



Republic of Kenya

MINISTRY OF PUBLIC HEALTH AND SANITATION  
&  
MINISTRY OF MEDICAL SERVICES, KENYA

**Antimalarial Medicines and Diagnostics Requirements for  
the Financial Year July 2011 – June 2012**

July 2011

*Report prepared by: The Drug Supply Management Sub-Committee, Division of Malaria  
Control*



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# TABLE OF CONTENTS

<b>ACRONYMS</b> .....	<b>IV</b>
<b>ACKNOWLEDGMENTS</b> .....	<b>VI</b>
<b>EXECUTIVE SUMMARY</b> .....	<b>VII</b>
<b>1.0 BACKGROUND</b> .....	<b>9</b>
<b>2.0 INTRODUCTION</b> .....	<b>11</b>
2.1 SCOPE.....	11
2.2 MALARIA STANDARD TREATMENT GUIDELINES.....	11
<b>3.0 METHODOLOGY</b> .....	<b>13</b>
3.1 GENERAL ASSUMPTIONS .....	14
<b>4.0 ARTEMETHER-LUMEFANTRINE</b> .....	<b>15</b>
4.1 TREATMENT REGIMEN .....	15
4.2 METHODOLOGY .....	15
4.3 RESULTS.....	18
<b>5.0 SULPHADOXINE-PYRIMETHAMINE (SP)</b> .....	<b>20</b>
5.1 TREATMENT REGIMEN .....	20
5.2 METHODOLOGY .....	20
5.3 SPECIFIC ASSUMPTIONS .....	20
5.4 RESULTS .....	21
<b>6.0 DIHYDROARTEMESININ PIPERAQUINE (DHAP)</b> .....	<b>22</b>
6.1 TREATMENT REGIMEN .....	22
6.2 METHODOLOGY .....	22
6.3 RESULTS.....	22
<b>7.0 QUANTIFICATION FOR SEVERE MALARIA</b> .....	<b>23</b>
7.1: QUININE DI-HYDROCHLORIDE INJECTION .....	24
7.2 QUININE SULPHATE TABLETS.....	25
7.3 ARTESUNATE INJECTION: .....	26
7.4 RECTAL ARTESUNATE: .....	27
<b>8.0 MALARIA RAPID DIAGNOSTICS TESTS (RDTS)</b> .....	<b>29</b>
8.1 SPECIFIC ASSUMPTIONS.....	29
8.2: METHODOLOGY.....	29
<b>9.0 SITUATIONAL ANALYSIS OF AL STOCK STATUS AND DELIVERY SCHEDULE FOR JULY 2011 TO JUNE 2012.</b> 31	
9.1 ASSUMPTIONS .....	31
9.2 RESULTS.....	31
9.3 DELIVERY SCHEDULE OF AL .....	32
<b>10.0 FIVE YEAR FORECAST OF AL REQUIREMENTS (FY2011-2016)</b> .....	<b>35</b>
10.1 BACKGROUND: .....	35
10.2 FORECASTING OBJECTIVES .....	35
10.3 RESULTS.....	35
<b>11.0 GAP ANALYSIS FOR ANTIMALARIAL COMMODITIES REQUIREMENTS FOR FY 2011/2012:</b> .....	<b>37</b>
<b>12.0 RECOMMENDATIONS</b> .....	<b>38</b>
<b>13.0 LIMITATIONS OF THE QUANTIFICATION PROCESS</b> .....	<b>39</b>
<b>14.0 REFERENCES</b> .....	<b>40</b>

## ACRONYMS

ACT	Artemisinin-based combination therapy
AL	Artemether –Lumefantrine
AMFm	Affordable Medicines Facility – malaria
AMC	Average monthly consumption
Amp	Ampoule
ANC	Antenatal care
CHAI	Clinton Health Access Initiative
DHAP	DihydroArtemesinin- Piperaquine
DOMC	Division of Malaria Control
DOP	Department of Pharmacy
CMTWG	Case Management Technical Working Group
DSMSC	Drug Supply Management Sub Committee
F&Q	Forecasting and Quantification
GF	Global Fund
GFATM	Global fund to fight AIDS, Tuberculosis, and Malaria
HCSM	Health Commodities & Services Management (program)
HIS	Health information system
IPTp	Intermittent preventive treatment in pregnancy
IM	Intramuscular
IRS	Indoor Residual Spraying
IV	Intravenous
KEMSA	Kenya Medical Supplies Agency
KNBS	Kenya National Bureau of Statistics
LMIS	Logistics Management Information System
LMU	Logistics Management Unit
MEDS	Mission for Essential Drugs and Supplies
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health & Sanitation
MOS	Months of Stock
MSH	Management Sciences for Health
NMS	National Malaria Strategy
OPD	outpatient department

PHFs	Peripheral Health Facilities
PMI	(USG) President's Malaria Initiative
RDTs	Rapid Diagnostic Tests
RPM Plus	Rational Pharmaceutical Management Plus Program
SP	Sulfadoxine-pyrimethamine
SOH	Stock on Hand
SPS	Strengthening Pharmaceutical Systems Program
STGs	standard treatment guidelines
USAID	United States Agency for International Development
WHO	World Health Organization

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This forecasting & quantification (F&Q) exercise was undertaken through a collaborative effort of members of the Drug Supply Management Sub-Committee (DSMSC) of the Drug Policy Technical Working group (DPTWG), Division of Malaria Control, Ministry of Public Health and Sanitation, Kenya.

The quantification was achieved through a workshop funded by the U.S. Agency for International Development's Health Commodities & Services Management (HCSM) program implemented through Management Sciences for Health. Sincere appreciation goes to the Drug Policy Technical Working group chaired by Dr. Elizabeth Juma, Head of the Division of Malaria Control for the guidance and technical inputs into the F&Q process

In particular the technical contribution of the DSMSC members listed below is acknowledged and appreciated:-

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## EXECUTIVE SUMMARY

Over the past few years, the Division of Malaria Control (DOMC) in collaboration with partners has been carrying out an annual forecasting & quantification exercise to establish the antimalarial commodity requirements for the country. This activity is guided by the *Modus Operandi for the Annual National Quantification of Antimalarial Medicines in Kenya, 2008*. The quantification exercise is spearheaded by the Drug Supply Management Subcommittee (DSMSC) of the Drug Policy Technical Working group of the DOMC. This committee comprises the DOMC, Management Sciences for Health (MSH), Kenya Medical Supplies Agency (KEMSA), Mission for Essential Drugs and Supplies (MEDS), the Department of Pharmacy, and Clinton Health Access Initiative (CHAI). One of the key functions of the DSMSC is to advise the DOMC on commodity security and supply chain related issues for antimalarial commodities.

The main objective of the exercise this year was to determine the national requirements for antimalarial medicines and diagnostics (specifically Rapid Diagnostic Tests (RDTs)) for the financial year 2011-2012.

In May 2010, the DOMC released the updated national guidelines - *National Guidelines for Diagnosis, Treatment and Prevention of Malaria in Kenya, 2010* in line with the recommendation by WHO for countries to review their malaria treatment guidelines to embrace a universal diagnostic policy for all age groups and across all epidemiologic zones. Consequently, RDTs have been identified as a tool that will help bridge the diagnostic coverage gap in lower level facilities in Kenya. This year's forecasting & quantification exercise included an estimation of the RDT requirements for the public sector as the country plans to introduce and scale up RDT coverage from early 2012.

Both consumption and morbidity based methods were applied in the forecasting and quantification exercise. The consumption-based method was applied in quantifying for Artemether Lumefantrine (AL) and quinine, while the morbidity-based method was applied for Sulphadoxine Pyrimethamine (SP) and DihydroArtemesinin Piperavaquine (DHAP).

## Key Results from 2011-12 Quantification

**Table 1: Summary of antimalarial commodities requirements for FY 2011/2012**

Product	Unit	Net requirement	Available from PMI/USAID	Available from GFATM	Available from GOK	Gap in Quantity
Artemether Lumefantrine 6s	Pack of 6's	7,378,546	1,440,000	5,988,876	0	0
Artemether Lumefantrine 6s	Pack of 12's	4,094,193	480000	2,851,186	0	763,007
Artemether Lumefantrine 6s	Pack of 18's	2,002,106	215,520	1,243,250	0	543,336
Artemether Lumefantrine 6s	Pack of 24's	9,020,723	936,000	6,498,058	0	1,586,665
Quinine Dihydrochloride Injection	Amps	3,391,729	0	0	2,736,100	655,629
Quinine sulphate 200 mg	Tabts	647,596	0	0	20,895,000	0
Sulphadoxine/Pyrimethamine	Tin of 1000s	(33,924,000)	0	0	0	0
Dihydroartemesinin/Piperaquine 160 mg	Tabts	7,004,438	0	0	0	7,004,438
Dihydroartemesinin/Piperaquine 320 mg	Tabts	12,030,001	0	0	0	12,030,001
Artesunate rectal caps 50 mg	caps	372,290	0	0	0	372,290
Artesunate rectal caps 200mg	caps	101,534	0	0	0	101,534
Artesunate injection	60mg vials	4,258,289	0	0	0	4,258,289
Rapid Diagnostic Tests	Tests	1,212,244	0	0	0	1,212,244

### Key Conclusions/Recommendations

Timely full procurement of the required antimalarial medicines as well as adherence to delivery schedules will ensure a full pipeline and prevent stock outs at the central and facility levels.

An immediate recommendation is to start procurement of AL formulations under GF AMFm Year 2 funding by latest November 2011 according to the quantification procurement plan to maintain the stock levels at central level at above the minimum recommended stock level of 6 months.

A situational analysis of AL stock status for the coming year shows alternative funding to purchase five months of stock in May 2012 needs to be sought to maintain stock levels at above minimum and prevent a stock out, if any delay were to occur in the GF AMFm Year 2 procurement.

## 1.0 BACKGROUND

Malaria remains one of the country's key public health concerns and is a leading cause of morbidity and mortality in Kenya. Clinically diagnosed malaria is responsible for 30 percent of outpatient consultations, 15 per cent of hospital admissions and 3-5 per cent of inpatient deaths. In 2007, there were 9.2 million cases of clinically diagnosed malaria reported across health facilities in the country<sup>1</sup>.

In 2004, Kenya adopted the new ACT policy with Artemether/Lumefantrine (AL) for treatment of uncomplicated malaria. The first AL consignment was received in country in 2006. Since the adoption of the new treatment policy, the Drug Management subcommittee of the Drug Policy Technical Working Group of the DOMC has played a primary role in forecasting and quantification as well as monitoring of stock status of antimalarial medicines recommended in the *National Guidelines for Diagnosis, Treatment and Prevention of Malaria for Health Workers in Kenya, 2008*. In 2010, these treatment guidelines were updated to include universal access to malaria diagnosis for all age groups and a second line treatment for uncomplicated malaria.

One of the key strategic interventions of the DOMC as outlined in the National Malaria Strategy (2009-2017) is to provide for prompt and effective treatment of malaria with 100 per cent of fever cases who present to health facilities receiving parasitological diagnosis before treatment by 2013<sup>2</sup>. To improve rational use of malaria medicines, the DOMC adopted a universal diagnostic policy for all age groups. In order to improve diagnostic coverage, the DOMC has advocated for a phased roll-in approach for the introduction of rapid diagnostic test kits and scale-up coupled with strengthening quality assurance for microscopy.

An uninterrupted supply of diagnostics and antimalarial medicines is crucial and beneficial to increasing access to treatment and providing quality care to malaria patients.

In an effort to assure continuous availability of malaria medicines the DOMC in collaboration with partners have carried out five annual F&Q exercises since 2006 using different quantification approaches. In the initial years, morbidity-based estimates were used since there were challenges in obtaining the consumption data due to low health facility reporting rates, inaccurate and incomplete reports, a weak Logistics Management Information System (LMIS) for Malaria medicines and lack of inventory management tools at health facilities.

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<sup>1</sup> Ministry of Public Health and Sanitation, Kenya. National Malaria Policy, April 2010

<sup>2</sup> DOMC/MOPHS. 2009. *National Malaria Strategy 2009–2017*. Nairobi: DOMC/MOPHS.

However, from June 2009, the DOMC improved the LMIS system that has since provided consumption data for key antimalarial medicines. This data was used to quantify antimalarial Commodities requirements in 2010 and also in the current year (2011).

On 1<sup>st</sup> July 2011, the DOMC in collaboration with partners from MSH/HCSM, KEMSA, MEDS, DOP and CHAI carried out a national quantification exercise to determine the national antimalarial medicines and RDT requirements for FY 11/12. This activity was supported by MSH/HCSM using funds from PMI/USAID. One other workshop supported by MSH/HCSM was then held to further refine the assumptions and determine the commodity requirements.

The key objectives of the exercise were to:

- Forecast AL medicine requirements for 5 years (2012-2016)
- Determine antimalarial medicine needs for the financial year July 2011 - June 2012
- Carry out a gap analysis for antimalarial medicines for the period 2011 – 2012
- Carry out a situational analysis for AL stock status to identify when the country may be stocked out of AL, for further action
- Forecast RDT requirements for 5 years (2012 - 2016)
- Determine RDT requirements for the financial year July 2011 - June 2012
- Develop a delivery schedule for the expected procurements.

## **2.0 INTRODUCTION**

### **2.1 Scope**

This F&Q targeted commodity requirements for the Kenyan public health sector and covered the period July 2011–June 2012. It also served to provide a forecast of antimalarial commodity requirements for the five year period starting July 2012 to June 2016. The selected commodities were as recommended by the National *Guidelines for Diagnosis, Treatment and Prevention of Malaria in Kenya (2010)*.

The national guidelines recommend that all suspected malaria cases be tested for Malaria before treatment. Previously, the guidelines allowed for presumptive treatment of fever in children under the age of five years. In order to improve malaria diagnostics coverage in health facilities countrywide, the DOMC intends to roll out RDTs in the public sector in various malaria zones. This quantification exercise also generated estimates of the required quantities of RDTs for the public sector, for the year beginning July 2011 to June 2012. A forecast of RDT requirements for the period July 2012 to June 2016 is also provided.

### **2.2 Malaria standard treatment guidelines**

A total of 4 different conditions with specific recommendations for treatment were identified and used for the purposes of quantification in a process guided by the *Modus Operandi for the Annual National Quantification of Antimalarial Medicines in Kenya*.

Table 2 below provides the breakdown for each specific condition along with the associated treatment regimens.

**Table 2: Standard Treatment Guidelines for Malaria**

Condition	Treatment	Dosage
1. Uncomplicated malaria (First-line treatment)	Artemether + Lumefantrine 20mg/120mg for patients of weight band 5-14kg (6 tabs)	Taken two times a day for three days at 0, 8, 24, 48, 60 and 72 hours
	Artemether + Lumefantrine 20mg/120mg for patients of weight band 15-24kg (12 tabs)	
	Artemether + Lumefantrine 20mg/120mg for patients of weight band 25-34kg (18 tabs)	
	Artemether + Lumefantrine 20mg/120mg for patients of weight band >35 kg (24 tabs)	
2. Treatment failure in uncomplicated malaria	Dihydroartemesinin piperaquine (DHAP) - available in adult and paediatric fixed dose combination tablets	4mg/kg/day Dihydroartemesinin and 18mg/kg/day piperaquine taken once a day for 3 days
3. Severe (Complicated) malaria	Quinine dihydrochloride injection	Loading dose of 20mg/kg (max 1200 mg) and then 10mg every 8 hours administered parenterally until the patient can take oral formulation
	Quinine Sulphate tabs (continuation phase)	10 mg/kg every 8 hrs (max 600mg) to complete a total (Parenteral + oral) 7 days of quinine therapy
	Artesunate (All age groups)	2.4 mg/kg to start then at 12 hours and then daily for 6 days
4. Intermittent preventive treatment	Sulphadoxine-Pyrimethamine	3 tablets administered 4 weeks apart for a total of three doses following quickening

### 3.0 METHODOLOGY

Determining the method of quantification to use is an important part of the quantification process; medicine needs can be estimated using one or a combination of three standard methods: the consumption-based method, the morbidity-based method, and the adjusted consumption method (MSH & WHO, 1997). The method selected is based on data and information available, the number and types of patients receiving services as well as the resources available for conducting the exercise. Table 3 below provides an analysis of quantification methods by data and limitations, taking into consideration the Kenyan situation.

**Table 3: Comparison of Quantification Methods**

Method	Essential Data	Situation analysis for Kenya
<b>1. Consumption</b>	<ul style="list-style-type: none"> <li>Reliable inventory records</li> <li>Records of supplier lead time</li> <li>Projected medicine costs</li> </ul>	<p>The Logistics Management Information System (LMIS) for malaria medicines was implemented in Kenya in June 2009. It has provided useful consumption data on a monthly basis. At the time of the first workshop in July 2011, 18 months of reliable data were available for use.</p> <p>Past records of supplier lead time and medicine costs are available from previously awarded tenders.</p>
<b>2. Morbidity</b>	<ul style="list-style-type: none"> <li>Data on population and patient attendances</li> <li>Actual or projected incidence of health problems</li> <li>Standard treatments (ideal, actual)</li> <li>Projected medicine costs</li> </ul>	<p>Morbidity data, comprising information on confirmed and clinical malaria cases, is collected by the Division of HIS, MoPHS.</p> <p>Currently, the main limitations of HIS data are:- low reporting rates, lack of adjustment for facility reporting rates and delayed compilation of data by the HIS.</p> <p>Standard Treatment guidelines are available at most public health facilities but Quality of Care Survey results show poor adherence to case management guidelines.</p>
<b>Adjusted Consumption</b>	<ul style="list-style-type: none"> <li>Comparison area or system with good per capita data on consumption, patient attendances, service level and morbidity</li> <li>Number of local health facilities by category</li> </ul>	<p>Questionable comparability of patient populations, morbidity, treatment patterns and health-seeking behaviour practices</p>

- 
- |  |  |  |
|--|--|--|
|  | <ul style="list-style-type: none"><li>• Estimation of local user population broken down by age</li></ul> |  |
|--|--|--|
- 

*Adapted from: Management Sciences for Health/World Health Organization. 1997. "Quantifying Drug Requirements" in Managing Drug Supply. 2nd ed. West Hartford, CT: Kumarian Press.*

### 3.1 General assumptions

In quantifying the antimalarial commodity requirements, the following general assumptions were applied:-

- The proportion of patients per weight band – based on actual patient numbers data obtained through the LMIS, monitored over a 18 month period is
  - 5-14kg = 33%
  - 15-25kg = 18%
  - 25-34kg = 9%
  - >35kg = 40%.

These above patient ratios have been used where applicable throughout this F&Q.

- The minimum stock level at the central level is set at 6 months of stock (MOS)
- The maximum stock level at the central level is set at 9 MOS.
- Physical count for end June 2011 was used while information on stocks pending with suppliers at the same time was obtained from KEMSA.
- Buffer stock level was set at 6 months
- Prices were obtained from either KEMSA or the international price indicator guide.

Each commodity's quantification will be guided by both the general assumptions above as well as any specific ones applicable to the commodity under consideration.

## 4.0 ARTEMETHER-LUMEFANTRINE

### 4.1 Treatment regimen

The current recommended first line medicine for uncomplicated malaria is AL given as a 3 day dose depending on the weight of the patient upon diagnosis.

### 4.2 Methodology

This quantification process for AL and Quinine relied heavily on data from the Logistics Management Information System (LMIS) for malaria commodities.

The key indicators tracked by this system are as shown in Box 1 below:

#### **Box 1: Key indicators tracked under the LMIS**

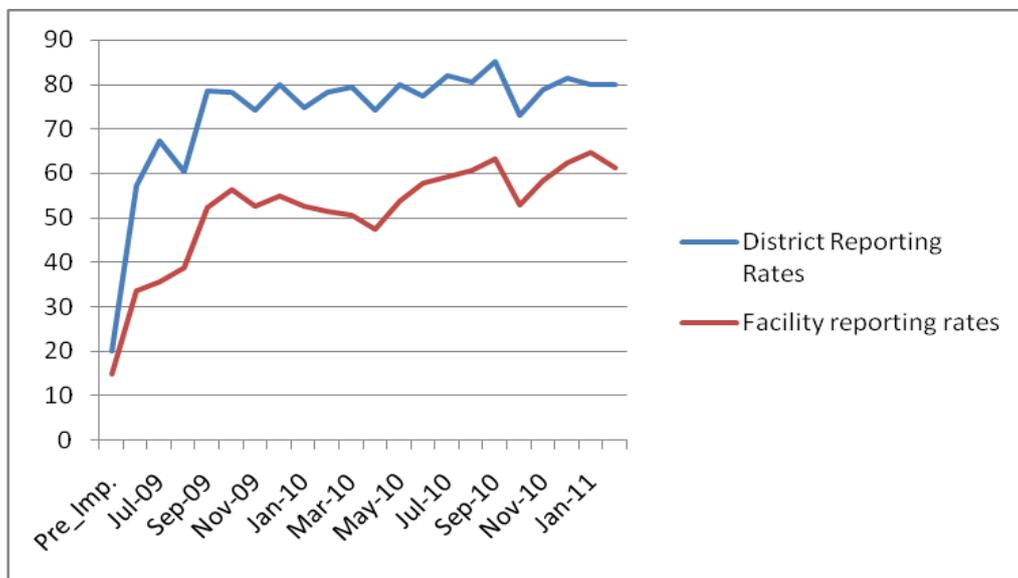
- National reporting rate
- Monthly aggregated adjusted AL consumption by weight band
- Percentage of facilities stocked out of AL (for each weight band) for more than seven consecutive days
- Aggregated losses
- Aggregated expired stock
- Aggregated number of patients on AL by weight band.

*Note: The same data is collected for all other antimalaria commodities*

Following its implementation in June 2009, there has been a steady increase in national LMIS reporting rates by health facilities from an average of 11% in 2009 to 61% in Feb 2011.

Figure 1 below shows the reporting rate trends over that period.

**Figure 1: Facility and District LMIS reporting rates over time**



The Health Facility Monthly summary form (*see Appendix 1*) provides a summary of the indicators shown in Box 1 above, for each facility. This data is then aggregated by the District Pharmaceutical facilitator (DPF) into a District Monthly summary form which is then forwarded to the Logistics Management Unit (LMU) for entry into the central level LMIS database.

During dispensing, the health workers are allowed to spilt or combine any of the four different weight bands to treat patients whose specific weight band is not available, e.g. if the paediatric 6 tablet packs are not available, the health worker can still dispense a quarter of the 24 tablet pack. Likewise, an adult patient can be treated with four of the 6 tablet packs if it is the only dosage form available.

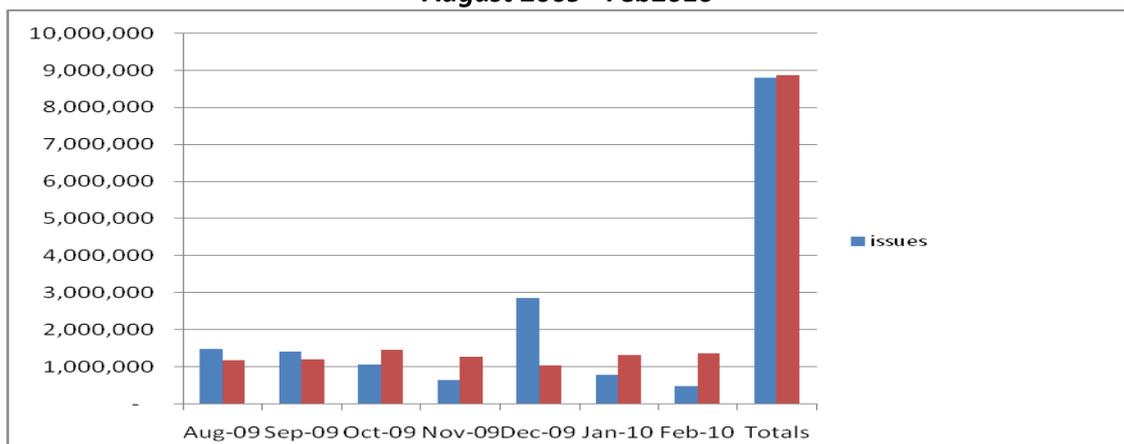
For this reason, and bearing in mind that these splits and combinations are fairly common, the DSMSC considered that a better measure of consumption would be the number of patients actually treated with an antimalarial for each weight band as opposed to the actual aggregated adjusted consumption reported by the facilities. The information on number of patients dispensed with AL is collected in the Health Facility Monthly summary form.

### 4.3 Assumptions

During the previous quantification process (2010-2011), we compared the data from the LMIS with issues / distribution data from KEMSA's database. For the period August 2009 to February 2010, when we had both reliable issues and LMIS data, we found that the total amount of issues from KEMSA and MEDS closely matched the adjusted reported number of patients on AL.

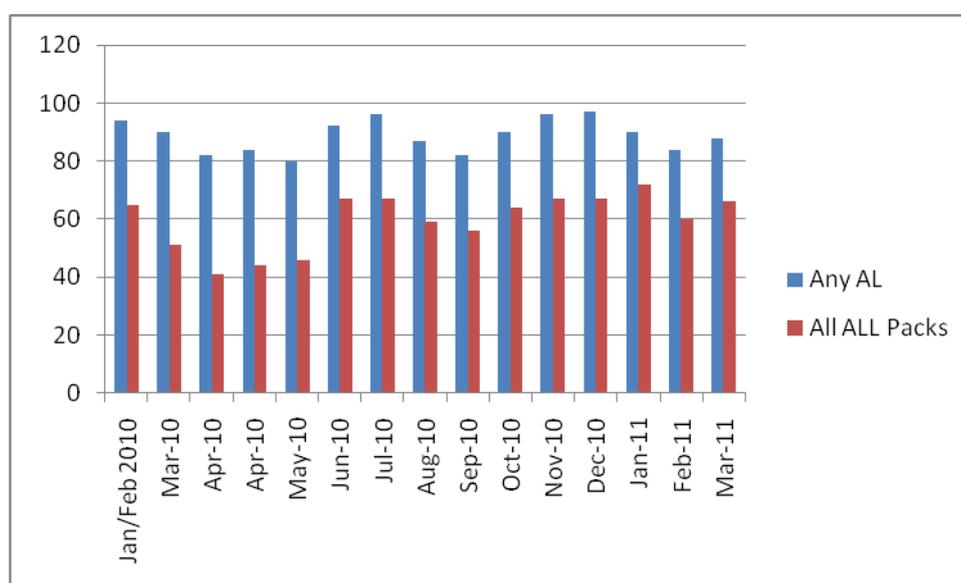
This suggests that the system was able to reliably account for the malaria medicines issued out to facilities country wide.

**Figure 2: Comparison of Patient data from the LMIS vs KEMSA issues data from AL: August 2009 - Feb2010**



Based on the analysis of LMIS data for 18 months, September 2009 to February 2011, the number of patients that received AL per weight band was compiled. The LMIS data collection tools do not capture information on total stock outs of AL (i.e. percentage of time that facilities are fully stocked out of AL), therefore findings from the bi-annual Quality of Care survey conducted for the first time in January - February 2010, in 174 randomly selected public health facilities were utilised. Between the bi-annual surveys, monthly calls were made to these facilities to determine their stock status. The findings obtained are representative and can be generalised for the country. The results showed the average total stock out of AL across the country to be 11.2%<sup>3</sup> (see figure below).

**Fig 3: Availability of Artemether-Lumefantrine in survey facilities**



The total number of projected malaria cases, was then apportioned according to the ratios for each weight category as derived from the LMIS data. It is assumed here that each patient will receive AL corresponding to his/her weight category with no splitting or combining of treatment doses, therefore the number of patients is equivalent to the number of treatment doses as shown in Table 4 below.

<sup>3</sup> Memusi D. et al. 2010. Monitoring outpatient malaria case management under the 2010 diagnostic and treatment policy in Kenya - baseline results. Nairobi: Division of Malaria Control, Ministry of Public Health and Sanitation. June 2010.

**Table 4: Estimated number of patients receiving AL**

Total no. of patients receiving AL from Sept 2009 to Feb 2011 (18 months) (a)	Adjusted number of patients receiving AL in 12 months (b)	Average total stock out rate (c)	Projected number of patient receiving AL, adjusted for stock out (d)
19,976,064	13,317,376	11.2%	14,997,045

- Obtained from LMIS data over the period September 2009 to February 2011. This figure is adjusted for reporting rates in each month over the period.
- Calculated as (a)/18 \*12 to get the estimated number of patients receiving AL in one year
- Based on data collected through biannual Quality of care surveys conducted in February 2010 and November 2010, and subsequent post survey phone calls, which showed on average a total stock out of AL of 11.2% in public health facilities. The F&Q team therefore assumed that 11.2% patients were not treated, as a result not captured by the LMIS.
- Refers to the total number of patients on AL per year, adjusted for stock outs (b/88.8\*100).

## 4.4 Results

**Table 5: Requirements for AL doses per weight band for FY 2011/12**

AL dosage pack (a)	Weight band (b)	Ratio (c)	Estimated Number of patients (d)	Number of doses required (e)	Six months buffer stock (f)	Total doses required (including 6 months' buffer stock) (g)
AL 6s	5-14 kg	32.80%	4,919,031	4,919,031	2,459,515	7,378,546
AL 12s	15-25 kg	18.20%	2,729,462	2,729,462	1,364,731	4,094,193
AL 18s	25-34 kg	8.90%	1,334,737	1,334,737	667,369	2,002,106
AL 24s	≥35 kg	40.10%	6,013,815	6,013,815	3,006,908	9,020,723
<b>Total</b>		<b>100%</b>	<b>14,997,045</b>	<b>14,997,045</b>	<b>7,498,523</b>	<b>22,495,568</b>

Notes for Table 5:

- AL blister pack
- The four weight categories
- Patient ratios for each weight band obtained from LMIS data over a 18 month period
- Obtained by multiplying the total number of projected number of patients requiring AL adjusted for stock out from table 4 above by the ration for each dosage pack
- Equivalent to total number of patients in each weight band
- Obtained as AMC x Minimum MOS
- Sum of columns (e) and (f)

Six months of buffer stock was then added to each weight category to determine the total number of doses required.

Estimated average monthly consumption (AMC) = (14,997,045/12) = 1,249,754 treatment doses.

AMC is used to calculate buffer stock as follows:-  $\text{Buffer stock} = \text{AMC} \times \text{Minimum MOS}$   
(i.e. 6 MOS)

The total number of AL treatments required for FY 11/12, including buffer stock, is 22,495,568.

## **5.0 Sulphadoxine-pyrimethamine (SP)**

### **5.1 Treatment regimen**

The current recommended medicine for IPTp is SP tablets (500mg Sulfadoxine + 25mg Pyrimethamine) given as a dose of three tablets upon presentation of the patient in an Antenatal care clinic. It is administered as three or four doses, each a month apart, after quickening to ensure protection against malaria.

The morbidity-based method combined with demographic estimates was used for quantification of SP for endemic regions only.

### **5.2 Methodology**

The LMIS consumption data for SP that was collected over the 18 month period (Sept 2009-February 2011) was found to be inaccurate and could not be used for quantification purposes. This was due to the fact that some facilities reported consumption as tablets while others reported as tins. In addition, SP is still used for treatment of uncomplicated malaria in some facilities making it difficult to establish the 'real' consumption. To correct this error in reporting, the DOMC has revised the health facility monthly summary report to capture the number of women receiving IPT in order to enable a comparison to be made between patients receiving IPTp and tablets consumed.

The National Malaria Standard Treatment guidelines advocate for use of SP for IPTp in malaria endemic areas only. Quantification of SP was therefore carried out using population data estimates for pregnant women in malaria endemic areas only as provided in the National Malaria Strategy 2009-17.<sup>4</sup>

### **5.3 Specific assumptions**

1. The projected population of pregnant women at risk of malaria and living in endemic zones is 504,569 (NMS 2009-2017).
2. The quantification caters for all (100%) expected pregnancies in areas of high transmission since advocacy and IEC activities will be scaled up to encourage women to attend ANC.

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<sup>4</sup> DOMC/MOPHS. 2009. National Malaria Strategy, 2009-2017. Nairobi: DOMC/MOPHS. July 2009

3. Each pregnant woman will receive a total of 4 doses, each 1 month apart after quickening (National Malaria STGs, 2010).
4. 60% of patients seek health services from public health facilities (Kenya Malaria Indicator Survey, 2007).

## 5.4 RESULTS

### 1. *Determination of pregnant women living in endemic areas*

The revised NMS (2009-17) estimates a total of 504,569 pregnant women living in endemic areas.

### 2. *Determination of the projected no. of pregnant women seeking health services from public health facilities*

60% of 504,569 = 302,741 pregnant women

### 3. *The National Malaria Treatment Policy targets four doses of SP (IPT4) to be given to pregnant women during the attendance of ANC clinics in endemic areas.*

The DSMSC used four doses for computation.

Therefore the number of tablets required is:

$$302,741 \times 3 \text{ tablets} \times 4 \text{ doses} = 3,632,897 \text{ tablets}$$

### 4. *SP for the public sector in Kenya is usually packed in tins of 1,000 tablets, therefore, rounding off to the nearest thousand, the total quantity required will be 3,633 tins.*

### 5. *6 months' buffer stock for the central level is obtained by multiplying the AMC by 6 months, i.e. Buffer stock = 3,633 × 6/12 = 1,818 tins.*

Hence the total requirement for SP = (3,633 + 1,818) tins.

The total quantity required for SP for FY10/11 are 5,451 Tins of 1000's, however the country is overstocked with SP in the central stores, with over 5 years of stock on hand in KEMSA.

Recommendation: No procurement of SP is required in the current financial year. Close monitoring of movement of existing stocks at KEMSA is required to determine future procurements.

## 6.0 DIHYDROARTEMESININ PIPERAQUINE (DHAP)

### 6.1 Treatment Regimen

The recommended second line treatment for uncomplicated malaria in Kenya is Dihydroartemisinin-piperaquine (DHAP). This is currently available as a fixed-dose combination with adult tablets containing 40 mg of dihydroartemisinin and 320 mg of piperaquine, and paediatric tablets containing 20mg dihydroartemisinin and 160mg of piperaquine. It is administered once daily for three days at a dose of 4 mg/kg/day dihydroartemisinin and 18 mg/kg/day for piperaquine, with a therapeutic dose range between 2–10 mg/kg/day of dihydroartemisinin and 16–26 mg/kg/day of piperaquine.

### 6.2 Methodology

In determining the quantity of DHAP required, it is assumed that the number of treatment failures will be 5% of uncomplicated cases given the 95% efficacy of AL. The number of tablets required per day was determined by computing the median patient weight (for each of the four weight bands) multiplied by the median dose of piperaquine required to achieve therapeutic efficacy (21 mg/kg/dose) and divided by the quantity of piperaquine per tablet (160 mg for the pediatric and 320 mg for the adult tablet). For each of the computed doses, the dosing for Dihydroartemisinin was checked to ensure that it is within the therapeutic dose range (2-10 mg/kg/dose).

### 6.3 Results

**Table 6: Projected requirements for DHAP tablets**

Weight band category	Median weight for weight category	Ratio of patients seen (%)	Number of patients per weight band	Patients expected to require 2nd line treatment (5%)	No. of DHAP tablets per dose	No. of tablets per dose rounded off to nearest divisible tablet	Number of tablets per day	Number of tablets for whole 3 days course	Total number of tablets required	Total Requirements (includes 6 months buffer)
(a)	(b)		(c)	(d)	(e)			(f)	(g)	(h)
<b>Dihydroartemisinin/ Piperaquine 160 mg Tablets</b>										
5-14 kgs	10	32.8	4,919,031	245,952	1.3	1.5	3	9	2,213,564	3,320,346
15-25 kgs	20	18.2	2,729,462	136,474	2.6	3.0	6	18	2,456,516	3,684,774
Sub-Total		51%								7,005,120
<b>Dihydroartemisinin/ Piperaquine 320 mg Tablets</b>										

25-34 kgs	30	8.9	1,334,737	66,737	2.0	2.0	4	12	800,842	1,201,263
≥35 kgs	60	40.1	6,013,815	300,691	3.9	4.0	8	24	7,216,578	10,824,867
<b>Sub-Total</b>		<b>49%</b>								<b>12,026,130</b>
<b>TOTAL</b>		<b>100%</b>	<b>14,997,045</b>	<b>749,852</b>						

Footnotes for Table 6:

- The weight categories of patients
- The median weight for each category
- Number of patients requiring AL as per adjusted consumption data; from Table 5 column b
- Obtained as 5% of the total projected number of cases that require AL
- Refers to the number of tablets required per patient per day, computed to deliver a median of 21 mg of piperazine / day (Therapeutic range is 16 - 26 mg per kg per dose). These doses were counterchecked to ensure that they deliver Dihydroartemesinin at doses within the therapeutic range of 2-10 mg per kg per dose. The number of tablets computed was then rounded off to the nearest half tablet. Taking into account that the patients in the two lower weight bands 5-14 kg and 15-25 kgs will use the pediatric formulation of piperazine 160mg, while the 25-34kg and 35+ kg weight band will use the adult formulation (piperazine 320mg)
- Total number of tablets for each patient, based on the three days recommended dosing
- Computed by multiplying (d) and (f)
- This is the computed by adding 6 months of stock obtained as follows:- (g) + ((g)/12) x 6).

The total number of DHAP tablets required for FY 10/11 including buffer stock is 7,004,438 of the 160mg tablets and 12,030,001 of the 320 mg tablets. There needs to be computation of doses based on the packaging – these are packed differently by different manufacturers so it was thought best to calculate in tablets, not in doses.

## 7.0 QUANTIFICATION FOR SEVERE MALARIA

The DSMSC utilised Quinine injection consumption data collected from September 2009 to February 2011 as the basis for the consumption-based quantification of medicines for severe malaria because it was found to be fairly accurate. There are currently three options for the treatment of severe malaria: Quinine, Artesunate and Artemether. New evidence suggests that Artesunate, when used to treat severe malaria, is more effective and leads to reduced mortality from malaria<sup>5</sup>.

In light of this evidence, the committee quantified for the country's needs for Quinine and Artesunate only for the treatment of the population with severe malaria.

<sup>5</sup> Dondorp AM, Fanello CI, Hendriksen IC, Gomes E, Seni A, et al, Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. Lancet. 2010 Nov 13; 376(9753):1647-57. E pub 2010 Nov 7.

Quinine is procured by KEMSA through government funding and is routinely distributed to all public health facilities. Artesunate is normally procured through donor funding for epidemic response preparedness.

### **7.1 Assumptions**

- The weight band ratios for uncomplicated malaria were assumed to also apply for severe malaria.
- Parenteral therapy is given for an average of 3 days
- The average continuation phase for all severe malaria cases is 4 days.
- Once an ampoule is opened, it will be discarded after the first dose is administered
- Quinine and Artesunate will be quantified exclusive of each other because Artesunate is expected to substitute Quinine under the new WHO recommendations. The F&Q team decided to determine what the country would require if either of the two were used for case management.
- Needles, syringes, gloves and other medical commodities required for parenteral administration of antimalarial injections are not included in this quantification. It is assumed that these will be quantified alongside other non pharmaceuticals.

## **7.2 Quinine Di-hydrochloride injection**

### **7.2.1 Treatment regimen**

Quinine dihydrochloride is indicated for the management of severe malaria and is administered parentally (IV/ IM). In both adults and children, a loading dose of 20 mg per kg is given followed by maintenance dose of 10mg/kg (max 600mg) every 8 hours, until the patient can take oral medication.

### **7.2.2 Methodology**

To quantify the country's requirements of quinine injection, we used consumption data from the LMIS.

The consumption of quinine ampoules (300mg/ml, 2ml ampoules) reported from the LMIS was adjusted for both stock outs and the average reporting rates over the 18 months. Six months of buffer stock was then added to determine the total requirements for the year.

### 7.2.3: Results

**Table 7: Projected doses of Quinine injection ampoules**

<b>Total adjusted aggregated consumption of Quinine ampoules (18 months data) (a)</b>	<b>Annual consumption (b)</b>	<b>Six months buffer stock (c)</b>	<b>Total Requirements (amps) (d)</b>
<b>4,439,272</b>	<b>2,959,515</b>	<b>1,479,758</b>	<b>4,439,272</b>

Footnotes for Table 7:

- a) Total quantity of quinine injection consumed over 18 months period obtained from LMIS data and adjusted for stock-outs.
- b) Annual consumption computed as (a) / 18 x 12
- c) Six months of buffer stock computed as (b) X 6/12
- d) Total estimated country requirements: (d) = (b) + (c)

## 7.3 Quinine sulphate tablets

### 7.3.1 Treatment regimen

Quinine sulphate (available as 300mg tablets) is indicated for the continuation phase in the management of severe malaria. In both adults and children, quinine tablets are administered at a dose of 10 mg/kg every 8 hrs (up to a maximum of 600mg daily) to complete 7 days of quinine therapy.

### 7.3.2 Methodology for quinine sulphate tablets

The consumption data for quinine tablets from the LMIS was found to be unreliable due to use of varied units of issue for reporting (some facilities reported consumption in tins of 1000 tablets while others reported in unit tablets) resulting in inaccurate data.

Therefore, the Quinine Injection consumption was used to derive the expected number of severe malaria cases for the continuation phase – disaggregated by weight band using the ratios previously determined under section 3.1.

This was followed by a computation of the total number of quinine tablets required per weight band assuming a total of four days of oral therapy. The number of severe malaria patient cases estimated by this method was also used in the estimation of requirements for Artemether as well as Artesunate (IV and Rectal).

### 7.3.3 Results

**Table 8: Projected quantities of Quinine Tablets**

Weight band category	Ratio	Median weight	Total estimated annual consumption - ampoules	Number of cases	Tablets per dose???	Total Number of tablets per case	Quantity required of Quinine sulphate tabs.	Total Quantity required (including 6 months' buffer stock)
(a)		(b)	(c)	(d)			(e)	(f)
5-15 kg	32.80%	10	744,579	124,097	0.5	6	744,579	1,116,869
15-25kg	18.20%	20	406,134	67,689	1.0	12	812,268	1,218,403
25-34 kg	8.90%	30	304,600	33,845	1.0	12	406,134	609,201
Above 35 kg	40.10%	60	1,504,201	150,420	2.0	24	3,610,082	5,415,123
<b>Total</b>	<b>100%</b>		<b>2,959,515</b>	<b>376,050</b>			<b>5,573,064</b>	<b>8,359,596</b>

Footnotes for Table 8:

- (a) Weight bands
- (b) Median weight for each weight band
- (c) The total estimated annual consumption of quinine injection based on the ratios per weight band and the respective expected number of ampoules per patient.
- (d) The total number of cases of severe malaria, computed from the average number of ampoules per patient as per recommended dosing schedule. It was assumed that each ampoule was used only once and discarded.
- (e) Total number of tablets required to treat patients as per recommended dosing schedule.
  - a. 5-15kg: were assumed to be taking half a tablet per dose
  - b. 15-25kg and 25-35kg: were assumed to be taking one tablet per dose
  - c. ≥35kg: were assumed to be taking 2 tablets per dose
- (f) The number of tablets in (e) plus six months of buffer stock.

### 7.4 Artesunate injection

Artesunate can also be used for severe treatment of malaria since it is able to rapidly reduce the parasite load. The administration of Artesunate injection (IM and IV) is easier compared to quinine and therefore easier to use in health facilities without the capacity for IV treatment.

#### 7.4.1 Treatment regimen

Artesunate is administered by the IM/IV route at 2.4 mg/kg to start, then 2.4 mg/ kg at 12 hours, 24 hours, and 48 hours. After that it is assumed all patients will be able to tolerate oral medicine.

#### 7.4.2: Methodology

Refer to 7.3.2 above.

#### 7.4.3 Results

**Table 9: Requirements of Artesunate 60mg/amp injection ampoules**

Artesunate 60mg injection							
Weight band category	Median weight	Projected number of severe malaria cases	Amps. per dose	Round off to nearest full amp	No. of amps per patient for treatment duration	Quantity of amps. required	Total Quantity required (including 6 months' buffer stock)
(a)	(b)	(c)	(d)		(e)	(f)	(g)
4-14 kgs	10	124,097	0.4	1	4	496,386	744,579
15-25 kgs	20	67,689	0.8	1	4	270,756	406,134
25-34 kgs	30	33,845	1.2	2	8	270,756	406,134
Above 35 kg	60	150,420	2.4	3	12	1,805,041	2,707,561
<b>Totals</b>		<b>376,050</b>					<b>4,264,409</b>

Footnotes for Table 9:

- (a) Patient category per weight band.
- (b) Median weight per weight category
- (c) Projected number of severe malaria cases computed from quinine injection consumption figures (Table 8, column d).
- (d) Number of ampoules per patient per dose computed as per the recommended dosing schedule.
- (e) Total number of ampoules required to treat a patient as per the recommended dosing schedule assuming that the patients are able to take oral medication after 48 hours.
- (f) (CxE) giving the total number of ampoules required.
- (g) Total country requirement after adding six months of Buffer stock

## 7.5 Rectal Artesunate

In the absence of quinine injection, the guidelines also recommend that rectal Artesunate can be used to initiate treatment in cases of severe malaria.

### 7.5.1 Treatment regimen

It is administered at a dose of 10mg/kg. A second dose may be given after 24 hours if the patient is unable to access parenteral therapy.

### 7.5.2: Methodology

Refer to 7.3.2 above.

### 7.5.3 Specific Assumptions

- The number of patients requiring pre-referral treatment are estimated by the DOMC at 50% of all severe malaria cases
- Rectal Artesunate capsules will be used for pre referral treatment in children under 25 kgs.
- The 50mg capsule will be used for 5-15kg patients while the 200mg capsule will be used for 15-25 kg patients.

- Each child will receive two doses of the rectal Artesunate.

## 7.5.4 Results

**Table 10: Requirements of rectal Artesunate for pre-referral care**

Weight band category (kg)	Median weight	Projected number of severe malaria cases	patients requiring pre-referral treatment	Capsules per dose	Number of doses	Total no. of capsules per patient	Total capsules required	6 months Buffer stock	Total Quantity required (including 6 months' buffer stock)
(a)	(b)	(c)	(d)	(e)		(f)	(g)		(h)
<b>50mg/cap formulation</b>									
5-15kg	10	124,097	62,048	2	2	4	248,193	124,097	372,290
<b>200mg/cap formulation</b>									
15-25kg	20	67,689	33,845	1	2	2	67,689	33,845	101,534

Footnotes for Table 10:

- (a) Refers to the various weight categories
- (b) Refers to the median weight for each weight category
- (c) Estimated number of severe malaria cases per weight category, computed from quinine injection consumption figures (Table 8, column d)
- (d) The number of patients requiring pre-referral treatment (estimated by the DOMC at 50% of all severe malaria cases).
- (e) Refers to the number of capsules required per dose for a patient within the weight category.
- (f) Refers to the total quantity of Artesunate capsules required per patient
- (g) The total country requirements per year.
- (h) The total country requirements after adding six months buffer stock.

## **8.0 MALARIA RAPID DIAGNOSTICS TESTS (RDTS)**

### **8.1 Specific assumptions**

- The diagnostic coverage in the country at baseline as at 2010 is 25% of which 20% is attributed to microscopy.
- Diagnostic coverage overall shall be increased from 25% to 80% from 2011 to 2016.
- Diagnostic coverage by microscopy over the next 6 years will increase from 20% to 35% due to human resource issues.
- RDTs shall be introduced for use at the community level in 2014 in Western and Nyanza provinces and, given the population targeted; the diagnostic coverage by RDT shall account for 1% in that year and shall expand to 5% in a period of 3 years.

### **8.2 Methodology**

The quantification for RDTs was based on the Global Fund Round 10 proposal developed by the DOMC.

The quantities required were determined by working backwards from AL consumption reports as data for fever statistics was not available from any of the health-related information systems.

As shown on Table 11 below: From a total of approx 17 million doses (obtained from the 2010/2011 quantification of AL), we worked back to establish the total number of malaria cases in the country seen in all sectors - public, private and mission facilities. This gave a figure of 21,786,493. The malaria cases were multiplied by two to approximate the total numbers of fevers expected.

Country targets for diagnostic coverage were set and the microscopy contribution to the total diagnostic coverage was also set. From this, the total number of RDTs required for the entire duration of the grant was computed to be 79,568,694. Of this total RDT need, PMI has pledged support for 5 million tests by 2014. In writing the proposal, the financial years (July-June) were used; therefore the first and last halves of 2011 and 2016 requirements were deducted, amounting to 11,950,539 tests. Private sector requirements of 10% were deducted from this arriving at a requirement of 56,356,339 tests to be procured under GF support.

### **8.3: Results**

**Table 11: RDT forecast & quantification**

<b>Parameter</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Total number of malaria cases</b>	21,786,493	22,970,784	21,350,961	23,364,839	24,019,054	24,691,588
<b>Total number of fever cases (calculated as no. of Malaria cases x 2)</b>	43,572,985	45,941,568	42,701,922	46,729,677	48,038,108	49,383,175
<b>Country target for diagnostic coverage (Baseline 25% in 2010)</b>	25%	40%	55%	60%	70%	80%
% diagnostic coverage by microscopy	20%	20.0%	25%	25%	35%	35%
% diagnostic coverage by RDT	5%	20%	30%	35%	35%	45%
% coverage of Public sector by RDTs	5%	20%	30%	34%	32%	40%
% coverage of community by RDTs				1%	3%	5%
<b>Total RDTs needed (tests)</b>	<b>2,178,649</b>	<b>9,188,314</b>	<b>12,810,577</b>	<b>16,355,387</b>	<b>16,813,338</b>	<b>22,222,429</b>

## 9.0 AL STOCK STATUS AND PROPOSED DELIVERY SCHEDULE FOR PERIOD JULY 2011 TO JUNE 2012

In order to ensure an uninterrupted supply of Artemether-Lumefantrine (AL) a situation analysis of the present stock and pipeline status was identified as one of the tasks to be carried out during the National F&Q exercise by the DSMSC. The specific objectives of this task were to:

- Identify the quantities of AL that are in the pipeline for the FY 2011/12
- Calculate the quantities of AL required for delivery and the various intervals (time periods) during which this should occur.
- Anticipate possible stock outs and calculate the quantities of AL required to fill the gap.

### 9.1 Assumptions

1. Minimum stock level at central level is 6 Months of Stock (MOS)
2. Maximum stock level at central level is 9 MOS
3. Annual requirements for the year 2011-12 based on consumption method of quantification were determined to be 14,997,045 **treatment doses** for uncomplicated malaria.

### 9.2 Results

**Table 12: Situational Analysis of AL as at 1st July 2011**

Product	No. of doses require in FY 11/12	AMC	SOH at KEMSA	Stocks on Order				Total stock on order (Pipeline)	MOS on order
				Balance treatment doses on order from PMI	AL stocks with UNICEF	Quantities from GFATM R 4 procurement			
						Novartis	Ajanta		
		(a)	(b)	(c)	(d)	(e)		(f)	(g)
AL 6s	<b>7,378,546</b>	409,919	0	1,440,000	79,380	5,988,876	0	7,508,256	18
AL 12s	<b>4,094,193</b>	227,455	0	480,000	99,120	2,851,186	0	3,430,306	15
AL 18s	<b>2,002,106</b>	111,228	0	215,520	0	0	1,243,250	1,458,770	13
AL 24s	<b>9,020,723</b>	501,151	0	936,000	0	0	6,498,058	7,434,058	15
<b>TOTAL</b>	xxx	1,249,754	0	<b>3,071,520</b>	<b>178,500</b>	<b>8,840,062</b>	<b>7,741,308</b>	19,831,390	

Footnotes for Table 12:

- (a) AMC – refers to the average monthly consumption for the country for each AL weight band as per the Antimalarial medicines requirements quantification report for FY 11/12
- (b) Refers to the Stock on hand at KEMSA at the end of June 2011, obtained by Physical count.
- (c) Refers to the quantity of AL on order from Novartis using PMI funding.
- (d) Refers to stock in UNICEF's possession that the DOMC has decided to distribute through KEMSA.
- (e) Refers to the balance of quantities yet to be called down of AL from the GFATM Round 4 Procurement.
- (f) Refers to the TOTAL stock on order (c) + (d) + (e)
- (g) Refers to the Months of Stock on order which is obtained by dividing (f) Total Stock on Order by (a) AMC

As shown in the table above, while there were no stocks of AL at central level on 1<sup>st</sup> July 2011, there was a total of 16 MOS on order from various sources. This consists of 3,071,520 doses ordered by PMI from Novartis and about 16.6 Million doses ordered from both Ajanta and Novartis through GFATM. Of the GFATM order quantity, only 50% has been called down, with the balance of 50% set to be ordered as required. The DMSC by taking into consideration the expected delivery dates, monthly consumption and optimum stock holdings at central level, worked out a delivery schedule during this quantification process as shown in Table 13 below. The schedules are worked out to maintain, as much as possible, a minimum of 6 MOS at any given time.

### 9.3 Delivery schedule of AL

**Table 13: Proposed call down schedule of AL from suppliers**

	PMI Novartis due in country by end Sept. 2011	GFATM 1st call down (50%) due in country as at end Aug. 2011	Balance on GFATM R4 P3 Tender as at Aug 2011	2nd call down (25%) to be in country by 1st Oct 2011	Balance on GFATM R4 P3 Tender as at Oct 2011	3rd call down (25%) to be in country by Jan 31st 2012	MOS as at end April 2012
AL 6s	1,440,000	2,994,438	2,994,438	1,497,219	1,497,219	1,497,219	8
AL 12s	480,000	1,425,593	1,425,593	712,797	712,797	712,797	5
AL 18s	215,520	621,625	621,625	310,813	310,813	310,813	3
AL 24s	936,000	3,249,029	3,249,029	1,624,515	1,624,515	1,624,515	5
<b>TOTAL</b>	<b>3,071,520</b>	<b>8,290,685</b>	<b>8,290,685</b>	<b>4,145,343</b>	<b>4,145,343</b>	<b>4,145,343</b>	<b>6</b>



Notes for Figure 5:

- (a) The period that the AL under the AMFm Y1 will be consumed. The red part shows the time the stock level will be below the recommended minimum, and therefore alternative funding will be required to fill the pipeline.
- (b) The period of time required to complete the GF AMFm Y2 procurement.
- (c) The procurement period for GF R10 Year 1.
- (d) The required supplemental procurement to start in January 2012, so that products are in country by end of May 2012.

## 10.0 FIVE YEAR FORECAST OF AL REQUIREMENTS (FY 2011 - 2016)

### 10.1 Background:

The Drug Supply Management subcommittee carried out a five year country forecast for AL for the period 2011 to 2016. This strategic information, adapted from the GF Round 10 proposal, was useful for advising the DOMC and partners on the anticipated country requirements for AL the FY 2011 to 2016.

### 10.2 Forecasting objectives

- To maintain adequate stock of AL at both central and facility levels
- To ensure timely procurement
- To ensure flexibility in procurement planning
- To provide information to partners
- To advocate for funding for any gaps that may be identified

### 10.3 Results

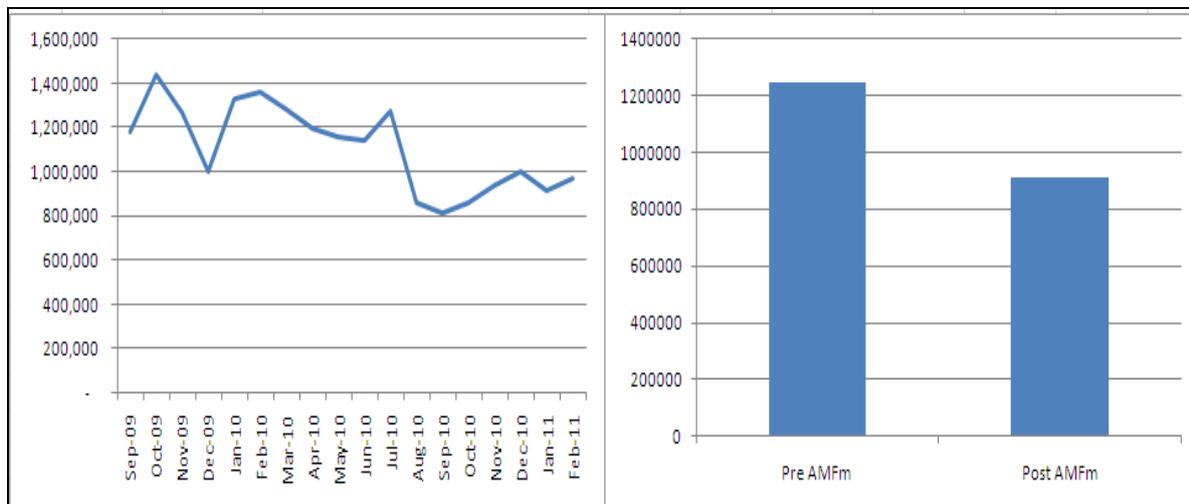
Table 14, below, adapted from the Global Fund Round 10 proposal, shows the computation of the total AL requirements over the next 5 years through to 2016 (*see detailed computation in Appendix 2*).

**Table 14: Forecast of AL requirements from 2011- 2016**

AL	Weight band	Ratio	2011	2012	2013	2014	2015	2016
AL 6s	5-14 kg	32.80%	5,565,611	5,485,056	4,567,838	4,407,770	4,251,868	3,956,161
AL 12s	15-25 kg	18.20%	3,088,235	3,043,537	2,534,593	2,445,775	2,359,268	2,195,187
AL 18s	25-34 kg	8.90%	1,510,181	1,488,323	1,239,444	1,196,011	1,153,708	1,073,470
AL 24s	35+kg	40.10%	6,804,299	6,705,815	5,584,461	5,388,767	5,198,167	4,836,648
<b>Total</b>			<b>16,968,326</b>	<b>16,722,731</b>	<b>13,926,336</b>	<b>13,438,322</b>	<b>12,963,011</b>	<b>12,061,466</b>

The five year forecast computed in the last financial year predicts a reduction of AL requirements from 17,606,564 in 2010/2011 to 16,968,326 in the year 2011/2012. At the time of writing the GFATM proposal, the LMIS data indeed showed this to be the annual requirements. However, when LMIS data is analysed during the AMFm pilot period, it shows a larger decline in the requirement of the product, to 14,997,045, probably as a result of the overwhelming uptake of AL by the private sector, ordering a cumulative total of 12 million doses, under the AMFm, in the period between July 2010 and February 2011 as shown in the figure 6 below. Figure 6 shows the decline in the number of patients seeking care in public facilities before and after the start of the AMFm initiative.

**Figure 6: Aggregated number of patients seen in the public sector before and after AMFm Initiative.**



There has also been a slight uptake of diagnostics in the treatment of malaria, with data from the Quality of Care survey showing an increase in percentage of fever cases tested as per the guidelines from 23.9% in January 2010 to 30.9% in December 2011

We expect to see similar reduction in the consumption of AL in the public sector as we increase coverage with other malaria interventions, including mass net distributions and IRS.

## 11.0 GAP ANALYSIS FOR ANTIMALARIAL COMMODITIES REQUIREMENTS FOR FY 2011/2012

*Table 15: Summary requirements for antimalarial commodities for FY 2011/2012*

Product	Unit	Requirement	Stock at hand on 31st June 2011	Net requirement	Available from PMI/USAID	Available from GFATM	Available from GOK	Gap in Quantity	Unit price in Ksh	TOTAL FUNDING GAP (Ksh.)
A	B	C	D	E	F	G	H	J	K	L
AL 6's	Pack of 6's	7,378,546	0	7,378,546	1,440,000	5988876	0	(50,330)	39.537	0
AL 12's	Pack of 12's	4,094,193	0	4,094,193	480000	2851186	0	763,007	73.287	55,918,515
AL18's	Pack of 18's	2,002,106	0	2,002,106	215,520	1243250	0	543,336	118.287	64,269,527
AL 24's	Pack of 24's	9,020,723	0	9,020,723	936,000	6498058	0	1,586,665	127.386	202,118,853
Quinine Dihydrochloride Injection	Amps	4,439,272	1,047,543	3,391,729	0	0	2,736,100	655,629	51.174	33,551,158
Qunine sulphate 200 mg	Tabs	8,359,596	7,712,000	647,596	0	0	20,895,000	(20,247,404)	2.844	0
Sulphadoxine/Pyrimethamine	Tin of 1000s	5,451,000	39,375,000	(33,924,000)	0	0		(33,924,000)	1400	0
Dihydroartemesinin/Piperaquine 160 mg	Tabs	7,004,438	0	7,004,438	0	0	0	7,004,438	58.311	408,435,784
Dihydroartemesinin/Piperaquine 320 mg	Tabs	12,030,001	0	12,030,001	0	0	0	12,030,001	58.311	701,481,388
Artesunate rectal caps 50 mg	caps	372,290	0	372,290	0	0	0	372,290	33.597	12,507,827
Artesunate rectal caps 200mg	caps	101,534	0	101,534	0	0	0	101,534	62.550	6,350,952
Artesunate injection	60mg vials	4,264,409	6,120	4,258,289	0	0	0	4,258,289	93.000	396,020,877
Rapid Diagnostic Tests	Tests	2,178,649	966,405	1,212,244	0	0	0	1,212,244	1.499	1,817,154

## 12.0 RECOMMENDATIONS

### Recommendations for the DOMC

#### Immediate

- Based on the proposed call down schedules, initiate the call-down of 25% of GF AMFm Year 1 quantities immediately to ensure the products are in-country by 1<sup>st</sup> October 2011.
- Initiate, as soon as possible, the procurement of AL under GF AMFm Y2 so that the products arrive in-country no later than September 2012.
- Based on the fact that KEMSA is overstocked with Sulphadoxine/Pyrimethamine (SP) tablets, the DOMC should communicate with KEMSA, via the Department of Pharmacy, to ensure that no further SP is procured for the public sector for the present financial year.
- Continue to monitor the stock situation on a monthly basis to enable prompt response to emerging issues.

#### Medium term

- There should be a fallback plan to allow for direct procurement of antimalarials, when delays in the regular procurement process are eminent.
- Funding for the procurement of first line antimalarials is currently entirely provided by donors. The government of Kenya should set aside funds to purchase these commodities, in the absence of donor funding.
- There should be regular monitoring of the procurement process as well as management of the contracts.
- Quantification for malaria medicines is a multiple step exercise that requires advance planning to assure the achievement of all set objectives. Close monitoring of the timelines, activities and responsibilities outlined in the *Modus Operandi to guide annual Quantification of malaria medicines, 2008* should be closely adhered to in order to allow for timely and valid estimates of country requirements.
- The Drug Supply Management Sub-Committee should continue to play their role in the facilitation of all urgent and system issues that are within their scope of responsibilities to improve management of malaria medicines.
- The supportive supervision role of health facilities by District Pharmaceutical Facilitators and Malaria focal persons should be strengthened to allow for improved inventory

management and continuous flow of timely and accurate consumption data for decision making.

- The Logistics Management Information system for malaria medicines should be strengthened to ensure increased reporting rates as well as improved data quality.
- Findings from the Bi-annual Pharmaceutical Management of Malaria Medicines assessments/ Quality of care surveys that seek to establish the status of pharmaceutical indicators should be utilised to provide input into the annual quantification exercise.
- Continuous monitoring of the stock situation in the country is a key to timely identification and stop gaps intervention as well improving access to treatment for malaria.
- Annual review of the procurement process is important in identifying bottlenecks that may result in interrupted flow of antimalarial medicines.

### **13.0 LIMITATIONS OF THE QUANTIFICATION PROCESS**

- The Drug Supply Management Subcommittee used consumption data for quantification of country needs of antimalarials. However, the committee acknowledges that there were some weaknesses in the data available and a lot of work still needs to be done to improve the quality of the reports we receive under the LMIS.
- The DSMSC also acknowledge that the reporting rates from facilities need to increase in order that the quantification gives more precise reports. The committee is working with all the relevant stakeholders to ensure measures are put in place to realise improved data quality and reporting rates.

## 14.0 REFERENCES

- 1) Division of Malaria Control/Ministry of Public Health & Sanitation, Kenya. 2009. *National Malaria Strategy, 2010–2017*. Nairobi: DOMC/MOPHS, Kenya.
- 2) MOMS & MOPHS. 2010. *National Guidelines for Diagnosis, Treatment and Prevention of Malaria in Kenya*. Nairobi: DOMC/MOPHS, Kenya.
- 3) DOMC/MoPHS, KNBS & NCAPD. 2009. *2007 Kenya Malaria Indicator Survey*. Nairobi: DOMC/MOPHS, Kenya.
- 4) Central Bureau of Statistics (CBS) [Kenya], Ministry of Health (MOH) [Kenya], and ORC Macro. 2004. *Kenya Demographic and Health Survey 2003*. Calverton, Maryland: CBS, MOH, and ORC Macro.
- 5) Dondorp AM, Fanello CI, Hendriksen IC, Gomes E, Seni A, et al, Artesunate versus quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomised trial. *Lancet*. 2010 Nov 13; 376(9753):1647-57. E pub 2010 Nov 7.
- 6) Division of Malaria Control/Ministry of Public Health & Sanitation, Kenya. 2008. *A Modus Operandi for the Annual National Quantification of Antimalarial Medicines in Kenya*. Nairobi: Division of Malaria Control
- 7) Management Sciences for Health & the World Health Organization. 1997. “Quantifying Drug Requirements” in *Managing Drug Supply: The Selection, Procurement, Distribution and Use of Pharmaceuticals*. 2nd Edition, 1997. West Hartford, CT: Kumarian Press, Inc.
- 8) Management Sciences for Health & the World Health Organization. 2007. *International Drug Price Indicator Guide*. 2010 edition. Cambridge, MA: Management Sciences for Health.
- 9) Amin, A., Tetteh, G., et al. 2007. *Quantification of Artemether Lumefantrine and other antimalarial medicines for Year 2 of ACT Policy implementation in Kenya*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health
- 10) Division of Malaria Control/Ministry of Public Health & Sanitation, Kenya. 2008. *Antimalarial Medicine Requirements for July 2008- June 2009: Report of the Drug Supply Management Sub-committee*. Nairobi: DOMC/MOPHS, Kenya.
- 11) Division of Malaria Control/Ministry of Public Health & Sanitation, Kenya. 2009. *Antimalarial Medicine requirements for July 2009 - June 2010: Report of the Drug supply Management sub-committee*. Nairobi: DOMC/MOPHS, Kenya.

- 12) Division of Malaria Control/Ministry of Public Health & Sanitation, Kenya. 2010.  
*Antimalarial Medicine and diagnostics Requirements for July 2010 – June 2011: Report of the Drug Supply Management Sub-Committee.* Nairobi: Division of Malaria Control/MOPHS, Kenya.
- 13) Memusi, D. et al. 2010. *Monitoring outpatient malaria case management under the 2010 diagnostic and treatment policy in Kenya - baseline results.* Nairobi: Division of Malaria Control, Ministry of Public Health and Sanitation. June 2010.



## Appendix 2: Detailed AL Gap analysis and forecast for 2011-2016

	2011	2012	2013	2014	2015	2016
Consumption data (a)	18,248,515	18,759,474	19,284,739	19,824,712	20,379,804	20,950,438
Total number of malaria cases extrapolated from consumption data (b)	37,241,868	38,284,640	39,356,610	40,458,595	41,591,436	42,755,996
Target coverage						
National target coverage of malaria cases % (c)	65.0%	75.0%	77.5%	82.5%	82.5%	82.5%
Target coverage by sector (d-f)						
Health Facility	54	60	60	65	65	65
Community Case Management	1	5	7.5	7.5	7.5	7.5
Private Sector	10	10	10	10	10	10
Number of treatments required (g)						
Health Facility	20,110,609	22,970,784	23,613,966	26,298,087	27,034,433	27,791,397
Community Case Management	372,419	1,914,232	2,951,746	3,034,395	3,119,358	3,206,700
Private Sector	3,724,187	3,828,464	3,935,661	4,045,860	4,159,144	4,275,600
Total	24,207,214	28,713,480	30,501,373	33,378,341	34,312,935	35,273,697
Factor in decreasing consumption with vector control (h)	10%	20%	30%	30%	30%	30%
No of malaria cases reduced with vector control	2,420,721	5,742,696	9,150,412	10,013,502	10,293,880	10,582,109
Total Number of treatment after subtracting number reduced vector control	21,786,493	22,970,784	21,350,961	23,364,839	24,019,054	24,691,588
Factor in decreasing consumption with increasing diagnosis (i)						
Percentage diagnosis	25%	30%	45%	60%	70%	80%
Percentage positive tests (.5)	50%	50%	50%	50%	50%	50%
Correcting for compliance	50%	60%	70%	90%	90%	95%
No of malaria cases reduced with increasing diagnosis	1,361,656	2,067,371	3,362,776	6,308,506	7,566,002	9,382,803
Total Number of treatment after subtracting number reduced due to increasing diagnosis	20,424,837	20,903,414	17,988,185	17,056,332	16,453,052	15,308,784
Proportion of malaria cases by sector (j)						
Health Facility	83%	80%	77%	79%	79%	79%
Community Case Management	2%	7%	10%	9%	9%	9%
Private Sector	15%	13%	13%	12%	12%	12%
Number of malaria cases by sector						
Health Facility	16,968,326	16,722,731	13,926,336	13,438,322	12,963,011	12,061,466
Community Case Management	314,228	1,393,561	1,740,792	1,550,576	1,495,732	1,391,708
Private Sector	3,142,283	2,787,122	2,321,056	2,067,434	1,994,309	1,855,610

**ASSUMPTION A:** The consumption data was obtained from LMIS data from June 2009 to April 2010. The figures obtained were extrapolated for 12 months, corrected for % reporting rate and stock out periods

**ASSUMPTION B:** Data from the KDHS 2010 indicate that 48.6% of the population access health services through the public health sector, hence % health facility coverage data extrapolated to 100% population coverage

**ASSUMPTION C:** This is the proportion of malaria cases that are treated with ACTs as aligned with the National Malaria Strategy 2009-2017

**ASSUMPTION D:** This is the proportional contribution to access from each sector. Currently, there are no ACTs at the community and private sector. The current 48:6% coverage by the public sector is to be increased 65% by 2014.

**ASSUMPTION G:** This was derived by multiplying the total number of malaria cases by the % coverage expected for each sector

**ASSUMPTION H:** With Universal coverage to be attained the assumption of 10%, 20% and 30% reduction in malaria cases has been applied from the year following universal coverage

**ASSUMPTION I:** For each percentage coverage of fevers to be diagnosed, it is expected that there will be a 50% reduction in presumptive diagnosis of malaria. This is being triangulated with the anticipated level of compliance to the RDT result.