance structure, starting by an assessment of what is already available.	<ul style="list-style-type: none"> - Assessment of available and potential digital tools (3, 42, 43) - Suggest a stepwise plan for digitalizing the whole system: Establish an Expert Advisory Panel to collaborate in designing a national strategy or roadmap for digitalizing healthcare to consider and cover both the policy component and the technical infrastructure component. 	M	MOPH IT team, OPL	MOPH	1	<ul style="list-style-type: none"> - Assessment and planning documents - New tools
7.2.2 Enhance traceability of medications and expand it to reach the patients.	Expand the 2D Barcode system	M	MOPH IT team, OPL	MOPH	1	Expanded 2D Barcode
7.2.3 Optimize the MOPH official site.	Help the MOPH in making the website more useful	M	MOPH IT team, OPL	MOPH	1	Updates of the MOPH website
7.3 Promote the rational use of medications through electronic prescriptions and patient profiles.						



<p>7.3.1 Use the unified prescription electronically and link it to clinics, hospitals, and pharmacies.</p> <p>7.3.2 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).</p> <p>7.3.3 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).</p> <p>7.3.4 Consider the Medication Card as a complement to the electronic prescription program.</p>	<p>Activate the suggested electronic platforms (electronic patient profile) (43)</p>	<p>M</p>	<p>MOPH IT team, OPL</p>	<p>MOPH</p>	<p>1</p>	<p>Active Patient Profile platform according to suggested ideas</p>
<p>7.3.5 Regulate Digital Health applications (intended for patients).</p>	<p>Regulate the use of Digital Health Applications according to clear criteria</p>	<p>M</p>	<p>MOPH, OPL, LPG, SPIL</p>	<p>MOPH</p>	<p>2</p>	<p>Regulation document</p>



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