PPB/MIP/PMS/RPT/03/16-17

MINISTRY OF HEALTH

Pharmacy and Poisons Board and National Malaria Control Program

Monitoring the Quality of Antimalarial Medicines Circulating in Kenya: Round 6

August 2017

Pharmacy & Poisons Board, Kenya	**Monitoring the Quality of Antimalarial Medicines Circulating in Kenya: Round 6**			Revision No. 0
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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. Availability of good quality medicines is essential in ensuring prompt and effective treatment of malaria according to the current national malaria strategy.

Under this round, 11 sites participated in the minilab testing of antimalarial medicines. Each of the eleven sites screened 80 samples of antimalarials bought or picked from both private and public health facilities and chemists in their surrounding sites.

The eleven sites were selected based on whether they were located in malaria endemic/epidemic or ports of entry of medicines into Kenya.

Due to the increased number of sentinel site, sample collection and field-testing of the medicines took place between 22nd August and 2nd September 2016. The eleven sites were divided into two with the first five teams carrying out the activity between 22nd to 27th August 2016 and the second group of six teams carrying out the activity between 29th August 2016 and 3rd September 2016

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 sixth round and compares the results obtained with first, second, third, fourth and fifth 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 most collected samples at the sentinel sites. This was followed by confirmatory testing of 10 percent of the samples that passed minilab analysis, all doubtful samples and all failed samples at the Missions for Essential Drugs and Supplies (MEDS) laboratory.

The results indicate that the presence of unregistered and substandard anti-malarials in the market has reduced over time. For the samples that underwent compendial testing 96.4% passed analysis while 99.3% of the samples were found to be registered with the Pharmacy and Poisons Board.

This shows that the antimalarial medicines in Kenya are generally 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
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).

Round six of the Monitoring Quality of Medicines (MQM) was a continuation of the previous five rounds that have been taking place in Kenya in order to monitor the quality of antimalarial medicines used in the country. The medicines are screened at 11 sentinel sites by use of minilab technology.

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 Kenya, malaria remains a major cause of morbidity and mortality with more than 70 per cent of the population at risk of the disease (MOH 2014).

The Ministry of Health, through the National Malaria Control Programme (NMCP), has implemented sound policies and evidence-based strategies in the fight against malaria. Key interventions include the provision of long-lasting insecticidal nets, intermittent preventive treatment for pregnant women, and prompt diagnosis and effective treatment of all malaria cases. Interventions also include improving the capacity of health providers and strengthening the supply chain to deliver diagnostic tests and quality-assured medicines at all levels of the health system.

In the last 5 years, there has been overall reduction in malaria prevalence in Kenya as compared with the 2010. 8 per cent of children ages 6 months to 14 years have malaria compared with 11 per cent in the 2010 KMIS (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) lives 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 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 Six 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.

Kisumu County is located in the former Nyanza Province and its headquarters is Kisumu City, which is, situated approximately 370km west of the Kenyan Capital, Nairobi. According to 2009 census, Kisumu County had a population of 968,879 people and covers an area landmass of 2085.9km^2 and 567km^2 covered by water. Kenya National Bureau of Statistics website indicates that 60% of the population in Kisumu County is living in extreme poverty against a national of 46%.

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 should approve of 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.
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

Figure 1 Kenyan map showing the different 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 that 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.

- Round five of the monitoring quality of medicines for antimalarials carried out in 2015 showed a 90.24% pass rate for compedial testing. 99.6% of the samples collected (884) were also found to be registered with PPB.

1.3. Aims and Objectives

The primary objective of 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:

- To identify unregistered products in the selected sites
- To determine the quality of medicines in the selected sites
- To develop a medicine's quality database, for trend analysis of circulating medicines
- Provide evidence-based data for enforcement actions
- Propose strategies and implementation plans to address problems identified in the study

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 (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. Each site was to collect samples as per the table below;

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**

Table 1 The sites sampling strategy

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. For the purpose of the malaria control program, samples were collected from the eleven sentinel sites defined in the sample site selection section. 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. The training was facilitated by PQM with support from the Malaria Control Unit (MCU), PPB and NQCL. The refresher training was carried out at both Pharmacy and Poisons Board and at National Quality Control Laboratory between the dates **25th - 29th January 2016.**

There were a total of 30 participants for the refresher training distributed as follows;

- 9 from NQCL
- 8 from the counties
- 1 from MEDS
- 12 from PPB

of the above, 12 members had participated in the previous rounds while 18 were new members mostly from NQCL and counties. (Participants list is attached)

During this round of refresher training, counties that have minilabs were encouraged to sponsor participants so as to increase the number of persons trained on the use of minilabs. Because of this we received 4 participants sponsored by the counties. These were members from Uasin Gishu (Eldoret), Migori, Kajiado and Kakamega. These were in addition to the persons who were sponsored by USP to attend the training.

The training took participants through the protocol and what was expected of them, including the sample collection technique and the types and quantities of samples to be collected. This was followed by presentation on the results of the previous four rounds and the trends observed. Each of the team leaders from the 11 sites presented on how the last round was in their regions. They presented on the challenges experienced and their recommendations on how to improve the forthcoming round.

2.2. Site Selection

Sites for sample collection were identified in collaboration with PPB, 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).

Table 2: Field Sampling Strategy for Tablets

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*"

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 60 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 two levels (Figure 1). Level 1 is the sentinel site using Minilab tests (Physical inspection, disintegration and Thin Layer Chromatography (TLC)), Level 2 is 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)

These tests were 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 were graded as follows

i. Pass: Conforms to the above 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]

[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

- 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.

2.9.2. Level 2: Verification of Basic Tests at NQCL

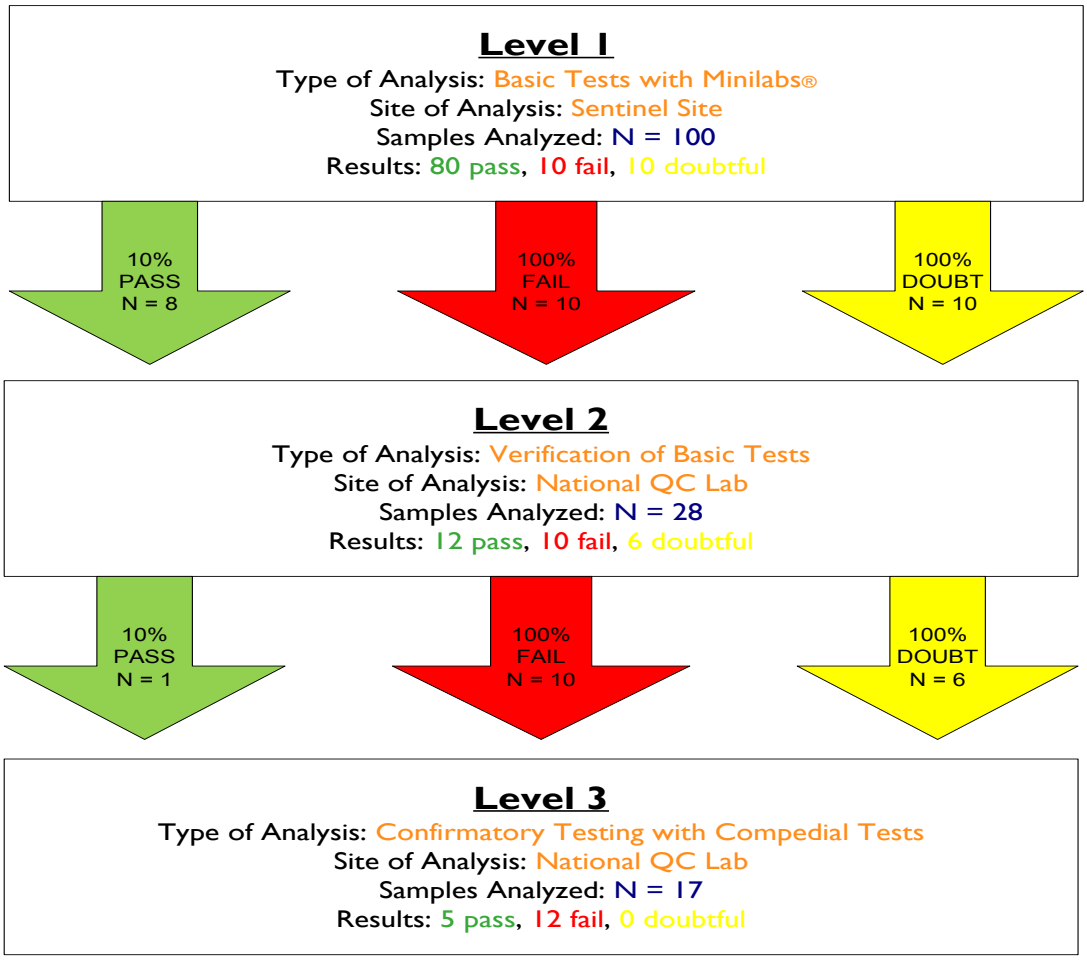
NQCL performed verification testing by repeating basic tests on the subset of samples (as described above). Results of each sample were recorded clearly on the Basic Tests Analysis Form for National Quality Control Laboratory Staff (Annex 4).

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 2: 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

Each of the 11 teams who participated in the activity was to collect and analyze 60 samples. A total of 673 samples were collected across the 11 sites. The sampling was done in three sectors namely the private, public and informal sectors. The samples collected were as indicated in table three below.

Sector	No. of samples
Private	477
Public	178
Informal	18
Total	**673**

Table 3 Sampling by Sector

3.1.2. Sampling by API

Of the 673 samples collected during the round six activity, AL was the most sampled antimalarial followed by SPs, which is consistent with their availability.

API	No. of samples
Artemether/ Lumefantrine	487
Artesunate/ Amodiaquine	3
Dihydroartemisinin Piperaquine	57
Quinine Dihydrochloride	25
Quinine Sulphate	5
Sulfadoxine/ Pyrimethamine	63
Other	33
Total	**673**

Table 4 Distribution of samples by Active Pharmaceuticals Ingredients (API)

3.1.3. Sampling by Region

In the round six activity, samples were collected from five regions as indicted below. The largest number of samples was collected in Nyanza followed by Rift Valley, Western, Coast and Nairobi regions in that order.

Region	No. of samples
Coast	119
Nairobi	61
Nyanza	186
Rift Valley	181
Western	126
Total	**673**

Table 5 Distribution of samples by region

3.1.4. Summary of Sampling

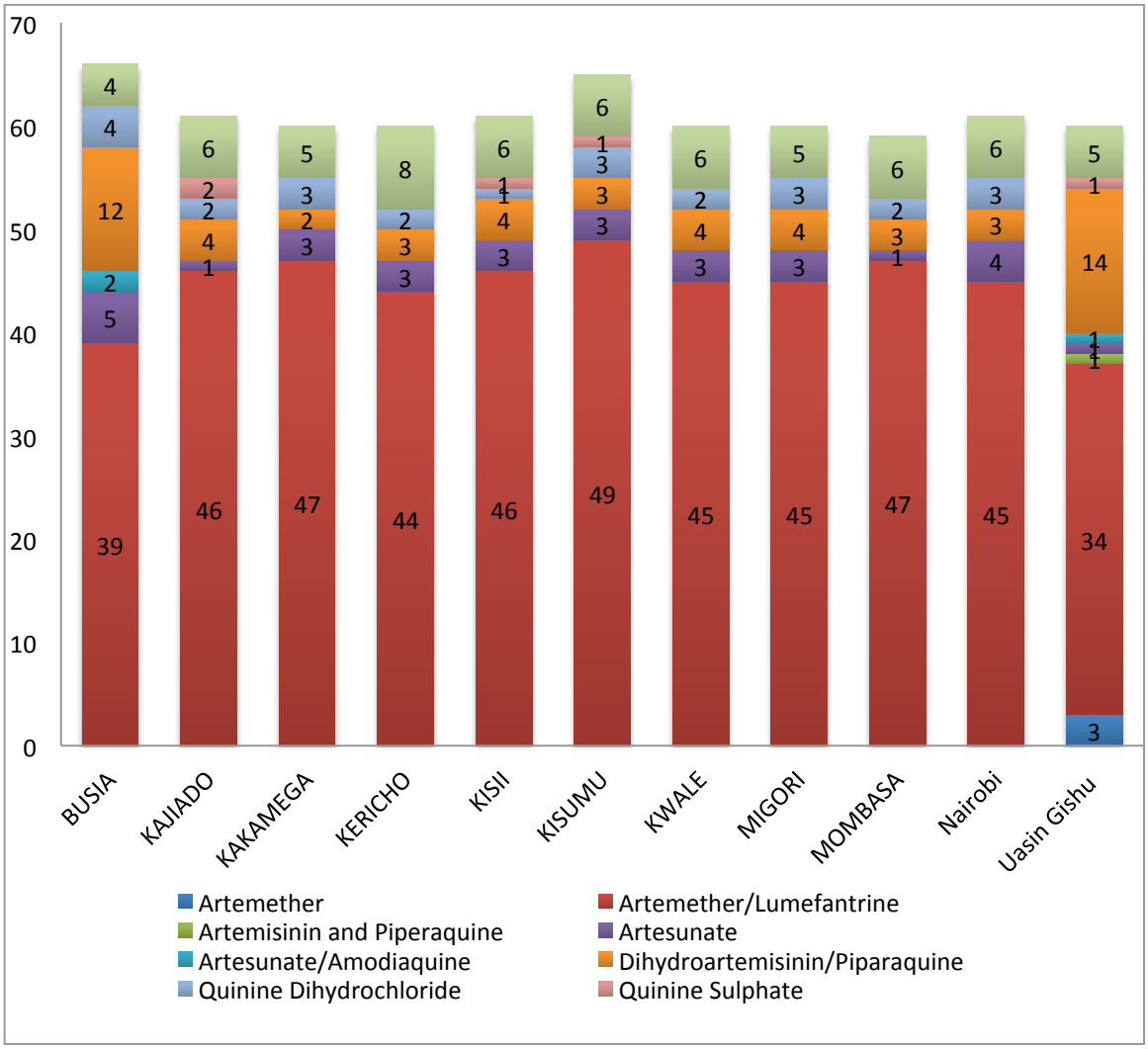


Figure 6 Distribution of sampled medicines by sites

Round	Total # of Samples Collected	# of samples analyzed in the field using Minilab (Level 1)	# of Samples analyzed at NQCL using Minilab (Level 2)	# of samples analyzed at using compendia methods (Level 3)
No. of samples	673	671	None	83

Table 5 Summary of sampling and analysis of the six rounds

3.2. Registration with the Pharmacy and Poisons Board

Figure 2 shows the registration status of the samples over the six rounds of post marketing surveillance. The percentage of unregistered samples has consistently decreased over time. During the round six activity, 100% of the samples collected were duly registered with PPB.

3.3. Basic and Compendial Test Results

3.3.1. Level 1 Screening Test Results

Of the 673 samples screen at the sites, the proportion of samples in round six that passed level one screening was 94.5% with 5.2% being doubtful while 0.3% failed the screening test.

3.3.2. Level 3 Compedial Test Results

83 samples were subjected to compendial testing of which 80 (96.39%)samples passed all the tests. 3.61% of the submitted samples failed the compedial test.

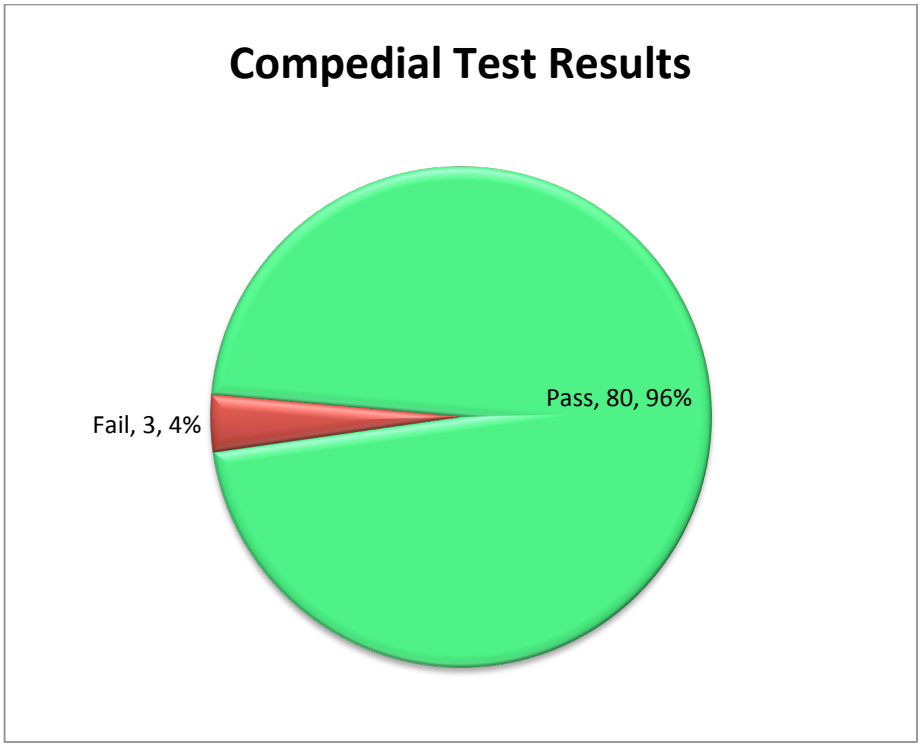


Figure 3 Compedial test results

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 six rounds of sampling (i.e. from 2011 – 2016).

Sector	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
Private	312	373	301	415	675	**477**
Public	169	118	229	157	194	**178**
Informal	55	8	15	33	21	**18**
Total	**536**	**499**	**545**	**605**	**890**	**673**

Table 6 Sampling by Sector

4.1.2. Sampling by API

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

API	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
Artemether/ Lumefantrine	290	258	288	349	457	**487**
Sulfadoxine/ Pyrimethamine	101	105	106	133	112	**63**
Quinine Sulphate	83	85	77	77	10	**5**
Artesunate/ Amodiaquine	14	40	21	42	46	**3**
Quinine Dihydrochloride	-	-	3	4	98	**25**
Sulfamethopyrazine/Pyrimethamine	-	11	-	-	-	
Dihydroartemisinin Piperaquine	19	-	49	-	126	**57**
Other	29	-	1	-		**33**
Total	**536**	**499**	**545**	**605**	**890**	**673**

Table 7 Distribution of samples by Active Pharmaceutical Ingredient (API)

4.1.3. Sampling by Region

In the round six activity, the largest number of samples was collected in Nyanza followed by Rift Valley, Western, Coast and Nairobi regions in that order.

Region	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
Coast	107	99	115	100	158	**119**
Rift Valley	128	100	105	102	241	**181**
Nairobi	100	100	108	101	80	**61**
Nyanza	101	100	100	101	246	**186**
Western	100	100	117	101	165	**126**
Garissa	-	-	-	49	-	
Turkana	-	-	-	52	-	
Total	**536**	**499**	**545**	**606**	**890**	**673**

Table 8 Distribution of samples by region

4.1.4. Summary of Sampling

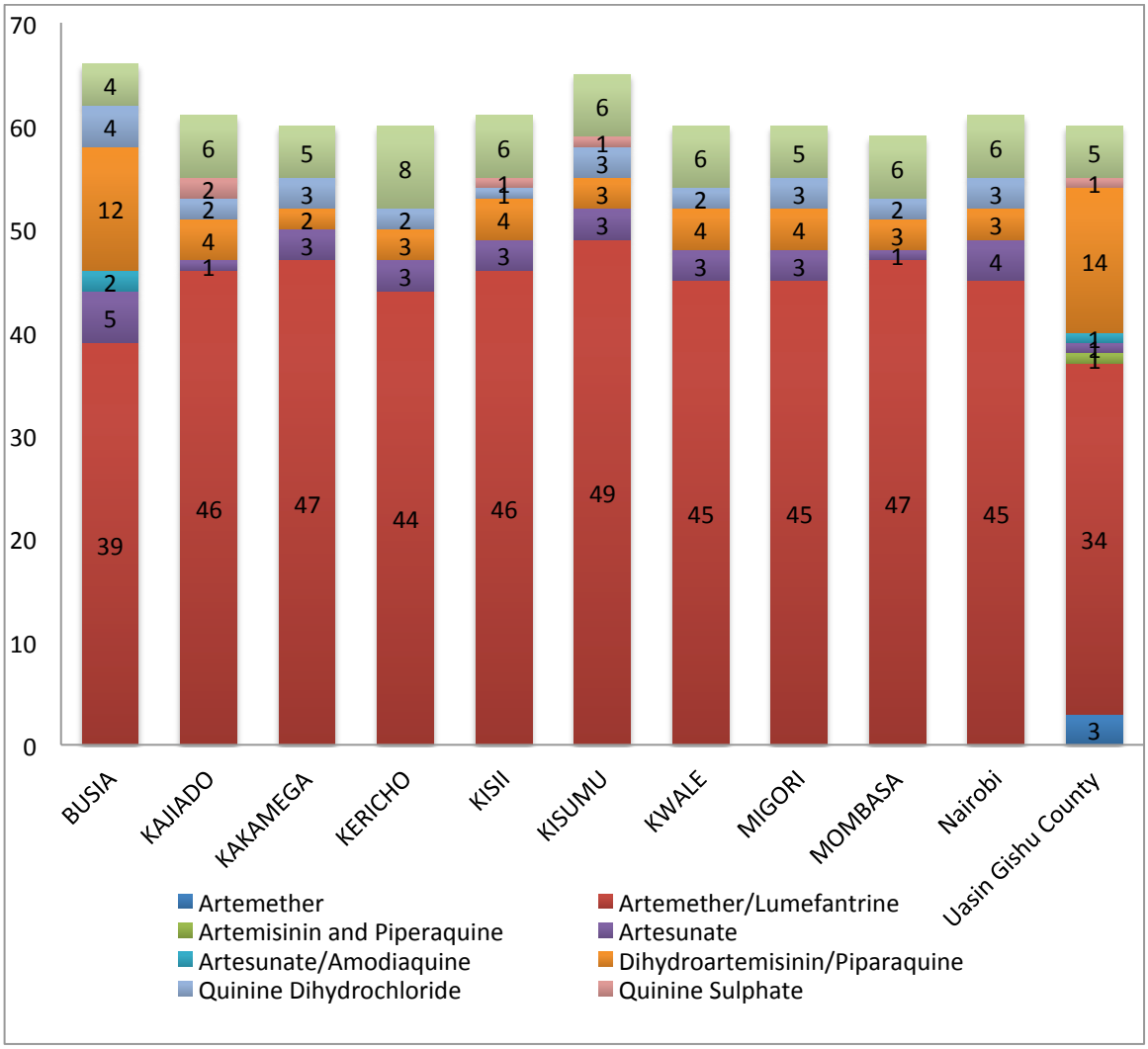


Figure 4 Distribution of sampled medicines by sites

Round	Total # of Samples Collected	# of samples analyzed in the field using Minilab (Level 1)	# of Samples analyzed at NQCL using Minilab (Level 2)	# of samples analyzed at 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	156	52
Round 6	**673**	**671**		**83**

Table 9 Summary of sampling and analysis of the six rounds

4.2. Registration with the Pharmacy and Poisons Board

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

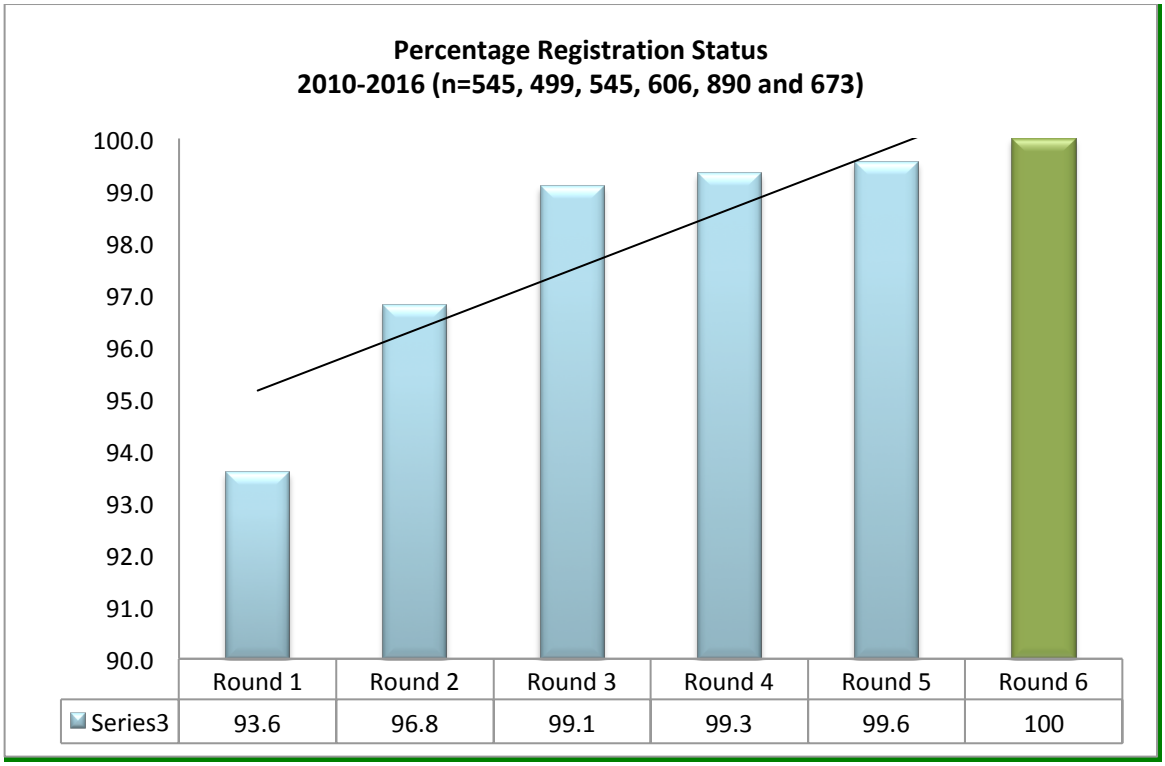


Figure 5 Registration status of collected samples

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 six that passed level one screening was 94.5%. 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. 5.2% of the screened samples were doubtful while 0.3% failed the screening tests. The highest-level 1 screening failure was during round one where 5% of the samples failed. 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.

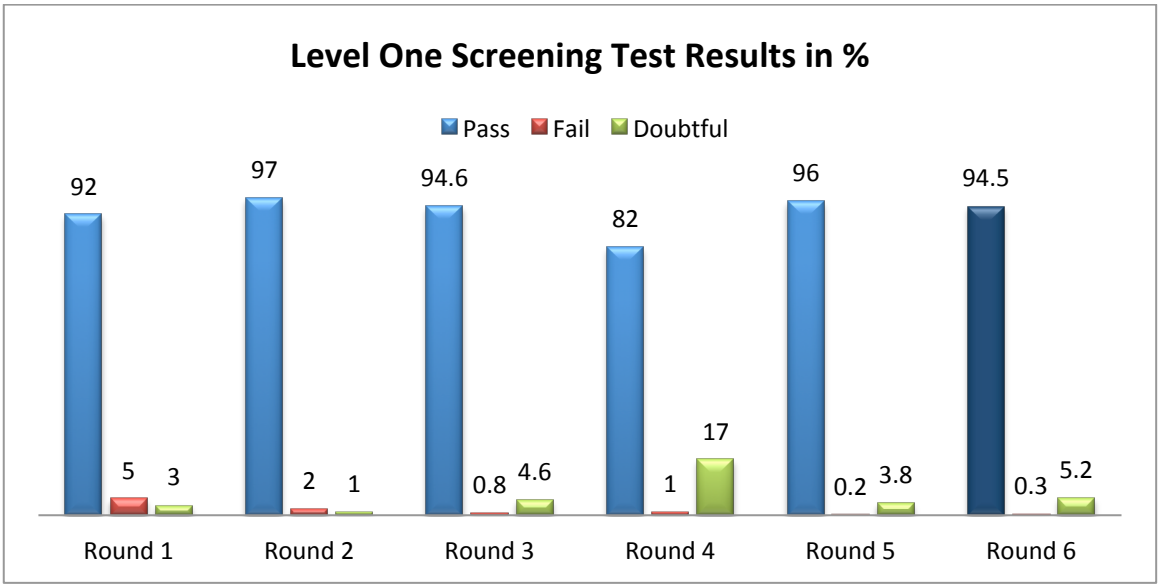


Figure 6 Results of level 1 testing

4.3.2. Level 2 Screening Test Results

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

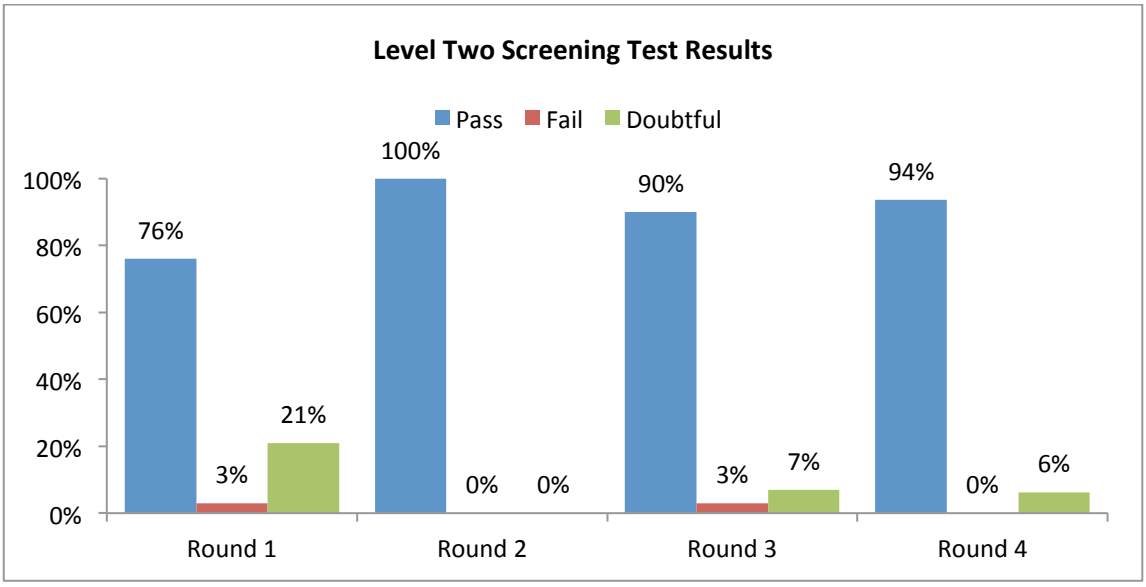


Figure 7 Level 2 testing results

4.3.3. Level 3 Compedial Test Results

83 samples were subjected to compendial testing of which 80 (96.39%)samples passed all the tests. There was an improvement from round five results whereby the results from round six shows a pass rate of 96.39% as compared to round five that had a pass rate of 90.24%.

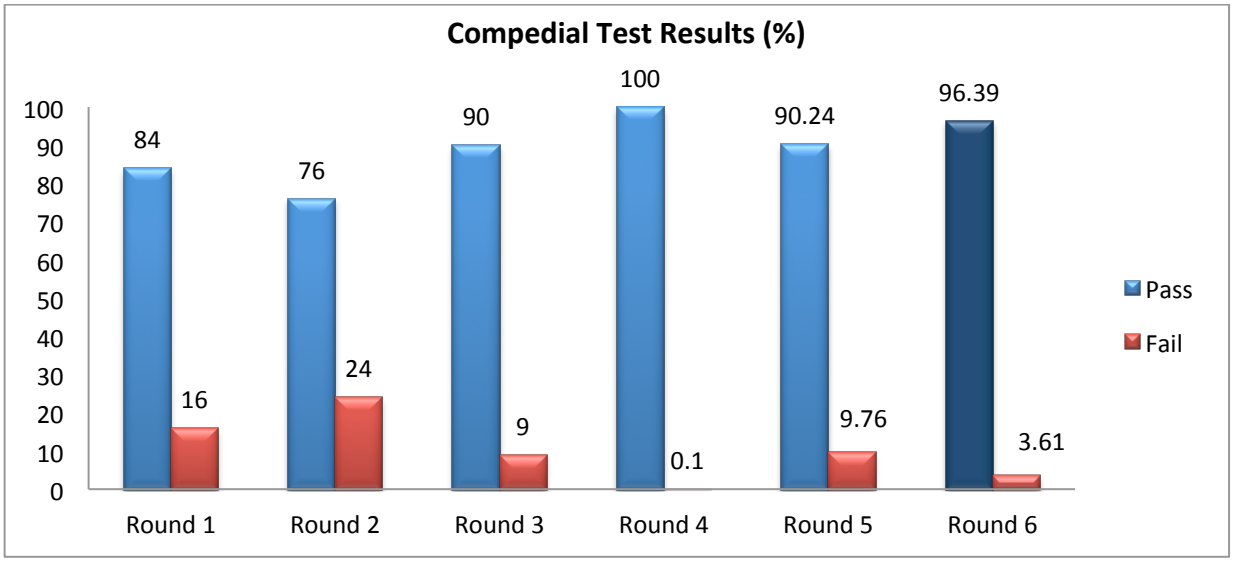


Figure 8 Compedial testing results

4.4. Determinants of Conformity

4.4.1. Sector of Health

Public sector and private/ informal sector samples had almost equal chances of passing the level I screening test. Two samples were not tested at the sites due to lack of

Table 10: Sector and Conformity

Sector	Level 1 Test Results		Total
	Pass	Fail/ Doubtful	
Public	171 (96.1%)	7	**178**
Private/ Informal	464(94.1%)	29	**493**
	635(94.6%)	**36**	**671**

Table 11 Sector and conformity

4.5. Sensitivity and Specificity of the Minilab Tests

Sensitivity of a test refers to the percentage of samples that passed one level of testing and then went on to pass the next level of testing i.e. the proportion of samples that were correctly identified as conforming (true positives).

Specificity of a test refers to the percentage of samples that failed one level of testing and then went on to fail the next level of testing too i.e. the proportion of samples that were correctly identified as non-conforming (true negatives).

4.6. Registration Status

The Pharmacy and Poisons Board had registered all the samples that were collected. This was the first time since the inceptions of the MQM activity that all 673 collected samples were found to be registered.

4.7. Screening and Compedial Test Results

94.5% of the 671 samples screened in level one passed the test while 5.2% were doubtful and 0.3% failed the screening test. The proportions were not statistically different when compared to the round five results of 96%, 3.8% and 0.2% respectively. The leading cause of doubtful results was the presence of extra peaks. 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 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.

A high proportion of anti-malarials, both in the public sector (96.1%) and private sectors (94.1%), passed the level 1 screening test. The overall findings demonstrate the continued availability of good quality antimalarial medicines in the market

The following three products failed compedial testing.

No.	Product Name	Active Pharmaceutical Ingredient	Formulation	Manufacturer	Test Failed
1.	Methomine-S B/No. 421214	Sulfadoxine 500mg/ Pyrimethamine 25mg	Tablets	Universal Corp. Ltd	Dissolution
2.	P- Alaxin B/No. F1AFN005	Dihydroartemisinin 40mg/Piperaquine Phosphate 320mg	Tablets	Bliss DVS pharma Ltd	Assay
3.	Methomine-S B/No. 421214	Sulfadoxine 500mg/ Pyrimethamine 25mg	Tablets	Universal Corp. Ltd	Dissolution

Table 12 Summary of failed samples

4.8. Regulatory Actions Undertaken by PPB

The above three products were all quarantined, recalled from the market and the manufacturers asked to present an investigational report on them.

5. Conclusion and Recommendations

5.1. Conclusion

The proportion of poor quality anti-malarials continues to decline with the increased surveillance and improved regulation. Almost all the antimalarials in the market are registered and meet quality standards. Of particular importance is that all the ACTs, including those locally manufactured, 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

- 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
- Quality assurance mechanisms should be put in place for minilab testing to ensure that only reliable results are reported
- 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
- Dissemination of the report in various forums as best practice/model for other disease areas in the health system so that they can learn from it e.g. in TWG's/national committees, COG, Kenya Health care federation, NGO and FBO forums if funds available.
- All the 47 counties of Kenya should be involved in carrying out the exercise so that we can assure the citizens of the quality of the medicines
- Minilabs should be established in every border point and county so as to enhance Pharmaceutical Surveillances activities.
- Frequent trainings on new technologies should be conducted when and if they occur so as to keep touch with the dynamic world of Pharmaceuticals.
- More staff need to be trained at the county level to be able to carry out the testing.
- This exercise should be carried out more frequently so that more samples can be obtained and a wider range of drugs can be covered in each phase
- More financial and human resources should be added for the minilab work to ensure sustainability and ownership of PMS activities at both the national and county level.

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.

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	
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		

[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.

[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 = $\frac{|0.55\text{-}0.57|}{0.55} \times 100 = \frac{0.02}{0.55} \times 100 = 3.6\%$

○ 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: _____

[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	Sector	Type
Busia	Bungoma Chemist, Malaba Branch	Private	Pharmacy
Busia	Busia County Health Commodity Store	Public	County Store
Busia	Busia County Referral	Public	Hospital
Busia	Healthside Medical Pharmacy	Private	Pharmacy
Busia	Khunyangu Sub-County Hospital	Public	Hospital
Busia	Mama Rehema Shop	Informal	Kiosk
Busia	Mareba Chemist	Private	Pharmacy
Busia	Matayos Health Centre	Public	Hospital
Busia	Next To Homeboyz Kinyozi, Lukolis	Informal	Kiosk
Busia	Scorpion Pharmacy	Private	Pharmacy
Busia	Tanaka Nursing Home	Private	Hospital
Kajiado	Alpha Medical Clinic	Private	Clinic
Kajiado	The Nairobi Womens Hospital	Private	Hospital
Kajiado	Penda Clinic	Private	Clinic
Kajiado	Orkongo Pharmacy	Informal	Pharmacy
Kajiado	Ngong Sub-County Hospital	Public	Hospital
Kajiado	New Steta Pharmacy	Private	Pharmacy
Kajiado	Namanga Healthcentre	Public	Health Centre
Kajiado	Nalepo Pharmacy	Private	Pharmacy
Kajiado	Lexa Medical Centre	Private	Hospital
Kajiado	Kitengela Medical Services	Private	Hospital
Kajiado	Kisaju Pharmaceuticals	Informal	Pharmacy
Kajiado	Kajiado Pharmaceuticals	Private	Wholesaler
Kajiado	Kajiado County Referral Hospital	Public	County Store
Kajiado	Jojo Pharmaceuticals Ltd	Private	Pharmacy
Kajiado	Jamii Medical Clinic	Private	Clinic
Kajiado	Gosfa Chemist	Private	Pharmacy
Kajiado	Esupen Pharmaceuticals	Private	Pharmacy
Kajiado	Embulbul Catholic Dispensary	Public	Dispensary
Kajiado	Edmerc Pharmacy	Private	Wholesaler
Kajiado	Cloriti/Latesi Pharmaceuticals Ltd	Private	Wholesaler
Kajiado	Amboseli Pharmacy	Private	Pharmacy
Kajiado	AIC Church Hospital	Public	Faith Based Organization
Kakamega	Chebwai Sda Dispensary	Public	Faith Based Organization
Kakamega	County Chemist	Private	Pharmacy
Kakamega	Emukhaya Sub County Hospital	Public	Hospital
Kakamega	Emusanda Health Centre	Public	Health Centre
Kakamega	Equator Medical Services	Private	Hospital
Kakamega	Grams Medical Clinic	Private	Clinic
Kakamega	Kakamega County Hospital	Public	Hospital
Kakamega	Khayega Clinic	Private	Clinic
Kakamega	Reeya Pharmaceuticals	Private	Wholesaler
Kakamega	Rithi Pharmaceuticals	Private	Wholesaler
Kakamega	Sparkles Pharmaceuticals	Private	Wholesaler
Kakamega	St. Elizabeth Mukumu	Public	Faith Based Organization

Kakamega	Tesina Pharmacy	Private	Pharmacy
Kakamega	Turi Pharmacy	Private	Pharmacy
Kericho	Adakim Chemist Ltd	Private	Pharmacy
Kericho	Aic Litein Mission Hospital	Private	Faith Based Organization
Kericho	Belgut Chemist	Private	Pharmacy
Kericho	Delach Chemist	Private	Pharmacy
Kericho	Dopemarks Chemist	Private	Pharmacy
Kericho	Elementaita Pharmaceuticals Ltd	Private	Pharmacy
Kericho	Favours Chemist	Private	Pharmacy
Kericho	Kapkatet Sub County Hospital	Public	Hospital
Kericho	Kericho Central Pharmaceuticals	Private	Pharmacy
Kericho	Kericho County Hospital	Public	Hospital
Kericho	Kericho Nursing Home	Private	Hospital
Kericho	Litein Mission Hospital	Private	Hospital
Kericho	Medifare Chemist	Private	Pharmacy
Kericho	Misfam Chemist	Private	Pharmacy
Kericho	Nile Pharmacy	Private	Pharmacy
Kericho	Siloam Hospital	Private	Hospital
Kericho	Skylex Chemist	Private	Pharmacy
Kericho	Skylex Chemist	Private	Pharmacy
Kericho	Skylex Chemist Ltd	Private	Pharmacy
Kericho	Skylex Chemist Ltd	Private	Pharmacy
Kericho	Sosiot Medical Centre	Private	Health Centre
Kericho	Tealands Chemist	Private	Pharmacy
Kericho	Tembur Pharmacy Ltd	Private	Pharmacy
Kericho	Zawadi Chemist	Private	Pharmacy
Kisii	Gesusu Subcounty Hospital	Public	Hospital
Kisii	Bright Horizons Pharmacare Ltd	Private	Pharmacy
Kisii	Choice Pharmaceuticals	Private	Pharmacy
Kisii	Demo Clinic	Private	Clinic
Kisii	Ichuni Chemist	Private	Pharmacy
Kisii	Inka Medical Centre	Private	Clinic
Kisii	Jacks Pharmacy	Private	Pharmacy
Kisii	Jamii Medical Clinic	Private	Clinic
Kisii	Josepharm Chemist	Private	Pharmacy
Kisii	Keroka District Hospital	Public	Hospital
Kisii	Kisii Teaching And Referral Hospital	Public	Hospital
Kisii	Manga Chemist	Private	Pharmacy
Kisii	Mogwa Chemist	Private	Pharmacy
Kisii	Nyabisio Chemist	Private	Pharmacy
Kisii	Nyakoe Pharmcaeutical	Private	Pharmacy
Kisii	Nyamira Chemist	Private	Pharmacy
Kisii	Nyamira County Hospital	Public	Hospital
Kisii	Nyamira Nursing Home	Private	Hospital
Kisii	Oasis Hospital	Private	Hospital
Kisii	Omogwa Chemist	Private	Pharmacy
Kisii	Oryx Chemist	Private	Pharmacy
Kisii	Prelion Chemist	Private	Pharmacy

Kisii	Rangopharm Ltd	Private	Pharmacy
Kisii	Roks Chemist	Private	Pharmacy
Kisii	Roselyn Chemist	Private	Pharmacy
Kisii	Sanya Chemist	Private	Pharmacy
Kisii	Sapac Healthcare Ltd	Private	Pharmacy
Kisii	Tembo Pharmaceuticals	Private	Pharmacy
Kisii	Transwide Ltd	Private	Pharmacy
Kisii	Zen Pharmaceuticals Ltd	Private	Pharmacy
Kisumu	A To Z Pharmacy Limited	Private	Wholesaler
Kisumu	Avenue Healthcare Kisumu	Private	Hospital
Kisumu	Chiral Chemist	Private	Pharmacy
Kisumu	Elians Limited	Private	Pharmacy
Kisumu	Elites Chemist	Private	Pharmacy
Kisumu	In 2 Health Medical Supplies	Private	Pharmacy
Kisumu	Jalaram Nursing And Maternity Home	Private	Hospital
Kisumu	Jann's Chemist/Book Shop	Informal	Pharmacy
Kisumu	Jaramogi Oginga Teaching Hospital	Public	Hospital
Kisumu	Kentons Limited	Private	Wholesaler
Kisumu	Kombewa County Hospital	Public	Hospital
Kisumu	Lakepharm Limited	Private	Wholesaler
Kisumu	Leo Chemists Limited	Private	Wholesaler
Kisumu	Lifecheck Pharmacy	Private	Pharmacy
Kisumu	Mogwa Clinic	Private	Clinic
Kisumu	Monique Cosmetics	Informal	Pharmacy
Kisumu	Nyamasaria Pharmacy	Private	Pharmacy
Kisumu	Port Florence Community Hospital	Private	Hospital
Kisumu	Rabuor Sub-County Hospital	Public	Health Centre
Kisumu	Ramogi Chemists Limited	Private	Wholesaler
Kisumu	St. Joseph Hospital Nyabondo	Private	Faith Based Organization
Kisumu	Tayyibah Medical Clinic	Private	Clinic
Kisumu	Wema Healthcare Laboratory	Private	Clinic
Kwale	Care And Cure Pharmacy	Private	Pharmacy
Kwale	Chogoria Pharmacy	Private	Pharmacy
Kwale	Diani Beach Hospital	Private	Hospital
Kwale	Diani Health Centre	Public	Health Centre
Kwale	K Chande Late Night Chemist	Private	Pharmacy
Kwale	Kinango Pharmacy	Private	Pharmacy
Kwale	Kinango Subcounty Hospital	Public	Hospital
Kwale	Kinondo Kwetu Health Services	Private	Hospital
Kwale	Konna Pharmacy	Private	Hospital
Kwale	Lunga Lunga Chemist	Private	Pharmacy
Kwale	Lunga Lunga Health Center	Public	Hospital
Kwale	Msabweni County Refferal Hospital	Public	Hospital
Kwale	Natures Ayuvedic Remedies Pharmacy	Private	Pharmacy
Kwale	Ochieng Chemist	Private	Pharmacy
Kwale	Seaside Pharmacy	Private	Pharmacy
Kwale	Southcoast Pharmaceuticals	Private	Pharmacy
Kwale	Ukunda Catholic Dispensary	Public	Health Centre

Migori	Awendo Stage Pharmacy	Private	Pharmacy
Migori	Dancuns Chemist	Private	Pharmacy
Migori	Flehova Chemist	Private	Pharmacy
Migori	Kandaria Chemist	Private	Pharmacy
Migori	Kehancha Ntunyigi Clinic	Private	Clinic
Migori	Kisao Pharmaceuticals	Private	Wholesaler
Migori	Macalder Mission Disp.	Public	Faith Based Organization
Migori	Midila Chemist	Informal	Pharmacy
Migori	Migori County Store	Public	Warehouse
Migori	Monicare Chemist	Private	Pharmacy
Migori	Mugabo Dispensary	Public	Health Centre
Migori	Ntimaru Medical Clinic	Private	Clinic
Migori	Nyaranga Chemist	Private	Pharmacy
Migori	Ombo Mission Hospital	Public	Faith Based Organization
Migori	Opapo Chemist	Private	Pharmacy
Migori	Rongo Sub County Hosp	Public	Hospital
Migori	Royal Medical Clinic	Private	Clinic
Migori	Sori Lakeside Hospital	Private	Hospital
Migori	Unnamed Chemist	Informal	Pharmacy
Migori	Unnamed Chemist	Informal	Pharmacy
Mombasa	Al-Habib Pharmacy	Private	Pharmacy
Mombasa	Badar Chemist	Private	Pharmacy
Mombasa	Citadel Pharmaceuticals	Private	Wholesaler
Mombasa	Coast General Hospital	Public	Hospital
Mombasa	Edward St. Rose	Private	Pharmacy
Mombasa	Ideal County Chemist	Private	Pharmacy
Mombasa	Jocham Hospital	Private	Hospital
Mombasa	Kisauni Pharmacy	Private	Pharmacy
Mombasa	Late Coast Phatmacy	Private	Pharmacy
Mombasa	Makadara Chemist	Private	Wholesaler
Mombasa	Makupa Chemist	Private	Pharmacy
Mombasa	Medlife Pharmacy	Private	Pharmacy
Mombasa	Mikindani Medical Centre	Private	Clinic
Mombasa	Mlaleo Cdf	Public	Clinic
Mombasa	Montreal Pharmacy	Private	Pharmacy
Mombasa	Njimia Pharmaceuticals	Private	Pharmacy
Mombasa	Nyali Healthcare	Private	Clinic
Mombasa	Perazim Pharmacy	Private	Pharmacy
Mombasa	Portreitz Subcounty Hospital	Public	Hospital
Mombasa	Sayyida Fatima	Public	Hospital
Mombasa	Serena Pharmacy	Private	Pharmacy
Mombasa	Terichem Pharmacy	Private	Pharmacy
Mombasa	Wessex Pharmaceuticals	Private	Wholesaler
Nairobi	Wima Medical Centre	Private	Clinic
Nairobi	Elimac Medicare Africa	Informal	Clinic
Nairobi	Goodlife Hurlingham Branch	Private	Pharmacy
Nairobi	Greencross Pharmaceuticals	Private	Hospital
Nairobi	Jambo Medical Stores Ltd & Clinic	Private	Pharmacy

Nairobi	Jomac Pharmaceuticals Ltd	Private	Pharmacy
Nairobi	KEMSA	Public	Warehouse
Nairobi	Kenyatta National Hospital	Public	Hospital
Nairobi	Kibera Slums	Private	Kiosk
Nairobi	Krishna Chemists Limited	Private	Wholesaler
Nairobi	Malibu Pharmacy Limited	Private	Pharmacy
Nairobi	Mbagathi District Hospital	Public	Hospital
Nairobi	Naftali & Sons Pharmaceuticals	Private	Pharmacy
Nairobi	Nairobi Hospital	Private	Hospital
Nairobi	Nivina Towers Westlands Road	Private	Wholesaler
Nairobi	Praise Pharmacy	Informal	Pharmacy
Nairobi	Pumwani Majengo Health Centre	Public	Hospital
Nairobi	Rangechem City Centre	Private	Pharmacy
Nairobi	Skylink Chemist	Private	Pharmacy
Nairobi	St. Mary's Mission Hospital	Public	Faith Based Organization
Nairobi	Tamaro Chemist	Private	Pharmacy
Nairobi	The Nairobi West Hospital Limited	Private	Hospital
Nairobi	Transchem Pharmaceuticals Limited,	Private	Wholesaler
Nairobi	VIPS Health Services Limited	Private	Hospital
Nairobi	Wakwa Pharmacy	Private	Pharmacy
Uasin Gishu	Pharmax Africa Limited	Private	Pharmacy
Uasin Gishu	Best Health Services	Private	Pharmacy
Uasin Gishu	Biodex Pharmacy	Private	Pharmacy
Uasin Gishu	Damza Clinic	Private	Pharmacy
Uasin Gishu	Eagles Pharmaceuticals Ltd	Private	Pharmacy
Uasin Gishu	Eldo Hospital Pharmaceuticals Ltd	Private	Hospital
Uasin Gishu	Eldobase Chemist Ltd	Private	Pharmacy
Uasin Gishu	Eldohighway Dispensing Chemist	Private	Pharmacy
Uasin Gishu	Eldokap Chemist	Private	Pharmacy
Uasin Gishu	Horeb Chemist	Private	Pharmacy
Uasin Gishu	Huruma County Hospital	Public	Hospital
Uasin Gishu	Jamii Medical Clinic	Private	Clinic
Uasin Gishu	Laborex Kenya Ltd	Private	Wholesaler
Uasin Gishu	Langas Resource Health Centre	Public	Health Centre
Uasin Gishu	Lifecare Pharmaceuticals	Private	Pharmacy
Uasin Gishu	Northpharm Chemist	Private	Pharmacy
Uasin Gishu	Northpharm Chemist	Private	Pharmacy
Uasin Gishu	Pharmax Africa Limited	Private	Wholesaler
Uasin Gishu	Pioneer Health Centre	Public	Health Centre
Uasin Gishu	Reale Hospital	Private	Pharmacy
Uasin Gishu	Shalom Pharm Chemist	Private	Pharmacy
Uasin Gishu	St Lukes Orthopaedic And Trauma	Private	Faith Based Organization
Uasin Gishu	Transwide Pharmaceutical Ltd	Private	Wholesaler
Uasin Gishu	Uasin Gishu District Hospital	Public	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
2	1. Gedion Too 2. Beatrice Rosanna 3. June Mibey 4. Gladwel Cheruiyot	Baringo Uasin Gishu Trans Nzoia Elgeyo Marakwet
3	1. Molly Okoth 2. Henry Chweya 3. Peter Kiptoo 4. Beatrice Obinge	Siaya Kisumu
4	1. Enow Haji 2. Athman Hemed 3. Nancy Nyambega 4. Emily Siminyu	Taita Taveta Mombasa Kilifi
5	1. Mercy K. Siyoi 2. George Sankale 3. Gladys Bogonko 4. Dr Mikal Ayiro	Kajiado
6	1. Valentine Mokaya 2. Stephen Ochieng 3. Ronald Wandera 4. Cosmas Rotich	Migori Homabay
7	1. Dr Donald Ratemo 2. Dr Samuel Kerama 3. Phillip Mutinda 4. Abdinasir Sheikh	Kisii, Nyamira
8	1. Milton Anono 3. Primrose Muthoni 4. George Muthuri 5. Kefa Bota	Busia
9	1. Dr Agnes Ayoti 2. Winnie Rotich 3. Phillip Mutinda 4. Richard Gachukia	Kericho
10	1. Yusuf Dimba 2. Dr Kelvin Nduhiu 3. Jane Matundura 4. James King'ori	Kwale
11	1. Patrick Kibet 2. Mary Kendi 3. Washington Oyoo 4. Patrick Kibiego	Kakamega Vihiga
12.	1. Yusuf Suraw 2. Edward Abwao 3. Latifa El Hadry	Central Supervisory, M& E

Figure 9 Kisii team with one of the minilabs

Figure 10 Kisumu team members carrying out physical examination of a sample

Figure 11 Dr. Latifa demonstrating how to label a TLC plate to Kisii team members

Figure 11 Participants being trained on use of minilabs

Figure 12 Participants getting hands on training on use of minilabs technology

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