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

September 2019

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PPB/MIP/PMS/RPT/03/19-20	**Monitoring the Quality of Antimalarial Medicines Circulating in Kenya: Round 6**	

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[1] NMCP = National Malaria Control Program

Executive Summary

Health products and technologies are essential components of healthcare service delivery. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal 3.b emphasizes the need to develop medicines to address persistent treatment gaps. Access to good quality health products and technologies increases public confidence in healthcare systems.

Malaria still accounts for 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.

Twelve (12) counties were selected for sample collection based on epidemiological data demonstrating prevalence of malaria, medicines availability and accessibility, medicines circulating freely originating from border towns, ports of entry, and availability of human resources.
Sample collection and field-testing of the medicines took place between 22nd July and 2nd August 2019. This was followed by the level 2 verification testing that took place at PPB laboratory while compedial testing was carried out at NQCL in August 2019.

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 seventh round and compares the results obtained with the previous six rounds of monitoring of the quality of anti-malarials that have been done over the last eight years.

Sixty antimalarial samples were targeted for counties clustered into two and forty samples for counties clustered into three to form a cluster site. The purposive sampling of anti-malarials included artemisinin-based

combination therapy (ACT) and Sulfadoxine-Pyrimethamine (SPs), artesunate injection , quinine tablets , dihydroartemesinin piperaquine (DHAP) 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 verification y testing of 10 percent of the samples that passed minilab analysis, all doubtful samples and all failed samples at the PPB 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 all of them (100%) passed analysis while 99.6% 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 sustained and continuous monitoring of the antimalarials has led to improved quality and registration status over time. The results also show the advantage of utilizing screening technologies like minilabs for rapid and cost-effective way 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

Health products and technologies are essential components of healthcare service delivery. Essential medicines policies are crucial to promoting health and achieving sustainable development. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal 3.b emphasizes the need to develop medicines to address persistent treatment gaps. Anti-malarial medicines are included in the primary benefits package of UHC. Access to good quality health products and technologies increases public confidence in healthcare systems.

A collaboration of the National Medicines Regulatory Authorities (NMRA) with National Quality Control Laboratories and public health programs which include the National Malaria Control Program (NMCP), National AIDS and STI Control Program (NASCOP), and National TB and Leprosy Program (NLTP), Neglected Tropical Diseases Program (NTDP) and the National Vaccines and Immunization program (NVIP) represents a promising strategy towards the Sustainable Development Goal of ensuring access to quality, safe and efficacious health products and technologies.

The Pharmacy and Poisons Board (PPB) is the National Medicine Regulatory Authority established in 1957 by an Act of parliament, the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya. PPB is charged with the responsibility of regulating the practice of pharmacy and trade in pharmaceuticals and related products. Its core mandate is to ensure the provision of quality, safe and efficacious medicinal substances. This is achieved through evaluation and registration of medicinal products, promotion of rational use of drugs, inspection and surveillance activities. It also includes licensing professionals and institutions, clinical trial authorization and advising the Government on any matter relating to regulation of medicines and related products.

The National Quality Control Laboratory (NQCL) is the official medicines control laboratory and was established in 1992 through an amendment of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya. NQCL is the body mandated with carrying out quality control of all health products and technologies in the country.

1.1. POST-MARKET SURVEILLANCE OF MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES

Post market surveillance is an important tool in monitoring quality of health products and technologies post authorization. Assuring the quality and safety of medicines is needed to prevent harm to patients. Despite impressive progress, serious problems with medicine quality and safety remain, particularly in LMICs. These problems threaten the health of people and waste resources. Quality, safety and efficacy of health products and technologies can be compromised during the manufacturing process and or distribution chain.

Post market surveillance enables the detection of Sub-standard and Falsified (SF) products, registration status and the effects of storage conditions on the quality and stability of the products. In line with ensuring that the Kenyan public continuously has access to quality, safe and efficacious health products towards attaining UHC, PPB in collaboration with NMCP and United States Pharmacopoeia Promoting quality of Medicines (USP/PQM), a USAID funded program set out to conduct a survey to assess the quality of anti-malarials circulating in the Kenyan market

The selection of anti-malarial medicines for sampling was based on the NMCPs national treatment guidelines and the availability of monographs for analysis. Sampling of the medicines was based on it availability and use. These medicines included:

a) The first line treatment – Artemether Lumefantrine (AL)
b) Second line treatment – Dihydroartemisin + Piperaquine (DHA- PPQ)

c) Intermittent Preventive treatment (IPTp) – Sulphadoxine – Pyrimethamine
d) Treatment for Severe malaria - Injectable Artesunate, injectable Artemether, and oral and injectable quinine.

1.2. CURRENT MALARIA SITUATION

Malaria endemicity is driven by altitude, rainfall patterns, and temperature as well as malaria prevalence. This information continues to guide implementation of malaria interventions in the four epidemiological zones namely; endemic, seasonal malaria transmission, malaria epidemic prone areas of western highlands and low risk malaria areas; as provided in the national malaria policy and in the Kenya Malaria Strategy (KMS) 2019 – 2023.

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 percent of the population at risk of the disease (MOH 2014).

Malaria remains a significant public health concern in Kenya even in the context of reducing prevalence nationally. Three-quarters of the population are at risk of the disease and older children ages 10-14 years appear to have the highest prevalence at 11 percent. More importantly, the burden of the disease in the country is not homogenous since variations are observed across the different epidemiological zones. Kenya has noted a decline in prevalence, among children age 6 months to 14 years, in the lake endemic areas from 38% in 2010 to 27% in 2015 and a slight increase in prevalence in the coast endemic areas from 4% in 2010 to 8%

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.

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 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.

1.3. SITUATION ANALYSIS

Pharmacy and Poisons Board in collaboration with the National Malaria Control Program, development partners and other relevant stakeholders has been conducting surveys to monitor the quality of anti-malarial in Kenya since 2011. Round one survey on quality of anti-malarials was carried out in November 2011 and formed the baseline data on quality of anti-malarials circulating in the Kenyan market. Of the 536 samples collected, 94% were registered by Pharmacy and Poisons Board. A total of 519 samples were analyzed using Minilabs at level 1, 80 at level 2 and 44 were subjected to compendial testing at NQCL. The survey found that 92% complied at level 1, 76% complied at level 2 and 84% complied with specifications of the compendial testing.

The results of round 6 of anti-malarials quality survey indicated that the presence of unregistered and substandard anti-malarials in the market have reduced over time. Of the 100% samples collected were duly registered with PPB. Of the samples collected 94.5% complied level 1 testing, 5.2% were doubtful, while 0.3% failed to comply with the tests. Among the samples collected, 83 were subjected to compendial testing, of which 80 (96.4%) complied with specifications for all tests performed.

Round seven of the Monitoring Quality of Medicines (MQM) was a continuation of the previous six rounds that have been taking place in Kenya in order to monitor the quality of antimalarial medicines used in the country by use of minilab technology.

2. MAIN OBJECTIVE

The main objective of this survey is to assess the quality of selected antimalarial medicines circulating in the Kenyan market in selected 12 counties .

2.1. SPECIFIC OBJECTIVES

1. To determine the registration and retention status of sampled antimalarials in Kenya
2. To screen sampled antimalarial medicines from selected counties using minilab technology (Level 1)
3. Carry out verification at PPB lab of sampled medicines (10% passed, ALL doubtful and ALL failed at Level 1) -Level 2
4. To carry out compendial testing of ALL failed, All doubtful and 10% of samples that passed at level 2 (Level 3)

3. METHODOLOGY

3.1. SAMPLING STRATEGY AND TRAINING

The sampling strategy involved risk based purposive sampling from the various levels in the distribution chain including public health facilities, Non-governmental organizations (NGOs), faith-based organizations, private for-profits (hospitals, pharmacies), and informal markets. Covert approach was used to collect samples from informal markets while overt approach was applied for formal markets.

Samples were collected from 12 counties defined in the sample site selection section. The strategy ensured that samples were obtained from all sectors where patients were likely to be exposed to medicines.

3.2. SITE SELECTION

Twelve (12) counties were identified for sample collection based on epidemiological data demonstrating prevalence of malaria, medicines availability and accessibility, medicines circulating freely originating from border towns, ports of entry, and availability of human resources.

The counties selected were:
Bungoma, Busia, Homa bay, Kakamega, Kilifi, Kisii, Kisumu, Kwale, Migori, Mombasa, Siaya and Vihiga.

Table 1 Sites for level 1 testing

NO.	CLUSTER SITE	COUNTIES COVERED
1	Mombasa	Mombasa, Kilifi and Kwale
2	Kisumu	Kisumu and Siaya
3	Kisii	Kisii, Migori and Homabay
4	Kakamega	Kakamega and Vihiga
5	Busia	Busia and Bungoma

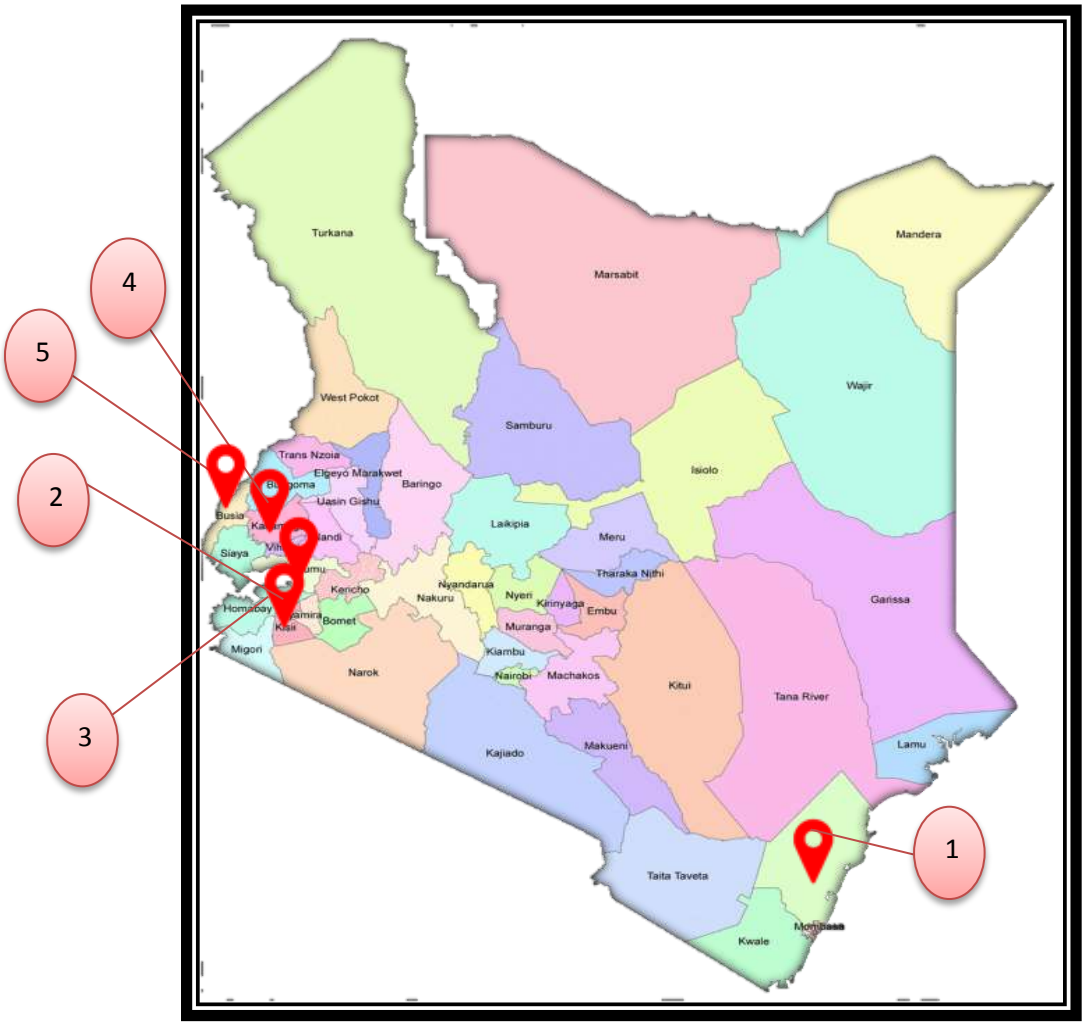

Figure 1 Map showing sentinel site locations

3.3. Medicines Selected For Sampling

The antimalarial medicines selected for sampling were based on the national malarial control program strategy for malarial control in Kenya. They include first-line treatment, second-line treatment, intermittent preventive treatment (IPT) for malaria in pregnancy, and treatment for

severe malaria.

First-line treatment

- Artemether & Lumefantrine (AL (all weight bands)) 50%

Second-line treatment

- Dihydroartemesinin & Piperaquine (DHAP) 10%

Severe malaria

- Artesunate injection 5%

Parenteral quinine 5%

- Oral quinine 5%

Intermittent Preventive Treatment (IPT)

- Sulphadoxine & Pyrimethamine (SP) 25%

For each county, approximately 60 samples were collected therefore, the total number of samples per molecule shall be a percentile fraction i.e. Al forms 50% of total samples hence 0.5 X 60=30 samples etc.

3.4. CRITERIA FOR PRIORITIZATION OF SAMPLING

Priority in sampling was given to the following APIs and Dosage forms:

1. First-line treatment at the national level in the National Health Program (i.e., National Malaria Control Program (NMCP)) treatment guidelines;
2. Most-sold medicines;
3. Most commonly-used medicines to reflect the reality of consumed medicines from all available sectors; and,
4. Medicines known or suspected to be counterfeit or sub-standard
5. Budget considerations should also be considered.

The sampling strategy involved collecting samples from various levels operating in the distribution chain, including public sector facilities, (public health facilities, health centers), Faith Based Organizations , 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;

Table 2 Samples to be collected by health sector

No.	Sector	Percentages
1.	Public	40
2.	Private	40
3.	Faith based organizations	15
4.	Informal	5
	Total	**100%**

Table 3 Samples to be collected from different types of facilities

Sector	Sampling Level	Number of samples	Total number of samples
Public	Public hospital	12	24
	Health **center** / Dispensary	12	
Private	Importer/ Distributor/ Wholesaler	6	24
	Retailers	10	
	Private hospital	4	
	Clinics	4	
Faith Based Organization (FBO)	Faith Based facilities	9	9
Informal	Kiosks/ Supermarkets/ Streets	3	3
Total samples			**60**

3.5. CRITERIA FOR DIVERSIFICATION OF SAMPLING

An attempt was made to try and diversify the samples collected from each site to reflect the availability in the market. The following characteristics

was used to diversify the sampling:

1. Different brands of the same API;
2. Different batch/lots numbers;
3. Multiple dosage forms (tablets, capsules, injectables, etc.);
4. Different sectors (private/public/informal);
5. Different sources or outlets of same product with same lots from different outlets;
6. Suspicious medicines;
7. Improperly stored medicines at the sampling site (exposed to sunlight, humid/wet conditions, etc.); and,
8. Different packaging of same product (i.e., blister vs. bulk).

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.

3.5.1. TRAINING OF PARTICIPANTS OF THE ACTIVITY ON THE USE OF MINILABS

Before the PMS, activity, The participants were trained before the sampling and testing PQM, PPB, and NQCL organized and facilitated a Minilab™ training for both national and county staff at NQCL on May 20–24, 2019. The training was attended by 23 participants from 10 counties (Bungoma, Busia, Homabay, Kakamega, Kisii, Kisumu, Migori, Mombasa, Siaya, and Vihiga), NQCL, PPB, public health programs (National Malaria Control Program; Neglected Tropical Diseases; Department of Reproductive Health; and National Tuberculosis, Leprosy and Lung Disease Program), who were

trained for 5 days on Minilab™ sampling and testing, including a demonstration of Raman screening technology using a Truscan by PPB.

The training agenda on the first day included the official opening by NQCL Director Dr. Hezekiah Chepkwony. This was followed by review of the agenda, training objectives, expected outcomes, and a pre-training test. Later, the participants were taken through an overview of PMS activities in Kenya, introduction to USP and PQM, Minilab™ introduction and safety, and volumetric techniques in the laboratory. On the second day, participants were introduced to the concept of the three-level approach for quality control of medicines and Minilab™ and Raman spectroscopy demonstration. The third day involved hands-on work in which participants used three basic Minilab™ techniques (visual inspection, disintegration, and thin-layer chromatography) to test two products: artemether/lumefantrine tablets and artesunate injection.

On the fourth day, participants were taken through the reviewed antimalarial PMS protocol, which they will use to carry out sampling and testing in their counties. They were also trained to complete the sample collection forms and capture data on the medicines quality monitoring reporting template. On the fifth and last day, the participants formed 5 teams, each consisting of PPB, NQCL, and county staff to be involved in the sampling and testing of antimalarial medicines in the 12 counties. The training ended with a post-training test and presentation of certificates of completion. The efficiency of the training was evaluated by both trainers (through the administration of pre- and post-tests) and trainees (using a questionnaire) independently.

3.6. Sample Definition

For the purpose of this study, a sample was defined as a medicine containing a defined API, dosage form, strength and a unique batch of a product collected from a specific facility/site i.e. products of the same brand with the same batch number and formulation collected from two different

sites would constitute two distinct samples. Efforts were made to collect different brands of different formulations from different facilities.

3.6.1. Number of Units to Collect per Sample

A maximum quantity of 50 tablets and a minimum quantity of 20 tablets for oral solid dosage forms were collected. For injectable samples, 50 units were collected while for oral suspensions 20 units were collected.

Table 4: Field Sampling Strategy for Tablets

Minimum Units	Maximum Units	Comments
Initial Sampling		
20	50	If the minimum of 20 units was not feasible, not less than 5 units was collected .
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*"

3.7. 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.

3.7.1. Estimating the number of samples to collect per round

Each round of sampling was planned to contain approximately 120 samples per cluster site, approximately 60 samples per county. The cluster sites with three counties, targeted to obtain 40 samples per county.

3.7.1.1. Sample collection

1. A Sampling Checklist (Annex 1) was provided to samplers prior to their departure to collection sites and emphasized the need for its consistent use. Sample integrity was safeguarded by ensuring that all samples were collected in their original, sealed, clearly labeled containers and maintained until delivery of the products for laboratory testing.
2. Each sample was packed individually in an envelope and accompanied with a duly filled out *Sample Collection Form* in an envelope (Annex xxx). Details of the site of collection was captured in the appropriate *Facility Form* (Annex xxx).
3. Information from the sample collection form was entered an Excel PMS sample aggregation worksheet before packing the samples in designated boxes. This was done to maintains a traceable record of the identity of the sample should it test —fail or doubtful and should action needed to be taken.

3.7.1.2. Substitution Criteria

In cases where a the team was unable to obtain a sample from a health facility, the nearest health facility that falls in the same sector (public/private/ NGO/ FBO/informal) and level (level 2,3,4,5) was considered for sampling.

3.7.1.3. Sampling transportation and handling

The samples were packed, transport and stored in such a way as to prevent any deterioration, contamination, or adulteration. The samples were stored and transported in their original sealed containers, according to the storage instructions for the respective product. Appropriate measures and adequate care were taken to ensure that samples reach the test site – whether for Minilab™® or confirmatory testing – without any physical or chemical damage. In addition, the samples were stored in the appropriate environmental condition at all times.

3.7.2. Sample Analysis

Once samples have been collected, they need to be tested in three stages or levels (Figure 1). Level 1 is the sentinel site minilab tests, level 2 is the verification test carried out at PPB lab and level 3 is the confirmatory testing done using full compendial testing at NQCL.

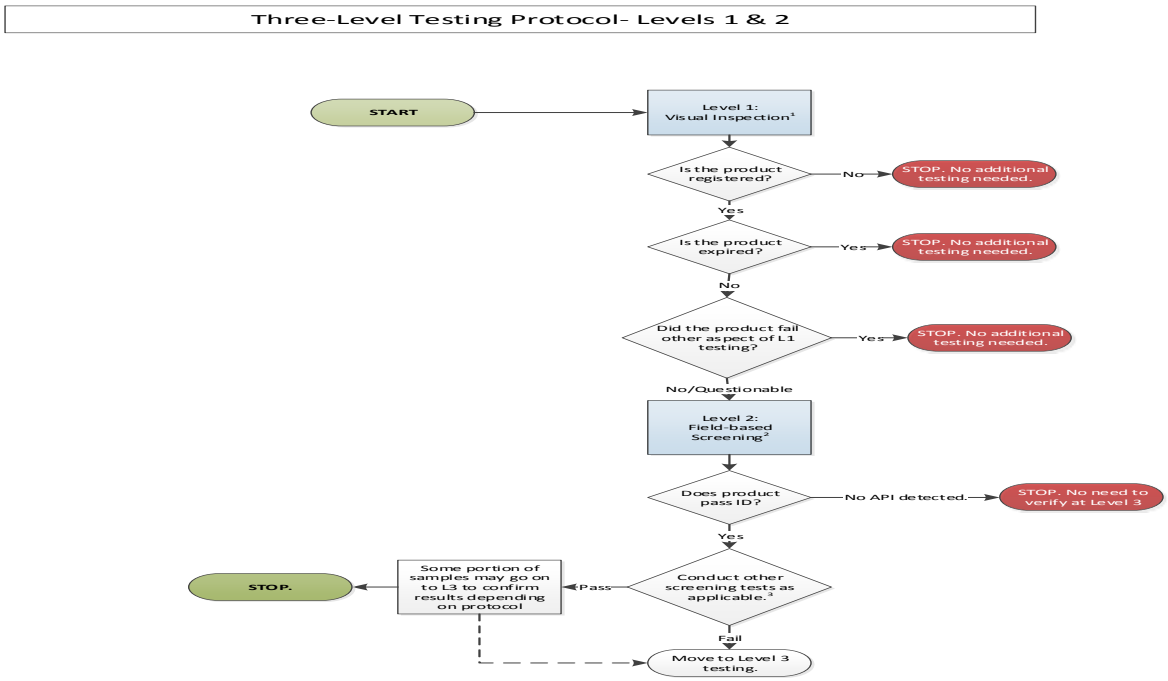

Figure 1 Guidance for visual and field-based screening (Levels 1 and 2)

Footnotes:

1. Level 1: Visual inspection included assessment of registration status, expiration date, labelling, batch number, scientific name, company logo, number of units per container, dosage form, strength, manufacturer's address, presence of a package insert, damage to packaging.
2. Level 2: Field-based screening included assessment of a product's identity (ID) and other screening tests as applicable.
3. If a product passed identification, additional tests were prioritized in the following order: content, disintegration, and

3.8. Sample Analysis

Once samples were collected, they were tested at two levels (Figure 1). Level 1 is the sentinel site testing using Minilab tests (Physical inspection, disintegration and Thin Layer Chromatography (TLC)), level 2 is the verification test carried out at PPB lab and level 3 is the confirmatory testing done using full compendial testing at NQCL.

Basic tests included Physical/Visual (P/V) Inspection, Disintegration, and 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).

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

- 10% 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.

3.8.1. Levels 1 & 2: Basic Tests

3.8.1.1. Level 1: Basic Tests with Minilabs® at Sentinel Site

Basic tests including Physical/Visual (P/V) Inspection, Disintegration, and Thin Layer
Chromatography (TLC) were carried out at the five sites.

- The collected samples were tested at the sentinel site using the Minilab™®. The Sentinel site staff had been trained, prior to sampling, in the use of the Minilab™® for testing and on interpretation of basic tests.)
- The test results for each sample were recorded on the Basic Tests Analysis Form for Sentinel Site Staff (Annex 3).

[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

- A subset of samples was sent to the PPB lab for verification testing, as follows: (Refer to Figure 1.)
  - 10% of samples that passed*
  - 100% of samples that failed**
  - 100% of samples that are doubtful***
- The selected subset of samples were 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.

3.8.2. Verification at PPB Quality Control Laboratory

Verification testing was carried out by repeating basic tests on the subset of samples.

- The results of each sample were recorded on the *Basic Tests Analysis Form for PPB Laboratory Staff* (Annex 4).
- For any samples that failed or were doubtful, the third stage of analysis was carried out by performing complete compendial testing.
- Compendial testing was performed on the following samples: (Refer to Figure 1—PMS Analysis Flow Chart.)
  - 10% of samples that passed verification testing*
  - 100% of samples that failed verification testing**
  - 100% of samples that were doubtful for verification testing***
  - 50-100% of sulfadoxine-pyrimethamine (S/P) tablets/capsules and other medicines with known dissolution failures
  - Since S/P tablets are known to have high dissolution failure rates, always perform compendial analysis on S/P tablets.

* Pass: Conforms to all three (3) tests

** Fail: Does NOT conform to at least one (1) of the three (3) tests

*** Doubtful: Conflicting or inconclusive results for at least one (1) of the three (3) tests

3.8.3. Stage/Level 3: Compendial Testing at NQCL

Confirmatory testing was done in logical sequence, rather than carrying out the full compendial testing all at once (Table 1). Priority was given to compendial tests that evaluated quality attributes that yielded failed or doubtful results during Basic Tests.

For samples with no official compendial method, the MAH provided a valid quality control method of analysis. Results of compendial analysis were recorded on the *Confirmatory Tests Using Compendial Methods Form* (Annex 5) for each sample tested.

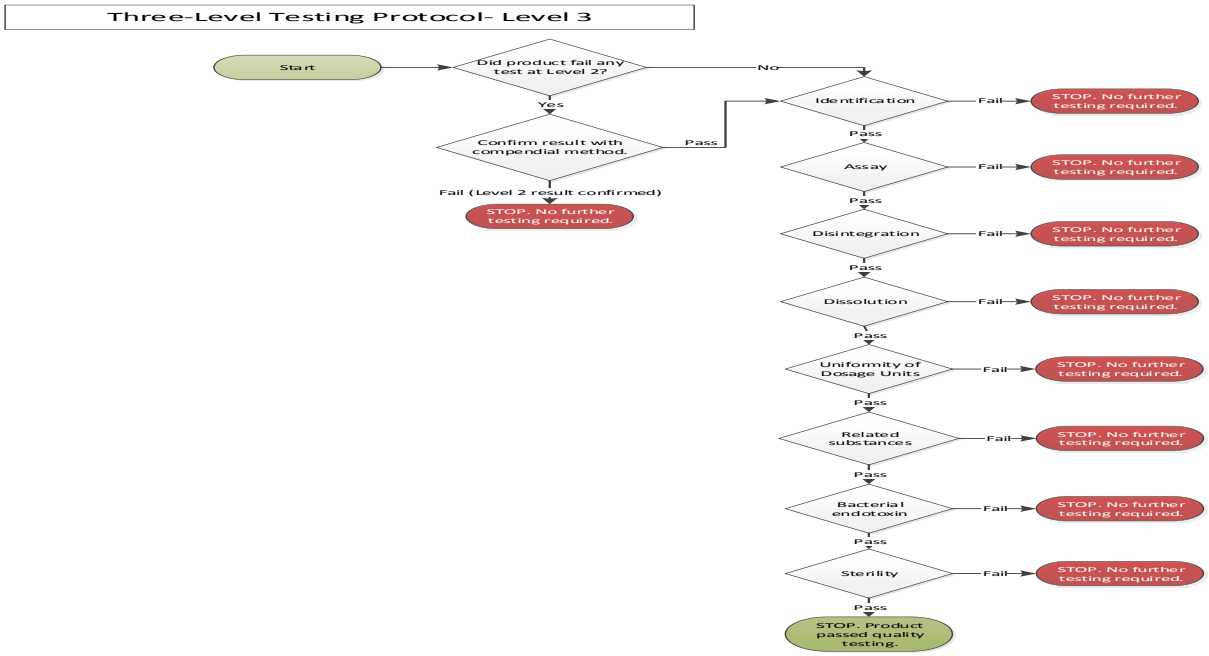

Figure 2 Level three Testing Protocol

3.9. Reporting Data

Reporting data on the *PMS Reporting Excel Datasheet* (See Annex 6 for a visual representation of the Excel file) should be assigned to a sentinel site team leader or to the PMS focal point. In either case, the final PMS reporting Excel Datasheet should be reviewed and completed by PMS focal point. A copy of this document should be sent along with a final report of PMS activities to the PQM program manager for review.

3.9.1. Level 2: Verification of Basic Tests at PPB

PPB 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.)

- 10% 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.

3.9.2. 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.

4. RESULTS

4.1. Sample Description

4.1.1. Samples collected by counties

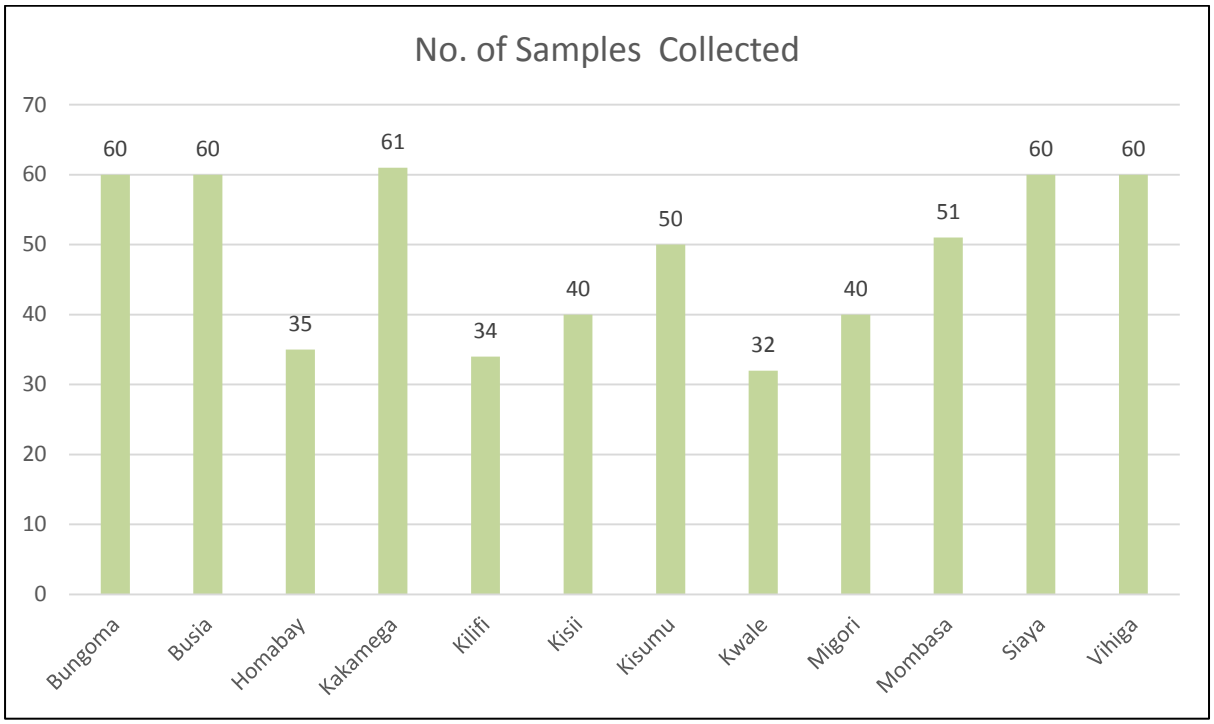

Figure 3 Samples collected per county

4.1.2. 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 this was followed by samples from public sector and the least samples were collected from the informal sector. The sample sizes are compared across the seven rounds of sampling (i.e. from 2011 – 2019) in the table below.

Sector	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Private	312	373	301	415	675	477	343
Public	169	118	229	157	194	178	216
Informal	55	8	15	33	21	18	24
Total	**536**	**499**	**545**	**605**	**890**	**673**	**583**

Table 5 Sampling by Sector

4.1.3. Sampling by API

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

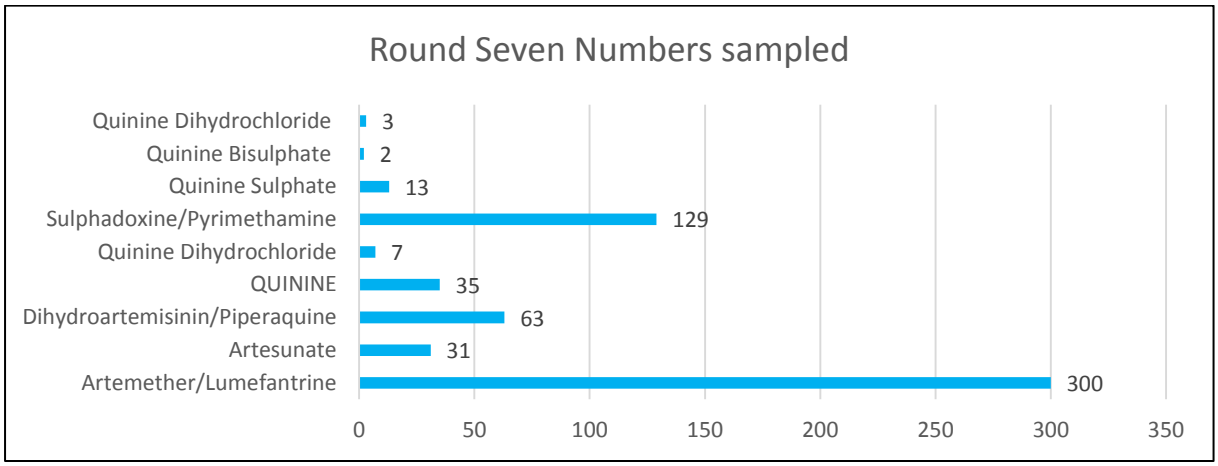

Table 6: Distribution of Samples by Active Pharmaceutical Ingredient (API)

API	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Artemether/ Lumefantrine	290	258	288	349	457	487	300
Sulfadoxine/ Pyrimethamine	101	105	106	133	112	63	129
Quinine Sulphate	83	85	77	77	10	5	15
Artesunate/ Amodiaquine	14	40	21	42	46	3	-
Quinine Dihydrochloride	-	-	3	4	98	25	3
Sulfamethopyrazine/Pyrimethamine	-	11	-	-	-		
Dihydroartemisinin Piperaquine	19	-	49	-	126	57	63
Other	29	-	1	-		33	73
Total	**536**	**499**	**545**	**605**	**890**	**673**	**583**

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

4.1.4. Sampling by Region

In the round seven activity, the largest number of samples was collected from counties in the former Western province followed by counties in Nyanza and finally the counties from the former coast province. Table 8 below shows the number of samples in the various regions from Round 1 to Round 7

Table 8 Distribution of samples by regions

Region	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Coast	107	99	115	100	158	119	117
Rift Valley	128	100	105	102	241	181	-
Nairobi	100	100	108	101	80	61	-
Nyanza	101	100	100	101	246	186	225
Western	100	100	117	101	165	126	241
Garissa	-	-	-	49	-		-
Turkana	-	-	-	52	-		-
Total	**536**	**499**	**545**	**606**	**890**	**673**	**583**

4.1.5. Summary of Sampling

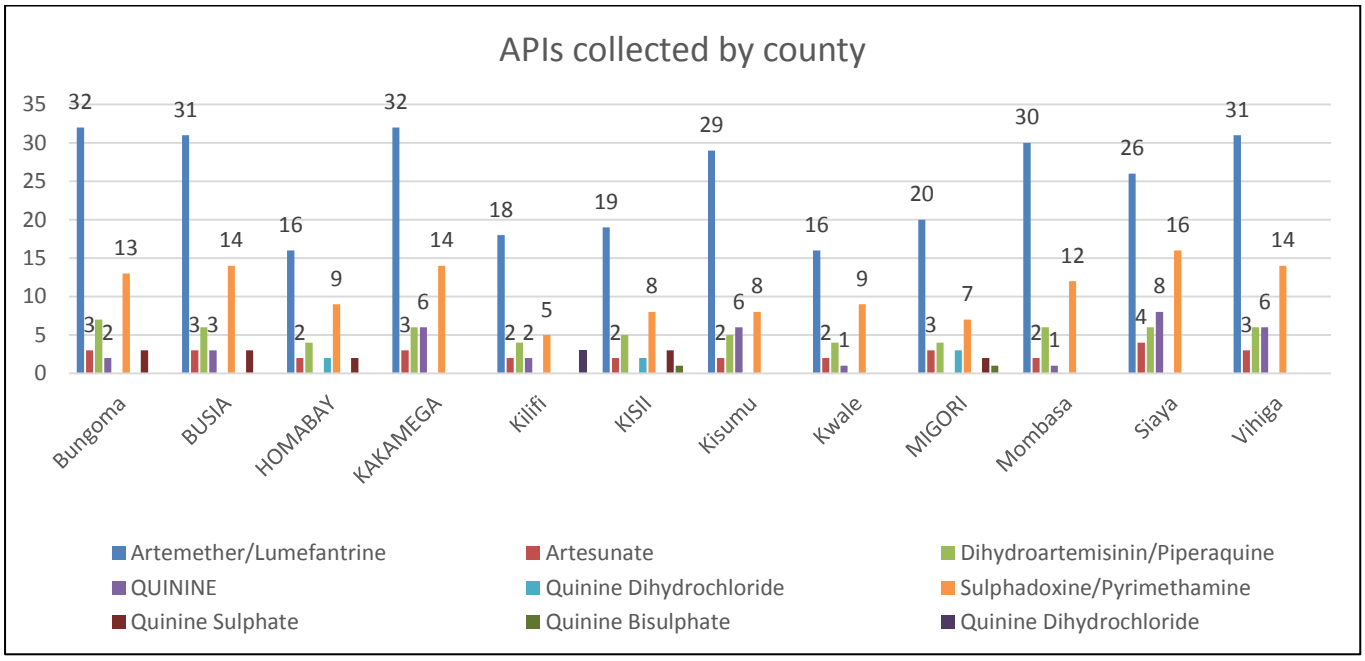

Figure 4 APIs collected by counties

Artemether/Lumefantrine was the highest collected API across the twelve counties. This was followed by Sulphadoxine/Pyrimethamine as seen in the figure above.

Table 9 Summary of sampling and analysis of the seven rounds

Over the seven rounds spanning nine years, 4,332 samples have been collected across the country and 4,041 screened by use of minilabs in the country. Out of these 401 samples have undergone compedial testing at the reference laboratories.

4.2. Registration with the Pharmacy and Poisons Board

The figure below 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.

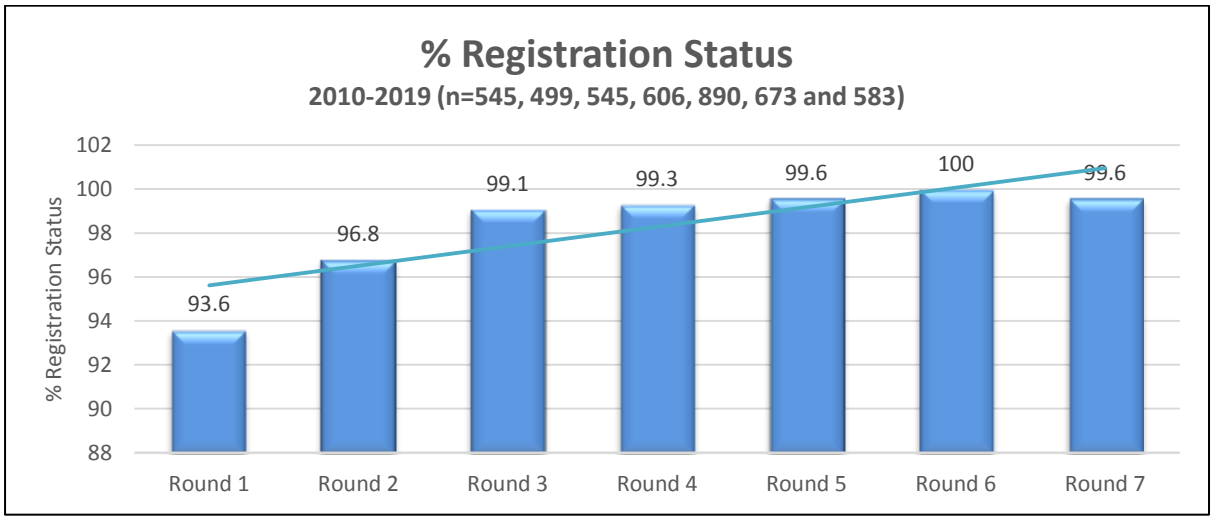

Figure 5 Registration status of the samples collected over the seven rounds

4.3. Basic and Compendial Test Results

4.3.1. Level 1 Screening Test Results

513 samples were screened at the sites. Out of these, 96% of the samples passed level one screening with only 4% being doubtful and no failure. 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. 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.

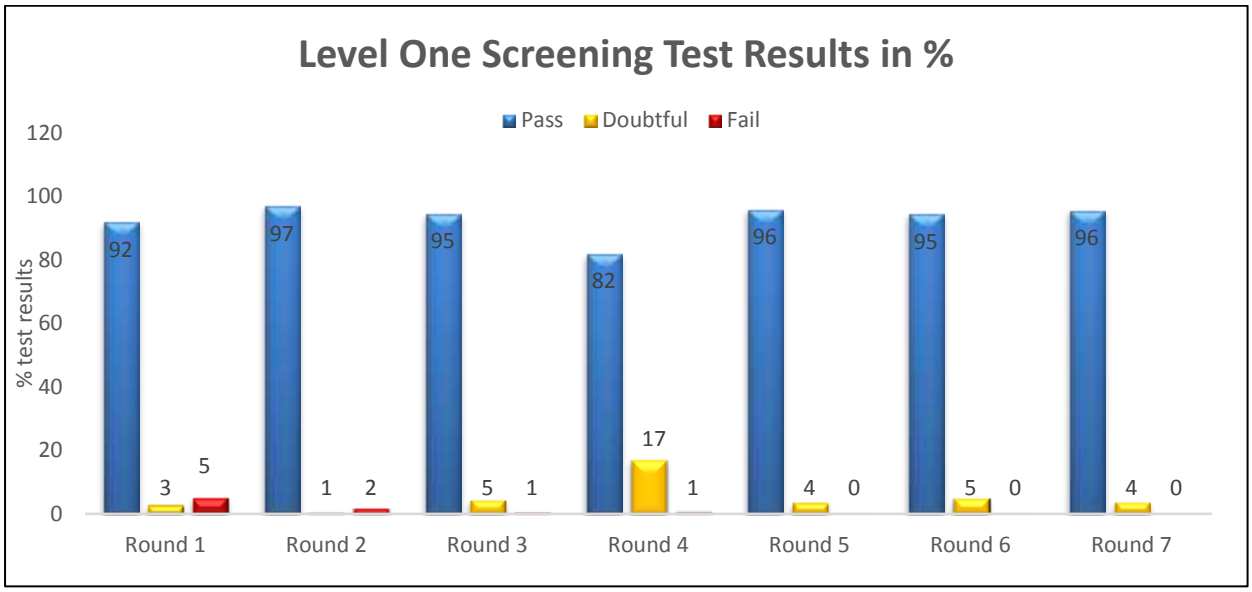

Figure 6 Level 1 testing results

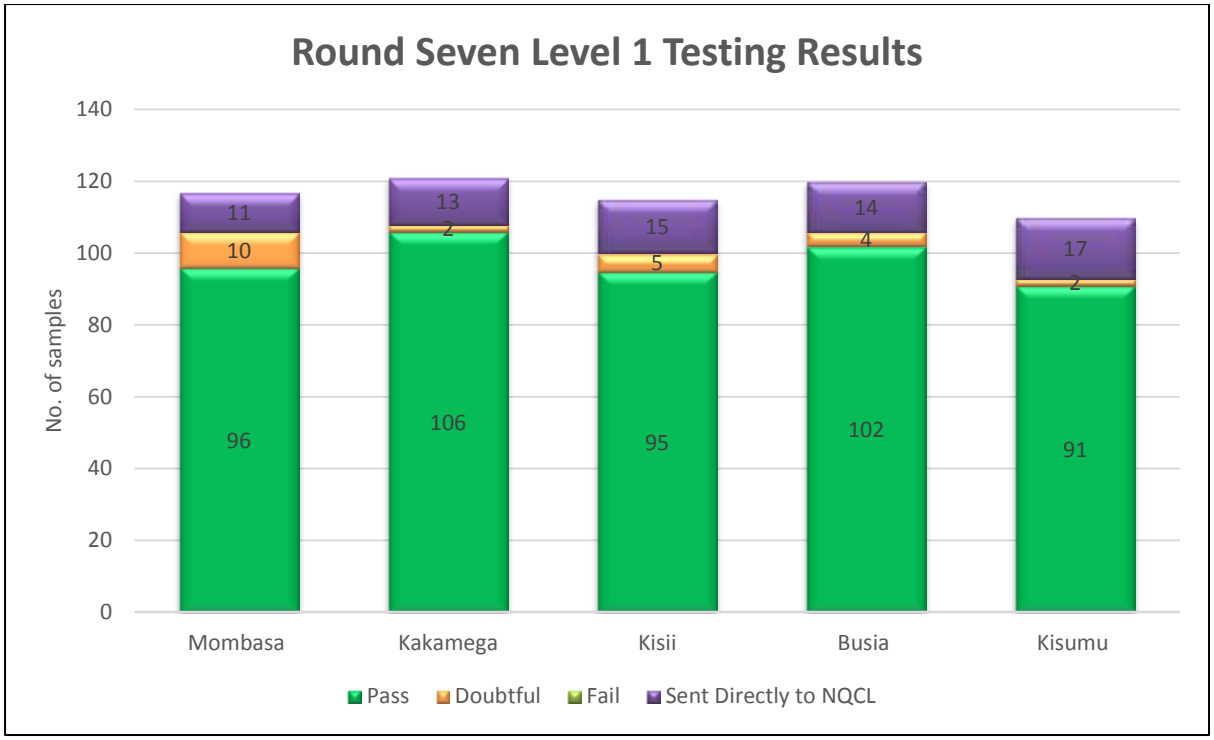

Figure 7 Round Seven, Level 1 testing results by clusters

The figure above summarizes the results of samples analyzed at the various clusters during the round seven level 1 testing.

4.3.2. Level 2 Screening Test Results

The figure below shows results of the previous level II testing. All the 86 samples tested during the level II verification activity passed testing.

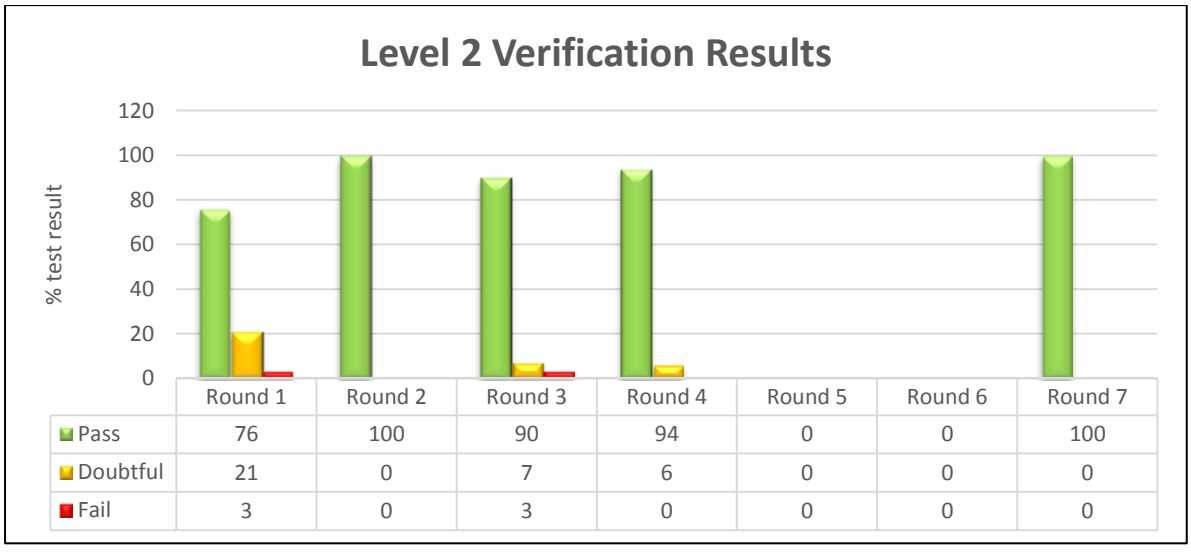

Figure 8 Level two verification results

4.3.3. Level 3 Compedial Test Results

The table below summarizes the samples subjected to level 3 compedial laboratory analysis. Artesunate injection formed majority of the samples at 16 followed AL and Quinine Dihydrochloride as seen below.

Table 10 Samples subjected to level 3, compedial, testing

No.	Formulated Drug Product	No of samples.
1.	Quinine Sulfate Tablets	3
2.	Artemether and Lumefantrine (AL) suspension	5
3.	Dihydroartemisinin and Piperaquine (DHAP) Tablets	8
4.	Sulfadoxine and Pyrimethamine (SP) Tablets	8
5.	Artemether and Lumefantrine (AL) Tablets	11
6.	Quinine Dihydrochloride Injection	11
7.	Artesunate Injection	16
	Total	**62**

4.3.3.1. Sample Description

Artesunate injections were the majority of the sixty-two (62) samples at 16 (25.8%) samples, followed by Quinine injections and Artemether/Lumefantrine tablets at 11 (17.7%) samples each, Dihydroartemisinin/Piperaquine tablets and Sulfadoxine/Pyrimethamine tablets at 8 (12.9%) samples each, Artemether/Lumefantrine suspension at 5 (8.1%) samples and Quinine tablets at 3 (4.8%) samples (Figure 9).

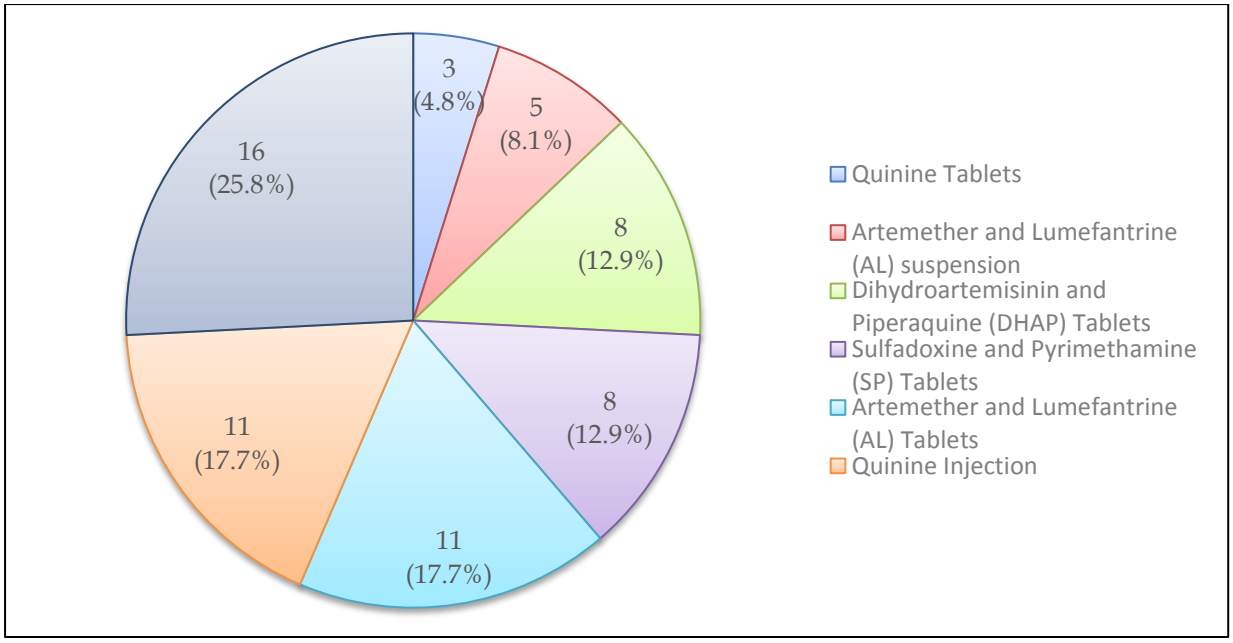

Figure 9: Sample Distribution

Samples from twelve counties were tested and are distributed as shown in Table 11 below.

Table 11: Sample Distribution by County

County	AL Suspension	AL Tablets	ART	DHAP	QUI Injection	QUI Tablets	SP	TOTAL
Kisii	0	0	1	0	1	0	0	2
Busia	0	0	1	0	1	0	0	2
Vihiga	0	0	1	0	1	0	0	2
Homabay	0	1	1	0	1	1	0	4
Mombasa	0	1	1	0	1	0	1	4
Kisumu	1	0	2	1	1	0	0	5
Migori	0	1	1	2	1	0	0	5
Kakamega	0	1	1	1	0	0	2	5
Kilifi	0	1	1	0	1	0	3	6
Kwale	0	4	1	0	1	0	1	7
Siaya	1	1	4	2	1	0	0	9
Bungoma	3	1	1	2	1	2	1	11
TOTAL	**5**	**11**	**16**	**8**	**11**	**3**	**8**	**62**

AL = Artemether/Lumefantrine, ART = Artesunate, QUI = Quinine, SP = Sulfadoxine/Pyrimethamine, DHAP = Dihydroartemisinin/ Piperaquine

Bungoma county had the most samples (11) and was the only county where all the sample types were represented.

The samples were collected from different facilities and sectors (Table 12).

Table 12: Samples by Sector and Facility Type

	Faith Based	Informal	Private	Public	TOTAL
Retail-Drug Outlet	0	0	1	0	1
Unknown	0	1	0	0	1
Warehouse	0	0	1	0	1
Distributor	0	0	2	0	2
Health Clinic	3	0	2	0	5
Hospital	3	0	8	14	25
Pharmacy	0	0	27	0	27
TOTAL	**6**	**1**	**41**	**14**	**62**

Most of the drug products (41) were collected from the private sector representing 66% of the total samples tested.

The 62 samples were subjected to compendial testing of which all of them (100%) passed. This was an improvement from round six 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%

Table 13 The type of compedial tests carried out

Formulated Drug Product	Tests Requested	Compendia
Artemether and Lumefantrine (AL) or al suspension	Microbial examination of non-sterile preparations, Identification & Assay	Ph. Int.
Artemether and Lumefantrine (AL)	Uniformity of Weight,	Ph. Int.

Tablets	Identification & Assay	
Artesunate IM/IV Injection	Sterility, Identification & Assay	Ph. Int.
Dihydroartemisinin and Piperaquine (DHAP) Tablets	Uniformity of Weight, Identification, Dissolution & Assay	Adopted In-House Method
Quinine Dihydrochloride Injection	Sterility, Identification, pH & Assay	Ph. Int.
Quinine Sulfate Tablets	Uniformity of Weight, Identification, Dissolution & Assay	USP 42 NF 37
Sulfadoxine and Pyrimethamine (SP) Tablets	Uniformity of Weight, Identification, Dissolution & Assay	USP 42 NF 37

4.3.4. Compendia Used

Official and non-official compendia were used in the analysis of the samples as listed below;

a) United States Pharmacopoeia 42 National Formulary 37 (USP 42 NF 37), (2019), The United States Pharmacopoeial Convention, Rockville, Maryland.
b) The International Pharmacopoeia (Ph. Int.), 8th Edition, 2018, World Health Organization.
c) Manufacturer's In-house methods.
d) Validated Adopted In-house methods.

4.3.5. Reagents and Solvents

All chemicals, reagents and solvents used were of analytical grade and of the highest purity as specified in the compendia listed above.

Chemical Reference Standards

Primary chemical reference substances obtained from the USP, Rockville, Maryland, USA or working chemical reference substances traceable to a primary chemical reference substance whenever possible were used in the quantitative tests.

4.3.6. Instrumentation

All testing equipment used were suitably calibrated and deemed appropriate for the testing required using internal standard operating procedures.

4.3.7. Sample Preparation

The sample and chemical reference standard solutions were freshly prepared for each analysis as outlined in the product monographs contained in the appropriate compendia listed above.

4.3.8. Analytical Tests

Consistency of Formulated Preparations

The Uniformity of Weight (Mass) test from the BP was used. All the drug samples formulated as solid dosage forms (i.e. tablets and capsules) were subjected to this test.

The test involved individually weighing 20 units taken at random; where the number of samples taken were insufficient, 10 units were taken.

4.3.9. Microbiological Examination of Non-Sterile Preparations

The procedure outlined in the BP was used. This involved inoculating and incubating an appropriate mass or volume of sample in an appropriate culture medium for the specified duration under carefully controlled conditions. The Total Aerobic Microbial Count (TAMC) and Total Combined Yeasts/Moulds Count (TYMC) should not exceed 200 Colony forming Units (CFU) and 20 CFU per unit volume or weight of product respectively.

4.3.10. Sterility

The test is applied to substances, preparations or articles which are required to be sterile. The test for sterility is carried out under aseptic conditions. The precautions taken to avoid contamination are such that they do not affect any micro-organisms which are to be revealed in the test. The working conditions in which the tests are performed are monitored regularly by appropriate sampling of the working area and by carrying out appropriate controls. The basis of the sterility test, as a culture-based method, is as

described in the harmonized pharmacopoeias. The actual test involves either:

Membrane Filtration Technique or;

4.3.11. Direct Inoculation

The sample/media is then incubated for at least 14 days to facilitate any growth in the media at 30 – 35 °C for anaerobic and aerobic bacteria, and at 20 – 25 °C for fungi and moulds in case any of these are present in the product.

4.3.12. pH

The test involved taking an appropriate volume of sample and determining its pH using a suitably calibrated electronic pH meter. The observed value was compared against the limits specified in the appropriate monograph.

4.3.13. Dissolution

The dissolution test was carried out as a means of determining the in vitro release of active ingredients in tablet formulations in a specified volume of liquid medium maintained at 37 ± 2 ºC over a specified duration under carefully regulated conditions of ionic concentration, pH and agitation as specified in the appropriate monograph.

Six tablets were run individually in the dissolution tester and the amount dissolved as a percentage of the stated amount determined using an appropriate quantification procedure as specified in the appropriate monograph. Provision for testing additional of units is provided for in case the first six do not meet the specifications.

4.3.14. Assay

This involved the determination of the amount of active ingredient in a pharmaceutical preparation expressed as a percentage of the stated amount. The sample and chemical reference substance preparation, the testing parameters and instrumentation were as specified in the appropriate monograph.

The amount of active ingredient in the sample was determined by comparing the response due to the sample solution to the response of the chemical reference substance solution whose concentration was known. The result

was expressed as a percentage of the stated amount and compared against the limits specified in the appropriate monograph.

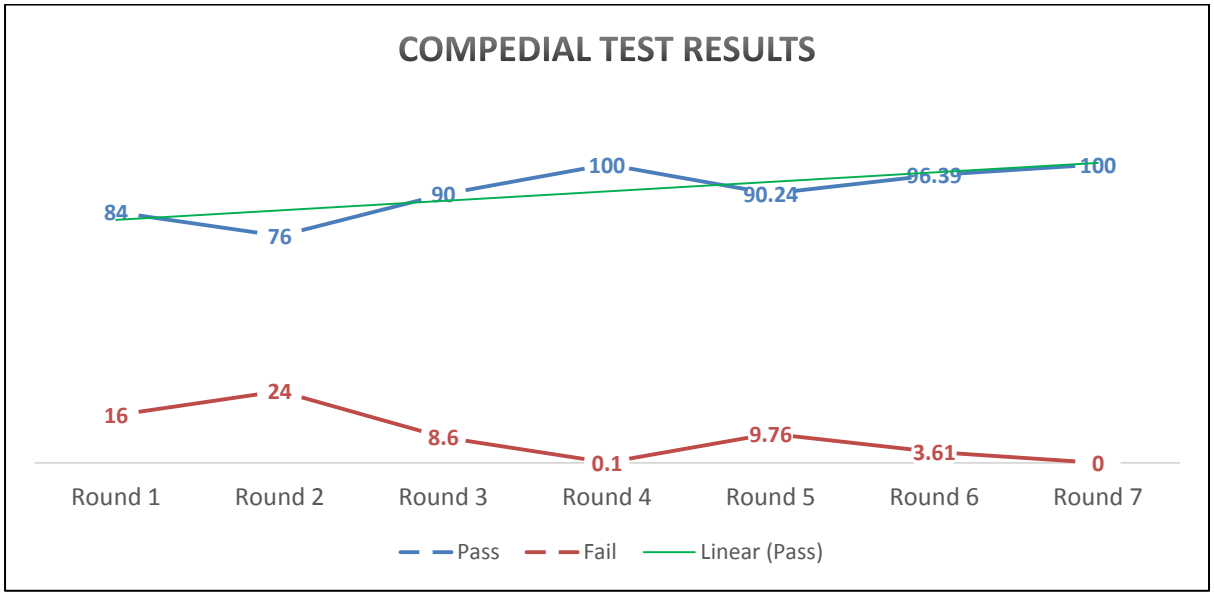

Figure 10 Compedial Test Results

5. DISCUSSION

5.1. Registration Status

Two products were found to be unregistered while four products were found as not retained as indicated below.

1. Unregistered products	Manufacturer
a) Malarem tablets	Ratnamani Healthcare PVT. LTD.
b) Sulphadoxine+ Pyrimethamine	Remedica
2. Un-retained products	
a) Duo-Cotexin 40/320	KBN-Zhejiang Pharmaceutical CO. LTD
b) Game 20/120 mg -12 pack	Osaka Pharmaceuticals PVT. LTD.
c) Game 2-/120 mg -6 pack	Osaka Pharmaceuticals PVT. LTD.
d) Darte -Q capsules	Gosun Pharma Corp. (GPC)

5.2. Screening and Compedial Test Results

513 samples were screened at the sites. Out of these, 96% of the samples passed level one screening with only 4% being doubtful and there was no failure. The proportions were similar when compared to the round six results of 95% and 5%respectively.

Considering the remarkably lower cost of minilab testing and how fast results are available compared to laboratory testing, these findings highlights the value of risk based- post marketing surveillance (RB-PMS) approach. The efficiency and value for money component for using Minilabs is a key proponent for sustainability of PMS activities in low and middle income countries (LMICs).

The overall findings demonstrate the continued availability of good quality antimalarial medicines in the market

5.3. Regulatory Actions Undertaken by PPB

The owners of the unregistered and un-retained products were contacted and asked to explain why the products were in the Kenyan market without PPB'

6. CONCLUSION AND RECOMMENDATIONS

6.1. 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 screening technologies a cost effective and rapid methodology which can be institutionalized as a risk based post marketing 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.

6.2. 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.

7. 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.

8. ANNEXES

8.1. 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.*

8.2. 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.

8.3. 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	Intensity of sample spot compared to standard:	

[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.

☐ No Rf Standard: _____ Rf Sample: _____ Rf % Sample difference:[5] _____	○ 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

8.4. 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)	

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

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% ○ 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: _____

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

[10] If applicable

8.5. List of Sampled Facilities

County	Name of Facility	Sector	Type of Facility
Bungoma	Amylin Chemist	Private	Pharmacy
Bungoma	Bokoli Sub County Hospital	Public	Pharmacy
Bungoma	Bungoma County Referral Hospital	Public	Hospital
Bungoma	Bungoma West Hospital	Private	Hospital
Bungoma	Eyat Pharmacy	Private	Pharmacy
Bungoma	Hillside Pharmacy	Private	Pharmacy
Bungoma	Jaware Chemist	Private	Pharmacy
Bungoma	Kimilili Sub County Hospital	Public	Hospital
Bungoma	Lugulu Mission Hospital	Faith Based	Hospital
Bungoma	Matulo Dispensary	Public	Health Clinic
Bungoma	Mwema Chemist	Informal	Pharmacy
Bungoma	Rash Medical Clinic	Private	Health Clinic
Bungoma	Rash Medical Clinic	Private	Health Clinic
Bungoma	Sunrise K Medical Centre	Private	Health Clinic
Bungoma	Sunsse K. Clinic	Private	Health Clinic
Bungoma	Syria Chemist	Private	Pharmacy
Bungoma	Webuye County Hospital	Public	Hospital
Bungoma	Webuye Health Centre	Public	Health Clinic
Busia	Bujumba Mission Dispensary	Faith Based	Hospital
Busia	Bunyala Healthcare Pharmacy	Private	Pharmacy
Busia	Burinda Dispensary	Public	Health Clinic
Busia	Busia County Referral Hospital	Public	Hospital
Busia	Butula Mission Hospital	Faith Based	Hospital
Busia	Calino Chemist	Informal	Pharmacy
Busia	CFW Clinic Bumala	Private	Health Clinic
Busia	Charles Juma Store	Informal	Pharmacy
Busia	Drogen Pharmacy	Private	Pharmacy
Busia	Jaspa Pharmacy	Private	Pharmacy
Busia	John Chairman's Drug Store	Informal	Pharmacy
Busia	Khunyangu Sub. County Hospital	Public	Hospital
Busia	Migele Enterprise Ltd	Private	Pharmacy
Busia	Nambale Sub County Hospital	Public	Hospital
Busia	Osmox Pharmacy	Informal	Pharmacy
Busia	Port Victoria Sub County Hospital	Public	Hospital
Busia	Roma Medical Clinic	Private	Health Clinic
Busia	Scorpion Pharmaceuticals	Private	Pharmacy

Busia	Tanaka Nursing Home	Private	Hospital
Busia	Zemella Pharmacy	Private	Pharmacy
Homabay	A Shop In Asumbi	Private	Informal
Homabay	Asumbi Mission Hospital	Faith Based	Hospital
Homabay	Homabay County Referral Hospital	Public	Hospital
Homabay	Kowade Pharmacy	Private	Informal
Homabay	Marindi Sub-County Hospital	Public	Hospital
Homabay	Medicare Pharmacy Ltd	Private	Pharmacy
Homabay	Mediocare Pharmaceutical Ltd.	Private	Pharmacy
Homabay	Nyagoro Health Centre	Public	Hospital
Homabay	Port Florence Community Hospital Clinic	Private	Clinic
Homabay	Rangwe Town Pharmacy	Private	Pharmacy
Homabay	Wakula Pharmacy	Private	Pharmacy
Homabay	Wikoteng Dispensary	Public	Dispensary
Kakamega	Aakash Pharmacy Limited	Private	Retail-Drug Outlet
Kakamega	Chebwai S.D.A Dispensary	Faith Based	Health Clinic
Kakamega	Duka La Dawa	Informal	Unknown
Kakamega	Ekero Medicyl Agency	Private	Retail-Drug Outlet
Kakamega	Iguhu County Hospital	Public	Hospital
Kakamega	Jamia Medical Centre	Faith Based	Health Clinic
Kakamega	Kakamega County Referral Hospital	Public	Hospital
Kakamega	Malava County Hospital	Public	Hospital
Kakamega	Malava County Hospital	Public	Hospital
Kakamega	Mashe Chemist	Private	Retail-Drug Outlet
Kakamega	Mitra Pharmaceuticlals Ltd	Private	Warehouse
Kakamega	Monyameds Chemist	Private	Retail-Drug Outlet
Kakamega	Mulembe Dispensing Chemist	Private	Retail-Drug Outlet
Kakamega	Reeya Pharmaceuticals Ltd	Private	Warehouse
Kakamega	Riddhi Pharmaceuticals	Private	Retail-Drug Outlet
Kakamega	Rondo Pharmacy	Private	Retail-Drug Outlet
Kakamega	Samers Pharmacy	Private	Retail-Drug Outlet
Kakamega	Shamberere Health Centre	Public	Health Clinic
Kakamega	St. Elizabeth Mukumu Hospital	Faith Based	Hospital
Kilifi	Afya International Hospital	Private	Hospital
Kilifi	Aga Khan Medical Centre	Private	Hospital
Kilifi	Burhani Pharmacy	Private	Pharmacy
Kilifi	Curative Chemist	Private	Pharmacy
Kilifi	Geomir Chemists	Private	Pharmacy

Kilifi	Kanamai Pharmacy	Private	Pharmacy
Kilifi	Kilifi County Referral Hospital	Public	Hospital
Kilifi	Maimoon Medical Centre	Private	Pharmacy
Kilifi	Malindi Chemists	Private	Pharmacy
Kilifi	Malindi Sub - County Hospital	Public	Hospital
Kilifi	Meridian Hospital	Private	Hospital
Kilifi	Mtwapa Health Centre	Public	Health Clinic
Kilifi	New Kilifi Mwananchi Maternity And Nursing Home	Private	Health Clinic
Kilifi	New Vipingo Pharmacy	Private	Pharmacy
Kilifi	Reenland Pharmacy	Private	Pharmacy
Kilifi	Renchem Chemist	Private	Pharmacy
Kilifi	Sabaki Pharmacy	Private	Pharmacy
Kilifi	Shell Chemsit	Informal	Pharmacy
Kilifi	Watamu Dispensary	Public	Health Clinic
Kisii	Briaya Chemist	Private	Pharmacy
Kisii	Brovan Chemist	Private	Pharmacy
Kisii	Colvis Chemist	Private	Pharmacy
Kisii	Gucha Sub-County Hospital	Public	Hospital
Kisii	Keumbu Sub-County Hospital	Public	Hospital
Kisii	Kisii Teaching And Referral Hospital	Public	Hospital
Kisii	Lenmek Hospital	Private	Hospital
Kisii	Magena Health Centre	Public	Health Centre
Kisii	Meridian Four Pharmacy	Private	Pharmacy
Kisii	Nyanchwa	Informal	Pharmacy
Kisii	Nyaranga Chemist	Private	Pharmacy
Kisii	Palmat Chemist	Private	Pharmacy
Kisii	Ramot Chemist	Private	Pharmacy
Kisii	Ramu Chemist	Private	Pharmacy
Kisii	Royal Clinic And Laboratory	Informal	Pharmacy
Kisii	St. John's Magena Clinic	Private	Informal
Kisii	Transwide Pharmaceutical Co. Ltd	Private	Pharmacy
Kisii	Waca Pharma	Private	Pharmacy
Kisumu	A To Z Pharmacy	Private	Pharmacy
Kisumu	Ack Maseno Mission Hospital	Faith Based	Hospital
Kisumu	Ahero County Hospital	Public	Hospital
Kisumu	Ahero County Hospital	Public	Hospital
Kisumu	Ahero Door Step Pharmacy	Private	Pharmacy
Kisumu	Avenue Hospital	Private	Hospital

Kisumu	Chuchu Pharmacy	Private	Pharmacy
Kisumu	Chulaimbo Subcounty Hospital	Public	Hospital
Kisumu	Getway Medical Services	Private	Pharmacy
Kisumu	Glory Pharmacy	Private	Pharmacy
Kisumu	Informal Sector	Informal	Street Vendor
Kisumu	Jambo Chemist	Private	Pharmacy
Kisumu	Jeckypharm Chemist	Private	Pharmacy
Kisumu	Kisumu County Hospital	Public	Hospital
Kisumu	Kombewa County Referral Hospital	Public	Hospital
Kisumu	Nyabondo Mission	Faith Based	Hospital
Kisumu	Nyakach County Hospital	Public	Hospital
Kisumu	Portflorance	Private	Health Clinic
Kisumu	Rae Health Center	Public	Health Clinic
Kisumu	Ramogi Chemist	Private	Pharmacy
Kisumu	Riat Dispensary	Public	Health Clinic
Kisumu	Sinyolo Pharmacy And Laboratory	Private	Pharmacy
Kisumu	St Mark Lela Health Center	Public	Health Clinic
Kisumu	St Monica Mission Hospital	Faith Based	Hospital
Kisumu	Winam Chemist	Private	Pharmacy
Kwale	Afia Chemist Kinango	Private	Pharmacy
Kwale	Care and Cure Pharmacy	Private	Pharmacy
Kwale	Chogoria Pharmacy	Private	Pharmacy
Kwale	Citadel Pharmaceuticals-Ukunda	Private	Pharmacy
Kwale	Diani Beach Hospital	Private	Hospital
Kwale	Japhyram Chemist	Informal	Pharmacy
Kwale	Kaya Medicalcentre-Ukunda	Private	Health Clinic
Kwale	Ken's Pharmacy	Private	Pharmacy
Kwale	Kinango Pharmacy	Private	Pharmacy
Kwale	Kinango Sub - County Hospital	Public	Hospital
Kwale	Kwale Sub - County Hospital	Public	Hospital
Kwale	Matuga Dispensary	Public	Health Clinic
Kwale	Msambweni Hospital	Public	Hospital
Kwale	Musa Medical Centre	Private	Health Clinic
Kwale	Ochieng Chemists Limited	Private	Pharmacy
Kwale	Palm Beach Hospital	Private	Hospital
Kwale	Palm Beach Hospital	Private	Hospital
Kwale	Southroad Pharmaceuticals	Private	Pharmacy
Kwale	Southroad Pharmaceuticals	Private	Pharmacy

Migori	Awendo Stage Pharmacy	Private	Pharmacy
Migori	Awendo Sub-County Hospital	Public	Hospital
Migori	Hibwa Chemists	Private	Pharmacy
Migori	Kisao Pharmacy	Private	Pharmacy
Migori	Migland Pharmacy	Private	Pharmacy
Migori	Migori County Referral Hospital	Public	Hospital
Migori	Rongo Sub-County Hospital	Public	Hospital
Migori	Royal Hospital	Private	Hospital
Migori	Shivling Chemists Limited	Private	Pharmacy
Migori	St. Joseph's Mission Hospital	Faith Based	Hospital
Mombasa	Badar Pharmacy	Private	Pharmacy
Mombasa	Bamburi Light Pharmacy	Private	Pharmacy
Mombasa	Coast General Hospital	Public	Hospital
Mombasa	Esmac Chemist	Private	Pharmacy
Mombasa	Favour Chemist	Private	Pharmacy
Mombasa	Jocham Hospital	Private	Hospital
Mombasa	Kefer Pharmacy	Private	Pharmacy
Mombasa	Kwale Sub - County Hospital	Public	Hospital
Mombasa	Laborex Kenya Ltd	Private	Pharmacy
Mombasa	Likoni Sub-County Hospital	Public	Hospital
Mombasa	Lunar Chemists	Private	Pharmacy
Mombasa	Makadara Chemist	Private	Pharmacy
Mombasa	Makupa Chemists	Private	Retail-Drug Outlet
Mombasa	Mlaleo CDF Health Centre	Public	Health Clinic
Mombasa	Mokeens Pharmaceuticals Ltd	Informal	Pharmacy
Mombasa	Mombasa Catholic C.B.H.C Services (Mikindani Dispensary)	Faith Based	Health Clinic
Mombasa	Mrima Health Centre	Public	Hospital
Mombasa	Mvita Health Centre	Public	Health Clinic
Mombasa	Noki Pharmaceuticals Ltd	Private	Pharmacy
Mombasa	Not Indicated	Private	Pharmacy
Mombasa	Not Indicated (Formerly Elshalom Pharmacy Premises)	Informal	Pharmacy
Mombasa	Pandya Memorial Hospital	Private	Hospital
Mombasa	Pharmaplus Pharamceuticals Ltd	Private	Pharmacy
Mombasa	Port Reitz Sub - County Hospital	Public	Hospital
Mombasa	Salaam Hospital	Private	Hospital
Mombasa	Sayyida Fatimah Hospital	Private	Hospital

Mombasa	Shifachem	Private	Pharmacy
Mombasa	Smartpharm Chemist	Informal	Pharmacy
Mombasa	Tranleos Chemist	Private	Pharmacy
Mombasa	Tudor Sub - County Hospital	Public	Hospital
Mombasa	Tudor Sub - County Hospital	Public	Hospital
Mombasa	Utange Dispensary	Public	Pharmacy
Mombasa	Yeshua Medicare	Private	Health Clinic
Siaya	Akala Health Center	Public	Health Clinic
Siaya	Ambira Subcounty Hospital	Public	Hospital
Siaya	Barchan Pharmaceuticals	Private	Pharmacy
Siaya	Bondo Medical Center	Private	Health Clinic
Siaya	Ditox Pharma Chemist	Private	Pharmacy
Siaya	Endtime Chemist	Private	Pharmacy
Siaya	Gabi Chemist	Private	Pharmacy
Siaya	Greenlife Pharmacy	Private	Pharmacy
Siaya	Jancare Pharmacy	Private	Pharmacy
Siaya	Malanga Health Center	Public	Hospital
Siaya	Matibabu Wholesalers	Private	Distributor
Siaya	Ndori Health Center	Public	Health Clinic
Siaya	Ndori Health Center	Public	Health Clinic
Siaya	Nyandiwa	Private	Pharmacy
Siaya	Od Yath	Private	Pharmacy
Siaya	Peanoh Chemist	Private	Pharmacy
Siaya	Sagam Community Hospital	Private	Health Clinic
Siaya	Sanpharmchemist	Private	Pharmacy
Siaya	Sega Dispensary	Private	Pharmacy
Siaya	Sidindi Medical Clinic	Private	Pharmacy
Siaya	Simenya Health Center	Public	Health Clinic
Siaya	St Elizabeth Lwak	Faith Based	Hospital
Siaya	Tusmart Chemist	Private	Pharmacy
Siaya	Tyvane Chemist	Private	Pharmacy
Siaya	Tyvane Chemist	Private	Pharmacy
Siaya	Ukwala Subcounty Hospital	Public	Hospital
Siaya	Valland Pharmacare	Private	Pharmacy
Siaya	Wilco Chemist	Private	Pharmacy
Siaya	Yala Subcounty Hospital	Public	Hospital
Vihiga	Champions Stalls Pharmacy	Informal	Warehouse
Vihiga	Coptic Hospital Maseno	Faith Based	Hospital

Vihiga	Dawalife Pharmacy Ltd	Private	Retail-Drug Outlet
Vihiga	Emuhaya Sub County Hospital	Public	Hospital
Vihiga	Ipali Health Centre	Public	Health Clinic
Vihiga	Itando Mission Hospital	Faith Based	Hospital
Vihiga	Kegoye Chemist	Private	Retail-Drug Outlet
Vihiga	Mabawa Logistics Ltd	Private	Retail-Drug Outlet
Vihiga	Maragoli Chemists	Private	Retail-Drug Outlet
Vihiga	Mungoma Chemist	Private	Retail-Drug Outlet
Vihiga	Nidas Pharmaceuticals	Private	Retail-Drug Outlet
Vihiga	Sabatia Sub County Hospital	Public	Hospital
Vihiga	Serem Health Centre	Public	Health Clinic
Vihiga	Simbi Chemist	Private	Retail-Drug Outlet
Vihiga	Tiba Chemist	Private	Retail-Drug Outlet
Vihiga	Vihiga County Referral Hospital	Public	Hospital
Vihiga	Vihiga Health Centre	Public	Health Clinic

8.6. List of Data/ Sample Collection Team

S/N	Name	Cluster counties
1	Dr. Tiberius Aluda Adeya	Busia, Bungoma
2	Dr. Anyanzwa J. L. Amoi	
3	Dr. Emily Siminyu	
4	**Michael Bugigi- Team Leader**	
1	Dr Erick Mutua	Kakamega, Vihiga
2	Dr. Koitany Benjamin	
3	Dr. Lindsay Olima	
4	**Peter Kiptoo- Team Leader**	
1	Dr. Elias Onyango	Kisumu, Siaya
2	Dr. Rodgers Omolo	
3	Joyfrida Chepchumba	
4	**Dr. Vivian Rakuomi - Team Leader**	
1	Dr. Abonyo Edgar	Kisii, Migori, Homabay
2	Dr. Joshua Ohanga Ondigo	
3	Dr. Kephar Mogere	
4	Dr. Fredrick Okari Morande	
5	David Moenga	
5	**Abdinasir Sheikh- Team Leader**	
1	Dr. Nevyll S. Jimmy	Kwale, Kilifi, Mombasa
2	Dr. Karima Dawoodbhai	
3	Dr. Mathayo Kwena	
4	Yusuf Suraw	
5	**Dr. Karim Wanga- Team Leader**	
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2	Dr Chege	
3	Dr Stephen Kimatu	

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