

**PQM Medicines Regulatory Inspections Technical Assistance to the Liberian Medicines and Health Products Regulatory Authority**

**Monrovia, Liberia  
June 17 – June 30, 2012**

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***Trip Report***

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## **Executive Summary**

As part of the support to the Liberia Medicines and Health Products Regulatory Authority (LMHRA), PQM engaged Mr. Benjamin Kwame Botwe to provide technical assistance (TA) to LMHRA, June 17-30, 2012. This TA focused on strengthening medicines regulatory inspection capacity and assisting with the establishment of a regulatory authority in Liberia.

Mr. Botwe's scope of work focused on the following activities, which were all completed during the two-week trip:

- Train LMHRA and National Drug Service (NDS) staff on medicines regulatory inspections.
- Provide TA and direction on inspections and other regulatory activities of the LMHRA.
- Develop tools to assist the Managing Director (MD) in monitoring and evaluation of inspectorate activities at the LMHRA.
- Assist in the development and review of materials for public education and awareness.
- Assist the Inspectorate department to develop inspection plans for the LMHRA.
- Assist in defining strategies for combating counterfeiting and sale of medicines.

In addition, at the direct request of LMHRA, Mr. Botwe assisted with drafting a letter banning antimalarial monotherapies, developing an advertisement for a Managing Director, and training on inspection report writing.

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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.

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- Mrs. Clavenda Bright Parker, the Chairperson and Acting Managing Director of the LMHRA, for her input, guidance, and cooperation during the trip.
- LMHRA staff for their cooperation and support.
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington, D.C., for their support and advice.

## ACRONYMS

Ag. MD	Acting Managing Director
DQI	Drug Quality and Information Program
LMHRA	Liberia Medicines and Health Products Regulatory Authority
MD	Managing Director
MOH&SW	Ministry of Health and Social Welfare
MSH	Management Sciences for Health
PBL	Pharmacy Board of Liberia
PQM	The Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SOW	Scope of Work
TA	Technical Assistance
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WAHO	West African Health Organization
WHO	World Health Organization
WI	Work Instructions

## **Background**

The United States Agency for International Development (USAID) and the United States Pharmacopeia (USP) have been providing technical assistance to Liberia in the areas of quality assurance and quality control of medicines since 2008, first through the USP Drug Quality and Information (DQI) program and, currently, through the Promoting the Quality of Medicines (PQM) program. Recently, PQM has begun helping the LMHRA develop their capacity to undertake effective medicine regulatory inspections, as well as supporting other key regulatory strategies to strengthen the operations of the Authority.

## **Purpose of Trip**

The following was Mr. Botwe's scope of work (SOW):

- Train LMHRA and National Drug Service (NDS) staff on medicines regulatory inspections.
- Provide TA and direction on inspections and other regulatory activities of the LMHRA.
- Develop tools to assist the Managing Director (MD) in monitoring and evaluation of inspectorate activities at the LMHRA.
- Assist in the development and review of materials for public education and awareness.
- Assist the Inspectorate department to develop inspection plans for the LMHRA.
- Assist in defining strategies for combating counterfeiting and sale of medicines.
- Perform other assignments as may be required by the LMHRA.

## **Overview of Activities**

### ***Briefing the Chairman/Acting MD of LMHRA***

Mr. Botwe met with Ambassador Clavenda Bright-Parker, the Chairperson and Acting Managing Director (Ag. MD) of the LMHRA, to discuss the SOW any other assignments, as may be requested by the LMHRA. Apart from agreeing on the activities in the original SOW, the Ag. MD requested that Mr. Botwe assist in the following:

- **Draft a letter banning antimalarial monotherapies**  
Prepare a draft letter banning the importation, distribution, sale, and use of antimalarial monotherapies for the signature of the Minister of Health and Social Welfare (MOH&SW).
- **Develop an advertisement for a Managing Director**  
Develop an advertisement to be published in local newspapers to recruit a MD. The Authority has been put on the national budget, and there will now be funds to pay a MD.
- **Train on inspection report writing**  
Mr. Botwe was informed that three teams of inspectors made up of staff from the LMHRA and the Pharmacy Board of Liberia (PBL) have been sent out to inspect warehouses and wholesale and retail pharmacies and medicine stores throughout the country from June 8-19, 2012. A training was therefore requested which should include inspection report writing.

### ***Ban of antimalarial monotherapies***

Following the results from the last two years of PQM's medicine quality monitoring (MQM) program—which focused on the quality of antimalarial medicines—the MOH&SW decided to ban the importation, sale, and use of artesunate monotherapies for the treatment of

uncomplicated malaria in Liberia. In a meeting between the Minister and the Chairperson of the LMHRA, the Minister requested the Authority to prepare a draft letter for the signature of the Minister. As requested by the Ag. MD, Mr. Botwe prepared a draft letter for review.

***Appointment of Managing Director***

Through the efforts of Ambassador Clavenda Bright-Parker, LMHRA has been included in the national budget of the Government of Liberia. Provisions have been made for the payment of salaries and benefits of all staff, including a Managing Director. As requested by LMHRA, Mr. Botwe drafted an advertisement for the recruitment of a Managing Director, which was reviewed and approved. The advertisement was emailed to all pharmacists in Liberia on June 29, and published in two local newspapers on July 2, 2012.

***Training on Medicines Regulatory Inspections***

A training program was organized for inspectorate staff of the LMHRA and PBL. A summary of the report of the training is as below.

ITEM	ACTIVITY
Specific Objectives/ Expected Outcomes	<p>The training was aimed at building capacity of regulatory staff in inspections of pharmaceutical products and facilities. Specifically, it was to:</p> <ul style="list-style-type: none"> <li>• Ensure that officers understand the legal basis for pharmaceutical inspections in Liberia</li> <li>• Ensure that officers can independently create standard operating procedures (SOPs) for the jobs they do on daily basis</li> <li>• Provide insights into the need for professionalism in the conduct of inspections</li> <li>• Assist officers to write reports and undertake post-inspection activities</li> </ul>
Training Venue	Conference Room, LMHRA, Randell Street, Monrovia
Organizer	PQM and LMHRA
Trainer/Facilitator	Benjamin K. Botwe, PQM Consultant
Training Agenda	Refer to <b><i>Annex 1</i></b>
Participants	Inspectorate, Registration, and Laboratory staff from LMHRA; inspectors from PBL; and pharmacy students on attachment to LMHRA. A detailed list is included in <b><i>Annex 2</i></b>
Evaluation	A summary of the participants' evaluations is included in <b><i>Annex 3</i></b>
Conclusions	Based on the participants' evaluations, the training was successful and will help them in their daily work.
Next Steps	Some participants stated that additional, regular training would be valuable. Additional trainings and topics will be discussed with LMHRA and USAID/Liberia.

***Roadmap and implementation plan***

Mr. Botwe assisted the LMHRA in drafting a roadmap of activities that is in line with their three-year strategic plan. The roadmap is provided in the table below:

<b>DRAFT LMHRA PROGRAM OF WORK – MAY TO DECEMBER 2012</b>			
<b>MONTH</b>	<b>ACTIVITIES</b>	<b>EXPECTED OUTCOMES</b>	<b>STATUS</b>
May	<ol style="list-style-type: none"> <li>1. Awareness creation activities</li> <li>2. Standards for accreditation of medicines stores</li> <li>3. Recruitment of officer to be in charge of the Accredited Medicines Stores (AMS) project at the LMHRAs</li> </ol>	<ol style="list-style-type: none"> <li>1. Public awareness created</li> <li>2. AMS project started</li> </ol>	<p>Has begun and on-going</p> <p>Zero draft of standards completed</p> <p>Recruitment in process</p>
June	<ol style="list-style-type: none"> <li>1. Countywide joint inspections with PBL</li> <li>2. Inspectors training and review of inspectorate activities</li> <li>3. Improve Pharmacovigilance activities</li> <li>4. Receipt and recording of registration applications received</li> </ol>	<ol style="list-style-type: none"> <li>1. Inspection reports to provide the state of affairs of pharmaceutical services</li> <li>2. Inspectors trained and department strengthened</li> <li>3. Safety reporting system in place</li> <li>4. Full registration of products began</li> </ol>	<p>Inspection completed</p> <p>Inspectors trained and department strengthened</p> <p>Yet to be initiated</p> <p>Has began but slow</p>
July	<ol style="list-style-type: none"> <li>1. Appointment of a Managing Director</li> <li>2. Hands on training on registration and Dossier evaluation</li> <li>3. Development of Tools for monitoring registration activities</li> <li>4. Strengthen QC Laboratory by hands on training</li> </ol>	<ol style="list-style-type: none"> <li>1. MD appointed</li> <li>2. Training conducted and department strengthened</li> <li>3. Tools developed</li> <li>4. Consultant at post for mentoring</li> </ol>	<p>Process initiated</p>
August	<ol style="list-style-type: none"> <li>1. Pricing Study</li> <li>2. Joint operations with DEA to rid the market of street vendors</li> <li>3. Finalization and implementation of conditions of service for staff</li> </ol>	<ol style="list-style-type: none"> <li>1. Pricing study report available</li> <li>2. Sale of medicines on the streets reduced</li> <li>3. Staff service conditions implemented</li> </ol>	

	4. Pharmacovigilance training and reports collation	4. Safety monitoring improved	
September	<ol style="list-style-type: none"> <li>1. Discuss and design a new building complex for the authority.</li> <li>2. Develop guidelines for <ol style="list-style-type: none"> <li>a. control of narcotic drugs and psychotropic substances</li> <li>b. advertising and promotion of medicines</li> <li>c. disposal of pharmaceutical waste</li> <li>d. Clinical studies</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Design of complex available</li> <li>2. Guidelines and necessary forms developed for implementation</li> </ol>	
October	<ol style="list-style-type: none"> <li>1. Establish Experts Committee on Pharmacovigilance and provide training</li> <li>2. Conduct a country-wide counterfeits study</li> <li>3. Procure vehicles for inspections and other activities of the Authority.</li> </ol>	<ol style="list-style-type: none"> <li>1. Expert Committee in place and working</li> <li>2. Counterfeit study report available and acted upon</li> <li>3. Vehicles available to improve inspections</li> </ol>	
November	<ol style="list-style-type: none"> <li>1. Full regulatory assessment of LMHRA using WHO tools</li> <li>2. Regulatory Officers re-training and re-orientation</li> <li>3. Follow up Institutional Contact Persons on Safety monitoring and reporting</li> </ol>	<ol style="list-style-type: none"> <li>1. Assessment report with recommendations</li> <li>2. Officers re-trained for improved performance</li> <li>3. Efficiency of Reporting improved</li> </ol>	
December	<ol style="list-style-type: none"> <li>1. Annual review meetings at departmental and Board level</li> <li>2. Annual report writing and submission</li> <li>3. Review of Annual work plans for implementation in January 2013</li> </ol>	<ol style="list-style-type: none"> <li>1. Annual report and work plans available</li> </ol>	

**Note: Technical Assistance will be engaged for the laboratory for on-the-job and hands-on training and capacity building from July to December 2012**

### ***MD's tools for monitoring and evaluation of inspectorate activities at the LMHRA***

In order to monitor and evaluate the activities of the inspectorate department to ensure efficiency and effectiveness of inspections, Mr. Botwe assisted the LMHRA in drafting a strategy. This strategy includes planning, organization, and implementation of activities in the department as well as monitoring the performance of the individuals who have been assigned specific jobs in the department. In summary:

- The department will draw up an annual inspection plan and submit to the MD for validation and approval. This plan should be based on the annual work plan of the Authority approved by the Board and should be subdivided into quarterly implementation plans with specific timelines and expected outcomes.
- Department heads are to assign specific responsibilities to officers in the respective departments on a monthly basis and submit copies of plans to MD.
- Department heads are to collate all inspection reports and summarize them for the attention of the MD on a weekly basis. These reports should include actions taken and recommendations for addressing non-compliances.

### ***Review materials for public education and awareness-raising***

On May 28, 2012, a national sensitization and awareness-raising workshop was organized by the LMHRA in Monrovia and widely publicized in the media. The Ag. MD and four other staff of the Authority also participated in a panel discussion on the safe use of medicines, using samples collected from the nationwide inspections as education materials. This was to be aired July 2, on Real TV, a local station.

As part of the campaign, the Authority issued a press statement covering its mandate and scope of operations. A brochure on the functions and responsibilities of the Authority was also prepared and distributed, together with handbills, stickers, and posters. Copies of various publications and materials are included in ***Annex 4***. Mr. Botwe reviewed these documents and offered suggestions which will be taken into consideration before printing of subsequent batches.

### ***Strategies for combating counterfeiting and sale of medicines in the open market***

Mr. Botwe discussed various strategies to combat substandard and counterfeit medicines with the Inspectorate department, and the following were found to be useful tools that could be employed for anti-counterfeiting activities and to deal with the sale of medicines in the open market:

- *Conduct an assessment of the medicines situation in Liberia*

It will be worthwhile to conduct a full assessment of the substandard and counterfeit medicines situation in Liberia. This will establish a real basis for future action.

- *Inter-agency approach*

The issue of combating the availability and sale of counterfeit products in the open market calls for an inter-agency approach. Customs, Police, Immigration, the Legislature, Judiciary, Drug Enforcement Agency (DEA), Ministry of Commerce, and city authorities all have their roles to play. The LMHRA should therefore become a rallying point around which their activities will be planned, implemented, coordinated, and monitored. A national medicines anti-counterfeiting committee could be established under the chairmanship of the LMHRA and charged with the responsibility of ridding the market of sale of counterfeit and substandard medicines. This will

go a long way towards sanitizing the medicines distribution systems and ensuring quality, safety, and efficacy.

During the time of this trip, the LMHRA Inspectorate collaborated with the DEA of the Ministry of Justice to apprehend a number of medicines peddlers from the streets and markets in central Monrovia. Large consignments of medicines that were unregistered/unlisted as well as suspected counterfeits were confiscated and are awaiting further evaluation and subsequent destruction. Some pictures taken during this operation are shown in *Annex 5*.

- *Special pharmaceutical outlets*

The “Accredited Medicines Stores” concept—where special shops will be opened by trained individuals and supported to provide essential medicines to the public—should be immediately implemented. This project, which is under technical sponsorship from Management Sciences for Health (MSH), will serve as a major source of quality medicines at affordable prices.

- *Use of technology to report suspected counterfeits*

Mobile phone technology could be used, by both practitioners and consumers, to report suspected counterfeits. The LMHRA might have to secure dedicated telephone lines for this, and strong public education would also be necessary. The mobile phone service companies in Liberia could be approached to support this as a social responsibility.

- *Appointment of anti-counterfeiting focal persons in the counties*

Reports from the nationwide inspections carried out by the joint inspection teams from the LMHRA and the Pharmacy Board indicate that suspected counterfeit products were confiscated in all counties. In order to decentralize the fight against counterfeits, the LMHRA may wish to appoint medicines anti-counterfeiting focal persons in the counties. The County Pharmacists who are influential members of the County Health Teams could be assigned this responsibility. The Authority may therefore need to give them additional training, educational materials, and a budget to facilitate their work.

- *Use of Minilabs<sup>®</sup> in the field*

The use of Minilabs<sup>®</sup> as field testing kits could help tremendously in the detection of substandard and counterfeit medicines in the counties as well as the ports of entry. This will necessitate a budget, Minilabs<sup>®</sup> will have to be procured and installed, and selected focal persons trained.

- *Public education and awareness-raising programs*

Sustained public education and awareness-raising programs hold a major key to combating counterfeit and substandard medicines. The activities that have already begun need to be supported and expanded.

### **Registration**

Companies have been given until July 15, 2012 to submit documentation for registration and pay the new fee of USD \$300 per product, renewable every three years. It is expected that the registration software ‘PHARMADEX’ developed by MSH will be installed for use by the Authority.

### ***Enforcement actions***

A number of enforcement actions have been taken recently. Mr. Botwe and the Ag.MD met with the laboratory staff to establish which laboratory testing results needed immediate regulatory follow-up. It was decided that those products that failed only visual inspections because the samples were not in their original packs should be separated, and the rest that failed both visual and HPLC tests should be compiled for the necessary recalls to be effected. The laboratory is in the process of providing this information to the MD.

### ***Nationwide Inspection***

A nationwide inspection of pharmaceutical outlets and products was undertaken by a joint team of inspectors from the LMHRA Inspectorate, Quality Control Laboratory, and Pharmacy Board of Liberia, June 8-20, 2012. Three teams made up of three officers each were set up and assigned different counties, covering all the counties in Liberia except Montserrado. The inspections covered warehousing and storage facilities of major hospitals and NGOs, pharmacies, medicines stores, and the general market.

The purpose was to ensure safe, efficacious, and quality pharmaceutical products are available on the Liberian market, that they are distributed from licensed facilities by qualified personnel, and also to establish the extent of the availability counterfeit, expired, substandard, adulterated, or unregistered/unlisted pharmaceutical products on the Liberian market. In addition, the inspection would also help raise awareness on the work of the LMHRA.

It was generally observed that in terms of premises, most pharmacies and particularly medicines stores were either not licensed by the Pharmacy Board of Liberia or their licenses had long expired. General storage conditions in hospital and NGO warehouses were found to be inadequate and in a state of neglect. A number of products were also confiscated during the inspection as a result of poor packaging, inadequate labelling information, expiry date, no manufacturer address, and/or poor storage conditions, especially for biological products. A summary of the inspection report is provided in *Annex 6*.

The experiences gained and raw data gathered during the nationwide inspections were used during the inspector training given by Mr. Botwe, especially for the report writing and post-inspection activities.

### ***Inspection plan for July-December 2012***

Mr. Botwe assisted the Inspectorate department of LMHRA to develop a plan to inspect pharmaceutical facilities and products from July to December 2012. This concentrates on Montserrado County, as all the other counties were inspected during the previous inspection. The draft to be submitted to the Managing Director for approval is attached as *Annex 7*.

## **Mr. Botwe's Recommendations**

### **For LMHRA:**

1. Follow the plan of work systematically to the end of the year and review performance vis a vis the plan; determine shortfalls and devise strategies to deal with challenges encountered.

2. Follow up on the banned antimalarial monotherapies and ensure that they are withdrawn from the market.
3. Complete the process of recruitment of the Managing Director and provide the necessary technical and administrative tools to enable him/her perform.
4. Ensure that the Inspectorate department complies with the monitoring tools described so that their performance can be measured.
5. Deepen and sustain the public education and awareness-raising that has been started. Corrections made on various print materials are to be taken to the Board before the next set of printing.
6. Undertake anti-counterfeiting strategies defined in this report, particularly the inter-agency approach where the DEA, the police, and the County Health Teams could help deal with the issues.
7. Institute immediate recalls for all products that failed both visual inspection and HPLC tests and for all subsequent samples tested.

#### **For USP/PQM**

1. Continue to provide support to the Quality Control laboratory in terms of reference standards, chemicals, reagents and supplies.
2. Provide technical assistance for medicines registration and build capacity through dossier evaluation retreats.
3. Support the public education and awareness programs.
4. When the Managing Director is appointed, there will be the need to continue to provide technical assistance to enable him/her to consolidate what has been achieved and to build an effective medicines regulatory system in Liberia.
5. Provide support to the inter-agency approach to dealing with counterfeits and sale of medicines in the open market.

#### **Conclusions**

Mr. Botwe's trip to assist the LMHRA was successful; all originally proposed activities were accomplished, and the additional assistance requested by LMHRA was completed.

## INSPECTORS TRAINING AGENDA

Day 1 25 Jun 2012	9.00 am – 10.00 am	LEGAL BASIS FOR REGULATORY INSPECTIONS
	10.00 am – 11.00 am	DESIGNING SOPs FOR INSPECTIONS
	11.00 am – 12.00 noon	CLASS ASSIGNMENTS
Day 2 26 Jun 2012	9.00 am – 10.00 am	REVIEW AN MARKING OF PREVIOUS DAY'S ASSIGNMENT
	10.00 am – 11.00 am	INSPECTIONS – PLANNING, PROCESS, ETHICS, SECURITY
	11.00 am – 12.00 noon	CLASS ASSIGNMENTS
Day 3 27 Jun 2012	9.00 am – 10.00 am	REVIEW AN MARKING OF PREVIOUS DAY'S ASSIGNMENT
	10.00 am – 11.00 am	REPORT WRITING AND POST INSPECTION ACTIVITIES
	11.00 am – 12.00 noon	CLASS ASSIGNMENTS

## LIST OF PARTICIPANTS

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### PQM INSPECTORS TRAINING EVALUATION ♦ June 25-27, 2012

In order for PQM to evaluate the efficacy of each training module and improve the level of the courses, we as asked all participants to kindly provide their feedback by filling out evaluation sheets. The responses of the participants to the various questions asked are tabulated below.

#### A. Evaluation of the Specific Aspects of the Training Workshop

TRAINING	EXTENT TO WHICH THE TRAINING MET YOUR OVERALL EXPECTATIONS			
	Exceeded Expectations	Met Expectations	Met Some Expectations	Unsatisfactory
LEGAL BASIS FOR INSPECTIONS	6	5	2	
SOPS WRITING	4	6	3	
INSPECTION	3	10		
REPORTING WRITING	4	7	2	
ASSIGNMENTS	2	6	5	

#### B. Overall Evaluation of the Training Workshop

	Strongly Agree	Agree	Somewhat Disagree
Course objectives were relevant to my needs	11	2	
The training materials helped me understand and better organize my activities	6	7	
I was able to understand the content of the materials presented	7	6	
Overall, the course was useful and helped me do my job better	10	3	
There were enough practical exercises to facilitate understanding of the course	6	6	1
The pacing of the various sessions was appropriate for my understanding of course materials	4	9	
The sequence in which the sessions were presented was appropriate for my understanding	5	8	
The instructor allowed an appropriate level of participation	13		

#### C. Other Comments/Suggestions

- Trainees were allowed to participate
- Views, questions/comments of trainees were taken into account
- Assessment of participant knowledge in SOP writing, inspection, and post-inspection activities was useful
- Practical examples were applicable to the realities in the field of inspections
- Participants were not awarded certificates of participation
- Course did not cover how to become an inspector
- Duration of training sessions should be increased
- Inspectors should be exposed to other training especially outside of Liberia
- Workshop trainings should be conducted bi-monthly or quarterly to build inspectors' capacities.

## PRESS CUTTING

# INQUIRER

## Will Be Dealt With" ...Says LMHRA

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) says any importer who brings fake medicines into Liberia will be dealt with severely according

to the law.

The LMHRA said similarly, any trader who purchases medicines from unregistered wholesalers will be answerable to the

"Traders who purchase substandard medicines from registered wholesalers would be required to produce receipts of purchase. In such cases the LMHRA will take issue with the respective wholesaler," the LMHRA headed by Mrs.

on page 22

The INQUIRER, Friday, May 18, 2012 Page 22

### "Fake Medicines Importer

Cont'd from front page

Clavenda Bright-Parker, Liberia's first pharmacist said.

The LMHRA said, "If the trader cannot produce such a receipt then the trader would be held responsible."

The group in a statement issued in Monrovia yesterday said in pushing this course of action forward, it has the support of the Government of Liberia and will work together with other relevant government departments to protect the health of the Liberian people.

The LMHRA said it had accelerated efforts to protect the public from exposure to counterfeit and substandard medicines.

The LMHRA said Liberia has rapidly transitioned from an emergency relief model of health service delivery to a functioning results-driven health system.

"While primary health-care services have improved tremendously over a short period of time, pharmaceutical services, particularly in the private sector, continue to lag behind those of our friends and neighbors in the region," the group said.

As part of medicines registration LMHRA said previously, all medicines for sale in Liberia were required to be listed with the LMHRA and now all drugs to be manufactured for sale, imported or supplied must be registered with the LMHRA.

Touching on substandard medicines, the LMHRA said it

tackle the issue of medicine peddling on Liberia's streets.

"Not only are these practices illegal, but the medicines are often exposed to the sun, dust and humid conditions, thus compromising the quality of these medicines," the group said.

"In addition, those who sell these medicines have no training on how to use them. This exposes the Liberian people to worsening medical conditions in the case of maltreatment, adverse drug reactions to certain medicines, and the emergence of drug resistance that threatens the health of the entire population," the LMHRA noted.

The LMHRA said it will work with relevant Ministries to remove drug peddlers off our streets and it will be done in an orderly manner.

The LMHRA said in Liberia, the law allows authorized persons to run private pharmacies and medicine stores and licensing these business ventures help to ensure that the products and services they provide adhere to the standards required by the LMHRA.

However, he LMHRA said it is aware that the standards in some licensed pharmacies and medicine stores still fall short of what is acceptable.

"In addition, some shops have allowed their licenses to lapse while others are not licensed at all, in collaboration with the Pharmacy Board of

accelerated efforts to protect the public from exposure to counterfeit and substandard medicines.

The LMHRA said Liberia has rapidly transitioned from an emergency relief model of health service delivery to a functioning results-driven health system.

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and the emergence of drug resistance that threatens the health of the entire population," the LMHRA noted.

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The LMHRA said in Liberia, the law allows authorized

## PRESS RELEASE

Heritage, Friday, May 18, 2012

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# LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)



A.T.C Building, South Randal Street, Opposite J-mart  
Monrovia, Liberia

Cell: + (231) / 886 544 390 / 777 544 399 / 886 512 999 / 886 380 731

## Press Statement

The Liberia Medicines and Health Products Regulatory Authority accelerates efforts to protect the public from exposure to counterfeit and substandard medicines. Liberia has rapidly transitioned from an emergency relief model of health service delivery to a functioning, results-driven health system. While primary health-care services have improved tremendously over a short period of time, pharmaceutical services, particularly in the private sector, continue to lag behind those of our friends and neighbors in the region. On our streets, we continue to witness the problem of drug peddling, while some pharmacies and medicines stores charge exorbitant prices for medicines. In addition, some of the medicines we find on our streets are counterfeit and of substandard quality.

For those who trade in counterfeit and substandard medicines to the detriment of our children, we would like to say this is the end of the road for them. For the Liberian market, we usher in a new era of a properly regulated and rigorously supervised pharmaceutical sector. The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was formed by an Act of the Legislature.

### **About the LMHRA**

The LMHRA was established in 2010 by the LMHRA Act, enacted into law by the Liberian Legislature and signed by the President of Liberia. The purpose of the Act is to:

- ☛ Ensure, safe, effective, and good quality medicines
- ☛ 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 LMHRA will carry out its mandate through registration of medicines and health products, inspection, supervision, and policing activities, such as those described below.

### **Medicines Registration**

Previously, all medicines for sale in Liberia were required to be listed with the LMHRA. All drugs to be manufactured for sale, imported or supplied must be registered with the LMHRA.

### **Substandard Medicines**

The LMHRA has now established laboratory services capable of analyzing a number of medicines. Recently, with the help of the USP/PQM program funded by USAID, the LMHRA sampled a number of medicines, including antimalarial drugs on the market, for quality analyses. A number of brands failed these quality analyses, while some drugs were found to contain no active ingredient. Whether deliberate or intentional, the LMHRA intends to clamp down on this trade in fake and substandard medicines, particularly antimalarials. An importer who brings fake medicines into Liberia will be dealt with severely according to the law. Similarly, any trader who purchases medicines from registered wholesalers will be answerable to the law. Traders who purchase substandard medicines from registered wholesalers would be required to produce receipts of purchase. In such cases the LMHRA will take issue with the respective wholesaler. If the trader cannot produce such a receipt then the trader would be held responsible. In pushing this course of action forward, we have the support of the Government of Liberia, and we will work together with other relevant government departments, to protect the health of the Liberian people.

### **Unauthorized Medicine Sellers**

One major issue that the LMHRA will tackle is the issue of medicine peddling on our streets. Not only are these practices illegal, but the medicines are often exposed to the sun, dust and humid conditions, thus compromising the quality of these medicines. In addition, those who sell these medicines have no training on how to use them. This exposes the Liberian people to worsening medical conditions in the case of self-treatment, adverse drug reactions to certain medicines, and the emergence of drug resistance that threatens the health of the entire population. The LMHRA will work with relevant Ministries to remove drug peddlers off our streets. This will be done in an orderly and humane manner. Even though the LMHRA acknowledges the plight of those who are involved in this trade, it is in the interest of every Liberian that medicines are not sold on the streets by unauthorized and untrained persons.

### **Licensed Medicine Outlets**

In Liberia, the law allows authorized persons to run private pharmacies and medicine stores. Licensing these business ventures helps to ensure that the products and services they provide adhere to the standards required by the LMHRA. However, we are aware that the standards in some licensed pharmacies and medicine stores still fall short of what is acceptable. In addition, some shops have allowed their licenses to lapse while others are not licensed at all. In collaboration with the Pharmacy Board of Liberia, the LMHRA will conduct more frequent inspections of facilities and those who are found breaching any laws and operating below standard will face consequences.

### **Collaboration with Other Government Agencies**

The LMHRA cannot act alone in advancing the course of medicine safety and the quality of pharmaceutical services for the Liberian people. First, and foremost, there are other arms of the Liberian government that deal with the management of medicines. These include the Pharmacy Board of Liberia, the Pharmacy Division of the Ministry of Health, the Pharmaceutical Association of Liberia, and the National Drug Services. The LMHRA works with these entities to safeguard medicine safety in the country. In addition, our work is supported by other relevant government agencies, such as customs, standards, and the police.

In summary, for those who have been profiteering from malpractices with regards to the sale and distribution of medicines, we say it is over! Starting this year, the LMHRA will reinvigorate its efforts to safeguard the system and protect the health of the Liberian people. So, when the law takes its course, let not those who get caught say they were not warned!

**PHARM. CLAVENDA BRIGHT-PARKER**  
**CHAIR AND ACTING MANAGING DIRECTOR,**

A representative of an appropriate consumer interest group or association; and  
 The Managing Director of the Authority, a non-voting member shall serve as secretary to the Board of Directors.

**FUNCTIONS & DUTIES OF THE AUTHORITY**

Functions and duties of the Authority include:  
 1. Induct registration of medicines and health products;  
 2. 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, sale of medicines and health products, excluding retail pharmaceutical outlets;  
 3. and when deemed necessary by the Authority, suspend, revoke, or revoke such license or permits in accordance with regulations;  
 4. Establish an inspectorate and conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold;  
 5. Enforce expiration, substandard, counterfeit, or unregistered medicines in accordance with regulations;  
 6. Establish and operate quality control laboratories to ensure safe, effective, and good quality medicines and health products for domestic and foreign markets;  
 7. Induct post-marketing surveillance of medicines and health products;  
 8. Induct pharmacovigilance of medicines and health products;  
 9. Issue warnings and conduct recalls of products;  
 10. Regulate the conduct of clinical studies of medicines and health products;  
 11. Prepare, keep, and update a registry of medicines and health products registered and approved for marketing in the public of Liberia;  
 12. Establish standards of quality, safety, and efficacy of medicines and health products;  
 13. Investigate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act;  
 14. Develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority;  
 15. Provide wide current and unbiased information on medicines and health products to health care professionals and the general public;  
 16. Facilitate advertising and promotion of medicines and health products;  
 17. Be responsible for its human resources development;

18. Promote, monitor, and evaluate the implementation of this Act;

19. Receive and investigate complaints regarding alleged violations of the Act or any regulations promulgated by the Authority, and impose appropriate sanctions.

**ACHIEVEMENT**

The identified strengths of the LMHRA are as follows:

- i. Enactment of the LMHRA Act;
- ii. Listing of Pharmaceutical Products currently on the Liberian Market;
- iii. Availability of draft regulatory guidelines such as; listing, imports and advertisement guidelines;
- iv. Some basic training done for local pharmacists on dossier evaluation and registration;
- v. Development of capacity of inspectorate staff and laboratory staff in the use of the minilab;
- vi. Commencement of inspection activities;
- vii. Availability of a Pharmacovigilance plan
- viii. Presence of a draft organizational structure
- ix. Availability of a draft annual work plan for 2011.

**FUNDING**

The funds of the Authority according to the Act that created it are drawn from the following sources:

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

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

Motto:

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



YOUR HEALTH.....

Liberia Medicines and Health Products Regulatory Authority  
 ATC Building, South Rasball Street - Opposite J-mart  
 Monrovia, Liberia - West Africa

Call: +(231) 880 441 446/ +(231) 777 450 980  
 +(231) 994 824 491

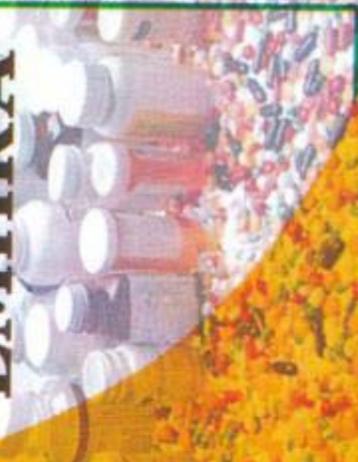
Web: www.lmhra.org  
 Email: contact@lmhra.org / lmhbra@gmail.com

# Liberia Medicines and Health Products Regulatory Authority



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

# LMHRA



## LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY - (LMHRA)

### BACKGROUND

In 2001 the National Drug Service (NDS) and the Ministry of Health & Social Welfare (MOSHWS) issued the National Drug Policy (NDP) in collaboration with WHO and other partners. The NDP mentioned the need to establish a drug regulatory authority to enact and update drug regulations to regulate the pharmaceutical sector. The NDP also calls for the establishment of a national quality control laboratory under the drug regulatory authority. In keeping with the NDP, the Minister of Health & Social Welfare established the Liberia Medicines Regulatory Committee. The primary mandate among others was to create an Act to establishing a medicines Regulatory Authority in Liberia.

### RELATIONSHIP BETWEEN LMHRA AND OTHER REGULATORY BODIES IN THE PHARMACEUTICAL SECTOR

Upon request of the Government of Liberia, in 2007, an assessment report from the European Union consultants on the Pharmaceuticals Sector in Liberia recommended that the sector be organized along four (4) clear lines. These are:

Office of the Chief Pharmacist be responsible for Policy, Essential Medicines Programme, Standard Treatment Guidelines and Pharmaceutical Services in the Public Sector  
The Pharmacy Board of Liberia to be responsible for professional licensing, premises registration and licensing and professional disciplinary matters

The National Drug Service to be in charge of Public Procurement, storage, distribution and drug management

The establishment of a new Medicines Regulatory Authority (MRA) to be set up to be in charge of Medicines registration, import and export control, inspections, post market surveillance and quality control activities among others

The Liberia Medicines & Health Products Regulatory Authority (LMHRA) was established by an Act of the National Legislature on September 29, 2010.

### THE MANDATE OF THE LMHRA

The Terms of Reference for the Medicines Regulatory Committee were as follows:

1. To register all medicines that are locally manufactured, imported, distributed, sold and used in Liberia.
2. To prepare, update and keep the register of medicines used in both the private and public sector in Liberia.
3. To remove from the register and prohibit manufacture, importation, distribution sale and use of any medicine whose quality, safety or efficacy is brought to question.

4. To set up systems for post marketing surveillance of all medicines in circulation by sampling same for quality control analysis.
5. To set up a system to monitor the safety of all medicines in use in the country (Pharmacovigilance)
6. To set up a quality control laboratory to undertake laboratory analysis of all medicines to be imported and used in Liberia
7. To provide quality and safety monitoring services for drugs and non-drug consumables imported for use in priority disease control programmes.
8. To institute measures for GMP compliance inspections of companies intending to export medicines to Liberia.
9. To institute measures for the inspection of warehouse and storage facilities for medicines in both the public and private sectors for compliance to Good Storage and Warehousing Practices
10. To issue permits for authorization of import and export of medicines and non-drug healthcare products into and out of Liberia.
11. To source for and provide adequate financial, human and other resources for the proper functioning of the LMRC
12. To facilitate the provision of decent and adequate office and laboratory accommodation for operations of the LMRC



### ORGANIZATIONAL PROFILE

Liberia subscribes to a regional medicines regulatory body called West Africa Health Organization (WAHO) in Burkina Faso (Mali), the World Health Organization (WHO) Collaborating Center in Ghana, WHO and Medicines Sciences for Health (MSH) on:

1. Medicines Harmonization
2. Pharmacovigilance
3. Quality Control and Assurance

The Main policy area of the Authority focuses on six key priorities as spelled out in the Three-year National Strategic Framework. They are as follows:

1. Develop and establish the requisite medicines regulatory Infrastructure in Liberia
2. Develop and Implement an appropriate IE & C Strategy
3. Develop and Implement appropriate Regulatory Tools for the efficient operations of the LMHRA
4. Strengthen the implementation of Regulatory Functions
5. Undertake Operational Research activities to support regulatory functions

6. Establish a functioning Quality Control Lab to support regulatory activities

### STRUCTURE / COMPOSITION OF THE LMHRA

The structure of the LMHRA comprises of a Board of Directors, Managing Director, Technical Assistant (a role of a consultant), four main departments (Administrative & Finance; Medicines Registration & Pharmacovigilance; Quality Control Laboratory Inspection & Surveillance), three of which are policy areas. Work are interdependent. Each of the four departments has several units.

### VISION

Establish and Operate a Medicines and Health Products Regulatory Authority of Excellence in Liberia that Protects the Health of All.

### MISSION

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) exist to implement the provisions of the LMHRA Act employing Good Regulatory Practices to ensure that medicines and health products used in Liberia conform to the highest standards of quality, safety and efficacy.

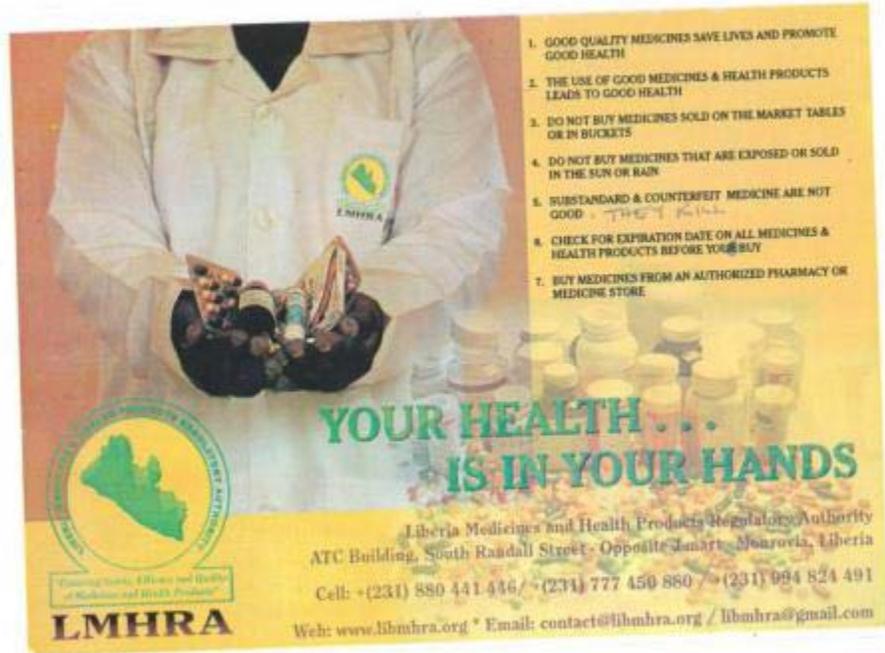
### BOARD OF DIRECTORS

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

### MEMBERS OF THE BOARD

1. The Board of Directors is consist of the following members:
  - a. The Chief Pharmacist, representing the Ministry of Health and Social Welfare;
  - b. The head of the Pharmacy Board
  - c. A lawyer representing the Ministry of Justice;
  - d. The head of Customs, representing the Ministry of Finance;
  - e. The head of the National Bureau of Standards representing the Ministry of Commerce;
  - f. A representative of the School of Pharmacy of the University of Liberia;
  - g. A representative of the Liberia Medical and Dental Council;
  - h. A representative of the Pharmaceutical Association of Liberia;
  - i. A veterinarian;
2. A qualified Liberian Pharmacist, who shall be appointed by the President of the Republic of Liberia can chair the Board of Directors.

**FLIER, STICKER, POSTER**



1. GOOD QUALITY MEDICINES SAVE LIVES AND PROMOTE GOOD HEALTH

2. THE USE OF GOOD MEDICINES & HEALTH PRODUCTS LEADS TO GOOD HEALTH

3. DO NOT BUY MEDICINES SOLD ON THE MARKET TABLES OR IN BUCKETS

4. DO NOT BUY MEDICINES THAT ARE EXPOSED OR SOLD IN THE SUN OR RAIN

5. SUBSTANDARD & COUNTERFEIT MEDICINE ARE NOT GOOD - ~~THEY KILL~~

6. CHECK FOR EXPIRATION DATE ON ALL MEDICINES & HEALTH PRODUCTS BEFORE YOU BUY

7. BUY MEDICINES FROM AN AUTHORIZED PHARMACY OR MEDICINE STORE

**YOUR HEALTH . . .  
IS IN YOUR HANDS**

Liberia Medicines and Health Products Regulatory Authority  
ATC Building, South Randal Street - Opposite Jamar, Monrovia, Liberia  
Cell: +(231) 880 441 446 / +(231) 777 450 880 / +(231) 994 824 491  
Web: [www.libmhra.org](http://www.libmhra.org) \* Email: [contact@libmhra.org](mailto:contact@libmhra.org) / [libmhra@gmail.com](mailto:libmhra@gmail.com)

**LMHRA**  
Ensuring Quality, Efficiency and Health  
of Medicines and Health Products

Pictures from the DEA/LMHRA Operation



**Top:** Samples of confiscated medicines from street peddlers



**Left :** Samples and transparent bucket used for display by peddlers

**Bottom Left:** Arrested peddler with a bag containing medicines he sells



**Bottom:** Confiscated samples, including antimalarial monotherapy

Liberia Medicines & Health Products Regulatory Authority (LMHRA)  
A.T.C. Building, Opposite J-mart Randall Street, Monrovia

**LMHRA/PBL FIRST NATIONAL INSPECTIONS REPORT**

**Date: June 28, 2012**

**I. Introduction**

The Inspectorate team of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) in collaboration with the Pharmacy Board of Liberia (PBL) conducted a joint inspection for all medicines stores, pharmacies, hospital pharmacies and NGO warehouses that are engaged in pharmaceuticals in thirteen (13) Counties. The inspections commenced on Friday, June 8, 2012 and ended on Wednesday, June 20, 2012. Three inspection teams were set up and charge with different counties and towns as follows.

**Team A**

1. Pharm. Archibald O. Kromah ----- Team Leader
2. Beatrice H. Kemokai
3. Isreal Acolatse
4. Henry K. Gbormoi

No.	County	Towns and areas visited	Dates
1	Gbarpolu	Gbarma, Barpolu and adjacent towns	June 8, 2012
2	Grand Bassa	Cotton Tree, Edena, Compound #1, Howlensville	June 11, 2012
3	River Cess	Cestos and adjacent towns	June 13, 2012
4	Parts of Lower Margibi	Shefflin, Smell no Taste, Charlesville, Harbel	June 11, 2012
5	Parts of Nimba County	Sanniquelli and adjacent towns, parts of Ganta	June 18, 19 – 20, 2012

\*Buchanan, LAC, Degar, Tapeta, Zahn, Mehia, Graie, Botohnwe, Bahn, Sagleipea

(Gbarpolu, Grand Bassa, River Cess Counties and parts of Lower Margibi and Nimba Counties).

**Team B**

1. James D. K. Goteh (LMHRA) ..... Team Leader
2. Early Flan (PBL) ..... Member
3. Esther T. Beyslow (LMHRA) ..... Member
4. One Driver

No.	County	Towns and areas visited	Dates
1	Bomi County	Klay, Tubmanburg and adjacent towns	June 8, 2012

2	Margibi County	Kakata and adjacent towns, Weala, Konola	June 11, 2012
3	Bong County	Salala, Totota, Sanoyea, Gbatala, Suakoko, SKT, Phebe, Gbarnga, Belefana, Naama, Gbalatua, Palala, Foequelleh, Baila	June 12 – 13, 2012
4	Lofa County	Salayea, Zorzor and adjacent towns, Voinjama and adjacent towns, Kolahun and adjacent towns, Foya and adjacent towns	June 13 – 18, 2012
5	Nimba County	Kpain and adjacent towns, parts of Ganta	June 19 – 20, 2012

### Team C

1. Diana Jeator
2. Samuel Toe
3. J. William Nyanti

No.	County	Towns and areas visited	Dates
1	Cape Mount	Robertsport, The, Tiene	June 8, 2012
2	Grand Gedeh	Zwedru and adjacent towns, Bawo	June 11 -12, 2012
3	River Gee	Tiehnpo, Fish Town and adjacent towns	June 13, 2012
4	Maryland	Plebo, Harpeh	June 14, 2012
5	Grand Kru	Grand Cess, Sass Town, Barclayville	June 15, 2012
6	Sinoe	Greenville and adjacent towns	June 17-19, 2012
7	Nimba	Ganta	June 19-20, 2012

### A. Purpose

1. To ensure safe, efficacious and quality pharmaceutical products are available on the Liberian market and that they are distributed from licensed facilities by qualified personnel.
2. To establish the extent of the availability counterfeit, expired, substandard, adulterated, unregistered/unlisted pharmaceutical products on the Liberian market.

### Aim and objectives:

1. To ensure safety, efficacy, and quality of all medicines and health products.
2. To create awareness of the functions and duties of the Authority
3. To make sure that every pharmaceutical outlet has trained and qualified dispenser
4. To ensure that all pharmaceutical premises are duly registered

### II. Inspection Process

#### 1. Tools

- a. Three vehicle
- b. Fuel
- c. Checklists for importers/wholesalers, hospitals, NGOs, retail pharmacies and Medicine stores.

- d. Confiscation forms
- e. Quarantine forms
- f. Plastic bags
- g. Stationeries (pens, pencils, note pads, carbon sheet, markers, erasers, sharpeners, etc.)
- h. Letter of authorization and identification cards
- i. LMHRA 2010 Act
- j. LMHRA brochures, fliers
- k. LMHRA/PBL Draft regulations for Accredited Pharmacies and Medicine stores
- l. Scotch tapes

**2. Methodology**

- a. Team formation (7 persons; 4 from LMHRA, 2 from PBL and a driver)
- b. Communications (letters, interviews, phone calls, etc.)
- c. Counties were divided into districts

**3. Training/Orientation**

One day training/orientation was held on June 7, 2012 before the commencement of the inspection; purpose and aim/objective were explained by the Managing Director of LMHRA.

**III. Findings**

**TEAM A**

**I. A) County Specific Findings**

<b>GBARPOLU COUNTY</b>					
<b>Time</b>	<b>No. Medicine Stores</b>	<b>No. of Pharmacies</b>	<b>No. of Hospitals</b>	<b>Comments</b>	<b>Recommendations</b>
<b>Fri., June 8, 2012</b>	4	N/A	1	Untidiness, untrained dispensers, counters made of plastics, storage of biological on shelves, lack grill doors, improper temperature, expired products, and products not properly arranged	Need tidy facilities, fan, change counters to glass, install grill doors, do stock rotations, avoid the sale of injectables, etc.
<b>LOWER MARGIBI COUNTY</b>					
<b>Mon., June 11, 2012</b>	8	4	N/A	Untrained dispensers, not register with Pharmacy Board of Liberia, sales of	All health products on shelves must be properly arranged, have good storage condition, trained

				biologicals on shelves, expired products sold on shelves, poor storage temperature, untidiness, no available invoices, health product not properly arranged on shelves.	dispenser, register with Pharmacy board of Liberia etc
<b>GRAND BASSA COUNTY</b>					
<b>Tue., June 12, 2012</b>	25	3	3	Unqualified dispensers, not register with Pharmacy board of Liberia, no electricity, no toilet and hand wash, untidiness, and dispensers not uniform	Need trained dispensers, register with pharmacy of Liberia, have toilet, face basin for hand washing, clean facilities, good storage, etc.
<b>RIVER CESS COUNTY</b>					
<b>Wed., Jun. 13, 2012</b>	2	N/A	1	One opened, unregistered, drugs not properly arranged on shelves, stock rotation poor	Practice stock rotation, proper arrangement of drugs on shelves, should register with Pharmacy Board of Liberia
<b>NIMBA COUNTY</b>					
<b>Thur., June 14 - Wed., June 20, 2012</b>	44	N/A	3	Majority not registered with Pharmacy Board of Liberia, drugs not arranged properly, sale of biological products on shelves, unqualified dispensers, untidiness, expired products, products lack manufacturer's name & address	To register with pharmacy Board of Liberia, have train dispensers, have all drugs properly labeled (have full manufacturer's name and address), stop the purchase of medicines from Guinea

### III. B. General Observations

#### 1. Medicine stores

- A. Medicines not properly arranged
- B. Inadequate ventilation
- C. Unqualified dispensers
- D. Walls not easily cleanable
- E. Sale of biological on shelves
- F. Presence of expired medicines
- G. Some products lack manufacturer's name and address

#### 2. Pharmacy

- A. Poor storage condition
- B. Unqualified dispensers

- C. Inadequate ventilation
  - D. Floors are not easily cleanable
3. Hospital Pharmacy/county depot
    - A. Dispensers were not using gloves and masks
    - B. Improper storage of biologicals

**IV. Findings**

1. Most of the medicine stores are not registered with the Pharmacy Board of Liberia
2. Presence of expired, substandard and counterfeit medicines in medicine stores, pharmacies and some hospitals
3. There are poor storage of biological in pharmaceutical outlets

The use of unqualified dispensers in medicine stores and pharmacies

**TEAM B**

The general observations from the inspection conducted from June 8-20, 2012 are summarized in the below table:

<b>NONCONFORMANCES</b>			
<b>Pharmacies</b>	<b>Non-Governmental Organizations</b>	<b>Hospitals</b>	<b>Medicine Stores</b>
1. No refrigerator to store biological products 2. Poor ventilation 3. Do not consult PBL to dispose of expired medicines.	1. No trained personnel to manage the pharmaceutical warehouse 2. No easily cleanable walls 3. No Superintendent Pharmacists	1. No smooth shelves 2. No adequate manpower (dispensers) 3. No current LMHRA License	1. Most of the medicine stores are not registered with PBL 2. No adequate ventilation 3. No qualified dispensers in most stores 4. No strong grilled doors and windows 5. No easily cleanable floor 6. Counterfeit and substandard medicines were confiscated 7. Floors are not clean and disinfected regularly. 8. Most shelves not smooth 9. No ceiling fans
<b>CONFORMANCES</b>			
<b>Pharmacies</b>	<b>Non-Governmental Organizations</b>	<b>Hospitals</b>	<b>Medicine Stores</b>
1. Conducive environment for the sale of pharmaceutical products. 2. Superintendent by licensed	1. Conducive environment 2. Presence of acceptable lighting condition 3. Presence of	1. Most of the hospitals have resident qualified pharmacists 2. Cooperative 3. Presence of	1. Most of the medicine stores are assessable. 2. Willingness to improve stores 3. Very cooperative 4. All products on shelves 5. Presence of telephone contacts

3. Presence of telephone contacts	strong grilled doors 4. Presence of telephone contacts	acceptable cooling air conditioning system 4. Presence of telephone contacts	
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- Details of the above findings could be found in the duly filled checklists used for the conduct of inspections for each facility.
  - a. Nonconformances generally observed on products
    - No manufacturers
    - No expiry dates
    - Cold-chain not maintained for biological products
    - Discolorations some products such syrups, suspensions, etc.

**TEAM C**

**GENERAL FINDINGS ON PREMISES**

4. Pharmacy

<b>Conformity</b>	<b>Non-conformity</b>
Products are well arranged on shelves	Inadequate cooling system
Premises are duly registered	Inadequate ventilation
Good lighting system	Non easily cleanable floor

5. Medicine stores

<b>Conformity</b>	<b>Non-conformity</b>
Premise is located in a conducive environment	Inadequate ventilation
	Unqualified dispensers

6. Hospital Pharmacy/county depot

<b>Conformity</b>	<b>Non-conformity</b>
Good lighting system	No thermo hygrometer
Good cooling system	Unqualified dispenser
	No hospital pharmacist

7. NGOS pharmaceutical warehouses

<b>Conformity</b>	<b>Non-conformity</b>
Most warehouse s are ideally located	Unqualified warehouse managers
Thermo hygrometer in warehouse(Merlin, River Gee)	Limited storage capacity
Good cooling system	Warehouse close to dumpsite (Merlin in Greenville)
	Wall of warehouse is being eaten by

	termites and has spread to the products on the shelves (Merlin in Greenville)
	Both floor and wall not easily cleanable

**General finding on products**

1. Poor storage condition of biological (TAT)
2. Some medicines without manufacturer name and address
3. Some medicines without manufacturer date and expiry date
4. Expired products found on shelves
5. FEFO (first to expire first out not been practice)
6. Many damaged (caked) suspension powder found on shelves
7. Biological and psychotropic substances not found in hospitals

**V. Challenges**

1. Bad road conditions
2. Time for inspections was too short and the process disturbed by rains and overflow of rivers
3. Delay in granting permission for the inspection of hospitals and pharmacies

**VI. Conclusion**

The inspection tour covered thirteen Counties. Only Montserrado County was not included. During the inspection tour of the counties, a total of three hundred and six (306) medicine stores, eighteen (18) pharmacies, twenty three (23) hospitals and five (5) NGO ware houses were inspected. It can be concluded from the findings that most of the medicine stores are unregistered with the Pharmacy Board of Liberia and have many suspected counterfeits and substandard medicines on their shelves. Biological products are poorly stored and the medicines shops are not regularly cleaned. The use of unqualified dispensers in almost all pharmaceutical outlets and medicines stores is rampant.

The expected outcomes of the nation-wide inspection were considerably achieved. That is, health facilities and authorities and the public across the country were informed about the establishment and functions of the Liberia Medicines & Health Products Regulation Authority (LMHRA). It is now hoped that pharmaceutical facilities and proprietors will work in consultation with the LMHRA to promote safety, efficacy and quality of all medicines and health products in Liberia. Most medicine stores are engaged in wholesale while the hospitals lack hospital pharmacists. Hospitals lack medicines thus patients are sent to medicine stores to purchase medicines, eg. T.A.T. Drug depots hospitals are poorly ventilated no cooling system, and poor lighting system.

**VII. Recommendations**

From the observation, the following actions are recommended.

1. The Pharmacy Board of Liberia decentralizes the registration process of retail pharmacies and medicine stores.
2. The Pharmacy Board of Liberia encourages the operation of retail pharmacies in every major cities/towns to sell injectables.

3. Pharmaceutical outlets engaged in the sale of biologicals should have proper storage capacities.
4. That national inspections be conducted more regularly (quarterly).
5. That LMHRA should divide Liberia into five regions and establish regional offices
6. That LMHRA in collaboration with PBL conduct periodic workshops/training seminar for managers and dispensers.
7. To enhance efficiency, there should be deployment of county pharmacist for each county and hospital pharmacist for each hospital and major health centre.
8. That LMHRA/PBL in collaboration with the county health team conduct workshop with local leaders (Township commissioners, Town chiefs, etc. etc.) in order to disseminate information about the harmful effects of purchasing medicines from peddles and “black baggers”

**ANNEX 7**

**LMHRA Inspection Plan July 8 – December 3, 2012**

<b>NO.</b>	<b>ACTIVITY</b>	<b>OBJECTIVES</b>	<b>METHODOLOGY</b>	<b>TIME OF IMPLEMENTATION</b>
1	Inspection of all warehouses of Pharmaceutical importers in Monrovia	To ensure that good warehousing practices are employed to conserve the quality of products	Teams will be formed and assigned to particular companies in zones. Companies will be expected to take corrective actions after the inspections	July 10 – August 8, 2012
1	Inspection of all pharmaceutical containers	To ensure that all medicines entering the country are inspected before distribution.	Pharmaceutical products & documents will be inspected during the offloading of containers.	August 11 – 20, 2012
2	Incineration of pharmaceutical products confiscated	To dispose of all expired & products that failed the analysis test.	Products will be transported to incineration site by the owner.	August 21 – 23, 2012
3	Writing of reports & also inspections of pharmaceutical containers	To give accounts by written documents & ensuring that all medicines entering the country are inspected before distribution.	Reports will be written by the two Inspectors and submitted to the Head of Inspectorate for verification.	August 23 – 30, 2012
4	Post Market Surveillance of anti-malaria in medicine stores, pharmacies, hospitals, NGOs warehouses, & informers & also inspection of containers.	<ol style="list-style-type: none"> <li>1. To ensure that quality anti-malarial products are circulating in the Liberian Market.</li> <li>2. To ensure that the Malaria Control Treatment Policy is practiced by using combined Artesunate based therapy.</li> </ol>	<ol style="list-style-type: none"> <li>1. Project proposal will be written to Global Fund &amp; Malaria Control.</li> <li>2. Anti-malarial drugs will be purchased from the markets. Anti-malarial medicines will be collected from hospitals &amp; NGOs.</li> <li>3. Anti-malarial drugs purchased &amp; collected from markets, hospitals &amp; NGOs will be transferred to LMHRA Quality Laboratory for analysis.</li> </ol>	September 1 – 30, 2012
5	Inspections of pharmaceutical	To ensure that quality medicines are sold in the	1. There will be three (3) teams & three (3)	October 1 – 31, 2012

	outlets & containers	outlets.	<p>persons will be in each team.</p> <p>2. There will be alternate working schedule to ensure that one team is in the office everyday to write reports &amp; takes care of office matters &amp; inspect containers.</p>	
6	Follow-up inspections for pharmaceutical warehouses & outlets.	To ensure that all non-conformances are corrected	<p>3. There will be three (3) teams &amp; three (3) persons will be in each team.</p> <p>4. There will be alternate working schedule to ensure that one team is in the office everyday to write reports &amp; takes care of office matters &amp; inspect containers.</p>	November 10 – December 4, 2012
7	<p>1. Incineration of expired &amp; products that failed analysis tests.</p> <p>2. Writing of reports</p> <p>3. Inspections of containers</p>	<p>1. To dispose of all expired &amp; products that failed the analysis test.</p> <p>2. To give accounts by written documents &amp; ensuring that all medicines entering the country are inspected before distribution.</p> <p>3. To ensure that all medicines entering the country are inspected before distribution.</p>	<p>1. Products will be transported to incineration site by the owner.</p> <p>2. There will be alternate working schedule to ensure that one team is in the office every day.</p> <p>3. Pharmaceutical products &amp; documents will be inspected during the offloading of containers.</p>	December 5 – 31, 2012