

Monitoring and Evaluation of Minilab[®] Activities at Mombasa and Nairobi Sentinel Sites with Detection of Quinine Sulfate containing No Active Principle Ingredient

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Trip Report

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Executive Summary

According to the World Health Organization (WHO), approximately 40% of the world population living in developing countries, including Kenya, is still at risk from malaria. Medicines intended for the treatment of severe malaria that are fake, counterfeit, or substandard pose a profound health risk to patients who rely upon the drugs to be effective.

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 the third round of monitoring the quality of antimalarial medicines (MQM) at five sentinel sites. During this exercise, the sentinel site team of Kisumu and Kakamega found samples of quinine sulfate—a commonly used treatment for severe cases of malaria—with no active pharmaceutical ingredient (API). The PPB deemed these to be counterfeit products, quickly withdrew them from the market, and sent the supplier to jail.

Another non-registered antimalarial quinine injection was found in a Nairobi sentinel site. This sample failed confirmatory testing. Like the fake quinine sulfate, PPB took the necessary regulatory actions; investigations are ongoing in both cases.

During the monitoring and evaluation visits of the Mombasa and Nairobi sites, PQM staff found other antimalarial samples that failed basic testing. The NQCL staff will carry out confirmatory testing on all failed samples and on 20 % of samples that pass the Minilab[®] basic tests.

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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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- Our Kenyan partners from the Ministry of Medical Services, Pharmacy and Poisons Board, Division of Malaria Control, and National Quality Control Laboratory
- The sentinel site teams of Mombasa and Nairobi for their valuable participation during the monitoring and evaluation visits of their respective sites
- The sentinel site team of Kisumu and Kakamega for tracking down the fake quinine
- PQM colleagues for their valuable contributions in organizing my trip and editing this report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their guidance and helpful advice

ACRONYMS

| | |
|-------|--|
| ADE | Adverse Drug Event |
| ADR | Adverse Drug Reaction |
| DOMC | Division of Malaria Control |
| DQI | Drug Quality and Information Program |
| HCSM | Health Commodities and Services Management |
| ISO | International Organization for Standardization |
| MOH | Ministry of Health |
| MOP | Malaria Operational Plan |
| 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 |
| PV | Pharmacovigilance |
| QA | Quality Assurance |
| QC | Quality Control |
| TAP | Technical Assistance Program, sponsored by USP |
| TLC | Thin Layer Chromatography |
| USAID | United States Agency for International Development |
| USP | United States Pharmacopeia |

Background

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID) and implemented by the United States Pharmacopeia (USP), began working in Kenya in November 2009, when it conducted an assessment of the quality assurance structures in the country. Following that, PQM established a sustainable protocol for monitoring the quality of antimalarial medicines at five sentinel sites.

In January 2010, PQM trained 14 staff members from the central and regional levels on sampling strategies, Minilab[®] basic tests, and data reporting. That spring, the first round of medicines quality monitoring (MQM) took place and a total of 536 samples were collected. The results of basic testing for this round revealed that 45 antimalarials were not registered and 74 had expired. The companies associated with the unregistered products were identified and the inspectorate team was instructed to take appropriate action.

In September 2010, PQM evaluated the first round of Minilab[®] activities and validated the samples selected for confirmatory testing at the National Quality Control Laboratory (NQCL) in Nairobi. While observing the validation of the Minilab[®] testing, PQM staff pointed out process gaps to the sentinel site teams and provided solutions to improve future rounds of testing. The main challenge was the lack of availability of trained personnel during sample testing. Therefore, all concerned parties—including the Pharmacy and Poisons Board (PPB), Division of Malaria Control (DOMC), and NQCL—suggested a need for training additional personnel from NQCL and the sentinel sites.

In January 2011, PQM facilitated Minilab[®] training for an additional 14 staff from PPB and NQCL. The Minilab[®] program team leaders rolled out this training in March 2011 at the NQCL.

In January 2012, PQM presented the results of past post-marketing surveillance (PMS) rounds and the actions taken by the Pharmacy and Poisons Board (PPB) in regards to unregistered, expired, and failed antimalarial samples. This presentation was given at a meeting organized in collaboration with the 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 the way forward with emphasis on how to integrate PMS activities under one program.

Purpose of Trip

- Conduct a monitoring and evaluation (M&E) visit to two sentinel sites;
- Collect samples with related adverse drug events from selected outlets;
- Present the results of the M&E visit to the DOMC and other relevant stakeholders;
- Meet with the new NQCL acting director and discuss the plan to assist NQCL in obtaining ISO/IEC 17025:2005 accreditation; and,
- Meet with the USAID Mission.

Source of Funding

This trip was supported with funds from the President's Malaria Initiative (PMI) through USAID/Kenya.

Overview of Activities

Dr. El Hadri briefed Dr. Kaendi Munguti, Senior Malaria Advisor, on the planned activities for this trip via phone call. Both parties agreed to conduct a full debriefing at the end of the mission.

Planning the Monitoring and Evaluation (M&E) Visits

Dr. El Hadri had shared the planned activities with the sentinel site teams prior to her trip to Kenya ([Annex 1-Agenda](#)). The main purpose of the visit was to monitor and evaluate how the sentinel site teams conduct sampling in the field, and how they conduct Minilab[®] testing on samples they collect. Another goal for this visit was to discuss with the teams the challenges they encountered in the field and to offer them recommendations on improving future rounds.

To accomplish these goals, Dr. El Hadri and Dr. Andrew Nyandigisi, Program Officer from the Division of Malaria Control (DOMC), traveled to the Mombasa and Nairobi sentinel sites.

Monitoring and Evaluation of Minilab[®] Activities at the Mombasa Site

This M&E session was planned to identify major gaps in the implementation of the protocol at Level 1, testing collected samples using Minilab[®] basic kits. The session was held at the lab of the Coast Provincial General Hospital–Mombasa and attended by the following Mombasa sentinel site team members:

- Mr. James Kingori, PPB Inspector
- Dr. Emily Siminyu, Hospital Pharmacist, Coast Provincial General Hospital
- Mr. Philip Mutinda, PPB Inspector
- Ms. Gladys Bogonko, NQCL Analyst

The major findings are summarized in the table below.

| Monitoring and Evaluation of Minilab[®] Activities at Mombasa Site | | |
|--|---|---|
| Protocol Guidelines | Report Findings | Way Forward |
| Sampling strategies/distribution | <ul style="list-style-type: none"> • Slight discrepancy in sampling distribution. • Considerable variation in number of units collected per sample. • Adequate number of samples collected in this site. | The team leader should review the sampling strategies with the team before the onset of sample collection in the field. |
| Sample code | Sample codes were respected, according to the protocol; however, some samples were not clearly labelled, which may not allow the samples to be traced to the source. | <ul style="list-style-type: none"> • Need to make sure that primary and secondary packaging is well labelled using the same sample code. • Harmonization of sample code is necessary to permit sample traceability in 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"> • Inspectors were involved in sample collection, resulting in biased sampling (most retailers know the inspectors | Use of analysts from the lab and/or mystery shoppers. |

Monitoring and Evaluation of Minilab[®] Activities at Mombasa and Nairobi Sentinel Sites

| | | |
|-----------------|---|--|
| | <p>and will either hide bad samples or give them good samples).</p> <ul style="list-style-type: none"> On the other hand, in some cases, the presence of the inspectors is needed in case a pharmacist/dispenser is not willing to provide information on the collected samples. | |
| Sample handling | <p>Some tested samples were not placed with their respective thin layer chromatography (TLC) plates. Other than that, collected samples were placed in labelled boxes ready to be transported to the NQCL.</p> | <ul style="list-style-type: none"> Having the TLC plate with the collecting form is important for the NQCL analyst during the verification with Minilab[®] kits and compendial testing. 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. |
| Testing | <p>Some TLCs were not labelled properly and were not spotted according to the training. This may result in an inaccurate interpretation of TLC test results.</p> | <p>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[®] refresher training to the sentinel site team since three senior lab analysts (team leaders) have left the NQCL.</p> |
| Reporting | <ul style="list-style-type: none"> Raw data on an Excel spreadsheet was not presented with the report. Registration statuses were not captured. | <ul style="list-style-type: none"> Use of a spreadsheet will allow exploration of other findings on collected medicines and will enable PPB to take immediate action on failed samples. 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 non-registered samples on the sites. |

During this M&E visit, PQM demonstrated correct spotting, labeling, and reporting. She 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 API strength of the medicines and the thin layer chromatography (TLC) method as described in the Minilab[®] manual. No major non-conforming samples were found during the initial testing. Following this session, Dr. El Hadri and Dr. Nyandigisi, accompanied by the sentinel site team, went to the market to monitor how the team can play the role of mystery shoppers to buy some samples. After visiting a few outlets, Dr. El Hadri pointed out how to use some key information in order to get more sample units without raising the suspicion of the dispenser. PQM staff noted that there are situations where the pharmacist can give a 10% to 15% discount on each procured sample.

Monitoring and Evaluation of Minilab[®] Activities at the Nairobi Site

As with the M& E visit at the Mombasa site, this session was supervised by both Dr. El Hadri and Dr. Nyandigisi; it took place at the lab of the National Spinal Injury Hospital–Nairobi. The sentinel site team members involved in this activity were:

- Mr. George Muthuri, Pharmacovigilance, PPB

Monitoring and Evaluation of Minilab[®] Activities at Mombasa and Nairobi Sentinel Sites

- Dr. Serah Chesaro, GMP Inspector, PPB, and former NQCL Analyst
- Ms. Lily J. Kipkeno Inspector, PPB
- Ms. Eunice Shankil, NQCL Analyst

During the M&E session, PQM staff supervised the testing and provided recommendations to effectively conduct subsequent rounds of Minilab activities. The major findings of this visit are summarized in the following table:

| Protocol Guidelines | Report Findings | Ways Forward |
|----------------------------------|---|---|
| Sampling strategies/distribution | <ul style="list-style-type: none"> • No discrepancy in sampling strategies. Samples were taken from various outlets and from different sectors according to the MQM protocol. • There were not enough units of some samples to conduct further testing. The number of units collected per sample varied considerably. • Adequate total number of samples was collected from this site. | <ul style="list-style-type: none"> • Need to adhere to the protocol in terms of number of units to be collected per sample—at least 40 units per sample. • Use analysts from the lab and/or mystery shoppers to get more samples. |
| Sample code | <ul style="list-style-type: none"> • Sample codes were respected according to the protocol. • Some samples were not clearly labeled on their primary packaging, which may cause difficulty in identifying tested samples. • Some sampling forms did not include storage condition. | <ul style="list-style-type: none"> • Need to make sure that primary and secondary packaging is well labelled, using the same sample code. • Description of the storage conditions should be included on the collection forms. |
| Sample collection | The total number of samples collected was 100, according to the protocol. | Have the site team leader review, sign, and date the recorded information and interpretation of TLC plates. |
| Sample handling | <ul style="list-style-type: none"> • Samples were organized in different boxes but were poorly labelled. • Some tested samples were not placed with their respective TLC plates. • Collected samples were placed in labeled boxes ready to be transported to the NQCL. | <ul style="list-style-type: none"> • Sample handling and organization is very important to locate samples easily and to save time during the testing of similar products. • Samples should be organized in separate boxes (failed, doubtful, and passed) to facilitate selection of samples to be tested at the NQCL. |
| Testing | <ul style="list-style-type: none"> • Some TLCs were not labeled properly and were not spotted according to the training. This may result in inaccurate interpretation of TLC test results. • Team tested samples in separate sequence. | <ul style="list-style-type: none"> • Label each TLC plate and insert it into the plastic bag with the corresponding form. • Each analyst should test the whole sample from grinding the samples to spotting and detecting the active principle ingredient. • The site team leader should review the recorded information and interpretation of TLC plates. Samples failing basic tests should be the top priority for NQCL confirmatory testing. |

| | | |
|-----------|---|--|
| Reporting | <ul style="list-style-type: none"> • Raw data on an Excel spreadsheet was not presented with the report. • Registration statuses were not captured. | <ul style="list-style-type: none"> • Use uniform abbreviations for medicines and sites in the sample codes and on the Excel reporting sheet. • Registration status was completed by PPB focal point. On next round, PPB needs to submit the list of registered antimalarials to the team leaders. This way, they can detect non-registered samples on the sites. |
|-----------|---|--|

The results of samples tested during this session revealed that three samples of sulfadoxine and pyrimethamine (SP) failed TLC tests and were submitted to NQCL for further testing.

Presentation to DOMC, PPB, and NQCL of the Outcomes of M&E Visits

This meeting was held at the NQCL in the presence of Dr. Ali Arale, NQCL Acting Director, and other representatives from DOMC, PPB, and NQCL. For the complete list of participants, see [Annex 2](#).

Dr. El Hadri and Dr. Nyandigisi presented the results of the M&E visits to the audience and made the following observations and recommendations:

1. The Nairobi team was well organized and analysts could conduct Minilab[®] testing on more than five samples at a time. On the other hand, the Mombasa team’s lab was disorganized and samples were spread all over the place without being properly labeled.
2. The team leader of each site should review the analytical methods, check the sample preparation/extraction/dilution, and verify that the methods comply with the Minilab[®] TLC method. The team leader should also review, sign, and date the recorded information.
3. Analysts should be more careful during the spotting and interpretation of the TLC plates.
4. Samples should be labeled clearly and handled properly before sending them to the NQCL for verification and compendial testing.
5. The Mombasa site needs to be provided with the proper working environment (air conditioning/fan, stools, and small lab equipment).
6. The duration of the Minilab[®] exercise in the field should be expanded from two weeks to three-to-four weeks, if needed, corresponding to the accessibility of the medicines outlets and the distance between them.
7. Teams should determine the best ways of obtaining more unit samples without raising the suspicions of the sellers.
8. The sentinel site teams need refresher training on the Minilab[®] basic tests, including the newly developed TLC methods.

Challenges faced by the Minilab[®] team in collecting antimalarial medicines with related ADEs and samples from refugee camps

During this meeting, Dr. Stephen Kimatu, focal point of the MQM program, informed the attendees that it was not possible to obtain antimalarial samples with related adverse drug reactions (ADRs) and samples from the refugee camps. The main reasons he gave were the:

- Impracticality of tracing back the batches with reported ADR cases;

- Travel logistics to the refugee camps; and,
- Endless unsuccessful efforts to seek assistance from the Red Cross to facilitate communication with the personnel in charge of the refugee camps.

Major Findings of the Minilab[®] Program, Round 3

During this exercise, the sentinel site team of Kisumu and Kakamega found samples of quinine sulfate tablets—a commonly used treatment for severe cases of malaria—that contained no active pharmaceutical ingredient (API). Because the samples contained no API, it was deemed to be a critical violation. The PPB took swift action by withdrawing the fake medicines from the market and sending the supplier to jail pending further judicial proceedings.

An unregistered sample of quinine injection was found through the Nairobi sentinel site. This sample failed confirmatory testing. As with the fake quinine sulfate tablets found by Kisumu and Kakamega, the PPB quickly took the necessary regulatory actions. Investigations are ongoing on both cases; for more information, see [Annex 3](#).



L: PPB inspectors address press during a raid that resulted from discovery of the fake quinine through MQM activities.

R: Some of the 4000+ products PBB confiscated during the raid.

Photo credit: PPB staff



Planning for ISO 17025 accreditation of NQCL

The National Quality Control Laboratory (NQCL) was pre-qualified in July 2008 by the World Health Organization, making it the first public laboratory in sub-Saharan Africa to reach this status. The NQCL began the process of accreditation with the Kenya Accreditation Service (KENAS), an accrediting body recognized only by the government of Kenya.

To be recognized at on the international level, PQM proposed to Dr. Ali Arale, NQCL Acting Managing Director, and Dr. Ernest Mbae, NQCL Deputy Director, to consider applying with the South African National Accreditation System (SANAS). Dr. El Hadri encouraged their taking this step for the following reasons:

- SANAS is an internationally recognized accrediting body and a signatory to a mutual recognition agreement with the International Laboratory Accreditation Cooperation (ILAC); SANAS is a full ILAC member, whereas KENAS is an associate member.
- Accreditation by SANAS would result in recognition across the globe, whereas KENAS would only grant recognition at a national/sub-regional level.

Monitoring and Evaluation of Minilab[®] Activities at Mombasa and Nairobi Sentinel Sites

- The purpose of SANAS is to assess and recognize the competence of laboratories to competently perform specified calibration and tests and, by monitoring, to ensure that required accreditation standards are maintained.

Following the meeting, PQM staff assisted the NQCL lab in finalizing and submitting the application to SANAS. PQM pledged to provide assistance preparing all the necessary documentation, resolving any observations made by SANAS, and covering the cost of the application fee, document review, pre-assessment visit, and three-day assessment visit.

Briefing USAID Mission

Dr. El Hadri briefed Dr. Kaendi Munguti, Senior Malaria Advisor, and Dr. Megan Fotheringham, Public Health Advisor, on the outcomes of the M&E visits. She pointed out the need to provide refresher training on the new Minilab[®] TLC monographs. She also informed them about the fake quinine found through MQM and related the regulatory actions taken by PPB against the supplier and the pharmacist. Drs. Munguti and Fotheringham were pleased that the MQM program is working well and that PPB is taking forceful regulatory actions against unlawful sellers and suppliers. During this discussion, Dr. Munguti pointed to the alarming results of failed SP revealed by a study conducted in Kenya and asked PQM staff to carefully look into the quality of SPs collected during this round.

Next Steps

PQM

- Plan a refresher Minilab[®] training using the new TLC monographs.
- In collaboration with PPB, find the best ways to obtain more sample units during sampling without raising the suspension of the sellers.
- Provide NQCL with all the needed documents to apply for ISO 17025 accreditation by SANAS. Cover the application fees.

NQCL

- Test the non-conforming samples identified and 20% of passed samples. Test at least 50% of SPs.
- Follow up on the application with SANAS.

PPB

- Follow up on the regulatory actions taken on failed samples.

Conclusion

The success of the MQM program in Kenya to detect counterfeit and poor quality medicines has stimulated the PPB inspectors, as part of the sentinel sites teams, to strengthen their fight against fake medicines in Kenya. In addition to the major finding of fake quinine tablets and injection, PPB inspectors were recently able to uncover one of the largest consignments of falsified, fake, burned, and unregistered medicines in Kenya.



Draft Agenda For Kenya June 2012 Visit

| Date | Planned Activities | Descriptions | Comments |
|--------------|---|--|----------|
| 17 | Travel to Mombasa sentinel site | <ul style="list-style-type: none"> Meet with the Mombasa team in the afternoon if possible to discuss the visit logistics (will send my local phone number by email on Saturday) | |
| 18 | Conduct monitoring and evaluation (M&E) visit | <ul style="list-style-type: none"> Review the collected samples and evaluate sampling and testing on site Collect few samples on site and test them with team (need to collect samples reported with adverse drug reactions, samples from refugee camps if any, donated samples if any) Review the excel data sheet | |
| 19 Morning | Complete the activities of the M& E | <ul style="list-style-type: none"> Report of the M& E visit | |
| 19 Afternoon | Travel to Nairobi | <ul style="list-style-type: none"> Meeting at 3:30 Pm at NQCL to discuss the visit logistics | |
| 20 | Conduct monitoring and evaluation (M&E) visit | <ul style="list-style-type: none"> Review the collected samples and evaluate sampling and testing on site Collect few samples on site and test them with team (need to collect samples reported with adverse drug reactions, samples from refugee camps if any, donated samples if any) Review the excel data sheet | |
| 21 Morning | Meeting at NQCL | <ul style="list-style-type: none"> Complete the activities of the M& E visit Validate samples to be tested by NQCL | |
| 21 Afternoon | Meetings | <ul style="list-style-type: none"> Present the results of the M&E visit to the Division of Malaria Program and other relevant stakeholders Meet with the new NQCL Acting Director and discuss the plan to assist NQCL in obtaining ISO/IEC 17025 accreditation | |
| | Meeting with the Mission | <ul style="list-style-type: none"> Debrief the Mission on the outcomes of the trip activities | |

ANNEX 2



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NQM RANO III DEBRIEFING MEETING 21-JUN-12

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| 11. | | | | |
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| 13. | | | | |
| 14. | | | | |
| 15. | | | | |



Minilab[®] 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[®] sampling and testing in the five sentinel sites established in Kenya.

To date, the sentinel site (SS) team collected 613 number of antimalarial samples from all five sites. The samples (548) underwent Minilab[®] 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.

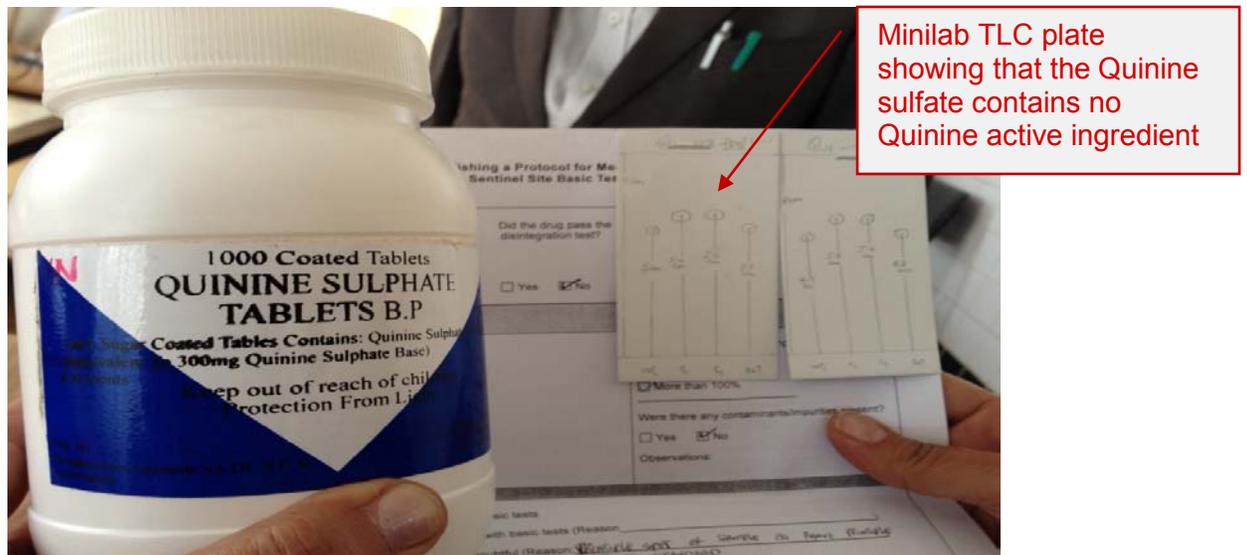
NQCL has analyzed all the SPs and initial reports indicate that all samples passed QC testing. The Quinine samples will be analyzed by the first week of October 2012.

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

| | |
|---------------|---|
| Name: | Quinine Sulphate |
| Batch No. | D469 |
| Man. Date: | Oct. 2009 |
| Exp. Date: | Oct. 2013 |
| Manufacturer: | Farmaceuticos Lakeside S. A DF SCV, Netherlands. I Googled this company and it looks phony. Is it registered with PPB? |
| 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[®] 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 – 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 sample is deemed to be counterfeit.

The team concluded that the sample had failed the TLC test.

PPB investigation on the fake Quinine sulphate

The team went back to Mainstreet 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 2012. 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)of 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[®] activities

The sentinel site team found a sample of quinine injection at the Kakamega site. Minilab[®] 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.

Monitoring and Evaluation of Minilab® Activities at Mombasa and Nairobi Sentinel Sites

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 samples 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.

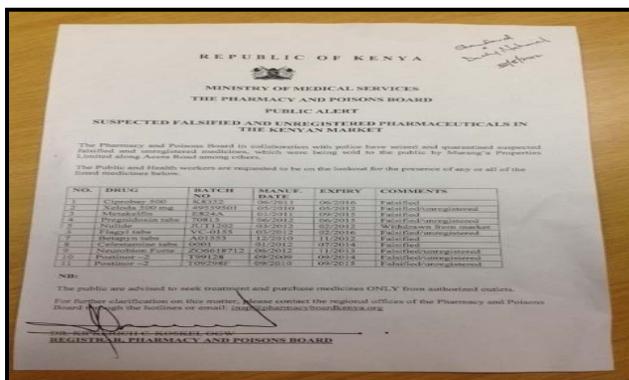
Additional photos of fake or substandard medicines confiscated during the raid in the Nairobi Central business district by PPB officials and the Kenyan police.



Fake Coartem from the government AMFM program was 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” product in national newspapers



Boxes, bags, and suitcases of medicines were confiscated