Liberia Medicines & Health Products Regulatory Authority [LMHRA]

STRATEGIC & OPERATIONAL PLAN 2021 - 2025

"Ensuring Safety, Efficacy and Quality of Medicines & Health Products"

AUGUST 2021

STRATEGIC GOALS

- Establish an effective and efficient medicines and related products regulatory system
- Set up a Quality Management System (QMS) and Undertake Operational Research activities to support regulatory functions
- Develop and Implement an effective Information Management System
- Promote partnership, cooperation, collaboration and decentralization
- Recruit, develop and maintain adequate Human Resource (HR) Capacity
- Mobilize technical and financial resources for the implementation of Regulatory Functions

VISION

A Leading Medicines and Related Products Regulatory Authority of excellence in Africa.

MISSION

The Liberia Medicines and Health Products Regulatory Authority exists to achieve the highest possible standards of quality, safety and efficacy for medicines and health products by employing legal, effective, efficient and transparent regulatory systems using competent and highly motivated human resource backed by adequate technology, to safeguard public health.

MANAGEMENT TEAM

Pharm. Keturah C. Smith
BSc, BPharm, MPCPharm, RPh
Managing Director

Pharm. Luke L. Bawo
Board Chairman

Contacts

0777-140-555/0888-140555
info@lmhra.gov.lr

ABBREVIATIONS

AfT	- Agenda for Transformation
AU	– African Union
DEA	– Drug Enforcement Authority
ECOWAS	– Economic Community of West African States
EU	– European Union
FDA	– Food & Drugs Authority
GMP	– Good Manufacturing Practice
GoL	- Government of Liberia
HR	– Human Resource
IE &C	– Information, Education & Communication
ICT	– Information & Communication Technology
IEC	– Information, Education and Communication
LMHRA	- Liberia Medicines and Health Products Authority
MD	- Managing Director
MOH	– Ministry of Health
MOU	– Memorandum of Understanding
NAFDAC	– National Authority for Food & Drug Administration & Control
NDP	– National Drug Plan
NEPAD	– New Partnership for Africa's Development
NGOs	– Non- Governmental Organizations
NTK	– Need To Know
PAPD	- Pro-Poor Agenda for Prosperity and Development
PESTEL	– Political, Economic, Social, Technical, Environmental, Legal
QA	– Quality Assurance
QC	– Quality Control
QMS	– Quality Management System
SBCC	– Social Behavioral Change Communication

SOPs	– Standard Operational Procedures
SWOT	– Strengths, Weaknesses, Opportunities, Threats
TA	– Technical Assistance
WAHO	– West African Health Organization
UNICEF	– United Nations International Children's Emergency Fund
USP	- United States Pharmacopoeia
WHO	– World Health Organization

ACKNOWLEDGEMENTS

The Liberia Medicines and Health Products Authority (LMHRA) would like to acknowledge the USP PQM+ Program with funding from USAID, led by Mr. Kwasi Poku Boateng, Director of USP-Ghana & PQM+ West Africa for accepting to include this activity in the plan for Liberia and his personal presence to ensure the activity is carried through successfully. The Authority is indebted to the main consultant Benjamin Kwame Botwe for his in-depth knowledge of the subject matter and for assessing, drafting, facilitating the completion of the strategic plan and its attendant operational plan and budget.

Finally, the Authority wishes to acknowledge the Board Chair and Members of the LMHRA, the Managing Director and staff, the various stakeholders in the Public Sector, the Legislature, the Ministry of Health, Private Sector, International Organizations, NGOs and the staff of the Authority, who have contributed in diverse ways to make this Strategic Plan a reality. Without your input and cooperation, it would not have been possible to carry out this assignment.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was established by an Act of the Liberian Legislature in 2010. The purpose of the Act is to ensure that, in the national medicine supply system, safe, effective, and good quality medicines reach the Liberian public; protect the Liberian public from the harmful effects of substandard and falsified medicines and health products; ensure fair trade practices in medicines and health products; promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products; and conduct or facilitate necessary research and development, promote Pharmacovigilance, and disseminate timely drug information.

Related product has been defined by the Act to mean an article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal.

Upon the setting up of the Authority by the appointment and inauguration of the Board and the appointment of the first Managing Director and some other critical staff, a strategic plan (2011-2015) was drawn up to give direction for the first five years of the existence of the LMHRA

The Five-Year Strategic Plan 2019-2023 is therefore developed based on the mandate given by the Act, experiences and lessons learnt over the last ten years of the existence of the Authority, international best practices and results of some internal and environmental assessments undertaken so far.

The purpose of this first strategic plan is to:

1. *Design strategies for achieving the vision, mission and objectives of the Authority.*
2. *Provide a long-term perspective of what the Authority would look like in the future.*
3. *Develop performance indicators for monitoring and evaluation.*
4. *Develop an operational plan and budget as a basis to see for both technical and financial assistance to facilitate the achievement of the set objectives.*

The process of developing this strategic plan involved and assessment of the state of implementation of the first strategic plan, the self-assessment of the LMHRA on its regulatory functions using the World Health Organization (WHO) Global Benchmarking Tools, and a further assessment on Quality Management Systems situation by WAHO. All levels of management, staff and various stakeholders and professional groups were engaged for their inputs and buy-in. Upon performing a SWOT and PESTEL analysis, vision and mission statements were developed and strategic goals identified to be able to achieve the mission of the LMHRA.

STRATEGIC GOALS

- Establish an effective and efficient medicines and related products regulatory system
- Set up a Quality Management System (QMS) and Undertake Operational Research activities to support regulatory functions
- Develop and Implement an effective Information management System
- Promote partnership, cooperation, collaboration and decentralization
- Recruit, develop and maintain adequate Human Resource (HR) Capacity
- Mobilize technical and financial resources for the implementation of Regulatory Functions

For each of the strategic goals above, some specific objectives were set and corresponding activities identified to achieve them. Key performance indicators were specified for each of the specific objectives while activity inputs, budgets and timelines have been provided in the Operational Plan attached as Annex I.

A new organogram has been developed creating a total of five (5) directorates. Two of them – Finance and Administration and Quality Control Laboratory- report directly to the Managing Director while the remaining three – Licensing, Inspection and Post Marketing Surveillance; Clinical Trials and Pharmacovigilance and Evaluation and Registration report to the Managing Director through the Deputy Managing Director.

The Office of the Managing Director is also responsible for other supporting Departments, vis Programs & Planning Office, Legal Office, Information Technology, Communication/Public Relations Office, Internal Audit, Procurement Office, Quality Systems Manager, Client Service Centre and Research and Development Office.

The organogram is attached as Annex II.

1 BACKGROUND

1.1. Pro-Poor Agenda for Prosperity and Development (PAPD)

The Pro-Poor Agenda for Prosperity and Development (PAPD) 2018 to 2023 is the second in the series of 5-year National Development Plans (NDP) anticipated under the Liberia Vision 2030 framework. It follows the Agenda for Transformation 2012-2017 (AfT).

Goal 3 of the Pro-poor Agenda for Prosperity and Development seeks to ensure healthy lives and promote well-being for all at all ages. Among the strategies outlined in the agenda to achieve Goal 3 is to strengthen the LMHRA by establishing appropriate quality assurance (QA) laboratory for testing of healthcare products and technology to identify and destroy expired, counterfeit and damaged medicines and medical supplies. It also aims to improve storage facilities at central and decentralized levels which are part of the inspectorate functions of the LMHRA. The construction of a new multipurpose quality control laboratory for the LMHRA has already started.

1.2 National Medicines Policy

The National Medicines Policy of the Republic of Liberia which was developed in 2013 provides a comprehensive framework for the development of the Pharmaceutical Sector over a ten-year period with periodic reviews. The goal of the Policy is to ensure that pharmaceutical services are developed using available resources such that high quality, safe, efficacious and cost-effective pharmaceutical products and services are available for use in the health services of Liberia.

Section 5 of the policy dwells on medicines regulation and provides for statements on Regulation of medicines prescription and distribution, registration and licensing, quality assurance and control, and post marketing surveillance. Other provisions are made on the control of narcotics and psychotropic substances, medicines donation, disposal of expired and unwanted medicines, medicines advertising, manufacture, import and export of medicines, traditional medicines. and promotion and sale of medicines. It worthy to note that this policy explicitly makes provision for technical cooperation with other countries and international organizations which has become critically important in contemporary times.

1.3 The LMHRA Act

The Act to establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 was passed with the purpose to ensure that, in the national medicine supply system, safe, effective, and good quality medicines reach the Liberian public; protect the Liberian public from the harmful effects of substandard and counterfeit medicines and health products; ensure fair trade practices in medicines and health products; promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products; conduct or facilitate necessary research and development, promote pharmacovigilance, and disseminate timely drug information.

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was established from and immediately upon the passage of this Act to perform the following functions:

a) *Conduct registration of medicines and health products;*
b) *Issue licenses or permits for premises and personnel to engage in the manufacture, import, export, transit into or out of the Republic of Liberia, supply, storage, distribution, or sale of medicines and health products, excluding retail pharmaceutical outlets;*
c) *As and when deemed necessary by the Authority, suspend, cancel, or revoke such license or permits referred to in Part II, Section 2.1(b) in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;*
d) *Establish an inspectorate and conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold;*
e) *Confiscate expired, substandard, counterfeit, or unregistered medicines in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;*
f) *Establish and operate quality control laboratories to ensure safe, effective, and good quality medicines and health products for domestic and foreign markets;*
g) *Conduct post-marketing surveillance of medicines and health products;*
h) *Conduct Pharmacovigilance of medicines and health products;*
i) *Issue warnings and conduct recalls of products in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;*
j) *Regulate the conduct of clinical studies of medicines and health products;*
k) *Prepare, keep, and update a registry of medicines and health products registered and approved for marketing in the Republic of Liberia;*
l) *Set standards of quality, safety, and efficacy of medicines and health products;*
m) *Promulgate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act;*
n) *Develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority;*
o) *Provide current and unbiased information on medicines and health products to health care professionals and the general public;*
p) *Regulate advertising and promotion of medicines and health products;*
q) *Be responsible for its human resources development;*
r) *Promote, monitor, and evaluate the implementation of this Act;*
s) *Receive and investigate complaints regarding alleged violations of the Act or any regulations promulgated by the Authority, and impose appropriate sanctions in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;*
t) *Establish and collect charges or fees for services rendered by the Authority; and*
u) *Carry out other functions as deemed necessary by the Authority for the effective and fair implementation* of this Act.

In performing the above functions, the Act enjoins the Authority to apply principles of Good Regulatory Practices, which include but not limited to:

a. Ensuring transparency and accountability;
b. Promoting stakeholders' participation and building consensus; and
c. Observing a code of conduct and managing any potential conflict of interests.

2 SITUATIONAL ANALYSIS

A desk review of existing documentation was done. This was followed by internal and external stakeholder consultations. The following stakeholders were involved in the process:

- Managing Director
- LMHRA Management Staff;
- LMHRA Board Members;
- Ministry of Health
- Pharmacy Board
- Malaria Control Program
- TB Control Program
- Public sector, NGOs and International Organizations;

The following key issues were identified based on the outcomes of the reviews, consultations with political and technical stakeholders, Board members, partners and other stakeholders

a. Inadequate Human Resources for the LMHRA in terms of numbers, technical know-how and skills mix.
b. Intensified public relations and community outreach and awareness as part of efforts to combat Substandard and Falsified Medicines (SFs)
c. Decentralization of LMHRA activities to Regional and subsequently to Counties particularly those at the border points. Buy-in from Customs will be critical
d. Need to provide adequate infrastructure and Resources for Quality Control Laboratory with adequate QMS
e. Need to improve on the use of technology particularly the Website and other databases
f. Need to strengthen the existing regulatory systems for registration and licensing, inspections, post market surveillance, Pharmacovigilance, control of clinical trials among others
g. Need to mobilize adequate and sustainable financial resources to facilitate effective regulation
h. Currently there are overlaps in some functions stipulated in the LMHRA Act 2010 and those of other agencies like the Customs, DEA and the Pharmacy Board. There is need for collaboration between these agencies to ensure effective regulation
i. Inadequate communication on list of registered products and other reports by the LMHRA to the MOH, the public and other agencies is a concern. Need for the website to publish this for public consumption, awareness and use
j. Non-existence of a clear monitoring and evaluation plan for the activities of the LMHRA
k. The current take-off organogram needs to be reviewed and a workable one with clear departmental responsibilities proposed.
l. General knowledge of the workings of the LMHRA among the populace is low. There is need for increased public education on medicines in general

3 ENVIRONMENTAL ANAYLSIS

3.2 SWOT ANALYSIS

This analysis is aimed at categorizing the issues identified into internal and external factors affecting LMHRA which will be useful in planning a strategy to address them.

a. The analysis of internal factors focused on the:
   - Internal abilities which the LMHRA could use or build upon to achieve its goals (strengths).
   - Internal abilities that are available on a reduced scale, unable to serve as the basis of support for the LMHRA and which may become internal obstacles to the achievement of its mandate (weaknesses).

b. The analysis of the external factors focused on issues external to the LMHRA, they included:
   - Issues that could be beneficial to the LMHRA in achieving its mandate (opportunities).
   - Issues that could hinder the LMHRA from achieving its mandate (threats).

STRENGTHS	**WEAKNESSES**
▶ Enactment of LMHRA Act and establishment of LMHRA as an autonomous body- ▶ Listing and registration of medicines and related products currently on the Liberian market ▶ Some Policy documents and guidelines in place to ensure guided implementation ▶ Availability and implementation of a Quality Management System (QMS) ISO 9001 and 17025; ▶ Inspections, Post-Marketing Surveillance and Pharmacovigilance Activities on going. ▶ System in place for authorization of Clinical Trials ▶ Presence of an organizational structure (under revision) ▶ Availability of a Quality Control Laboratory (construction of a new complex has begun)	The following weaknesses were noted: ▶ Inadequate office infrastructure ▶ No level of testing in the quality control laboratory ▶ Inadequate institutional capacity for medicines and related products regulation and quality control ▶ Inadequate technical expertise both in terms of sufficient numbers and appropriate skills ▶ Inadequate logistical support for running LMHRA operations (Inspections and PMS) ▶ Inadequate financial resources. ▶ Inadequate public awareness on the workings of the LMHRA ▶ Inadequate education of the general public on safe use of medicines and related products. ▶ Conflict of interest; ▶ Lack of appropriate technologies to fully implement its regulatory functions (registration software,

▶ Self-benchmarking of LMHRA using the WHO Global Benchmarking Tool ▶ Adapted the WAHO Common Technical Document for registration of medicines (introduced). ▶ Draft HR Policy document available. ▶ LMHRA website developed ▶ Enthusiastic workforce	Accounting software, tracking devices for SF medicines and health products;
OPPORTUNITIES ▶ Political commitment to support medicines and related products regulation – demonstrated by the enactment of the LMHRA Act ▶ Existence of development partners and diseases control programs to support the development of the human and technical resources to the LMHRA ▶ Collaboration with other Medicines Regulatory Authorities within the sub-region and globally in the areas of informtion sharing, capacity building etc. ▶ Recognition on the part of key stakeholders with regards to the importance of medicines regulation in achieving national healthcare objectives ▶ Placement of 90% of the Authority staff on government's payroll; ▶ Potential for collaboration with state and security agencies such as Customs, Liberia Ports Authority, Police, DEA and National Environmental Authority and professional bodies e.g. Pharmacy, Medical and Dental, Nurses and Veterinary Council to enhance the Authority's regulatory activities.	**THREATS** ▶ The potential for other state agencies and professional bodies to consider some aspects of the LMHRA functions as an overlap on their functions or roles leading to conflict. ▶ Inability of government to adequately fund the activities of the LMHRA. ▶ The tendency for some stakeholders or business interests to view the LMHRA as an additional bureaucratic bottleneck that may affect their usual way of doing business. ▶ Presence of Sub-standard and Falsified (SF) medicines and health products in the market. ▶ Inadequate financial support and sustainability. ▶ The lack of permanent building for headquarters in Monrovia as provided for in the LMHRA Act; ▶ Conflict of interest.

3.3 PESTEL ANALYSIS

Political

The political dispensation in Liberia hopes to provide a new focus and a new direction as far as health is concerned. National policies on health as well as Ministerial Health Policies and strategies are likely to gather a new momentum of implementation. Currently, the operational cost of the LMHRA (e.g. salaries, renting of office space) is being met by the Government of Liberia (GoL) through the disbursement of its subvention by Ministry of Finance. However, the increase in its allocation is necessary for LMHRA to build its capacity and improve services and these will affect the strategic direction of the LMHRA.

Economic

The LMHRA is a government sub-vented Authority and will definitely be affected by national budget and economic health. For that matter budgetary allocations to the Authority which is, the main income source of the Authority, the internally generated funds obtained from fees charged, is likely to be affected by overall economy and purchasing power of the country.

Social

Like any developing country south of the Sahara and within the ECOWAS region, there is a high disease burden that calls for multi-sectorial approach to health provision. There is wide availability of medicines and related products through government or the private sector. Inadequate regulation of such products is likely to affect health outcomes. With the general literacy rate in the country, general attitude towards quality and safety of products, illegal and irrational use of medicines, there is the need for effective medicines and related products regulation.

Technological

The depth of penetration of mobile technology within the country provides a very useful opportunity for information dissemination on product quality, safety and efficacy. It also provides an avenue for participation of the citizenry in regulation through a properly organized feedback system. Technology will be harnessed internally to improve on inter-departmental communication and thereby improve efficiency and effectiveness. Technology externally will improve information dissemination to professionals, applicants and the general public. Mobile phone technology could be used as a means of authentication of registered products by the general public as a means of fighting the presence of substandard and falsified medicines and related products on the Liberian market.

Environmental

Work Culture and ethics of the general population including staff and clients of the LMHRA are likely to influence the workings of the Authority. The plurality of the press, both print and electronic, presents as a strength and opportunity for the operations of the LMHRA. The presence of other agencies in the regulatory space and the perceived overlap of function also poses a threat to the LMHRA.

Legal

The existence of an enabling law that provides the legal basis for the regulation of medicines and related products clearly sets the scope and extent of the working of the LMHRA. Liberia is also a member of international health agencies like the WHO, WAHO and UNICEF. Additionally, it is a signatory to various international conventions including the International Conventions on Narcotics and Psychotropic substances that provide addition legal basis and benchmarking.

4 MANDATE, VISION, MISSION

4.1 MANDATE

The Act to establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 mandates the Authority to:

- To ensure that, in the national medicine supply system, safe, effective, and good quality medicines reach the Liberian public.
- To protect the Liberian public from the harmful effects of substandard and counterfeit medicines and health products.
- To ensure fair trade practices in medicines and health products.
- To promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products.
- To conduct or facilitate necessary research and development, promote pharmacovigilance, and disseminate timely drug information.

4.2 VISION

A Leading Medicines and Related Products Regulatory Authority of excellence in Africa.

4.3 MISSION

The Liberia Medicines and Health Products Regulatory Authority exists to achieve the highest possible standards of quality, safety and efficacy for medicines and health products by employing legal, effective, efficient and transparent regulatory systems using competent and highly motivated human resource backed by adequate technology, to safeguard public health.

5 STRATEGIC GOALS, OBJECTIVES AND ACTIVITIES

From the SWOT and PESTEL analyses, as well as gaps identified in the WHO assessment, WHO benchmarking and the QMS assessment reports, the following thematic areas were identified for which strategic goals or broad objectives are to be set and worked on in the next five years to achieve the mandate, vision and mission of the LMHRA.

5.2.1 Thematic Areas

a. Regulatory System Strengthening
    i. Legislation and regulations
    ii. Evaluation and registration
    iii. Inspections and import and export control
    iv. Post Market Surveillance
    v. Pharmacovigilance and Clinical Trials
    vi. Quality Control
b. Quality Management System
c. Human Resource Development
d. Harmonization, Collaboration and Decentralization
e. Financial sustainability
f. Communication and Information Technology

5.2.2 STRATEGIC GOALS

- Establish an effective and efficient medicines and related products regulatory system
- Set up a Quality Management System (QMS) and Undertake Operational Research activities to support regulatory functions
- Develop and Implement an effective Information management System
- Promote partnership, cooperation, collaboration and decentralization
- Recruit, develop and maintain adequate Human Resource (HR) Capacity
- Mobilize infrastructural, monitoring and financial resources to ensure sustainability

5.3 SPECIFIC OBJECTIVES AND ACTIVITIES

For each goal, specific objectives are set, which are measurable, and activities to achieve the objectives indicated as below. Timelines will be set for each of the activities and this is used to design an implementation framework.

GOAL 1: Establish an effective and efficient medicines and related products regulatory system

Specific objective 1

- Develop and provide appropriate regulatory tools for the efficient operations of LMHRA

Activities

- Review existing legislation and bring it in line with the AU Model Law
- Identify, draft and promulgate regulations required by the LMHRA Act
- Identify and prepare required guidelines, forms, policies, manuals & standard operating procedures (SOPs) and work instructions based on best practices
- Organize stakeholder retreats to validate the tools
- Print and/or disseminate the tools
- Monitor and evaluate use of the regulatory tools

Specific objective 2

- Create a robust and efficient product evaluation and registration system.

Activities

- Establish and Operationalize the Technical Advisory Committee on Product Registration
- Source, procure and install a medicines and related products registration software
- Set up an archival and retrieval system for product dossiers.
- Organize dossier evaluation retreats
- Develop, publish and disseminate product registers
- Organize training for manufacturers and importers on registration guidelines and dossier submission rules.
- Train assessors on dossier assessment including the use of the new ECOWAS CTD format

Specific Objective 3

Strengthen Licensing, Inspections, Post Marketing Surveillance (PMS) and import and export control systems

Activities

- Conduct market monitoring activities to clean market of illegal sale of medicines
- Strengthen system for import and export control
- Develop and sign MOU with Customs on import and export control
- Inspect premises including warehouses of Central Medical Stores, NGOs, and Importers
- License manufacturers, Importers and warehouses/ storage facilities
- Conduct Post market surveillance for products of public health importance
- Organize training for organizations involved in manufacture, importation, warehousing/ storage on developed regulatory tools

Specific Objective 4

Strengthen and operationalize Pharmacovigilance and control of Clinical Trials

Activities

- Review and implement the existing PV plan
- Review and update existing PV guidelines and tools
- Set up and operationalize the Medicines Safety Expert Committee
- Sensitize and train public and private health professionals on PV
- Train and motivate PV contact persons in healthcare facilities to encourage reporting
- Develop and roll out a mobile application for adverse reactions reporting
- Maintain full membership of the WHO Collaborative Centre (Uppsala Monitoring Centre)
- Create a Clinical Trial repository
- Review guidelines for control of clinical trials
- Conduct Good Clinical Practice (GCP) Inspections
- Train staff on Clinical Trial Application evaluation and Good Clinical Practice

Specific Objective 5

Create a functioning Quality Control Laboratory to support regulatory activities

Activities

- Complete the construction of the ultramodern Quality Control Laboratory
- Identify and list equipment, reagents and other laboratory consumables needs
- Procure, install and qualify the equipment, reagents and consumables
- Identify laboratory HR needs, recruit, train and retain
- Review and implement Laboratory Quality Manual, SOPs, validation processes and Recording systems
- Procure and install an appropriate Laboratory Information Management System
- Seek accreditation of laboratory to ISO 17025:2017 and WHO Prequalification

GOAL 2: Strengthen the Quality Management System (QMS) and Undertake Operational Research activities to Support Regulatory Functions

Specific Objectives 1

- Review the QMS plan towards ISO 9001:2015 certification and Pre-qualification

Activities

- Recruit a consultant to support the LMHRA to establish a Quality Management System
- Develop a roadmap towards implementation and maintaining of QMS
- Develop relevant SOPs for implementation of QMS
- Train staff on QMS implementation
- Implement roadmap and seek certification for ISO 9001:2015
- Conduct internal audits of the state of implementation of the QMS
- Conduct external audit of the system for purposes of accreditation/ certifications

Specific objective 2

- Develop and implement appropriate systems for information and documentation management

Activities

- Identify all the documents needed
- Identify and procure appropriate software
- Train staff and end users on the software
- Develop a data protection policy, SOP and document control system for QMS

Specific objective 4

- Conduct research into medicines importation, distribution and usage patterns

Activities

- Conduct research on antibiotic and controlled medicines use patterns
- Study the types and forms of medicines imported
- Conduct a survey on substandard and falsified medicines on Liberian market

GOAL 3: Develop/Review and Implement an Effective Information Management System

Specific Objective 1

- Develop and maintain a management information system a website

Activities

- Recruit consultant to develop computerized Information Management System and train staff on its use
- Upgrade the intranet for internal communications
- Review and constantly update information on the website
- Set up software application for interaction with stakeholders

Specific objective 2

- Keep healthcare professionals and other stakeholders informed about product quality, safety and efficacy issues

Activities

- Issue "Dear Healthcare Professional Letters" to disseminate information
- Issue advertisers' announcements, disclaimers and drug alerts to educate the public
- Conduct orientation session for stakeholders and policy makers

Specific objective 3

- Educate the general public on the safe use of medicines and related products

Activities

- Organize orientation session for Senior journalist and Association of Health Journalists (AOHJ) members
- Participate in TV and Radio talk shows and program and publish articles

Specific objective 4

- Create Public Awareness on the existence & functions of the LMHRA

Activities

- Launch the LMHRA with adequate publicity
- Celebrate 10th Anniversary of LMHRA with adequate publicity
- Orientation/ Sensitization visits to Political and Traditional Heads in Counties

Specific objective 5

- Develop Social and Behavioral Change Communication (SBCC) strategy

Activities

- Conduct rapid assessment of SBCC approaches for medicines regulation
- Develop messages based on the outcome of the assessment
- Pre-test the messages
- Validate the messages
- Produce posters, fliers, hand-outs, billboards, leaflets and stickers, TV and radio spots, SBCC manuals and flip charts

- Dissemination through TV, radio, print, website, community engagement (district authorities, MDTFs and IPC networks) and a hotline

GOAL 4: International Collaboration, Harmonization and Decentralization

Specific objective 1

- Participate in the ECOWAS and African Medicines Harmonization initiatives

Activities

- Undertake a study tour more advanced NMRAs and lead auditors training
- Attend ECOWAS heads of NMRAs meetings

Specific objective 2

- Participate in international conferences and exchanges on medicines and related products regulation

Activities

- Attend International Conference of Drug Regulatory Authorities and International Federation of Pharmacists
- Attend AU NEPAD regional regulatory meetings
- Attend World Health Assembly and other WHO facilitated meetings

Specific Objective 3

Decentralize activities of the LMHRA

Activities

- Open and furnish LMHRA offices in 4 regions
- Recruit/ Post staff to these offices and provide accommodation
- Provide cross country vehicle for the regional offices

GOAL 5: Develop and Maintain Adequate Human Resource Capacity

Specific Objective 1

Perform human resource needs assessment and develop a human resource plan

Activities

- Recruit consultant to perform needs assessment and develop HR plan
- Organize stakeholder meetings to validate plan

Specific Objective 2

Develop staff scheme and conditions of service

Activities

- Recruit consultant to develop staff scheme and conditions of service
- Develop job descriptions for all staff
- Organize stakeholder meetings to validate the drafts and finalize

Specific Objective 3

Identify training needs and develop training plan

Activities

- Review current staff and match qualifications with position
- Recommend specific training for specific staff

GOAL 6: Mobilize Adequate Financial and Infrastructural Resources to Sustain the Operation of the LMHRA

Specific Objective 1

Build and furnish a national Headquarters of LMHRA in Monrovia

Activities

- Acquire land for the building of LMHRA headquarters
- Produce an architectural design of the LMHRA office Complex
- Recruit a consultant for the building project
- Construct the LMHRA office complex
- Procure and install needed office furniture and IT resources

- Organize official ceremony to open the LMHRA headquarters

Specific Objective 2

Provide and maintain adequate logistics and infrastructure

Activities

- Procure the necessary office infrastructure
- Acquire necessary operational vehicles
- Undertake Planned Preventive maintenance of equipment, vehicles and other infrastructure
- Procure server, computers and other hardware, appropriate software and accessories

Specific Objective 3

- Ensure that there is a results-based monitoring and evaluation system

Activities

- Develop M&E plan
- Conduct regular monitoring
- Schedule end line evaluation
- Write and disseminate M&E reports

Specific Objective 4

Ensure sustainable financing of regulatory activities

Activities

- Review existing fee schedule
- Advocate for specific tariff on imported medicines and heath products to support LMHRA activities
- Seek external funding from partners for specific projects

6 GUIDING PRINCIPLES AND STRATEGY

6.1 Good Regulatory Practices

In performing its functions, the Authority shall apply principles of Good Regulatory Practices, which include but are not limited to:

- Ensuring transparency and accountability;
- Promoting stakeholders' participation and building consensus; and
- Observing a code of conduct and managing any potential conflict of interests.

6.2 Technical Advisory Committees

The LMHRA shall perform its scientific functions through the use of Scientific and Technical Advisory Committees. This is premised on the fact that products regulated under the Medicines and Related Products Act 2014 are used for practice in various scientific and health professional areas. Disciplines like Clinical Trials, Pharmacovigilance, Veterinary medicines and related products call for such an approach.

6.3 International Harmonization

The Authority shall fully participate in international medicines and related products regulatory harmonization efforts at the WHO, AU NEPAD and WAHO levels. It will enter into MOUs with other regulatory agencies where necessary and participate in various cooperating arrangements within the world health environment. The LMHRA will consider the scientific opinions expressed by other stringent NMRAs and international bodies such as ICH, WHO and OIE in its decisions on medicines and related products quality, safety and efficacy.

6.4 Decentralization

Taking note of the fact that the functions of the Authority cannot all be performed in Monrovia, LMHRA will deploy staff at strategic locations and other Health regions over the next five years. In the meantime, MOU will be established with regional health administrations and also with Customs for the control of the ports of entry. Training will be provided for staff of other agencies approved to perform some of the functions of the LMHRA on its behalf.

6.5 Human Resource management

Staff recruitment will be through advertisements and interviews. The existing staff shall be given first preference and offered permanent placement in accordance with their levels of competence.

In terms of staff capacity buildings, short, medium- and long-term strategies will be employed. In the short term, the LMHRA will:

- Engage consultants to conduct training workshops for staff on Dossier Evaluation, Inspection and the relevant WHO Good Practices such as Good Storage and Distribution Practices, etc.
- Contact WHO, Global Fund and other bilateral or multilateral partners to assist in the establishment of a Level 1 Quality Control Laboratory to start with.

- Contact international agencies such as WHO and WAHO for their schedule for training workshops and apply for staff to participate in program relevant to the LMHRA.

In the medium term, the LMHRA will;

- Collaborate with Medicines Regulatory Authorities (e.g. Ghana's FDB and Nigeria's NAFDAC) with regards to attachment of Staff to their agencies for training.
- Identify opportunities for training attachments at the SWISSMEDIC, Health Canada, Indonesian and Malaysian Medicines Regulatory Authority amongst others.

In the long term, the LMHRA will identify potential staff to be developed through appropriate post-graduate academic and professional training for senior positions within the LMHRA. These potential staff may pursue a Master's Degree or Membership and Fellowship in the following areas among others:

- Pharmaceutical Analysis & Quality Control
- Pharmaceutical Quality Assurance & GMP
- Pharmaceutical Science & Management Studies
- Pharmaceutical Services & Medicines Control
- Pharmaceutical Microbiology
- Financial Management
- Medical Products Regulatory Affairs
- Planning and Project management
- Administration and Human resource management

These courses are offered many Universities and Institutes in Ghana, Nigeria, UK, Ireland and other professional academic institutions such as the West Africa Post Graduate College of Pharmacists, the Ghana College of Pharmacists and the Ghana Institute of Management and Public Administration

6.6 Monitoring and Evaluation

The Strategic Plan shall be monitored through a results-oriented monitoring and evaluation scheme annually. This will form the basis for operational planning and for annual or midterm review of objectives and strategies, activities and key performance indicators to achieve the overall goals of the LMHRA.

7 ORGANIZATIONAL CULTURE AND ETHICS

In order to discharge its duties effectively, the LMHRA shall function within a corporate cultural environment that safeguards its independence of action, integrity, effectiveness and impartiality. Procedures would be laid down giving the mechanism by which employees of the Authority are appointed and the security of their tenure of service guaranteed. The conditions of service, remuneration and working arrangements will be such that vested interests cannot exert any undue influence over staff or others working for the Authority.

By the nature and operations of the LMHRA staff are supposed to abide by the following:

- Dressing appropriately when on duty
- Not divulging information (Need-To-Know Principle)
- Ensure the confidentiality of sensitive data
- To observe the oath of secrecy
- Key technical staff must be well informed on issues relating to medicines and related products
- Staff must be courteous
- Staff must be faithful, sincere and of high integrity
- Staff should not be involved in any activity that is liable to create a conflict of interest.
- Ready to work outside the normal working hours
- Staff should not overly expose themselves to the public
- All categories of staff should not grant interviews without authorization

8 GOVERNANCE STRUCTURE

The LMHRA shall be made up of the following organizational features:

- Board of Directors
- Office of the Managing Director;
- Deputy Managing Director
- Finance and Administration;
- Quality Control Laboratory;
- Inspection, Post-marketing Surveillance and Enforcement;
- Pharmacovigilance and Clinical Trials;
- Medicines and Related Products Evaluation and Registration;

The functions performed by the Departments may be organized under various Units for the efficient administration of the organization.

The organogram of the LMHRA is attached as Annex 1.

8.1 GOVERNING BOARD

1) The Board of Directors shall have eleven (11) voting members, to be appointed by the President of the Republic of Liberia.

2) The Board of Directors shall consist of the following members, at least three (3) of whom shall be women:

    a. A qualified Liberian Pharmacist, who shall be appointed by the President of the Republic of Liberia to chair the Board of Directors;
    b. The Chief Pharmacist, representing the Ministry of Health;
    c. The head of the Pharmacy Board
    d. A lawyer representing the Ministry of Justice;
    e. The head of Customs, representing the Ministry of Finance;
    f. The head of the National Bureau of Standards, representing the Ministry of Commerce;
    g. A representative of the School of Pharmacy of the University of Liberia;
    h. A representative of the Liberia Medical and Dental Council;
    i. A representative of the Pharmaceutical Association of Liberia;
    j. A veterinarian;
    k. A representative of an appropriate consumer interest group or association; and
    l. The Managing Director of the Authority, who shall serve as secretary to the Board of Directors, and who shall be a non-voting member.

The Governing Board shall have the powers and duties to:

- Approve regulations for implementation of the Act;
- Approve the strategic plan of the Authority;
- Approve the annual work plan and budget of the Authority;
- Review the quarterly reports presented by the Managing Director;
- Monitor and evaluate implementation of the Act;
- Approve the individuals recommended to be Directors by the Managing Director;
- Establish committees whenever it deems necessary, and
- By a two-thirds (2/3) majority vote of the full membership of the Board of Directors, remove Managers or recommend to the President for removal of any member of the Board of Directors, in either case only for acts incompatible with the Authority's or Board's rules or regulations.

8.2 MANAGEMENT

The Managing Director, Deputy Managing Director and the Directors of Departments shall constitute the strategic or top management team of the LMHRA.

The general management staff of the LMHRA shall be made up of the Managing Director, Deputy Managing Director and the Directors of the various Departments and Heads of Units.

Functions of the Various Officers and Departments

The functions for the various officers and departments are as described below:

8.2.1 MANAGING DIRECTOR

The **Office of the Managing Director** shall house the Programs & Planning Office, Legal Office, Information Technology, Communication/Public Relations Office, Internal Audit, Procurement Office, Quality Systems Manager, Client Service Center and Research and Development Office.

There will be an Administrative Assistant to assist in the day-to-day management of the office.

Functions of the **Managing Director** shall be as follows, among others:

- The Managing Director shall be the administrative and technical head of the Authority and shall direct and administer the day-to-day activities of the Authority.
- Recommend Departmental Directors for appointment by the Governing Board
- Oversee the preparation and implementation of the Strategic and Operational plans of the Authority.
- Develop and establish a Quality Management System for the efficient and effective management of the organization.
- Exercise the functions and duties of the Authority.
- Administer personnel of the Authority following the basic principles of Liberia Labor legislation.
- Prepare and submit to the Governing Board an annual operational plan and budget of the Authority and implement same upon approval.
- Submit quarterly reports to the Governing Board.
- Establish Technical Advisory Committees with the approval of the Governing Board.
- Approve registrations for medicines and related products upon recommendations from the Medicines Evaluation Committee.
- Approve and issue appropriate licenses and certificates.
- The Managing Director may delegate part of his/her functions to Deputy Managing Director, Directors or other employees of the Authority to the extent necessary for the efficient performance of its activities.

8.2.2 DEPUTY MANAGING DIRECTOR

The **Deputy Managing Director** shall among others;

- Act in the absence of the Managing Director
- Report to the Managing Director and provide technical direction to the LMHRA to ensure its efficient operation.
- Be required to provide basic training where necessary and on the job mentoring to staff in the technical departments.

- Facilitate and coordinate capacity building of personnel of organizations dealing with products regulated by the Authority
- Coordinate the activities of the Technical Advisory Committees for the core regulatory activities
- Coordinate the activities of the Directorates for Evaluation and Registration, Licensing, Inspection and Post Marketing Surveillance and Clinical Trials and Pharmacovigilance and report to the Managing Director on these Directorates
- Support the Managing Director in identifying technical areas that need external consultancy services, develop TORs and assist in the processes leading to the procurement of such services.

8.2.3 DIRECTOR, FINANCE AND ADMINISTRATION

The Director of the Department of Finance and Administration shall report to the Managing Director and shall carry out the following functions to support the core regulatory activities of the Authority:

- Coordinate the preparation of the annual operational budget of the Authority;
- Ensure accountability of the resources of the Authority
- Prepare quarterly statement of Accounts for the attention of the Managing Director
- Lead in the resource mobilization efforts of the Authority
- Be in charge of the Human Resource management activities with the Authority
- Be in charge of general administration duties including transport, maintenance, security and estates

8.2.4 DIRECTOR, QUALITY CONTROL LABORATORY

The Director of the Quality Control Laboratory shall report to the Managing Director and be responsible for the following functions:

- Laboratory management;
- Laboratory accreditation and maintenance of same
- Laboratory equipment, chemicals and reagents management
- Pre- and post-registration analysis of products regulated by the Authority;
- Issue certificate of analysis for all products tested;
- Laboratory samples receipt, documentation and storage
- Development, review and validation of analytical methods;
- Support Post Market Surveillance activities
- Research into product quality trends.

8.2.5 DIRECTOR LICENSING, INSPECTION AND POST-MARKETING SURVEILLANCE,

The Director of the Department of Licensing, Inspection, and Post-marketing Surveillance shall report to the **Managing Director** through the **Deputy Managing Director** and shall be responsible for the following functions:

- Pre-licensing and post-licensing inspections of premises and organizations involved in manufacturing, import, export, distribution, sale or supply of products regulated by the Authority;
- Routine inspection of medical stores, warehouses and other storage facilities;
- Post-marketing surveillance activities;
- Port of Entry inspections and sampling of products for import and export of products regulated by the Authority;
- Enforcement of quality management systems in organizations dealing with products regulated by the Authority;
- Collection of data on imports and exports of products regulated by the Authority;
- Liaise with the Drugs Enforcement Authority on issues relating to Narcotics and Psychotropic medicines;
- Supervise safe disposal of products regulated by the Authority;
- Liaise with the National Environmental Authority on issues relating to manufacturing and disposal of products regulated by the LMHRA.

8.2.6 DIRECTOR CLINICAL TRIALS AND PHARMACOVIGILANCE

The Director of the Department of Medicines Safety Monitoring (Pharmacovigilance) and Clinical Trials shall report to the **Managing Director** through the **Deputy Managing Director** and shall be responsible for the following functions:

- Conduct Pharmacovigilance (safety monitoring) of medicines and other products regulated by the Authority;
- Coordinate with other Agencies on the monitoring of Adverse Events after Immunization;
- Be responsible for vaccines control and regulation of blood and blood products;
- Be responsible for Lot Release of Biological products
- Receive and evaluate applications for clinical trials;
- Follow up on clinical trials to ensure compliance with Good Clinical Practice and Good Clinical Laboratory Practice.

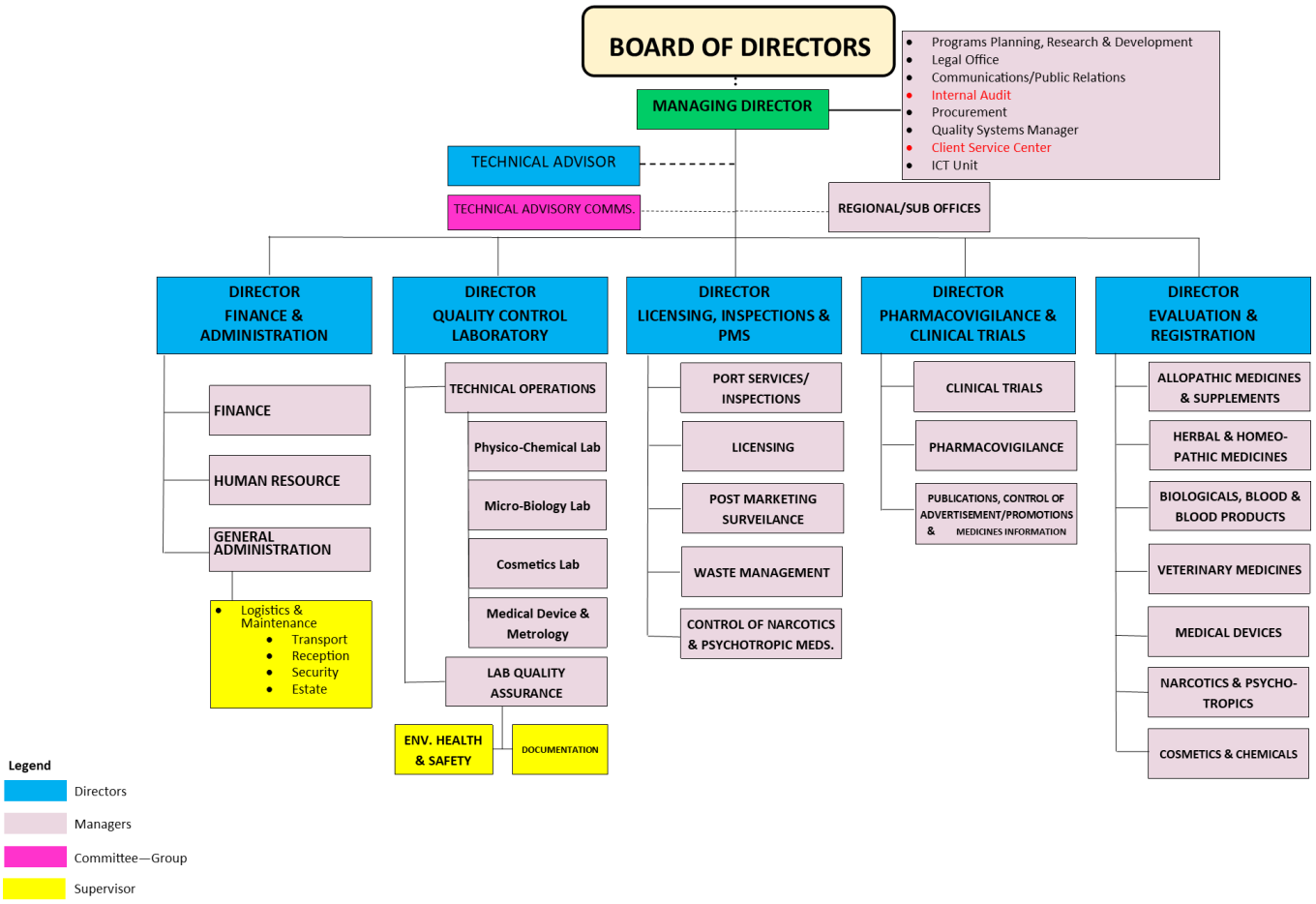
8.2.7 DIRECTOR EVALUATION AND REGISTRATION

The Director of the Department of Medicines and Related Products Evaluation and Registration shall report to the **Managing Director** through the **Deputy Managing Director** and shall be responsible for the following functions:

- Receiving of applications for registration of products regulated by the Authority including dossiers and samples;
- Evaluation of dossiers and submission of samples for QC analysis;
- Liaise with stakeholders in the Classification of medicines and related products;
- Creation and maintenance of product registers;
- Review of labelling and promotional information;
- Receipt and processing of applications for advertisements of products regulated by the Authority;
- Dissemination of current product information and alerts;
- Review of standards and specifications;
- Receive and evaluate applications for import and export permits for products regulated by the Authority.

ANNEXURES

ANNEX 1: ORGANOGRAM



Note: Internal Auditors are seconded by the Internal Audit Agency (IAA); while the Client Service Center is headed by an Officer

ANNEX 2: OPERATIONAL PLAN AND BUDGET

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
Establish an effective and efficient medicines and related products regulatory system	Develop and provide appropriate regulatory tools for the efficient operations of LMHRA	Review LMHRA Act 2011 and bring in line with AU Model Law	Gap Analysis report and draft New law	Consultant Meetings	15,000	Q4 2021	LMHRA Partners Legislature
		Identify, draft and promulgate regulations required by the LMHRA Act	Number of Regulations developed and passed	Facilitator, TWG meetings	10,000	Q3 2021 to Q1 2022	LMHRA Partners
		Identify and prepare required guidelines, forms, policies, manuals & standard operating procedures (SOPs) and work instructions based on best practices	Number Required guidelines, forms etc, developed	Facilitator, Technical Working Group, Meetings	10,000	Q4 2021	LMHRA Partners
		Organize stakeholder retreats to validate the tools	Tools validated	Consultancy	8,000	Q1 2022	LMHRA
		Print and/or disseminate the tools	Tools disseminated	Printing materials Social and other media	5,000	Q1 2021	LMHRA
		Monitor and evaluate use of the regulatory tools	Number Monitoring visits done and documented	Facilitator Staff cost	15,000	Q4 2022 Q4 2023 Q4 2024	LMHRA Partners
	Create a robust and efficient product evaluation and registration system.	Establish and Operationalize the Technical Advisory Committee (TAC) on Product Registration	TAC for registration established and operational	Meetings	5,000	Q3 2021	LMHRA
		Source, procure and install a medicines and related products registration software	Registration software operational	Specifications IT consultant Meetings	15,000	Q3 2021 to Q4 2021	LMHRA
		Set up an archival and retrieval system for product dossiers	Archival and retrieval system established	Procurement process IT support	60,000	Q2 2022	LMHRA Partners
		Organize dossier evaluation retreats	No. of dossiers evaluated	Hotel costs Conference packages Meetings	100,000	Q4 2019 to Q4 2021	LMHRA

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
		Develop, publish and disseminate product registers	Number Product registers available	Printing Media	20,000	Q1 2022 TO Q4 2025	LMHRA
		Organize training for manufacturers and importers on registration guidelines and dossier submission rules.	Number of trainings organized Number of manufacturers & importers trained	Biennial Meetings	25,000	Q4 2021 Q4 2023 Q4 2025	LMHRA
		Train assessors on dossier assessment including the use of the new ECOWAS CTD format	Number of Assessors trained	Facilitator Meetings	15,000	Q3 2021 Q3 2023 Q3 2025	LMHRA Partners
	Strengthen Licensing, Inspections, Post Marketing Surveillance (PMS) and import and export control systems	Conduct market monitoring activities to clean market of illegal sale of medicines	Reduction in % illegal sales	Transport Personnel cost Hotel	35,000	Q1 2021 to Q4 2026	LMHRA
		Strengthen system for import and export control	Import and export controls in place	Computers and accessories Staff cost	40,000	Q1 2022 to Q3 2022	LMHRA
		Develop and sign MOU with Customs on import and export control	MOUs signed	Facilitator meetings	15,000	Q2 2022	LMHRA OTHER GOVERNMENT INSTITUTIONS
		Inspect premises including warehouses of Central Medical Stores, NGOs, and Importers	Number of Inspections conducted annually Number of warehouses, NGOs and importers inspected	Transport Accommodation Staff cost	50,000	Q1 2021 to Q4 2026	LMHRA
		License manufacturers, Importers and warehouses/ storage facilities	Number of Companies licensed	Administrative set up	10,000	Q4 2021	LMHRA
		Conduct Post market surveillance for products of public health importance	Number of PMS visits conducted annually	Training Transport Staff cost	50,000	Q2 2021 to Q4 2025	LMHRA

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
		Organize training for organizations involved in manufacture, importation, warehousing/ storage on developed regulatory tools	Number of organizations trained Number of trainings conducted	Meetings	15,000	Q4 2021	LMHRA Partners
	Strengthen and operationalize Pharmacovigilance and control of Clinical Trials	Review and implement the existing pharmacovigilance plan	PV plan reviewed and implemented	TWG, human resources, logistics	20,000	Q4 2021	LMHRA
		Review and update existing PV guidelines and tools	Number of PV guidelines and tools reviewed and updated	TWG, logistics	40,000	Q1 2022	LMHRA, Partners
		Set up and operationalize the Medicines Safety Expert Committee	Committee set up and operationalized	Training, meetings, logistics	50,000	Q4 2021	LMHRA Partners
		Sensitization and training of public and private health professionals on PV	No. of Professionals sensitized and trained	Training materials, logistics training	30,000	Q2 2022	LMHRA
		Train and motivate PV contact persons to encourage reporting	No. of reports received	Training materials, logistics	20,000	Q3 2022	LMHRA
		Become full member of the WHO Collaborative Centre (Uppsala Monitoring Centre)	No. of reports sent membership attained	Logistics, funds for fee payment	28,000	Q3 2022	LMHRA
		Develop and launch mobile application for adverse reactions reporting	Application developed and launched	Consultant Logistics meeting	25,000	Q4 2022	LMHRA
		Create a Clinical Trial repository	CT repository created	IT infrastructure, logistics	25,000	Q4 2021	LMHRA, WAHO, WHO
		Adapt AVAREF guidelines for control of clinical trials	Guidelines available	TWG, logistics	8,000	Q2 2022	LMHRA
		Conduct Good Clinical Practice (GCP) Inspections	No. of GCP inspections conducted	Human resource, training, logistics	46,000	Q4 2022	LMHRA WAHO
		Train staff on Clinical Trial Application evaluation and	No. of staff trained	Training materials, logistics	75,000	Q3 2022	LMHRA WAHO WHO

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
		Good Clinical Practice					
	Create a functioning Quality Control Laboratory to support regulatory activities	Complete the construction of the ultramodern Quality Control Laboratory	QC Lab construction completed	Consultant Contractor	3,100,000.00	ON-GOING	LMHRA GOL, Partners
		Identify and list equipment, reagents and other laboratory consumables needs	Laboratory materials inventory available	Facilitator	20,000	Q4 2021	LMHRA Partners
		Procure, install and/ or qualify the equipment, furniture, reagents and consumables	Equipment/ reagents procured, installed and qualified/standardized	Procurement process	3,300,000	Q1 2023	LMHRA
		Identify laboratory HR needs, recruit, train and retain	Number of Laboratory staff trained	Facilitator Meeting	200,000	Q1 2022	LMHRA Partners
		Review and implement Laboratory Quality Manual, SOPs, validation processes and Recording systems	Laboratory Manuals developed	Facilitator Meetings	52,000	Q3 2022	LMHRA Partners
		Procure and install an appropriate Laboratory Information Management System	LIMS Installed and operational	Procurement process	75,000	Q3 2022	LMHRA Partners
		Seek accreditation of laboratory to ISO 17025:2017 and WHO Prequalification	QCL accredited/ prequalified	Consultant Accreditation body	120,000	Q1 2023	LMHRA Partners
Strengthen the Quality Management System (QMS) and Undertake Operational Research activities to support	Review the QMS plan towards ISO 9001:2015 certification and Prequalification	Recruit a consultant to support the LMHRA to establish a Quality Management System	QMS established	Consultant, logistics	25,000	Q3 2021	LMHRA Partners
		Review the roadmap towards implementation and maintaining of QMS	Roadmap developed, Audit reports	TA, TWG, Accreditation bodies	50,000	Q4 2021	LMHRA, Partners, WAHO

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
regulatory functions		Review and develop relevant SOPs for implementation of QMS	SOPs developed, No. of staff trained, QMS installed in all departments	TWG, training materials, IT infrastructure, logistics	75,000	Q1 2022	LMHRA, Partners,
		Train staff on QMS implementation					
		Implement roadmap and seek certification for ISO 9001:2015	QMS tools implemented, ISO certification obtained	TA, TWG, accreditation bodies	120,000	Q1 2022 – Q1 2023	LMHRA PARTNERS
		Conduct internal audits of the state of implementation of the QMS					
		Conduct external audit of the system for purposes of accreditation/ certifications and prequalification					
	Develop and implement appropriate systems for information and documentation management	Review the list of QMS documents needed	Documents listed Software procured, Training report, data protection policy available	TA, TWG, IT infrastructure, logistics	28,000	Q4 2021	LMHRA PARTNERS
		Identify and procure appropriate software					
		Train staff and end users on the software					
		Develop a data protection policy, SOP and document control system for QMS					
	Conduct research into medicines importation, distribution and usage patterns	Conduct research on antibiotic and controlled medicines use patterns	Research report	Concept paper, TWG, logistics	15,000	Q2 2022	LMHRA PARTNERS
		Study the types and forms of medicines imported	Study findings and report	Concept paper, TWG, Logistics	8,000	Q2 2023	LMHRA PARTNERS
		Conduct a survey on substandard and falsified medicines on Liberian market	Survey report	Concept paper, TWG, Logistics	12,000	Q3 2023 Q3 2025	LMHRA PARTNERS
Develop and Implement an effective Information	Develop and maintain a management information	Recruit consultant to develop computerized Information	Consultancy and training reports available	IT Consultant, logistics server, work stations, network	33.000	Q4 2021 to Q3 2022	LMHRA, WAHO, Partners

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
management System	system and website	Management System and train staff on its use	Availability of functional internet installed software for interaction				
		Upgrade the intranet for internal communications	Availability of functional intranet	Consultant, server, work stations, network and network port	15,000	Q3 2021	LMHRA WAHO PARTNERS
		Review and constantly update information on the website	No. of website visits, enquiries, phone calls and physical visits, installed software for interaction,	IT Consultant	20,000	Q4 2021	LMHRA PARTNERS
		Set up software application for interaction with stakeholders					
	Keep healthcare professionals and other stakeholders informed about product quality, safety and efficacy issues	Issue "Dear Healthcare Professional Letters" to disseminate information	No. of letters issued and disseminated	Functional internet and website, logistics	10,000	Q1 2022	LMHRA
		Issue advertisers' announcements, disclaimers and drug alerts to educate the public	No. of advertisements announcements, disclaimers and drug alerts to educate the public made	Print and electronic media	25,000	Q3 2021 to Q3 2025	LMHRA
		Conduct orientation sessions for stakeholders and policy makers	No. of orientation sessions conducted	Workshops, seminars, outreach programs	35,000	Q3 2021 annually	LMHRA
	Educate the general public on the safe use of medicines and related products	Organize orientation session for Senior journalist and Association of Health Journalists (AOHJ) members	No. of media interactions conducted	Workshops and soirees	10,000	Q1 2022	LMHRA
		Participate in TV and Radio talk shows and programmes and publish articles	No. of TV and Radio talk shows conducted and articles published	Cost of airtime and publications	10,000	Q4 2021	LMHRA
	Create Public Awareness on the existence & functions of the LMHRA	Celebrate 10th Anniversary of LMHRA with adequate publicity	Anniversary Celebrated	Planning Committee Brochure Meetings	75,000	Q4 2021	LMHRA Partners Local Stakeholders
		Develop and implement an advocacy plan	Advocacy plan developed	Technical working group, logistics	5,000	Q3 2019	LMHRA
		Orientation/ Sensitization	Orientation reports	Logistics, Drama Groups	25,000	Q3/ Q4 2021	LMHRA

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
		visits to Political and Traditional Heads in Counties					
	Develop Social and Behavioral Change Communication (SBCC) strategy	Conduct rapid assessment of SBCC approaches for medicines regulation	Rapid assessment report. Availability of messages, Types of Messages pre-tested and validated. SBCC support materials produced and distributed. Number of radio and TV programs conducted and number of spots aired. Number of community structures reached and engaged.	Communication and advocacy technical working group	100,000	Q2 2022	LMHRA PARTNERS
		Develop messages based on the outcome of the assessment					
		Pre-test the messages					
		Validate the messages					
		Produce posters, fliers, hand-outs, billboards, leaflets and stickers, TV and radio spots, SBCC manuals and flip charts					
		Dissemination through TV, radio, print, website, community engagement (district authorities, MDTFs and IPC networks) and a hotline					
International collaboration, harmonization and decentralization	Participate in the ECOWAS and African Medicines Harmonization initiatives	Undertake a study tour at advanced NMRAs and lead auditors training	Study tour and training report available	Ticket, training cost, Accommodation, Per-diem	16,000	Q2 2022	LMHRA, WAHO PATNERS
		Attend ECOWAS heads of NMRAs meetings	Meeting reports available	Ticket, Accommodation, Per-diem	50,000	Q3 2021 T0 Q4 2025	LMHRA, WAHO PATNERS
	Participate in international conferences and exchanges on medicines and related products regulation	Attend International Conference of Drug Regulatory Authorities and International Federation of Pharmacists	Conference reports available	Ticket, Accommodation, Per-diem	50,000	Q3 2019 T0 Q4 2023	LMHRA, WAHO PATNERS WHO
		Attend AU NEPAD regional regulatory meetings	Meeting reports available	Ticket, Accommodation, Per-diem	50,000	Q3 2019 T0 Q4 2023	LMHRA, WAHO PATNERS AU, WB

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
		Attend World Health Assembly and other WHO facilitated meetings	Meeting reports available	Ticket, Accommodation, Per-diem	50,000	Q3 2019 T0 Q4 2023	LMHRA, PATNERS WHO
	Decentralize activities of the LMHRA	Open and furnish LMHRA offices in 4 regions	Regional offices operational	Office Accommodation Furniture Computers/ stationery	100,000	Q1 2022 to Q3 2023	LMHRA
		Recruit/ Post staff to these offices and provide accommodation	Number of Officers recruited and at post	Staff Accommodation	50,000	Q1 2022 to Q3 2023	LMHRA
		Provide cross country vehicle for the regional offices	Number of vehicles procured	Vehicles	180,000	Q1 2022 to Q3 2023	LMHRA
Develop and maintain adequate human resource capacity	Perform human resource needs assessment and develop a human resource plan	Recruit consultant to perform needs assessment and develop HR plan	Needs assessment report HR Plan developed	Facilitator/ consultant TWG	40,000	Q1 2022	LMHRA Partners
		Organize stakeholder meetings to validate plan	Validated HR plan available	Meeting logistics	5,000	Q1 2022	LMHRA Partners
	Develop staff scheme and conditions of service	• Recruit consultant to develop staff scheme and conditions of service	Scheme of Service document Conditions of service	Consultant TWG	25,000	Q2 2022	LMHRA Partners
		• Develop job descriptions for all staff	JD Document	Consultant TWG	25,000	Q2 2022	LMHRA Partners
		• Organize stakeholder meetings to validate the drafts and finalize	Validated SS, CS and JD	Consultant TWG	15,000	Q2 2022	LMHRA Partners
	Identify training needs and develop training plan	Review current staff and match qualifications with position	Staff review report	Consultant TWG	20,000	Q2 2022	LMHRA Partners
		Recommend specific training for specific staff	Individual training need identified	Consultant TWG	10,000	Q2 2022	LMHRA Partners
		Develop short-, medium- and long-term training plan	Training plan available	Consultant TWG	20,000	Q2 2022	LMHRA Partners

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
Mobilize infrastructural, monitoring and financial resources to ensure sustainability	Build and furnish a national Headquarters of LMHRA in Monrovia	Acquire land for the building of LMHRA headquarters	Land acquired and registered	Meetings Procurement process	250,000.00	Q4 2021	LMHRA, GOL, Partners
		Produce an architectural design of the LMHRA office Complex	Architectural drawings available	Consultant Meetings	50,000.00	Q4 2021	LMHRA, GOL, Partners
		Recruit a consultant for the building project	Consultant recruited	Consultant Meetings	75,000.00	Q2 2022	LMHRA, GOL, Partners
		Construct the LMHRA office complex	Office complex	Contractor	1,700,000	2023	LMHRA, GOL, Partners
		Procure and install needed office furniture and IT resources	Office complex fully furnished	Contractors Procurement Process	2,000,000	2023	LMHRA, GOL, Partners
		Organize official ceremony to open the LMHRA headquarters	Official opening held	Publicity Meetings	15,000	2023	LMHRA, GOL, Partners
	Provide and maintain adequate logistics and infrastructure	Procure the necessary office infrastructure for current office	Office infrastructure identified and procured	Procurement process	180,000	Q3 2021 – Q3 2022	LMHRA Partners
		Acquire necessary operational vehicles	Vehicles available	Procurement process	300,000	Q3 2021 – Q3 2022	LMHRA Partners
		Undertake Planned Preventive maintenance of equipment, vehicles and other infrastructure	Maintenance schedules and reports	Maintenance contracts Procurement of spares	350,000	Q3 2021 to Q4 2025	LMHRA
		Procure server, computers and other hardware, appropriate software and accessories	IT infrastructure provided	Procurement process installation	200,000	Q1 2022	LMHRA Partners
	Ensure that there is a results-based monitoring and	Develop M&E plan	M&E plan available	TA, TWG, logistics	50,000	Q4 2021	LMHRA
		Conduct regular monitoring and evaluation	M&E conducted, Reports available	Logistics for Board and staff	50,000	Q3 2021 to Q4 2025	LMHRA Partners

STRATEGIC GOAL	STRATEGIC OBJECTIVES	ACTIVITIES	KEY PERFORMANCE INDICATOR(S)	INPUTS	BUDGET ($)	TIMELINES	RESPON-SIBILITY
	evaluation system	Write and disseminate M & E reports	Reports available and published	computers and database	15,000	Q3 2021	LMHRA
	Ensure sustainable financing of regulatory activities	Review existing fee schedule	Revised fee schedule	Meetings Logistics	5,000	Q3 2021	LMHRA
		Advocate for specific tariff on imported medicines and heath products to support LMHRA activities	Tariffs approved and imposed	Advocacy Meetings Logistics Study tour	55,000	Q4 2021 to Q4 2022	LMHRA Partners Legislature
		Seek external funding from partners for specific projects	Funding received	Marketing of strategic plan Meetings	25,000	Q3 2021	LMHRA Partners

This Strategic Plan is Submitted for Approval to the Board of Directors on this 20th Day of April A. D. 2023 by the Managing Director of the Authority.

Managing Director / LMHRA

This Strategic Plan is approved by the Board of Directors on this 20th Day of April A. D. 2023.

Chairman / Board of Directors