MINISTRY OF PUBLIC HEALTH AND SANITATION &
MINISTRY OF MEDICAL SERVICES

DIVISION OF MALARIA CONTROL & PHARMACY AND POISONS BOARD

Monitoring the Quality of Antimalarial Medicines Circulating in Kenya

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LIST OF ACRONYMS

ACT	Artemisinin-Based Combination Therapy
AL	Artemether Lumefantrine
AMFm	Affordable Medicines for Malaria
ARVs	Antiretroviral Medicines
DOMC	Division of Malaria Control.
DQI	Drug Quality and Information Program implemented by USP
FDC	Fixed-dose Combination
GPHF	Global Pharma Health Fund
IPTp	Intermittent preventive treatment in pregnancy
MQM	Medicines Quality Monitoring
NQCL	National Quality Control Laboratory
PMS	Post Market Surveillance
PQM	Promoting the Quality of medicines
PPB	Pharmacy and Poisons Board
QAMSA	Quality of Antimalarials in Sub-Saharan Africa
QA	Quality Assurance
QC	Quality Control
SP	Sulfadoxine-Pyrimethamine fixed-dose combination
TLC	Thin-Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
USP-NF	United States Pharmacopeia-National Formulary
WHO	World Health Organization

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. This report presents the findings of the first, second and third rounds of monitoring of the quality of antimalarials that have been done over the last two years using minilabs.

500 antimalarial samples were targeted in each round in five sentinel sites which were purposively selected. Purposive sampling of antimalarials was done and included artemisinin-based combination therapy (ACT) and sulfadoxine-Pyrimethamine (SPs) among other antimalarials according to their availability. The sampling was done in the public sector, the private sector and the informal sector.

Basic testing using the Global Pharma Health Fund (GPHF) Minilab kit was performed on most collected samples at the sentinel sites. This was followed by verification analysis of 10 percent of the samples that passed minilab analysis, all doubtful samples and all failed samples at the National Quality Control Laboratory (NQCL) using the Minilab. A similar sampling strategy was used to select samples that were subject to confirmatory testing using full compendial analysis at NQCL.

The results indicate that the proportion of unregistered and substandard antimalarials circulating in the market is on the decline. The results also suggest that all ACTs in the market are of good quality. The results also show that minilabs are an effective way of screening for poor quality medicines.

INTRODUCTION

1.1 Malaria in Kenya

Malaria continues to be one of the major public health problems in Africa, Asia and Latin America. *Plasmodium falciparum* malaria is estimated to be the direct cause of 500 million cases and over 1 million deaths per year, mostly in women and children under the age of 5 years (Guerra, Gikandi, & Tatem, 2008). In Kenya, malaria is responsible for 30 per cent of outpatient consultations, 19 per cent of hospital admissions and 3–5 per cent of inpatient deaths. Seventy per cent of Kenya's population lives in malarious areas. (Ministry of Public Health and Sanitation, 2009). It is for this reason that the government has prioritised the prevention and treatment of malaria in Kenya.

In collaboration with partners, the Division of Malaria Control (DOMC) developed an 8-year Kenya National Malaria Strategy (KNMS) 2009-2017 which was launched in 4th November 2009 (Ministry of Public Health and Sanitation, 2009). The goal of the National Malaria Strategy is to reduce morbidity and mortality associated with malaria by 30percent by 2009 and to maintain it to 2017.

Prior to 2009, the country was stratified into 4 main malaria eco-epidemiological zones: endemic, seasonal transmission, epidemic-prone and low risk zones. A malaria indicator survey by DOMC in 2007 showed that there are variations in malaria parasite prevalence across the eco-epidemiological zones of the country among children under 5 years of age: 17 per cent in endemic areas, 1.4 per cent in areas of seasonal malaria transmission (arid and semiarid lowlands), 1 per cent in epidemic prone areas, and 0.4 per cent in low risk transmission areas. Increasing evidence shows that the epidemiology and risk of malaria in Kenya are declining. A comparison of previous malaria maps and recently updated maps on malaria prevalence shows the shrinking of malaria endemic areas and expansion of low transmission zones. It is estimated that 60-70 per cent of the Kenyan land mass has a parasite prevalence of less than 5 per cent where 78 per cent of the population of Kenya lives. On the other hand, there is also a decline in the level of malaria prevalence in endemic areas characterised by a reversal in the age group with the highest prevalence among children less than five years old and those between 5-15 years of age.

In 2009, a model-based map of the intensity of *P. falciparum* transmission in Kenya as defined by the proportion of infected children aged 2-9 years in the community was produced (Noor, 2009). Based on the malaria risk map and the eco-epidemiology of malaria in Kenya, districts have been stratified into 4: Lake stable endemic & Coast seasonal stable endemic (risk class equal to or above 20 per cent); Highland epidemic-prone districts (risk class 5- <20 per cent); Seasonal low transmission including arid and Semi arid districts (risk class less than 5 per cent); low risk districts (risk class less than 0.1 per cent).

1.2 The Quality of Antimalarials

Various studies have been undertaken on the quality of medicines in Kenya. These continue to inform current and future initiatives towards a comprehensive post – marketing surveillance (PMS) system. Some of the studies are highlighted below:

a) A nationwide study of antimalarials by the Pharmacy and Poisons Board in collaboration with DOMC in May 2006, found that a wide range of antimalarials existed in the market, and the majority were not in the national malaria treatment guidelines; that a large proportion (42.6percent) of antimalarial medicines were not registered, and that some antimalarial medicines found in the market did not meet quality standards -. The survey enabled an innovative approach to the regulation of medicines for priority conditions, with the regulator and disease control programme working collaboratively to address an issue of public health importance (Ministry of Health, 2007).
b) During 2009, NASCOP and DLTLD undertook similar studies on quality of ARVs and TB medicines respectively. The studies were modeled along the 2007 AM survey, with modifications and adaptations to suit the context of ARVs and TB medicines. The results of both studies are being finalized, and are expected to inform further strategies for post-market surveillance of HIV and TB medicines.
c) PPB and DOMC also participated collaboratively in a multi-country study on quality of antimalarials in Africa (QAMSA) in 2008. Results from the study showed that 96 percent 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 SP samples were found compliant (WHO, 2010).
d) Concerning ARVs, a WHO multi-country study undertaken in 2005 did not demonstrate any failures of ARVs sampled from Kenya, which comprised both imported and locally produced ARVs. A recent follow up study is yet to be published.

MAIN OBJECTIVE OF THE PROGRAM

The primary objective of the program in general is to monitor the safety of medicines and conformity with established specifications for quality as declared in the registration dossier or recognized pharmacopeia specifications. It will provide regular information on the quality of medicines circulating in the country.

2.1 Specific Objectives

The specific objectives of the program include the following:

- To determine the proportion of unregistered products in the selected sites
- To determine the proportion of medicines in the selected sites that conform to quality standards
- To develop a medicine information database on the quality of medicines in circulation for trend analysis
- Disseminate information on the quality of medicines to stakeholders involved in medicines procurement, use, and regulation
- Promote communication and cooperation between stakeholders involved in medicines procurement, use, and regulation
- Provide evidence-based data for enforcement actions
- Propose possible strategies and implementation plans to address the problems identified in the study

METHODOLOGY

3.1 Sampling Strategy and Training

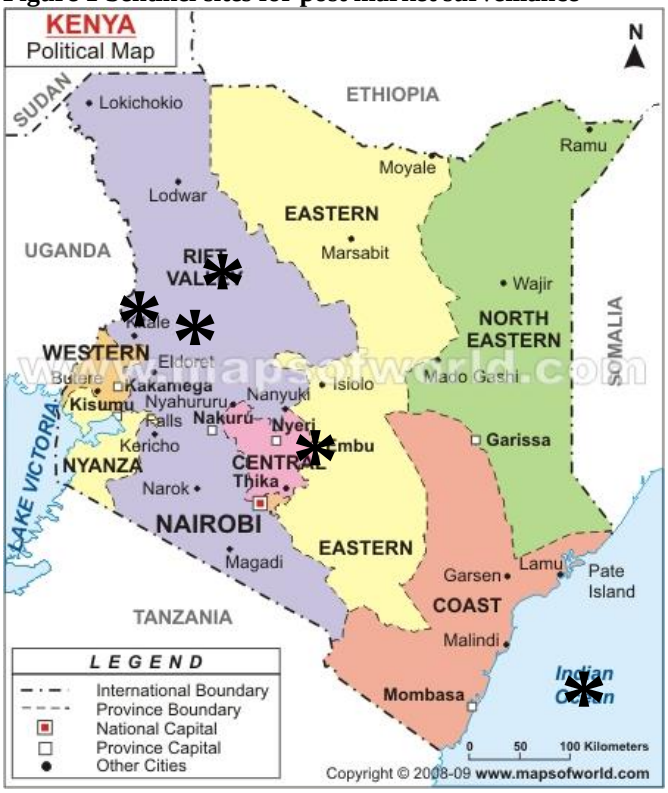
The sampling strategy involved purposive sampling from the various levels in the distribution chain including public (KEMSA, public health facilities, health centers), non-governmental organizations (NGOs), faith-based organizations (such as Mission of Essential Medicines Services (MEDS), private for-profits (pharmacies), hospitals (private and public), and illicit (informal) markets. Samples were collected using "mystery shoppers" in the private sector to simulate the real life situation in how patients access medicines to avoid alerting traders. For the purpose of the malaria control program, samples were collected from five sentinel sites defined in the sample site selection section. This strategy ensured that samples were obtained from all sectors where patients are likely to be exposed to medicines.

The training was facilitated by PQM with support from DOMC, PPB and NQCL.

3.2 Site Selection

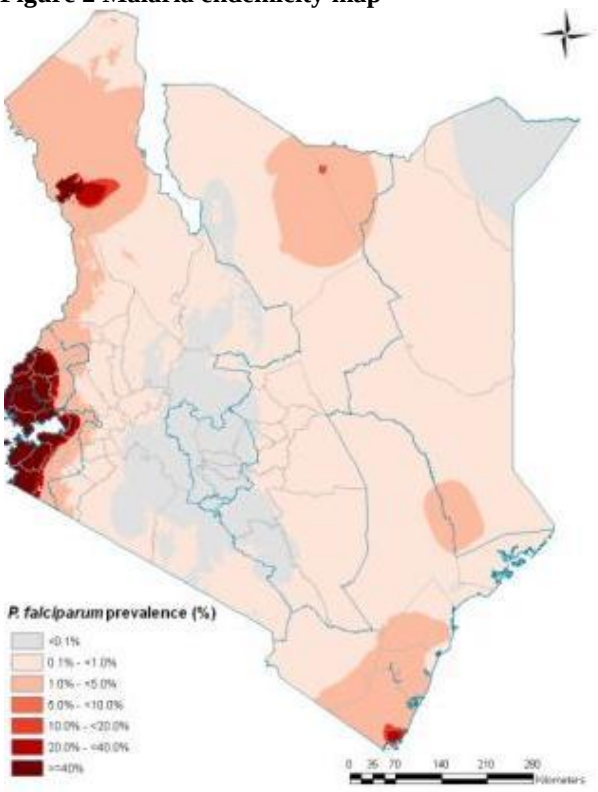
For the purpose of the Division of Malarial Control, five sites were identified in collaboration with PPB, NQCL, and PQM for sample collection based on epidemiological data demonstrating prevalence of the disease, medicines availability and accessibility, medicines circulating freely originating from border towns, ports of entry, and availability of human resources. The sites where sampling was done were as follows

Figure 1 Sentinel sites for post market surveillance



Sentinel Sites
Kisumu (Nyanza)
Kakamega (Western)
Eldoret (Rift valley)
Mombasa (Coastal)
Nairobi (Capital city)

Figure 2 Malaria endemicity map



Samples were collected from importers, wholesalers, Non-Governmental Organizations (NGOs), central stores, regulated retailers, hospitals, private sources, and informal markets.

3.3 Medicines Selected for Sampling

The antimalarial medicines selected for sampling were based on the DOMC'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-ling 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 only collected but not tested for purposes of monitoring the shift from monotherapies to ACTs and to evaluate their availability in the market.

3.4 Sample Definition

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

3.5 Number of Units to Collect per Sample

The number of units collected per sample was determined by the types of conclusions which can be drawn regarding product quality. Refer to table below.

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

Table 1 Field sampling strategy for tablets

Initial Sampling		
Minimum Units	Maximum Units	Comments
20	40	• If the "minimum" of **20** units is not feasible, collect what is available but no less than **5** units

Table 2 Re-sampling strategy for compendial testing

Re-sampling for Compendial Testing (if necessary)		
Minimum Units	Maximum Units	Comments
50	100	• If the "minimum" of **50** units is not feasible, refer to the Number of Units Needed in Table 1: Guidelines for Compendial Testing

3.6 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 counterfeit or sub-standard or with reported adverse drug events.

3.7 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).

3.8 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 100 samples although some sites collected more than this number.

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 the identity of the sample should it fail or 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.

3.9 Sample Analysis

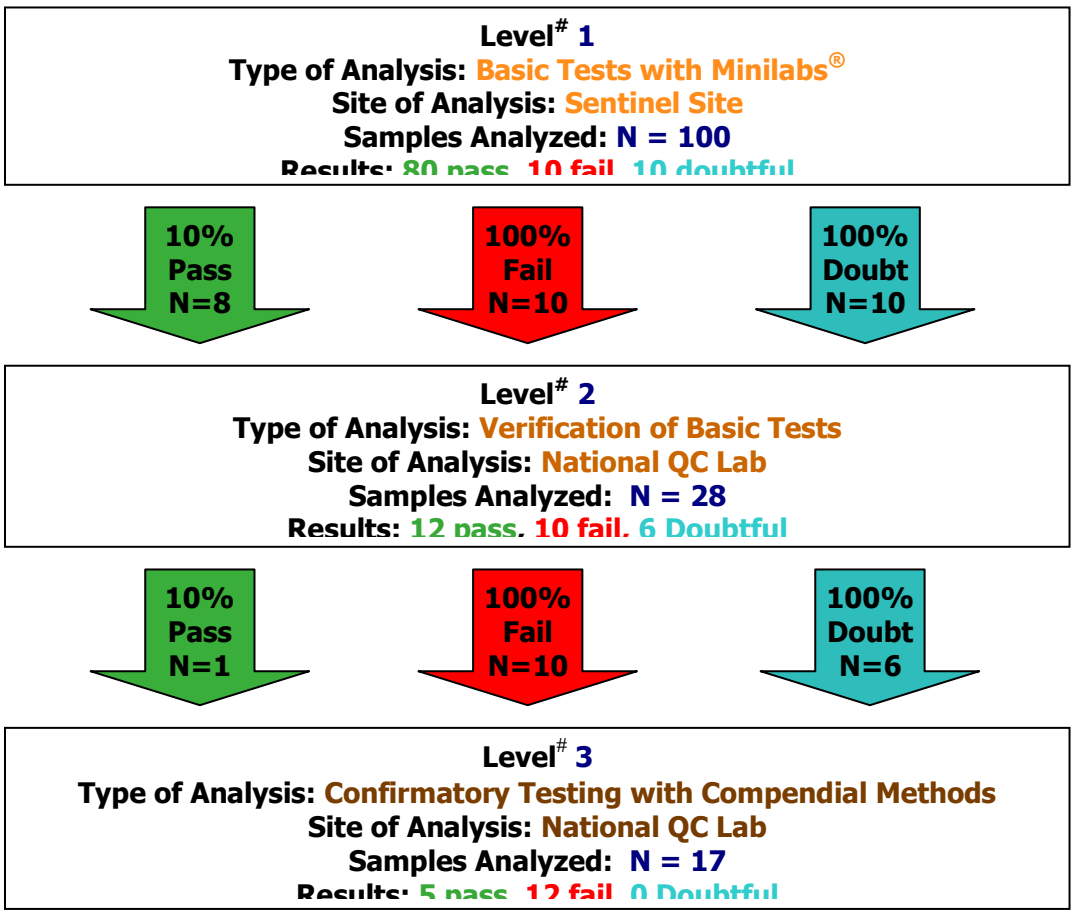
Once samples were collected, they were tested at three levels (Figure 1). Level 1 is the sentinel site using Minilab tests, level 2 is the verification test carried out in the lab using Minilab basic tests to verify sentinel site data and level 3 is the confirmatory testing done using full compendial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

3.10 Level 1 Basic Tests Minilabs at Sentinel Site

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 NQCL for verification testing, as follows: (Refer to Figure 1—MQM Analysis Flow Chart.)

- 10% of samples that passed*
- 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.



Protocols may define "stages" or "levels" differently; individual protocols should clearly indicate the terminology to be utilized and its specific meaning.

3.11 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.)

- 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 dissolution failures.

* 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

3.12 Stage/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.

4.1 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 antimalarials. As per the protocol, the target number of samples for all sectors was 500 which was achieved in all the rounds.

Table 3 Sampling by Sector

Sector	Round 1	Round 2	Round 3
Private	312	373	301
Public	169	118	229
Informal	55	8	15
Grand Total	536	499	545

4.1.2 Sampling by API

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

Table 4 Distribution of samples by API

Active Pharmaceutical Ingredient(s) (API)	Round 1	Round 2	Round 3
Artemether/Lumefantrine	290	258	288
Sulfadoxine/Pyrimethamine	101	105	106
Quinine Sulphate	83	85	77
Quinine Dihydrochloride	-	-	3
Artesunate/Amodiaquine	14	40	21
Sulfamethopyrazine/Pyrimethamine	-	11	-
Dihydroartemisinin Piperaquine	19	-	49
Other	29	-	1
Grand Total	536	499	545

4.1.3 Sampling by Sentinel Site

Sampling in each region was even and the target of 100 samples was achieved in all the rounds.

Table 5 Sampling by Sentinel Site

Province or Region (within country)	Round 1	Round 2	Round 3
Coast	107	99	115
Eldoret	128	100	105
Nairobi	100	100	108
Nyanza	101	100	100
Western	100	100	117
Grand total	536	499	545

4.1.4 Summary of Sampling

Table 6: Summary of Sampling per Round

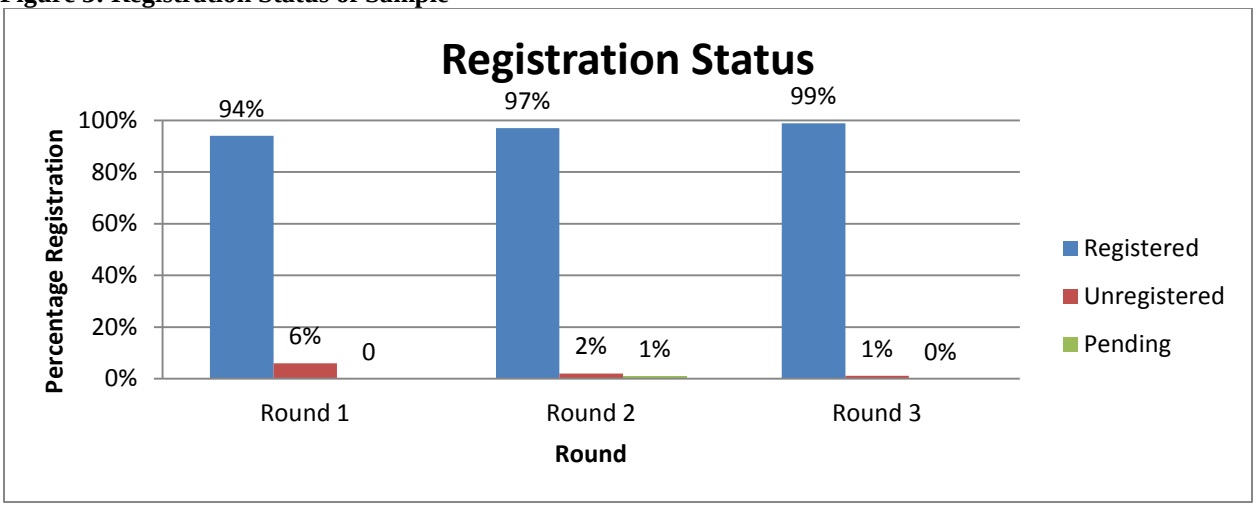
Round	Total Number of Samples Collected	Number of samples analyzed in the field using Minilab (Level 1)	Number of Samples analyzed using Minilab at NQCL (Level 2)	Number of Samples analyzed using compendial methods (Level 3)
Round 1	536	451	80	44
Round 2	499	496	65	25
Round 3	545	514	71	20

4.2 Registration with PPB

Figure 3 below shows the registration status of the samples over the three rounds. The percentage of unregistered samples has consistently been decreasing.

4.2.1 Registration Status of Samples

Figure 3: Registration Status of Sample

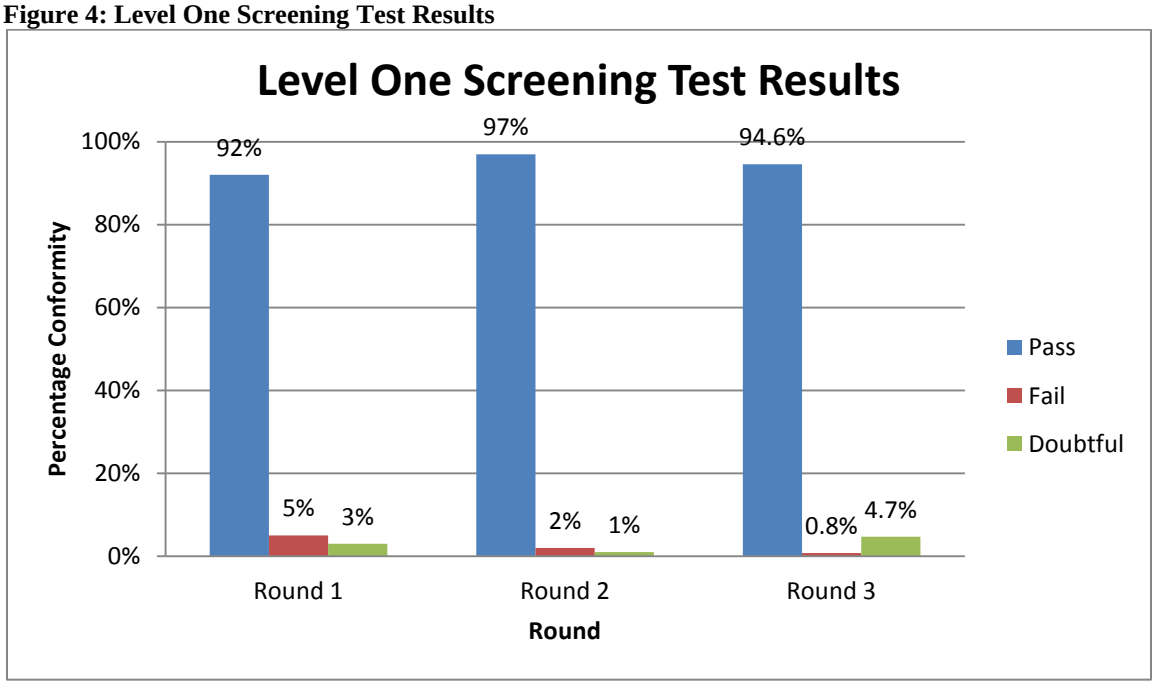


4.3 Basic and Compendial Test Results

4.3.1 Level One Basic Test Results

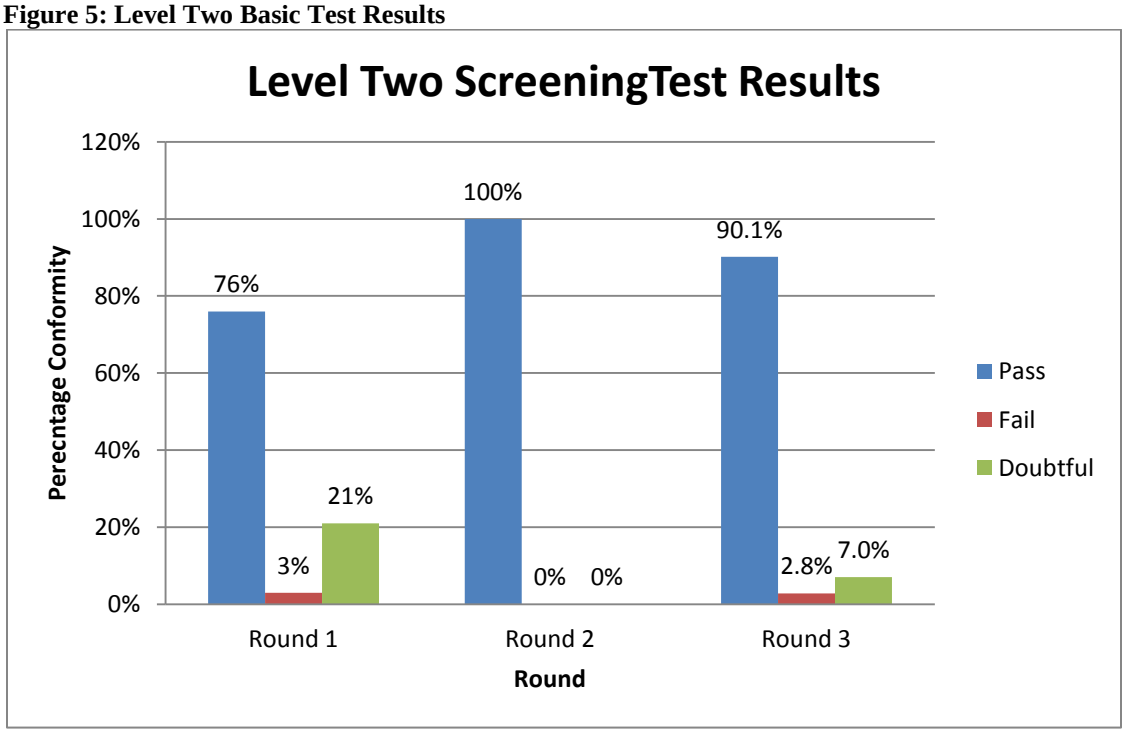
The percentage of samples failing the level one basic test has also decreased consistently from 5percent to less than 1 percent. Those complying with the test results have maintained at over 90 percent.

Figure 4: Level One Screening Test Results



4.3.2 Level Two Basic Test Results

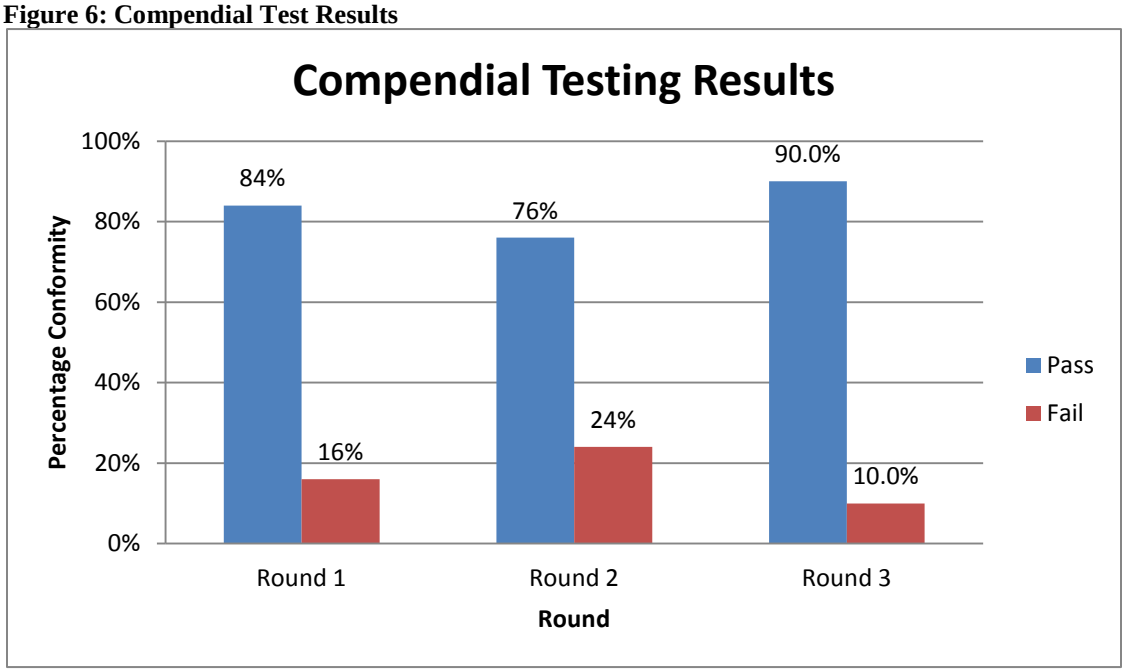
Figure 5: Level Two Basic Test Results



4.3.3 Compendial Testing Results

The percentage of samples complying with compendial tests has improved to 90 percent from 76 percent.

Figure 6: Compendial Test Results



4.3.4 Summary of Round Three Compendial Testing Results

Only one sample failed compendial testing namely Quinine Sulfate. All ACTs (Including ACTm) that were tested at level three complied with compendial tests.

Table 7: Summary of Round Three Compendial Testing Results

Result	Active Pharmaceutical Ingredient(s) (API)	Manufacturer	Brand Name	No of Samples
Fail	Quinine sulphate	Farmaceuticus lakecity s.a df	Quinine sulfate	2
Fail total				**2**
Pass	Artemether lumefantrine	Ajanta pharma limited	Artefan	2
		Ipca laboratories limited	Artemether lumefantrine	1
		Novartis pharmaceuticals corporation	Coartem	1
	Quinine sulphate	Elys chemical industries ltd	Quinine sulphate	1
		Flamingo pharmaceuticals ltd	Flaci-quin	2
		Universal corporation	Quinine sulfate	4
	Sulfadoxine pyrimethamine	Cosmos ltd	Falcidin	1
		Dawa limited	Fanlar	1
		Elys chemical industries ltd	Orodar	1
		F. Hoffmann-la roche ltd, basel, switzerland	Fansidar	1
		Laboratory and allied limited	Malodar	3
Pass total				**18**
Grand total				**20**

4.4 Determinants of Conformity

Table 8: Prevalence Ratio Calculation

	TEST RESULTS		TOTAL
Conformity determinant	**Pass**	**Fail/Doubtful**	
Pass	a	b	a+b
Fail/Doubtful	c	d	c+d
TOTAL	a+c	b+d	a+b+c+d

Prevalence ratio= a/(a+b) / c/(c+d)

4.4.1 Conformity and Registration

Registered samples were 1.3 times as likely to comply with screening tests as compared to unregistered samples as shown in table 8 below (Prevalence ration 1.3).

Table 9: Registration and Conformity

	LEVEL 1 TEST RESULTS		TOTAL
REGISTERED	**Pass**	**Fail/Doubtful**	
Yes	483	3	486
No	3	1	4
Total	486	4	490

4.4.2 Sector and Conformity

Public sector samples were 1.06 times as likely to comply with screening tests as compared to private and informal sector samples (Prevalence ratio 1.06).

Table 10: Sector and Conformity

	LEVEL 1 TEST RESULTS		TOTAL
SECTOR	**Pass**	**Fail/Doubtful**	
Public	220	5	225
Private/Informal	266	23	289
Total	486	28	514

4.4.3 ACTm and Conformity

ACTm were 1.08 times as likely to conform to compendial tests as compared to non ACTm antimalarials (Prevalence ratio 1.08).

Table 11: ACTm and Conformity

	LEVEL 3 TEST RESULTS		TOTAL
ANTIMALARIAL	**Pass**	**Fail**	
ACTm	4	0	4
Non ACTm	12	1	13
Total	16	1	17

4.5 Sensitivity and Specificity of the Minilab Tests

Due to the sampling procedure, the sensitivity of the minilab tests was done as follows: the gold standard for level one testing was taken to be level two testing, and the gold standard for level two was taken to be level three (compendial testing). Table 11 below shows the calculation for sensitivity and specificity

Table 12: Specificity and Sensitivity Calculation

	Gold Standard		TOTAL
Test	**Pass**	**Fail/Doubtful**	
Pass	a	b	a+b
Fail/Doubtful	c	d	c+d
TOTAL	a+c	b+d	a+b+c+d

Sensitivity= a/a+c

Specificity = d/b+d

4.5.1 Level One Sensitivity and Specificity

Level one sensitivity and specificity was 70.3% and 100% respectively. This means that the level one screening was able to correctly report 70% of all the samples that conformed and 100% of all the samples that failed.

This section needs to be clarified. The sensitivity and specificity, referred to here, is based on the results of level 2 testing of that were doubtful or failed the testing in the field plus 10% of total passed samples. All 49 samples that passed screening tests at the sentinel site and underwent verification testing passed (100% specificity). Only 7 out of 19 failed/doubtful samples failed level 2 verification testing

Table 13: Level One Sensitivity and Specificity

	LEVEL 2		TOTAL
LEVEL 1	**Pass**	**Fail/Doubtful**	
Pass	45	0	45
Fail/Doubtful	19	7	26
TOTAL	64	7	71

4.5.2 Level Two Sensitivity and Specificity

Level two sensitivity and specificity was 72.2% and 100% respectively. This means that the level two minilab test was able to correctly report 72.2% of all the samples that conformed and 100% of all the samples that failed.

Table 14: Level Two Sensitivity and Specificity

	LEVEL 3		TOTAL
LEVEL 2	**Pass**	**Fail**	
Pass	13	0	13
Fail	5	2	7
TOTAL	18	2	20

DISCUSSION

5.1 Registration Status

The proportion of unregistered antimalarials has decreased over the three rounds of testing from 6 percent to 2 percent to 0 percent. This is indicative of an improved regulatory environment or of a crowding out of the unregistered antimalarials. Initiatives such as AMFm have ensured that non recommended antimalarials don't compete with quality assured ACTs on price. It is therefore expected that the black market for antimalarials will shrink should the subsidy under the AMFm work. One of the key characteristics of the black market is proliferation of unregistered medicines which are smuggled into the country without the due registration process. An increased surveillance by the PPB through regular post market surveillance and the scale up of AMFm can therefore partly explain the decline in the unregistered antimalarials.

The fact that some products pending registration were found in the market is an issue. Were these product given marketing authorization prior to their registration? Also, the report provides neither the number of products sampled that were pending registration nor the number of products of which the registration status was unknown.

5.2 Screening and Compendial Test Results

The failure rate of samples screened at level one has consistently decreased from 5 to 0.8 percent indicating an improvement in the quality of antimalarials circulating in the Kenyan Market. Minilabs are an effective tool in detecting poor quality medicines as is demonstrated by their specificity of 100 percent. This means that the minilab is able to correctly detect all the samples that are truly of substandard quality. Out of a total of around 500 samples collected and screened in each round, the only samples that failed the screening tests were less than 5 percent. This percentage in round three was 0.8 percent representing the lowest since the inception of the post market surveillance program.

With the introduction of AMFm, quality assured ACTs were made available in both the public and private sectors at an affordable price (less than Kshs 40). The main objective of the AMFm was to increase access to ACTm while crowding out monotherapies and other non recommended antimalarials such as amodiaquine. Part of the supporting interventions of the AMFm was post market surveillance to ensure that banned antimalarials did not re emerge and that any substandard antimalarial circulating in the market was detected and weeded out. The challenge of post market surveillance is that it is an expensive exercise and is therefore usually deemed unsustainable. The AMFm intervention seems to be bearing fruits as evidenced by the declining prevalence of poor quality antimalarials. The absence of oral artemisinin monotherapies from the sampled antimalarials also indicates that the objective of crowding out monotherapies is being achieved.

Out of 514 samples tested at level 1, only 71 were screened at level two and only 20 were analyzed using compendial methods. Whilst the cost of minilab testing is affordable, compendial methods average Kshs 25,000 per sample. A specificity of 100% ensures that all suspected failures are sampled for confirmatory testing at level two and three. This makes minilab testing a cost effective method of carrying out post market surveillance.

5.3 Determinants of Conformity

Registered antimalarial samples were more likely to conform to screening tests than unregistered samples. The need for a robust post market surveillance system to rid the market of unregistered

samples can therefore not be over emphasized. Sustained vigilance at the ports of entry should also be maintained to ensure that unregistered products are not smuggled into the country.

Antimalarials samples from the public sector were marginally more likely to conform to screening tests. This may indicate that those seeking treatment in either the public or private sectors are equally likely to receive good quality medicines according to the round three results. The AMFm objective of availing affordable ACTs which are quality assured in the private sector is being met according to these results.

Quality assured ACTs under AMFm (ACTm) were more likely to comply with quality standards as compared to other antimalarials albeit marginally. This is a reassurance that although ACTs under the AMFm have been manufactured and distributed at a large scale, the quality standards have not been compromised. This also indicates that the private sector supply chain is able to maintain the quality standards up until when the medicine reaches the patient. Considering that ACTs were the most sampled medicine (due to their wider availability), it is encouraging that none of the samples failed compendial testing as is demonstrated by table 7. The AMFm objective of ensuring only quality assured antimalarials are availed in both the public and private sectors is being achieved.

5.4 Sensitivity and Specificity of the Minilab Tests

The sensitivity of level one minilab testing for round three was 70.3percent while that for level two was 72.2percent. This means at level one, 70.3 percent of the samples that met the quality standards were detected correctly using the minilab. The remaining percentage may have been reported as doubtful or failed which posed no risk because the sampling strategy requires that all failed or doubtful samples be forwarded to the next level for testing. The specificity of level one was reported as 100percent. This means that all the true failures were detected by the minilab which makes the minilab an effective tool in screening medicines that may not meet the quality standards. This makes the minilab invaluable in a low resource environment which is at risk of counterfeit and substandard medicines. The sensitivity and specificity of level one and two were comparable at 70.3percent/72.2percent and 100percent/100percent respectively. This further confirms the effectiveness of the minilab test as a screening tool.

CONCLUSION & RECOMMENDATIONS

6.1 Conclusion

The proportion of poor quality antimalarials is declining with the increased surveillance, improved regulation and the scale up of the AMFm program. Most antimalarials in the market are registered and meet the quality standards. All the ACTs including those locally manufactured meet the quality standards. The minilab is a cost effective method of institutionalizing post market surveillance especially in border towns and areas prone to substandard medicines.

6.2 Recommendations

- AMFm should be sustained to ensure the availability of good quality anti-malarial medicines in the private sector
- Regular post market surveillance should be institutionalized at the county level preferably using minilabs to ensure that all antimalarials being sold meet the required quality standards.
- Re-training of analysts on the minilab is required to ensure that only high quality results are reported.
- Other medicines of public health importance should be included in the post market surveillance eg ARVs and anti TB medicines.
- Efforts should made to prevent unregistered medicines from entering the market
- Prompt and decisive regulatory action needs to be taken on manufacturers whose products do not meet the quality standards.

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