

# Support to Finalize the Draft Law Establishing a Liberian Medicines and Health Product Regulatory Authority

Monrovia, Liberia  
October 28 - November 6, 2009

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## *Trip Report*

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## **Promoting the Quality of Medicines Program**

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## **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## **Abstract**

In November 2009, a PQM team traveled to Liberia to attend a stakeholders meeting organized by the Liberian Medicines Regulatory Authority (LMRC). The meeting provided an opportunity for final input and comments on the "Draft Zero" (final version) of the proposed legislation to be submitted to the Minister of Health to establish a new medicines regulatory authority in Liberia. USAID and PQM's main focus was on ensuring that the final draft maintained the necessary provisions to make the future Liberian Medicines Regulatory Authority operational and effective, in line with World Health Organization (WHO) guidelines and good regulatory practices. The PQM team also assessed the site for a future quality control (QC) laboratory and worked with the LMRC, USAID, and the national Malaria Control Program to plan appropriate drug quality surveillance activities for FY10.

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## **Key Words**

LMRA, LMRC, Legislation, Good Regulatory Practices, PQM, drug quality control, antimalarial medicines.

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- Mr. Christopher McDermott, for participating in the opening of the workshop and for making valuable remarks, and Dr. Kassahun Belay and Mr. Kaa Williams, for their great support and valuable contribution to the process.
- The PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.
- PQM AOTR Mr. Anthony Boni at USAID Washington for his guidance and helpful insights throughout the preparation stages of the workshop.

## ACRONYMS

AOTR	Agreement Officer's Technical Representative
DQ	Drug Quality
DQI	Drug Quality and Information Program
LMRA	Liberian Medicines Regulatory Authority
LMRC	Liberian Medicines Regulatory Committee
MCP	Malaria Control Program
MOH	Ministry of Health
PMI	President's Malaria Initiative
QA	Quality Assurance
QC	Quality Control
USAID	United States Agency for International Development
PQM	Promoting the Quality of Medicines Program
USP	U.S. Pharmacopeia
WHO	World Health Organization

## **Background**

The Drug Quality and Information (DQI) Program, implemented by the United States Pharmacopeia (USP), conducted an assessment of drug quality control and drug quality assurance capabilities of the Republic of Liberia in November 2008. Based on that assessment, DQI concluded that the first priority in building a functioning quality assurance system was to support the process to establish a new medicines regulatory authority.

In February 2009, DQI and the Liberian Medicines Regulatory Committee (LMRC) organized a workshop with representatives from the World Health Organization (WHO) and USAID to finalize a first draft of the legislation. The draft was circulated and reviewed by Liberian government authorities and stakeholders in the months thereafter.

As of September 2009, all DQI activities in Liberia fall under the successor program, Promoting the Quality of Medicines (PQM), also implemented by the U.S. Pharmacopeia.

## **Purpose of Trip**

Ms. Coignez and Dr. Smine (hereafter, the “PQM team”) traveled to Monrovia for a two-day workshop to discuss the legislation and finalize the “Draft Zero” (final version) to be submitted to the Minister of Health. The team also:

- Met with the USAID Mission to provide an update on the progress made and discuss proposed activities for FY10
- Met with the Malaria Control Program to discuss PQM program activities
- Worked with the Liberian Medicines Regulatory Committee (LMRC) on planning drug quality activities

## **Source of Funding**

This activity was funded by the USAID Mission in Liberia and the PMI program.

## **Overview of Activities**

### ***Meeting with USAID Mission***

Dr. Smine met with Dr. Kassahun Belay and discussed program progress and proposed activities for FY10. Dr. Belay requested that PQM focus primarily on carrying out basic antimalarial drug quality control activities. USAID and PQM agreed that the support for the legislative process would end with the planned stakeholder’s workshop.

Dr. Smine proposed that PQM support a team from the Malaria Control Program (MCP) and the LMRC to collect and test samples of antimalarial medicines from Monrovia. PQM will provide the sampling team with clear sampling guidelines and train MCP and LMRC scientific staff on the use of the already available Minilabs<sup>®</sup> for basic analytical testing.

Ms. Veerle Coignez met with Mr. Christopher McDermott at the beginning of the trip to discuss the status of the draft legislation. USAID and PQM had concerns about some changes made to the February draft, which had been developed with USAID support. The PQM Team agreed to discuss all concerns about the changes made during the workshop and to help ensure that the final draft of the legislation would be in line with good regulatory standards.

Ms. Coignez briefed Mr. McDermott at the end of the week on the accomplishments and submitted a proposed work plan for PQM activities in FY10.

### ***Meeting with MCP***

The PQM team met with the deputy manager of the MCP and discussed the plan to collect and test antimalarial medicines from Monrovia. He supported the idea of conducting quality checks on antimalarials to establish a baseline since the program does not have any medicine quality data. The lack of drug quality control capacity and drug regulations in Liberia makes the country vulnerable to the threat of fake and substandard medicines. The deputy manager also agreed to allow MCP pharmacists to be involved in all future PQM activities in drug quality. The PQM team assured the deputy manager that PQM will work very closely with MCP in the future and invited MCP to attend the LMRC workshop and contribute to finalizing the zero draft legislation.

### ***Meetings with LMRC***

The PQM team met several times with the LMRC team to discuss the logistics and preparation for the stakeholders' workshop.

PQM also organized a roundtable discussion with the LMRC, MCP, and the Board of Pharmacy about initiating activities focused on quality control of antimalarial medicines. The group agreed that a team of pharmacists from LMRC, MCP and the Board of Pharmacy would collect antimalarial medicines from greater Monrovia.

The sampling will target antimalarials commonly used by the public and will cover all three sectors (public, private, and informal). Based on the information gained, PQM will develop a sampling plan and detailed guidelines on how to proceed. When the sampling is completed, a PQM team will come to Monrovia to train LMRC and MCP staff using Minilabs<sup>®</sup> as stated above. This is tentatively planned for January/February 2010. PQM will procure and ship all required reference standards and reagents and will assist the Liberian counterparts as they test the samples collected. This will provide an opportunity for PQM to monitor the impact of the training and to provide immediate feedback. The exercise will also help establish a baseline on antimalarial drug quality in Monrovia. The results will be presented in a report to all relevant stakeholders.

### ***Visit to QC Laboratory Site***

The PQM team visited the facility where LMRC is planning to set up a small interim QC laboratory. The facility is currently part of the John F. Kennedy teaching hospitals. If upgraded correctly, this facility can be used as a basic QC lab under LMRA. The PQM team assessed the site and compiled a list of upgrades that are required to make the

facility operational. An overview of identified tasks to ready the facility is attached in *Annex 1*. It is recommended that the LMRC start work immediately in order for this site to be ready for the training and basic tests planned for late January 2010.

***Stakeholders Workshop on Draft Legislation to Establish a Liberian Medicines Regulatory Authority (LMRA)***

The two-day workshop took place on Nov 4-5. The first day was reserved for representatives of the public sector, while representatives of the private sector were invited to join on the second day. The workshop was well attended on both days. The list of the participants, provided by the LMRC secretariat, is attached in *Annex2*.

The workshop opened with remarks from the chair, Ambassador C. Bright Parker. Mr. Chris McDermott, the USAID Health Team Leader, also spoke.

The main purpose of the first day was to review the entire draft. The majority of participants actively contributed to the discussion and presented their comments. Two U.S. lawyers were present at the meeting – one assisting the Ministry of Justice and the other assisting the Ministry of Health – and their contributions were very valuable.

The draft had undergone changes since February 2009. USAID and PQM were concerned that some changes would affect the roles and responsibilities of the managing director of the LMRA and hence the ability of the Authority to function as an independent technical agency. For USAID and PQM, it is important that the managing director be responsible for managing the day-to-day work, including decision making on drug registration, *without* the need for approval from the Board of Directors for every action. The discussion on the roles and functions of the managing director and managers of the LMRA vs. the responsibilities and roles of the Board of Directors took most of the day. In the end, there was common agreement to restore the balance of power between the Board of Directors and the managing director, with the draft now explicitly ensuring that the managing director and his team have the mandate to do the technical work of the LMRA without needing to secure approval from the Board.

At the end of the day, the amended version was accepted unanimously. The Final Draft (Zero Draft) of the LMRA legislation is attached in *Annex3*.

The second day was open to participation from the private sector. Several wholesalers and private pharmacists provided valuable feedback. The wholesalers expressed their satisfaction, stating unambiguously that the law is highly needed. The genuine wholesalers and pharmacists are frustrated with having illegal operators in the market, and they look forward to the introduction of drug regulations and quality control enforcement in Liberia.

## **Conclusion**

The PQM team achieved the major objectives of the trip:

- The trip allowed close coordination with USAID and local partners on (i) the direction of the draft legislation and (ii) the activities for the FY10 work plan. At the end of the trip, a draft work plan was presented to the USAID Mission.
- PQM will focus mainly on quality control of antimalarial medicines in the course of this FY. To achieve this, PQM will coordinate sampling of antimalarial medicines in the greater Monrovia area and will train LMRA and MCP staff on basic testing using the Minilabs<sup>®</sup> available at the National Drug Services.
- PQM will support the LMRC in upgrading the interim lab facility, to be used until the new QC lab can be built.
- The workshop to review and finalize the draft LMRA legislation was successful. A draft law that is in line with good regulatory practices is ready for the Minister of Health to submit to Parliament and the President of Liberia. It is expected that the President will issue an executive order on the basis of the draft to allow for the establishment of the LMRA pending adoption of the law by Parliament.

Given the current enthusiasm of the private sector for a Medicines Regulatory Authority to establish control over the pharmaceutical sector in Liberia, the PQM team strongly recommends that the USAID Mission consider supporting follow-up activities that can have a visible impact in the short term. Concretely, it is recommended that the USAID Mission support building up the existing inspection team to enable corrective actions against substandard and counterfeit medicines identified during post-marketing surveillance. This is likely to secure ongoing support from the private sector, which is key to introducing transparency and good governance in the pharmaceutical sector. The support gained through these kinds of actions and impact are also likely to provide an effective counterweight to the likely emergence of frustrations if it takes the LMRA several years before it is able to undertake medicines registration on technical grounds in a timely fashion.

## **Action Items and Next Steps**

- LMRC will contract out the work necessary to upgrade the QC laboratory facility, using the recommendations made by PQM, in order to have the facility ready for the Minilab<sup>®</sup> training (tentatively scheduled for January/February 2010)
- PQM will finalize the sampling plan and all relevant guidelines to collect antimalarial samples from Monrovia and its suburbs
- After the sampling plan and guidelines have been finalized, the LMRC and MCP will begin sampling in December 2009/January 2010
- PQM will procure and ship all required reference standards and reagents and prepare for training LMRC and MCP staff on basic tests using Minilabs<sup>®</sup> (tentatively scheduled for January/February 2010)
- PQM will assist Liberian counterparts as they test the samples collected. The results will be presented in a report to all relevant stakeholders
- PQM will continue to monitor the progress of the draft legislation

## **Work Needed to Upgrade the Future QC Laboratory**

### **1. Description**

The front door opens into “Room 1,” which is separated by a low wall and glass partition from “Room 2” on the left, where there is a sink. On the right, “Room 1” gives access to a narrow corridor, which leads to a small “Storage Room”, a small non-functioning “Bathroom”, and an “Office.” See the schematic description below.

### **2. General Repairs/Rehabilitation Required**

- Replace outer top roof; it is leaking as evidenced by water spots on interior ceiling
- Replace interior fake ceiling throughout the space
- Improve the electrical wiring, with at least three sockets at medium height on each side of the rooms
- Replace the windows with sliding aluminum to save energy and limit dust
- Install a quality air-conditioning system in all rooms
- Fix bathroom, including toilet
- Replace the carpet and fix the window in the office
- Paint all the rooms in a light color
- Place large vinyl tiles on the floor (easy to clean) and fill all holes
- Install quality locks with keys on all lab doors

In addition to the general work mentioned above, there is need for:

### **3. The Main Entry**

- Install a double entry so that the opening of the front door does not interfere with the ongoing biochemical work. This will also save on energy.

### **4. Room One**

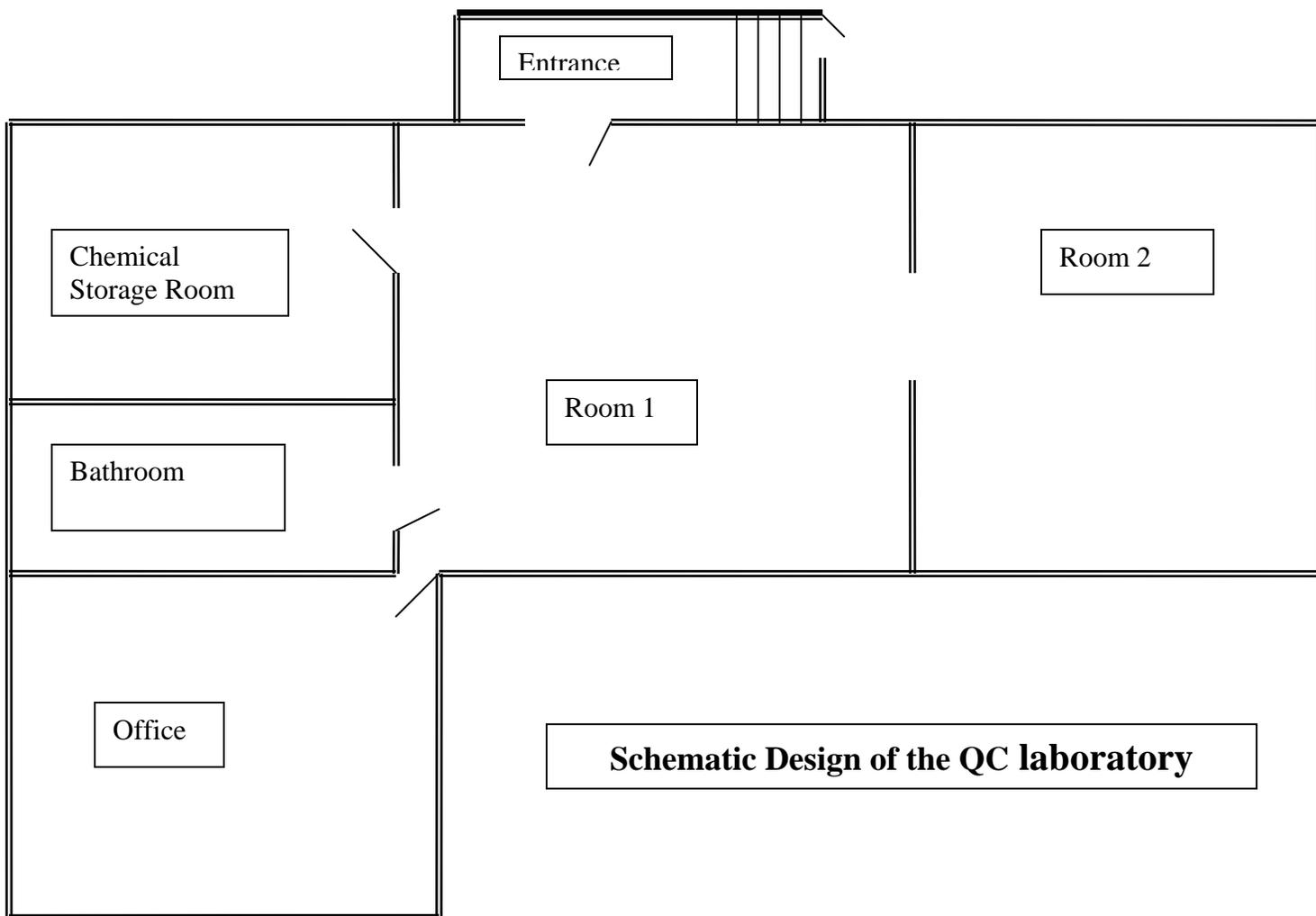
- Install an aeration system (revolving fans on the outer walls)
- Repair the sink and check the plumbing
- Install a small dishwasher for cleaning glassware
- Fix cabinets (under and upper) and benches and install shelves

### **5. Room Two**

- Install an aeration system
- Install a hood with exhaust going up and out of the lab
- Add a work station/bench (use table bench with glass tops)
- Fix cabinets and install shelves, where appropriate

### **6. Storage Room**

- Close wall opening into Room 1
- Install small air conditioning and aeration system
- Install shelves to three walls of the storage room
- Fix the door



**STAKEHOLDERS CONFERENCE ON THE DRAFT ACT OF THE LMRC**

**LIST OF PARTICIPANTS  
(Provided by LMRC Secretariat)**

1. House Chairman on Health
2. Senate Chairman on Health
3. House Chairman on Executive
4. Senate Chairman on Executive
5. Rep. Ministry of Justice
6. Rep. Ministry of Finance (Custom)
7. Legal Council / Ministry of Health
8. Rep. Ministry of Commerce (Standards)
9. Rep. Christian Aid Ministry
10. Rep. ELWA Hospital
11. Rep. Ministry of Information
12. Rep. Liberia Marketing Association (LMA)
13. Rep. PHARMSAL (Pharmaceutical Students Association of Liberia)
14. Rep. LMDA (Liberia Medical & Dental Association)
15. Rep. Pharmaceutical Business Association of Liberia
16. Acting Deran, School of Pharmacy
17. Pharm. Clavenda Bright-Parker
18. Pharm. Hasipha C. Tarpeh
19. Pharm. Seth Akiti
20. Pharm. Tijli Tyee
21. Pharm. Joseph S. Weah (Registrar, Pharmacy Board of Liberia)
22. Pharm Osbert K. Newlands
23. Pharm. Beyan K. Johnson
24. Pharm. David Sumo
25. Pharm Thomas Wolapaye
26. Pharm Kpakama Kromah
27. Intern Pharm. Jackson Togba
28. Head, Drug Enforcement Agency
29. Dean, School of Medicine
30. President, Nursing Association
31. Rep. Liberia Business Association (LBA)
32. Rep. Catholic Hospital
33. Rep. Redemption Hospital
34. Rep. John F. Kennedy Hospital
35. Rep. Firestone Hospital
36. Rep. SOS Hospital
37. Mr. Jolo Mulbah
38. Chief Medical Officer/MOH
39. Deputy Ministry for Planning and Research/MOH

**The Liberia Medicines and Health Products Regulatory Authority (LMHRA)  
Proposed Act 2009 to the National Legislature**

**PREAMBLE**

WHEREAS it is recognized that health care plays a significant role in securing well-being and productivity of the people, as well as economic development of the country, and it is recognized that medicines and health products play a vital role in the health care of humans, as well as animals;

WHEREAS it is found necessary to ensure the quality, safety, and efficacy of medicines and health products used in the Republic of Liberia;

WHEREAS it is incumbent upon the Government of the Republic of Liberia to promulgate laws to ensure good quality, safe and efficacious medicines and health products for the enhancement of quality health services in the country; and

WHEREAS, to achieve these ends, it is found necessary to establish an effective Medicines and Health Products Regulatory Authority;

THEREFORE, in keeping with the Constitution of the Republic of Liberia, it is hereby proclaimed:

**PART ONE  
General Provisions**

**Title**

This Act shall be cited as the “Liberia Medicines and Health Products Regulatory Authority Act, 2009” No. \_\_\_\_\_.

**Purpose of the Act**

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.

## **Definitions**

In this Act, unless there is anything abhorrent in the subject or context:

**“Medicine”** means any substance or mixture of substances intended for use in:

the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in man or animal, or

restoring, correcting, or beneficial modification of organic or mental functions in man or animal.

This shall include traditional medicines, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals, but not health products as defined herein.

**“Narcotic Drug”** means any substance subject to control according to the Single Narcotic Drugs Conventions, 1962, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a narcotic drug.

**“Psychotropic Substance”** means any substance subject to control according to the Conventions on Psychotropic Substances, 1971, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a psychotropic substance.

**“Cosmetic”** means any preparation intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance without affecting the body’s structure or functions.

**“Health Product”** includes:

**“Medical Device,”** which means any instrument that is not a medicine, as defined herein, that is intended for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring, correcting, or beneficial modification of organic or mental functions in human or animal; and

**“Medical Supply,”** which means any article that is intended for diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring, correcting, or beneficial modification of organic or mental functions in human or animal. This includes suturing

materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and X-Ray film and other similar articles.

**“Packaging Material”** means any article that may be used for filling, inserting, wrapping, or packing medicines and health products. The primary package is the container directly in contact with the product, and the secondary package is whatever covers the primary package. This includes packaging of excipients and active pharmaceutical ingredients.

**“Label”** means any material that is printed or affixed to packaging material, including a leaflet that provides the necessary information about a medicine.

**“Counterfeit Medicine”** means a medicine that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit products may be branded or generic medicines, and may include products with the correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake packaging materials.

**“Substandard Medicine”** means a medicine that does not comply with the applicable quality standards adopted by the Authority.

**“Adulteration”** means the causing or doing any act that affects the purity, potency, strength, or content of a product, so that it is not of good quality, safe and effective, or not what it purports to be.

**“Authority”** herein means the Liberia Medicines and Health Products Regulatory Authority established under PART TWO Section I.1 of this Act.

**“Radiopharmaceutical”** means an article intended for diagnostic or therapeutic use that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear radiation.

**“Pharmacovigilance”** means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.

## **PART TWO**

### **Administrative and Organizational Provisions**

#### **Establishment of the Authority**

Pursuant to the Public Authorities Law, there is hereby established by this Act a body to be known as the Liberia Medicines and Health Products Regulatory Authority, herein referred to as the “Authority.”

The Authority shall be autonomous and accountable to the President of the Republic of Liberia.

The Authority shall have its head office in the capital, and may establish county offices, contingent on its necessities and requirements.

### **Functions and Duties of the Authority.**

- The functions and duties of the Authority shall include:
- 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 TWO Section II.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 its functions, the Authority shall apply principles of Good Regulatory Practices, which include but are not limited to:
  - Ensuring transparency and accountability;
  - Promoting stakeholders' participation and building consensus; and
  - Observing a code of conduct and managing any potential conflict of interests.

### **Organization of the Authority**

The Authority shall have:

- A Board of Directors;
- A Managing Director, who is responsible for running the Authority;
- Managers heading different units of the Authority; and
- A Managing Committee composed of the Managers, with the Managing Director as its head.

## **Board of Directors**

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

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

- A qualified health care professional, 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 Association;
- A representative of the Pharmaceutical Association of Liberia;
- A veterinarian;
- A representative of an appropriate consumer interest group or association; and
- The Managing Director of the Authority, who shall serve as secretary to the Board of Directors, and who shall be a non-voting member.

The Board of Directors shall have the powers and duties to:

- Approve regulations for implementation of this Act;
- Approve the strategic plan of the Authority;
- Approve the annual work plan and budget of the Authority;
- Review the quarterly reports presented by the Managing Director;
- Monitor and evaluate implementation of this Act;

- Approve the individuals recommended to be Managers by the Managing Director;
- Establish committees whenever it deems necessary; and
- By a two-thirds (2/3) majority vote of the full membership during a regular meeting of the Board of Directors, remove Managers or recommend to the President for removal any member of the Board of Directors, in either case only for acts incompatible with the Authority's or Board's rules or regulations.
- Without prejudice to the provisions of this Act, the Board of Directors shall issue its own rules of procedure for the conduct of meetings, and establish a code of conduct governing the activities of the Board and members of the Board.

### **The Managing Director of the Authority**

- The Managing Director shall be the administrative and technical head of the Authority, and shall direct and administer the day-to-day activities of the Authority.
- The Managing Director shall recommend the Managers to be appointed by the Board of Directors.
- The Managing Director shall in consultation with his Managers exercise the following duties:
  - Exercise the functions and duties of the Authority specified under PART TWO, Section II.1 of this Act;
  - Administer personnel of the Authority consistent with the basic principles of the Liberia Labor Law;
  - Prepare and submit to the Board of Directors the annual plan and budget of the Authority and implement upon approval;
  - Effect payments in accordance with approved budget in line with the approved annual plan of the Authority;
  - Submit quarterly reports to the Board of Directors;
  - Establish technical committees, including a medicines evaluation committee, with the approval of the Board of Directors;
  - Approve registration of medicines and health products upon recommendation of the medicines evaluation committee;
  - Approve licenses for pharmaceutical premises as referred to in PART TWO Section II.1.b.

- The Managing Director may delegate part of his functions to other employees of the Authority to the extent necessary for the efficient performance of its activities.
- In the event of the occurrence of a vacancy emanating from the death, resignation, retirement or dismissal of the Managing Director, the President of Liberia shall designate one of the other Managers as Acting Managing Director, pending the appointment of the Managing Director proper.

### **Administration of the Authority and Delegation of Powers and Duties**

The Authority shall have the power to determine the level of officers and employees deemed required, and to establish the positions thereof to optimize the performance of the Authority's functions.

By general or special order in writing, the Authority may temporarily delegate any part of its powers and duties to other government agencies, to the extent the Board of Directors deems it necessary for the efficient performance of the Authority's functions. Such delegation shall be limited to a specific time period, and restricted to those functions specifically identified in the written order of delegation.

### **Funding**

The funds of the Authority shall be drawn from the following sources:

- Budget allocated by the government;
- Fees collected for services provided; and
- Any other authorized sources that are devoid of any conflict of interest.

The Authority shall open and maintain bank accounts in the name of the Authority.

### **Books of Accounts**

The Authority shall ensure that its Financial Department keeps complete and accurate books of accounts in accordance with any applicable financial laws of Liberia, whether currently in existence or enacted in the future, and Generally Accepted Accounting Principles (where applicable). The Authority shall also ensure that its Internal Audit Unit conducts regular audits to guide compliance with such financial laws and accounting principles.

The books of accounts and other financial documents of the Authority shall be audited annually by the Auditor General of the Republic of Liberia.

The Board of Directors may also choose to engage the services of an external auditor.

## **PART THREE**

### **Specific Provisions**

#### **Registration of Medicines and Health Products**

No medicine or health product, whether manufactured locally or imported, shall be put into use in the Republic of Liberia unless it is duly registered by the Authority.

Medicines registration licenses shall be granted by the Authority. The registration shall be done in accordance with regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses.

#### **Control of Import, Export, and Transit of Medicines and Health Products**

No person/organization shall import, export, or transit into or out of the Republic of Liberia any medicine or health product, unless the product is duly registered by the Authority, and the person/organization has been issued a license or permit by the Authority.

The conditions of issuance of a license or permit for the import, export, or transit of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses or permits.

#### **Supply, Storage, Distribution, and Sale of Medicines and Health Products**

No person/organization shall supply, store, distribute or sell any medicine or health product, unless the product is duly registered by the Authority, and the person/organization has been issued a license or permit by the Authority.

The conditions of issuance of a license or permit for the supplying, storage, distribution, or sale of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses or permits.

#### **Manufacture of Medicines and Health Products**

No person/organization shall manufacture any medicine or health product, unless the person/organization has been issued a license or permit by the Authority.

The conditions of issuance of a license or permit for the manufacture of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses or permits.

## **Clinical Studies**

No person/organization shall conduct clinical studies in humans or animals of medicines or health products without the authorization of the Authority.

The conditions for authorization of such clinical studies shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such authorizations.

## **Advertising and Promotion of Medicines and Health Products**

No person/organization shall advertise or promote any medicine or health product in a way that is false or misleading.

The Authority shall promulgate regulations that: (i) establish standards for determining when any advertising or promotional activity is false or misleading, (ii) provide for review of advertising and promotional activities or materials, and (iii) provide for enforcement of the prohibition of false or misleading activities or materials.

## **Donations of Medicines and Health Products**

Donated medicines and health products must respond to national needs identified or established by the Ministry of Health and Social Welfare.

Donated medicines and health products are subject to the provisions of PART THREE, as applicable.

In the case of emergency or disaster, the Authority may expedite or, as necessary, waive the registration of donated medicines or health products.

## **PART FOUR Narcotic Drugs and Psychotropic Substances**

No person/organization shall import, export, transit into or out of the Republic of Liberia, manufacture, store, distribute, sell, prescribe, dispense, or administer any narcotic drug or psychotropic substance, unless the person/organization has been issued a special license for such purpose by the Authority. This special license shall be in addition to any license, permit or other requirement or restriction of PART THREE.

No person/organization shall dispense or administer any narcotic drug or psychotropic substance except in accordance with a valid prescription from a license health care practitioner authorized to prescribe such products.

The conditions for issuance of a special license for the import, export, transit, manufacture, storage, distribution, sale of narcotic drugs or psychotropic substances shall

be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such special licenses.

The conditions for the prescribing, dispensing, or administration of narcotic drugs or psychotropic substances shall be stipulated in regulations promulgated by the Authority.

## **PART FIVE Radiopharmaceuticals**

No person/organization shall import, export, transit into or out of the Republic of Liberia, manufacture, store, distribute, sell or dispose of any radiopharmaceutical, unless the person/organization has been issued a special permit for such permit by the Authority. This special permit shall be in addition to any license, permit or other requirement or restriction of PART THREE.

The conditions for issuance of a special permit for the import, export, transit, manufacture, storage, distribution, sale or disposal of radiopharmaceuticals shall be stipulated in regulations promulgated by the Authority that shall be in accordance with any recommendations received from the International Atomic Energy Agency, and shall provide for the issuance, renewal, suspension, cancellation and revocation of such special permits.

## **PART SIX Violations and Enforcement**

### **Administrative Sanctions**

Any person/organization who cause or takes any action, or any failure to act, that violates any provision of this Act or any regulation promulgated under this Act may be subject to enforcement action in accordance with the provisions of this PART SIX Section I. The civil administrative penalties provided for herein are in addition to any applicable criminal penalties.

### **Confiscation**

Any medicine or health product that has been put into use, imported, exported, transited into or out of the Republic of Liberia, supplied, stored, distributed, sold, offered for sale, manufactured, used in a clinical study in humans, advertised or promoted, or donated in violation of the Act or any regulation promulgated under this Act may be confiscated by the Authority and destroyed or otherwise disposed of or used as the Authority deems appropriate and is consistent with this Act.

### **License or Permit Revocation**

Any person/organization who causes or takes any action, or any failure to act, that violates this Act or any regulation promulgated under this Act may have its license, permit or special permit suspended, revoked or withdrawn.

## Civil Penalties

Any person/organization who causes or takes any action, or any failure to act, that violates this Act or any regulation promulgated under this Act may be subject to civil penalties, as follows:

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for impeding any inspection or investigation carried out under the Act.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any action or failure to act involving an unregistered drug in violation of PART THREE.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any importation, exportation or transit into or out of the Republic of Liberia in violation of PART THREE Section II.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any supply, storage, distribution, sale or offer to sell in violation of PART THREE Section III.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any manufacturing in violation of PART THREE Section IV.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any clinical study in humans in violation of PART THREE Section V.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any advertising or promotion in violation of PART THREE Section VI.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any donation of medicines or health products in violation of PART THREE Section VII.

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any importation, exportation, transit into or out of the Republic of Liberia, manufacturing, storage, distribution, sale, offer to sell, dispensing or administering of, or issuance of a prescription for, any narcotic drug or psychotropic substance in violation of PART FOUR.

***[Unlike the prior draft, this does not include an explicit penalty for promoting or encouraging the abuse of narcotics. By expanding this entire section to include not just the doing of any act, but also the causing of any act, and having it apply to the various acts, I think it may have gotten close to addressing the prohibition on promoting or encouraging abuse.]***

A penalty of not more than \_\_\_\_\_ Liberian dollars may be imposed for any importation, exportation, transit into or out of the Republic of Liberia, manufacturing, storage, distribution, sale, offer to sell, or disposal of any radiopharmaceutical in violation of PART FIVE.

As deemed necessary, but no more frequently than once every two years, the Authority may adjust the maximum penalties identified herein.

### Regulations

The Authority shall promulgate regulations to establish the process, procedures, and standards by which any of the penalties of this PART SIX Section I may be imposed. Such process shall include notice to the person/organization, a right to an administrative hearing, appeal within the Authority, and judicial review.

The Authority shall promulgate regulations to establish the process, procedures and standards by which any adjustment in the civil penalties provided for in PART SIX Section I.3 shall be made.

Any regulation promulgated by the Authority under this PART SIX shall be consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of the Law.

### **Criminal Penalties**

Any person/organization who cause or takes any action, or any failure to act, enumerated in PART SIX Section I may be subject to criminal prosecution in accordance with the provisions of this PART SIX Section II or the Penal Code of the Republic of Liberia, whichever act provides a greater length of imprisonment or higher fine. The criminal penalties provided for herein are in addition to any applicable civil administrative penalties.

#### Initial Violation

Any person/organization who causes or takes any action, or any failure to act, enumerated in PART SIX Section I shall be imprisoned for not more than \_\_\_\_\_ years or fined not more than \_\_\_\_\_ Liberian dollars, or both.

#### Second and Further Violations; Violation with Intent to Defraud or Mislead

Notwithstanding the provisions of PART SIX Section II.1, any person/organization who commits any such violation after a conviction under this section has become final, or commits such a violation with the intent to defraud or mislead, shall be imprisoned for not more than \_\_\_\_\_ years or fined not more than \_\_\_\_\_ Liberian dollars, or both.

### **PART SEVEN Miscellaneous**

The passage of this Act into law will repeal any provision of the Public Health Law, July 1976, running contrary to the present Act and the regulations thereof.

With the enactment of this Act, all drug control matters as promulgated in the DEA Act shall be restricted to only illicit drugs as recognized by the United Nations conventions of 1961, 1971, and 1988.

With the enactment of this Act, all regulatory functions of the Pharmacy Board of Liberia shall be surrendered to the Authority, except for the following functions, which shall remain the responsibility of the Pharmacy Board of Liberia, notwithstanding any provisions of this Act or any regulations promulgated under this Act:

Administer examinations for the qualification of graduate pharmacists and dispensers who have completed the requirements for licensure.

Register and maintain the register of all pharmacists and dispensers practicing in Liberia.

Supervise and control the ethical behavior of practicing pharmacists and dispensers in Liberia.

Ensure the continuing professional development of pharmacists and dispensers.

Inspect retail pharmaceutical outlets for annual registration documents, conditions of premises, and qualifications of dispensers in stores.

Issue permits to retailers annually.

Evaluate curricula and issue annual permits to pharmaceutical training institutions.

Set standards and define requirements for establishing and operating retail pharmaceutical outlets.

Licenses issued prior to the coming into force of this Act shall be deemed to have been issued under, and subject to the provisions of, this Act and any regulations promulgated under this Act.