Republic of Kenya

**Ministry of Public Health and Sanitation
and
Ministry of Medical Services, Kenya**

**Antimalarial Medicine Requirements for July 2009–June 2010:
Report of the Drug Supply Management Sub-Committee of the
Division of Malaria Control**

July 2009

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The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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ACRONYMS AND ABBREVIATIONS

AL	artemether-lumefantrine
AMC	average monthly consumption
DOMC	Division of Malaria Control
DPTWG	Drug Policy Technical Working Group
DSMSC	Drug Supply Management Sub-Committee
FY	fiscal year
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
IPTp	intermittent preventive treatment in pregnancy
JSI	John Snow, Incorporated
KEMSA	Kenya Medical Supplies Agency
KES	Kenya shillings
KNBS	Kenya National Bureau of Statistics
LMIS	logistics management information system
MEDS	Mission for Essential Drugs and Supplies
MOS	months of stock
MSH	Management Sciences for Health
NMS	National Malaria Strategy
OPD	outpatient department
PMI	President's Malaria Initiative
PSCMC	Procurement and Supply Chain Management Consortium
SP	sulfadoxine-pyrimethamine
SOH	stock on hand
SPS	Strengthening Pharmaceutical Systems Program
USAID	U.S. Agency for International Development

ACKNOWLEDGMENTS

EXECUTIVE SUMMARY

Over the past few years, the Division of Malaria Control (DOMC), in collaboration with partners, has been carrying out an annual quantification exercise to establish Kenya's antimalarial medicine requirements. The Drug Supply Management Sub-Committee (DSMSC) of the Drug Policy Technical Working Group of the DOMC spearheads this activity. One of the key functions of the DSMSC is to advise the DOMC on commodity security and supply chain–related issues for antimalarial medicines.

In line with the *Modus Operandi for the Annual National Quantification of Antimalarial Medicines in Kenya* (DOMC 2008), developed to guide the process of annual quantification and following the successful national quantification for malaria medicines for fiscal year (FY) 2008/09, the DOMC organized a one-day quantification workshop on June 23, 2009. Using funding made available through the President's Malaria Initiative (PMI) and the U.S. Agency for International Development (USAID), Management Sciences for Health/Strengthening Pharmaceutical Systems Program (MSH/SPS) hosted the meeting. Attendees included members of the DSMSC from the DOMC, the Kenya Medical Supplies Agency (KEMSA), the Mission for Essential Drugs and Supplies (MEDS), John Snow, Inc./Procurement and Supply Chain Management Consortium (JSI/PSCMC), and MSH/SPS.

The main objective of the workshop was to determine the national antimalarial medicine needs for FY 2009/10.

Despite attempts made to improve the accuracy of the quantification exercise (July 2008), lack of sufficient and accurate consumption data coupled with the generally low facility reporting rates made it difficult to use the consumption method for the quantification. The DSMSC therefore decided to use the morbidity method for quantification of artemether-lumefantrine (AL) and all other antimalarial medicines for FY 09/10.

Key Results

- The total quantity of AL treatments required for FY 2008/09 is 27,237,339.

- The quantification and situational analysis of AL requirements revealed that according to the stock status at end-June 2009 and expected delivery schedules for ongoing procurement, stock-outs of AL may occur at the central level by the end of October 2009.

- The total quantity of sulfadoxine-pyrimethamine (SP) required for the provision of intermittent preventive treatment in pregnancy (IPTp) is 5,713,000 tablets.

- The total quantity of malaria medicines required for treatment of severe malaria is quinine dihydrochloride ampoules (600 mg) 12,172,508 vials and 30,758,505 quinine sulfate tablets (200 mg).

- The total quantity of artemether required for prereferral treatment in epidemic-prone areas is 590,356 and 868,368 for the 40 mg/ml and 80 mg/ml formulations, respectively.

- The total quantity of artesunate 60 mg injection required is 2,573,809 ampoules.

- The total quantity of rectal artesunate required for prereferral treatment in epidemic-prone areas is 399,847 and 95,254 capsules for the 50 mg per capsule and 200 mg per capsule preparations, respectively. *x*

Key Conclusions and Recommendations

Timely procurement of required antimalarial medicines in adequate quantities (annual requirements and buffer stock) 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 an emergency procurement of AL formulations according to the quantification procurement plan to avert anticipated stock-outs of AL in early November 2009.

BACKGROUND

Malaria remains one of Kenya's key public health concerns and is a leading cause of morbidity and mortality in the country. The total at-risk population for malaria based on 2009 population projections[1] is approximately 27.6 million, or 70 percent of the population (MoH 2008). This figure includes an estimated 4,633,075 children under five years of age and 1,241,833 pregnant women who bear the brunt of the disease. Clinically diagnosed malaria is responsible for 30 percent of outpatient consultations, 19 percent of hospital admissions, and 3 to 5 percent of inpatient deaths. In 2007, 9.2 million clinically diagnosed malaria cases were reported across health facilities in the country (MoH 2007).

In 2004, Kenya adopted a new artemisinin-based combination therapy policy with 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 DSMSC of the DPTWG 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* (MoH 2006).

One of the key strategic interventions of the DOMC as outlined in the National Malaria Strategy: 2000–2010 (NMS) is to provide early diagnosis and prompt treatment of malaria using effective medicines. An uninterrupted supply of antimalarial medicines is beneficial in increasing access to treatment for those at risk of malaria. In an effort to ensure continuous availability of malaria medicines, the DOMC, in collaboration with partners, has carried out three quantification exercises for the periods July 2006–June 2007, July 2007–June 2008, and July 2008–June 2009, using different quantification approaches. Although the consumption method of quantification is most suited for estimating country requirements, the DOMC has faced challenges in obtaining consumption data caused by 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. However, from June 2009, the DOMC instituted an LMIS system that will provide consumption data for future quantification and forecasting exercises.

In June 2009, the DOMC in collaboration with partners from MSH/SPS, KEMSA, MEDS, and JSI/PSCMS carried out a national quantification exercise to determine the national antimalarial medicine requirements for FY 09/10. This activity was supported by MSH/SPS using PMI/USAID funds.

The key objectives of the exercise were to—

- Carry out a national quantification exercise to estimate antimalarial medicine needs for the procurement cycle July 2009–June 2010

- Forecast AL medicine requirements for five years (2009–2014)

- Carry out a situational analysis for AL stock status and develop a delivery schedule for the expected procurement

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[1] Kenya National Bureau of Statistics, 2008. Population projections made from the 1999 census, Central Bureau of Statistics. 1994. Kenya population census, 1989, Vol. 1. Nairobi: Central Bureau of Statistics, Kenya Ministry of Planning and National Development.

INTRODUCTION

Scope

This quantification exercise was conducted for the Kenya public health sector and covered the period July 2009–June 2010. The commodities quantified follow the *National Guidelines for Diagnosis, Treatment and Prevention of Malaria for Health Workers in Kenya* (MoH 2006). Five different conditions with specific recommendations for treatment were identified and used for the purposes of quantification in a process guided by *A Modus Operandi for the Annual National Quantification of Antimalarial Medicines in Kenya* (DOMC 2008).

Malaria Standard Treatment Guidelines

Table 1 provides the breakdown for each specific condition along with the associated treatment regimens.

Table 1. Malaria Standard Treatment Guidelines

Condition	Treatment	Dosage
Uncomplicated malaria	Artemether + lumefantrine 20 mg/120 mg 5–14kg (6 tabs)	Taken two times a day for three days at 0, 8, 24, 48, 60, and 72 hours
	Artemether + lumefantrine 20 mg/120 mg 15–24kg (12 tabs)	
	Artemether + lumefantrine 20 mg/120 mg 25–34kg (18 tabs)	
	Artemether + lumefantrine 20 mg/120 mg > 35 kg (24 tabs)	
Severe (complicated) malaria	*Quinine (adults)*	600 mg every 8 hours for 7 days
	Quinine dihydrochloride amp 300 mg/ml	
	Quinine sulphate300 mg	
	Quinine (children)	10 mg/kg body weight every 8 hours for 7 days
	Quinine dihydrochloride amp 300 mg/ml	
	Quinine Sulphate 300 mg	
	Artemether (adults)	3.2 mg/kg to start, then 1.6 mg/kg daily for another 6 days
	Artemether 80 mg amp	
	Artemether (children)	
	Artemether 40 mg amp	
	Artesunate (all age groups)	2.4 mg/kg to start, then at 12 hours and daily for 6 days
	Artesunate 60 mg amp	

QUANTIFICATION OF ANTIMALARIAL MEDICINES

Determining 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, and the resources available for conducting the exercise. Table 2 provides a comparison of quantification methods by use, data, limitations, and assumptions.

Table 2. Comparison of Quantification Methods

Method	Essential Data	Situational Analysis for Kenya
Consumption	• Reliable inventory records • Records of supplier lead time • Projected medicine costs	• Consumption data for FY 08/09 is neither complete nor accurate. • Use of consumption data may perpetuate irrational use. The Kenya malaria treatment policy recommends presumptive treatment where use of diagnostics is not possible.
Morbidity	• Data on population and patient attendances • Actual or projected incidence of health problems • Standard treatments (ideal, actual) • Projected medicine costs	• Morbidity data on malaria are available; however, reporting rates are low. • Morbidity data provide information on confirmed and clinical malaria cases only. • Malaria standard treatment guidelines are available, and health workers have been trained on them.
Adjusted Consumption	• Comparison area or system with good per capita data on consumption, patient attendances, service level, and morbidity • Number of local health facilities by category • Estimation of local user population broken down by age	Comparability of patient populations, morbidity, treatment patterns and health-seeking behavior practices is questionable.

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

Selection of Morbidity-Based Methodology

Both technical and programmatic issues are considered when selecting quantification methodology. Before the quantification workshop, all possible data sources for the different quantification methods were assessed, including LMIS reports for July 2008–June 2009. This assessment revealed a lack of accurate, complete, and sufficient consumption data for antimalarial medicines at health facilities coupled with low health facility reporting rates. A decision was made to use morbidity methodology to estimate needs for antimalarial medicines needs based on data available. Demographic information on the estimated number of pregnant women and children under five was also used to complete the antimalarial medicines forecast.

Commodity needs were estimated based on the application of the malaria standard treatment guidelines to the projected number of malaria cases within the forecast period.

To do these calculations and complete the quantification with the most reliable and accurate information available, forecasters required the following data elements—

- Annual projected population for FY09 and FY10

- Proportion of the population at risk for malaria

- Estimated total number of malaria cases for the year

- Estimated number of cases to be diagnosed and treated for various conditions, including uncomplicated or severe malaria, malaria in pregnancy, prereferral treatment, and IPTp within the forecast period (per malaria treatment guidelines, table 1)

- Estimated number of pregnant women who will receive IPTp for malaria

In addition to the demographic data on various population groups (pregnant women, children under five, and adults), the process required use of informed assumptions (see section on Assumptions below) to arrive at the estimated number of cases to be treated with antimalarial medicines.

Quantification Elements and Parameters

Table 3 outlines the elements and parameters used in the quantification.

Table 3. Overview of Quantification Elements and Parameters

Elements Borrowed from Quantimed Database Used in Quantification	Parameter Details
Quantification method	• Morbidity-based quantification
Established list of medicines	• National Malaria Strategy and Malaria Treatment Guidelines used to provide information on antimalarial medicines in use in Kenya
Established cost parameters, currency codes, currency exchange rates, and price types (several sources)	• International pricing index guidelines • Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) prices • Ministry of Public Health and Sanitation • Open international tender FY08/09 prices
Established health conditions	• Complicated malaria • Uncomplicated malaria • Malaria in pregnancy
Regimens and percentages established for each health condition	• Based on Kenya Malaria Treatment Guidelines 2008 and agreed assumptions
Morbidity-based estimates	• Based on interviews with the DOMC and different stakeholders during the assumption building process
Quantification reports	• Type of antimalarials, estimated requirements, and value

Once the national target for total numbers of treatments cases was established, specific treatment regimens were assigned to uncomplicated and complicated malaria conditions. All the requisite information collected was entered into Excel spreadsheets along with the assumptions on the expected number of patients for the forecast period and the breakdown of patients by regimens.

Assumptions

One of the main objectives of conducting a quantification exercise is to produce an adequate and rational procurement plan to ensure commodities are available and appropriately managed. During the quantification exercise, the DMSCM discussed general and specific assumptions that would guide the process. These are outlined below in the following subsections.

General Assumptions

- Projected population for 2009 is 39,423,268 and for 2010 is 40,406,411 (Kenya National Bureau of Statistics [KNBS] 2008).

- About 70 percent of the Kenyan population is at risk of malaria (NMS 2009–17).

- Of all malaria cases, 50 percent are expected to seek care in peripheral health facilities (health centers and dispensaries) and the other 50 percent in hospitals (DOMC estimates).

- Projected population growth rate is 2.5 percent (KNBS 2008).

- Since 80 percent universal coverage with insecticide-treated nets and indoor residual spraying has not been achieved, no reduction in malaria caseload is anticipated (DOMC).

- Annual increase in malaria episodes per 1,000 population is 8 percent, taking into consideration 2006 and 2007 health management information system reported uncomplicated malaria cases.

- The number of malaria episodes per 1,000 population in 2007 was 347. Thus, for 2008 the estimated incidence of malaria is expected to be 374.76 episodes per 1,000.

- On average, data obtained from the four DOMC sentinel sites shows that outpatient department (OPD) attendances in public health facilities comprise the following age groups—
  - < 3years   6.5 percent
  - 3–9 years   17.2 percent
  - 9–11 years 7.5 percent
  - 14 years   39.2 percent

Adherence to and Application of Standard Treatment Guidelines

- Current treatment guidelines remain unchanged for the quantification period and are consistently applied for first-line treatment of malaria, IPTp, prereferral, and severe malaria treatment.

- One hundred percent of malaria cases will be given first-line treatment.

- Each malaria episode is treated with one dose of AL corresponding to the patient's weight.

- The contents of each ampoule of quinine 600 mg artesunate injection and artemether injection are assumed to be discarded after treating each patient.

Supply Chain Assumptions

- AL is packaged according to four different weight bands.
- The minimum stock level at the central level is six months of stock (MOS).
- The maximum stock level at central level is nine MOS.

Malaria in Pregnancy

Many pregnant women in their first trimester will be unaware of their pregnancy. It has therefore been assumed that this group of women will most likely present as outpatients in the general OPD and will be treated with AL.

QUANTIFICATION OF ARTEMETHER-LUMEFANTRINE

Treatment Regimen

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

Specific Assumptions

The malaria episodes per 1,000 population were projected to be 8 percent; this percentage was then applied to the projected annual population figures for 2009 and 2010. This calculation results calendar year estimates of total malaria episodes as 14,774264 and 16,354,123, respectively. For the period, the average number of cases is (14,774,264 + 16,354,123) / 2 = 15,564,194.

Table 4. Projected Malaria Episodes, 2009 and 2010

Year	2009	2010
Projected annual population based on 1999 census (KNBS 2008)	39,423,268	40,406,411
Episodes per 1,000 population extrapolated by 8 percent	374.76	404.7408
Projected malaria cases (2009)	14,774,264	16,354,123

To determine the quantities of AL required for July 2009–June 2010, the average of the estimated annual quantities required for FY 09 and FY 10 was calculated as 15,564,194 treatment doses.

Average Monthly Consumption (AMC) = (15,564,194 / 12) = 1,297,016 treatment doses. (AMC is used to calculate the amount of buffer stock required as follows: Buffer stock = AMC $\times$ maximum MOS.)

Table 5. Projected Doses of AL per Weight Band Including Buffer Stock

Weight band (kg) (a)	Percentage (b)	Malaria Cases for FY 09/10 Adjusted for Age Groups (c)	Estimated Number of First-Line Treatments (d)	Buffer Stock (9 MOS) (e)	Estimated Annual Requirements for FY 09/10 (f)	Stock on Hand End-June 2009 (g)	Quantity to Order (h)
5–14	36	5,618,674	5,618,674	4,214,005	9,832,679	1,119,655	8,618,499
15–24	17	2,677,041	2,677,041	2,007,781	4,684,822	999,017	3,773,968
25–34	8	1,167,315	1,167,315	875,486	2,042,801	396,424	1,540,591
35+	39	6,101,164	6,101,164	4,575,873	10,677,037	2,501,868	7,999,817
Total	**100**	**15,564,194**	**15,564,194**	**11,673,145**	**27,237,339**	**5,294,464**	**21,932,875**

a. AL weight bands.
b. On average, data obtained from the four DOMC sentinel sites show that of all OPD attendances in public health facilities comprise the following age groups: < 3years, 36.5 percent; 3–9 years, 17.2 percent; 9–11 years, 7.5 percent;14 years, 39.2 percent.
c. Calculated as the average of the estimated annual quantities required for FY 09 and FY 10.
d. Assumes that all cases presenting for malaria will receive AL treatment doses.
e. Buffer stock at central level is calculated by multiplying AMC of AL by nine months.
f. The sum of columns (d) and (e).
g. Physical stock count of all AL at central level (KEMSA and MEDS) as of June 30, 2009.
h. Difference between columns (f) and (g).

Total number of AL treatments required for FY 09/10 including buffer stock is 27,237,339 treatments. However, considering stock on hand (SOH) to be 5 million doses, the amount to order will be 21,982,875.

QUANTIFICATION OF SULFADOXINE-PYRIMETHAMINE

Treatment Regimen

The current recommended medicine for IPTp is SP tablets (500 mg sulfadoxine + 25 mg pyrimethamine) given as a dose of three tablets upon presentation to a prenatal clinic. Thereafter, SP 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.

Specific Assumptions

- The projected population of pregnant women at risk of malaria and living in endemic zones is 453,376 (NMS 2009–2017).

- Procured SP quantities will be distributed by KEMSA for use by pregnant women living in endemic malaria zones.

- The quantification considers all expected pregnancies in areas of high transmission regardless of the current prenatal care attendance because advocacy and information, education, and communication activities will be scaled up to encourage women to attend prenatal care.

- Each pregnant woman will receive a total of four doses a month apart after quickening (MoH 2008).

- 60 percent of patients seek health services from public health facilities (DOMC 2007).

To determine the quantities of SP required for July 2009–June 2010—

1. *Determination of number of pregnant women living in endemic areas*
   The revised NMS (2009–17) estimates a total of 453,376 pregnant women living in endemic areas.

2. *Determination of the projected number of pregnant women seeking health services from public health facilities*
   (60 percent × 453,376) = 272,026 pregnant women

3. *The National Malaria Treatment Policy* targets at least three to four doses of SP (IPT4) to be given to pregnant women during attendance at prenatal clinics in endemic areas. The DMSCM used four doses for computation: 272,026 × 3 × 4 = 3,264,312 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 3,265 tins.

5. The buffer stock at central level is equivalent to nine MOS. This is obtained by multiplying the AMC by 9 months: AMC = 272 tins; therefore, buffer stock = 272×9 = 2,448 tins. Hence, total requirements = (3,265 + 2,448) tins.

The total requirements for SP for FY 09–10 is 5,713 tins.

QUANTIFICATION FOR SEVERE MALARIA

The DSMSC quantified needs for severe malaria treatment in endemic and epidemic zones separately because of the apparent differences in the presentation of severe malaria in these two strata. KEMSA routinely procures malaria medicines for treatment of severe malaria in the public health system. These medicines are—

- Quinine dihydrochloride injection
- Quinine tablets

Artemether/artesunate injection is quantified as an option for prereferral treatment in response to epidemics, when partners or the government makes funds available. In the absence of such funds, all severe malaria cases in the country are treated using quinine. Therefore, the amount of quinine determined under this quantification exercise will be enough to treat all cases, regardless of the availability of the other artemesinin-based parenteral medications.

Treatment of Severe Malaria with Quinine Injection or Tablets

In children, parenteral quinine is given as an infusion with a loading dose of 15 mg (salt)/kg and then followed by a maintenance dose of 10 mg/kg every 12 hours until the patient can tolerate oral medication. In adults, a loading dose of 20 mg per kg is given followed by a maintenance dose of 10 mg/kg (maximum 600 mg) every 8 hours.

Table 6 shows the amounts of quinine required to treat patients, based on the following assumptions—

- The number of treatment failures will be 5 percent of uncomplicated cases, given 95 percent efficacy of AL.

- The time needed on parenteral treatment until patients can tolerate oral feeding is three days.

- All patients proceed to take quinine tablets in the continuation phase.

Table 6. Estimated Number of Cases of Severe Malaria in Epidemic-Prone and Non-Epidemic-Prone Areas

Malaria-Epidemic Zones	Projected Population (a)	Projected Malaria Cases (b)	Uncomplicated Malaria Cases (c)	Severe Malaria Cases at First Presentation (d)	Severe Malaria Cases Caused by AL Treatment Failure (e)	Total Severe Malaria Cases
Epidemic zone	9,239,323	683,709	136,742	546,967	6837	553,804
Non-epidemic zone	18,078,494	6,775,097	6,775,097	0	338,755	338,755
Total						**892,559**

a. Projected total population at risk of malaria.
b. For epidemic-prone areas, malaria cases are computed using the parasite prevalence of 7.4 percent (based on the Malaria Indicator Survey 2007) assuming a single episode over the period; for non epidemic regions, projected malaria cases are obtained as 5 percent (based on a 95 percent Adequate Clinical and Parasitological Response for AL) failure rate of projected FY 09/10 uncomplicated malaria cases.
c. In the absence of accurate data, the DOMC estimates that 20 percent of cases during an epidemic outbreak will present at health facilities with uncomplicated malaria, and 80 percent will present with severe malaria.
d. Difference between (b) and (c) for epidemic-prone areas.
e. For epidemic areas, this is calculated as 5 percent of uncomplicated malaria cases. For non epidemic areas, this is calculated as 5 percent of malaria cases presenting at peripheral health facilities.
f. Total severe malaria cases in each zone.

Table 7. Quinine Injection Ampoules and Tablets Required to Treat Severe Malaria

Corresponding Weight on Average (kg)	Median Weight	OPD Attendances in Sentinel Sites (%)	Projected Number of Cases	Quinine Ampoules Required	Total Quinine Ampoules Including Buffer Stock	Quinine Tablets Required for Continuation Phase	Total Quinine Tablets Including Buffer Stock
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
5–15	10	36.1	322,214	1,933,285	3,383,248	1,933,285	3,383,248
15–25	20	17.2	153,520	921,122	1,611,963	1,842,244	3,223,926
25–35	30	7.5	66,942	602,478	1,054,336	1,204,956	2,108,673
Above 35	60	39.2	349,883	3,498,835	6,122,961	12,595,804	22,042,658
Total			**892,559**	**6,955,719**	**12,172,508**	**17,576,288**	**30,758,505**

a. The four weight categories.
b. The median weight within each weight band.
c. On average, data obtained from the four DOMC sentinel sites shows that of all OPD attendances in public health facilities comprise the following: < 3years, 36.5 percent; 3–9 years, 17.2 percent; 9–11 years, 7.5 percent;14 years, 39.2 percent. In the absence of data on severe malaria attendances, the same ratio is assumed to hold.
d. Calculated by multiplying (c) by projected total number of severe malaria cases from table 5.
e. Total quinine ampoules for loading and maintenance for a three-day period for the different weight bands.
f. Total quinine ampoules including nine months of buffer stock.
g. Total quinine tablets required for the continuation phase taking into account the dose for the different weight bands.
h. Total quinine tablets including nine months of buffer stock.

A total of 12,172,508 ampoules of quinine dihydrocloride and 30,758,505 tablets of quinine sulfate are required for FY09/10.

Prereferral Treatment of Severe Malaria Using Artemesinin-Based Injections

Artesunate and artemether are preferred in management of epidemics because they are able to rapidly reduce the parasite load. Their administration is easier compared to that of quinine and, thus, they are quantified for procurement when funds are available as part of epidemic mitigation efforts.

Treatment Regimen

Artesunate is administered by the intramuscular or intravenous route at 2.4 mg/kg to start, then 2.4 mg per kg at 12 hours and 24 hours, then 2.4 mg/kg daily for two days. By then, it is assumed all patients will be able to tolerate oral medicines.

When used for treating severe malaria, artemether should be administered by the intramuscular route at a loading dose of 3.2 mg/kg to start, then 1.6 mg/kg daily for two days, after which they are put on oral AL.

Assumptions

- Of patients with severe malaria, 50 percent will attend peripheral health facilities for pre referral care, which is (546,967 / 2) = 276,903.

- Each medicine will be quantified exclusively as if it is the only medicine available for management of severe malaria.

- The quantities estimated in tables 8 and 9 for each medicine assume that no other antimalarial is available for treatment of severe malaria.

Table 8. Requirements of Artesunate 60 mg Injection Ampoules

Weight Band (kg) (a)	Median Weight (b)	OPD Attendances in Sentinel Sites (%) (c)	Projected Number of Severe Malaria Cases (d)	Ampoules per Dose (e)	Rounded Number of Ampoules (f)	Number of Ampoules per Patient (g)	Total Ampoules (h)
5–15	10	36.10	99,962	0.4	1	5	499,809
15–25	20	17.20	47,627	0.8	1	5	238,136
25–35	30	7.50	20,768	1.2	2	10	207,677
Above 35	60	39.20	108,546	2.4	3	15	1,628,187
Total			**276,903**				**2,573,809**

a. Weight categories.
b. Median weight for each weight category.
c. On average, data obtained from the four DOMC sentinel sites show that of all OPD attendances in public health facilities comprise the following: < 3years, 36.5 percent; 3–9 years, 17.2 percent; 9–11 years, 7.5 percent;14 years, 39.2 percent.
d. Calculated by multiplying (c) by 50 percent of projected total number of severe malaria cases visiting peripheral health facilities.
e. Ampoules required per dose for a patient within the weight category.
f. Assuming an ampoule is discarded after opening, each dose requirement is rounded off to the nearest whole number.
g. Total ampoules of artemether required per patient based on the recommended dosage.
h. Total artemether ampoules required for the projected number of severe malaria prereferral cases.

Table 9. Requirements of Artemether 40 mg/ml or 80 mg/ml Injections

Weight Band (kg) (a)	Median Weight (b)	OPD Attendances in Sentinel Sites (%) (c)	Projected Number of Severe Malaria Cases (d)	Ampoules per Dose (e)	Rounded Number of Ampoules (f)	Number of Ampoules per Patient (g)	Total Ampoules (h)
40 mg/ml formulation							
5–15	10	36.10	99,962	0.4	1	4	399,848
15–25	20	17.20	47,627	0.8	1	4	190,508
Total							**590,356**
80 mg/ml formulation							
25–35	30	7.50	20,768	0.6	1	4	83,072
Above 35	60	39.20	108,546	1.2	2	8	868,368
Total							**951,440**

a. Weight categories.
b. Median weight for each weight category.
c. On average, data obtained from the four DOMC sentinel sites show that of all OPD attendances in public health facilities comprise the following: < 3years, 36.5 percent; 3–9 years, 17.2 percent; 9–11 years, 7.5 percent;14 years, 39.2 percent.
d. Calculated by multiplying (c) by projected total number of severe malaria cases visiting Rural Health Facilities.
e. Ampoules required per dose for a patient within the weight category.
f. Assuming an ampoule is discarded after opening, each dose requirement is rounded off to the nearest whole number.
g. Total ampoules of artemether required per patient according to the guidelines.
h. Total artemether ampoules required for the projected number of severe malaria prereferral cases.

Requirements for Rectal Artesunate for Prereferral Treatment

In the absence of quinine injection, the guidelines also recommend that rectal artesunate can be used to initiate treatment in cases of severe malaria. It may be preferable to use artesunate rectal capsules in the case of an epidemic.

Treatment Regimen

Rectal artesunate is administered at a dose of 10 mg/kg. If the rectal capsule is expelled within the first hour, another rectal capsule should be inserted. A second dose may be given after 24 hours if the patient is unable to access parenteral therapy.

Assumptions

- Rectal artesunate capsules are used for prereferral treatment in children under 25 kg.

- The 50 mg capsule is used for 5–15 kg patients, and the 200 mg capsule is used for 15–25 kg patients.

- Each child receives two doses of the rectal artesunate.

- All children tolerate the initial treatment given.

Table 10. Requirements of Rectal Artesunate for Prereferral Care

Weight Band (a)	Median Weight (b)	OPD Attendances in Sentinel Sites (%) (c)	Projected Number of Severe Malaria Cases (d)	Capsules per Dose (e)	Number of Doses (f)	Total per Patient (g)	Total Capsules Required (h)
50 mg/cap formulation							
5–15 kg	10	36.10	99,962	2	2	4	399,847
200 mg/cap formulation							
15–25 kg	20	17.20	47,627	1	2	2	95,254

a. Weight categories.
b. Median weight for each weight category.
c. On average, data obtained from the four DOMC sentinel sites show that of all OPD attendances in public health facilities comprise the following: < 3years, 36.5 percent; 3–9 years, 17.2 percent; 9–11 years, 7.5 percent;14 years, 39.2 percent.
d. Calculated by multiplying (c) by projected total number of severe malaria cases visiting Rural Health Facilities.
e. Ampoules required per dose for a patient within the weight category.
f. Assuming an ampoule is discarded after opening, each dose requirement is rounded off to the nearest whole number.
g. Total ampoules of artemether required per patient.
h. Total artemether ampoules required for the projected number of severe malaria pre-referral cases.

Table 11. Summary Requirements of Antimalarial Medicines for FY 2009/2010

Product	Unit	Requirement	Stock on Hand June 30, 2009	Net Requirement	PMI/USAID	GFATM	Government of Kenya	Gap in Quantity	Unit Price (KES)	Total Funding Gap (KES)
A	B	C	D	E	F	G	H	J	K	L
AL 6	Pack of 6	9,832,679	1,119,655	8,713,024	1,944,000	4,169,807	0	2,599,217	21.75	56,532,970
AL 12	Pack of 12	4,684,822	999,017	3,685,805	918,000	1,986,723	0	781,082	42.75	33,391,256
AL18	Pack of 18	2,042,801	396,424	1,646,377	432,000	866,304	0	348,073	66	22,972,818
AL 24	Pack of 24	10,677,037	2,501,868	8,175,169	2,106,000	4,527,880	0	1,541,289	82.5	127,156,343
Quinine 300 mg tablets	Tin of 1000	30,759	1,091	29,668	0	0	27,782	1,886	3670	6,921,620
Quinine injection 600 mg/2 ml	2 ml ampoules	12,172,508	1,931,299	10,241,209	0	0	2,386,800	7,854,409	14	109,961,726
Artesunate rectal capsules 50 mg	Capsules	399,847	0	399,847	0	0	0	399,847	39.13	15,646,013
Artesunate rectal capsules 200 mg	Capsules	95,254	0	95,254	0	0	0	95,254	58.63	5,584,742
Artesunate injection	60 mg vials	2,573,809	0	2,573,809	0	0	0	2,573,809	93.75	241,294,594
Artemether 40 mg/ml injection	Ampoules	590,356	30,000	560,356	0	0	0	560,356	51	28,578,156
Artemether 80 mg/ml injection	Ampoules	868,368	30,000	838,368	0	0	0	838,368	73.5	61,620,048

C = Total number of units required, including the buffer stock and minus the SOH at June 30, 2009.
F, G, H, and I = Quantity of medicines estimated to be procured through government and donor funding.
J = Difference between the annual requirements and the quantities committed for procurement.
L = Prices for AL were computed as the weighted average of the different GFATM tender prices. Quinine prices are given as the most recent KEMSA tender prices published on KEMSA's website. Prices for the artemether-based injections and suppositories were derived from MSH's *International Drug Price Indicator Guide*. All currency conversions were done at a rate of 75 KES = 1 USD.

SITUATIONAL ANALYSIS OF AL STOCK STATUS AND DELIVERY SCHEDULE FOR JULY 2009–JUNE 2010

To ensure an uninterrupted supply of AL, the DSMSC identified a situational analysis of the present stock and pipeline position as one of the tasks to be carried out during the national quantification exercise June 23, 2009. The aim of this task was as follows—

- To identify the quantities of AL that are in the pipeline for the FY 09/10

- To calculate the quantities of AL required for delivery and the various intervals (time periods) during which this should occur

- To anticipate possible stock-outs and calculate the quantities of AL required to fill the gap

Assumptions

- Minimum stock level at central level is six MOS.

- Maximum stock level at central level is nine MOS

- Annual requirements for FY 09/10 based on morbidity method of quantification was determined to be 15,564,194 treatment doses.

Table 12. Situational Analysis of AL, June 2009

Pack Size	Annual Requirements by Weight Band	Monthly Requirements by Weight Band	Buffer Stock	Total Country Requirements	SOH at Central Level June 2009	MOS at Central Level
(a)	(b)	(c)	(d)	(e)	(f)	(g)
Prepack tablets 6 × 1	5,618,674	468,223	4,214,006	9,832,680	1,119,655	2
Prepack tablets 6 × 2	2,677,041	223,087	2,007,781	4,684,822	999,017	4
Prepack tablets 6 × 3	1,167,315	97,276	875,486	2,042,800	396,424	4
Prepack tablets 6 × 4	6,101,164	508,430	4,575,873	10,677,037	2,501,868	5
Total	**15,564,194**	**1,297,016**	**11,673,146**	**27,237,340**	**5,016,964**	**4**

a. AL pack sizes.
b. Projected annual requirements based on malaria cases for FY 09/10 based on the morbidity method.
c. AMC of AL. It refers to the total annual requirements of AL divided by 12 months.
d. Buffer stock of 9 months obtained as AMC multiplied by maximum stock level (9 months).
e. Total AL requirements obtained as sum of annual requirements (b) and buffer stock (d) for each weight band.
f. SOH at the central level (KEMSA and MEDS) by June 30, 2009.
g. MOS at central level calculated by SOH at central level for each weight band divided by the AMC.

Table 12 clearly shows four MOS at central level by June 30, 2009, obtained using the average monthly consumption of 1,297,016 treatment doses. Assuming a regular monthly distribution, this stock is likely to be exhausted by end-October 2009 and a central-level stock-out is anticipated beginning November 2009.

To fill this gap, the country requires funds to procure at least six MOS—the minimum central stock holding level, which is equivalent to 7,782,097 treatment doses.

The delivery periods and the quantities for delivery as shown in table 13 are for the Open International Tender FY 09/10 that was advertised on June 23, 2009. These supplies are expected in country by December 2009. The quantities provided are based on last tender price awarded for FY 08/09 and approximates provided from the FY 09/10 forecast and OIT FY 09/10. The delivery schedule proposed would ensure a maximum stock holding level of nine months and a minimum stock holding of six months at the central level.

Table 13. Proposed Delivery Schedule for GFATM Round 4, Phase 2, Year 3

Weight Band (kg)	Pack Size	Approximate AL Quantities to Be Procured under OIT FY 09/10	GFATM First Delivery Due in Country December 2009	Balance on GFATM Round 4 Tender as at December 2009	Second Delivery in October to Be in Country by March 2010
5–14	Prepack tabs 6 × 1	5,147,911	**4,214,006**	933,905	**933,905**
15–24	Prepack tabs 6 × 2	2,452,744	**2,007,781**	444,963	**444,963**
25–35	Prepack tabs 6 × 3	1,069,511	**875,486**	194,025	**194,025**
35+	Prepack tabs 6 × 4	5,589,975	**4,575,873**	1,014,102	**1,014,102**
Total		**14,260,140**	**11,673,146**	**2,586,996**	**2,586,996**

The total gap required to fill the pipeline is approximately 13 million treatment doses. The December delivery schedule quantities may be adjusted downward if six MOS—7.8 million treatment doses—are procured through donor support and delivered by early November 2009.

FIVE-YEAR FORECAST OF AL REQUIREMENTS (2009–2014)

Background

In June 2008, the DSMSC carried out a quantification of annual AL country requirements and in addition a five-year forecast for AL country for the period 2008–2013. This strategic information was useful for advising the DOMC and partners on the anticipated country requirements for the OIT FY 09/10 for AL. One of the key objectives of the FY 09/10 quantification exercise carried out in June 2009 was to forecast the country's AL requirements for 2009–2014.

Forecasting objectives were as follows—

- 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 funding for any gaps that may be identified

Assumptions

- An annual increase in malaria case reporting of 8 percent is expected.

- The effect of universal coverage and widespread use of insecticide-treated nets has not been factored into the forecast.

- The effect of sustained insecticide residual sparing in the malaria epidemic-prone districts has not been factored into the forecast.

- The standard treatment guidelines for malaria remain unchanged for the forecast period.

- The projected malaria episodes per 1,000 population were applied to the projected population figures to obtain the calendar year estimates of total malaria episodes for the period 2009–2014.

Table 14. Projected Malaria Cases for Calendar Years 2009–2014

Calendar Year	2008	2009	2010	2011	2012	2013	2014
Episodes per 1,000 population projected 8% increase	347	375	405	437	472	510	551
Projected annual population (KNBS 2008)		39,423,268	40,406,411	41,409,249	42,435,603	43,489,031	44,542,459
Projected malaria cases		14,774,264	16,354,123	18,100,814	20,033,410	22,173,180	24,527,100

Table 15 illustrates estimated number of malaria cases using linear interpolation applied to the forecast period.

Table 15. Projected Malaria Cases for FY 2009–2014

Fiscal Year	2009–2010	2010–2011	2011–2012	2012–2013	2013–2014
Malaria cases	15,564,194	17,227,468	19,067,112	21,103,295	23,350,140

Results

Table 16 provides the estimated number of cases per weight band that translates to the total treatment doses of AL required for each weight category. These doses exclude buffer stock.

Table 16. Projected Requirements of Treatment Doses for AL for FYs 2009–2014

Forecast for 2010–2014		Treatment Doses per Weight Band			
Weight Band (kg)	Percentage	2010–2011	2011–2012	2012–2013	2013–2014
5–14	36.10	6,219,116	6,883,227	7,618,289	8,429,400
15–24	17.20	2,963,125	3,279,543	3,629,767	4,016,224
25–34	7.50	1,292,060	1,430,033	1,582,747	1,751,260
35+	39.20	6,753,168	7,474,308	8,272,492	9,153,255
Total	**100.00**	**17,227,468**	**19,067,112**	**21,103,295**	**23,350,140**

<center>**Recommendations and Conclusions**</center>

Although the DSMSC recognizes that the consumption-based method is preferred for quantifying antimalarial medicines, the use of consumption data in this particular instance was severely limited by the low reporting rates of AL consumption data from public sector health facilities and the total lack of consumption data for the other antimalarial medicines for the year ending June 30, 2009.

The quantification of AL requirements revealed a shortfall in the current procurement plan of 13 million treatment doses. It also calls for an emergency procurement of an additional 7.8 million treatment doses to avert an anticipated stock-out in early November 2009.

Recommendations for the DOMC

Immediate

- Initiate an emergency procurement of AL formulations according to the quantities outlined in the procurement plan to avert an anticipated stock-out in early November2009.

- Continue to monitor the stock situation on a monthly basis to enable prompt response to emerging issues.

Medium Term

- Have a fallback plan for direct procurement of antimalarials when delays in the regular procurement process are eminent.

- Set aside funds from the government of Kenya for procurement of first-line antimalarials in the event the funding currently entirely provided by donors is absent.

- Monitor the procurement process regularly as well as management of the contracts.

- Plan in advance for quantification of malaria medicines to ensure the achievement of all set objectives in the multiple-step exercise. Monitor closely and adhere to timelines, activities, and responsibilities outlined in the *Modus Operandi to Guide Annual Quantification of Malaria Medicines* to allow for timely and valid estimates of country requirements.

- Have DSMSC continue to play its role in the facilitation of all urgent and system issues that are within their scope of its responsibilities to improve management of malaria medicines.

- Strengthen the supportive supervision role of health facilities by district pharmaceutical facilitators and malaria focal persons to allow for improved inventory management and continuous flow of timely and accurate consumption data for decision making.

- Strengthen the newly set up LMIS for malaria medicines to ensure timely receipt of consumption data to allow informed decision making and responsiveness in allocation of medicines by malaria zone and level of care.

- Use findings from the biannual Pharmaceutical Management of Malaria Medicines assessments that seek to establish the status of pharmaceutical indicators to provide input into the annual quantification exercise.

- Take into account available study results on patient flow in the Kenya health care system, data on proportion of malaria cases that result in severe malaria, and reports of therapeutic efficacy during the quantification exercise.

- Monitor the stock situation in the country continuously to ensure uninterrupted supply of antimalarial medicines.

- Review the procurement process annually to help in identifying bottlenecks that may result in interrupted flow of antimalarial medicines.

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APPENDIX 1. THE WORKSHOP AGENDA

Date: June 23, 2009
Chair: DOMC

Time	Activity	Facilitator
9.00–9.15 am	Opening remarks, introductions	DOMC
9.15–9.30 am	Quantification objectives	DOMC
9.30–11.00 am	Quantification of AL • Assumption • Methodology	Charles Kareithi
11.00–11.15 AM TEA BREAK		
11.15 am–Noon	Five-year AL forecast	Andrew Nyandigisi
Noon–1.00 pm	Quantification of SP	Mildred Shieshia
1.00–2.00 PM LUNCH		
2.00–3.30 pm	Quantification for severe malaria	Joan Wakori
3.30–4.30 pm	Situational analysis and delivery schedule	Mildred Shieshia/ Dorothy Memusi
4.30–5.00 pm	Tea break, Closure, and Departure	All

APPENDIX 2: PARTICIPANT REGISTRATION LIST

Venue: Sarova Panafric Hotel
Date: June 23, 2009

Quantification of Antimalarial Medicines Drug Management Subcommittee Workshop

Name	Gender	Position	Facility	Address	Telephone	E-mail address
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