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Monitoring the Quality of Antimalarial Medicines Circulating in Kenya: Round 5

July 2017

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[1] NMCP = National Malaria Control Program

Executive Summary

Malaria still accounts for the most number of deaths and outpatient visits in the Kenyan health care system. Malaria is a significant public health problem in Kenya. More than 70 percent of the population live in malaria risk areas, including those most vulnerable to the disease: children and pregnant women (Malaria Indicator Survey 2015). Availability of good quality medicines is essential in ensuring prompt and effective treatment of malaria according to the current national malaria strategy.

11 sites participated in the minilab testing of antimalarial medicines during this round of activity. Each of the eleven sites screened 80 samples of anti-malarials bought or picked from both private and public health facilities and chemists in their surrounding sites.

Due to the increased number of sentinel site, sample collection and field-testing of the medicines took place between 24th August 2014 and 19th September 2014. The eleven sites were divided into two with the first five teams carrying out the activity between 25th August to 5th September 2014 and the second group of six teams carrying out the activity between 8th and 19th September 2014

Availability of good quality medicines is essential in ensuring prompt and effective treatment of malaria according to the current national malaria strategy. This report presents the findings of the fifth round and also compares the results obtained in the first, second, third and fourth and fourth rounds of monitoring of the quality of anti-malarials that have been done over the last five years.

Eighty antimalarial samples were targeted in each of the eleven sentinel sites. The purposive sampling of anti-malarials included artemisinin-based combination therapy (ACT) and Sulfadoxine-Pyrimethamine (SPs), among others, based on their availability. Sampling was done in the public, private and informal sectors.

Basic testing using the Global Pharma Health Fund (GPHF) Minilab™ was performed on the collected samples at the sentinel sites. This was followed by analysis of 10 percent of the samples that passed minilab analysis, all doubtful samples and all failed samples at the National Quality Control Laboratory (NQCL) or at Missions for Essential Medicines and Supplies (MEDS).

The results indicate that the presence of unregistered and substandard anti-malarials in the market has reduced over time as 100% of samples collected were registered with Pharmacy and Poisons Board (PPB). 99.3% of all the samples collected during the round five activity were found to be registered by PPB. For the samples that underwent compendial testing, 90.24% passed.

The results indicate that ACTs in the public, private and informal sectors were of good quality. The results also show the convenience of utilizing minilabs as a safe, rapid and cost-effective way of screening anti-malarial medicines in the field.

Acronyms and Abbreviations

ACTm	Artemisinine-based Combination Therapy for malaria
AL	Artemether Lumefantrine
AMFm	Affordable Medicines for Malaria
HCSM	Health Commodities and Services Management
MCU	Malaria Control Unit
MSH	Management Sciences for Health
MIP	Medicines Information and Pharmacovigilance
NMCP	National Malaria Control Program
NQCL	National Quality Control Laboratory
PMS	Post Market Surveillance
PQM	Promoting the Quality of Medicines
PPB	Pharmacy and Poisons Board
TLC	Thin-Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
USP-NF	United States Pharmacopeia-National Formulary
USP PQM	United States Pharmacopeia-Promoting Quality of Medicines

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1. INTRODUCTION

Malaria is a global health problem. The World Health Organization (WHO) estimates that 3.2 billion people are at risk of malaria worldwide. Sub-Saharan Africa is disproportionally affected; in 2015, the region had 88% of malaria cases and 90% of malaria deaths (WHO 2016). In Kenya, malaria remains a major cause of morbidity and mortality with more than 70% of the population at risk of the disease (MOH 2014).

1.1. Malaria in Kenya

The malaria burden in Kenya is not homogenous. The areas around Lake Victoria and on the coast present the highest risk, and children under age 5 and pregnant women are the most vulnerable to infection. In the last 5 years, there has been overall reduction in malaria prevalence in Kenya as compared with the 2010. The current malaria prevalent rate is 8% (Kenya Malaria Indicator Survey (KMIS) 2015)

Malaria transmission and infection risk in Kenya is determined largely by altitude, rainfall patterns and temperature. Therefore, malaria prevalence varies considerably by season and across geographic regions. The variations in altitude and terrain create contrasts in the country's climate, which ranges from tropical along the coast to temperate in the interior to very dry in the north and northeast. There are two rainy seasons—the long rains occur from April to June and the short rains from October to December. The highest temperatures are from February to March and the lowest from July to August.

The 2015 KMIS results indicate that much progress has been made in malaria control in Kenya. To sustain the gains, investment levels need to be maintained, especially in the high burden areas around Lake Victoria and in the coastal region.

The majority of the at-risk population (17 million people) live in areas of epidemic and seasonal malaria transmission where *P. falciparum* parasite prevalence is usually less than 5%. For the purposes of malaria control, the country has been stratified into four epidemiological zones to address the varied risks:

- **Endemic areas:** These areas of stable malaria have altitudes ranging from 0 to 1,300 meters around Lake Victoria in western Kenya and in the coastal regions of the country. Transmission is intense throughout the year. The vector life cycle is usually short with a high survival rate due to the suitable climatic conditions. The malaria prevalence rate is 27% in the endemic region (KMIS 2015).

- **Highland epidemic-prone areas:** Malaria transmission in the western highlands is seasonal with considerable year-to-year variation. The whole population is vulnerable, and case fatality rates during an epidemic can be up to 10 times greater than what is experienced in regions where malaria occurs regularly. Here the malaria prevalence rate is 3%

- **Semi- arid, seasonal malaria transmission areas:** This epidemiological zone comprises of arid and semi- arid areas of northern and southeastern parts of the

country which experience short periods of intense malaria transmission during the rainy seasons the average malaria prevalence rate is less than 1%. Temperatures are usually high, and water pools created during the rainy season provide the malaria vectors with breeding sites. Extreme climatic conditions such as the El Niño southern oscillation lead to flooding in these areas, resulting in epidemic outbreaks with high morbidity rates due to the population's low immune status

- **Low malaria risk areas:** This zone covers the central highlands of Kenya including Nairobi. Temperatures are usually too low to allow completion of the sporogonic cycle of the malaria parasite in the vector. However, increasing temperatures and changes in the hydrological cycle associated with climate change are likely to increase the areas suitable for malaria vector breeding and introduce malaria transmission in areas where it did not previously exist.

Sites of Round Five Activity

Kajiado County is located in South rift valley region of Kenya. It borders Narok to the north, Nairobi to the east, Tanzania to the south and Taveta to the west. The population is largely cosmopolitan with the Maasai being the predominant community who have strong cultural beliefs. The county has a population of approximately 510,000 people. Women and children account for 65% of this population and are most vulnerable to malaria. The population is largely cosmopolitan with the Maasai being the predominant community who have strong cultural beliefs. Malaria is prevalent in the southwest regions of Kajiado.

Kisii County is a county in the Western Part of Kenya in the former Nyanza province. It has a total population of 1,152,282; 245,029 Households and covers an area of 1,317.4 km^2. The population density 874.7 people per km^2 and 51% of the population live below the poverty line.

Nyamira County is a county in the Nyanza Province of Kenya. It has a total Population of 598,252; 131,039 House holds and covers an area of 899.3 km^2. The Population density 665 people km^2 and 46.6% of the population live below the poverty line. The team here covered Kisii and Nyamira counties, within Nyanza region in western Kenya. These two counties have a cumulative population of 1.75 million according to the 2009 population census.

Kericho County is found in Rift Valley province and the population in 2013 was estimated at 849,032 and is expected to be about 970,930 in the year 2017. The number of males is estimated at 416,026 and the number of females is estimated at 433,006, which is a ratio of 49:51. It measures about 2,479 km^2. The County has 6 sub counties: Belgut, Ainamoi, Kipkelion East, Kipkelion West, Bureti, Sigowet/Soin

Migori County is found in the former Nyanza Province of southwestern Kenya. Its capital is Migori, which is its largest town. The county has a population of 1,098,343. It has an area of 2,586 km^2. Migori County has 8 constituencies (Awendo, Rongo, Suna East, Suna West, Uriri, Nyatike and Kuria East and Kuria West.)

Mombasa County is located in Coast province and constitutes 6 constituencies (Changamwe, Jomvu, Kisauni, Nyali, Likoni and Mvita). Mombasa is also a port city where a majority of imports to Kenya comes through. This also includes medicines and medical equipment. The port city also handles imports for East and Central Africa.

Uasin Gishu County is located in the Rift Valley province and constitutes 6 constituencies (Soy, Turbo, Moiben, Ainabkoi, Kapseret, Kesses). Its headquarters is Eldoret town, which has a number of medical facilities, notably Moi Teaching & Referral Hospital, Uasin Gishu District Hospital, Eldoret Hospital, Mediheal Hospital, Elgon View Hospital among others. Eldoret also has the third biggest airport in the county and a number of imports come into the country through the airport.

Sentinel testing Site Selection

Each of the 11 teams selected a site to carry out the minilab testing of the collected samples. The testing sites were selected based on; availability of electricity, running water, secure storage space and enough workspace. In addition, the manager of the site was required to approve the site being used for testing. The eleven sites selected for the activity were either malaria prone areas or ports of entry or a combination of both. The table below gives the summary

No.	Port of Entry	County	Criteria for selection
1.	Namanga	Kajiado	Port of entry
2.	Isebania	Migori	Port of entry/Endemic Zone
3.	Vanga	Kwale	Port of entry/Endemic Zone
4.	Busia	Busia	Port of entry/ Endemic Zone
5.	Nairobi (JKIA, Wilson airports)	Nairobi	Port of entry (Most medicines to Kenya come in through Nairobi by Air. It's the biggest source of medicines to the other parts of the country and the region)
6.	Eldoret (Moi Airport)	Eldoret	Port of entry (An alternate port of entry for medicines coming into Kenya by air)
7.	Mombasa (Sea Port)	Mombasa	Port of entry (All medicines that come to Kenya and the region by Sea come in through Mombasa)
8.		Kisii	Epidemic Zone
9.		Kericho	Epidemic Zone
10.		Kakamega	Endemic Zone
11.		Kisumu	Endemic Zone

Table 1 Summary of the minilab sites

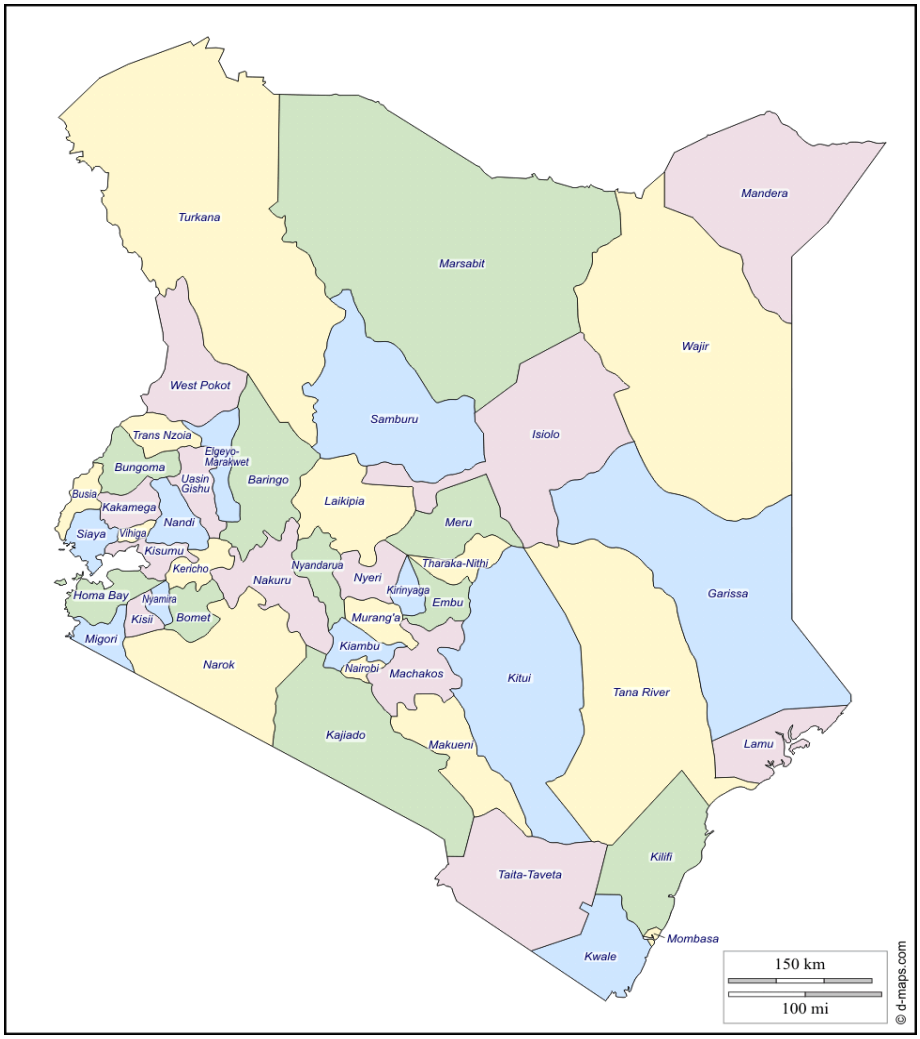

Figure 1 Kenya counties

2. OBJECTIVE

Good quality medicine is a pre-requisite for prompt and effective treatment of malaria. Post Market-Surveillance (PMS) is the regular sampling and testing of medicines after registration and presence of the product in the market.

The objectives were:

i. To monitor the quality and registration status of antimalarials in the country.
ii. To monitor the safety of medicines and conformity with the established specifications for quality as declared in the recognized pharmacopoeia specifications.
iii. To determine the proportion of antimalarials in Kenya that conforms to quality standards.

1.2. Quality of Anti Malarials in Kenya

Several studies to assess the quality of anti malarials in Kenya have been undertaken in the last decade and continue to inform current and future initiatives towards a comprehensive post –marketing surveillance (PMS) system. The main findings of some of these previous studies include:

- In 2008, PPB and DOMC collaborated in a multi-country study on quality of anti-malarials in Africa (QAMSA). Results from the study showed that 96% of the 44 samples collected from Kenya fully conformed to quality specifications. Only two of 24 ACT samples tested failed (both on limit tests for presence of impurities), and all Sulfadoxine/ Pyrimethamine samples were compliant with specifications (WHO, 2010).
- In 2010, a nationwide survey of anti-malarials by the PPB and Malaria Control Unit (MCU) found that 93% of the 535 samples collected were registered in the country; 91.8%, (n=451), 76.3% (n=80) and 84.1% (n=44) of the samples analyzed passed Level 1, Level 2 and Level 3 analysis respectively.
- In 2011, another nationwide survey of anti-malarials by the PPB and Malaria Control Unit (MCU) found that 96.8% of the 499 samples collected were registered in the country; 97%, (n=496), 100% (n=65) and 76% (n=25) of the samples analyzed passed Level 1, Level 2 and Level 3 analysis respectively.
- In 2012 the round three of the monitoring quality of medicines for antimalarials conducted by the PPB and MCU in 2012, showed that 99.1% of the 545 samples collected were registered in the country; 94.6%, (n=514), 90% (n=71) and 90% (n=20) of the samples analyzed passed Level 1, Level 2 and Level 3 analysis respectively.
- Round four of the monitoring quality of medicines for antimalarials carried out in 2014 showed that that 99.3% of the 606 samples collected were registered in the country; 82%, (n=606), and 100% (n=115) of the samples analyzed passed Level 1, and Level 3 analysis respectively.

1.3. Aims and Objectives

The primary objective of the post marketing surveillance is to monitor the safety of medicines and their conformity with the specifications for quality declared in the registration dossier or recognized in the pharmacopeias. When conducted regularly, this exercise helps provide continuous information on the quality of medicines circulating in the country.

The specific objectives of the PMS exercise were:

a) To identify unregistered products in the selected sites

b) To determine the quality of medicines in the selected sites

c) To develop a medicine's quality database, for trend analysis of circulating medicines

d) Disseminate information on medicines' quality to stakeholders involved in medicines procurement, use, and regulation

e) Provide evidence-based data for enforcement actions

2. METHODOLOGY

2.1. Sampling Strategy and Training

The sampling strategy involved collecting samples from various levels operating in the distribution chain, including public sector facilities Kenya Medical Supplies Authority (KEMSA, public health facilities, health centers), non-governmental organizations (NGOs), faith-based organizations (such as Mission of Essential Medicines Services (MEDS), private for-profits dispensing sites (pharmacies), hospitals (private and public), and the illicit (informal) markets.

Samples in the private sector were collected using the "mystery shopper" approach, to avoid alerting traders by simulating the real life situation of how patients access medicines.

This strategy ensured that samples were obtained from all sectors where patients are most likely to be exposed to medicines.

The participants were trained before the sampling and testing was carried out. Monitoring Quality of Medicines (MQM) facilitated the training with support from the Malaria Control Unit (MCU), PPB and NQCL.

Sector	Sampling Location	No. of Samples	Total No. of Samples
Public	County Store	3	15
	Public Hospital/FBO	6	
	Health Centre/ Dispensary	6	
Private	Importer/ Distributor/ Wholesaler	9	42
	Retailers	18	
	Private Hospital	9	
	Clinics	6	
Informal	Kiosks/ Supermarkets	3	3
Total			**60**

2.2. Site Selection

Sites for sample collection were identified in collaboration with PPB, NMCP, NQCL and PQM based on several factors such as epidemiological data showing prevalence of the disease, medicines availability and accessibility, freely circulating medicines originating from border towns, ports of entry, refugee camps and availability of human resources.

2.3. Medicines Selected for Sampling

The selection of antimalarial medicines for sampling was based on MCU's national treatment guidelines and the availability of monographs for analysis. They include first-line treatment, second-line treatment, intermittent preventive treatment (IPT) for malaria in pregnant women, chemoprophylaxis, and treatment for severe malaria.

- First-line treatment

- Artemether Lumefantrine (AL)
- Second-line treatment
  - Dihydroartemesinin & Piperaquine (DHAP)
- Severe malaria
  - Parenteral quinine
  - Oral quinine
  - Artemether/Artesunate injection
  - Rectal Artesunate
- Intermittent Preventive Treatment (IPT)
  - Sulphadoxine & Pyrimethamine (SP)
- Chemoprophylaxis
  - Doxycycline
  - Atovaquone/Proguanil
- Other ACTs
  - Artesunate Amodiaquine
- Monotherapies
  - Monotherapies were not tested; they were collected only for the purpose of monitoring the shift from monotherapies to ACTs and to evaluate their availability in the market.

2.4. Sample Definition

For the purpose of this study, a sample was defined as a medicine containing a defined API, dosage form, strength, and lot number from a particular level in the distribution chain. Samples with the same attributes described above and the same lot number were only collected if they were found in a different level in the distribution chain, such as wholesaler versus retailer, etc. Medicines with the same lot number were not collected from similar or same level facilities (for example, two pharmacies or retailers).

2.5. Number of Units to Collect per Sample

The number of units collected per sample was determined by the required tests to be performed on the samples. Refer to table below.

The following example of sample collection applies only to solid dosage forms (tablets and capsules).

Minimum Units	Maximum Units	Comments
Initial Sampling		
20	40	If the minimum of 20 units is not feasible, collect what is available but no less than 5 units
Re-Sampling for Compedial Testing		
50	100	If the —minimum of 50 units is not feasible, refer to the Number of Units Needed in "*Guidelines for Compendial Testing*"

Figure 2 Field Sampling strategy for tablets

2.6. Criteria for Prioritization of Sampling

Priority was given to the following APIs and dosage forms:

- First-line treatment in the DOMC treatment guidelines
- Most-sold medicines
- Most commonly-used medicines to reflect the reality of consumed medicines from all available sectors
- Medicines known or suspected to be counterfeits or sub-standard or for which adverse drug events had been reported.

2.7. Criteria for Diversification of Sampling

Attempts were made to try and diversify the samples collected from each site to reflect the availability in the market. The following characteristics to diversify the sampling were considered:

- Different brands of the same API;
- Different batch/lot numbers;
- Multiple dosage forms (tablets, capsules, oral suspensions, injectables, suppositories, etc.);
- Different sectors (private/public/informal);
- Different sources or outlets of the same product with same lot number
- Suspicious medicines;
- Improperly stored medicines at the sampling site (exposed to sunlight, humid/wet conditions, etc.); and,
- Different packaging of same product (i.e., blister vs. bulk)

2.8. Sample Collection

A Sampling Checklist (Annex 1) - was provided to the sampling team prior to their departure to collection sites and the need for its consistent use was emphasized. Each site planned to collect approximately 80 samples although some sites collected larger amounts.

Each collected sample was secured in a plastic container or sealable plastic bag and attached to its corresponding Sample Collection Form (Annex 2). The Sample Collection Form contained all traceable data that accompanied the sample from the site of the collection to the site of Minilab testing and then to the quality control laboratory for confirmatory testing. This was done in order to maintain a traceable record of sample's identity should it fail or results be doubtful.

Samples were then packed, transported, and stored in such a way as to prevent any deterioration, contamination, or adulteration. Samples were stored and transported in their original sealed containers, according to the storage instructions for the respective product.

2.9. Sample Analysis

Once samples were collected, they were tested at three levels (Figure 1). Level 1 was the sentinel site using Minilab tests (Physical inspection, disintegration and Thin Layer Chromatography (TLC)), Level 2 was the verification test carried out in the lab using Minilab basic tests to verify sentinel site data and level 3 was the confirmatory testing done using full compendial testing.

2.9.1. Level 1 Basic Tests utilizing the Minilabs at Sentinel Site

Basic tests included

a) Physical/Visual (P/V) Inspection,
b) Disintegration, and
c) Thin Layer Chromatography (TLC) and

This was carried out at the sentinel sites. Test results were clearly recorded for each sample on the Basic Tests Analysis Form for Sentinel Site Staff (Annex 3). The test results are graded as follows

i. Pass: Conforms to all three (3) tests
ii. Fail: Does NOT conform to at least one (1) of the three (3) tests
iii. Doubtful: Conflicting or inconclusive results for at least one (1) of the three (3) tests

A subset of samples was sent to the laboratory for verification testing, as follows: (Refer to Figure 1—MQM Analysis Flow Chart.)

- 20% of samples that passed*[2]
- 100% of samples that failed**
- 100% of samples that are doubtful***

This subset of samples was sent with their respective forms attached (Sample Collection Form and Basic Tests Analysis Form for Sentinel Site Staff) to the NQCL for verification and confirmatory testing.

[2] * Pass: Conforms to all 3 tests; ** Fail: Does not conform to at least one of the three tests; Doubtful: Conflicting or inconclusive results for at least one of the three tests

2.9.2. Level 2: Verification of Basic Tests at NQCL

NQCL performed verification testing by repeating basic tests on the subset of samples (as described above). Results of each sample were recorded clearly on the Basic Tests Analysis Form for National Quality Control Laboratory Staff (Annex 4).

For any samples that failed or were doubtful, they continued to the third stage of analysis for complete compendial testing.

Compendial testing was performed on the following samples: (Refer to Figure 1—MQM Analysis Flow Chart.)

- 20% of samples that pass verification testing
- 100% of samples that fail verification testing
- 100% of samples that are doubtful for verification testing
- 50-100% of sulfadoxine-pyrimethamine (S/P) tablets/capsules and other medicines with known precedents of dissolution failures.

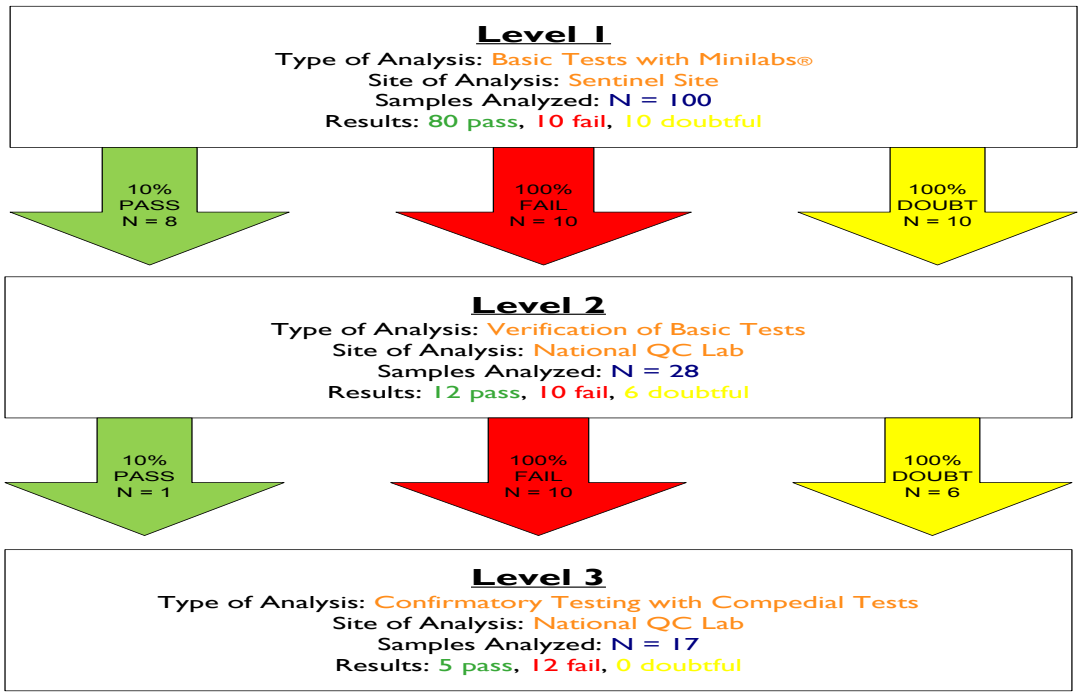

Figure 3 Example of sample flow for quality testing

2.9.3. Level 3: Confirmatory Testing with Compendial Methods at NQCL

If compendial testing was to be conducted and there were insufficient units, more units of the same sample were collected to ensure full compendial testing took place.

3. RESULTS

3.1. Sample Description

3.1.1. Sampling by Sector

The sampling was done from three sectors namely the private, public and informal sectors. Sampling in the private sector was highest owing to the wider range of anti-malarials 675 samples came from the private sector representing 76% of all the samples. This was followed by samples from public that accounted for 22%

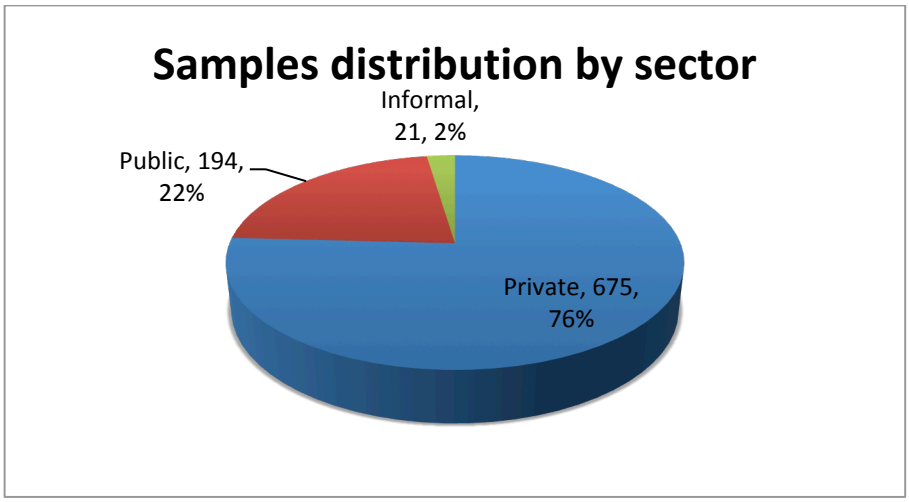

Figure 4 Number of samples collected by sector

3.1.2. Sampling by API

AL was the most sampled antimalarial followed by SPs, which is consistent with their availability.

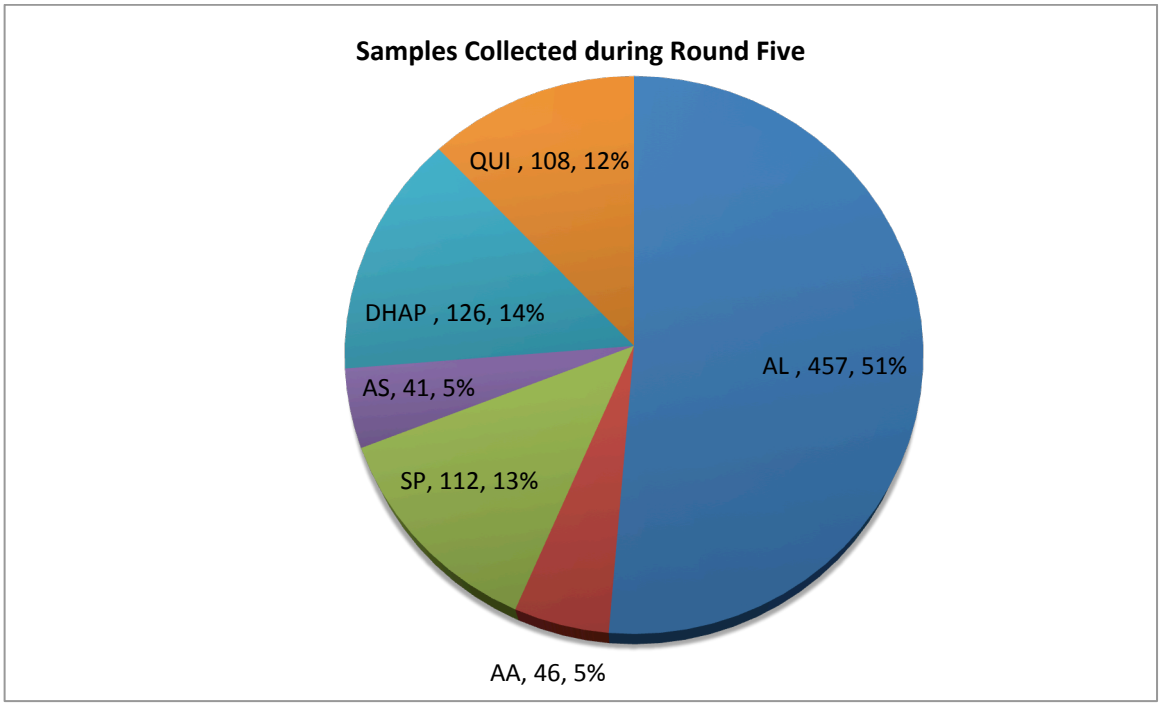

Figure 5 Samples collected by API

3.1.3. Sampling by Region

During round five fieldwork activity, the largest number of samples was collected in Nyanza followed by Rift valley, Western, Coast and Nairobi regions in that order.

No.	Region	Round 5
1.	Coast	158
2.	Nairobi	80
3.	Nyanza	246
4.	Rift Valley	241
5.	Western	165
	Total	**890**

Table 2 Distribution of Samples collected by region

3.1.4. Summary of Sampling

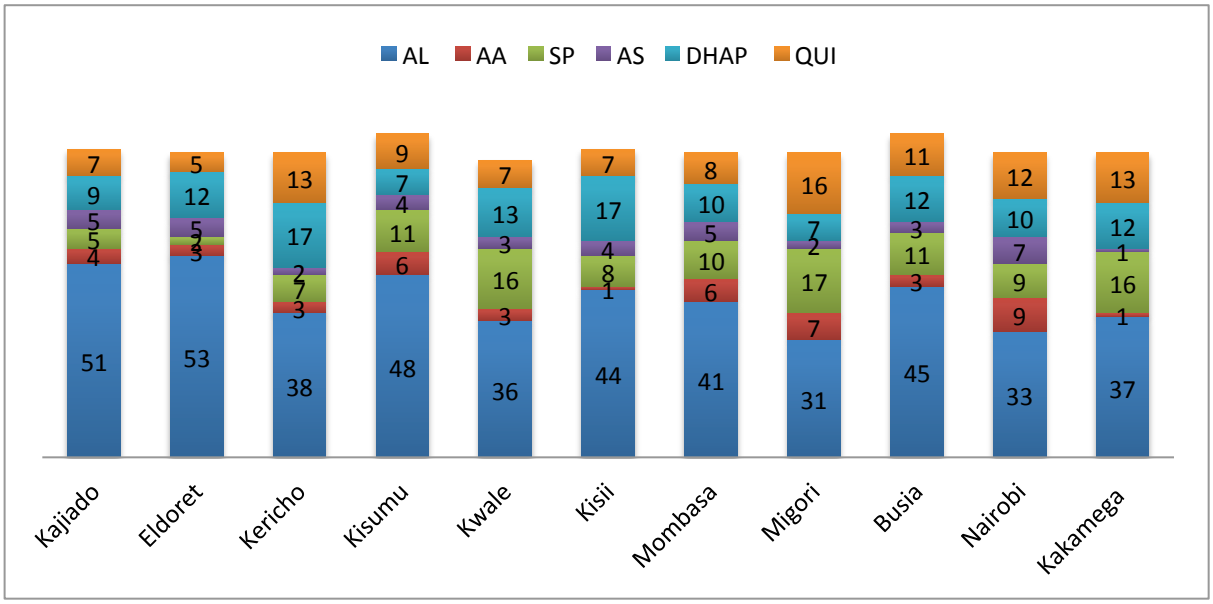

Figure 6 Distribution of sampled medicines by sites

Round	# of Samples Collected	# of samples analyzed using Minilab (Level 1)	# of Samples for Level 2 analysis	# of samples analyzed by compendia methods (Level 3)
Round 5	890	879	102	82

Table 3 Summary of sampling and analysis of the five rounds

3.2. Registration with the Pharmacy and Poisons Board

99.6% of the samples collected during the activity were duly registered with PPB. The percentage of unregistered samples has consistently decreased ver time.

3.3. Basic and Compendial Test Results

3.3.1. Level 1 Screening Test Results

Of the 879 samples screened at the sites, the proportion of samples in Round 5 that passed round one screening was 96%. 3.8% of the samples were considered doubtful while 0.2% failed the screening test.

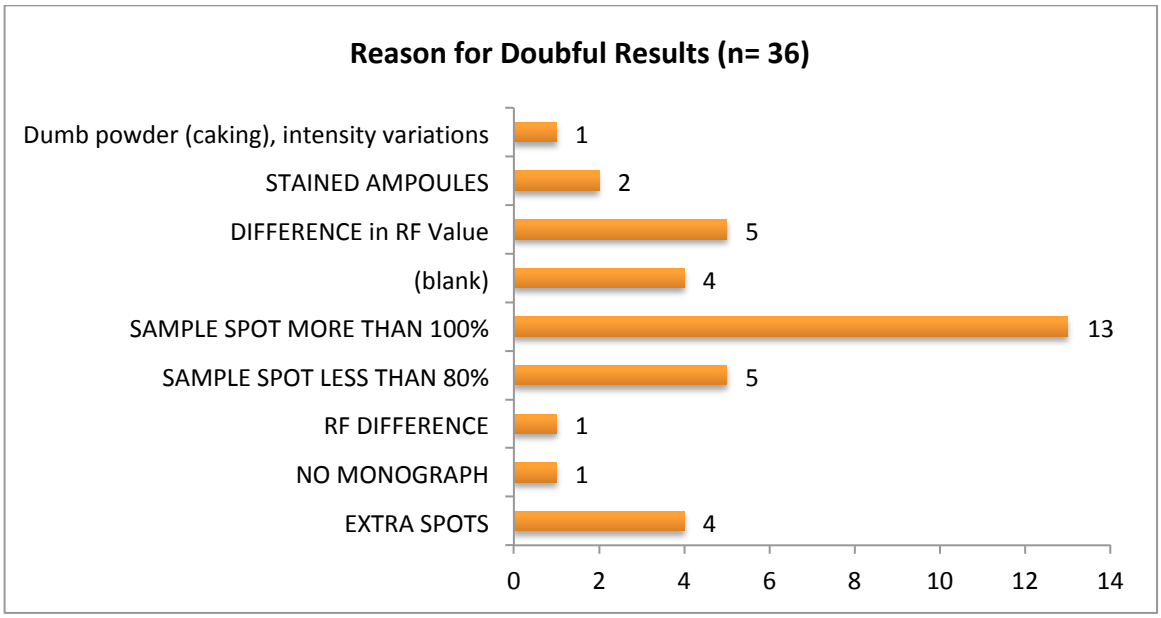

Figure 7 Reason for doubtful result in Level 1 Testing

3.3.2. Level 2 Screening Test Results

For round five, level II testing was not done but instead, all samples delivered to the laboratory underwent compedial testing.

3.3.3. Level 3 Compedial Test Results

As there was no level 2-minilab testing, all the 102 samples from level 1 testing were submitted for compendial testing. 82 of the samples were analyzed while 20 samples were not analyzed as they had already expired by the time of analysis. 74 samples or 90.24% of the samples analyzed passed analysis while 9.76% failed.

4. Discussion

4.1. Sample Description

4.1.1. Sampling by Sector

The sampling was done in three sectors namely the private, public and informal sectors. Sampling in the private sector was highest owing to the wider range of anti-malarials. The sample sizes are compared across the five rounds of sampling (i.e. from 2011 – 2014). The provate sector contributed the highest number of samples at 675 followed by public sector at 194 samples and the least number of samples was from the informal sector at 21. The private sector has a wide variety of products compared with the public sector hence the highest number of samples as compared with the other sectors. The sampling during this round mirrors the sampling in the previous four rounds whereby more samples were collected in the private sector followed by public and informal sector respectively.

Sector	Round 1	Round 2	Round 3	Round 4	Round 5
Private	312	373	301	415	675
Public	169	118	229	157	194
Informal	55	8	15	33	21
Total	**536**	**499**	**545**	**605**	**890**

Table 4 Number of samples collected for the rounds

4.1.2. Sampling by API

AL was the most sampled antimalarial followed by SPs which is consistent with their availability.

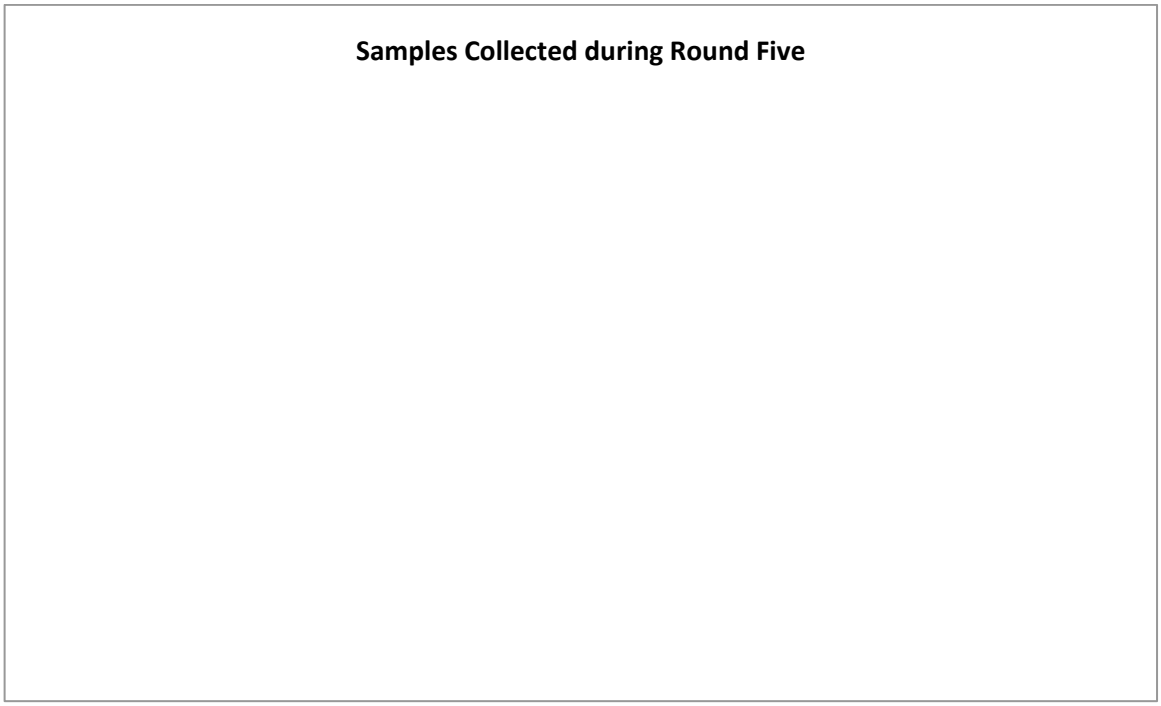

Figure 8 Samples collected by AP

API	Round 1	Round 2	Round 3	Round 4	Round 5
Artemether/ Lumefantrine	290	258	288	349	457
Sulfadoxine/ Pyrimethamine	101	105	106	133	112
Quinine Sulphate	83	85	77	77	10
Artesunate/ Amodiaquine	14	40	21	42	46
Quinine Dihydrochloride	-	-	3	4	98
Sulfamethopyrazine/Pyrimethamine	-	11	-	-	-
Dihydroartemisinin Piperaquine	19	-	49	-	126
Other	29	-	1	-	
Total	**536**	**499**	**545**	**605**	**890**

Table 5 Distribution of samples by Active Pharmaceutical Ingredients

4.1.3. Sampling by Region

During round five fieldwork activity, the largest number of samples was collected in Nyanza followed by Rift valley, Western, Coast and Nairobi regions in that order.

The table below shows the number of samples in the various regions from Round 1 to Round 5

No.	Region	Round 1	Round 2	Round 3	Round 4	Round 5
1.	Coast	107	99	115	100	158
2.	Rift Valley	128	100	105	102	241
3.	Nairobi	100	100	108	101	80
4.	Nyanza	101	100	100	101	246
5.	Western	100	100	117	101	165
6.	Garissa	-	-	-	49	-
7.	Turkana	-	-	-	52	-
	Total	**536**	**499**	**545**	**606**	**890**

Table 6 Distribution of Samples collected by region

4.1.4. Summary of Sampling

Figure 9 Distribution of sampled medicines by sites

Round	Total # of Samples Collected	# of samples analyzed in the field using Minilab (Level 1)	# of Samples submitted to reference lab for Level 2 analysis	# of samples analyzed at reference lab using compendia methods (Level 3)
Round 1	536	451	80	44
Round 2	499	496	65	25
Round 3	545	514	71	20
Round 4	606	117	112	115
Round 5	890	879	102	82

Table 7 Summary of sampling and analysis of the five rounds

4.2. Registration with the Pharmacy and Poisons Board

Figure 2 shows the registration status of the samples over the five rounds of post marketing surveillance. The percentage of unregistered samples has consistently decreased over time.

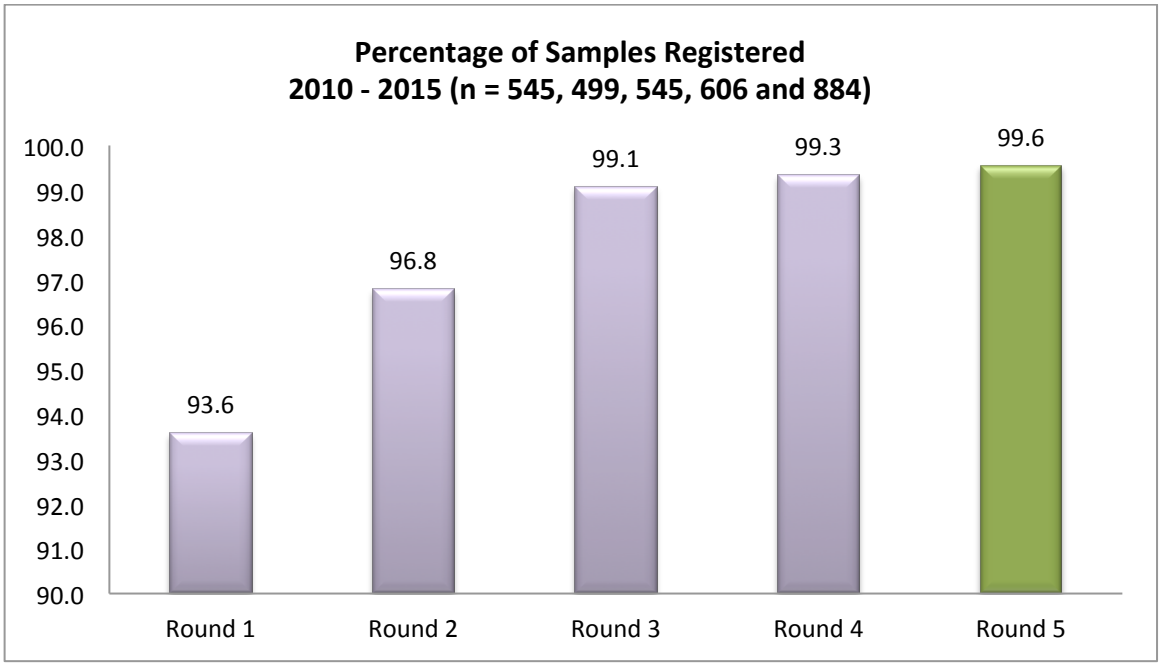

Figure 10 Registration Status of PMS samples over the five rounds

4.3. Basic and Compendial Test Results

4.3.1. Level 1 Screening Test Results

Of the 879 samples screen at the sites, the proportion of samples in Round 5 that passed round one screening was 96%. The highest screening pass rate was in round two where 97% of the screened samples passed while the least was in round four where 82% passed. 3.8% of the screened samples were doubtful while 0.2% failed the screening tests. The highest-level 1 screening failure was during round one where 5% of the samples failed analysis. Round 4 had the highest doubtful results at 17% while round 2 had the least at 1%. The summary of the previous level 1 screening tests can be seen in the figure below.

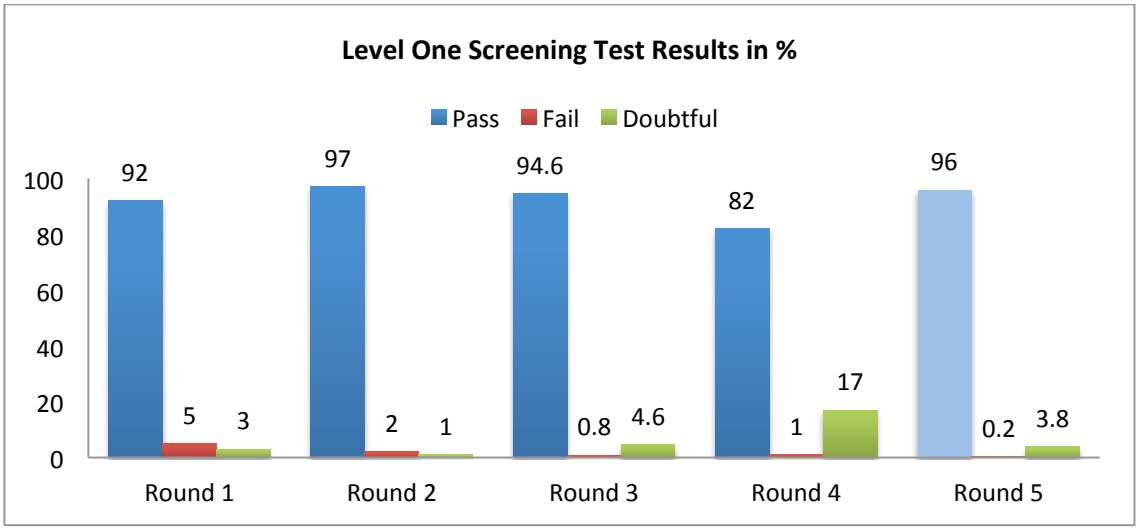

Figure 11 Results of level 1 screening

Figure 12: Results of Level 1 Testing

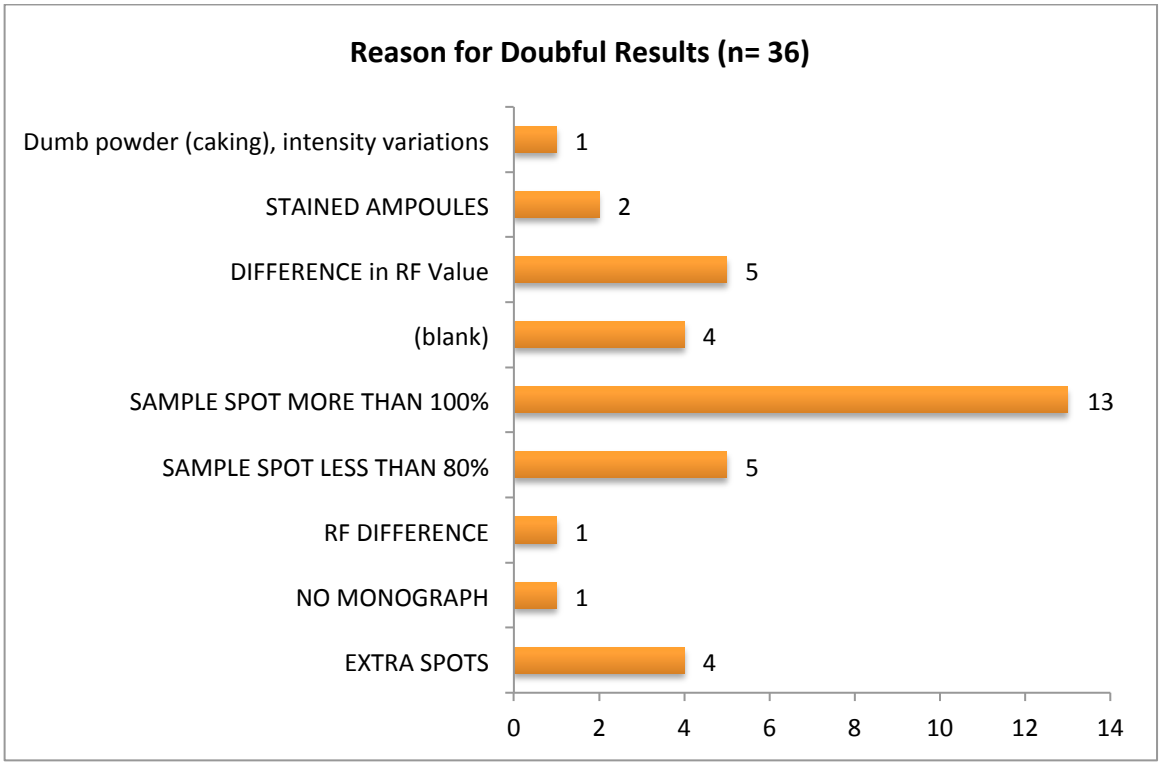

Figure 13 Reason for doubtful result in Level 1 Testing

4.3.2. Level 2 Screening Test Results

The figure below shows results of the previous level II testing. **For round five, level II testing was not done but instead, all samples delivered to the laboratory underwent compedial testing.**

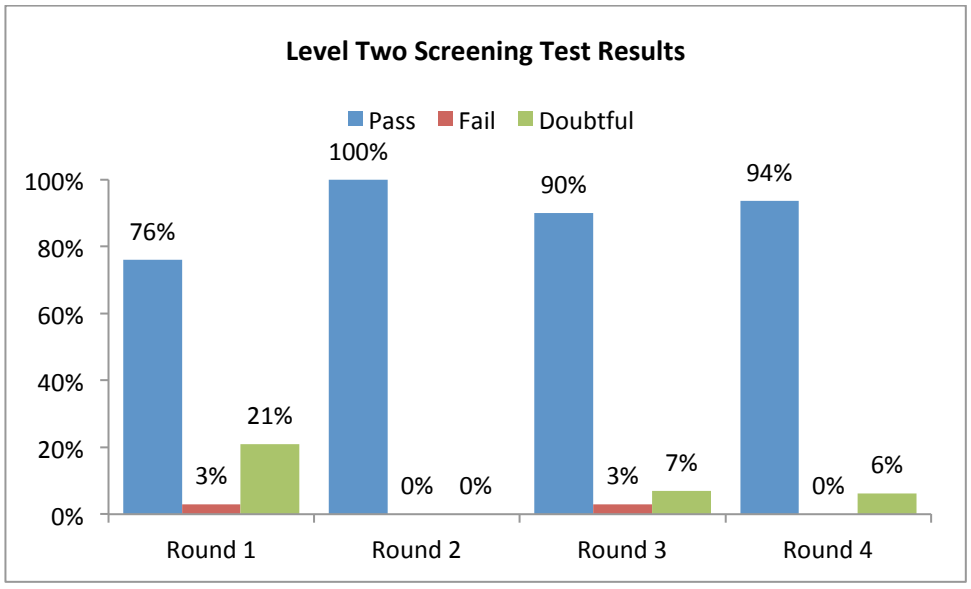

Figure 14: Results of Level 2 Testing

4.3.3. Level 3 Compedial Test Results

As there was no level 2 minilab testing, all the 102 samples from level 1 testing were submitted for compendial testing.

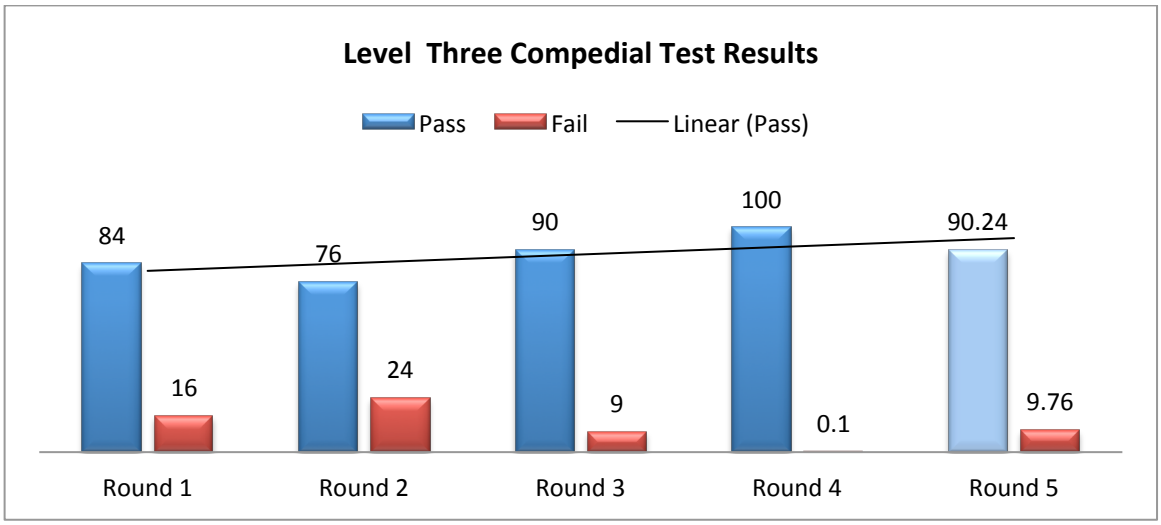

Figure 15 Compedial testing results

4.4. Determinants of Conformity

4.4.1. Sector of Health

Samples from Public sector and private/ informal sectors had almost equal chances of passing the level I screening test. There was no significance difference in the results from the two sectors although samples from public sectors had a higher pass rate of 96.9% as compared to 95.2% in the private/ informal sector.

Sector	Level 1 Test Results		Total
	Pass	Fail/ Doubtful	
Public	188 (96.91%)	6	**194**
Private/ Informal	655(95.20%)	33	**688**
	843(95.58%)	**39**	**882**

Table 8 Sample screening results by sector

4.5. Registration Status

The Pharmacy and Poisons Board registered 99.6% of round five samples collected. This compares well with the 99.3% of the samples that were found to be registered during round four. This is the highest proportion registered since Malaria PMS started in 2010. However, there was one product, Darte-Q Dihydroartemisinin/Piperaquine Phosphate Powder manufactured by Gosun Pharma Corp. (G.P.C) that was not registered in the country although it passed compedial analysis. The unregistered product was quarantined and removed from the market.

4.6. Screening and Compedial Test Results

The proportion of samples in Round 5 that passed leval one screening was 96%. The highest screening pass rate was in round two where 97% of the screened samples passed while the least was in round four where 82% passed. Impurities in the TLC plate and intensity of sample >80% accounted for more than half of the failed and doubtful samples.

Considering the remarkably lower cost of minilab testing and how fast results are available compared to laboratory testing, these findings highlights the value of this approach and encourage its continued use. The efficiency and value for money component for using Minilabs is a key proponent for sustainability of the tracking quality of medicines at sub national levels.

Of the 102 samples submitted for compedial analysis, 82 were analyzed while 20 samples were not analyzed as they expired before being subjected to analysis.

74 of the 82 that were analyzed passed compedial testing, giving a pass rate of 90.24%. This was a drop from round four compedial testing where there was 100% pass rate.

The following eight samples failed analysis

No.	Product Name	Active Pharmaceutical Ingredient	Formulation	Manufacturer	Test Failed
1.	Artefan B/No. SB0074F	Artemether 180mg/ Lumefantrine 1080mg per 60ml	Suspension	Ajanta Pharma Ltd	Assay
2.	Co-corither Dry Syrup B/No. UCU1401	Artemether 180mg/ Lumefantrine 1080mg per 60ml	Syrup	Coral Laboratories	Assay
3.	Lonart Suspension B/No. LO-246	Artemether 180mg/ Lumefantrine 1080mg per 60ml	Suspension	Bliss GVS Pharma Ltd	Assay
4.	Fansider Tablets B/No. Z0248	Sulfadoxine 500mg/ Pyrimethamine 25mg	Tablets	Akacia Healthcare Ltd	Assay and Weight Variation
5.	Lonart Suspension B/No. LO-243	Artemether 180mg/ Lumefantrine 1080mg per 60ml	Suspension	Bliss GVS Pharma Ltd	Assay
6.	Cofantrin Forte Tablets B/No. CF-101	Artemether 80mg/ Lumefantrine 480mg	Tablets	Comet Healthcare Ltd	Assay and Weight Variation
7.	Co-corither Dry Syrup B/No. UCU1401	Artemether 180mg/ Lumefantrine 1080mg per 60ml	Syrup	Coral Laboratories	Assay
8.	P- Alaxin B/No. PAS-13	Dihydroartemisinin 80mg/ Piperaquine Phosphate 640mg	Suspension	Bliss GVS Pharma Ltd	Assay

Table 9 List of products that failed compedial testing

Level 1 testing had high sensitivity and specificity rates for detection of poor quality anti-malarials. Considering the remarkably lower cost of minilab testing and how fast results are available compared to laboratory testing, these findings highlight the value of this approach and encourage its continued use.

A high proportion of anti-malarials, both in the public and private sectors, conformed to the requisite quality standards. The overall findings demonstrate the continued availability of good quality antimalarial medicines in the market- both ACTm and non-ACTm in the country.

4.7. Regulatory Actions Undertaken by PPB

The eight products that failed analysis were quarantined and removed from the market. The same applied to the product that was found as not registered in the country. PPB also instituted investigations to trace the source of the product.

5. Conclusion and Recommendations

5.1. Conclusion

The proportion of poor quality anti-malarials continues to decline with the increased surveillance, improved regulation. Almost all the antimalarials in the market are registered and meet quality standards.

The results obtained with the minilab show that this cost effective and rapid methodology is of value and it is recommendable of institutionalize its use for post market surveillance, especially in border towns and areas prone to substandard medicines (risk-based Post market surveillance). The efficiency and value for money component for using Minilabs is a key proponent for sustainability for tracking quality of medicines at sub national levels.

5.2. Recommendations

1. Regular post market surveillance should be institutionalized at the county level, preferably using minilabs for screening purposes, to ensure that all anti-malarials available to the population meet the required quality standards
2. Prompt and decisive regulatory action needs to be taken on failed samples to rapidly take them out of the market and on manufacturers whose products do not meet regulatory requirements
3. Products with longer expiry dates should be considered when the fieldwork is being carried out.

4. Prompt compedial analysis of the samples collected from the field should be carried out so as to prevent the expiry of samples before analysis.
5. A database of the post marketing surveillance should be developed and regularly updated so as to monitor products that repeatedly fail analysis
6. Counties and other public health programs should consider using this type of monitoring the quality of their medicines as it is affordable and one gets results faster
7. Expand the use of minilab to monitoring other groups of medicines apart from antimalarials
8. Promote the technique to the counties so that they can use it to monitor the quality of medicines that they are procuring

6. REFERENCES

1. **President's Malaria Initiative.** President's Malaria Initiative: Fighting Malaria and Saving Lives. [Online] [Cited: May 19, 2015.] http://www.pmi.gov/where-we-work/kenya.

2. **Division of Malaria Control [Ministry of Public Health and Sanitation], Kenya National Bureau of Statistics,and ICF Macro.** *2010 Kenya Malaria Indicator Survey.* Nairobi : DOMC, KNBS and ICF Macro, 2011.

3. **President's Malaria Initiative (PMI).** *Malaria Operational Plan FY 2015.* 2015.

4. **Kenya Malaria Indicator Survey 2015**, NMCP, KNBS, ICF International

7. ANNEXES

7.1. Sampling Checklist

Before departing for sentinel sites with the intention of sampling for a Medicine Quality Monitoring (MQM) program, check that you have all the items listed below.

Task
1. Sufficient Sampling Forms *Fill out one form for each sample.*
2. Sampling Plan *Prepare a sampling plan in accordance with the MQM protocol and plan ahead for each day of sampling.*
3. Sampling Tools *Each sampling team must have the following tools:*
• New plastic or glass, opaque, clean containers to store and transport samples
• Map for the designated site with listed sources of sample collection
• Scissors, gloves, clean spatula or spoon, forceps, tape, watch, labels
• Indelible markers for labeling the sampling containers
• Indelible pens to complete forms
• Cardboard box(es) to store collected samples.
4. Notebook *(one per sampling team)* *Use a notebook dedicated to only MQM collections to record additional information about sampling activities.*
5. Logistics *Money for transportation, purchasing samples, food, lodging, and other incidentals.*
6. Optional items *Digital or conventional camera, mobile phone, global positioning system device, and other items as necessary.*

7.2. Sample Collection Form

Date (day/month/year)	
Name of Site	
Name of Collector	
Signature of Collector	

SAMPLE INFORMATION	
Sample code [1]	
Complete site address *(Name of location, street address, contact information, if applicable)*	
Sector of site (public, private or informal)	
Description of dispensing site (pharmacy, health clinic, hospital, warehouse, etc.)	
Commercial drug name	
INN[2]	
Pharmaceutical presentation (tablet, capsule, injectable, etc.)	
Dosage (mg)	
Manufacturer name	
Manufacturer's batch or lot number	
Manufacturing date (if present)	
Expiry date	
Registration or license number (if applicable)	
Manufacturer address	
Number of units collected[3]	
Package description: • Type of package (blister pack/card, bottle, others specify) • Number of units/pack • Presence of insert/leaflet	
Check one:	taken in original package taken from bulk container
Instructions to store sample (e.g., keep medicine away from light and at 25◦)	
Storage conditions at site[4]	

[1] Adapt according to program or country needs, suggested will be (A/B/C/D/E): A: Name of Country, B: INN/API, C: Collection Site; D: Date of Collection; E: Sequential Number.

[2] INN is the International Non-proprietary Name of a drug product, also known as Active Pharmaceutical Ingredient (API)

[3] If fewer than the number required by the protocol, please explain.

[4] Please describe the general storage conditions of the sampling site (e.g., medicines exposed to sun and/or air, no temperature and/or humidity control, water visible in storage room, medicines stacked inappropriately, etc.)

* Sample collection form should be attached to the sample and additional copies should be retained as indicated in the project protocol.

7.3. Basic Tests Analysis Form for Sentinel Site Staff

Sample Code	
Date of Analysis (dd/mmm/yyy)	
Sentinel Site of Analysis	
Name of Analyst	
Signature of Analyst	

TEST 1: VISUAL & PHYSICAL INSPECTION		
Visual Inspection:		
Please confirm that all of the recorded information in the Sample Collection Form (Annex 2) is consistent with the packaging and labeling of the medicine. Correct the Sample Collection Form (Annex 2) if there are any errors and/or omissions.[3] Have any corrections and/or additions been made to Sample Collection Form (Annex 2): □ Yes □ No		
Other Comments (description of hologram, any print on the backing foil, etc.)		
Physical Inspection:		
Shape (circular, oval, flat sides, other)		
Uniformity of shape		
Uniformity of color		
No physical damage (cracks, breaks, erosion, abrasion, sticky)		
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)		
TEST 2: DISINTEGRATION[4]		
Time of observed disintegration (minutes) 1. _____ 2. _____ 3. _____	Did the drug pass the disintegration test? □ Yes □ No	

[3] If any corrections/ additions were made to the Sample Collection Form, initial and date all added information
[4] Disintegration tests are 30 minutes; for testing at sentinel sites perform only 3 tablets/capsules. If one or more units do not disintegrate classify the sample as failing basic tests and send for confirmatory tests. For confirmatory testing please refer to the testing protocol.

TEST 3: TLC	
Did the sample have a spot? □ Yes □ No Rf Standard: _____ Rf Sample: _____ Rf % Sample difference:[5] _____	Intensity of sample spot compared to standard: ○ Less than 80% ○ Between 80% and 100% ○ More than 100% Were there any contaminants/impurities present? □ Yes □ No Observations: _____
FINAL RESULTS	
○ The sample conformed with basic tests ○ The sample did not conform with basic tests Reason: _____ ○ The sample is considered doubtful Reason: _____	
How many units are remained after basic tests? _____	
REPORT REVIEWED BY[6]:	
Name: _____ Signature: _____ Date: _____	

[5] Rf % Sample Difference = $\frac{|\text{Rf (Standard)-Rf (Sample)}|}{\text{Rf (standard)}} \times 100$

In this formula $|Rf\ (Standard) - Rf\ (Sample)|$ represents the absolute value of the difference between the Rf's of the standard and the sample.

Ex: In a TLC run the following values are obtained: Rf (standard) = 0,55, Rf (sample) = 0,57; The Rf % Sample Difference = $\frac{|0.55\text{-}0.57|}{0.55} \times 100 = \frac{0.02}{0.55} \times 100 = 3.6\%$

[6] If applicable

7.4. Basic Tests Analysis Form for National Quality Control Laboratory Staff

Sample Code	
Date of Analysis (dd/mmm/yyy)	
Sentinel Site of Analysis	
Name of Analyst	
Signature of Analyst	

TEST 1: VISUAL & PHYSICAL INSPECTION	
Visual Inspection:	
Please confirm that all of the recorded information in the Sample Collection Form (Annex 2) is consistent with the packaging and labeling of the medicine. Correct the Sample Collection Form (Annex 2) if there are any errors and/or omissions.[7] Have any corrections and/or additions been made to Sample Collection Form (Annex 2): □ Yes □ No	
Other Comments (description of hologram, any print on the backing foil, etc.)	
Physical Inspection:	
Shape (circular, oval, flat sides, other)	
Uniformity of shape	
Uniformity of color	
No physical damage (cracks, breaks, erosion, abrasion, sticky)	
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)	

TEST 2: DISINTEGRATION[8]		
Time of observed disintegration (minutes) 1. _____ 2. _____ 3. _____	Did the drug pass the disintegration test? □ Yes □ No	

TEST 3: TLC	
Did the sample have a spot? □ Yes □ No Rf Standard: _____ Rf Sample: _____ Rf % Sample difference:[9] _____	Intensity of sample spot compared to standard: ○ Less than 80% ○ Between 80% and 100%

[7] If any corrections/ additions were made to the Sample Collection Form, initial and date all added information

[8] Disintegration tests are 30 minutes; for testing at sentinel sites perform only 3 tablets/capsules. If one or more units do not disintegrate classify the sample as failing basic tests and send for confirmatory tests. For confirmatory testing please refer to the testing protocol.

[9] Rf % Sample Difference = $\frac{|\text{Rf (Standard)-Rf (Sample)}|}{\text{Rf (standard)}} \times 100$

In this formula $|Rf\ (Standard) - Rf\ (Sample)|$ represents the absolute value of the difference between the Rf's of the standard and the sample.

Ex: In a TLC run the following values are obtained: Rf (standard) = 0,55, Rf (sample) = 0,57; The Rf % Sample Difference = $\frac{|0.55-0.57|}{0.55} \times 100 = \frac{0.02}{0.55} \times 100 = 3.6\%$

	○ More than 100% Were there any contaminants/impurities present? □ Yes □ No Observations: _____
FINAL RESULTS	
○ The sample conformed with basic tests ○ The sample did not conform with basic tests Reason: _____ ○ The sample is considered doubtful Reason: _____	
How many units are remained after basic tests? _____	
REPORT REVIEWED BY[10]:	
Name: _____ Signature: _____ Date: _____	

[10] If applicable

7.5. List of Sampled Facilities

Region	Name of Facility	Address	Sector	Type
Busia	Namulwani Chemist	Port Victoria	Private	Pharmacy
Busia	Alupe Sub County Hosp	Box 35 Busia	Public	Hospital
Busia	Amo Pharmacy	Box 322 Maraba	Private	Pharmacy
Busia	Amukura Pharmacy	Box 353 - 50408 Kimurai	Private	Pharmacy
Busia	Bungoma Chemists Ltd	Box 1053 Bungoma	Private	Wholesale
Busia	Bungoma District Hosp	Box 14 Bungoma	Public	Hospital
Busia	Bunyala Healthcare Chemist	Port Victoria	Private	Pharmacy
Busia	Busia County Referral Hosp	Box 87, Busia	Public	Hospital
Busia	CFW Clinics Bumala	Box 1630-00606 Nairobi	Private	Pharmacy
Busia	East End Chemist Ltd	Box 782 Bungoma	Private	Wholesale
Busia	Holy Famiily Hospital Nangina	Box 57 Funyula - Samia	Private	Hospital
Busia	Kimaeti Health Centre	Box 2313 Bungoma	Public	Health Centre
Busia	Malaba Dispensary	Malaba	Public	Dispensary
Busia	Mubwekas Medical Clinic	Box 777 Busia	Private	Clinic
Busia	Namulwani Chemist	Port Victoria	Private	Pharmacy
Busia	Ogmax Chemist	Port Victoria	Private	Informal
Busia	Port Victoria Sub-County Hospital	Port Victoria	Public	Hospital
Busia	Scorpion Pharmacy Ltd	Busia	Private	Pharmacy
Busia	The Eagle Pharmacy	Box 85, Funyula	Private	Informal
Kajiado	AIC Hospital	Along Namanga-Kajiado Road	Public	Hospital
Kajiado	Bellmont Late Night Chemist	Sampu Building,Main Street, Kajiado Town	Private	Wholesale
Kajiado	Cloriti Pharmaceuticals (E.A) Ltd	Dayalal & Sons Building- Ngon Town	Private	Whole
Kajiado	Drug Heal Pharmacy	Along Pipeline Road	Private	Informal
Kajiado	Edmerc Pharmacy	Kazaro Building, Opp. Eastmatt Supermarket	Private	Retail
Kajiado	Embulbul Catholic Dispensary	Off Ngong Karen Road	Private	Dispensary
Kajiado	Ereteti Dispensary	Along Pipeline Road	Public	Dispensary
Kajiado	Isinya Heathcentre	Off Namanga Kajiado Road	Public	Healthcentre
Kajiado	Island Pharmaceuticals	Along Kajiado Town Main Street Opp. Central Hotel	Private	Retail
Kajiado	Kajiado District Hospital	Off Namanga Road	Public	County Stores
Kajiado	Kenmaiso Pharmaceuticals Ltd	Maili Tisa Stage-Namanga	Private	Retail
Kajiado	Kisaju Pharmaceuticals	Along Isinya Healthcentre Road	Private	Retail
Kajiado	Kitengela Medical Services	EPZ Viwandani Road	Private	Hospital

Kajiado	Kitengela Sub County Hosp	Prisons Road	Public	Hospital
Kajiado	Lexa Medical Centre	Along Namanga Amboseli Road	Private	Hospital
Kajiado	Mabrouk Pharmaceuticals	Off Namanga Kajiado Road	Private	Retail
Kajiado	Magadi Soda Company Hospital	Magadi Soda Kiserian Road	Private	Hospital
Kajiado	Mile 9 Chemist	Along Kajiado Namanga Road	Private	Informal
Kajiado	Montana Healthcare	Along Nairobi Namanga Road	Private	Retail
Kajiado	Namanga Drug House	Off Namanga Road	Private	Wholesaler
Kajiado	Ngong Sub-County Hospital	Off Ngong Road	Public	Hospital
Kajiado	Samjos Pharmacy	Leiser Hill Plaza, Off Magadi Road, Ongata Rongai	Private	Retail
Kajiado	Shephards Chemist & Agrovet	Along Equity Street, Opposite Cooperative Bank	Private	Retail
Kajiado	St. Theresa Dispensary Carmelite Missionaries	Market Area, Kitengela	Public	Hospital
Kajiado	Topcare Nursing Home	Along Miriam Road	Private	Clinic
Kajiado	Uzima Medical Clinic	Na Manga Town	Private	Clinic
Kajiado	Zamzam Medical Services	Off Ngong Road	Private	Clinic
Kakamega	Ahmadiya Muslim Hospital, Shianda,	Off Mumias-Kakamega Road	Private	Hospital
Kakamega	Emuhaya Centre P.O 50. Emuhaya	Along Luanda - Standkisa Road	Public	Hospital
Kakamega	Equator Medical Services	Along Kisumu- Busia Road	Private	Clinic
Kakamega	Iguhu County Hospital,	Off Ksm- Kakamega Road	Public	Hospital
Kakamega	Jamia Medical Centre,	Off Mumias-Kakamega Road	Private	Hospital
Kakamega	Jamii Tosha Pharmacy	Opp. Kakamega County Referral Hospital	Private	Pharmacy
Kakamega	Kakamega County Referral Hospital,	Kakamega- Kisumu Road	Public	Pharmacy
Kakamega	Khayega Medical Clinic,	Along Kakamega- Kisumu Road	Private	Health Clinic
Kakamega	Kilingili Health Centre,	Kilingili Market, Stand Kisa-Luanda Road	Public	Hospital
Kakamega	Lukose Chemist,	Chavakali Market	Informal	Pharmacy
Kakamega	Makunga Rural Health Development Centre,	Off Kakamega- Mumias Road	Public	Hospital
Kakamega	Malava County Hospital	Malava Town,Kakamega West Road	Public	Hospital
Kakamega	Rayet Chemist	Luanda Market , Kisumu- Busia Road	Private	Pharmacy
Kakamega	St Elizabeth Mukumu Mission Hospital	Khayega, Along Kakamega-Kisumu Road	Private	Hospital
Kakamega	St Marys Mission Hospital Mumias,	Mumias-Kakamega, Mumias	Private	Hospital
Kakamega	Tiba Chemists,	Chavakali Town, Kisumu-	Private	Pharmacy

		Kakamega Highway		
Kakamega	Tony Chemist,	Kakamega-Kisumu Road	Private	Pharmacy
Kakamega	Vihiga County Referral Hospital,	Mbale Town	Public	Hospital
Kericho	Adakim Chemists	Kericho	Private	Wholesalers
Kericho	Delach Chemists	Kericho	Private	Pharmacy
Kericho	Discount Pharmacy	Kericho	Private	Retail
Kericho	Elementaita Pharmacy	Naivasha Town	Private	Pharmacy
Kericho	Elim Pharmacy	Nakuru	Private	Wholesalers
Kericho	Favours Chemist	Kericho	Private	Pharmacy
Kericho	Fig Tree Health Options	Kericho	Private	Clinic
Kericho	G.K. Prison Dispensary	Kericho	Public	Dispensary
Kericho	Kapkatet County Hosp	Kericho	Public	Hospital
Kericho	Kericho County Stores	Kericho	Public	Stores
Kericho	Kericho Medical Centre	Kericho	Private	Clinic
Kericho	Kericho Nursing Home	Kericho	Private	Hospital
Kericho	Kericho Outpatient Medical Centre	Kericho	Private	Clinic
Kericho	Kubwa Healthcare	Naivasha Town, Inside Naivas Supermarket	Private	Pharmacy
Kericho	Litein Mssion Hospital	Kericho	Private	Hospital
Kericho	Neuro Chemista	Kericho	Private	Pharmacy
Kericho	Pishon Chemist	Nakuru	Private	Pharmacy
Kericho	Siloam Hospital	Kericho	Private	Hospital
Kericho	St Leonards Kericho	Kericho	Private	Hospital
Kericho	St Mary's Mission Hospital	Naivasha Town	Private	Hospital
Kericho	St. Leonards Nyagacho	Kericho	Private	Hospital
Kericho	Tealands Chemists	Kericho	Private	Wholesalers
Kericho	Transwide Pharmaceuticals	Nakuru	Private	Pharmacy
Kericho	Unnamed Chemist	Kericho	Informal	Kiosk
Kisii	Amani Clinic	Suneka	Private	Clinic
Kisii	Bitare Health Centre	Nyambunwa	Public	Health Centre
Kisii	Bonmed Pharmacy	Keroka	Private	Pharmacy
Kisii	Bosongo Chemist	Kisii	Private	Pharmacy
Kisii	Getembe Pharmacy	Kisii	Private	Pharmacy
Kisii	Gucha Nursing Home	Keroka	Private	Nursing Home
Kisii	Imara Chemist	Mwembe	Private	Pharmacy
Kisii	Keroka Dist. Hospital	Keroka	Public	Hospital
Kisii	Keumbu District Hospital	Keumbu	Public	Hospital
Kisii	Kisii County Store	Kisii	Public	Store
Kisii	Meridian Four Pharmacy	Kisii	Private	Pharmacy
Kisii	Nyanchwa Medical Centre	Nyanchwa	Public	Hospital

Kisii	Ram Hospital	Kisii	Private	Hospital
Kisii	Space Chemist	Keroka	Private	Pharmacy
Kisii	Verleon	Mwembe	Private	Pharmacy
Kisumu	Aga Khan Hospital Kisumu	Kiisumu-Kakamega Road. Near Kibuye Market	Private	Hospital
Kisumu	Avenue Hospital	Kisumu-Kakamega Road.	Private	Hospital
Kisumu	Chador Clinic	Jomo Kenyatta Street Kisumu. Chekmulla Building	Private	Health Clinic
Kisumu	Chulaimbo Teaching And Referral Hospital	Kisumu-Busia Road Chulaimbo	Public	Hospital
Kisumu	God's Will Centre	Simba, Nyalenda, Kisumu.	Private	Clinic
Kisumu	Harleys Pharmaceuticals Ltd	Oginga Odinga Street. Kisumu Town	Private	Wholesale
Kisumu	Jalaram Hospital	Kisumu-Kakamega Road.	Private	Hospital
Kisumu	Katito Gateway Pharmacy	Kisumu-Oyugis Road.	Private	Retail
Kisumu	Kentons Ltd	Oginga Odinga Street. Kisumu Town	Private	Wholesale
Kisumu	Kibos Prison Dispensary	Kisumu-Kibos Road.	Public	Dispensary
Kisumu	Kisumu East District Hospital	Ang'awa Avenue.	Private	Public
Kisumu	Leo Chemists Ltd	Kisumu-Kakamega Road. Opp. JOOTRH	Private	Retail
Kisumu	Nameless Chemist	Kisumu-Oyugis Road. Katito Market	Informal	Kiosk
Kisumu	Nameless Chemist	Nyalenda. Next To Kilo Stage	Informal	Kiosk
Kisumu	Nameless Chemist	Kisumu-Nairobi Highway. Nyamasaria	Informal	Kiosk
Kisumu	Nameless Chemist	Kisumu-Oyugis Road. Katito Market	Informal	Kiosk
Kisumu	Port Florence Community Hospital	Oginga Odinga Street, Mega Plaza. Kisumu Town	Private	Health Clinic
Kisumu	Ramogi Chemists Ltd	Ang'awa Avenue. Next To Fire Station, Kisumu Town	Private	Retail
Kisumu	Shanob Pharmacy	Kondele-Kibos Road, Next To Juventure Guest House	Private	Retail
Kisumu	Sondu Health Centre	Kisumu-Oyugis Road. Sondu Market	Public	Health Clinic
Kisumu	St. Joseph's Nyabondo Mission Hospital	Kisumu-Oyugis Road Sondu. Nyabondo	Private	Hospital
Kisumu	St. Monica's Hospital	Kisumu-Kakamega Road.	Private	Hospital
Kisumu	Tayyibah Medical Centre	Next To Tayyibah Mosque,	Public	Health Clinic
Kisumu	Victoria Pharmaceuticals Ltd	Otuoma Street, Central Square. Kisumu Town	Private	Wholesale
Kwale	Afia Chemist	Kinango	Private	Pharmacy
Kwale	Corner Pharmaceuticals	Kinango	Private	Pharmacy
Kwale	Dyno Kombani Chemist	Likoni	Private	Pharmacy
Kwale	Fister Chemist	Lunga Lunga	Private	Pharmacy

Kwale	Kinondo Kwetu Health Services	Kinondo	Private	Health Clinic
Kwale	Lan Pharmaceuticals	Msabweni	Private	Pharmacy
Kwale	Likoni District Hospital	Likoni	Public	Hospital
Kwale	Msabweni District Hospital	Msabweni	Public	Hospital
Kwale	Oceanic Bright Pharmacy	Diani	Private	Pharmacy
Kwale	Otieno Chemist	Ukunda	Private	Pharmacy
Kwale	Palm Beach Hospital	Diani	Private	Hospital
Kwale	Savanah Chemist	Kinango	Private	Pharmacy
Kwale	Seaside Pharmacy	Ukunda	Private	Pharmacy
Kwale	Seaside Pharmacy	Likoni	Private	Pharmacy
Kwale	South Coast Pharmaceuticals	Ukunda	Private	Pharmacy
Kwale	Ukunda Catholic Dispensary	Ukunda	Public	Health Clinic
Kwale	Ukunda Medical Center	Ukunda	Private	Hospital
Migori	Akidiva Memorial Hospital	Off Migori - Sirare Highway	Private	Hospital
Migori	Boma Medicare Ltd	Opposite Post Office, Migori Town	Private	Health Clinic
Migori	Bukuria Medical Centre	Isebania Town - Opp Transline Bus Stage	Private	Health Clinic
Migori	Getontira Medical Clinic	Opp Mosque - Isebania Town	Private	Health Clinic
Migori	Igena Pharmacy	Isebania Town - Opp Transline Bus Stage	Private	Retail Pharmacy
Migori	Kandaria Pharmacy	Main Stage - Migori	Private	Retail Pharmacy
Migori	Kisao Pharmacy	Next To Kcb - Sirare	Private	Wholesale Pharmacy
Migori	Migori District Hospital	Next To County Government Offices	Public	Hospital
Migori	Migori Stage Pharmacy	Awendo - Mariwa Road	Private	Retail Retail Pharmacy
Migori	Millest Cosmetics And Pharmacy	Oruba Estate - Migori	Informal	Pharmacy
Migori	Monicare Pharmacy Ltd	Kisii - Migori Highway	Private	Retail Pharmacy
Migori	Nyaranga Central Pharmacy	Next To Sherling Supermarket - Migori	Private	Wholesale Pharmacy
Migori	Nyasese Dispensary	Next To Nyasese Primary School	Public	Dispensary
Migori	Pastor Machage Hospital	Migori - Sirare Highway	Private	Hospital
Migori	Pioneer Chemist And Cosmetics	Ranen Centre - Migori- Sirare Highway	Informal	Pharmacy
Migori	Pishon Chemist	Oruba Estate - Migori	Private	Retail Pharmacy
Migori	Rongo District Hospital	Off Kisii - Migori Highway	Public	Hospital
Migori	Silverlane Chemist	Rongo Town, Mimosa Street	Private	Retail Pharmacy
Migori	St. Joseph Mission	Opposite Migori High School	Private	Fbo Hospital

	Hospital, Ombo			
Migori	Stage View Chemist	Awendo - Mariwa Road	Private	Retail Pharmacy
Migori	Vibra Pharmacy	Kisii - Migiori Highway, Migori	Private	Wholesale Pharmacy
Migori	Zack - 4 Chemist	Rongo Town, Next Kcb	Private	Retail Pharmacy
Mombasa	Adams Chemists	Kericho Street	Private	Pharmacy
Mombasa	Coast General Hospital	Hospital Road	Public	Hospital
Mombasa	Community Health Services Pharmacy	Kongoea Estate	Private	Pharmacy
Mombasa	Framu Chemist	Kongoea Estate	Private	Pharmacy
Mombasa	Jocham Hospital	Kisauni-Malindi Road	Private	Hospital
Mombasa	Kengeleni Pharmacy	Kisauni-Malindi Road	Private	Pharmacy
Mombasa	Kisauni Pharmacy	Kisauni	Private	Pharmacy
Mombasa	Makupa Chemists	Kenyatta Avenue	Private	Pharmacy
Mombasa	Mewa Hospital	Majengo Estate	Private	Hospital
Mombasa	Midlife Pharmacy	Hospital Road	Private	Pharmacy
Mombasa	Mikindani Health Centre	Mikindani Estate	Public	Clinic
Mombasa	Mombasa Hospital	Mama Ngina Street	Private	Hospital
Mombasa	Njimia Pharmaceuticals	Digo Road	Private	Wholesaler
Mombasa	Pandya Memorial Hosp	Dedan Kimathi Street	Private	Hospital
Mombasa	Portreitz Subcounty Hospital	Airport Road	Public	Hospital
Mombasa	Psalmchem Chemist	Mikindani Estate	Private	Pharmacy
Mombasa	Serena Pharmacy Ltd	Hospital Road	Private	Pharmacy
Mombasa	Shifa Chem Limited	Kenyatta Avenue	Private	Pharmacy
Mombasa	Sumaiya Chemist	Kingorani Estate	Private	Pharmacy
Mombasa	Sumeb Plus Pharmacy	Airport Road	Private	Pharmacy
Mombasa	Surgipharm Ltd	Nyerere Avenue	Private	Importer
Mombasa	Terichem Chemist	Mikindani Estate	Private	Pharmacy
Mombasa	Tudor Subcounty Hospital	Tudor Estate	Public	Hospital
Nairobi	Batian Peak Pharmacy	KNH Plaza Nairobi	Private	Pharmacy
Nairobi	Capital Chemist	Along Olympic Road Kibera	Informal	Street Vendor
Nairobi	Chemist	Along Olympic Road Kibera	Informal	Retailer
Nairobi	Coptic Hospital	Ngong Road, Opp. Maki Apartments	Private	Fbo Hospital
Nairobi	Dajim Pharmacy Ltd	Naivasha Road Opp Post Bank Uthiru	Private	Pharmacy
Nairobi	Gakoe Dispensary	P.O Box 84 Gatundu Kiambu	Public	Hospital Pharmacy
Nairobi	Kagaa Dispensary	P.O Box 37 Githunguri Kiambu	Public	Hospital
Nairobi	Kent Pharmaceuticals Ltd	Nyaku House, Hurlingham	Private	Retailer
Nairobi	Kiandutu Health Centre	P.O Box 3304 - 01002 Thika	Public	Hospital Pharmacy
Nairobi	Kianyi Pharmacy	P.O Box 1986 - 00900 Kiambu	Private	Pharmacy
Nairobi	Makongeni Health Centre	P.O Box 1747 - 01000 Thika	Public	Hospital

		Makongeni Estate		Pharmacy
Nairobi	Malibu Pharmacy	P.O Box 69652 - 00400 - Nairobi	Private	Pharmacy
Nairobi	Max Pharmaceuticals	P.O Box 320 - 00519 Mlolongo	Private	Pharmacy
Nairobi	Mbagathi Hospital	Off Mbagathi Way Kenyatta Market Ngumo	Public	Hospital Pharmacy
Nairobi	Meds	Mombasa Road	Public	FBO Warehouse
Nairobi	Menya Chemists	P.O Box 2297 Thika	Private	Pharmacy
Nairobi	Mivjizi Clinic	Katwekera Kibera	Informal	Street Vendor
Nairobi	Nairobi West Hospital	Ghandia Avenue, Nairobi West	Private	Hospital Pharmacy
Nairobi	Nam Pharmacy	Uthiru' Off Naivasha Road	Private	Retailer
Nairobi	Njimia Pharmaceuticals	Landmark Plaza, 2nd Floor, Argwings Kodhek Road,	Private	Wholesaler
Nairobi	Olympic Chemist	Along Olympic Road Kibera	Informal	Street Vendor
Nairobi	Shalom Community Hosp	P.O Box 505 - Athi River	Private	Hospital Pharmacy
Nairobi	Solace Chemists	Muratha Road Kangemi	Private	Retailer
Nairobi	Surgipharm Limited	Ninina Towers, Westlands Rd, Opposite Cfc Stanbic	Private	Distributer
Nairobi	The Nairobi Womens Hospital	Off Argwings Kodhek Road, Hurlingham	Private	Hospital
Nairobi	Thika Nursing Home	Section 9 OAU - Road	Private	Hospital Pharmacy
Nairobi	Transchem Pharma	Uchumi Building Nairobi	Private	Wholesaler
Nairobi	VIPS Health Services Ltd	Woodley Along Kabarnet Road	Private	Fbo Hospital
Uasin Gishu	Abba Pharm Chemist	Eldoret Town	Private	Pharmacy
Uasin Gishu	Acacia Medical Clinic	Eldoret Town	Private	Clinic
Uasin Gishu	Baraka Clinic	Elortet Town	Private	Clinic
Uasin Gishu	Cedar Hospital	Eldoret Town	Private	Hospital
Uasin Gishu	Dominion Chemist	Eldoret Town	Private	Pharmacy
Uasin Gishu	Eldobase Chemists	Eldoret Town	Private	Pharmacy
Uasin Gishu	Eldohosp Pharmaceutical	Eldoret Town	Private	Wholesale
Uasin Gishu	Eldoret Rapha Clinic	Edoret Town	Private	Clinic
Uasin Gishu	Elgon View	Eldoret Town	Private	Hospital
Uasin Gishu	Elirs Chemist	Eldoret Town	Private	Pharmacy
Uasin Gishu	Glory Chemists	Eldoret Town	Private	Pharmacy
Uasin Gishu	Huruma District	Eldoret Town	Public	Hospital
Uasin Gishu	Kimumu Health Centre	Eldoret Town	Public	Health Centre
Uasin Gishu	Kuinet Dispensary	Eldoret Town	Public	Dispensary
Uasin Gishu	Laborex Kenya Ltd	Edoret Town	Private	Wholesale
Uasin Gishu	Mediheal Hospital and Fertility Centre	Eldoret Town	Private	Hospital
Uasin Gishu	Moi Teaching & Referral	Eldoret Town	Public	Hospital
Uasin Gishu	Moschem Pharmacy Ltd	Eldoret Town	Private	Pharmacy

Uasin Gishu	Reale Hospital	Eldoret Town	Private	Hospital
Uasin Gishu	Shades Pharmaceuticals	Eldoret Town	Private	Pharmacy
Uasin Gishu	Shayona Chemist Limited	Eldoret Town	Private	Pharmacy
Uasin Gishu	Sinapharm Sinai Chemist	Eldoret Town	Private	Pharmacy
Uasin Gishu	St Lukes Orthopedic And Trauma Hospital	Edoret Town	Private	Hospital
Uasin Gishu	Tayisha Pharmacy	Eldoret Town	Private	Pharmacy
Uasin Gishu	Transwide Pharmaceutials	Eldoret Town	Private	Wholesale
Uasin Gishu	Uasin Gishu District Hospital	Eldoret Town	Public	Pharmacy
Uasin Gishu	Victory Medical Clinic And Diagnostic Centre	Eldoret Town	Private	Clinic
Uasin Gishu	Westhealth	Eldoret Town	Private	Hospital

7.6. List of Data/ Sample Collection Team

Team #	Team Members	Counties Visited
1	1. Dr. Sarah Chesaro 2. Edwin Osano 3. Nehemia Birgen 4. Lilly Kipkeno	Nairobi Machakos Kiambu
2	1. Gedion Too 2. Lucy Mugambi 3. Evans Kiprono 4. Gladwel Cheruiyot	Baringo Uasin Gishu Trans Nzoia Elgeyo Marakwet
3	1. Patrick Kibet 2. Henry Chweya 3. Molly Okoth 4. Beatrice Obinge	Siaya Kisumu
4	1. Enow Haji 2. Athman Hemed 3. Patrick Kipyego 4. Emily Siminyu 5. Lawrence Nzumbu	Taita Taveta Mombasa Kilifi
5	1. Mercy K. Siyoi 2. George Sankale 3. Nehemiah Birgen 4. Dr Mikal Ayiro	Kajiado
6	1. Beatrice Obinge 2. Stephen Ochieng 3. Evans Kiprono 4. Peter Kiptoo	Migori Homabay
7	1. Dr Donald Ratemo 2. Dr Samuel Kerama 3. Phillip Mutinda 4. Abdinasir Sheikh	Kisii, Nyamira
8	1. Dr Tiberius Adeya 2. Milton Anono 3. George Muthuri 4. Nancy Nyambega	Busia
9	1. Dr Agnes Ayoti 2. Valentine Mokaya 3. Gladwell Cherogony 4. Allan Wambua	Kericho
10	1. Yusuf Dimba 2. Dr Kelvin Nduhiu 3. Patrick Gachukia 4. James King'ori	Kwale
11	1. Dr. Karim Wanga 2. Mary Kendi 3. Washington Oyoo 4. Patrick Kibiego	Kakamega Vihiga
12.	1. Andrew Nyandigisi 2. Edward Abwao 3. Latifa El Hadry	Central Supervisory, M& E

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