

**Monitoring and Evaluation of Minilab<sup>®</sup> Activities at Kakamega and Eldoret Sentinel Sites, Dissemination of Minilab<sup>®</sup> program results with stakeholders, and Meetings with the National Quality Control Laboratory**

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***Trip Report***

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## **Executive Summary**

In collaboration with the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL), and the Division of Malaria Control of Kenya (DOMC), the Promoting the Quality of Medicines (PQM) program organized two monitoring and evaluation (M&E) visits to two sentinel sites, Kakamega and Eldoret. The site visits were conducted with Dr. Andrew Nyandigisi, Program Officer from DOMC, and were aimed to evaluate sampling, testing, and reporting of Minilab<sup>®</sup> activities. The findings from the M&E visits include the need to improve sampling methods (to get good samples and an adequate number of units) and testing techniques using thin-layer chromatography (TLC). In addition, doubtful antimalarial samples were found, including four artemisinin-based combination therapies (artemether-lumefantrine tablets), one suspension, and one Sulfadoxine Pyrimethamine tablet. The doubtful samples were sent immediately to the NQCL for compendial testing as they are part of DOMC's national malaria treatment guidelines. Recommendations on how to address the Minilab<sup>®</sup> challenges were provided on site and ways of moving forward were discussed with MQM team leaders from PPB, NQCL, and DOMC.

The Health Commodities and Services Management (HCSM) Program held a dissemination meeting to present the results of medicine quality monitoring (MQM) round 3, and information was prepared jointly among PQM, PPB, NQCL, and DOMC. The main outcomes of the meeting encompass the expansion of the MQM program to include essential medicines in addition to antimalarials and expansion of the existing program to cover the eleven ports of entry.

During this trip, PQM met with the former NQCL director, Dr. Hezekia Chepkwony, who was reappointed in September 2013 as the director of the lab. Dr. El Hadri, the NQCL director, and other NQCL management staff discussed the findings from the PQM quality management system assessment performed in April 2013 and followed up on the lab's progress towards ISO 17025 accreditation.

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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 medicines quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensures 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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- The sentinel site teams of Kakamega and Eldoret for their valuable participation during the monitoring and evaluation visits of their respective sites
- Dr. Kusu Ndinda, Deputy Chief of Party, Health Commodities and Services Management Program, for her and her team's support at the Management Sciences for Health dissemination meeting
- PQM colleagues for their valuable contributions in organizing my trip and editing this report
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## Acronyms

API	Active Pharmaceutical Ingredient
DOMC	Division of Malaria Control
DQI	Drug Quality and Information Program
HCSM	Health Commodities and Services Management
M&E	Monitoring and Evaluation
MQM	Medicines Quality Monitoring
MSH	Management Sciences for Health
NQCL	National Quality Control Laboratory
PMI	President's Malaria Initiative
PMS	Post-marketing Surveillance
PPB	Pharmacy and Poisons Board
PQM	Promoting the Quality of Medicines Program
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia

## **Background**

PQM started working in Kenya in 2009 with the support of the President's Malaria Initiative (PMI) through USAID/Kenya. PQM created a protocol for medicines quality monitoring (MQM) in Kenya, and five sentinel sites for MQM were established. PQM initiated the first round of MQM activities in 2010 by training representatives of the Pharmacy and Poisons Board (PPB), the National Quality Control Laboratory (NQCL), and others in sampling strategies, Minilab<sup>®</sup> basic tests, and reporting and managing medicines quality data.

The second and third MQM rounds were carried out in 2011 and 2012. Based on findings, PPB has been able to take regulatory actions by jailing the sellers of counterfeit antimalarials, closing a manufacturer for selling poor quality and unregistered samples, recalling non-conforming samples, and destroying expired antimalarials.

In January 2012, PQM presented the findings and the actions taken by the PPB regarding unregistered, expired, and failed antimalarial samples. This presentation was given at a meeting organized in collaboration with the Division of Malaria Control (DOMC) and the Management Sciences for Health/Health Commodities and Services Management (MSH/HCSM) program. During this meeting, the participants discussed the challenges being encountered and devised a way forward, with emphasis on how to integrate post-marketing surveillance (PMS) activities under one program.

PQM also provides technical assistance to NQCL in the process of attaining ISO 17025 accreditation. Due to changes of management of the lab, the progress of this activity has been delayed, and major lab deficiencies were found during PQM's assessment of the lab. A detailed report on the findings was shared with the new director, and plans were made to address all the challenges.

## **Purpose of Trip**

- Conduct monitoring and evaluation (M&E) of Minilab<sup>®</sup> activities at Kakamega and Eldoret sentinel sites
- Review the sampling and testing of MQM Round 4
- Present results of MQM rounds 2 and 3 to relevant stakeholders
- Review the NQCL's progress towards ISO 17025 accreditation

## **Source of Funding**

This trip was supported with funds from PMI through USAID/Kenya.

## **Overview of Activities**

### ***Monitoring and Evaluation Visits to Kakamega and Eldoret sentinel sites***

Dr. El Hadri and Dr. Nyandigisi, DOMC Program Officer, traveled to Kakamega and Eldoret sites to monitor and evaluate the Minilab<sup>®</sup> activities at these sites. The PQM and DOMC staff conducted the M&E activities according to a pre-established plan between the team at the visited sites and the team coming from central level (See *Annex 1* for the agenda).

During the M&E visits, the main activities evaluated included how the sentinel site teams conduct sampling in the field and how they conduct Minilab<sup>®</sup> testing on the samples they collect. Additionally, this visit provided an opportunity to discuss with the teams the challenges they encounter in the field and recommendations on improving future rounds.



M&E visits at Eldoret and Kakamega sentinel sites



The major findings of the M&E visits are summarized in the table below:

<b>Monitoring and Evaluation of Minilab<sup>®</sup> Activities at Kakamega and Eldoret Sentinel Sites</b>		
<b>Protocol Guidelines</b>	<b>Report Findings</b>	<b>Way Forward</b>
Sampling strategies/ distribution	<ul style="list-style-type: none"> <li>Total number of samples to be collected from each was respected (100 samples)</li> <li>Slight discrepancy in sampling distribution due to difficulties in getting the 40 units for each sample with same batch number</li> <li>Less variation than the last round in the number of units collected per sample</li> </ul>	<ul style="list-style-type: none"> <li>The team leader should review the sampling strategies with the team before the onset of sample collection in the field.</li> </ul>
Sample code	<ul style="list-style-type: none"> <li>Sample codes were respected, according to the protocol. The primary and secondary packaging were clearly labelled.</li> </ul>	<ul style="list-style-type: none"> <li>Continue to make sure that primary and secondary packaging is well labelled using the same sample code.</li> <li>Harmonization of sample code is necessary to permit sample traceability in</li> </ul>

		case more sample units are needed for compendial testing and for tracking the sample to the source of collection should action need to be taken by PPB.
Sample collection	<ul style="list-style-type: none"> <li>Inspectors involved in sample collection are known by the majority of the retailers resulting in biased sampling (gave them good samples)</li> <li>Some pharmacists refused to sell more than one batch. Others requested results of the previous sample collection. The case of having pharmacists who refused to sell medicines to sample collectors is predominant in the public sector.</li> <li>Resident pharmacists of the hospitals where the Minilabs<sup>®</sup> are placed were not well informed about Minilab<sup>®</sup> activities and were not trained in Minilab basic tests.</li> </ul>	<ul style="list-style-type: none"> <li>Use analysts from the lab and/or mystery shoppers.</li> <li>Need to provide the names of pharmacies who refuse to sell medicines to PPB to address this issue with them</li> <li>Need to have the resident pharmacists involved actively in Minilab<sup>®</sup> activities. Next step is to provide Minilab<sup>®</sup> basic test training to resident pharmacists of sentinel sites.</li> </ul>
Sample handling	<ul style="list-style-type: none"> <li>Sample handling was improved and all collected and tested samples were placed in labelled boxes. However, failed samples were all placed within the same boxes as the passed samples.</li> </ul>	<ul style="list-style-type: none"> <li>Having the Thin Layer Chromatography (TLC) plate with the collecting form is important for the NQCL analyst during the verification with Minilab<sup>®</sup> and compendial testing.</li> <li>Proper sample handling and storage is important for further testing and for verifying medicines information, if needed, at the lab or by the PPB for regulatory actions.</li> </ul>
Testing	<ul style="list-style-type: none"> <li>Found more than 20 TLC plates poorly done with no labels. The remaining were clearly labelled and attached to the sample form.</li> </ul>	<ul style="list-style-type: none"> <li>Some samples were tested onsite and proper TLC plate spotting and recording information methods were shown to the team. There is a need to conduct a Minilab<sup>®</sup> refresher training for the sentinel site team since three senior lab analysts (team leaders) have left the NQCL.</li> </ul>
Reporting	<ul style="list-style-type: none"> <li>Data reporting was improved and registration statuses were captured.</li> </ul>	<ul style="list-style-type: none"> <li>Use of a spreadsheet will allow exploration of other findings on collected medicines and will enable PPB to take immediate action on failed samples.</li> <li>Registration status was completed by the PPB focal point. In the next round, PPB needs to submit the list of registered antimalarials to the team leaders. This way they can detect unregistered samples at the sites.</li> </ul>

During these M&E visits, PQM demonstrated correct spotting, labeling, and data reporting. Dr. El Hadri emphasized the need to review the analytical method in the manual before testing the collected samples and to make sure that the dilution factor is well calculated according to the active pharmaceutical ingredient strength and the TLC method as described in the Minilab<sup>®</sup> manual. Following this session, Dr. El Hadri, Dr. Nyandigisi, and the sentinel site teams went to the market to monitor how the team can

play the role of mystery shopper to buy samples. After visiting a few outlets, Dr. El Hadri discussed some techniques that mystery shoppers can use in order to get more sample units without raising the suspicion of the dispenser. For example, mystery shoppers can say that they need more units because they have large families, or that they need cheaper medicines because they cannot afford the more expensive brands. Dr. El Hadri also noted that there are situations where pharmacists can give a 10% to 15% discount on procured samples. In addition, Dr. El Hadri noticed that when she inquired about cheaper products, the dispenser provided her with products underneath the counter that were not displayed on the shelves.

In addition to the findings on Minilab<sup>®</sup> activities, the site visits revealed the following major outcomes:

- There were five doubtful artemether-lumefantrine (AL) products (tablets and suspension), three failed sulfadoxine-pyrimethamine (SP) tablets, and one failed quinine tablet. All failed and doubtful samples were sent to the NQCL for confirmatory testing using compendial methods.
- The regional inspectors who were previously trained on Minilab<sup>®</sup> basic tests were appointed to the ports of entry of the visited sites. Thus, there is an urgent need to train the resident pharmacists.
- The site teams showed that some medicines that were supposed to be for export only were found in the market.
- Dispensers at the visited sites reported that some patients were given quinine and came back three days later reporting that the medicines did not have any effect. Other health professionals mentioned that some patients showed resistance to AL.
- Some pharmacists and other healthcare staff at the health facilities inquired about the Minilab<sup>®</sup> activities and requested to be informed of the results of the medicines collected from their facilities.
- Some analysts mentioned that dispensers from some health outlets asked them to test herbal antimalarial tablets.
- In Nairobi sentinel sites, the team marked a stock out of some medicines (SP, quinine, artesunate-amodiaquine) in public and private sectors. Some artesunate-amodiaquine for pediatric usage had short expiry dates. Dr. El Hadri requested that team leaders note all this information during sampling and emphasized sending such information immediately to DOMC and to the MQM focal point.

### ***Presentation of MQM program results for round 3 at MSH office***

The Health Commodities and Services Management (HCSM) Program supported the dissemination meeting, and information was prepared jointly among PQM, PPB, NQCL, and DOMC. The purpose of this meeting was to present the results of MQM round 3 (2012) and discuss ways of harmonizing this activity and expanding it to other sites. Presentations given during the meeting can be obtained by contacting Dr. El Hadri at [lwe@usp.org](mailto:lwe@usp.org).

After the introduction of the participants, Dr. Nyandigisi gave an overview of the Minilab<sup>®</sup> program and subsequent compendial testing at NQCL. He then provided more information on the results of the third round of MQM activities. Following this presentation, Dr. Kimatu, focal point for MQM activities and director of PPB, shared with the audience the regulatory actions (see *Annex 2* for details) taken by PPB regarding the quinine tablet with no active pharmaceutical ingredient (API) and the substandard quinine injection. He also mentioned that there is a need to review the PPB law that enables the authority to take

action on counterfeit medicines and to increase fines and penalties for unlawful sellers and pharmacists. He mentioned that in Kenya any counterfeit product is handled by the counterfeit agency and not by PPB. Following his talk, Dr. El Hadri shared the findings of the M&E visits to Kakamega and Eldoret sites and showed samples of antimalarials that either failed visual inspection (in the case of quinine and lumefantrine suspension) or failed TLC testing (in the case of artemether and lumefantrine fixed dose combination). Pictures are included in *Annex 3*. To further investigate the quality of these products, Dr. El Hadri requested that the NQCL urgently conduct compendial testing of these products.

Following these presentations, the participants discussed ways forward to expand this activity to other sites and other medicines and to extend dissemination of the results to a larger audience including the resident pharmacists and chief doctors of the sentinel sites.

Major points for follow-up include:

- Present the results of MQM activities to decision makers and to other health programs
- Establish an integrated PMS system nationwide with itemized budget and share with other donors to increase funding
- Scale up the existing PMS to include the eleven ports of entry and to conduct two rounds of MQM per year
- Request funding from other partners besides PMI
- Empower the counties to screen procured medicines
- Enforce the PPB bills: the Pharmacy Practice Bill and Kenya FDA Bill to better regulate the practice of pharmacy and products



Dissemination meeting at the MSH office with stakeholders including the former CDC Resident Advisor/PMI Kenya, Gladys Tetteh, and the current CDC Resident Advisor/PMI Kenya, Ann Buff



### ***Follow up on the progress of NQCL ISO 17025 Accreditation***

One of the major obstacles to advancing NQCL's progress toward ISO 17025 accreditation was the high turnover of NQCL managers and directors. In less than one year, two acting directors were appointed, and four lab managers left NQCL. This issue has impacted the implementation of planned activities, especially the release of the quality control testing results in a timely manner.

In September 2013, the former NQCL director, Dr. Hezekia Chepkwony, was appointed as the director for the lab, and Dr. Paul Njaria was appointed the head of the Quality Assurance Unit. Having new management in place at NQCL, Dr. El Hadri organized a meeting with Dr. Chepkwony, Dr. Njaria, and Dr. Ernest Mbae, deputy director. The main objective of the meeting was to discuss how to advance the implementation of ISO 17025 action plan with the goal of having the lab accredited by the end of 2014. During this meeting, Dr. El Hadri followed up on the pending activities from the last quality management system evaluation and the remaining documents and reports that the NQCL should submit for PQM review.

After these discussions, NQCL management committed to respect the timelines for testing and to provide the internal audit report and management review report. In addition, they will follow up with: corrective and preventive actions from the quality management system and lab inspection, the Kenya Bureau of Standards on obtaining the weight certificates, and SANAS (the accrediting body) to update the new NQCL organization chart established after the appointment of the new NQCL director.

### ***Briefing USAID/Kenya***

Dr. El Hadri and Dr. Kimatu briefed Dr. Kaendi Munguti, Senior Malaria Advisor, on the activities of this trip. Based on a DOMC request at the dissemination meeting, the need to expand the MQM program to other ports of entry and to have two rounds of MQM activities next year was pointed out. In addition to expanding these activities, Dr. El Hadri shared with Dr. Kaendi that DOMC would like to include sampling and testing of other malaria products circulating in the market in addition to the ones in the national malaria treatment plan. For the regulatory aspect of MQM activities, Dr. Kimatu informed Dr. Kaendi that PPB has come up with two bills: the Pharmacy Practice Bill and Kenya FDA Bill to better regulate the practice of pharmacy and products. These bills aim to enforce the regulatory functions of PPB.

Dr. El Hadri shared with the PMI advisor the findings of the doubtful antimalarial products encountered during the current fourth round and the non-registered antimalarial found at Nairobi refugee camp.

At the end of this meeting, PQM discussed the activities for the coming fiscal year. Main activities proposed include having two rounds of MQM activities, training new staff at the regional level, and expanding MQM activities to selected ports of entry.

## **Next Steps**

### **PQM**

- Follow up on NQCL activities pertaining to ISO 17025 accreditation and testing the failed samples during the fourth round of MQM activities (by Oct- Nov 2013)
- Finalize the planned activities in collaboration with PPB and DOMC. (Completed)

- In collaboration with PPB, find the best ways to obtain more sample units during sampling without raising the suspicions of the seller (exercise will take place before the next sampling by December 2013)

#### **NQCL**

- Complete testing of the failed samples and send a complete report to NQCL (by the end of November 2013)
- Provide the ISO 17025 documents to PQM for review (by the end of October 2013)

#### **PPB**

- Follow up on the regulatory actions to be taken on failed samples and investigate the finding of the unregistered antimalarial found at a refugee camp (by the end of November 2013)

#### **DOMC**

- Establish a contract for testing the failed products and 20% of samples that passed basic tests with NQCL. This contract should clearly define the timelines for the results to be submitted by NQCL to DOMC ( by October 2013)

#### **Conclusion**

The site visits revealed the finding of doubtful artemisinin-based combination therapies that are part of national malaria treatment guidelines. Investigations are ongoing on the failed products, and quality control testing is being carried out by NQCL. The issue of NQCL management has been solved. These changes will help NQCL move forward toward the goal of being accredited by the end of 2014. The dissemination meeting was well attended by key stakeholders, and an action plan was made by DOMC to seek more funds from in-country donors, create a PMS program that incorporates additional medicines along with antimalarials, and expand MQM activities nationwide to all eleven ports of entry.

  			
PROMOTING THE QUALITY OF MEDICINES			
<b>Draft Agenda For Kenya June 2012 Visit</b>			
Day	Planned Activities	Description	Comments
Day 1	Travel to Eldoret sentinel site with DOMC program officer	<ul style="list-style-type: none"> <li>Meet with the Eldoret team in the afternoon and discuss the visit logistics</li> </ul>	
Day2	Conduct monitoring and evaluation (M&E) visit	<ul style="list-style-type: none"> <li>Review the collected samples and evaluate sampling and testing on site</li> <li>Collect few samples on site and test them with team</li> <li>Review the excel data sheet</li> </ul>	
Day 3	Complete the activities of the M&E	<ul style="list-style-type: none"> <li>Share the finding with sentinel site team and discuss how to address any challenges encountered during sampling, testing and reporting.</li> </ul>	
Day 4 and 5	Travel to Kakamega sentinel site		
Day 6	Meeting at NQCL with MQM focal point and team leaders from the sites and from the NQCL	<ul style="list-style-type: none"> <li>Share the findings of the M&amp;E visits.</li> <li>Present the challenges and discussion on how to address</li> <li>Validate the samples to be tested using compendial methods starting with the samples that failed level 1 of testing at the sites</li> </ul>	

### Minilab<sup>®</sup> Activities, Round 3 / Major Findings

The Pharmacy and Poisons Board, National Quality Control Laboratory, Division of Malaria Control, and Promoting the Quality of Medicines (PQM) program—funded by the United States Agency for International Development and implemented by the United States Pharmacopeial Convention (USP)—has begun Round 3 Minilab<sup>®</sup> sampling and testing in the five sentinel sites established in Kenya.

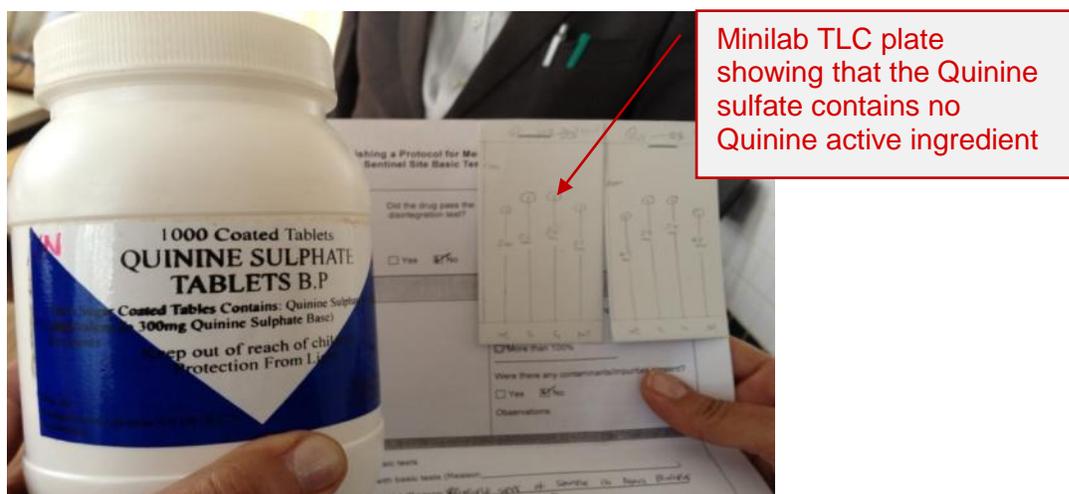
To date, the sentinel site (SS) team collected 613 antimalarial samples from all five sites. The samples (548) underwent Minilab<sup>®</sup> basic tests at the sites. Due to budget constraints, only the failed and doubtful (28 samples) will undergo confirmatory testing. The breakdown of the samples to be confirmed is as follows: SPs =8 samples; Quinine=10; AL= 7; and DHAP=3.

NQCL has analyzed all the SPs and initial reports indicate that all samples passed QC testing. The Quinine samples will be analyzed by the first week of October 2012.

During the sampling, the Kisumu team picked a sample of **Quinine Sulfate Tablets** from a private pharmacy which they suspected of being a counterfeit. The details of the product are listed below:

Name: Quinine Sulfate  
 Batch No. D469  
 Man. Date: Oct. 2009  
 Exp. Date: Oct. 2013  
 Manufacturer: Farmaceuticos Lakeside S. A DF SCV, Netherlands.  
 Sample site: Mainstreet Pharmaceuticals – Jomo Kenyatta Highway,  
 Kisumu (Private Pharmacy)

A picture of the sample can be found below. A similar product has been found at the Kakamega sentinel site.



## **SAMPLE OF FAKE QUININE FOUND IN KISUMU AND KAKAMEGA SENTINEL SITES**

### **Minilab<sup>®</sup> Thin Layer Chromatography (TLC) Testing of the Fake Quinine Sulfate**

The sample failed the TLC tests and a repeat test was run, which again failed.

Dissolution test – Failed (> 35mins)

TLC plate – Failed; only spots of the Standard Sample at 100% and 80% were observed under UV light. The spots of the sample in question were not picked up by the TLC plate, meaning the API was missing.

According to MQM protocol, such a sample is deemed to be counterfeit.

### **PPB investigation on the fake Quinine sulphate**

The team went back to Main Street Pharmaceuticals to investigate this product and get more samples to be sent to NQCL. On investigation, the owner of Main Street Pharmacy revealed that she bought the drug from a person who was hawking it in a briefcase. The hawker did not issue any supply documents, e.g., cash sale receipt, delivery note, or invoice. The team seized the remaining Quinine sulfate and requested the owner to call the supplier to make more deliveries.

Once the hawker agreed to bring more, the inspectors who were part of the team prepared to lay a trap. Together with police officers, the inspectors laid in wait so that the suspect could be arrested when he delivered the drugs. He was arrested when he was doing the sale transaction with the owner of Mainstreet pharmacy.

The culprit refused to reveal the source of the suspected fake product to either the inspectors or the police, only mentioning several locations which could not be verified.

The Inspectors swore an affidavit in Kisumu Law courts for the suspect to be remanded into custody while they conducted investigations. The Magistrate granted the affidavit and instructed the suspect be remanded for two weeks.

An unopened tin of the sample was sent to the NQCL immediately for compendial and other laboratory tests.

### **Regulatory actions taken by PPB**

The fake quinine sulfate was withdrawn from the shelves of the sites where it was found. Results of NQCL were relayed to Kisumu to strengthen the court case. The case came for mention on 27 June 2012 and a full hearing is scheduled for 17 September 2013. The suspect remains in prison since he has been unable to raise a bail of KShs 1 million, equivalent to US\$ 12,000.

The charges preferred against the suspect are:

#### **COUNT 1**

Unlawfully being in possession of part I poisons contrary to sections 26(1) as read with section 26(2) of the Pharmacy and Poisons Act, cap 244 laws of Kenya and as amended by the Kenya gazette supplement no.49 (act no.3) of June 2002.

### **COUNT 2**

Unlawfully carrying on the business of a pharmacist while not registered as a pharmacist by the pharmacy and poisons board contrary to section 19(1) as read with section 19(2) of the Pharmacy and Poisons Act, cap 244 laws of Kenya and as amended by the Kenya gazette supplement no.49 (act no.3) of June 2002.

### **COUNT 3**

Unlawful sale of Part I poisons contrary to section 29(5) as read with section 27(4) and punishable by section 51 of the Pharmacy and Poisons Act cap 244 laws of Kenya and as amended by the Kenya gazette supplement no.49 (act no.3) of June 2002.

### **COUNT 4**

Failing to keep poisons under lock and key contrary to rule 13(5) as read with rule 13(1)(c) of the pharmacy and poisons rules and punishable by section 51 of the Pharmacy and Poisons Act, cap 244 laws of Kenya and as amended by the Kenya gazette supplement no.49 (act no.3) of June 2002.

### **COUNT 5**

Unlawful possession (or sale) of unregistered drugs contrary to rule 3 as read with section 51 of the pharmacy and poisons rules (registration of drugs) made under section 44 of the Pharmacy and Poisons Act, cap 244 laws of Kenya and as amended by the Kenya Gazette supplement no.49 (act no.3) June 2002.

### **COUNT 6**

#### **Anti-counterfeit Act 2008**

Having in possession or control in the course of trade counterfeit medicines contrary to section 32(a) as read with section 35 (1,a) of the anti-counterfeit Act , 2008.

The Board is also following the owner of the Mainstreet Pharmacy in Kisumu to take disciplinary action against her for procuring medicines from unauthorized sources.

### **FAKE QUININE INJECTION FOUND IN NARIOBI SITE**



Falsified Quinine injection (Carequin) found during Minilab<sup>®</sup> activities

The sentinel site team found a sample of quinine injection at the Kakamega site. Minilab<sup>®</sup> results showed the presence of no API. The NQCL confirmed these results.

It is noteworthy to mention that the focal point requested the sentinel site teams to look for the same samples in their zones of sample collection.

The other sentinel sites also identified samples which have tested as failed or doubtful, and they have submitted them to the NQCL for analysis so that the PPB can go ahead to take action.

After confirming that the samples were fake and not safe for use, PPB withdrew all the products from their source and informed the DOMC and relevant partners.

It is noteworthy to mention that according to the DOMC guidelines, the Quinine sulphate is used to treat severe malaria cases.

Additional photos of fake or substandard medicines confiscated during the raid in the Nairobi Central business district by PPB officials and the Kenyan police.



Fake products labeled as Coartem from the government AMFM program were found



Fake Metakelfin S/P tablets (Pfizer) and Ciprobay (Bayer); Nulide, which had been withdrawn from the Kenyan market four years ago



PPB published a list of “Suspected Falsified and Unregistered” products in national newspapers



Boxes, bags, and suitcases of medicines were confiscated

Pictures of doubtful and failed antimalarial medicines



