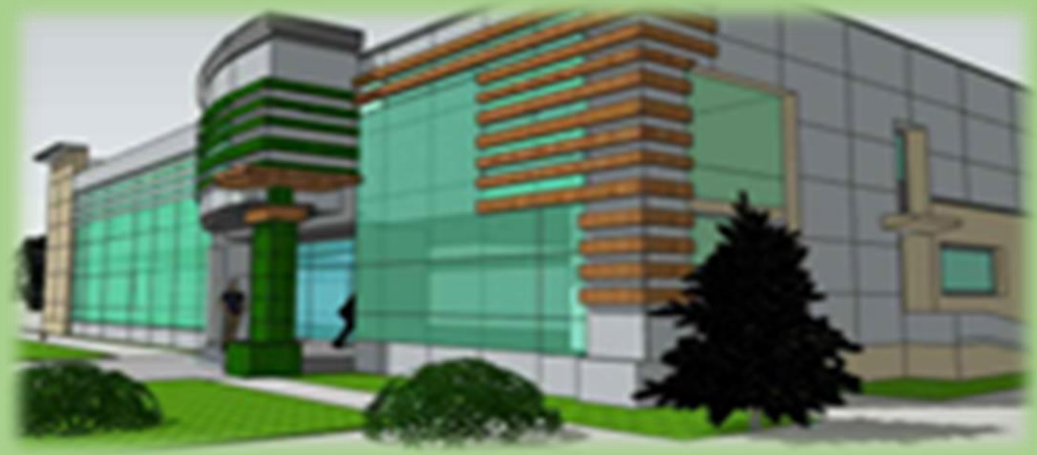
Liberia Medicines & Health Products Regulatory Authority [LMHRA]

BIENNIAL REPORT 2020 - 2021



"Ensuring a Strengthened and Efficient Regulatory Body to Protect against SF Medical Products"

NOVEMBER 2021

STRATEGIC GOALS

- Establish an effective and efficient medicines and related products regulatory system
- Strengthen the 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

MANAGEMENT TEAM

Pharm. Keturah C. Smith
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Managing Director

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LMHRA
REPORT TO: 5054 // or to www.lmhra.gov.lr
PLEASE REPORT ALL RE-STAMPED PRODUCTS TO THE LMHRA; SPEAK UP FOR SAFE, QUALITY MEDICINES NOW.
A MESSAGE FROM: LMHRA


LMHRA
DO NOT BUY MEDICINES THAT DON'T HAVE MANUFACTURING DATE, ADDRESS AND EXPIRATION DATE.
A MESSAGE FROM LMHRA
Report To: 5054
or to www.lmhra.gov.lr


LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
MEDICINES OR HEALTH PRODUCTS SOLD IN BUCKETS, BAGS OR ON MARKET TABLES
Are Not Safe Due to Exposure to Sunlight, Heat or Moisture
Can not be traced in case of Adverse Reactions or Side Effects
Are either Expired, Falsified (Counterfeited) or Substandard
Pharmacy
Bucket
0888 140 555 | 0777 140 555


LMHRA
CHARGED WITH THE RESPONSIBILITY OF PROTECTING THE LIBERIAN POPULACE FROM FAKE, EXPIRED AND SUBSTANDARD MEDICINES AND HEALTH PRODUCTS
MEDICINES OR HEALTH PRODUCTS SOLD IN BUCKETS, BAGS, OR ON MARKET TABLES ARE
NOT SAFE
DUE TO EXPOSURE TO SUNLIGHT, HEAT OR MOISTURE
Your Health is in your hands!
0888 140 555 | 0777 140 555


LMHRA
THE LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY(LMHRA)
IS RESPONSIBLE FOR THE QUALITY, SAFETY
AND EFFICACY OF ALL MEDICINES AND HEALTH PRODUCTS IN LIBERIA
Report To: 5054 | or to www.lmhra.gov.lr

H.E. Dr. George Manneh Weah
President of the Republic of Liberia

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ACRONYMS AND KEY DEFINITIONS

AfT	Agenda for Transformation
ADR	Adverse Drug Reaction
CHAL	Christian Health Association of Liberia
CMS	Central Medical Stores
CT	Clinical Trials
CTA	Clinical Trials Authorization
CTD	Common Technical Documents
CTO	Clinical Trials Oversight
CTU	Clinical Trials Unit
DEA	Drug Enforcement Agency
ECOWAS	Economic Community of West African States
EUA	Emergency Use Authorization
FDA	Food & Drugs Authority
FLB	Forward Logistics Base
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GF	Global Fund
GOL	Government of Liberia
GSA	General Services Agency
HPLC	High Performance Chromatography
ICT	Information Communication Technology
IEC	Information, Education and Communication
IPAT	Indicator-based Pharmacovigilance Assessment Tool
ISO	International Standard Organization
LHEF	Liberia Health Equity Fund
LMHRA	Liberia Medicines and Health Products Regulatory Authority
LRA	Liberia Revenue Authority
PAPD	Pro-Poor Agenda for Prosperity & Development
PESTEL	Political, Economic, Social, Technical, Environmental, Legal
PMS	Post-Market Surveillance
PMS-TWG	Post-Market Surveillance Technical Working Group

PQM	Promoting the Quality of Medicines
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QCL	Quality Control Laboratory
QMS	Quality Management Systems
SAC	Scientific Advisory Committee
SDGs	Sustainable Development Goals
SF	Sub-standard & Falsified
SWOT	Strength, Weakness, Opportunities & Threats
MedRS	Medicines Risk-Based Tools
MNCH	Maternity & New Born Child Health
MOH	Ministry of Health
MSF	Medicins San Frontiers
NGOs	Non-Governmental Organizations
NPA	National Port Authority
NRA	National Regulatory Authority
TB	Tuberculosis
TLC	Thin-Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WAHO	West Africa Health Organization
WHO	World Health Organization

MESSAGE FROM THE MANAGING DIRECTOR

Pharm. Keturah Smith-Chineh
Managing Director

With the mandate to "protect the public from the harmful effects of substandard and Falsified (SF) medicines and health products", coupled with "ensuring that, in the national medicine supply system, only safe, effective, and good quality medicines reach the Liberian public, promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products and fair trade practices", the LMHRA remained unwavering in enforcing established guidelines and regulations to attain its goals and objectives during the period 2020 - 2021.

When I assumed the responsibilities of managing the LMHRA, with the numerous challenges, ups and downs, and financial imbalances, I thought I couldn't make it, but somehow I managed to hold on for two years. I am deeply thankful to all those who have contributed to our success over the years. Without the trust and support of the President of the Republic of Liberia, HE Dr. George M. Weah, and the Government, both for their steer, support and understanding during these crucial years, we would not have made such remarkable progress, both in managing the LMHRA and the development of the Institution. Our achievements also have been built on the invaluable counsel and assistance provided by the friends we have, both in the private and public sectors.

I would like to express my gratitude to the vast majority of employees for their forbearance and support, without which the LMHRA would not have achieved such high results, despite the harsh economic circumstances. I wish to say that I have been very fortunate to have the staunch support of very capable, professional, dedicated and enthusiastic colleagues, whose commitment and hard work have been indispensable in enabling the LMHRA to achieve its mission and to deliver the level and quality of performance clearly demonstrated since my inception as Managing Director. I must also pay tribute specially to our partners, USP/USAID under its PQM+ Program, Global Fund, the West Africa Health Organization (WAHO), the World Health Organization (WHO) and the World Bank for their tremendous support to the Authority during the period, from training of staff, both foreign and local, to provision of laboratory supplies, including chemicals, reagents, reference standards, as well as technical, material and programmatic supports.

Overall, we are very grateful to the Almighty God for giving us the courage, wisdom and fortitude for our adroit management of the Authority over the past two years.

Despite the challenges we face, the Authority continued its steady, but fast growth, from strengthening of Region 2 (Bong, Lofa & Nimba) Offices, to the opening of a Sub-office at the Roberts International Airport and Region 3 Offices in Bo Waterside, covering three counties – Grand Cape Mount, Bomi & Gbarpolu.

With the spirit of achieving growth in development, the Authority remained steadfast in its engagement with partners and major stakeholders in medicines regulation, yielding to strengthened and stronger coordination between the LMHRA and the Liberia Revenue Authority (LRA). A key result worth mentioning is the training of five (5) LMHRA staff by the LRA on the use of ASYCODA System, followed by its installation at both RIA Sub-office and LMHRA HQ (Inspectorate), to enable us monitor all pharmaceuticals passing through the Customs System of Liberia. All these positive

and tangible deliverables are the results of commitment on the part of our team and I would like to use this opportunity to commend them.

I'm delighted to state that, and for the first time, the LMHRA can boast of a temporary Quality Control Laboratory facility of its own – built with revenue generated locally, and the construction of an ultra-modern Quality Laboratory Complex has started at our King's Farm, Careysburg property after discussions and endorsement of the Blue Print by USP/USAID and the World Health Organization.

Considering the existing challenges, coupled with the current economic situation in the country, the LMHRA is unable to mitigate all challenges, but greatly depends on support from extended partners, including Global Fund, USP/USAID, WHO, WAHO, etc. We are very delighted to report that during the period under review, the Authority received numerous support from our partners to help strengthen the Authority. This report outlines the various supports we received from them.

Pharmaceutical wastes across Liberia continue to be a major health hazard, coupled with the problem they pose to product storage facilities in the counties. The LMHRA continues to advocate with key partners and stakeholders for the proper disposal of these pharmaceutical wastes. Initial measures taken have been outlined in latter part of this report.

Despite efforts across the world to computerize medicines registration, the LMHRA still uses limited tools or manual processes. Seeing the need for an electronic tool for the entire regulatory processes including registration, licensing, inspection, quality control, pharmacovigilance, and medicine information, the Authority has started the development of a database and online tool. The tool is being built in modules where the respective databases are owned and updated by each unit that handles the function and then shares data across the entire regulatory authority and consumers; this will ensure efficient regulatory processes and functions. This tool will also enable our many clients to register their products online.

Since our incumbency, there has been tremendous improvement for the Authority in its operations. The performance of the LMHRA in respect of its regulatory functions of product registration, premise registration and licensing, market surveillance, import control, product testing and safety monitoring increased. However, the Authority is yet to begin full compendia testing of products at the temporary Quality Control Laboratory, coupled with other logistical challenges. This notwithstanding, there are still gains to be made regarding process indicators such as the percentage of product applications processed, percentage of license inspections conducted, and percentage of submitted products tested through mini-lab and visual inspection. Our gains still appear to be locked up by resource constraints: human resource (inadequate pharmacists and lab technicians), vehicles, computers, application software and laboratory consumables and materials, which are quite expensive. Addressing these will enhance the Authority's performance in the respective areas. This will ensure that issues that limited performance since our incumbency will be addressed to enhance performance within the next four years: 2022 - 2025.

Looking ahead, we look forward to working with stakeholders within the pharmaceutical sector, our partners and clients. Our focus continues to be on our public health role. We will continue to work to the highest levels of excellence and quality, working with and supporting our customers, partners and stakeholders to protect health and improve lives. Working closely with Government, we will consider the implications for the work of the Authority moving forward and to secure positive outcomes. Despite continued challenges and the ever changing and evolving environment in which

we operate, there are many exciting opportunities ahead of us, including the support we receive from the GOL and our partners. I am confident we will meet these challenges and we will be one of the leading regulatory Authorities for medicines and health products in the Region and Africa at large. And for me, it continues to be a massive privilege to be the Authority's Managing Director.

LMHRA'S TOP MANAGEMENT

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BSc., B.Pharm., RPh., MPCPharm
Managing Director

Dr. Flomoku G. Miller
Technical Advisor to the Managing Director

Pharm. Teedoh E. Beyslow
Director & Inspector General
Dept. of Inspectorate & Post-Marketing Surveillance

Dr. James D. K. Goteh
Director
Dept. of Pharmacovigilance & Clinical Trials

Pharm. Patricia Quaye-Freeman
Director
Dept. of Evaluation & Registration

Pharm. Akoi Fahnbulleh
Director
Quality Control Laboratory

Rev. Richard Redd
Director, Human Resources

Mrs. Antoinette N. Mulbah
General Administrator

Steve N. Bundor
Comptroller

Mrs. Hawa T. Tambah
Manager, Procurement

Who We Are

The Liberian Medicines and Health Product Regulatory Authority (LMHRA) was established in 2010 by an act of the National Legislature to protect the public from unsafe, falsified, and substandard medicines. In addition to assuring the quality of medicines, it is also mandated to 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 timely disseminate drug information.

What We Do

We are responsible for regulating a wide range of medicines and health products available in Liberia:

- *Medicines (traditional medicines, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals)*
- *Health Products (Medical devices and Medical Supply) for human use*
- *Cosmetics*
- *Medical or Diagnostics Equipment*

Other areas include clinical trials using human medicines, clinical field trials using veterinary medicines and clinical investigations using medical devices for human use. We regulate manufacturing, wholesale and distribution companies, as well as other health product facilities.

How we regulate

We grant licenses to companies/institutions to make, distribute and market medicines after a review of their safety, quality and effectiveness through the Quality Control Laboratory. We continuously monitor medicines, medical devices and other health products, responding quickly to any safety or quality concerns and produce safety and quality information to support the safe use of health products by conducting post-market surveillance. The Pharmacovigilance Department trains health workers, collects reports of adverse drug reaction (ADR), collates and analyses them and provides feedback for regulatory decisions when applicable. The reports are also uploaded onto the WHO collaborating Center database (VigiBase) at Uppsala in Sweden.

Through our Inspectorate Department, we conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold to ensure that they comply with relevant standards and legislation. We enforce the legislation (as a shared responsibility with other state agencies in some areas) by confiscating expired, substandard, counterfeit, or unregistered medicines in accordance with regulations promulgated by the Authority, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law; and as and when deemed necessary by the Authority, suspend, cancel, or revoke such license or permits in accordance with regulations promulgated by the Authority and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law.

EXECUTIVE SUMMARY

Consolidated Analysis of Registered Medicines

Prior to the approval of the Authority's consolidated budget of fiscal year 2020/2021 nine hundred seventy-seven (977) products were already registered with the Authority at the end of July 2020. With a total of eight hundred ninety (890) medicinal products registered between 2020 and 2021, the cumulative total of medicinal products registered with the Authority presently is **one thousand eight hundred sixty-seven (1,867).**

Premise Licensing

A total of 96 premises were registered during the period under review (2020 – 2021), 70 being old premises with 26 new premises. A total of 53 institutions registered for importer licenses; 32 old and 21 new.

Post-Market Surveillance

A total of 28 market surveillance operations were carried out across the country during the period under review: 2020 – 2021. Number of outlets that were visited increased by 55%, as compared to previous years. A total of **9** non-compliant products were identified in trade and recalled from the market.

Product Testing

The laboratory received 5,971 products in 2020 to 2021; with 1.6% (96) samples failing.

Adverse Drug Reaction Monitoring

The LMHRA conducted over ten (10) ADR monitoring visits to seven (7) counties, including Montserrado, Bomi, Grand Cape Mount, Gbarpolu, Margibi, Nimba and Bong Counties.

Clinical Trial Authorization

The Clinical Trials Unit conducted one Good Clinical Practice (GCP) inspection, two close-out visits to approve the closure of two clinical trials and issued waivers for the Emergency Use Authorization (EUA) for the AstraZeneca and J&J vaccines for COVID 19.

Import Control

During the year 2020, the Authority issued Ninety-seven (97) Port Clearances to twenty-one (21) importers of pharmaceuticals comprising of medical devices, medicines and health products; while in 2021 one hundred fifty-one (151) Port Clearances to twenty-eight (28) importers of pharmaceuticals comprising of medical devices, medicines and health products were issued. This represents a 64% increment compared to the previous year.

Institutional Development & Sustainability

As part of institutional growth, the Authority completed the construction of a temporary Quality Control Laboratory and relocated, in October 2020, the QC Lab from a rented facility. The construction of an ultra-modern Quality Control Laboratory has started – supported by internal revenue collection and GOL's initial contribution.

To boost the fight against SF medicines, the sub-office in Region 2 (covering Bong, Nimba & Lofa Counties) was re-opened and strengthened, with additional staff and logistics (a motorbike and vehicle). Additionally, a new sub-office was opened at the Roberts International Airport, with **13** staff assigned; Region 3, (covering Grand Cape Mount, Bomi & Gbarpolu Counties) was also opened with 5 staff, two motorbikes and other logistics. Region 2 (Bong, Nimba & Lofa) has 3 staff.

A two-acre land was purchased in Lower Margibi County to be used exclusively for waste management and disposal.

Support on COVID 19 Pandemic

As it is known that the LMHRA plays a pivotal role in ensuring the safety, efficacy and quality of medicines, including vaccines in Liberia, working with the health system to support the Country's response to the global pandemic has remained a commitment and has been proven by the timely provision of regulatory oversight to issues regarding donations brought in through the Roberts International Airport (RIA). Our team at the RIA and central management remained alert in their reportage and issuance of timely regulatory actions with both public and private pharmaceutical sector consignments relative to COVID 19.

LMHRA, through its Pharmacovigilance & Clinical Trials Department, deployed a team of monitors to follow up at facilities within Montserrado County and its environs, as well as Margibi, Bong, Nimba, Bomi & Grand Cape Mount Counties to ensure proper documentation of any unpleasant effects or ADRs during the COVID-19 vaccination process. Over 25 healthcare facilities were visited, including, John F. Kennedy Medical Center on 20th Street, Sinkor; ELWA Hospital in Paynesville; 14 Military Hospital, Margibi; SOS Hospital; Duport Road Health Center; St. Joseph Catholic Hospital; Redemption Hospital, and the James N. Davies, Jr. Memorial Hospital in Neezoe, Paynesville.

The key objectives of the monitoring outreach were to: i) follow-up on the assessment of benefit, effectiveness, unpleasant effects and risk of the vaccine candidates (AstraZeneca ChAdOx1 nCoV-19 (AZD1222) and J&J Ad26.COV2.S Vaccines) currently being used in Liberia; and ii) to improve patient care and safety in relation to the use of the vaccines and other medical or health products. Details are outlined in latter part of this report under Pharmacovigilance.

Improving Public Engagement

Engagements with the public is yielding an improved and diversified dimension with the collaboration of the communications and ICT Units in many ways, aimed at ensuring increase in dissemination of information of regulatory activities across the length and breadth of the country, as well as the world at large. Some of the activities that were implemented during this period are as follows:

- On two occasions, the Managing Director led an array of independent media practitioners on a guided tour of the mini Quality Control Lab (QCL) facility, the proposed State-of the-Art Quality Control Laboratory and the incineration site. The tour was meant to provide more understanding of the kind of work the LMHRA Quality Control Laboratory does in collaboration with support from the LMHRA management, the government and partners.

- Erection of 8'x5' billboards in Monrovia, Paynesville, Gbarnga, Bong County; Bo Water in Grand Cape Mount and Ganta, Nimba County.

- Two separate jingles were developed and aired on Adverse Drug Reaction (ADR), the Use of substandard and falsified (SF) medicines and health products, as well as drug peddling on local radio stations and social media networks for a period of one month each.

- These jingles have been translated into local vernaculars in aired at the Regional Offices (covering six counties).

- Four (4) major community outreach activities were carried out, mainly targeting street peddling and combating of SF medicines.

1.0 INTRODUCTION

Motto

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

Vision

The LMHRA envisions to be "A Leading Medicines and Related Products Regulatory Authority of excellence in Africa".

Mission Statement

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.

LMHRA's 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.

Strategic Goals (2021 – 2025)

- 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

Background

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:

- Conduct registration of medicines and health products;
- 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;
- 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;
- Establish an inspectorate and conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold;
- 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;
- Establish and operate quality control laboratories to ensure safe, effective, and good quality medicines and health products for domestic and foreign markets;
- Conduct post-marketing surveillance of medicines and health products;
- Conduct Pharmacovigilance of medicines and health products;
- 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;
- Regulate the conduct of clinical studies of medicines and health products;
- Prepare, keep, and update a registry of medicines and health products registered and approved for marketing in the Republic of Liberia;
- Set standards of quality, safety, and efficacy of medicines and health products;
- Promulgate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act;
- Develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority;
- Provide current and unbiased information on medicines and health products to health care professionals and the general public;
- Regulate advertising and promotion of medicines and health products;
- Be responsible for its human resources development;
- Promote, monitor, and evaluate the implementation of this Act;

- 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;
- Establish and collect charges or fees for services rendered by the Authority; and
- 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.

Health in the Pro-Poor Agenda for Prosperity & Development (PAPD)

LMHRA's objectives and goals are aligned with the Government of Liberia's Vision to "Build more capable and trusted state institutions that will lead to a stable, resilient, and inclusive nation. The Government of Liberia's strategic priority areas are also aligned to Africa Agenda 2063, and the Economic Community of West African States' Vision. 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).

The PAPD outlined a new development strategy for the Government of Liberia (GOL). The PAPD seeks to expand access to essential health services and, in doing so, to promote a healthy and thriving citizenry and economic productivity. It outlines eight strategic targets aimed at reducing maternal mortality, under five Mortality, under five malnutrition, malaria prevalence, lack of access to healthcare for rural population living beyond five kilometer radius to the nearest health facilities, the number of outbreaks responded to more than 48 hours following notification, the number of public health facilities reporting stock-out of essential medicines, and out of pocket payment for health care.

The PAPD highlights critical challenges in the health sector and the shortcomings of the free health care policy. It identifies strategic health priority interventions including improvement of health service delivery and infrastructure, achievement of efficiency and sustainable financing for health by strengthening existing financial management systems and offering an alternative strategy focused on the Liberia Health Equity Fund (LHEF). Additionally, it highlights delivery of the Essential Package of Health Services and strengthening of partnerships in health care delivery.

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 LMHRA remains key to the achievement of the above-mentioned objectives and goals of the PAPD. A well-functioning health care system depends upon the availability and affordability of

medical products that are safe, effective and of consistently assured quality. Effective medicines regulation promotes and protects public health by ensuring that: medicines are of the required quality, safety and efficacy; medicines are appropriately manufactured, stored, distributed and dispensed; illegal manufacturing and trade are detected and adequately sanctioned; health professionals and patients have the necessary information to enable them to use medicines rationally; promotion and advertising is fair, balanced and aimed at rational drug use.

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 is 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.

Sustainable Development Goals (SDGs)

People who work in health care expect the products they use to work as described on the box – in fact, to actually be what is described on the box. The fundamental issue is trust: just as patients need to be able to trust in the expertise of health care providers, health workers need to be able to trust the products they prescribe actually to do what they are meant to do: prevent illness or improve people's health.

Sustainable development goal 3 demands "access to safe, effective, quality and affordable essential medicines and vaccines for all." Experience teaches that this is impossible without robust, well-designed regulatory and procurement systems. Thus, support to the LMHRA aligns directly with SDG Goal 3.

2.0 MANAGEMENT & STRUCTURE OF THE LMHRA

The Authority is governed by the following structure:

- A Board of Directors
- A Managing Director, who shall be responsible for running the Authority;
- Directors heading different departments of the Authority, supported by Managers, heading different Units; and
- A Managing Committee composed of the Directors, with the Managing Director as its head.

Board of Directors

The Board of Directors comprises of eleven (11) voting members, appointed by the President of the Republic of Liberia, consisting of the following members:

- A qualified Liberian Pharmacist, who shall be appointed by the President of the Republic of Liberia to chair the Board of directors;
- The Chief Pharmacist, representing the Ministry of Health and Social Welfare;
- The head of the Pharmacy Board;
- A lawyer representing the Ministry of Justice;
- The head of Customs, representing the Ministry of Finance;
- The head of the National Bureau of Standards, representing the Ministry of Commerce;
- A representative of the School of Pharmacy of the University of Liberia:
- A representative of the Liberia Medical and Dental Council;
- A representative of the Pharmaceutical Association of Liberia
- A veterinarian from the Ministry of Agriculture;
- A representative of an appropriate consumer interest group or association; and
- The Managing Director of the Authority, who serves as secretary to the Board of Directors, and a non-voting member.

The Board Chair is appointed by the President of Liberia to serve for a period of two (2) years.

3.0 REGULATIONS STRENGTHENING

A strong medicines regulatory system is an essential component of the health system that helps protect populations by ensuring that medicines and other medical products are not only safe and effective but also of assured quality. Poor-quality medicines—those that are unregistered, substandard, or falsified—can endanger patients, extend illness unnecessarily, and even result in death. Poor-quality medicines also undermine efforts to improve health and strengthen health systems, erode public confidence in those same systems, and may contribute to antimicrobial resistance. Availability of and access to essential medicines underpins progress against diseases; however, it is only when these medicines are produced, distributed, and sold in a manner that ensures their quality that they can bring about positive outcomes for patients and public health, thus it is essential for strong guidelines and regulations to be in place for the products to be properly regulated, because it is critical to continue improving access to safe and effective medicines and medical products.

The lack of regulations to support the LMHRA Act of 2010 has been one of the major challenges to improving governance of medical product quality assurance in Liberia. It is against this backdrop that the Authority organized a retreat to draft Guidelines and Regulations to enable the strengthening of regulatory functions. Partnering with LMHRA, PQM+ facilitated the development of a list of priority regulations that support implementation of the LMHRA Act of 2010. PQM+ also supported the mapping of required legislation and sponsored a trip for senior staff of LMHRA to travel to the Ghana FDA on a study visit. Following the study visit, the LMHRA organized a special committee for drafting the regulations. The following Regulations were drafted and submitted to the Board for review and subsequent approval:

1. Regulations for the Treatment and Disposal of Unfit Medicines & Health Products
2. Regulations for Medicines & Health Products Recall, Withdrawal & Seizure
3. Regulations for Donation of Medicines & Health Products
4. Regulations for the Registration of Medicines & Health Products
5. Regulations for Labelling of Medicines & Health Products
6. Regulations on Importation & Exportation of Medicines & Health Products
7. Regulations on Advertisement of Medicines & Health Products
8. Regulations on Clinical Trials

Prior to drafting the above Regulations, at the end of the LMHRA Retreat in 2020, the following Guidelines to support regulatory strengthening were drafted and also submitted to the Board:

1. Guidelines on Registration of Medicines and Health Products
2. Guidelines on Post-Market Surveillance
3. Guidelines on Clinical Trial
4. Guidelines on Pharmaceutical Waste Management
5. Guidelines on Premise Licensing and Registration

All these Guidelines and Regulations, when approved by the Board, will enable the smooth regulation of medicines and health products across the country, including but not limited to importers, wholesalers and local manufacturers. By the end of the year 2021, it is expected that the Regulation on Pharmacovigilance will be completed and also submitted to the Board. This Regulation will help guide the monitoring of adverse effects of medicines and inform decisions made by healthcare practitioners (nurses, doctors, physician assistants, pharmacists, etc.).

4.0 2020 – 2021 OPERATIONAL PERFORMANCE

4.1 Administrative Performance & Achievements

4.1.1 Human Resource Administration

During the period under review, the Authority's human resource strength grew from **108** staff in 2019 to a workforce of 179 persons, including 27 Pharmacists, six (6) contractors and consultants, both at Head Office, the sub-offices and regional offices. As onboarding of new staff requires capacity building, several trainings, both local and foreign, online and in-person, were held to strengthen the human resource capacity. Trainings ranged from technical to administrative.

Improved staff welfare:

Considering the importance placed on staff welfare and development, the below key activities were implemented:

1. *Acquisition of 32-seater bus for staff transport (to and fro) at HQ level, and a 18-seater bus for the staff assigned at the Quality Control Laboratory in Careysburg, Montserrado County.*
2. *Provision of Medical Coverage for staff and dependents*
3. *Enhanced work-life balance for staff through social activities and other engagements to improve staff performance and productivity*
4. *Introduction of staff evaluation and appraisal to get staff feedback for improved management system.*

Implementation of new organogram

Based on SWOT and PESTEL analysis of the LMHRA, a new Organogram has been developed along with the 5-year strategic and operational plan and submitted to the Board of Directors for approval. Upon the Board's endorsement, it will be implemented during FY2022. Communication has been sent to the Director of the Civil Service Agency (CSA) for the Authority's human resource needs.

Recruitment of Additional Staff

To support the expansion scope of its regulatory activities, especially with the construction of the Quality Control Laboratory for start of full compendia testing of medicines and health products, the Authority will recruit additional staff, especially technical, as well as support staff (both operational & administrative).

Staff Remuneration

Thanks to the Government of Liberia, who has taken over about 98% of the Authority's staff remuneration, compared to about 60% previously paid by GOL before up to 2019 before we took over the management of the Authority, payment of LMHRA's salaries remained current during the period under review. However, it is worth noting that despite the Authority being a technical area (under the Health Sector) LMHRA staff are amongst the least paid in the country, compared to other GOL entities. There is a need to augment staff salaries for retention of staff, especially in the technical areas.

4.1.2 Information & Communications Technology (ICT)

As technology is key to efficient office and institutional operations, Management continued to place more emphasis on improving its IT operations, with few topologies on the Network Infrastructure revised, with improvement in Help-Desk Support, Printer Servicing & Maintenance, Desktop Support Services & Maintenance, Upgrade of Server and development of Database to support product registration and other technical departments, the following achievements were made:

- There was also an introduction and installation of a state of the art firewall, Cisco Meraki MX68. The Cisco device provides externally and internally secured connectivity against potential threats such as ransomware or malware. There is accurate accountability of data usage through monitoring and regulation. Data collection, storage and retrieval of the LMHRA data is now conducted with and under the supervision of the LMHRA ICTU.

- Predicated upon the prevailing health situation worldwide, which has promulgated the stay home or cut down of staffs within every sector, our ICT Unit has enabled staff to have remote access to the server from their homes. In order to meet international standards for large data handling and management, the Authority's corporate server will be migrated to a cloud base platform. This, when completed, will enable our employees to have access to data and platforms at anytime and anywhere, thus creating an exciting working environment for employees.

- A new LMHRA website was developed, with improved features, including publication of all registered medicines and health products in the country. The Website, email server, and DataBase are hosted via a cpanel platform, also including social media platforms such as YouTube, Facebook, and LinkedIn. The Website is directly managed by the Authority's ICTU instead of an outsourced third party firm as was previously done.

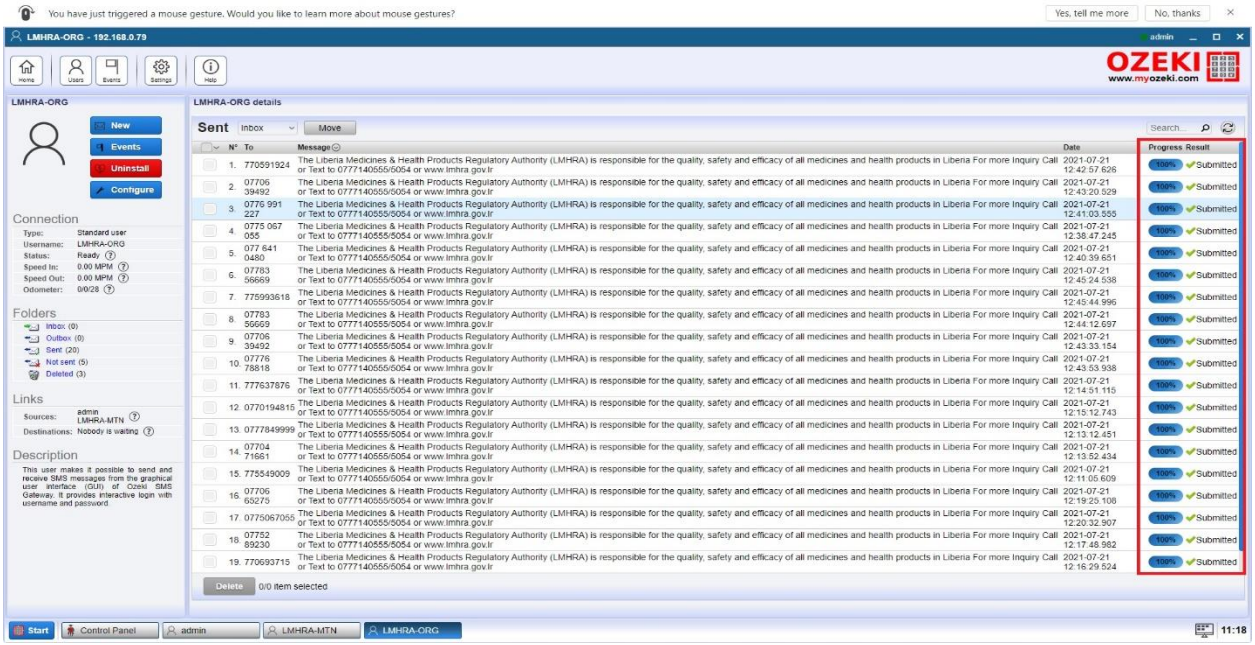
- Corporate emails have been created for top and middle management staff within the cpanel using the official domain: lmhra.gov.lr.

- The ICT Unit also deployed the following IT infrastructure to enhance operational effectiveness and efficiency:

    - *LAN/WAN (VPN) connection with dedicated VPN between the LMHRA HQ in Mamba to the LMHRA Quality Control Laboratory in Careysburg, Lower Montserrado County;*
    - *Installation of CISCO MX64 Firewall and Licenses;*
    - *NAS (Network Storage Attached) for centralized storage of data across all departments and units within the Authority;*
    - *Development of a technical database to enable efficient product registration and post-marketing surveillance;*
    - *Installation of Fiber Dual Mode Interconnection (provided by Orange Liberia);*
    - *Provision of power bank backups systems; and*
    - *Installation of HP ProLiant Secondary AD DC Server.*

Bulk SMS Rollout

As part of our efforts to reach out to the public, a bulk SMS scheme was introduced with Orange Liberia and MTN, upon obtaining of the short-code (5054) through the A2P system integration as was mandated by Orange Liberia and Liberia Telecommunications Authority (LTA).



A total of 250,000 persons were targeted, age range between 18 - 65, with monthly SMS rollout of 41,000 for a period of six months. Targeted locations included 70% in Monrovia, while 30% outside Monrovia, including rural Liberia.

Bulk Messages sent out included the following: *The Liberia Medicines & Health Products Regulatory Authority (LMHRA) is responsible for the quality, safety and efficacy of all medicines and health products in Liberia; Buying Medicines From Buckets And Market Tables Is Dangerous To your Health; Please register all medicines and health products; Buying medicines that have changed color or the powder have caked in the bottle is dangerous to your health; Medicines Are Not Medicines Unless They Work; Please report all re-stamped products to the LMHRA; Speak Up For Safe, Quality Medicines now; Do not buy medicines that don't have manufacturing date, address and expiration date; Let's Demand Medicines We Can Trust. Please report all side effects of medicines to the LMHRA; Do not buy Medicines from those selling in back-bags, buckets or on market tables.*

All these short messages were ended with: A message from LMHRA, For more Inquiry Call or Text to 5054 or www.lmhra.gov.lr

All the above were achieved with an ICT Unit of three (3) persons. In the coming year, we will strengthen our ICT Unit through acquisition of more state-of-the-act ICT infrastructure and software, as well as increase our ICT personnel to enable the following:

- *Complete migration to Microsoft Cloud (Azure Platform)*
- *Deploy of the Quality Control Lab Files, Print and DHCP Server*
- *Deploy POE, GB and Managed Network Switch*
- *Deploy high-end performance Access Point, to reduce timing out during work.*

- *Considering that routers and switches are the building blocks for all business communications, from data to voice, video and wireless access, we will deploy Cisco Routers across our network to increase our productivity, cut business costs and improve security and customer service.*
- *Install intercoms systems and expand our power backup to enable after work backup and maintenance.*

4.1.3 Communications & Public Outreach

Engagements with the public is yielding an improved and diversified dimension with the collaboration of the Communications and ICT Units in many ways, aimed at ensuring increase in dissemination of information of regulatory activities across the length and breadth of the country, as well as the world at large. Some of the activities that were implemented during this period are as follows:

- On two occasions, the Managing Director led an array of independent media practitioners on a guided tour of the mini–Quality Control Lab (QCL) facility, the proposed State-of the-Art Quality Control Laboratory and the incineration site. The tour was meant to provide more understanding of the kind of work the LMHRA Quality Control Laboratory does in collaboration with support from the LMHRA management, the government and partners.

- Erection of 8'x5' billboards in Monrovia, Paynesville, Gbarnga, Bong County; Bo Water in Grand Cape Mount and Ganta, Nimba County.

- Five separate jingles were developed and aired on Adverse Drug Reaction (ADR), the Use of substandard and falsified (SF) medicines and health products, as well as drug peddling on local media radio stations and social media, for a period of one month each.

- These jingles have been translated into local vernaculars and aired at the Regional Offices (covering six counties, as well as Montserrado & parts of Margibi). Vernaculars include: Mandingo, Kpelle, Bassa, Vai, Gola, Gio, Lorma.

- Four (4) major community outreach activities were carried out, mainly targeting street peddling and combating of SF medicines.

Working closely with local authorities and professional organizations to deliver information and design educational programs to create awareness and fight against falsified medical products and their potential damage to patients' health, the LMHRA, during the period under review, increased proactive measures aimed at eradicating illegal drug peddling and abuse within communities.

As part of the Authority's efforts, the following activities were implemented:

- A total of four (4) community engagements were conducted between 2020 and 2021, with the following objectives:
    - *Discourage drug peddling*
    - *Advice against the purchase of unregistered medicines (usage of expired, substandard and falsified medicines and health products) amongst the public*
    - *Encourage the public to purchase medicines and health products from registered pharmaceutical outlets*

The campaigns were carried out via radio talk shows, production and airing of jingles, distribution of flyers, stickers, T-shirts and live drama performances by some of Liberia best comedians. During the campaigns the LMHRA teams also carried out community outreach awareness in populated areas to adequately educate the public with respect to the supra-mentioned theme in Montserrado, Bong, Margibi and Nimba Counties via live drama and interactive discussions with the public.

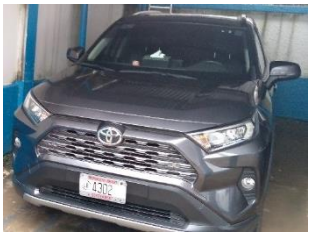
4.1.4 General Administration

Administratively, the Authority achieved tremendously, from relocation to a bigger office building in Mamba Point, paid for by the Government of Liberia, to the acquisition of additional vehicles, motorbikes, office equipment and supplies, to a well-structured office, networked with centralized storage capabilities and Internet connectivity.

Logistics & Maintenance

To support its operational effectiveness, the Authority increased its fleet from only 2 vehicles and 2 motorbikes to a fleet of eight (8) vehicles, four directly procured by the Authority and two donated by Global Fund; seven (7) motorbikes, six (6) directly procured by the Authority.

18-seater Toyota Hiace Bus to support the Quality Control Laboratory in Careysburg



Toyota RAV4 procured for Managing Director

32-seater Toyota Coaster bus to ease staff transportation to and from work at HQ

4x4 L76 Toyota Hardtop Jeeps to Support Region 2 (Bong, Nimba & Lofa Counties

4x4 L76 Toyota Hardtop Jeeps donated by Global Fund to Support Post-Marketing Surveillance

For maintenance and servicing of these vehicles and motorbikes, as well as generators, a service contract was entered into with local suppliers and vendors, after competitive bidding processes for the supply of spare parts and maintenance. With this, the Authority remained efficient operationally, though with need for additional logistics to support post-market surveillance, the Regional & Sub-Offices, as well as operations at HQ.

Procurement Services

Utilizing PPCC's guidelines and regulations on procurement of goods and services, the Authority procured equipment and other supplies for its smooth operations, including computers and accessories, vehicles, motorbikes, as well as carrying on competitive bidding processes for the construction of the temporary Quality Control Laboratory and the Ultra-Modern Quality Control Laboratory Complex.

In preparation for full conduct of full compendia testing of medicines, the Authority procured over US$100,000.00 worth of reagents and chemicals, as well as glass-wares and other Lab supplies.

For proper accountability, for the coming year, the Authority will strengthen the Procurement Unit to include additional staff and local trainings in procurement related courses.

4.1.5 Client Service Center

In order to improve customer services, especially with product registration, a Client Service Center was established within the Office of the Managing Director, staffed with one person, seconded from the Evaluation and Registration Department.

4.1.6 Decentralization

As we continue to find avenues for strengthening the LMHRA for full execution of its mandate, we have begun decentralizing our regulatory activities to the leeward counties; this has greatly improved our efforts towards post-market surveillance and monitoring of border points.

Region 2 office (Bong, Nimba & Lofa) was strengthened through the provision of a motorbike and a 4x4 Toyota Land cruiser Jeep and additional staffing. Region 2 is sharing offices with the Liberia Medical and Dentist Council (LMDC) in Gbarnga, Bong County. Based on our development plan, the Authority intends to construct its Regional Office and accommodation for staff in Gbarnga, Bong County in the coming year. It is also anticipated that one sub-office will be opened at the Ganta Border Point, with additional staffing. Please see below pictorials of the Region's staff in action:

Region 3 (covering Grand Cape Mount, Bomi and Gbarpolu), was opened, manned with five (5) staff. There are also plans for the construction of a Regional Office and accommodation at Bo Waterside the coming year, 2022. Please see pictorials below for the Region's activities:







Realizing the necessity to ensure the quality, safety, and as part of strengthening the regulations on importation of pharmaceuticals in Liberia, the LMHRA launched its second decentralization program by the opening of a sub-office at the Roberts International Airport (RIA), with a workforce of 13 staff. As part of capacity building, a one-day training was held for all RIA staff on SOPs for conducting regulatory affairs at the Roberts International Airport, covering the following topics:

- *SOP for review of documentation*
- *SOP for Confiscation or Quarantine of all Pharmaceuticals and Health Products*
- *SOP for the inspection of Cargo*
- *SOP for the release of Pharmaceuticals and Health Products*
- *Checklist for document review*

The LMHRA Offices at the Roberts International Airport is housed in the Customs building.



During the inception period of its opening, March – September 2020, the RIA Sub-Office detected 921 cartons, 1 pallet, 10,240 units and 2 unquantified boxes of assorted pharmaceuticals from 12

different entities. Seventy-five percent (75%) of these assorted pharmaceutical products were brought through the RIA without Authorization to Import and Authorization to clear by the LMHRA.

Additionally, the sub-office intercepted 11 cartons, 15 pallets and 4 units of laboratory supplies from five entities. Of these, 67% that came through the RIA were unauthorized by the LMHRA. In the same manner 383 cartons, 4,453 units, 12 EA; 26,535 pieces and an unquantified boxes of medical devices were brought through the RIA with 69% being unauthorized. These unauthorized importations of medical devices were associated with 16 entities.

Finally, 7,451,400 tablets; 26,633 cartons and 6 pallets were also tracked down by the LMHRA from ten entities. 80% of these medicines were not authorized by the LMHRA for importation and clearance.

With the above data, opening of the Sub-Office at the Roberts International Airport was one of the greatest achievements we've made since we took over the management of the Liberia Medicines & Health Products Regulatory Authority (LMHRA). All the products that were not authorized by the Authority were brought the country illegally, thus posing a threat to the population, as regulatory requirements were not ascertained.

With the plan to construct permanent offices and accommodation for staff assigned at the RIA Sub-office, several meetings were held with Airport authority for the acquisition of land space.

Samples of some of the products monitored by the RIA Sub-Office coming through the Airport

Additionally, LMHRA was given right to viewing the ASYCODA System of Customs; five LMHRA staff, including three staff from RIA and two from LMHRA central office, were trained on the usage of the Asycoda system by the LRA, and the system was setup at both RIA Sub-office and the Inspectorate.

Expansion to the South East

Depending on the availability of resources (both financial and human), the Authority has earmarked opening of two additional regional offices covering the Southeastern Counties of Grand Gedeh, Sinoe, River Gee, Grand Kru & Maryland Counties. Considering the geographical size of these counties, it is anticipated that one office will be in Zwedru, Grand Gedeh County, to cover Grand Gedeh, Sinoe & River Gee; while another will be opened in Harper, Maryland County, covering Maryland and Grand Kru Counties. Opening offices in these two counties is predicated upon the vulnerability of the border points, especially with Maryland County, where majority of commercial goods are obtained through the international border point between Pleebo and Harper Cities; coupled with the many unmanned porous border points.

Moreover, series of meetings have been held with the Management of the National Port Authority (NPA) to enable the LMHRA open an office at the Freeport of Monrovia. This will enhance our

monitoring efforts of all pharmaceutical products coming through the seaport, as we've done with those coming through the Airport at the RIA.

4.1.7 Capital Development & Investments

4.1.7.1 Construction of Temporary Quality Control Laboratory

With LMHRA's laboratory capacity destroyed by the fire and more than 18% of antibiotics, antimalarial and other essential drug samples failing international standards the country's population of more than four million is at risk. Medicines without a manufacturing date, expiration date, or those that are falsified pose serious health problems to those who consume them and can even be fatal. Additionally, consuming poor quality medicines can result in economic hardship, lack of trust in the health system, and contribute to antimicrobial resistance.

The LMHRA's operations have direct impact on diagnostic and treatment outcomes for almost all disease conditions. Since the QC Lab was gutted by fire, lack of required technology, extensive instrument breakdown and lack of reference materials. Prior to the fire disaster in 2017, the LMHRA's Quality Control Laboratory operated at Level 3 (according to WAHO's classification). An average of 500 medicines were tested annually via one or more compendia test parameters such as identification, pH check, content uniformity via weight variation, assay, disintegration performance and dissolution performance. Due to capacity constraints (i.e., unavailability of the high-cost impurity standards), the lab could not perform tests for related substances/impurities. After the fire disaster and up till now, the lab has not been able to conduct compendia testing. Product quality evaluation is limited to minilab testing with visual inspection being the major focus.

Considering the above challenges, a critical area of focus for LMHRA is the national quality control laboratory. LMHRA envisages a laboratory facility that is internationally accepted and accredited by the International Standard Organization (ISO 17025:2017) and pre-qualified by WHO.

With the strategic priority to restore LMHRA's capacity to test the quality of medicines procured and registered for sale in the country, the Authority constructed a temporary mini-lab on its King's Farm property in Careysburg from its local revenue generation. Please see below pictorials of the newly constructed temporary QC Laboratory.

Newly constructed QC Lab – Front View

Conference Room

Conference Room

Wet Area (Lab)

Wet Area (Lab)

One of the Offices

One of the Offices

Analysts' Room

Night view of the Lab – powered by Solar Panels

Reception Area

Rear View of the Building

Comparison between the Wet Area of the QC Lab in the rented apartment in Congo Town and the Current Temporary QC Lab in Careysburg:

Rented Facility

Newly Constructed Lab

Old Wet-Area (Lab)

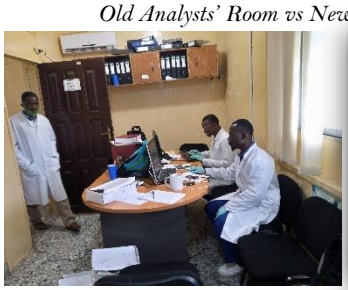



New Wet-Area (Lab)





Old Analysts' Room vs New Analysts' Room




Old Quality Control Office vs New QC & QA Offices



4.1.7.2 Construction of the Ultra-Modern Quality Control Laboratory

The construction of an Ultra-Modern Quality Control Laboratory remains the main focus of the Authority. During the period under review, several meetings with held between the World Health Organization (Liberia Office, East Africa & Geneva), the Architect, the Contractor and LMHRA team for discussions on the lab construction. After three months of meetings and redesigning of the structure per WHO's specifications, the final blue print was concluded and the Authority was authorized by WHO to begin construction works.

A stakeholders' meeting for the construction of the LMHRA's Quality Control Laboratory was held at the Mamba Point Hotel on Tuesday, 29 September 2020. In attendance were representatives from:

- United Nations Industrial Development Organization (UNIDO)
- World Health Organization (WHO)
- The Global Fund (Fiscal Agent)
- Chinese Medical Team
- Supply Chain Management Unit of the Ministry of Health (SCMU)
- Medicins San Frontier (MSF) – France
- United States Pharmacopeia (USP/PQM+)
- USAID

Also in attendance were LMHRA staff, including its Managing Director, Pharm. Keturah C. Smith, the Technical Advisor to the MD, and other technical staff drawn from the QC Lab, the Inspectorate & Post-Market Surveillance Department, Pharmaco-Vigilance & Clinical Trials Department, Medicines Evaluation & Registration Department, Communications Unit, Finance, Programs & Planning, as well as Procurement.

The main objective of the meeting was to get stakeholders' support, both financial and technical, for the construction of the Laboratory Complex to ensure the safety and efficacy of medicines and health products in Liberia, thus improving the health sector.

Key action points emanating from the meeting included the following: That LMHRA must present drawings and designs to the World Health Organization and USP (PQM+) for input and guidance, since the WHO will have to pre-qualify the Laboratory; LMHRA to Follow up with the Ministry of Health to obtain the official report of the Fire Incident that burned the LMHRA's Quality Control Laboratory within the JFK Medical Center and share with partners (USAID); Conduct Environmental Impact Assessment of the Construction Site; Elevate discussion with other donors and engage the Private Sector for their contribution Acquire and show commitments from the Government of Liberia and other donors; Engage the Ministry of Health (the Health Sector) on the LMHRA's aspiration, seeking their support.

Pictorials of the Stakeholders' Meeting



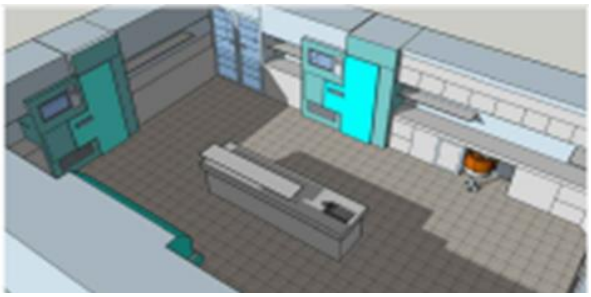
Over the period, the Authority has engaged with stakeholders and the Government of Liberia for the construction of the Lab Complex. Initial support from the GOL was received, the plans and designs of the laboratory were shared with USAID/USP and WHO. Both partners endorsed the plans and blue prints, prior to commencement of construction works.

Per the pictures below, construction of the foundation is at 85% and is expected to be completed by end of the January 2022.

New Lab Design








MD tours Construction Site



Current Status of Construction Works


View of formwork for ramp


View of form wok for access ramp


View of formwork for basement beam


View of conduit


View of rough plumbing for foundation


View of backfill in foundation


View of foundation with stair starter


View of round poles as support for basement formwork


View of basement being prepared for stair

Anticipated results from the construction of a modern Quality Control Laboratory

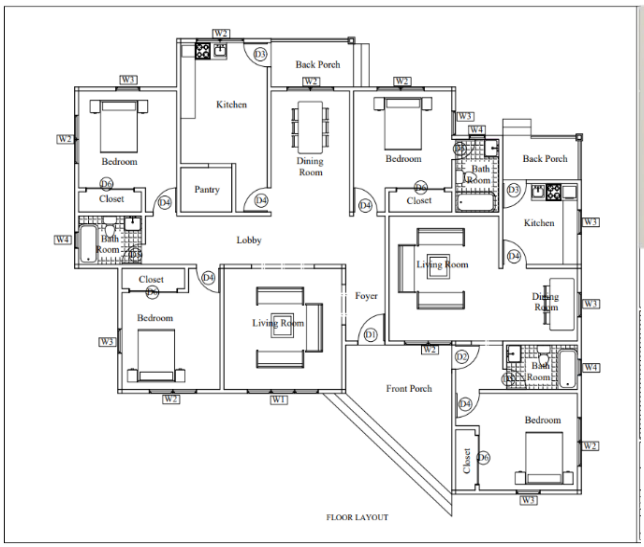
Utilizing the opportunities made available through our various partners, the LMHRA envisages the following outcomes from the construction of its modern laboratory complex:

- *National Quality Control Laboratory more spacious and fully operational.*
- *An ISO 17025:2017 accredited and WHO-prequalified laboratory.*
- *Robust quality assurance of medicines & health products.*
- *Expanded service delivery & Optimal Health Outcome*
- *Reduced negative economic and social impact of paying for substandard medications for the treatment of diseases.*
- *Improved medicine safety information dissemination.*
- *Increased revenue for LMHRA – if the national QC Laboratory is WHO-prequalified or ISO 17025-accredited, then it can be contracted to perform QC testing of grant-funded products.*

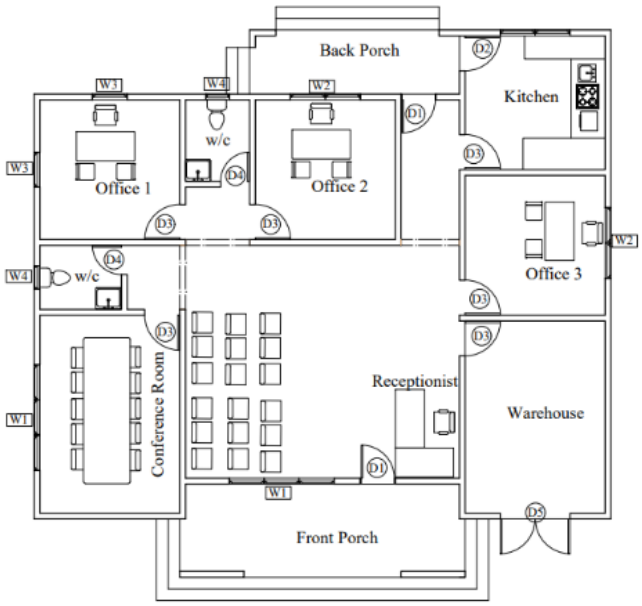
4.1.7.3 Planned Construction of LMHRA's National Headquarters, Regional Offices & Residential Structures

As part of its development plans, the Authority has earmarked the construction of its National Headquarters in Monrovia to avoid the payment of rent by Central Government. The major hurdle for this construction is the acquisition of land space, which will cost the Authority up to US$250,000.00. The total project cost is estimated at US3.8M.

Proposed Regional Residential Building



Proposed Regional Office Building



FLOOR LAYOUT

4.1.8 Donor Engagement & Support

The three main donors to the LMHRA during the period under review were: Global Fund to Fight TB, Malaria & HIV/AIDS; the West Africa Health Organization (WAHO); and Promoting the Quality of Medicines Plus (PQM+), through the United States Pharmacopeia, with the World Health Organization (WHO) providing technical support, especially with the lab construction, and the World Bank, with support for lab supplies and equipment and support for pharmacovigilance activities.

Following are details of support received from each of the donors during the period under review:

4.1.8.1 USP/PQM+ Support

The Promoting the Quality of Medicines Plus (PQM+) Program is a five-year cooperative agreement (No. AID-7200AA19CA00025) between the U.S. Agency for International Development (USAID) and the U.S. Pharmacopeia Convention (USP) to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs). PQM+ works to improve medical product quality through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps to create resilient and sustainable local health systems that ensure access to quality-assured essential medicines for HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and other infectious diseases as well as for reproductive, maternal, newborn, and child health.

The USAID Mission to Liberia requested support from the PQM+ program to provide technical assistance to strengthen Liberia's regulatory system, specifically focused on supporting the Liberia Medicines and Health Products Regulatory Authority (LMHRA) and its Quality Control laboratory. PQM+ visited Liberia in December 2019 for a scoping visit; based on the observations made during that visit, the program proposed the following activities:

- *Perform a rapid assessment of the pharmaceutical market to identify threats to quality- assured medicines in Liberia*
- *Conduct an analysis of selected LMHRA functions and fees*
- *Perform an in-depth assessment of laboratory needs to allow basic functionality*
- *Develop a strategic plan for the life of the program and specific activities to be implemented through the end of September 2020.*

YEAR 1 PROGRESS

The COVID-19 pandemic significantly impacted the program in its start-up year, as well as its ability to implement work at the country level. Eventually, the program started with virtual meetings for technical support.

During the first year of implementation, the first three activities above —the rapid assessment, analysis of LMHRA functions, and the lab needs assessment—were finalized. All three activities took into account the findings of the last World Health Organization Global Benchmarking Tool

(WHO GBT) from 2017 and built on those recommendations. It was noted that limited progress had been made in addressing findings from that assessment.

Draft reports on both the rapid assessment of the pharmaceutical market and the analysis of selected LMHRA functions and fees were submitted and reviewed by the PQM+ technical team. The final draft was completed during the quarter and shared with the Mission. Findings indicate that the LMHRA is severely restricted in performing key regulatory functions due to limited capacity of staff and funding constraints. Furthermore, fundamental policies, regulations, and guidelines that would provide an adequate enabling environment for LMHRA to perform its duties still needs to be drafted or enacted.

Finally, the assessment of lab functions occurred virtually with lab staff in collaboration with a local consultant and PQM+ Quality Assurance/Quality Control (QA/QC) expert based in Ethiopia. The report was finalized during the quarter and shared with the Mission.

During quarter 4, PQM+ shared the results of the assessment and plans for moving forward with the Mission. At the end of September, the LMHRA invited PQM+ to a meeting with other stakeholders to discuss the LMHRA's plans to relocate the lab to a new temporary space newly constructed located outside Monrovia (King's Farm, Careysburg) and initiate plans to build a new ultra-modern laboratory complex to hold all four units of the Laboratory, plus offices. Following this meeting, PQM+ met with the LMHRA to discuss proposed activities.

YEAR 2 PROGRESS

Year 2 started with building on what was planned and started in Year 1. During the 1st Quarter, PQM+ facilitated the development of a list of priority regulations that support implementation of the LMHRA Act of 2010. PQM+ also supported the mapping of required legislation and sponsored a trip for senior staff of LMHRA to travel to the Ghana FDA on a study visit. Following the study visit, the LMHRA organized a special committee for drafting the regulations. PQM+ has also facilitated establishment of a Post-Market Surveillance Technical Working Group, inaugurated December 18, 2020, with a chair and vice chair elected.

Support by PQM+ Objective

Objective 1: Governance for medical product quality assurance systems improved

The lack of regulations to support the LMHRA Act of 2010 has been a major challenge to improving governance of medical product quality assurance in Liberia. During Q1, PQM+ laid the foundation for good governance and regulatory practices by building consensus through discussion with LMHRA on the purpose and design of proposed regulations and a strategic plan.

PQM+ coordinated with the LMHRA to complete the mapping of required legislation by reviewing the LMHRA Act of 2010 and other documents, like the institutional development plan based on the WHO Global Benchmarking Tool for self-assessment and the strategic plan of 2011. The LMHRA and PQM+ identified 27 regulations that need to be developed. Priority regulations will strengthen enforcement actions, medicines registrations, marketing surveillance, and medicines importations. Once these regulations are in place, they will promote good governance of the medical product quality assurance system in Liberia by ensuring transparency, accountability, efficiency, and flexibility.
PQM+ arranged and supported a five-day (November 29 – December 3, 2020) study visit to the Ghana FDA for LMHRA's managing director and two other senior staff. The PQM+ Liberia

consultant accompanied the LMHRA delegation to Ghana. The visit has strengthened collaboration between the LMHRA and the Ghana FDA. It also allowed the LMHRA to learn from Ghana's successes (including regulations development) through in-person workshops, where FDA staff gave 14 presentations and site visits to laboratories in Accra and the Tema Port.

As a result of the visit, LMHRA set up a committee for drafting priority regulations, depending heavily on lessons learned from Ghana, with technical guidance from PQM+.

Support for development of LMHRA Strategic & Operational Plan

The most recent LMHRA three-year strategic plan expired in 2015 and has not been revised or updated. With the intent to develop a new Strategic Plan, LMHRA leadership coordinated with PQM+ to complete the terms of reference for a consultant to support development of a five-year strategic plan.

PQM+ hired a consultant to support LMHRA's development of the strategic plan. In February 2021, the consultant conducted a desk review of key documents and submitted an inception report to set the project's timelines, benchmarks and tools, which PQM+ shared with LMHRA. The consultant also carried out a stakeholder mapping and analysis from within the health sector. In March of the same year, the PQM+ consultant traveled to Liberia to meet with LMHRA leadership and board members, the School of Pharmacy, Liberia's chief pharmacist, and the deputy minister of planning at the Ministry of Health. On March 4, during a stakeholders meeting at the Bella Casa Hotel in Monrovia, the consultant presented an overview of the new strategic plan.

On April 28 in Monrovia, LMHRA management and its board of directors, representing the Ministry of Health, School of Pharmacy, Ministry of Justice, Ministry of Commerce, and the Consumers Groups Association, validated the drafted Strategic & Operational Plan. In May, PQM+ submitted the final copy of the Strategic Plan to LMHRA. In June, PQM+ conducted a human resources assessment at LMHRA, which included interviewing 15 employees, including the managing director. Results from this exercise will help LMHRA address its human resource capacity challenges. The draft Strategic & Operational Plan has been submitted to the LMHRA Board of Directors for final review and approval.

In October of 2020, the LMHRA lab relocated to a temporary facility constructed in King's Farm, Careysburg, about 39 kilometers from central Monrovia. To support the laboratory relocation, PQM+ advised on equipment decommissioning and installation, packing, transportation, documentation, and inventory of equipment and chemicals.

PQM+ also developed a standard registry for equipment, chemicals, and apparatus. The LMHRA is using the registry as a resource as it inspects the laboratory's inventory. Additionally, PQM+ reviewed LMHRA's new laboratory design and submitted its comments to the LMHRA for consideration. The comments were used to finalize the new lab design with the World Health Organization. Construction of the foundation is ongoing now.

Support for Post-Marketing Surveillance

On December 18, 2020, the LMHRA, with the support of PQM+, successfully launched the Post-Market Surveillance Technical Working Group (PMS-TWG) for Liberia. The launch was attended by 26 stakeholders (including online participants) from the LMHRA, Liberia National Police, Liberia Pharmacy Board, WHO, Liberia Drug Enforcement Agency, Ministry of Heath Supply Chain Unit, National Malarial Control Program, National AIDS Control Program, Central Medicines Stores, National Tuberculosis Control Program, and the Ministry of Health Neglected Tropical Disease Control Program. This TWG oversees PMS activities in Liberia to ensure an integrated and harmonized system.

PQM+ assisted the LMHRA to develop a ToR for the TWG and helped organize the inaugural meeting. Members of the TWG elected a chair (from the Central Medicines Stores) and vice chair (from the National Malarial Control Program). LMHRA heads the secretariat in accordance with the PMS-TWG ToR.

PQM+ conducted a five-day workshop from March 1 to 5 for 23 members of the National Technical Working Group on Post-Marketing Surveillance (TWG-PMS). The training focused on risk-based post-marketing surveillance. Participants joined from the National Malarial Control Program, National AIDS Control Program, TB and Leprosy Control Program, County Health Team, Neglected Tropical Diseases Program, Central Medical Store, and LMHRA. The training workshop introduced the MedRS tool and its applications to participants, who used the MedRS tool to evaluate risk factors associated with medicines, counties, cities, and facilities. At the end of the training, participants successfully developed risk-based PMS protocols for antimalarials and MNCH medicines. The USAID Mission in Liberia visited the training site. USAID's Health Office Director encouraged participants to make the most of the training.

In June, PQM+ coordinated with LMHRA to validate guidelines on RB-PMS and the sampling and testing protocol. The validation meeting was attended by 23 people from LMHRA, the Pharmacy Board, Ministry of Health disease control programs, and the Central Medical Store. PQM+ also trained 18 sample collectors from the national disease control programs and LMHRA. Later, sample collectors spent eight days collecting 303 antimalarial and MNCH medicines samples in Nimba, Lofa, Gbarpolu, Sinoe, and Grand Gedeh.

Investigation into Sale of donated Medicines

Several African countries have reported medicines being diverted from public facilities to private pharmacies, medicines stores, clinics, and open markets, including Liberia. This practice can lead to

stock-outs of essential medicines in the public sector. In Liberia, malaria is endemic and stock out of anti-malarials in public facilities could have a devastating effect.

On February 26, PQM+ received a request from USAID's Liberia Mission to ascertain the allegation that private markets in Montserrado County are selling ACTs procured by PMI and the Global Fund (GF). PQM+ coordinated with LMHRA, USAID Global Health Supply Chain Program's Procurement and Supply Management project (GHSC-PSM), and the Central Medicines Store to investigate the allegation. LMHRA inspectors inspected 56 private pharmacies, medicines stores, clinics, and open markets in Montserrado (Monrovia and Paynesville) and Nimba (Ganta). The LMHRA inspectors acted as mystery shoppers to purchase ACTs, antiretroviral drugs (ARVs), and mosquito nets from medicines stores and open markets. The PQM+-led investigation found evidence that the open markets in Monrovia and Paynesville are widely selling ACTs and mosquito nets procured by PMI and GF. It also found that 12 percent of medicine stores visited in Monrovia were selling ACTs procured by PMI and GF. PQM+ sent a detailed report to the USAID Mission in Liberia. PQM+ also presented the investigation's findings at the FY 2022 Malaria Operational Plan meeting held from March 22 to March 31.

Support to the Quality Control Laboratory

The LMHRA quality control lab has been a major source of revenue, as the Authority collects fees by screening medical products as they enter the country. However, the lab is currently not screening medical products, largely due to the lack of needed laboratory supplies. PQM+ is procuring at least 133 essential reagents, 374 apparatuses, 10 high-performance liquid chromatography (HPLC) columns, a dissolution tester, and 10 sets of minilab reference tablets and consumables. These items will allow the LMHRA to resume basic QC screening of medical products. During this year, PQM+ is focusing on supporting the LMHRA to develop a procurement plan and policy for lab consumables and reagents to ensure the use of qualified vendors while considering financial value. PQM+ is also working with the lab to develop a costing model for lab tests. The model is expected to help the LMHRA to recover actual testing costs. Additionally, PQM+ sponsored five LMHRA QCL lab staff members to travel to the USP Ghana lab in March, where they participated in basic QC training.

The lack of a complete and effective QMS in the LMHRA QC lab is adversely affecting LMHRA's capacity to ensure that only safe medicines reach the Liberian people. In April, PQM+ reviewed the status of the lab's QMS documentation and agreed with LMHRA on a plan for document development. PQM+ also delivered a three-day ISO/IEC 17025:2017 QMS awareness training to 34 LMHRA employees in April. Participants included staff from LMHRA's administration, human resources, internal auditing, finance, and QC lab. PQM+ inspected key equipment at the LMHRA lab and trained two staff in equipment preventive maintenance, then trained nine analysts on measurement uncertainty and internal auditing.

Additionally, PQM+ sponsored five LMHRA QCL lab staff members to travel to the USP Ghana lab where they participated in basic Quality Control training focusing on the following topics: Reference Standard Management, Loss on Drying, HPLC, Good Weighing Practices, Good Laboratory Practices, KF Titration, Proper use of Pharmacopeias, Good Documentation Practices, Basic Laboratory Safety, Analytical Methods Validation/verification Transfer, Disintegration Tester, Dissolution Tester, Ultraviolet – Visible Spectrophotometer and Friability. LMHRA QC Lab staff trained were:

- Pharm. Akoi Fahnbulleh, Lab Director

- Albert D.Z. Gbusseh, Deputy Quality Control Manager
- Pharm. David P. Namakpeh, Quality Assurance Manager
- Mr. Daniel F. Gbotoe, Lab Analyst
- Pharm. D. Nelson Tweh, Quality Assurance Officer

Mr. Geoffery Kwabla Togoh from far lift posting with QCL LMHRA Staff. In the middle is USP Ghana Staff

KF Titration practical
D. Nelson Tweh Hands On

Dissolution Performance Verification Test Hands-ON Training

Mechanical Calibration of Dissolution

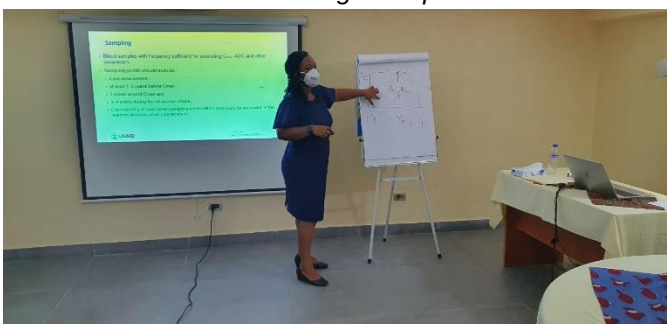
Support for Dossier Evaluation

PQM+ also delivered a 10-day intensive training for 13 employees of the LMHRA March 1–10 o Dossier Evaluation. The training topics included medicines dossier evaluation using the Common Technical Document (CTD) format, API stability, pharmaceutical product development, manufacturing and process validation, bioequivalence, API specification, and more. The USAID Mission in Liberia also visited the dossier evaluation training. Speaking to participants at the training, USAID's supply chain advisor/GHSC-PSM activity manager encouraged participants to take the training seriously. The 13 participants all achieved certification at the end of the training. LMHRA's Managing Director, speaking at the closing ceremony, lauded USAID and PQM+ for the training. The director also encouraged participants to put into practice what they have learned.

Medicines' registration is one of LMHRA's key regulatory functions. As a result of PQM+'s technical assistance, in April and May, LMHRA conducted its first dossier evaluations since 2017; 40 dossiers from a backlog of more than 150 were evaluated. In June, PQM+ delivered a 10-day hands-on dossier evaluation training for nine LMHRA senior dossier assessors.

Risk-based approach PMS training at Cape Hotel

Dossier Evaluation training at Cape Hotel



A Team from USP Ghana/PQM+ (USP Ghana Director, Boateng; USP Consultant Botwe) tours the LMHRA Temporary Quality Control Laboratory Facilities in Careysburg

Support for Local Manufacturing

The supply of quality assured essential medical products is important to public health. During the period under review, PQM+ helped LMHRA conduct a one-day gap analysis of Global Pharmaceutical's facility in Monrovia. PQM+ released the findings of the assessment to LMHRA. In addition to lauding PQM+'s report, LMHRA's managing director has said it will inform the agency's decision on Global Pharmaceutical's operation in Liberia.

Pictorials of visit to Global Pharmaceuticals' Facilities with USP Team from Ghana

4.1.8.2 Global Fund's Support

During the period under review, the Authority received a total of US$356,400.00 (Three Hundred Fifty-Six Thousand, four hundred) from Global Fund to support the Strengthening of LMHRA in assuring the quality and efficacy of medical products on the Liberian market, including post-market surveillance. Key achievements from Global Fund's support during the period are: Development & validation of a Quality Assurance Plan, procurement of lab equipment, reagents & chemicals, as well as office equipment, furniture, and other supplies; hiring of consultants to begin strengthening of the Authority's Pharmacovigilance System, maintain and calibrate equipment in the LMHRA Quality Control Laboratory. In addition to the above, two vehicles were procured and supplied by Global Fund to support post-market surveillance activities across all regions in the country.

Implementation of Activities

Validation of Quality Assurance Plan

To effectively perform the QA functions, LMHRA has set in place a system to ensure that product quality is maintained throughout the entire supply chain in both the public and private sectors. One of such systems is a quality assurance plan. The QA plan developed by LMHRA ensures that the products retain their potency during transportation, storage and distribution to end-users within the country. The QA Plan outlines the roles and responsibilities of all stakeholders involved in procurement, transportation, storage, distribution and quality monitoring of the medicinal products.
The QA Plan was validated prior to its usage at a one (1)-day workshop held at the Quality Control Laboratory facility of LMHRA on 31st January 2020. Stakeholders from the Central Medical Store (CMS), Supply Chain Management Unit, the Program Coordinating Unit of the Global Fund and LMHRA were in attendance. Please see photos below:

Support for Post-Market Surveillance Activities

Apart from strengthening of the Authority, over 50% of Global Fund's support is geared towards ensuring the quality of all Global Fund procured products; that is, post-market surveillance. To ensure this, the Authority conducts quarterly sampling of products for quality testing and also checks the condition of all product storage facilities across the country.

Sampling

For the period 2020 – 2021, 3 pre-distribution and post-distribution sampling exercises were conducted at the Central Medical Stores in Caldwell, Montserrado County and various drugs depots across the country.

During the 2nd quarter of 2020, a total of three hundred twenty-four (324) samples were collected in various categories (anti-malaria, antiretroviral, anti-TB and leprosy and antimicrobial). The distribution by county and therapeutic categories is tabulated below with the accompanying graphical display:

Table 1: Distribution of Samples by County and Therapeutic Class

County	Total # of Samples/Batches	# of Anti-malarial	# of Anti-retroviral	# of Anti-TB & Leprosy	# of Anti-microbial
Montserrado	40	5	13	12	10
Grand Bassa	15	3	6	5	1
Margibi	12	4	5	3	0
Rivercess	20	5	8	6	1
Bomi	35	13	14	7	1
Cape Mount	11	3	3	4	1
Gbarpolu	12	6	4	1	1
Bong	18	4	9	4	1
Lofa	26	7	6	11	2
Nimba	22	6	4	11	1
Grand Gedeh	15	3	9	3	0
River Gee	20	3	10	7	0
Maryland	30	7	13	10	0
Grand Kru	20	0	9	11	0
Sinoe	28	10	10	6	2
Totals	**324**	**79**	**123**	**101**	**21**

Figure 1: Percentage of Sample Collection Per County

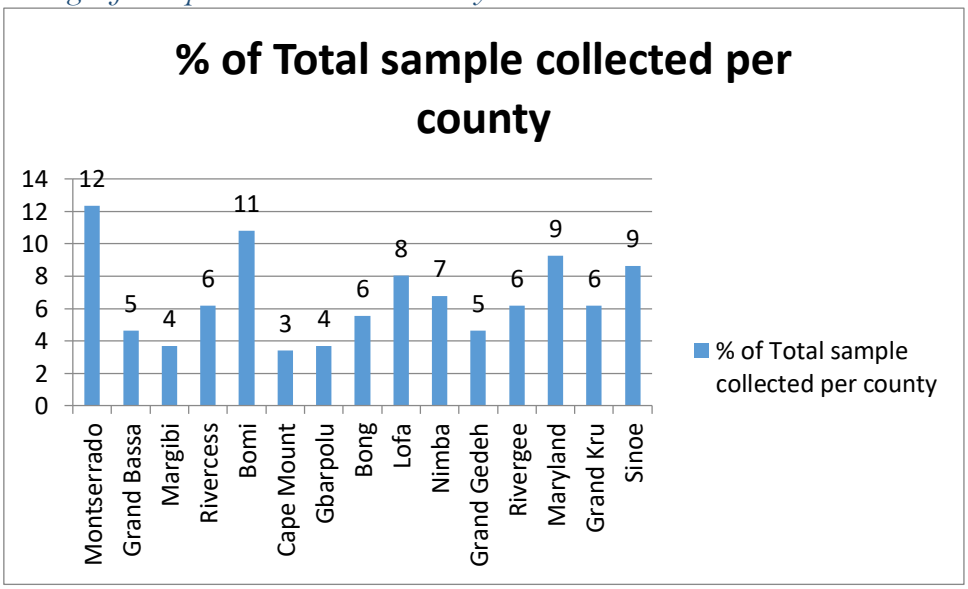
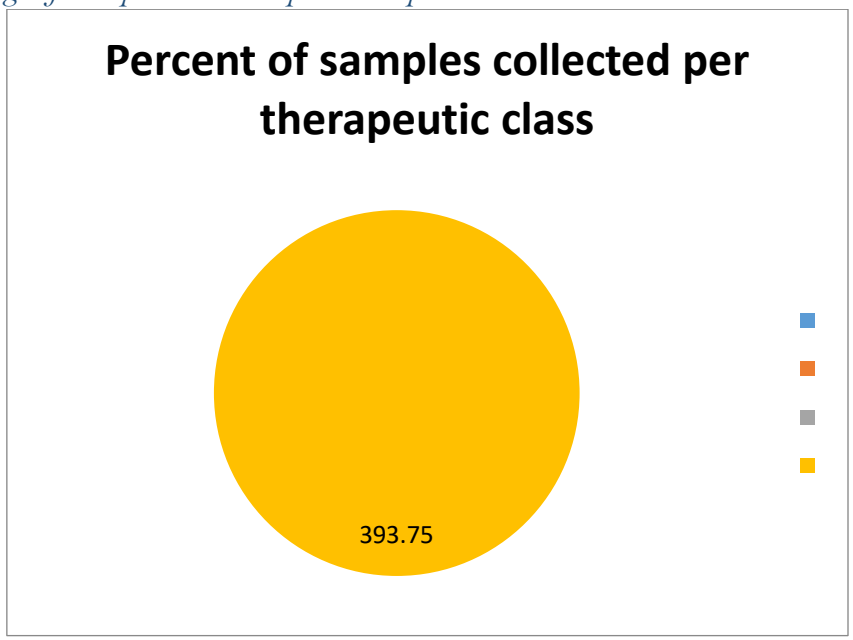


Figure 2: Percentage of Sample Collection per Therapeutic Class



During this period, majority of the samples were collected from Montserrado County, about 12%. Fewer samples were collected from Grand Cape Mount, Gbarpolu, Margibi Grand Bassa and Grand Gedeh Counties (ranging from 3-5% for the total). Also noteworthy of reporting is the number of samples per therapeutic class. Majority of the samples collected were anti-retrovirals representing 38.0% of the total collection, followed by anti-tuberculosis and leprosy representing 31.2%. Only few antimicrobials were collected (about 6.5%).

After PMS, all samples were subjected to basic screening via visual inspection by the Quality Control Laboratory. The QC Lab could not perform identification test via thin-layer chromatography (TLC) due to the COVID19 pandemic which affected the importation of minilab kit procured from Germany with funds given by the Global Fund. With the limited capacity of the QC Lab to conduct compendia testing, 8 batches of the samples collected from suspicious regions across the 15 counties were packaged and shipped to Ghana FDA for 3rd party testing.

The results reported by FDA Ghana indicated that ***all eight (8) samples passed quality assessment*** using the following test parameters: ***identification***, ***uniformity of dosage units (content uniformity, weight variation and uniformity of weight)***, ***dissolution performance***, ***assay*** and ***impurity profiling/related substances***.

During the 4th Quarter of 2020, additional PMS activities were conducted, including inspection of warehouses and storage facilities at various health centers, pharmacies, clinics, hospitals, etc. to investigate and ascertain the storage conductions of the products, the stock levels at the various facilities and depots and to conduct a survey within the communities if Global Fund funded commodities could be found at local pharmacies and medicine stores.

The Post Market Surveillance Department places premium on the storage conditions of pharmaceuticals and the conditions under which pharmaceuticals are distributed. On the broader spectrum, the LMHRA seeks to address the problems of substandard and counterfeit medicines in Liberia via the conduct of inspection phases.

During the collections, samples were taken from the following categories: Anti-Malaria, Anti-retrovirus (HIV), Tuberculosis (TB) and Reproductive Health Products.

Region One: Grand Cape Mount, Bomi & Gbarpolu

A total of 18 batches of HIV drugs were collected, 9 batches of TB drugs, 9 batches of Reproductive Health and 9 batches from the Anti-Malaria drugs given a total sum of 45 batches.

Samples were collected from all three program areas and reproductive health. Five (5) batches of anti-malaria products - Artesunate/ Amodiaquine, Artemether/ Lumefantrine and Sulfadoxine/ pyrimethamine – were collected; sixteen batches of Antiretroviral (HIV) products were collected (Lopinavir/ Ritonavir, Lamivudine/ Zidovudine, Efavirenz/ Lamivudine/Tenofovir, Lamivudine/ Nevirapine/ Zidovudine, Efavirenz, Dolutegravir, Dolutegravir/ Lamivudine/ Tenofovir, Nevirapine and Sulfamethoxazole/ Trimethoprim). For Reproductive Health, samples of three products were collected, consisting of five (5) batches: Medroxyprogesterone Acetate, Levonorgestrel/Ethinylestradiol and Levonorgestrel. Lastly, five (5) products and consisting of thirteen (13) batches of the anti-tuberculosis products were collected from. The names of the products are Ethionamide, Ethambutol, Pyridoxine HCl Teva, Rifampicin/Isoniazid and Pyrazinamide/Ethambutol, respectively.

Region Four: Grand Kru, Sinoe, River Gee, Grand Gedeh & Maryland Counties

Samples were collected from all three program areas and the reproductive health. Twenty-six (26) batches of anti-malaria medicines comprising the following products were collected: Artesunate/Amodiaquine, Artemether/ Lumefantrine and Sulfadoxine/ pyrimethamine. Fifty (50) batches of Antiretroviral (HIV) medicines comprising the following products were collected: (Lamivudine monotherapy, Lopinavir/Ritonavir, Lamivudine/Zidovudine/Nevirapine, Efavirenz monotherapy, Dolutegravir/Lamivudine/Tenofovir, and Abacavir/Lamivudine). For Reproductive Health, twenty-six (26) batches comprising the following products were collected: Microgynon, Microbut, Oxytocin, Depo-Provera, Calcium Gluconate Injection and Magnesium Sulfate Injection. Forty-seven (47) batches of the anti-tuberculosis medicines comprising the following products were collected: Ethambutol, Pyridoxine HCl Teva, Rifampicin/Isoniazid, Isoniazid Monotherapy and Rifampicin/Isoniazid/Pyrazinamide.

All samples were subjected to basic screening via visual inspection by the Quality Control Laboratory of LMHRA. The QC Lab could not perform identification test via thin-layer chromatography (TLC) with the procured minilab kit due to relocation of the Lab in October 2020; thus six (6) batches were sent to Ghana FDA for quality testing.

PMS Findings

One of the key findings of the PMS was that a large number of local pharmacies and medicine stores in the counties visited were distributing purported falsified and unregistered products to the public. Additionally, many of the facilities visited had Global Fund products on sale. These products were confiscated and brought to the Inspectorate Department of LMHRA. Report was shared with Global Fund and the Ministry of Health.

During each sample collection, the environmental conditions of the storage areas, the storage facilities and other storage conditions were observed and recorded. Most of the storage facilities in the counties lack electricity, ventilation and unkempt. Congestion due to lack of adequate was also discovered, especially with the huge pile of expired products reported in every county.

Post-Market Surveillance Activities in Pictures






Support for Pharmacovigilance

Under support for monitoring of adverse drug reaction, Global Fund's activities were centered on training of healthcare workers at several health facilities and strengthening of LMHRA's PV System through the hiring of an international firm (PATH).

Follow-up to Health Facilities on ADR

The collections and handling of Adverse Drug Reactions (ADR) is one of the cardinal functions of the Liberia Medicines and Health Products Regulatory Authority LMHRA in the discharge of its mandate to ensuring the safety of all medicines and health products. The LMHRA is a member of the World Health Organization (WHO) ADR System. Currently, the agency has developed an ADR form and embarked upon the distribution of these forms to all health facilities across the country.

Through the support of the Global Funds, the LMHRA through its Pharmacovigilance (PV) Unit rolled out these ADR forms to facilities in four counties, Gbarpolu, Bomi, Grand Cape Mount and Montserrado counties. The distributions covered: hospitals, health center, clinics, pharmacies and medicines stores.

The PV team worked through the county health teams (CHTs) of these four counties, a formal meeting between the PV team and the CHTs was held in Gbarpolu, Bomi and Grand Cape Mount counties to explain the relevance of this tool.

The PV team distributed the National ADR reporting booklet and subsequently conducted hands on training of staff on how to fill out these forms, after which they were also trained on how to report suspected adverse drug reaction cases and notify the LMHRA anytime they identify ADRs case.

In addition to the assessment done by the PATH Consultant, the LMHRA printed 275 ADR investigation & reporting booklets, for use at the various health centers. Training of ADR focal

persons at various health centers on using the forms will be conducted during the 1st Quarter of 2021; as well as on notifying LMHRA of any adverse effects. The initial follow-up visits will be in Gbarpolu, Cape Mount, Bomi & Montserrado Counties.

The roll-out and hands-on (on- the –spot) exercise could not cover all health facilities in each county due to limited resources.

Pharmacovigilance System Strengthening

The key objectives:

i. *SWOT analysis of the Pharmacovigilance system of LMHRA*
ii. *Review available Pharmacovigilance documents to conform to acceptable best practices*
iii. *Identify and draft PV development plan*
iv. *Identify and develop template for SOPs for all PV process*
v. *Provide hands-on training on causality assessment of adverse drug reactions for PV staff*

Scope of Services

Despite the objectives listed above, the scope of work of the consultancy covered only Phase I of the Pharmaco-Vigilance & Clinical Trials system review and strengthening, which is the Assessment of the National Pharmaco-Vigilance System due to limited resources for the period. Phase II of the consultancy is expected to cover the other objectives during the new GF allocation, when more resources have been recommended.

PHASE I: Assessment of National PV System

In July 2020, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) published a pharmacovigilance (PV) consultancy role with the objective to "Strengthen the capacity of PV/CT staff to become efficient in monitoring the safety of all medicines and health products, and support the collection, assessment (analysis), documentation and communication of reports on ADR surveillance in Liberia". The full terms of reference (TOR) of the PV consultancy, is intended to build a proficient national PV system, according to international norms and standards, in four phases: Assessment of national PV system; Development of customized improvement plan; Implement identified improvement interventions; and evaluate the impact of intervention. The consultancy TORs focused on Phase 1 of the strategy to strengthen the national PV system. In September 2020, LMHRA and PATH entered into a consulting agreement for Phase 1 (Assessment of national PV system).

The main objective of the consultancy was to perform an assessment of the capacity of the Liberian national PV system to identify strengths, gaps, weaknesses, and opportunities for improvement.

Main Findings of the Assessment

The assessment was qualitative and made use of a PV assessment tool developed for the purpose of the assessment, adapted from WHO Global Benchmarking Tool (GBT)[1], WHO pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems[2] and the Indicator-Based Pharmacovigilance Assessment Tool (IPAT)[3]. The findings of the assessment can be seen on appendix 2. PATH provided comments on the PV indicators assessed as well as initial suggestions to strengthen the PV system. For this assessment, data was collected only at the national level and responses provided by the Head of Pharmacovigilance at the LMHRA.

The assessment was conducted with the intention to improve the PV system in Liberia.

Concluding the first phase of the contract, on the overall, responses indicate that the PV system in Liberia has minimal capacity for PV[4]. There is a legal basic, that is, no legal or structural frameworks for PV systems and no coordinated passive or active surveillance in the country. It is important to acknowledge that PV is still very new to Liberia, who only became a member of the WHO Program for International Drug Monitoring in 2013. The proposed next phase of the project will be a stepwise approach to build and strengthen the national PV system in Liberia, which will begin with the development of an implementation plan, based on the availability of financial and human resources.

Strengthening of the LMHRA (ACQUISITION OF LAB SUPPLIES)

Testing of commodity at the LMHRA Quality Control Lab has not been ongoing since the lab was gutted by fire in May of 2017. However, in order to begin compendia testing of products, the LMHRA constructed a temporary Quality Control Laboratory, from resources generated three fees and other regulatory services rendered. With the construction of the laboratory comes the need for maintenance, calibration and repair of lab equipment that have been down for years, coupled with the need to procure lab reagents and install relevant software. Under Strengthening of the LMHRA, resources were allotted to support the QCL, including acquisition of the needed lab supplies.

However, it is important to note that as less amount (US8,500.00) was allocated in the Global Fund budget for this activity, the total cost of over US$25,000.00 for the supplies was cost-shared with the LMHRA – thus the LMHRA contributed over US$15,000.00.

Upon the relocation of the QC Lab and the acquisition of new equipment, there was need for the repair, maintenance and calibration. Accordingly, an expert was hired from Senegal to support the Laboratory. Mr. Modou Diouf performed maintenance for all equipment, including two HPLC sets: Agilent 1220 and Waters Alliance 2694, UV-Vis Spectrophotometer, pH Meter and the Analytical Balances. Mr. Diouf also assisted in the installation of a brand-new Mill-Q Direct Water Purification System. Lastly, he worked with LMHRA Lab Analysts to calibrate the Agilent 1220 HPLC System.

[1] World Health Organization (2018). WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system of medicinal products. Vigilance (VL): indicators and fact sheets

[2] World Health Organization (2015). WHO pharmacovigilance indicators—a practical manual for the assessment of pharmacovigilance systems.

[3] Strengthening Pharmaceutical Systems Program (2009). Indicator-based pharmacovigilance assessment tool: manual for conducting assessments in developing countries. Management Sciences for Health, Arlington.

[4] Strengthening Pharmaceutical Systems [SPS]. Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance. Arlington, VA: US Agency for international development by the strengthening pharmaceutical Systems (SPS) program; 2011.

However, this calibration process is to be continued by the QC Lab staff due to the unavailability of certain needed chemicals.

To install the equipment and software procured from HDTS, an expert was sent Liberia from Nigeria to install the software for the Waters Alliance 2695 HPLC System and conduct a comprehensive training of selected staff (3 persons) on the use of the software.

With all this development, it is expected that testing of products at the Laboratory will begin soon, though not at the highest level.

Pictorials of Consultant Repairing, Calibrating Equipment at the QC Lab, as well as training of the LMHRA Lab staff:

During the calibration and repair process, a Team from USP Ghana/PQM+ (USP Ghana Director, Boateng; USP Consultant Botwe) toured the LMHRA Temporary Quality Control Laboratory Facilities in Careysburg





Impact of Global Fund's Support to LMHRA

Noticeable improvements have been made at the LMHRA as a result of Global Fund's support, amongst which are:

- Acquisition of new equipment, reagents and chemicals for the QC Lab, as well as maintenance, repair and calibration of all equipment, which is essential to laboratory functions. A consultant was hired and the task have been completed. LMHRA will soon begin some chemical testing at the newly constructed QC Lab. This will potentially increase the quality of medicines found in the market.

- Through several community outreach activities in four (4) counties, including Montserrado, the public has been informed via electronic and print media about the danger of using substandard/falsified products.

- Capacity for post-marketing surveillance of medical products sustainably improved through the provision of two vehicles. Ensuring the quality of medical products throughout the supply chain and being able to authenticate the quality of medicines considering the present challenges of the quality control lab that extend beyond registration and procurement processes. Substandard medicines may occur due to poor manufacturing practices or as a result of poor storage conditions or practices. In addition, weak regulatory systems leading to unregulated distribution and sale of medicines and porous country borders facilitate the introduction of substandard, falsified, and unapproved medicines, as the case of Liberia. Considering the above, over 60% of Global Fund's support has gone towards supporting and strengthening post-marketing surveillance, including 3rd party testing of products at the Ghana FDA Laboratory. Our teams have been able to visit hard to reach areas across the country since the arrival of the two vehicles through provision of fuel and allowance to samplers for targeted sampling for products and locations where surveillance is most needed.

WAHO's Support

Between the period 2020-2021, WAHO's support to the Authority centered on strengthening of the Authority to ensure the quality and safety of medicines and health products. WAHO's supported included the following

1. Partial support to Networking of LMHRA's main offices for operational efficiency.
2. Donation of equipment, including computers and printers.
3. Provision of laboratory test kits to support post-market surveillance activities.
4. Capacity building for key LMHRA's technical staff through provision of training opportunities in Ghana.

4.1.8.3 Resource Mobilization: Operational Effectiveness & Efficiency

The outbreak of the novel coronavirus (COVID-19), declared by WHO as a "Global Pandemic" on 11 March 2020, has impacted activity and valuations in the economy, including the pharmaceutical sector. This has had serious impact on the Authority's revenue generation. Though the Authority has continued to produce a sustainable financial performance, despite the challenging business and economic conditions in Liberia which have resulted in reduced government funding.

The Authority's resource and capital expenditure requirements are financed by revenues generated from its activities, with the exception of about 98% of staff salaries, which is the Government's contribution to the Authority. This requires the Authority to ensure it has sufficient reserves of cash to enable it to undertake its statutory activities. The Authority's objective is to ensure continuity of funding and flexibility through resource mobilization from fees. The Authority's current operational cash flow is stable, but unpredictable due to the COVID pandemic, which is greatly affecting supply chain worldwide.

4.2 Operational Performance: Regulatory Activities

4.2.1 Product Evaluation & Registration

The Product Evaluation & Registration Department is one of the four technical departments of the LMHRA with the responsibility to receive applications for (medicines and health products) registration and provides feedback to applicants on the registration process; conduct evaluation of product dossiers; generate information for billing (i.e. payment for products registration, listing of medical devices, cosmetics, health products and premarket analysis); prepare Market Authorization (Import/Clearance); list medical devices, health products, and cosmetics; publish registered products; conduct regular workshops for clients – i.e. Importers, Pharmacists, etc. for information sharing; and generate and update registration guidelines and related documents.

Upon the establishment of the LMHRA, the Products Evaluation & Registration Department embarked on listing of Pharmaceutical products for human use in 2011. In 2012, with support from a consultant (Mr. Ben Botwe) from Ghana, the department began registration of medicinal products in Liberia. Currently, the department uses the ECOWAS agreed CTD protocol for dossier submission as ECOWAS member state for the harmonized registration procedure established through the efforts of the West African Health Organization (WAHO) in the ECOWAS region. In adherence to the ACT of 2010 which provides the provision for the Registration of all medicinal Products in circulation in the Pharmaceutical Sector in Liberia, the Department has moved to conduct:

¬ Full assessment for the registration of allopathic medicines
¬ Assessment for the registration of Herbal medicines and supplements
¬ Assessment for medical devices listing gearing to registration
¬ Listing of Health Products (Cosmetics)

The Department is yet to begin registration of Biosimilar medicines (Biological and Blood related substances and Psychotropic substances).

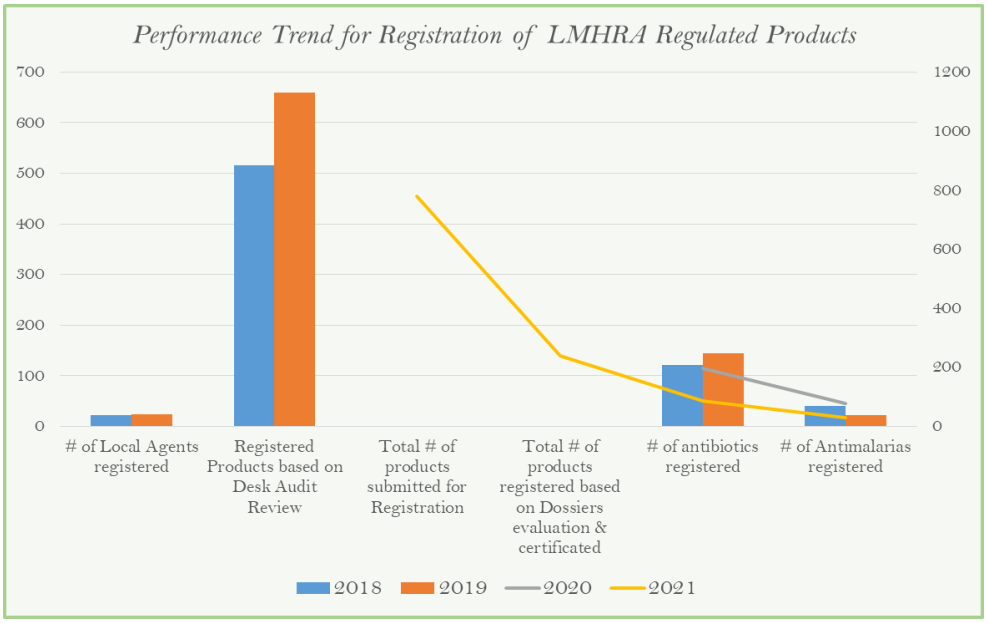
The Evaluation and Registration Department is headed by Pharmacist Quaye-Freeman (Mrs.) as Director, assisted by Pharmacist Mary Jalloh-Tozo as Deputy Director and seven unit managers. The Department comprises of the following Units: Reception, Medicines Registration, Cosmetics Registration, Medical Devices Registration, Research & Development, Records Management and Narcotics & Psychotropic Registration Units.

Data Analysis of Registered Medicines from 2018 through 2021

Performance trend of registered products

Per the analysis shown in the graph and table below, a total of 100 local agents have been registered with the Authority from 2018 to 2021; while a total of 3,327 products have been registered during the same period.

The graph below shows a representation of all products registered in the years 2018-21:



Performance trend for registration of LMHRA regulated products				
Decription	2018	2019	2020	2021
# of Local Agents registered	22	24	24	30
Registered Products based on Desk Audit Review	515	660		
Total # of products submitted for Registration			1132	780
Total # of products registered based on Dossiers evaluation & certificated				240
# of antibiotics registered	121	145	195	86
# of Antimalarias registered	41	22	77	29

Port Clearances

During the year 2020, the Authority issued Ninety-seven (97) Port Clearances to twenty-one (21) importers of pharmaceuticals comprising of medical devices, medicines and health products; compared to 151 clearances issued to twenty-eight (28) importers in 2021.

Importation Licenses issued for Narcotic & Psychotropic Products

Four Institutions were granted importation Licenses for the importation of Narcotic and Psychotropic products as was requested by them. During the period thirteen (13) importation licenses were issued.

Waiver for permits and clearances

The Authority regulates medicines and health products in both the private and public sectors of the health system of Liberia. The public sector in health is mainly occupied by donor institutions and the Government of Liberia through the Ministry of Health. Due to the composition of this sector waivers were issued for any entry of imported consignment of Pharmaceuticals based on request via the two approved ports of entry: the Freeport of Monrovia and the Roberts International Airport of Liberia. During the years 2020-2021, a total of Forty-Seven (47) waivers were issued to ten (10) national and International institutions in the public health sector

Below is a Chart showing total waivers by institution for the importation of pharmaceutical products into Liberia:

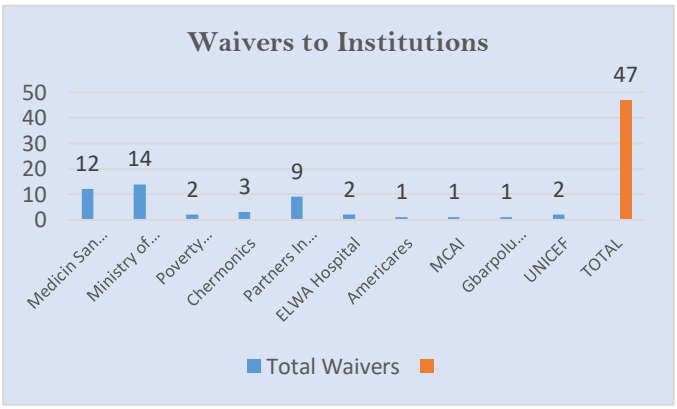


Figure 14: Graphical Presentation of the total Waivers Issued by Institution in 2020-2021

Dossier Evaluation

During the year 2021, a total of 240 products were evaluated using the Common Technical Document (CTD) format for the first time since its formulation in the Sub-Region in 2016.

After the evaluation, the Expert Committee on Products Evaluation was established, awaiting the Board's endorsement. However, the temporary Expert Committee met and approved the products evaluated by the Dossier Evaluation Committee. Please see approved listing on LMHRA Website.

4.2.2 Inspectorate & Post-Market Surveillance

The Inspectorate and Post Market Surveillance Department is one of the four technical departments of the LMHRA with the responsibility to inspect all medicines and health products in line with LMHRA's regulations and guidelines, carry on post-market surveillance activities, manage pharmaceutical wastes through incineration, and register and license premises (wholesale Pharmacies/Cosmetics shops/stores).

Headed by Pharm. Teedor Edward Beyslow, Sr., and assisted by Dr. Thomas B. L. Kokulo, the Department comprises of five (5) units, with several managers who head the various units within the Department: Post Market Surveillance Unit, Pharmaceutical Waste Management Unit, Port Inspection Unit, and Premise Licensing Unit & Regional County Offices. The Department has 10 pharmacists, 2 pharmacy technicians, 23 surveillance officers, 27intelligence officers, one (1) accounts officer and one (1) office assistant.

Operational Update on Inspection & Post-Market Surveillance

Data Analysis of Registered Medicines from 2018 through 2021

Trend of Pharmaceutical Premise Registration

Between 2019 to 2020, the Authority registered 61 premises, 51 old premises and 10 new; while between 2020 and 2021, a total of 96 premises were registered; 70 old premises being renewed, and 26 new premises.

Import License Registration

A total of 53 institutions registered for import licenses with 32 of the institutions being old and the other being 21 new institutions.

Exporter's License Registration

A total of 3 Institutions were registered for export license.

Cosmetics Premises

A total of 79 institutions were registered for cosmetic licenses and 62 of them are old institutions while 17 are new institutions.

Good Manufacturing Practice (Desk Audit)

A total of 10 Institutions were received for Good Manufacturing Practice Desk Audit.

Support for Local Manufacturing

The foundation of the distribution of pharmaceuticals and health products since the formation of Liberia has been wholly dependent on importation. Liberia, since its formation has never had a local

pharmaceutical manufacturing company. It can then be concluded that all pharmaceuticals distributed and consumed in Liberia have found themselves on the market through importation. Due to the porosity of the borders of Liberia, importation of pharmaceuticals is replete with plethora of challenges including costs, transportation and the huge importation of substandard and falsified medicines.

Based on the facts stated above, the need for the establishment of local pharmaceutical manufacturing companies in Liberia was demanding. Therefore, in 2018, Global Pharmaceuticals, an under construction local pharmaceutical manufacturing company started prospecting for the construction of a manufacturing company in order to contribute to the supplies of quality pharmaceuticals in the commerce of Liberia.

Prospects for Manufacturing

The construction of the Global Pharmaceuticals Manufacturing Plant has steadily progressed to an appreciable level, about eighty percent (80%) towards completion and utilization.

Machines, Equipment and some Active Pharmaceutical Ingredients (APIs) have all have been imported in the country. The machines and equipment have been installed with proven documents of installation qualification (IQ) provided to the LMHRA. All the machines and equipment installed are pending Operation Qualification (OQ) and Performance qualification (PQ).

The Personnel listing of the Global Pharmaceuticals Manufacturing Company Technical Staff have been submitted to LMHRA which is pending evaluation and licensing of the personnel by the Authority. The Authority has set forth timeline for evaluating, interviewing and subsequently licensing the Technical Staff of the company.

The Authority has issued preliminary Manufacturing License to Global Pharmaceuticals which expired December 31, 2021. Therefore, the mob production is poised to begin as soon as possible.

The submission of documents by Global Pharmaceuticals on the establishment of the manufacturing plant has well been on course. With the submission of documents for processing and approvals, the Global Pharmaceuticals has over the period been committed in submitting documents.

Pictorials of Global Pharmaceuticals Manufacturing Company

Waste Management

Under the Inspectorate & PMS Department, the Waste Management Unit is clad with the authority to quantify, dispose of or destroy pharmaceutical wastes within the territorial limits of Liberia.

Disposal of Wastes

In May of 2019, LMHRA, in collaboration with the CMS and MOH, a pharmaceutical waste assessment and de-junking was carried out at all health facilities to quantify the amount of wastes. The wastes were collected from all health facilities and transported to central locations at the country HQs. Wastes from Lofa, Bong & Nimba Counties were transported to the Forward Logistics Base in CARI, Bong County, for storage under the supervision of the GSA in collaboration with CHEMONICs. Thereafter, the quantified wastes were to be transported to the LMHRA Incineration cite for disposal. However, the final phase, transport of wastes to LMHRA disposal site and subsequent incineration, was not implemented.

Over the years, LMHRA received numerous calls from the County Health Teams across the country, complaining of a huge accumulation of wastes at all facilities, as there has been no disposal for years. To remedy the situation of accumulated wastes across the country, Chemonics approached the LMHRA to begin disposal of these wastes, starting with the Bong FLB. A team comprising of the General Services Agency (GSA), LMHRA, CMS and Chemonics was set up for quantification. After quantification, the wastes were transported to the LMHRA disposal site in Careysburg and disposed of.

During the period under review, over 105,505 Kilos of pharmaceutical wastes were disposed of, both internally and with support from USAID through CHEMONICS, drawn from CMS & the Bong FLB. Additionally, about 15,000kg of pharmaceutical wastes, from JFK, including expired COVID 19 vaccines, were disposed of. Despite the Authority's efforts, more than 10,000 tons of pharmaceutical wastes are still in the counties, awaiting disposal due to lack of resources. These wastes have become a serious health threat and hazard to the rural populations. Government's intervention is urgently needed to dispose of these wastes to free up much needed storage space.

INSPECTING THE BOTTLE CRUSHERS

SORTING OF WASTES

DECANTATION OF FLUIDS





THE MEDIA TOURED THE INCINERATION FACILITIES


ACTIVITY SEVEN: THE INCINERATION OF WASTES







CRUSHING OF EMPTY BOTTLES


4.2.2 Post-Market Surveillance Activities

Market surveillance and control, one of the nine functions of a regulatory authority as defined by the WHO GBT, plays a vital role in ensuring protection of the public from substandard and falsified medical products. Pharmaceutical supply chain in Liberia is vulnerable to the introduction and proliferation of substandard and falsified medicines and health products, considering Liberia's numerous porous borders. Therefore, continuous monitoring of medicines' quality across all levels of the supply chain is critical to ensuring the safety and efficacy of medicines being made available to the public.

Against this background, the quality of medicines and health products remains uncompromised until it reaches the consumers on the Liberian market. LMHRA conducts post-market surveillance with premium on the storage conditions of pharmaceuticals and the conditions under which pharmaceuticals are distributed. The LMHRA's PMS activities remained 'proactive' – activities are meant to anticipate and curtail events before they occur. The primary purpose for the conduct of PMS is to identify and collect information so that any safety signals that arise at any stage of the life cycle of the products are quickly identified and acted upon. Other essential components that were looked into include sale of drugs in local pharmacies and off the shelf within communities, as well as expiration dates.

During the period under review, the Authority carried out several post-marketing activities, including but not limited to the following:

Fighting Falsified Medical Products and Campaigns against Drug Peddling

Fighting falsified medical products represents a major public health challenge. The extent of this pharmaceutical crime is impossible to quantify. However, the WHO estimates that falsified medical products account for 10 % of the worldwide market and for more than 30% in some countries. Falsified medical products give rise to multiple risks because they:

- Endanger patients' health (according to the WHO, falsified medical products may be responsible for a large number of deaths worldwide), it is estimated to hundreds of thousands of deaths a year.
- Feed a parallel and freeloading economy, which is contrary to sustainable development and may present risks to safety, hygiene, the environment, ethics, human rights, etc.

The fight against falsified medical products mobilizes an increasing number of stakeholders, government, and healthcare authorities as well as the police, LDEA and customs officials. The fight against falsified medical products is part of the Authority's commitment to social responsibility in order to meet the needs of all patients. It is also part of our commitment to ensure a vibrant health system in Liberia. LMHRA's Inspectorate and Post-marketing Department takes a harmonized and holistic approach to tackling the issues related to falsified medical products, implemented through various initiatives.

Mop-up Exercises in the Rural Counties

Over 12 mopping exercises were carried on in markets and communities in Bong, Nimba, Lofa, Bomi and Montserrado Counties. During these campaigns, markets street peddlers and market stalls were raided of SF medicines.

Recall of Products

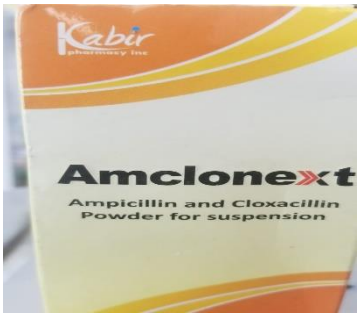
Pharmaceutical products imported in Liberia go through a complete supply chain system with side-by-side regulatory monitoring. LMHRA usually invigorate its technical departments to man the circulation of imported products in the country through the processes of container inspections, laboratory testing, post- market surveillance and the conduct of Pharmacovigilance.

The Post - Market Surveillance Department of LMHRA during the year under review conducted series of post-market surveillance thus leading to the recall of several products. The products re-called from the market were syrups, capsules, tablets, powders for suspension, etc. These products were imported in the country in the country in good condition and fit for consumption. However, with differences in stability zones and storage condition impacting, the quality of the products got compromised while in circulation.

The products re-called from circulation during the year 2021 included:

	PRODUCT	**IMPORTER/LOCAL AGENT**
1.	RONFIT COLD	AMIN PHARMACEUTICALS
2.	RONAKCLOX 500 (Cloxacillin 500mg Capsules)	AMIN PHARMACEUTICALS
3.	RONAKCLOX 500 (Cloxacillin 500mg Capsules)	AMIN PHARMACEUTICALS
4.	RONAKAMOX 500 (Amoxicillin 500mg Capsules)	AMIN PHARMACEUTICALS
5.	AMCLONEXT (AMPICILLIN & CLOXACILLIN Powder for Suspension (100ml)	KABIR PHARMACEUTICALS
6.	Amoxicillin Suspension	ABEER PHARMACEUTICALS
7.	FLUPEX 150 (Fluconazole 500mg Capsules)	B – KAY PHARMACY
8.	AMPICLOX 500 (Ampicillin & Cloxacillin)	L R & SON PHARMACY
9.	OSTEO-ZOX	ABEER PHARMACEUTICALS

Pictorials of recalled Products



4.3 Quality Testing

Overview of the Quality Control Laboratory (DEPARTMENT)

The Quality Control Laboratory is the bedrock of the Liberia Medicines & Health Products Regulatory Authority (LMHRA), with the responsibility to conduct testing of all medicines and health products circulating the commerce of Liberia. Testing is intended to ensure that medicines and health products are safe, of good quality and efficacious for use by the general population of Liberia.

The major functions of the QC Lab are: 1. Laboratory management, 2. Pre and Post market analysis of pharmaceutical products regulated by the Authority as well as analysis of pharmaceutical products on request, 3. Issuance of certificates of analysis for all medicines and health products tested, 4. Development, review and validation of analytical methods and 5. Research into quality swing.

The testing activities at the QC Laboratory are performed via Quality Assurance and Quality Control. The Quality Control Laboratory works in close collaboration with the other three technical departments to ensure that the mandate of the Authority is fully implemented.

The QC Lab was initially designed to run four (4) separate units: 1. Medicines Physico-Chemical Lab, 2. Medical Devices Lab, 3. Cosmetics Lab, and 4. Microbiology Lab. Presently, it is operating only the Physico-Chemical Unit.

STATUS OF THE QC LAB – Where we are and where we have come from

When the LMHRA was established in 2010, the QC Lab evolved as an offshoot of the Laboratory Section of the Pharmacy Division of the Ministry of Health (MOH). Up to 2011, the QC Laboratory operated at a limited capacity of 2-3 staff. Only minilab testing was performed at this time. In 2011, the lab was re-organized with more staff recruited & trained, thus increasing the work force to six (6) which included for the first time, a Quality Control Manager. Also, during this time, quality management system (QMS) was initiated at a lower level – the first set of standard operating procedures (SOPs) were written, and organized compendia tests began. By 2012, QMS was enhanced (i.e., Quality Manual was written with an organogram, quality policy, mission & vision statements included). More staff were recruited and training on the use of advanced analytical equipment (e.g. HPLC) was done with funding and expertise provided by USAID through the Promoting the Quality of Medicines (PQM), an implementing arm of the United States Pharmacopeia (USP) Convention. Work force increased from 6 to 14. By 2018, the workforce grew to 19 personnel, in 2021 the workforce has increased to 30 staff.

Amid all the achievements mentioned supra, the LMHRA QC Lab is challenged with limited facility to conduct pharmaceutical laboratory analysis due to the burning of its laboratory infrastructure and destruction of all available lab commodities on May 30, 2017. The fire was a Class "C" Type Fire as reported by the National Fire Service Bureau in September 2017. This rendered the Authority paralyzed and unable to carry out all its statutory mandates. As a result, measures taken to curb the distribution of sub-standard and falsified medicinal products seemed difficult.

To minimize the proliferation of sub-standard and falsified medicinal products on the market, the LMHRA management secured a facility in the Sophie Community under a sub-lease agreement to temporarily conduct laboratory activities in a residential apartment. In order to expand its operations, and to be more independent as the sub-lease agreement came to expiration by the end of 2020, the LMHRA management constructed a temporary structure on the 4-acre parcel of land in King's Farm, Careysburg for use by the Quality Control Laboratory, housing only one of the four units that are supposed to be in a quality control laboratory. The Lab relocated to King's Farm, Careysburg, Montserrado County to its new facility on the 16th of October, 2020.

Since the current lab facility is limited in terms of lab commodities needed to conduct full compendia testing, we have secured a service contract with an ISO 17025-certified and WHO pre-qualified laboratory (the FDA Ghana), to conduct confirmatory testing when necessary.

Currently, the LMHRA has acquired some needed lab equipment and supplies (glass-wares, chemicals, reagents, etc.) and USP/PQM+ Programs, as well as the World Bank are also supporting the acquisition of additional equipment to begin compendia testing at the newly constructed temporary Quality Control Laboratory in Careysburg. The lab staff have been trained and being readied for the start of the testing.

The New Temporary QCL & Workforce

The Lab has had some level of improvement at its new facility in the area of workforce, leadership, electricity and releasing of customers results on time. The workforce has increased from twenty **seven (27) in 2020 to thirty (30)** staff in 2021. The Lab is presently headed by Pharm. Akoi Fahnbulleh and his Deputy, Pharm. Diana M. Jeator. The Quality Control (QC) Section is headed by Mr. Alexander E. George and ably assisted by Mr. Albert D.Z. Gbusseh, Deputy QC Manager while the QA Section is headed by Pharm. David P. Namakpeh who is ably assisted by Pharm. Matu K. Fayiah-Nyanti, Deputy QA Manager.

The Lab conducts both **Quality Assurance** and **Quality Control** activities in the execution of its mandate, thus ensuring that no substandard/falsified medicinal products proliferate the Liberian market.

QC Lab Activities

During the period under review, the QC Lab continued providing its routine services of conducting quality assurance and quality control on medicines before granting authorization for use on the Liberian market. Additionally, the lab received and tested anti-malarials sampled during the PQM+ sponsored post-marketing surveillance of anti-malarials and MCH products in several counties in Liberia in 2021.

After completion of sampling, the products (mainly injectables) were shipped to Ghana for compendia testing. In order to give hands-on experience and build the capacity of lab staff, three technical staff from the QC Lab joined the USP Ghana Lab team to conduct the testing of the injectables. The two staffers opportune to have traveled were: Samuel S. Toe & Memore S. Palay during phase I, and Mr. Albert D. Z. Gbusseh, Deputy Quality Control Manager, for phase II.

Per the results coming from Ghana FDA, about **43%** of the samples sent to Ghana FDA failed the quality test.

Sample analysis data: Before 2020 vs 2020 - 2021

Per the table of analysis below, there was an increase in the number of samples received for testing in 2020 & 2021 by 19.7%, and a decrease in number of failed products between 2020-2021 by 54.3%.

PERIOD	TOTAL NUMBER OF SAMPLES RECEIVED & EVALUATED	TOTAL # OF SAMPLES PASSED	TOTAL # OF SAMPLES FAILED	% OF FAILED PRODUCT
BEFORE 2020 (2012-2019)	4,988	4,778	210	4.2%
2020 & 2021 (AS OF DEC. 16, 2021)	5,971	5.779	96	1.6%
DIFFERENCE	983	1,001	114	

Resumption of Full Compendia Testing

The resumption of full compendia testing at the QC Lab is yet to begin; preparations are about 75%. With support from USP/PQM+, coupled with the Authority's internal resources, additional lab equipment, reagents and chemicals were acquired to support this effort. The lab staff are presently undergoing internal trainings to be adequately prepared. It is important to note here that full compendia testing will entail more resources, for both power supply to the Lab during testing, overtime for staff, as well as replacement of lab consumables.

4.4 Safety Monitoring (Pharmacovigilance & Clinical Trials)

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) plays a key role in monitoring and ensuring the safety of medicines and health products in Liberia. However, this initiative is carried out through and by its Safety Monitoring department known as Pharmacovigilance & Clinical Trials. The Pharmacovigilance Department's main role in this regard is to support the coordination of the LMHRA's Safety Monitoring System and to disseminate timely information on the safe and effective use of medicines and health products in country. These engagements are done through public awareness, training, follow-up, data collection and analysis, and timely dissemination of drug information as provided for in **Part III, count number 5** of the Act that established the LMHRA.

As it is a known fact that prior to the authorization of a medicine for use, evidence of its safety and efficacy is limited to the results from clinical trials and other clinical researches. This means that at the time of a medicine's authorization, it will only have been tested in a relatively small number of patients for a limited length of time. As such, some side effects or adverse reactions may not be seen until a very large number of people have received the medicinal product and used it over short or longer time periods. This only happens once healthcare professionals begin prescribing the medicinal product for use in healthcare practice.

The Department of Pharmacovigilance & Clinical Trials of LMHRA has the minimal and required knowledge and skills to monitor the safety of medicines and health products, which is one of the core functions of the LMHRA.

COVID Vaccine Monitoring

The collection of Adverse Drug Reaction Reports (ADRs) remains a cardinal function of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) in guiding health policy managers to make informed decisions that will ensure the safety of medicines and health products in the country, as it is stipulated in the LMHRA Act of 2010.

During the period under review, the Department continued monitoring of the COVID vaccine, with visits to the following sites to ensure proper documentation of any unpleasant effects or ADRs by vaccinators during the first phase of the vaccination process:

Phase 1

- Community Sites: Paynesville Town Hall, Monrovia City Hall, Gardnersville Town Hall, Barnesville Town Hall, GSA Yard, Farmington Hotel.

- Market Sites: Waterside Market, Red light General Market, Goba-chop Market, Jacob Town Market, Redemption Day/Gardnersville Market, Jukpan Town Market, ELWA Market, Duala Market, Kuwait Market, Clara Town Market, Old road Market, poultry Market (Red Light), VOA Market, Duport road Market, Rehab Market, Rally Town Market,
- Wroto Town Market, Pepperwood town Market, Barnesville Market, 72nd Market.

- Health Facilities: The ELWA Hospital, SOS Hospital, 14th Military Hospital, St. Joseph Catholic Hospital, James N. Davies Jr. Memorial Hospital, JFK Medical Center, Redemption Hospital, R. H Ferguson Clinic, Bardnersville Health Center, Chocolate City Health Center, Hope for Women International, New Georgia Health Center, Iron Factory, Jamale Medical Solutions, Star of the Sea Hospital, Slip Way Clinic, Cynthia Nelson Clinic, Clara Town Health Center, Anthony Clinic, RCD

Some Observations during the vaccination process:

One incident reported from the GSA Yard on UN Drive: participant reported dizziness, chills and fever and later took Paracetamol to relieve symptoms.

- Soniwien Health Center: The participant reported generalized body pain, shivering and headache and later took Paracetamol and some unknown antibiotics to relieve symptoms. A 47 year old participant complaint about fever and severe headache the night after taking the vaccine and later took ACT, Paracetamol 500mg, fefa and diclofenac 75mg/3ml IM.

- Cynthia Nelson Clinic, Logan Town: Participant 1 reported pain in the arm and cough (sex: Female, Age: 48 yrs. Wt: 64kg); Participant 2 reported Headache, joint pain, vomiting (sex: Female, Age: 40 yrs. Wt: 60kg); Participant 3 reported joint chills and generalized body pain (sex: Female, Age: 43 yrs. Wt: 61kg); Participant 4 reported body pain and headache (sex: Female, Age: 39 yrs. Wt: 63kg); Participant 5 reported fever and body pain (sex: Female, Age: 44 yrs. Wt: 58kg); Participant 6 reported fever, cold and body pain (sex: male, Age: 50 yrs. Wt: 90kg); Participant 7 reported headache and body heaviness (sex: Female, Age: 54 yrs. Wt: N/A); Participant 8 reported fever, dizziness and sleepiness (sex: Female, Age: 45 yrs. Wt: 78kg); Participant 9 reported fever, cold and headache (sex: male, Age: 50 yrs. Wt: 70 kg); Participant 10 reported fever, weakness and pain (sex: Female, Age: 52 yrs. Wt: 45 kg); Participant 11 reported fever, headache and body pain (sex: Female, Age: 33 yrs. Wt: 65 kg)

- Star of the Sea Health Center, West Point: Participant 1 reported generalized body pain, weakness and fever x 3 days. (sex: male, Age: 42 yrs.); Participant 2 reported redness and swollen arm at injection site right after the vaccine was administered and was later taken to the medline clinic. (sex: male); Participant 3 reported fever and generalized body pain (sex: male).

The monitoring teams also visited the following sites in Grand Bassa: Liberian Government Hospital, Well Baby Clinic, CEM Clinic, Tubmanville Clinic, Camphor Mission Clinic, Barcolline Clinic, Big Fanti Town, Zoegar Market, Big Market, Four Houses market, Monrovia Junction market, St. John Clinic, Compound Clinic, Juah Town SOS, Waka Town, Gayegbokun, Jonny Tutue Town, Tepennie Town, LAC Hospital, Compound # 3 Clinic, Barsegiah Clinic, Saturday Town, Wayzohn market, Forest Camp Dolo Town, Timbo Town, Bamboo camp, Gardour Town Clinic, Desoe Town Clinic, Sue Town Clinic, Klien Town, St. John, Larsor Town, Bannie Town, Ceegba Clinic, Compound 4 Clinic, Little Kola Clinic, Zondo Clinic, Libinco Clinic, Gio Town Market, Korkor David Town, Ground Kola, Upper Ginah, Lloidvile Clinic, Little Bassa Clinic, Compound # 1 Clinic, Jacob Larteh Clinic, John Logan, Edina Clinic, Zana Town & Compound market, Dolo Town, Gorwor Town, Senyah Clinic, Morlu Town SDP, Bohn Town, Waka Town, Gborgar Town, John Diggs, Owen grove Clinic, Bokay Clinic, Zangar Town, Beon Town, Chavenklon, Joseph Russ

BOMI COUNTY

Senjeh District
Vaccination Site: LHG, Almadyya Health Center, Yomo Town Clinic,

Klay District
Vaccination Sites: Golodee Clinic, Behsao Clinic

Margibi County

Margibi County Health Team

Kakata District

Vaccination Sites/Fixed Site: C. H Hospital, Kakata Health Center, J.J Korhene Health care Clinic, Plan Parenthood Association Of Liberia Clinic, Modern Medical Clinic, Barcolleh Health Center, BWI Clinic

Mamba-Kaba District:

Vaccination Site: Triple T Clinic, Boys Town Clinic, Excellent Clinic, Marshall Health Center, Schiefflin Clinic, UHTC, Duside Hospital.

Community Pharmacies, Kakata

Ali Pharmaceuticals, Lucky Pharmacy, Nand Pharmacy, Redemption Pharmacy

During the visit to these counties, no major issues were reported as the result of the vaccine.

4.4.1 Clinical Trial Authorization

Clinical trials oversight (CTO) is a cardinal function of every National Regulatory Authority (NRA). During the period under review (2020- 2021), the Clinical Trials Unit at the LMHRA was very engaged with its oversight responsibilities since the outbreak of the Novel COVID-19 in 2020. CTU has been actively monitoring several trials that are currently on-going to ensure regulatory compliance for the safety of participants.

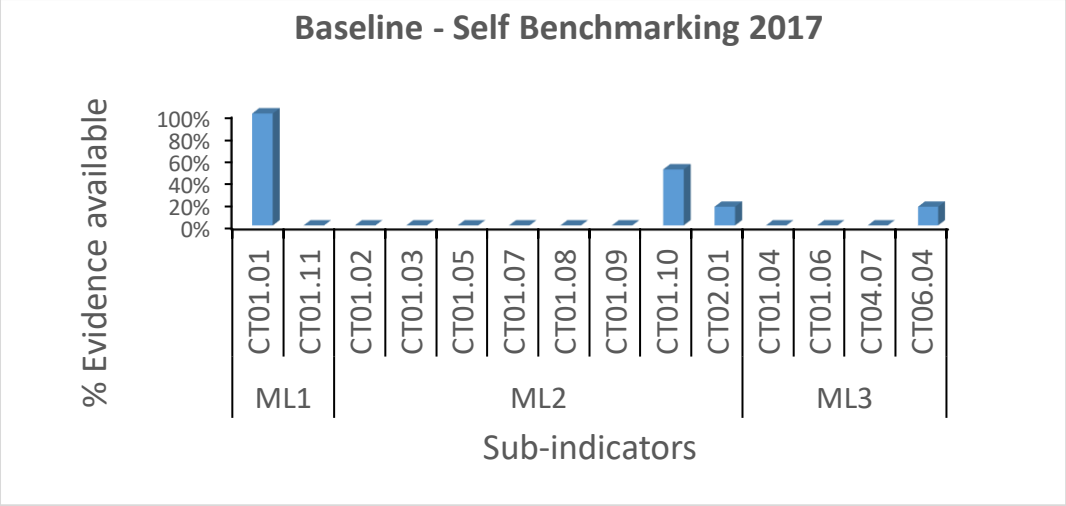
One Good Clinical Practice (GCP) Inspection was conducted, with two Close-Out visits to approve the closure of two clinical trials.

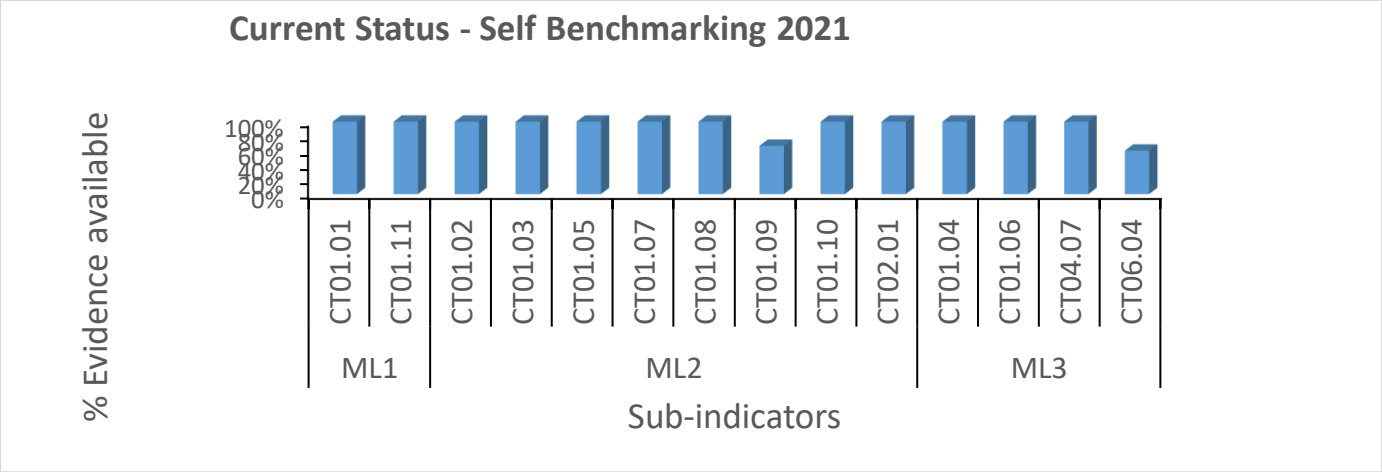
As part of our regulatory functions, the Authority issued three Emergency Use Authorization (EUA) for the AstraZeneca, J&J vaccines and 183,390 doses of Pfizer-BioNTech COVID-19 (BNT162b2, Comirnaty) vaccine, and provided appropriate advice.

As mandated by the LMHRA Act, the Clinical Trials Unit established an independent Scientific Advisory Committee (SAC). This committee was established to provide technical support for the review of clinical trial applications and for post approval safety and compliance issues. The Committee is mandated to review the overall decisions of the Clinical Trials Unit on Clinical Trials Authorization (CTA) and provide expert opinions for final decision on CTA activities.

Over the years, the Authority has made significant strides in Clinical Trials, evidenced by the World Health Organization (WHO)'s Global Benchmark Tool (GBT). The WHO's GBT results show that the LMHRA's Clinical Trial Unit is on track to advance from Maturity Level 1 to Maturity level 3. Please see below trend of the Authority's advancement on Clinical Trials.

The Authority is currently reviewing a clinical trials application on Lassa fever.


Baseline - Self Benchmarking 2017
% Evidence available
100%
80%
60%
40%
20%
0%
CT01.01
CT01.11
CT01.02
CT01.03
CT01.05
CT01.07
CT01.08
CT01.09
CT01.10
CT02.01
CT01.04
CT01.06
CT04.07
CT06.04
ML1
ML2
ML3
Sub-indicators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Sub-indicators

6.0 Summary of Key Achievements

Despite the many challenges faced by the Authority, the following key achievements were made:

1. Improved Regulatory System through the development of Regulations and Guidelines to ensure effective and efficient implementation of the Authority's statutory mandate.

2. Increased logistics through the acquisition of additional vehicles, from the two vehicles inherited to a fleet of eight (8) cars, mainly supporting post-marketing surveillance of medicines, coupled with six (6) motorcycles, also supporting post-marketing surveillance in the Regions and smooth operations at the QC Lab and LMHRA HQ.

3. Increased human resource capacity through the hiring of additional technical and other administrative staff and takeover of 98% of the Authority's payroll by Central Government.

4. Relocation of the Quality Control Laboratory from a rented residential apartment to a newly constructed temporary QC Lab on King's Farm, Careysburg, Montserrado County.

5. About 98% completion of the foundation for the ultra-modern Quality Control Laboratory Complex that will accommodate all the four (4) Units of a Quality Control Laboratory.

6. Improved LMHRA Website.

7. Database developed to support product evaluation and registration, as well as post-market surveillance. The Database has been linked to the LMHRA Website to enable importers have easier access to product registration, waste disposal, etc.

8. Enhanced decentralization of regulatory activities through the strengthening of Region 2 (Bong, Nimba & Lofa); opening of Region 3 (Bomi, Cape Mount & Gbarpolu) and opening of a sub-office at the Roberts International Airport. Negotiations for the opening of another sub-office at the Freeport of Monrovia are in advanced stage with the Management of the National Port Authority.

9. Acquisition of two acres (8 plots) of land in Lower Margibi County for waste disposal.

10. Improved staff welfare:

    a. *Acquisition of 32-seater bus for staff transport at HQ and 18 seater bus for staff in Careysburg*
    b. *Provision of Medical Coverage for staff and dependents*
    c. *Enhanced work-life balance for staff through social activities and other engagements to improve staff performance and productivity*
    d. *Introduction of staff evaluation and appraisal to get staff feedback for improved management system.*

11. Improved and effective customer services through the establishment of a Client Service Center.
12. Improved programs and planning activities through the establishment of a Programs & Planning Unit for donor funds coordination, resource mobilization and reporting and the hiring of a consultant.

7.0 Key Issues & Risks Facing the Authority in Delivery its Objectives

These are the main risks the Authority faces that, should they occur, would have the greatest material effect on the functioning of the Authority as a whole.

By considering such risks the Authority can assess the continuing viability of its strategy and work-plan against changes in circumstance, and make adjustments when necessary. This does not mean it expects the risks to materialize – instead it indicates that these are areas of risk of which it needs to be aware and to consider its response to in order to perform its role effectively.

Risks	Mitigating factors and actions
Failure to meet statutory and public health roles due to reduced funding.	Changes in work practices to increase efficiency. Seek alternative funding through donor support. Engage key stakeholders.
Financial instability	Evaluation of fees structure. Continue to build alternative revenue streams. Engage MFDP for increased budgetary support for operations, especially PMS.
Failure to prevent falsified medical products reaching the public via the illegitimate supply chain.	Increased PMS activities through monitoring Open additional Regional Offices in the Southeast and sub-office at the Ganta Border Post. Increased public awareness campaigns. Increased social media campaigns.
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.	Strengthen 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.
Technical Staff Retention	Improved staff remunerations and allowances Staff capacity building Engage Central Government and other partners for improved staff packages and staff development.
Delay of Board of Directors to approve drafted Guidelines, Regulations and other technical documents.	Improved engagement with Board of Directors Proactive Board of Directors

8.0 Priorities & Outlook for the Next Four (4) Years [2022 – 2025]

From the SWOT and PESTEL analyses, as well as gaps identified in the WHO assessment, WHO benchmarking and the QMS assessment reports of the LMHRA, the Authority's five strategic goals for the next five (5) years are:

- *Establish an effective and efficient medicines and related products regulatory system*
- *Strengthen the Quality Management System (QMS) and Undertake Operational Research activities to support regulatory functions*
- *Effective Information Management Systems developed and implemented.*
- *Promote partnership, cooperation, collaboration and decentralization*
- *Recruit, develop and maintain adequate Human Resource (HR) Capacity*
- *Mobilize infrastructural, monitoring and financial resources to ensure sustainability*

For each goal, specific objectives have been established, which are measurable, and activities to achieve the objectives developed. Timelines have been set for each of the activities, which have been used to design an implementation framework.

8.1 Technical Regulations

The LMHRA will continue to strengthen the following key activities; product registration, facility registration, market surveillance, product quality monitoring, product quality testing through compendia testing, safety monitoring of regulated products and clinical trials.

8.2 Administration

Estate Management

In the 2022 Fiscal Year Budget, the Authority has earmarked the acquisition of parcels of land in each Region, including the RIA Sub-Office in Margibi County, for the construction of Regional Offices and accommodation for assigned staff.

While we continue to await resources for the continuation of the construction works on the ultra-modern Quality Control Laboratory Complex from donors and partners, the Authority will endeavor to continue construction of the structural frame of the complex with internal revenue, and also call upon the GOL for its support, while also seeking resources for the acquisition of at least one acre of land for the construction of its National Headquarters.

The Authority will also endeavor to fence the two acres of land purchased in Lower Margibi County for Waste Disposal and relocate the four (4) incinerators.

Transport Management

To augment its fleet in support of its operational activities, especially for the Regional Offices and post-market surveillance, as well as Directors, the Authority will procure additional vehicles and motorcycles.

9.0 Way Forward

During the coming years, the LMHRA will continue to intensify core regulatory activities of product registration, premise licensing, market surveillance, full compendia testing of products, clinical trials and safety monitoring. Additionally, the Authority will:

- Continue to support the local pharmaceutical importers through capacity building and will pursue donor support in this regard towards the strengthening of same;
- Pursue the Civil Service Agency for recruitment of additional staff;
- Work with the Ministry of Finance and Development Planning for improved wages and salaries of its employees;
- Procure additional logistics – vehicles and ICT equipment to enhance operational efficiency;
- Complete the Construction of the ultra-modern Quality Control Laboratory Complex and relocate the QC Lab to its permanent building;
- Construct a residential building at the QC Lab facility to support full compendia testing of medicines and health products;
- Open two additional regional offices in the Southeast: Zwedru & Harper;
- Construct Regional Office & Residential Buildings, including the sub-office at the Roberts International Airport;
- Develop the Waste Management site in Lower Margibi County and source necessary resources for the acquisition of new incinerators for treatment of pharmaceutical wastes;
- Pursue ISO accreditation for the LMHRA Laboratory and maintain QMS certification;
- Continuation of the focus on winning public confidence through increased engagement and responsiveness to their needs;
- Zero Tolerance on street peddling of pharmaceutical products through community engagements;
- Intensified Public Education – The LMHRA will intensify public education and sensitization activities in all counties of the country. This is to ensure better understanding of our mandate and encourage self-regulation among consumers. We require the support of the media to complement our efforts.

10.0 Conclusion

Conclusively, the LMHRA is a government subsidized Authority and is definitely 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 affected by overall economy and purchasing power of the country.

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 and strategies are likely to gather a new momentum of implementation. Currently, part of the operational costs 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, which will affect the strategic direction of the LMHRA.

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 generally high illiteracy 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; which calls for improved collaboration with Government agencies within the Health and Regulatory Sectors, partners, both locally and in the region, as well as increased budgetary support to the Authority and not considering the Authority as a revenue agency, coupled with increased and improved resource mobilization efforts.

Notwithstanding, 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, not hindrance to our work. That is why for the coming years, it is our plan to identify a wide range of journalists and media practitioners, build their capacities to support the works of the Authority.

The presence of other agencies in the regulatory space and the perceived overlap of function also poses a threat to the LMHRA. 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. The Authority will exert every effort possible for improved and strengthened cooperation and collaboration with all relevant Government line Ministries and Agencies, as well as stakeholders within the Pharmaceutical Sector for improved regulation of medicines and health products within the borders of Liberia.

While we regulate medicines and other health products, expired and adulterated medicines pose a threat to the entire population. Storage facilities are filled to capacities in all counties with these expired products that need to be urgently treated and disposed of appropriately. There is need for an urgent action by National Government, our partners and stakeholders to avoid the health hazards and other threats they pose to our environment.

Finally, a well-functioning health care system depends upon the availability and affordability of medical products that are safe, effective and of consistently assured quality. The Liberia Medicines and Health Products Regulatory Authority (LMHRA) is the key Government institution that promotes access to quality-assured medicines and combat Sub-standard and Falsified medical products. The LMHRA's operations have direct impact on diagnostic and treatment outcomes for almost all disease conditions. LMHRA is paramount to the attainment of improved Health System with positive health outcomes within the Country.

Despite considerable progress made since the establishment of the LMHRA to strengthen medical product regulatory systems, capacity of the LMHRA is still insufficient and indeed, sometimes a barrier to access to quality medicines. Increased investments in regulatory system strengthening (RSS) are needed.

11.0 Appendixes

APPENDIX I - List of Board Members

Sn	***Name***	***Institution***
1	Hon. Hasipha C. Tarpeh	Board Chairman
2	Hon. Keturah Smith-Chineh	Secretary, LMHRA
3	Hon. Edrick F. Noah	Ministry of Justice
4	Hon. Joseph S. Tamba	Consumer Group
5	Hon. Morris K. Saryon	Ministry of Commerce
6	Hon. Luke L. Bawo	Pharmacists Association of Liberia
7	Hon. Joseph J. Coleman	LMDC
8	Hon. Joseph Anderson	Ministry of Agriculture
9	Hon. Plenseh Paye-McClain	School of Pharmacy
10	Hon. Joseph Weah	Pharmacy Board
11	Hon. John T. Harris	Chief Pharmacist
12	Hon. Saa Samoi	Head of Customs/LRA

APPENDIX II - List of Management Team Members

Sn	Name	Department	Position
1	Pharm. Keturah Smith-Chineh	Management	Managing Director
2	Dr. Flomoku G. Miller	MD's Office	Technical Advisor
3	Pharm. Teedor E. Beyslow, Sr.	Inspectorate & Post-Market Surveillance	Director & Inspector General
4	Pharm. Patricia Quaye-Freeman	Evaluation & Registration	Director
5	Pharm. Akoi Fahnbulleh	Quality Control Laboratory	Director
6	Dr. James D. K. Goteh	Pharmacovigilance & Clinical Trials	Director
6	Steve N. Bundor	Administration & Finance	Comptroller
7	Antoinette N. Mulbah	Administration & Finance	General Administrator
8	Hawa Tambah	Administration & Finance	Procurement Manager
9	John J. Weah, Jr.	Programs & Planning	Consultant
10	Dr. Thomas B. K. Kokulo	Inspectorate & Post-Market Surveillance	Deputy Director
11	Dr. Nuku B. Williams	Pharmacovigilance & Clinical Trials	Deputy Director
12	Pharm. Mary Jalloh-Tozo	Evaluation & Registration	Deputy Director
13	Pharm. Diana Jeator	Quality Control Laboratory	Deputy Director
14	Dr. Margaret Massaquoi	Pharmacovigilance & Clinical Trials	Manager, Pharmacovigilance
15	Dr. Juwe Kerkula	Pharmacovigilance & Clinical Trials	Manager, Clinical Trials
16	Dr. Kwo-A-Kpeh Dolo	Inspectorate & Post-Market Surveillance	Regional Coordinator
17	Pharm. Morrison Tamba	Inspectorate & Post-Market Surveillance	Regional Manager, Region 3
18	Pharm. Anthony Baysah	Inspectorate & Post-Market Surveillance	Regional Manager, Region 2
19	Pharm. John Cleeme	Inspectorate & Post-Market Surveillance	Manager, RIA Sub-Office
20	Alexander E. George	Quality Control Laboratory	Manager, Quality Control
21	Albert Gbusseh	Quality Control Laboratory	Dep. Manager, Quality Control
22	Pharm. David P. Namapheh	Quality Control Laboratory	Manager, Quality Assurance
23	Pharm. Martu Fayiah-Nyanti	Quality Control Laboratory	Dep. Manager, Quality Assurance
24	Momoh Siryon	Administration & Finance	Manager, Communications
25	Emmanuel Grimes	Administration & Finance	Supervisor, ICT
26	Rev. Joseph M. Redd	Administration & Finance	Director, Human Resources
27	Rev. Arthur Gbotoe	Administration & Finance	Dep. Director, Human Resources
28	Khalifa Kromah	Administration & Finance	Supervisor, Maintenance & Logistics
29	Del T. Nagbe	Programs & Planning	Dep. Manager
30	Pharm. Emmanuel Willie	Evaluation & Registration	Manager, Medicines Research, Records & Data
31	Dr. Sumo K. Maiwo	Evaluation & Registration	Manager, Medicines Evaluation & Registration
32	Pharm. Louis Mulbah	Evaluation & Registration	Manager, Cosmetics
33	Abraham K. Morris	Administration & Finance	Assistant Manager, Communications
34	Dr. Akoi Bazzie	Inspectorate & Post-Market Surveillance	Manager, Port Services
35	Dr. Jonathan Luciny	Inspectorate & Post-Market Surveillance	Manager, Waste Management
36	Pharm. Paul D. Y. Higgins	Inspectorate & Post-Market Surveillance	Manager, Post-Market Surveillance

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