



Republic of Kenya  
**MINISTRY OF PUBLIC HEALTH AND SANITATION &  
MINISTRY OF MEDICAL SERVICES, KENYA**

# **Antimalarial Medicine Requirements for July 2008 – June 2009**

*Report of the Drug Supply Management Sub-Committee of the Division  
of Malaria Control*

**July 2008**





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In particular, the technical contribution of the DSMSC members listed below is acknowledged and appreciated.

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## ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
AL	artemether-lumefantrine
ANC	antenatal care
DOMC	Division of Malaria Control
DPTWG	Drug Policy Technical Working Group
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
HMIS	health management information system
ITN	insecticide-treated net
IPTp	intermittent presumptive treatment in pregnancy
IM	intramuscular
IV	intravenous
JSI	John Snow, Inc.
KEMSA	Kenya Medical Supplies Agency
LMIS	logistics management information system
MEDS	Mission for Essential Drugs and Supplies
MOH	Ministry of Health
MSH	Management Sciences for Health
OPD	outpatient department
PSCM	Partnership for Supply Chain Management
RPM Plus	Rational Pharmaceutical Management Plus Program
SP	sulfadoxine-pyrimethamine
SPS	Strengthening Pharmaceutical Systems Program
USAID	U.S. Agency for International Development
USD	U.S. dollars
WHO	World Health Organization

## EXECUTIVE SUMMARY

The DOMC held a one-day quantification workshop in July 2007 to enable it to determine required artemether-lumefantrine (AL) quantities for Year 2 of the new policy implementation, July 2007 to June 2008. The meeting was hosted by RPM Plus, with USAID funding and under the auspices of the drug supply management (DSMSC) sub-committee of the drug policy technical working group (DPTWG). A second objective of the meeting was to determine required quantities and expected costs of other antimalarial medicines for the same procurement period. Representatives were present from the DOMC, WHO, 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 RPM Plus. The methods used for quantification of AL for the Year 2 of ACT policy implementation were (1) the consumption-based method and (2) the morbidity based method. For other antimalarials, needs for the same period were estimated using the morbidity method only.

Following the achievement of comprehensive medicine estimates by the DSMSC in 2007, it was felt that the Strengthening Pharmaceutical Systems program (RPM Plus' successor) should provide additional support for a national quantification exercise to determine the national antimalarial medicine needs for the year 2008-2009, and in addition, forecast needs for the next 5 years (2008-2013). To facilitate this activity, the DOMC and MSH /SPS organized a workshop from 26<sup>th</sup> to 27<sup>th</sup> June 2008.

The meeting objectives were:

- To carry out a National Quantification Exercise to estimate antimalarial medicine needs for the procurement cycle July 2008-June 2009
- To forecast antimalarial medicine requirements for 5 years (2008-2013)
- To provide inputs into the development of a modus operandi to guide the Ministry of Health and Division of Malaria Control in the process of annual Quantification of Antimalarials

Despite attempts made to improve on the efforts of the first quantification exercise (July 2007) the use of the consumption method for the quantification of Artemether-Lumefantrine tablets (AL) was hampered by the lack of sufficient and accurate consumption data. A major complication was the stock-out of AL nation-wide in early 2008, aggravated by generally low reporting rates. Because of these factors, it became apparent that the consumption records could not be used for any meaningful application to AL quantification in the activity for Yr 2008-2009, and the morbidity method (alone) was chosen instead, for AL and all other antimalarial medicines.

## **Outputs of the meeting:**

### Quantification Exercise: Year 2008-2009

- Antimalarial medicines list developed
- Antimalarial medicines requirements for Yr 2008-2009 determined
- Procurement and deliveries schedule for Yr 2008-2009 developed

### Forecasting Exercise: Years 2008-2013

- Forecasting assumptions developed
- A 5 year forecast for number of AL treatment doses determined
- 5 year costing plan developed

### A Modus Operandi for Annual Quantification of Antimalarial Medicines in Kenya

- A first presentation of the draft manual was made in plenary
- Inputs made to the manual in plenary and through the feedback from questionnaires administered to the meeting attendees

Results obtained from the Quantification of antimalarial needs for the Year 2008-2009 are as follows:

1. Artemether-lumefantrine annual requirements **13,203,834** treatment doses
2. Sulfadoxine-pyrimethamine annual requirements **12,695,498** tablets

## 1.0 INTRODUCTION

In 2004, the Government of Kenya made a decision to change first-line antimalarial treatment policy from sulphadoxine/sulfamethoxypyrazine-pyrimethamine (SP) to artemisinin-based combination therapy (ACT) due to a steep decline in the clinical efficacy of SP. In charting out the implementation process for the new treatment policy, the Drug Policy Technical Working Group (DPTWG) of the Division of Malaria Control (DOMC) formed various subcommittees to guide policy implementation under broad thematic areas. A key group within the DPTWG, the Drug Supply Management sub-committee (DSMSC), was tasked with guiding the achievement of key pharmaceutical management actions. One of the activities of the DSMSC is to provide technical support to the DOMC for the estimation of antimalarial medicine quantities needed to ensure an uninterrupted supply. This is to cover malaria treatment and prevention requirements for all vulnerable populations accessing treatment through public and mission sectors of the Kenya health care system.

The recommended ACT for first-line treatment of uncomplicated malaria was artemether-lumefantrine (AL). Furthermore, under the current malaria treatment guidelines (MOH 2008), approved medicines for severe malaria are quinine (tablets and injections), artemether injection and artesunate injection. Artesunate suppositories and artemether (intramuscular) injection have been approved for pre-referral treatment, whilst SP is approved for intermittent preventive treatment of malaria in pregnancy.

Following the achievement of comprehensive medicine estimates by a quantification team encompassing relevant stakeholders in 2007 with RPM Plus support, it was felt that the Strengthening Pharmaceutical Systems program should provide support for a national quantification exercise to determine the national antimalarial medicine needs for the year 2008-2009, and in addition, forecast needs for the next 5 years (2008-2013). To facilitate this activity, the DOMC and MSH /SPS organized a workshop from 26<sup>th</sup> to 27<sup>th</sup> June 2008.

The meeting objectives were:

- To carry out a National Quantification Exercise to estimate antimalarial medicine needs for the Year July 2008-June 2009
- To forecast antimalarial medicine requirements for 5 years (2008-2013)
- To provide inputs into the development of a *Modus Operandi* to guide the Ministry of Health and the DOMC in the quantification of antimalarials

## 2.0 PROCEEDINGS OF THE WORKSHOP

The workshop agenda was as follows:

DATE	Time	Activity	Facilitator
<b>THURSDAY 26<sup>TH</sup> JUNE 2008</b>	<b>Chair: DOMC</b>		
	9.00am -9.15am	Opening remarks, introductions, official opening of workshop	Mildred
	9.15am 9.45am	Workshop norms, program & objectives	Dorothy
	9.45am - 10.45am	Outline for quantification & Presentation of draft modus operandi	Kate
	10.45am-11.00am	<b>TEA BREAK</b>	
	11.00am – 12.00pm	Plenary discussion of modus operandi and how to refine it.	DSMSC
	12.00pm-1.00pm	Quantification methods, data sets. and assumptions	Gladys
	1.00pm-2.00pm	<b>LUNCH</b>	
	2.00 – 3.00 pm	Quantification of Antimalarials (AL-1)	Dorothy/Amin
	3.00pm – 4.00pm	Quantification of Antimalarials (AL-2)	Dorothy/Amin
	4.00pm-4.15pm	<b>TEA BREAK</b>	
4.15pm-5.00pm	Quantification of Antimalarials (SP)	Joan	
<b>FRIDAY 27<sup>TH</sup> JUNE 2008</b>	<b>Chair: DOMC</b>		
	9.00am – 9.15am	Recap/reorientation	Dorothy
	9.15 am-10.45am	Quantification of Antimalarials (Quinine /Artemether / Artesunate)	James/Joan
	10.45am-11.00am	<b>TEA BREAK</b>	
	11.00am-12.00pm	Situation Analysis of quantification figures & pipeline/expected stock	Mildred
	12.00pm-1.00pm	Assumptions for forecasting	Charles
	1.00pm-2.00pm	<b>LUNCH</b>	
	2.00pm-3.00pm	Five year forecast	Regina
	3.00pm-4.00pm	Wrap up	Dorothy
4.00pm-4.15pm	<b>TEA BREAK</b>		

The complete record of proceedings of the meeting may be found in Annex 1 of the report.

### 3.0 QUANTIFICATION OF ANTIMALARIAL MEDICINES: METHODOLOGY AND RESULTS

#### 3.1. 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 four standard methods: the consumption-based method, the morbidity-based method, the adjusted consumption method, and service-level extrapolation (MSH/WHO 1997). The method selected is based on data and information available as well as the resources available for conducting the exercise.

Table 1 provides a comparison of quantification methods by use, data, limitations, and assumptions.

**Table1 Comparison of Quantification Methods**

Method	Uses	Essential Data	Limitations
<b>Consumption</b>	First choice for procurement forecasts, given reliable data  Most reliable predictor of future consumption	Reliable inventory records  Records of supplier lead time  Projected medicine costs	Must have accurate consumption data  Can perpetuate irrational use
<b>Morbidity</b>	Estimating needs in new programs or disaster assistance  Comparing use with theoretical needs  Developing and justifying budgets	Data on population and patient attendances  Actual or projected incidence of health problems  Standard treatments (ideal, actual)  Projected medicine costs	Morbidity data not available for all diseases  Standard treatments may not really be used
<b>Adjusted Consumption</b>	Procurement forecasting when other methods are unreliable  Comparing use with other supply systems	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	Questionable comparability of patient populations, morbidity, and treatment practices
<b>Service-Level Projection of Budget Requirements</b>	Estimating budget needs	Use by service levels and facility type  Average medicine cost per attendance	Variable facility use, attendance, treatment patterns, and supply system efficiency

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

### 3.2 List of Antimalarial Medicines Quantified, by Method

The morbidity method was used by the Drug Management Subcommittee for the 2008-2009 quantification of the following medicines within the 2006 National Malaria Treatment Guidelines. The committee made the decision to adopt this method owing to the lack of (adequate) consumption data for Artemether-Lumefantrine, and negligible data for the others. The results section of this report describes quantification steps used for each of the listed antimalarial medicines.

1. Artemether-lumefantrine tablets
2. Sulfadoxine-Pyrimethamine tablets

### 3.3. Processes for Quantification

#### 3.3.1. Quantification of Antimalarial Medicines—Artemether-Lumefantrine

##### ***Treatment Regimen***

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

The population figures used for this exercise were obtained from Kenya National Bureau of statistics Population Projections:

Projected Population 2007 - 34,652,581

Projected Population 2008 - 35,265,273

The following steps and assumptions were incorporated into the morbidity-based quantification exercise -

##### ***Assumptions:***

1. Annual increase in malaria cases of 8% taking into consideration 2006 and 2007 reported uncomplicated malaria cases
2. HMIS Reporting rate 80%
3. Buffer stock (lead time + safety stock) = 9 months
4. Stock on hand at central level was 0
5. 100% of cases will be given first line treatment
6. Packaging of AL in 4 weight bands

**Table 2: Projected Malaria episodes in 2008**

	Population (2007)	Fever/malaria cases reporting to health facilities (2007)	Adjusted fever/malaria cases reporting to health facilities	Episodes per 1000 population	Projected no. of cases in 2008	Adjusted projected cases in 2008
<b>Malaria OPD cases</b>	34,652,581	9,610,691	12,013,364	347	12,225,772	13,203,834

- On average data obtained from the (4) DOMC sentinel sites shows that of all OPD attendances in public health facilities constitute: < 3years - 36.5%; 3-9 years – 17.2%; 9-11 years – 7.5%;14 years – 39.2%

**Table 3: Projected doses per weight band including buffer stock**

<b>Basic units</b>	<b>Malaria cases (2008) adjusted for age groups</b>	<b>Estimated number of first line treatments</b>	<b>Buffer stock (9 MOS)</b>	<b>Total quantity including buffer</b>
Prepack tabs (6x1)	4,766,584	4,766,584	3,574,938	8,341,522
Prepack tabs (6x2)	2,271,059	2,271,059	1,703,294	3,974,353
Prepack tabs (6x3)	990,288	990,288	742,716	1,733,004
Prepack tabs (6x4)	5,175,903	5,175,903	3,881,927	9,057,830
	<b>13,203,834</b>	<b>13,203,834</b>	<b>9,902,876</b>	<b>23,106,710</b>

Total number of AL treatments required for FY2008/09 is 13,203,834 inclusion of buffer stock yields a total quantity of 23,106,710 treatments.

### **3.2. Quantification of antimalarial medicines—Sulphadoxine-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 health facility. The guidelines recommend that at least three doses of SP be administered a month apart, after quickening to ensure protection against malaria.

#### ***Quantification of SP Tablets Using the Morbidity Method***

The Drug Management Subcommittee calculated quantities using the morbidity-based method because no reliable consumption data exists for SP. The calculation used the projected number of pregnant women in 2008, obtained as 5% of the projected population for the year 2008 (KNBS, 2008), followed by the assumption that 80% of these pregnant women live in endemic areas. It is assumed that all pregnant women will attend public health facilities for their ANC visits.

The following steps and assumptions were incorporated into the morbidity-based quantification exercise—

### **Assumptions**

1. Pregnant women constitute 5% of the population (Health Sector Indicator and standard operating procedures for health workers, 2008, Health Management Information Systems)
2. 80% of pregnant women live in endemic areas
3. Estimated SP quantities would be distributed by KEMSA alone for use only by pregnant women as part of intermittent presumptive treatment of malaria in pregnancy (IPTp).
4. All pregnant women in areas of high malaria transmission will receive 3 doses of IPTp.
5. There is no stock at hand or in the pipeline.

#### **1. Determination of projected number of pregnant women in the population**

Using the KNBS 2008 projected population of 35,265,273 and the assumption that 5% of these constitute pregnant women  
 $(5\% \times 35,265,273) = 1,763,264$  pregnant women

#### **2. Determination of the projected number of pregnant women leaving in endemic areas**

Using the assumption that 80% of the pregnant women live in endemic areas, then 80% of 1,755,609 = 1,410,611 pregnant women

**3. The national malaria policy** targets at least three doses of SP (IPT3) to be given to pregnant women during attendance at ANC clinics in endemic areas.

$1,410,611 \times 3 \times 3 = 12,695,498$  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 12,696 tins.

#### **3.3.3 Quantification of Antimalarial Medicines---- Medicines for Severe Malaria**

The DSMSC noted that there were constraints to the quantification of medicine needs for severe malaria during the current procurement cycle. In the last procurement cycle, the DSM SC had made recommendations to obtain relevant data to enable quantification for severe malaria because there was a great deal of uncertainty even on the most basic of indicators: just how many severe malaria cases are there in Kenya in a given year? MSH/SPS had commissioned a consulting firm to shed some light on the severe malaria case burden and avail the report in due course.

Another area of uncertainty was patient flows within the Kenyan health sector to enable the determination of the proportion of severe malaria cases who first present to lower level health

facilities and who will in theory need pre-referral treatment. It was agreed that more formative research needed to be done around this area and that the upcoming PMI workplan afforded an opportunity to redress this gap.

#### **4.0 SITUATIONAL ANALYSIS OF ARTEMETHER-LUMEFANTRINE - STOCK STATUS AND REQUIREMENTS FOR JULY 2008 TO JUNE 2009**

In order to ensure an uninterrupted supply of artemether-lumefantrine (AL) in Kenya a situation analysis of the present stock and pipeline position was identified as one of the tasks to be carried out by the Drug Management Subcommittee during the National Quantification exercise on 27<sup>th</sup> - 28<sup>th</sup> June 2008.

The aim of this task was:

- To establish the quantities of AL that are in the pipeline for the FY 2008-9
- To establish the quantities of AL required for call down and the various intervals (time periods) during which this should occur
- To identify the anticipated periods of stock out and establish what quantities of AL would be required to fill the gap

#### **Assumptions**

- Current Stock on Hand at central level is zero
- Minimum stock holding at central level is 6 Months of Stock (MOS)
- Maximum stock holding at central level is 9 MOS
- Annual requirements for the year 2008-9 based on the Quantification findings was **13,203,834** treatment doses

**TABLE 4: TOTAL AL DOSES EXPECTED IN COUNTRY UNDER DIFFERENT PROGRAMS IN FY JULY 2008 – JUNE 2009**

Pack size (a)	Annual requirements by weight band (b)	Monthly requirements by weight band (c)	Total AL Doses expected in country under different programs				
			July 2008 (PMI) (d)	August 2008 (GF Direct Procurement) (e)	Sep 2008 (PMI) (f)	Total SoH following all deliveries as at Sept 2008 (g)	GFATM round 4-Phase I, Open International Tender for 07/08 (g)
Prepack tabs 6x1	4,766,584	397,215	103,680	1,373,754	776,640	1,115,228	4,331,600
Prepack tabs 6x2	2,271,059	189,255	69,450	654,531	580,800	760,686	2,147,600
Prepack tabs 6x3	990,288	82,524	46,080	285,406	369,600	485,194	844,800
Prepack tabs 6x4	5,175,903	431,325	178,680	1,491,722	1,434,720	1,880,627	4,992,000
	<b>13,203,834</b>	<b>1,100,320</b>	<b>397,890</b>	<b>3,805,413</b>	<b>3,161,760</b>	<b>4,241,735</b>	<b>12,316,000</b>

**Table 4 footnotes**

- a- AL pack sizes
- b- These are projected malaria cases for 2008/2009 based on the morbidity method
- c- Is the average monthly consumption of AL. It refers to the total quantities obtained using the morbidity method divided by twelve months
- d- This is the first AL delivery under PMI (the President's Malaria Initiative) funding whose balance is expected in country by September 2008
- e- The procurement of AL through the open international tender (OIT) yielded a savings on the money allocated for procurement hence there will be a direct procurement of AL from Novartis Pharma AG using half<sup>1</sup> the savings and the figure here is the breakdown of quantities anticipated under that direct procurement
- f- Represents PMI second procurement quantities
- g- Is the anticipated stock on hand (SoH) as at September 2008 anticipating an average monthly consumption (AMC) as shown in column (c) and taking into account the scheduled deliveries in columns (d), (e) and (f) respectively.
- h- Is the total quantity to be procured under OIT where the award was made to Ajanta Pharmaceuticals of India

<sup>1</sup> The other half of the saved funds will be used to procure additional quantities of AL through an open international tender (OIT) in the near future. Since the MOH is still deciding when to launch this OIT, the potential AL quantities from that procurement have not been factored into this current stock analysis.

**TABLE 5: PROPOSED CALL DOWN SCHEDULE FOR GFATM R4-PHASE I (07/08) from Ajanta Pharma Limited**

Age group	Pack size	GFATM 1 <sup>st</sup> call down due incountry in Oct 2008	Balance on GFATM Round 4 tender as at Oct 2008	2 <sup>nd</sup> call down in October to be incountry by end DEC 2008	Balance on GFATM Round 4 tender as at Oct 2008	3 <sup>rd</sup> call down in December to be incountry by end March 2009	Balance on GFATM tender as at DEC 2008	Projected SOH at Central level in March 2009	MOS at central level in March 2009
<3 yrs	Prepack tabs 6x1	2,513,192	1,816,808	1,191,646	625,162	625,162	-	3,008,454	8
3-9 yrs	Prepack tabs 6x2	959,298	1,190,702	567,765	622,937	622,937	-	1,758,466	9
9-14 yrs	Prepack tabs 6x3	286,545	553,455	247,572	305,884	305,884	-	801,027	10
>14 yrs	Prepack tabs 6x4	2,060,437	2,929,563	1,293,976	1,635,587	1,635,587	-	4,223,539	10
<b>TOTAL</b>		<b>5,819,472</b>	<b>6,490,528</b>	<b>3,300,959</b>	<b>3,189,570</b>	<b>3,189,570</b>		<b>9,791,487</b>	

The call down periods and the quantities for call down as shown in the table above will ensure a maximum stock holding level of 9 months and a minimum stock holding of 6months at central level.

If AL is received in country at the stipulated times as presented in the table then beyond August 2008 no stock out for any of the weight bands is likely to occur.

## 5.0 FIVE -YEAR FORECASTS (FOR 2008-2013)

### Artemether-Lumefantrine --5-Year Forecast

#### Background:

- The DOMC in June 2008 did quantification and forecasting of antimalarial medicine needs in the country. A full quantification was done for July 2008 to June 2009, using the morbidity method. One of the key objectives of the quantification exercise was to forecast antimalarial medicine requirements for 5 years (2008-2013)

#### Objectives:

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

#### Forecasting Assumptions:

1. Annual increase in Malaria case reporting of 8 percent.
2. The effect of universal coverage and widespread use of ITNs has not been factored into the forecast.
3. The effect of sustained IRS in the malaria epidemic prone districts has not been factored into the forecast.
4. The standard treatment guidelines for malaria remain unchanged for the forecast period.

**The forecast for the four years is as follows:**

**Table 6: Projected number of Malaria cases for 2008-2012**

	<b>Projected Malaria cases (2008) adjusted for age groups</b>	<b>Projected Malaria cases (2009) adjusted for age groups</b>	<b>Projected Malaria cases (2010) adjusted for age groups</b>	<b>Projected Malaria cases (2011) adjusted for age groups</b>	<b>Projected Malaria cases (2012) adjusted for age groups</b>
<b>Projected cases</b>	<b>13,203,834</b>	<b>14,260,140</b>	<b>15,400,952</b>	<b>16,633,028</b>	<b>17,963,670</b>

**Table 7: Five-year forecast of number of treatment doses required of Artemether-Lumefantrine**

<b>Weight Category</b>	<b>Projected number of treatment doses adjusted for age groups 2008</b>	<b>Projected number of treatment doses adjusted for age groups 2009</b>	<b>Projected number of treatment doses adjusted for age groups 2010</b>	<b>Projected number of treatment doses adjusted for age groups 2011</b>	<b>Projected number of treatment doses adjusted for age groups 2012</b>
5-14kg	4,766,584	5,147,911	5,559,744	6,004,523	6,484,885
15-24kg	2,271,059	2,452,744	2,648,964	2,860,881	3,089,751
25-34kg	990,288	1,069,511	1,155,071	1,247,477	1,347,275
Over 35kg	5,175,903	5,589,975	6,037,173	6,520,147	7,041,759
<b>Projected total number of treatment Total</b>	<b>13,203,834</b>	<b>14,260,140</b>	<b>15,400,952</b>	<b>16,633,028</b>	<b>17,963,670</b>

## **6.0 LIMITATIONS OF THE QUANTIFICATION EXERCISE**

The accuracy of the just concluded exercise for the quantification of antimalarials in Kenya was limited by several factors which include:

- The low quality of the routinely obtained data, and the incomplete records in the actively obtained data (stock outs were not captured) for consumption of artemether-lumefantrine. Because of this limitation, it was necessary to use the morbidity-based method only.
- The lack of consumption data for other antimalarial medicines (SP). The capture of these data is currently being developed in conjunction with the ANC reporting system.
- The lack of nationally representative data on patient flows in the Kenyan health system, including the proportion of patients reporting to lower-tier facilities who will require treatment before being referred to and treated at higher-order facilities (e.g., district, provincial, and national referral hospitals).

This is compounded by the lack of nationally representative data on disease severity and therapeutic efficacy. It has been assumed that up to 95 percent of patients with clinical malaria will present with mild symptoms treatable in the OPD, with the remaining 5 percent requiring treatment for severe malaria.

Because of this gap in data, the quantification of the medicines for severe malaria (including pre-referral treatment) (Quinine (tablets and Injection), Artemether Injection and Artesunate (suppositories and injection) was put on hold until more conclusive data are obtained from an on-going study. This should be possible by January 2009.

## 7.0 RECOMMENDATIONS AND CONCLUSIONS

Although the DOMC and the Drug Management Subcommittee recognize 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.

### *Recommendations for the Division of Malaria Control*

- It is urgently required to set up the processes of addressing the problems of low reporting rates, with a careful study of the situation, with wide stakeholders input. The issues to be discussed should include a strategy for the monthly collection of consumption and qualitative (program information) reports, and subsequent aggregation of data before central quantification.
- Since annual surveys are necessary at this period, modalities to actualize its effectiveness and efficiency, with budgets and time lines should be finalized
- The rational use of antimalarial medicines, following appropriate case management is now critical in the chain of pharmaceutical management. Efforts towards actualizing rational use should be made a priority at this phase of the implementation of the new policy.
- Studies to describe patient flow in Kenya health care system, data on proportion of malaria cases that result in severe malaria, as well as reports of therapeutic efficacy need to be given attention
- The Drug Supply Management Sub-Committee offers a good opportunity for institutionalizing good pharmaceutical management of antimalarials. Efforts must be made to improve coordination within the subcommittee, and to address its coordination with other stakeholders, within and without the formal health sector.
- Disseminating results of quantification is important to its actualization. Traditional and novel ways of upgrading communication channels should be organized.
- Tracking and alerting on progress and deviations from quantification plans are important next steps after quantification exercises. Planning Periodic reviews of the Quantification Results will be necessary based on the issues arising with procurement and funding changes.
- The quantification has been shown to be a multiple step exercise. Planning for it should be commenced early enough to assure the achievement of all set objectives. The Practical Manual being developed should assume real use.
- Continued support for the Drug Supply Management Sub-Committee is necessary to facilitate all the urgent and system issues that are within their scope of responsibilities.

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## **ANNEX 1 - PROCEEDINGS OF THE QUANTIFICATION WORKSHOP**

### **Day One:**

**Session 1:** Opening Remarks, Introductions and Official Opening of Workshop.

*Facilitated by: Dr. Mildred Shieshia (MSH/SPS)*

The workshop commenced with self-introduction by all present. It was stressed that the workshop setting was an informal one, with the facilitators acting only as a lead to the interactive discussion sessions. Comments from members highlighted the fact that the committee had not met regularly in the past months, despite distributing a schedule, and they made resolutions with a commitment to make a definite change.

**Session 2:** Workshop Objectives.

*Facilitated by: Dr. Dorothy Memusi (DOMC)*

Dr. Dorothy Memusi outlined the objectives of the meeting. She emphasized the fact that the quantification of the anti-malarial medicine is not only for AL, but also for all antimalarial medicines. In addition, a two-stage quantification process had been outlined—the first being to determine quantities for the year 2008-2009, and then to use the figures obtained as a baseline for forecasting for five years (2008-2013).

In addition, she submitted that other objectives of the subcommittee should be to become more active, and to find ways of coming up with a monthly report to show the situation of drug supply and use in the country. She adjointed members to see the whole process as teamwork and not only the responsibility of DOMC. She re-iterated the objectives of an annual quantification exercise as including an institutionalized meeting that will make it easier for government and donors to buy into the period, first yearly for 2008-2009, and then for an extended five years -2008-2013. Revalidation of this forecast as a reference point can then be undertaken periodically.

**Session 3:** Outline of the 2 day Quantification Workshop:

*Presented by: Dr. Catherine Adegoke (MSH/SPS) Consultant)*

### **Rationale for Meeting**

- The Division of Malaria Control wishes to institutionalize an annual quantification of antimalarial medicines
- The figures derived when quantification for the 2008-2009 year is concluded will also be used as a baseline to project for a five-year forecast for years 2008-2013.
- The DOMC plans to begin a community access program and hence there is need to include the quantity of Antimalarials needed within this quantification

## **Outline of the 2-day meeting**

### Day One (Part 1):

- Communication of Workshop Objectives
- Read-through and Review the Outline of the “Practical Manual for Quantification of Antimalarials in Kenya”
- Refining the “Practical Manual” plus inputs by stakeholders
- Discussions on recurring data sets needed for quantification—(by methods and particular medicine) and likely sources

### Day One (Part 2):

- Discussions on antimalarial medicines
- Listing of actual data sets needed for quantification, according to formula
- Harvesting of assumptions/ revalidating current assumptions
- Discussions on different antimalarial medicines—methods, assumptions, calculations for quantification—start

### Day Two:

- Discussions on different antimalarial medicines—methods, assumptions, calculations for quantification—conclude
- Review of Situation Analysis of Quantification, (Stock in Inventory, Procurement Schedules, Distribution, Data Reporting etc.) in Kenya
- Assumptions and Methods for making a 5-year forecast
- Wrap up of the 2 day meeting

## **Session 4: Outline of the draft document: Practical manual for Annual Quantification**

*Facilitated by: Dr. Catherine Adegoke (MSH/SPS) Consultant*

The draft of the “Practical Manual for Quantification of antimalarial medicines in Kenya” was presented to the group, with comments and suggestions given at intervals. This session was also an unstructured review of the last quantification exercise, with the view of actually tracing actual practice through the outlines and recommendations of the manual.

The consensus of the group was that the preparation time allocated for the quantification was insufficient. In addition, a review period of twelve consecutive months was adjudged adequate for consumption method of quantification. For the actual quantification exercise, three full days were allocated, as a conclusion to previous meetings at which the mix of data (routine and active) should have been cleaned, and pre-analyzed.

### **1. Introduction 1–Rationale for the Manual**

- Piece-meal nature of quantification activities
- Need for coordination of staff undertaking activities
- Divergent assumptions by different groups
- Use of varied sub-sets of data
- Repetitive exercises leading to time loss
- Continuous quantification to fit various funding sources/procurement agent

### **2. Introduction 2—Situating quantification in pharmaceutical management**

- Quantification—situated as the first activity within the element of procurement. Its purpose is to ensure an uninterrupted supply while at the same time avoiding wastes due to overstocking

- 3. Introduction 3--Potential Applications of the Quantification Manual**
  - Outlines details of the quantification process (pre-, during and post activities)
  - Results of the quantification process are listed in a defined format
  - Available funding support is described for subsequent procurement activities
  - Users of the manual (Gok, MoH, DOMC and donors) are further enabled to:
    - track progress in dissemination of results; extract estimates from the grand outputs of the annual quantification exercises; track progress in procurement activities
  - The DOMC is enabled to alert on:
    - major events according to plan; major deviations from plans; new or increased opportunities to the quantification/procurement processes
- 4. Introduction 4 —Critical Decisions on the Quantification of Antimalarials in Kenya**
  - Periodicity of the quantification process
  - Centralized or decentralized quantification
  - Which methods of quantification to use
  - Computerization of the Quantification Process
  - Estimating Time Required
- 5. Basic Outline of Action Plan**
- 6. Responsibilities for the Quantification Process**
- 7. Defining Objectives, Coverage and Lists of Antimalarial Medicines**
- 8. Coordinating the Quantification Process**
- 9. Template of Work Plan for Annual Quantification of Antimalarials**
- 10. Check-lists for the quantification exercise**
- 11. Specific steps in the quantification process:**
  - Consumption based method
  - Morbidity based method
- 12. Concluding the Quantification Process:**
  - Adjusting for losses
  - Adjusting for program growth
  - Cross- checking estimates produced by different quantification methods
  - Estimating total procurement costs
- 13. Evaluate the Quantification Process**

**Plenary Discussions: Issues, Queries and Resolutions ----1**

**Draft Practical Manual on Quantification:**

<b>TOPIC</b>	<b>ISSUE OR QUERY</b>	<b>PLENARY RESOLUTION</b>
Specificity of the Manual	How specific is the Practical Manual?	The manual is specifically for use in annual quantification of antimalarials in Kenya using a centralized approach even though it can be adapted for other uses
The Annual Quantification Cycle: Establishing the timeline for annual quantification:	Should quantification be done at the beginning of each year (January) to know the national units for each year?	This might be challenging as it activities are normally low very early in the year and not all the data for the previous year may be available by then. A (12-month) review period such as December to November may be set as alternative. This way there will be enough time for cleaning up of the data. The process can therefore be carried out at the end of January or the beginning of February.
Data Review Period	What would the benefit of a particular review period be?	It can be done at anytime and the subcommittee to review and refine it. It does not matter what months are involved, as long as it is a trend that incorporates all the season. For example, by January 2009, all the data for December 2007- November 2008 will be in.
Guidelines for Procurement Cycles	There are different procurement cycles-- Government of Kenya (GOK) is in March. The proposals for the Global Fund (GF) are usually written in May. Any guidelines?	The GoK cycle will be used as the base line. This enables national figures to be put out each year. Other cycles will then be plugged in, and overlaps taken care of by specific reviews. This may open the way for national cycles, incorporating the government and all donors.
Coordination of Quantification Activities	Not all issues in the quantification process are directly under the control of the malaria stakeholders. This is a challenge to co-ordination.	The different stakeholders and pockets of information that they are responsible for should be coordinated into the planning.

<b>TOPIC</b>	<b>ISSUE OR QUERY</b>	<b>PLENARY RESOLUTION</b>
Time-line For Central Quantification Activities	<p>Would a 2 –day quantification meeting suffice?</p> <p>Should the main work be done during the meeting or before?</p>	<p>With the agenda of what is to be done to have a comprehensive quantification exercise, that incorporates the situation analysis and full calculations of needs, and call-up plans, a 3-4 day meeting might be more appropriate..</p> <p>Small meetings need to be arranged before the actual quantification meeting --to clean up and set the data. The three days will then be used to produce the actual figures.</p>
Reviews of the data for the Quantification Process	Are the reviews of the past quantification process to be done before the 3-day meeting?	Some aspects of the review should have been done during the normal monthly meeting; the only ones necessary during the new quantification exercise should be tied with the current situational analysis.
Data Capture for Quantification	For the annual quantification, should a mini-survey be used in addition to the routine method?	<p>Yes. This is because data quality is not so good at present; it might not be necessary later.</p> <p>For example, the data can be actively collected in January (collated from the lower levels) in January</p>
Data Capture: Quality and Completeness of Data for Quantification	When will we know that the data is good enough?	There are many indices of data quality— Timeliness, Completeness and Accuracy. When there is a reporting rate of 80% meeting the above indices, then they can be plugged in without need for additional surveys. At present, the HIMS data has many gaps.
	How can this be done?	<p>It is necessary to have a precise stakeholder meeting at all levels to fashion out the modalities, as well as uncover factors mediating against feedback.</p> <p>As a first measure, tie report collection with a monthly activity that can be checked (communicate defaulting facilities/districts). In addition, when reports are given, provide feedback to show that the information is actually used and important to the whole process.</p>

<b>TOPIC</b>	<b>ISSUE OR QUERY</b>	<b>PLENARY RESOLUTION</b>
Tracing Stock-outs	Is it possible to have a detailed tracking of stock out for 8 drugs over a 12-month period?	A 12-month period may be painstaking, as it will add greatly to fieldwork and personnel costs---but it is the ideal period, to capture all seasons
Capturing Inputs into Quantification	The work plan for annual quantification template should have a column for the inputs required added into it. Could outputs be added into that as well?	A single column will be added (to incorporate all shades of inputs—financial, HR etc.), but leaving detailed outputs out to keep the template simple and concise At a glance, it will be obvious what challenges are faced with the process.
Budgeting for Antimalarial Medicine Needs	Is it possible to use the manual for budgeting for the actual quantification activities?	Yes, when developing quantification plans, a critical part is the action plan. The costs will be known in terms of funding. The roles and responsibilities of the team will be outlined.
Presentation of Data	How to present the results of the quantification?	An outline of how to present the results obtained is recommended in the Practical manual.
Plugging of Donors into National Needs	How will the needs for antimalarial medicines be determined for other donors? For example, if requests are made to the GF for all needs, where do others who want to give come in?	The quantification process will lay out all the assumptions, results, and final figures for all the antimalarial needs, including the coverage and assistance needed for systems.  By this means, it will be possible to see the gaps left in the process because of funds or strategy limitations, and so open the gaps that can be addressed by all.

TOPIC	ISSUE OR QUERY	PLENARY RESOLUTION
<p>What to do during Stock outs?</p>	<p>Due to procurement or funding bottlenecks there may be dry periods and stock outs.</p> <p>Will it be possible to procure the drugs from elsewhere and then reprogram the money for something else?</p> <p>At what point can procurement re-arrangements be done?</p>	<p>Emergency procurement should be approached with caution even when extra drugs may be needed. The drugs that are expected could also be staggered or extended.</p> <p>There are provisions but the rules have to be checked in case there are steps that should be constituted. The flexibility of each donor should be researched and known. For GF if there are surplus products, be careful of re-directing, as grants are specific agreements. If the country re-programs with a strategy not already in the proposal, this may constitute as a major deviation. When there are major revisions, the work plan may have to be revised with another proposal.</p> <p>Once the country places definite orders, production is geared to supply this request.</p>

**Session 5:** Discussions on Data Sets for Quantification, Sources and Assumptions

*Facilitated by: Dr. Gladys Tetteh (MSH/SPS)*

This session was an interactive discussion on data needed for the Quantification Exercise.

**Plenary Discussions:** Issues, Queries And Resolutions ----2

**Data Sets for Quantification**

<b>TOPIC</b>	<b>ISSUE OR QUERY</b>	<b>PLENARY RESOLUTION</b>
Periodicity of Data Collection	Should this be monthly or quarterly?  Is the quarter system complicated?	Even though the system at present is to collect quarterly reports to harmonize with delivery of stock, efforts should be made to institute monthly data collection
Data Transmission	How does passive data get to central level?	It is normally sent by courier.
Survey Methods	When will a survey be done to look for data needs?	After a chosen review period to end around September-November of previous year.
	What are the benefits of having a survey if data is very clean?	This is a data verification process.  A survey is always necessary, but not necessarily from a central level, and should be budgeted.
Issues in Central quantification	How far should the data be aggregated from the lower levels, to start the central quantification?	The data normally comes aggregated, as it may be too heavy to work with daily consumption at the central level.
Data Quality	Where does the most error occur- At district level or national level?	It is easier and faster to check errors at the district level. It also helps to build their capacity and make them to be more responsible for data transmitted up.

<b>TOPIC</b>	<b>ISSUE OR QUERY</b>	<b>PLENARY RESOLUTION</b>
Data Entry/ Cleaning	In reviewing data sets, how do we explain the blank cells and the zero entries?	The reason for blank cells must be sought and found. Query the zero entries: Zero entries may mean many things--no consumption, no stock, no staff or the clinic was closed. It may also translate to the medicines not being given because RDTs confirm no malaria, even though stock is available. Information can be crosschecked by calling up the facility and asking what the zero entry depicts. Timeliness cannot be judged from this data.
Data Analysis	Could you use stock out days from the central levels to determine stock outs at facilities?	It can give a slight indication but is not totally presenting the true picture at the peripheral levels.
	Could a stable level be shown for the period before stock out?	There was never a stable level in the country.
	Are zones and regions updated/reviewed in terms of malaria epidemiology?	There are many policy decisions to be made before one can change a zone from high to low zone and vice versa
Consumption of SP	Is there a survey to show if SP is still being used for treatment?	In the formal public set up ACTs are the preferred choices. However, in the private informal set up amodiaquine and SP are still being used. Particularly, Amodiaquine syrup is being given to children, as it is easier to take than crushing AL tablets. There should be more information behind the data that comes in.
Quantification Activities	Adjustment for losses and program changes.	Presently, losses are not being captured, so it is difficult to make assumptions. Get information from LMU. There could also be a survey to look at physical inventory against bin card entry.
Adjusting For Program Changes	Should one assume that the prevalence rate for malaria is changing-up or down?	Records are showing a downward trend in malaria cases.

TOPIC	ISSUE OR QUERY	PLENARY RESOLUTION
Lead Time	What constitutes Lead Time?	<ol style="list-style-type: none"> <li>1. From time of need to when the tender advert comes out.(averagely one month)</li> <li>2. From the tender adverts to tender opening (averagely one month)</li> <li>3. From tender opening to award of contract (averagely one month)</li> <li>4. From award of contract to signing of contract (averagely one month)</li> <li>5. From signing of contract to when the commodity is delivered.(averagely three months for supplies out of the country, and one month for in-country supplies)</li> </ol> <p>Before annual quantification, all these times will be reviewed.</p>
	What is the Lead Time for goods to get to the Central Medical Stores?	A total of 9 months is a safe period for products procured offshore. However, the shelf life of the product should be considered. When the product is called down, it must be ready for immediate production and shipment.
Capacity For quantification	Can everyone in the Sub-committee use the Quantimed tool?	There is a plan for the members of the Sub committee to be trained in its use and to practice it immediately as it is easily forgotten if not used practically. Even when quantification is used using other spreadsheets such as Excel, it may be beneficial to use the Quantimed or other quantification software to cross check. However, there may be a need to review data sets again for input into Quantimed.

**Plenary Discussions: Issues, Queries and Resolutions – 3**

**Quantification of Antimalarial Medicines—Artemether-Lumefantrine**

TOPIC	ISSUE OR QUERY	PLENARY RESOLUTION
Rational Use of Medicines	Are there data on rational use of antimalarials?	These data could be abstracted from case management quality of care studies done by the KEMRI/Wellcome Trust Programme and other partners, in addition to previous drug use studies done in the country by MSH/SPS
Community Care	<p>Is the community home care under the public or private sector?</p> <p>What proportion of medicines—6s and `12s are to be issued for community access?</p> <p>Why is there a cut off at over 5 years for the community access component?</p>	<p>It differs, they are many times placed in the formal public sector and other times they are put in the informal private sector.</p> <p>Ratio 2: 1 respectively</p> <p>There are diagnostic issues-to place the care under IMCI. If the adults are included, we run the risk of therapy sharing.</p>
Buffer Stock	<p>How much stock is supposed to be at facility level and at central levels?</p> <p>What will the buffer stock be? Assuming that the pipeline is saturated, how do we synchronize the procurement process with the lead time</p>	<p>6 months and 9 months respectively</p> <p>A total of 15 months.</p> <p>Proper planning and organizing orders is the key.</p> <p>Set the buffer stock for 3 months at facility level and 6 months at central level giving a total of 9 months.</p>
Storage Capacity for Medicines	Can facilities cope with the storage of this amount of drugs?	The drugs need to be available for the use of facilities, whether they can store them or not, so that the central stores can hold the drugs and give without too much delay when called upon

**Plenary Discussions: Issues, Queries And Resolutions - 4**

**Situation Analysis of Antimalarial Medicines—Artemether-Lumefantrine**

TOPIC	ISSUE OR QUERY	PLENARY RESOLUTION
Receipt, Storage and Distribution of next order of antimalarials	KEMSA will be closed in July for stock-taking, when the PMI consignment arrives. They may not therefore be able to receive or distribute drugs during that month. Could these drugs go to MEDS instead?	It may not be possible. The insurance cost will be too high. Mildred Shieshia was tasked with coordinating with KEMSA on how this issue could be resolved.
Allocation of Antimalarial Medicines	KEMSA's distribution now includes some mission facilities that were formerly under MEDS, so MEDS should be given less stock.	Allocation to MEDS should reflect the changes in the number of facilities they now serve.
	The uptake of AL 6s is very small in mission hospitals. Could the mission facilities be giving the children something else instead of AL?	There could be the purchase of second line drugs as MEDS is not restricted to what KEMSA distributes.
	Since the 24's are exhausted earliest, is it possible that the quantification of AL 24's not accurate?	There are issues of the impacts of health seeking behaviour and stock outs of 24's due to irrational use. Also, the under 5's get sick more often, but a larger percentage of the population is over 35kg. It is also common practice to cut up 24s to give to lower weight bands thus explaining the quick stock-outs of this particular pack type.  It will be possible to address the different scenario as soon as the new tools for logistic management are rolled out.

## 5-YEARS FORECAST OF ANTIMALARIAL MEDICINES

### Rationale for Forecasting

Forecasting serves several purposes, including enabling stakeholders:

1. To plan for needs based on justifiable estimates
2. Inform funding agents on what they can provide
3. To fill gaps in capacity building.
4. To fill the gaps in the policy and regulatory framework
5. To assess the infrastructures needed for implementation

### Assumptions for 5 –Year Forecasts

For this forecasting exercise, these set of assumptions have been applied.

1. Period will be July 2008- June 2013.
2. Products are still the same as those quantified for 2008-2009.
3. Population/target

The five-year malaria burden forecast aims to be more preventative than cure. However, the use of SP for IPT<sub>P</sub> is not a very popular policy. For the forecasts, we need to assume that the IRS coverage will be sustained at current level

### **Plenary Discussions: Issues, Queries And Resolutions - 5**

#### **Five-Year Forecast of Antimalarial Medicines**

TOPIC	ISSUE OR QUERY	PLENARY RESOLUTION
Stability of Assumptions for Forecast	Will the products be the same ones quantified in the one-year estimates, or will there be new ones coming into the market?	It is very tricky as the forecast can change. Have a review every year in light of the changes that may have happened in that year. Forecast what is not likely to change much but know that policies, manufacturers and price can influence the change. For now let the products remain as they are in the quantification
	What are the possible issues that can change the forecasts of antimalarial needs?	<ol style="list-style-type: none"> <li>1.. Antimalarial Treatment Policy</li> <li>2. Funding</li> <li>3. Price changes</li> <li>4. Mitigating factors <ul style="list-style-type: none"> <li>• Effect of LLINs use</li> <li>• Effect of IRS</li> </ul> </li> </ol>
	The population at risk will therefore also keep changing if the risk factors are changing.	It will not always be 70% but this figure will be kept and will be reviewed over time.

	Can climate affect prevalence and subsequently forecasting?	Not readily, but urbanization and population movements can, to a greater extent.
Sulphadoxine-Pyrimethamine	Does the 41/1000 crude birth rate change from year to year? Does everything else remain the same, for example the number of women obtaining the third dose of SP?	The crude birth is changed only by population changes, but the rate is kept, for now.  If there is more awareness about ANC there will be more women going to the clinics. This will then lead to more women getting the third dose of SP
Second –line antimalarial medicines	Do we assume that the proportions remain the same?	There are too many unknowns, so more data are needed. In-patient rates of admission for malaria are being reported as declining due to ACT use, but there is yet no concrete data to support this.

