

PQM Regulatory Support and Technical Assistance to the Liberia Medicines and Health Products Regulatory Authority

**Monrovia, Liberia
March 28- April 7, 2011**

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

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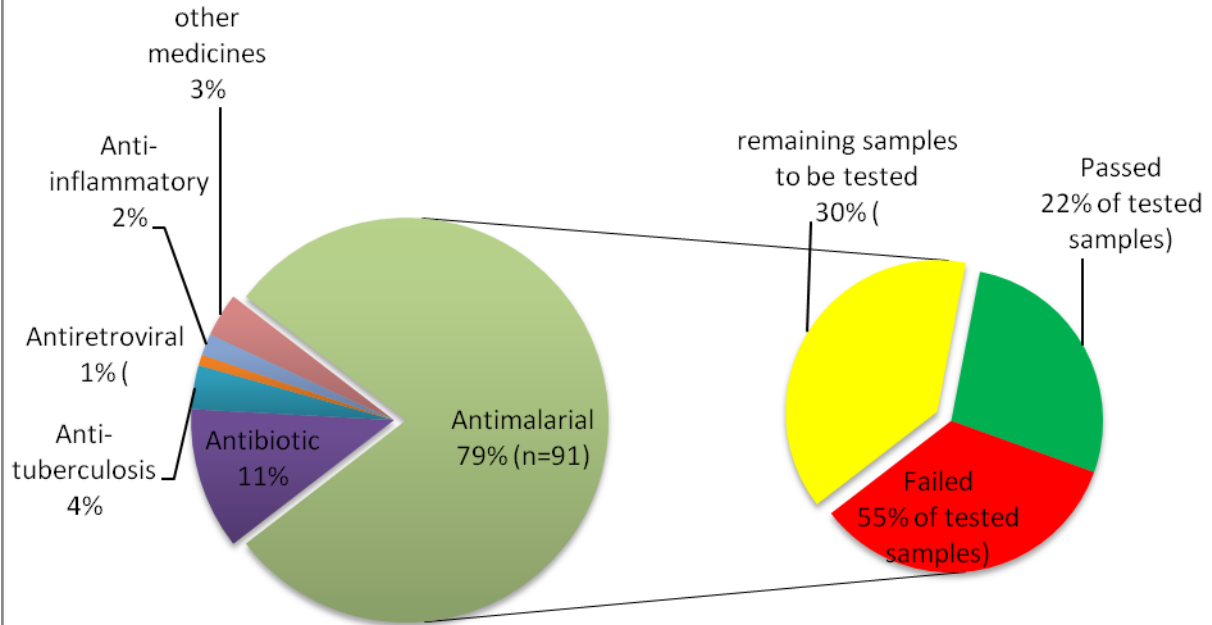
Annex 5

**Results of Collected and Tested Samples
MQM Round 2 / Monrovia, Liberia**

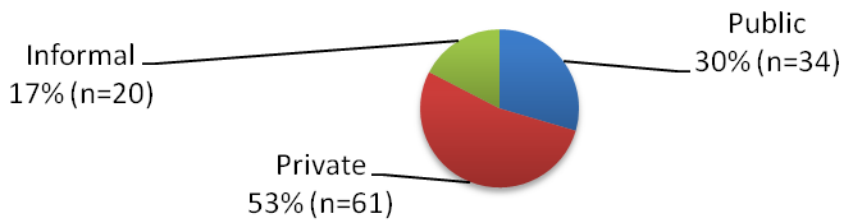
Table	Summary Results of Tested Samples: Round 2				
Name of Medicine	Dosage Form	Total Tested	Pass	Fail	% of Failed Samples
Amodiaquine	Tablet	6	2	4	67
Artesunate	Tablet	3	1	2	67
Artesunate/ Amodiaquine	Tablet	19	12	7	37
Artesunate/ Sulfamethoxypyrazine/ Pyrimethamine	Tablet	1	1	0	0
Chloroquine	Tablet	4	3	1	25
Quinine sulphate	Tablet	5	1	4	80
Quinine sulphate	Injection	5	0	5	100
Quinine sulphate	Syrup	1	0	1	100
Quinine sulphate	Suspension	3	0	3	100
Sulfadoxine/ Pyrimethamine	Tablet	9	5	4	44
Amoxicillin	Tablet	1	0	1	100
Ciprofloxacin	Tablet	3	3	0	0
Paracetamol	Tablet	1	1	0	0
Total		61	29	32	52

Summary of Collected (n=115) and tested (n=56) samples .

Minilab test results of tested antimalarial samples






Samples Collected in Liberia 2011 Round 2 - Sampling Distribution by Sector (n=115)

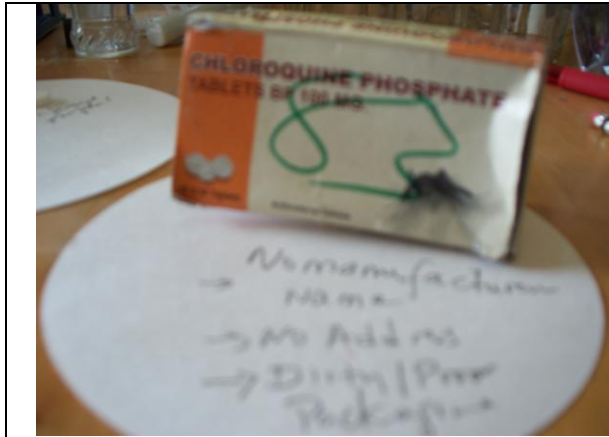


Annex 6

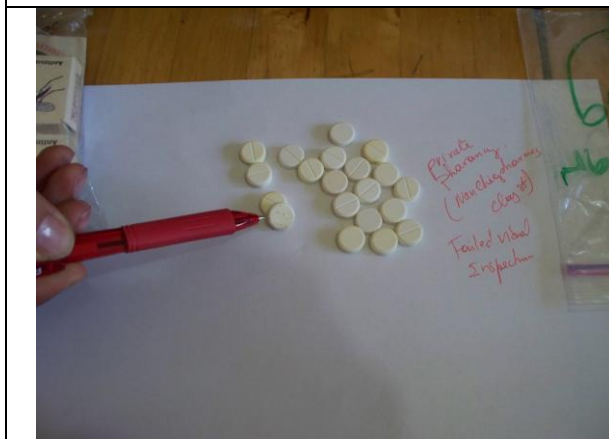
Counterfeits and substandard samples found in the Liberian market
Round 2 , Monrovia / Liberia, April 2011

Table	Round 2 : Major Findings		
API	Sector	Lot #	Comments
Samples with no API			
Quinine Solution	Private/Importer Pharmacy	ECQ-10001	Oral quinine solution with the brand name Colquine. TLC results showed no API. See Picture 1.
Quinine Solution	Private Pharmacy	ECQ-10001	
Artesunate Tablets	Private Pharmacy	07015FX	Artesunate tablets. Brand name Artesunate. TLC results showed no API. See Picture 2.
Samples failed visual inspection / Counterfeits			
Amoxicillin Tablets	Private Pharmacy	1011612	Amoxicillin tablets with the brand name Amoxicillin B.P. Was found to be substandard during the visual inspection. See Picture 3.
Chloroquine Tablets	Informal Vendor	1004P02	Chloroquine tablets with the brand name CHQ. This sample presented very poor packaging, dark spots on the tablets, and no manufacturer name and address. See Picture 4.
Artemether Injection	Importer/ Sonia	Not available	Artemether injection from one of the main importers in Liberia. This type of injection is used for severe malaria. The sample was found at LMHRA office to be listed as new medicine to be sold in the market. The sample failed visual inspection (presence of particles, ampoules in different colors, cloudy solution, and unequal solution volume). See Picture 5.
Quinine Suspension	Private Pharmacy	DQ-04	Oral quinine with the brand name PD-Quin. Was found to be substandard due to the presence of impurities and a TLC spot intensity < 80%. See Picture 6.
Quinine Suspension	Private Pharmacy	SX-20	Oral quinine with the brand name Dyquin. Was found to be substandard due to the presence of impurities and a TLC spot intensity < 80%. See Picture 7.
Sulfadoxine; Pyrimethamine Tablets	Private Pharmacy	Not available	Sulfadoxine; pyrimethamine tablets with the brand name Fansidar. Was found to be substandard during the visual inspection (dark spots and mold on the tablets, non-uniform color). TLC results confirmed that the sample was substandard. See Picture 8.
Additional Findings			
<ul style="list-style-type: none"> ✓ Artesunate-Amodiaquine (Winthrop) from Global Fund found diverted from public to private and informal. These are some lots #1026, 3045, 3046, 5113, 5125, 5154 sectors. See Picture 10. (41% of diverted ACTs) ✓ Some samples were sold in plastic bags. With hand written information. No assurance on what is claimed on the plastic bag Example : Chloroquine Tablets from private pharmacy See Picture 9. ✓ No oral formulation was found in good storage condition (temperature s above 37 degree Celsius and high humidity). ✓ Very poor storage condition at LMHRA, all private sectors (some pharmacies have small generators no electricity) ✓ Medicines are exposed to sun , and dust, Price not marked on the packaging of medicines ✓ Same antimalarial samples sold at different prices ✓ Medicines sold form the trunk of cars ✓ Untrained personnel selling medicines ✓ Samples sold in loose plastic bags with hand written information see picture 			

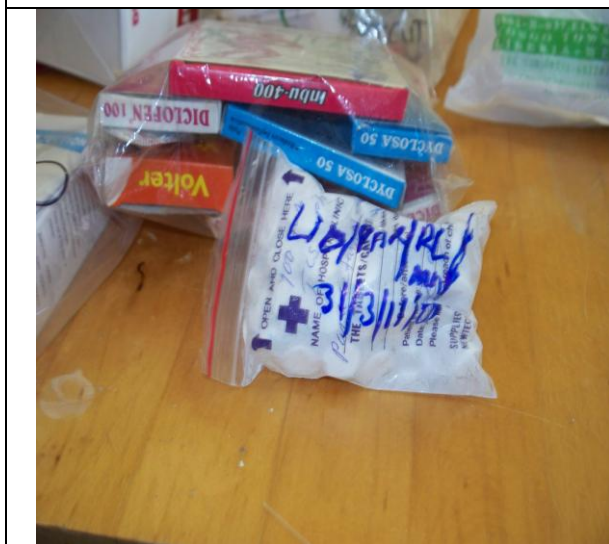
Counterfeits and substandard samples found in the Liberian market Round 2 , Monrovia / Liberia , April 2011	
Pictures:	Comments:
	<p>Picture 1: Sample 51 (oral quinine solution with the brand name Colquine and lot # ECQ100010). TLC results showed no API.(counterfeit)</p>
	<p>Picture 2: Sample 86 (artesunate tablets with the brand name Artesunat and lot # 07015FX) was found to contain no API(Counterfeit)</p>
	<p>Picture 3: Sonia is a registered importer. This sample was collected from LMHRA office. Sample sent by the importer to be listed as a new medicine to be sold in the market. Artemether injections are used for severe malaria.</p> <p>Fail visual inspection : ampoules of different colors, unequal volume solution , presence of particles and cloudy solution</p>



Picture 4: Sample 83 (Chloroquine tablets with the brand name CHQ and lot # 1004P02) was found to be substandard due to the lack of a manufacturer name or address on the packaging as well as failure during the visual inspection.



Picture 5: Sample 98 (sulfadoxine pyrimethamine tablets with the brand name Fansidar and lot #) failed visual inspection and TLC testing



Picture 6: Some samples were sold in bags such as this one. No assurance on what is claimed on the plastic bag: any API, dosage strength, or expiry date could be written on these bags without any way to check their validity.



Picture 7: Sample 55 (oral quinine with the brand name PD-Quin and lot # DQ-04) was found to be substandard due to the presence of impurities and a TLC spot intensity < 80%.



Picture 8: Artesunate; Amodiaquine (Winthrop) funded by Global Fund found for sale in the private and informal sectors.



Picture 9: Sample 63 (oral quinine with the brand name Dyquin and lot # SX-20) was found to be substandard due to the presence of impurities and TLC spot intensity < 80%.



Picture 10: Sample 113 (amoxicillin tablets with the brand name Amoxicillin B.P. and lot # 1011612) failed visual inspection.

Lab training and other pictures .Liberia visit March –April 2011



Picture 11: Lab staff handling chemicals outside the lab because there is no fume hood



Picture 12: Dr Parker Bright, Head of LMHRA thanking Dr Noe Rakotondrajaona , PMI / USAID, and Dr. Hernandez Filiberto CDC/ USAID for the lab supplies funded by USADI PMI Liberia Monrovia



Picture 13: Entrance of The Liberia Medicines and Health Products Regulatory Authority (LMHRA) building. The office is located in apartment 3 rd floor



Picture 14: Dr. El-Hadri speaks with a patient outside of the pharmacy of ELWA public hospital



Picture 15: The water used at the lab as distilled water was found to be contaminated.



Picture 16: Due to a lack of an adequate space to eat, technicians eat in a room within the lab.



Picture 17: Dr. El-Hadri shows how to interpret TLC results to QC lab analysts



Picture 18: Dr. El-Hadri presents the counterfeit artemether injection to USAID Mission



Picture 19: Dr Parker Bright, Head of LMHRA. Handing training certificate to lab staff trained by USP PQM .



Picture 20: Dr Smine , Dr Parker Bright, Head of LMHRA, Dr . El-Hadri, and the trainees of LMHRA QC lab .



Picture 21

Sampling team supervised by Dr El Hadri .

From right Nyenekon n. Won, MHO, Latifa El AHdri , USP/PQM, Arichabald o. Kromah, LMHRA, Patricia Freeman, LMHRA, and Suwah Kurbah , NDS. Monrovia Liberia march 31,2011



Picture 22: The Red-Light section of Monrovia is a large marketplace from which many medicine samples were collected from the informal and private sectors.



Picture 23: The collection team hard at work