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**Ministry of Public Health and Sanitation
Division of Malaria Control**

**A Modus Operandi for the Annual National Quantification of
Antimalarial Medicines in Kenya**

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About the Division of Malaria Control

The DOMC was known as the National Malaria Control Programme (NMCP) until October 2000. The NMCP was created by the Government of Kenya in 1994. The elevation of the NMCP to the status of a division underscores the importance that the Government of Kenya attaches to malaria control. The DOMC is now directly under the Department of Disease Prevention and Control.

The DOMC has the overall responsibility for planning and coordinating inputs and activities for malaria control at all levels. The Malaria Interagency Co-coordinating Committee advises and guides the Ministry of Public Health and Sanitation on national malaria policy, strategy, and priorities, and acts as a forum for exchange of information on partners' malaria control and research activities. The Drug Policy Technical Working Group advises the DOMC on policy issues related to case management it is one of the advisory Technical working groups of the MICC. The Drug Management subcommittee is one of the subcommittees of the DPTWG tasked with supply chain management activities, drug regulatory and safety and access issues.

PREFACE

Over the past recent years, national malaria control programs (NMCPs) have taken over the prime responsibility of ensuring accurate quantification and availability of antimalarial medicines recommended within the national malaria treatment guidelines. In particular the responsibility for quantification and resource mobilization for procurement of artemisinin-based combination therapies for use in the management of first-line uncomplicated malaria cases falls largely on the shoulders of the NMCP.

The Division of Malaria Control in Kenya has been leading quantification efforts through a team approach. In 2004 when a decision was made to change the country's malaria treatment policy to incorporate the use of artemisinin-based combination treatments (ACTs), 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.

Although quantification of Antimalarial Medicines has been achieved over the past few years, it has been observed that the practice had been for the DOMC to do piecemeal uncoordinated quantification exercises for different donors e.g. quantification for Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) proposal requirements; quantification for procurement using other donor funding; quantification for annual procurement of antimalarial medicines on the essential medicines list by the Kenya Medical Supplies Agency (KEMSA) using Ministry of Medical Services funds etc. The main impetus for this piecemeal quantification was the different pots of funding and the different times at which the estimates were needed by the varied agencies and procurement agents. The result of this piecemeal quantification practice was the use of divergent assumptions in estimating the needs and costs of antimalarial medicines; the use of varied sub-sets of data; and a loss of valuable time because of undertaking repetitive exercises in attempts to quantify requirements for each separate funding source/procurement agent.

In 2007, the Rational Pharmaceutical Management Plus (RPM Plus) program of Management Sciences for Health provided support to the DOMC for quantification of antimalarials for the period of July 2007 – June 2008¹. Following the achievement of comprehensive medicine estimates by a quantification team comprising all relevant stakeholders, a need was identified for RPM Plus' successor (the Strengthening Pharmaceutical Systems program) to provide support for the development of a document-a *modus operandi* - to outline and guide the process of systematic annual comprehensive quantification of antimalarials.

This document, partly generic, and partly specific to the needs of Kenya malaria control stakeholders aims at providing a reference for yearly national quantification activities. It details basic information required and critical activities for the antimalarial medicine quantification

process in a stepwise fashion, along with recommendations for optimizing the use of the document.

It is anticipated that the collective endorsement of this document by the would-be users will pave the way for synchronized and comprehensive estimates from an annual quantification of antimalarial medicines in Kenya.

1.0 INTRODUCTION

1.1. Situating Quantification in the Pharmaceutical Management of Antimalarials

Quantification is a process that involves estimating the quantities of a specific item required to be procured for a specific period of time. Quantification involves the financial requirements needed to purchase the items, human resource capacity, storage capacity, and the capacity of the system to deliver services. The purpose of quantification is to ensure an uninterrupted supply of medicines by supplying and re-stocking pipelines, while at the same time avoiding wastages due to overstocking.

The Pharmaceutical management cycle involves five main activities- drug selection, procurement, distribution, use and management support, which must be carefully coordinated. Each activity of the pharmaceutical drug management cycle relies on the success of the previous activity and contributes to the effectiveness of the next activity. Selection is the normal reference starting point in the cycle, followed by procurement. Quantification is situated as the first activity within the element of procurement.

1.2 Application of the Modus Operandi for Antimalarial Medicine Quantification

- Details of the Quantification Process (pre-, during and post activities) are outlined
- Results of the Quantification Process are listed in a defined format
- Available funding support is described for subsequent procurement activities
- Users of the manual (Government of Kenya, Ministry of Public Health and Sanitation and Ministry of Medical Services, Division of Malaria Control and Donors) are further enabled to:
 - Track progress in dissemination of annual antimalarial medicine requirements for the country
 - Identify the gaps in funding for antimalarial medicines and pledge funding within the context of national needs for the particular fiscal year
 - Track progress of procurement activities
- The DOMC is enabled to alert on:
 - Major upcoming events according to plan
 - Major deviations from plans
 - New or increased opportunities to the quantification/procurement processes

1.3 Critical Issues for Quantification of Antimalarials in Kenya

1.3.1. Options for the Periodicity of the Quantification Process

Major options exist in the preparations for, and the processes of carrying out a quantification exercise. The options are annual, scheduled, or perpetual. The option chosen for Kenya is a National Annual Quantification to determine the needs for annual procurement.

1.3.2. Centralized or Decentralized Quantification

A centralized approach has been adopted for Kenya since both the Kenya Medical Supplies Agency (KEMSA) and the Mission for Essential Medicines and Supplies (MEDS) operate under a typical central supply model where the procurement and distribution of medicines is coordinated at the central level. In addition, the distribution network is a two-level one with distribution of antimalarial medicines directly from central level to all public health facilities through a combination of push and pull ordering systems. A measure of de-centralization is provided for by the involvement of the facilities and districts in transmitting consumption data through a routine reporting system, which must be continually strengthened, and which when managed properly, can improve the accuracy of the results.

If decentralized quantification is to be embarked upon at any point in time in the future, it must be established how many levels of the supply system are involved and whether the quantification will be done by districts then collated at provincial and National level.

1.3.3. Method(s) of Quantification to Use

The four general methods for Quantification are:

- i. Consumption method
- ii. Morbidity method
- iii. Adjusted consumption method
- iv. Service-level projection of budget requirements

Quantification for antimalarials in Kenya will adopt the Consumption and/or Morbidity Methods, as applicable. Until there is confidence in available data provided for either method, both methods will be used with triangulation of results.

1.3.4. Manual or Computerized Method for Annual Quantification Activities

Computerized quantification has been chosen because it has three major advantages: *speed*, *accuracy* and *flexibility*. The process is much faster because once the requisite soft ware is developed, formulae can be programmed, basic assumptions developed and agreed upon and once the data are entered, calculations are done automatically. There are no errors of computation once the data and formulae are entered accurately. It is also much easier to do a “what if” analysis by making changes to any of the data sets.

**ONCE A COMPUTERIZED DRUG LIST AND QUANTIFICATION MODEL
HAVE BEEN DEVELOPED, THEY CAN BE RE-USED REPEATEDLY.**

1.3.5. Estimating the Time Required

Large-scale quantification is time-consuming and a realistic time frame must be established to cover all the steps in the quantification plan. In multi-level systems in which data are incomplete, it will require several months to produce useful quantification. The time frame required for the Quantification process for Kenya will depend on periodicity of quantification, procurement cycle lead times, the number of levels of supply systems and the type of data available. It has been agreed that a timeframe of six months be set for achieving national scale quantification.

2.0 ACTION PLAN FOR QUANTIFICATION

The Action Plan for Quantification of Antimalarials in Kenya details processes to be followed step wise for effective quantification activities.

BASIC OUTLINE OF THE ACTION PLAN

- Assemble procurement cycles and timelines for the Ministry of Public Health and Sanitation, Ministry of Medical Services and various donors
- Institute annual cycle for national quantification activities
- Activities for the quantification process are jumpstarted by the official(s) or office that will manage the process, define roles and responsibilities and coordinate activities of the offices, departments, and facilities involved
- The DOMC defines the objectives and coverage of the quantification
- The DOMC develops the list of drugs to be quantified, based on standard treatment guidelines, and country needs
- Working group alerted on annual quantification activities and roles-- and to manage quantification according to plan (adjusting for inevitable delays and unexpected constraints)
- Working group develops a work-plan and timeline for quantification with realistic deadlines for each phase
- Designated members of the working group prepare the list of data needed for the quantification activity
- The DOMC, along with other (designated) members of the working group examines the available data for appropriateness (accuracy and completeness)
- Arrange for a 2-day National Quantification Exercise for the Working Group
- Review the past quantification process, and the situation of procurement /supply/ distribution of antimalarial medicines
- Calculate quantities of antimalarial medicines needed (using the two methods of quantification as applicable for the product)
- Review quantities, adjust estimated quantities as needed
- Establish quantities of antimalarial medicines as outputs of the exercise
- Communicate and disseminate results of the quantification exercise
- Review the just concluded quantification process, with recommendations and plans to improve and to resolve problems encountered

2.1. Responsibilities for the Quantification Process

The DOMC will be responsible for the overall quantification process.

The Drug Management Sub Committee under the auspices of the Drug Policy Technical Working Group (DPTWG) will be mandated to undertake the quantification exercise including pre and post quantification activities.

The Division of Pharmacy will liaise with the DOMC regarding quantification and procurement.

The Procuring agency will be responsible for managing the procurement process and adherence of the supplier to contract terms.

The Ministry of Public Health and Sanitation (MOPHS) will ensure the availability of resources for procurement, warehousing and distribution of Antimalaria medicines. Presently, efforts have been made to secure GFATM resources for procurement and distribution of AL. MOPHS needs to institute a mechanism to sustain funding for malaria medicines.

2.2. Defining objectives, coverage and list of antimalarials for the quantification

The DOMC communicates the objective of the quantification exercise for the year to all members of the working group, with a yearly bias. However, the core objective would always be to determine the quantities of antimalarial medicines needed for the year for which quantification is being made.

The DOMC also communicates the list of medicines to be quantified, based on standard treatment guidelines, and country needs. The drug list is the central component of any quantification process. It is not possible to calculate quantities needed until it is known which products are needed.

Specifications for each medicine and the list should include:

- Drug description, generic name, or international non-proprietary name (INN);
- Dosage form, such as tablet, suppository, ampoule for injection;
- Strength—for example, 200mg, 5%;
- Package size in basic units;
- Projected purchase price per basic unit or per package.

LIST OF ANTIMALARIAL MEDICINES

1. Artemether-lumefantrine tablets
2. Sulfadoxine-pyrimethamine tablets
3. Quinine tablets
4. Quinine injectables
5. Artemether injectables
6. Artesunate injectables
7. Artesunate suppositories

2.3 Coordinating the Quantification Process

When embarking on centralized annual quantification, a mechanism must be put in place to inform decision making at central level for effective quantification. This coordination mechanism should target all major stakeholders.

In Kenya, this mechanism is designated as the Drug Supply Management Committee, comprising:

- i. The Division of Malaria Control (DOMC)
- ii. Kenya Medical Supplies Agency (KEMSA)
- iii. MEDS
- iv. Pharmacy and Poisons Board (PPB)
- v. Division of Pharmacy
- vi. MSH-Strengthening Pharmaceutical Systems (SPS)
- vii. John Snow Incorporated (JSI)
- viii. WHO /EDM
- ix. Other ad hoc members to be identified by the DSMSC sub-committee

The Drug Supply Management Committee guides the process of quantification from inception through to the final stage of furnishing the procurement with the final outputs.

When embarking on de-centralized annual quantification, the coordination mechanism will include officials in facility, district and provincial levels. Coordination across these different levels and locations of stakeholders becomes even more important from the central level. Adequate handling of information is essential to harmonize knowledge and its applications as well as timelines.

2.4. Work Plan for Quantification Activities

The working group should develop a work-plan annually for quantification with timelines and realistic deadlines agreed on for each phase. Below is a sample format.

Table 1: Work plan for quantification of antimalarial medicines in Kenya

Activity/ Sub-activity	Responsible <i>(Performing)</i>	Time lines
1.1. Establishment of annual cycle for national quantification activities	DOMC	September
1.2 Announcement for quantification process by the official(s) or office that will manage the process	DOMC	September
1.3 Working group reviews the past quantification process, and conduct a situation analysis of quantification methods, procurement /supply/ distribution of antimalarial medicines	DSMSC	September
1.4. The DOMC defines the objectives, coverage and scope of the quantification	DOMC	September
1.5 The DOMC develop the list of drugs to be quantified, based on standard treatment guidelines and national needs	DOMC	September
1.6. Roles and responsibilities are defined and allocated for each representing organization in the committee	DSMSC	September
2.1. Working group meets to develop a work-plan with timelines and realistic deadlines	DSMSC	September

2.2. Designated members of the working group prepare the list and formats of data needed for the quantification activity	DSMSC	September
2.3. Train (or re-train) relevant staff in the applicable quantification method(s) and in data collection, collation and analysis	DOMC and partners	October
2.4. Distribute / Collect/ Collate data collection forms	DOMC	October
2.5. Undertake Data Collection/Collation/Analysis activities	DOMC and Field staff	November
2.6. Working group examines the available data-- for (accuracy, completeness and applicability)	DSMSC	January
2.7. Arrange a 2-day National Quantification Exercise for the Working Group	DOMC	Feb24th-28th
2.8. Calculate quantities of antimalarial medicines needed using appropriate methods for quantification	DSMSC	Feb24th -28th
2.9. Review quantities, adjust estimated quantities as needed	DSMSC	Feb24th-28th
2.10 Establish quantities of antimalarial medicines as outputs of the exercise	DSMSC	Feb24th-28th
3.1. Establish streams of funding /donor support for procurement	DOMC	March
3.2. Develop plans for communication of quantification results	DOMC	March

3.3. Review the just concluded quantification process, with recommendations and plans to improve and to resolve problems encountered	DSMSC	August and December
3.4. Establish tracking system for post-quantification activities, including procurement and funding re-arrangements	DSMSC	Continuous

2.5. Checklists for the Quantification Exercise

CHECKLISTS ON DATA:

Consumption Method of Quantification

1. Is there data on past consumption?
2. Is it accurate and complete?
3. How accurate is it (% if possible)?

Morbidity Method of Quantification

4. When was the last DHS?
5. What is the target population for the quantification (public/private/Mission)?
6. Is there a breakdown of population by age group?
7. Where are estimates on disease burden obtained from?
8. Are national estimates available?
9. If no, are district level estimates available?
10. If not, are data available from a sample of health facilities?
11. Are the data accurate?
12. Is there a breakdown by age of disease burden? What are the age groups?
13. What is the evidence of adherence to the national treatment protocol?

CHECKLIST ON PROCUREMENT ARRANGEMENTS

14. Who does procurement for MOH?
15. Is there a procurement committee?
16. If yes, what is the interaction between the procurement and quantification committee?
17. Is a procurement agency used?

CHECKLIST ON COSTING OF MEDICINES

18. Who supplies the medicines procured?
19. What list is used to cost for medicines?

CHECKLIST ON STORAGE AND DISTRIBUTION OF ANTIMALARIAL MEDICINES

20. What is the storage capacity at the central, provincial and district levels?
21. What is the breakdown of the number of health facilities by type?
22. How is distribution carried out? Push system? Pull system?

3.0 SPECIFIC STEPS IN THE QUANTIFICATION PROCESS

3.1 Consumption–Based Method of Quantification

The consumption method starts from past consumption data obtained existing inventory records of the medicines concerned and makes the following preparations—

- Prepare a list of the medicines to be quantified

DATA FOR CONSUMPTION-BASED METHOD OF QUANTIFICATION

- Reliable Inventory records
- Records of supplier lead times
- Projected medicine costs

Next, these steps are followed to make the quantification—

Step 1: Select the period for which the consumption is to be calculated.

Step 2: Enter consumption data for each drug on the list:

- total quantity used during the review period, in basic units
- the number of days in the review period that the drug was out of stock

Note: it is important to use the most accurate and current records available
(Compile decentralized quantification (if applicable))

Step 3: Calculate the average monthly consumption for each drug during the period.

Step 4: Calculate the safety stock needed for each drug

Step 5: Calculate the quantity of each drug required in the next procurement period

Step 6: Drug consumption is reviewed and adjustment made for expected changes in consumption pattern

Step 7: Adjust for losses

Step 8: Estimate costs for each drug and total costs

Step 9: Compare total costs with budget and make adjustments if necessary

3.2. Morbidity-Based Method of Quantification

The morbidity method starts from two sets of data—

- Number of episodes of each malaria problem treated by the type(s) of facilities for which drug requirements are to be estimated
- Average standard treatment schedules for each malaria problem defined

Next, these steps are followed to make the quantification—

Step 1: Specify the list of malaria treatment categories and number of cases for which treatment is required.

DATA FOR MORBIDITY-BASED METHOD OF QUANTIFICATION

- Data on population and patient attendances
- Actual or projected incidence of uncomplicated and severe malaria
- Standard treatment guidelines
- Projected medicine costs

Step 2: Establish the list of drugs to be quantified

Step 3: Enter the details and quantity of drug(s) required for a standard treatment of uncomplicated and severe malaria.

Step 4: Collect morbidity data for uncomplicated and severe malaria

Step 5: Calculate the number of treatment episodes for each case of uncomplicated and severe malaria

Step 6: Calculate the quantity of drugs needed for each condition by multiplying the number of treatments by the drug quantities for each treatment.

Step 7: Combine the estimates of each drug from each condition into a master list.

Step 8: If applicable, make adjustments for stock on hand, stock on order and lead times

Step 9: Adjust the total quantities to allow for losses due to damage and waste.

Step 10: Estimate costs for each drug and total costs

Step 11: Compare total costs with budget and make adjustments where necessary

4.0 CONCLUDING THE QUANTIFICATION PROCESS

4.1. Adjustment of Estimated Quantities as Applicable

4.1.1. Adjusting for losses and for program growth

Inevitably, some medicines will be lost due to damage spoilage, expiration, and theft. If such losses are not considered in quantification and procurement, stock outs are likely to result. To prevent shortages, a percentage can be added to allow for losses when quantifying requirements.

In a supply system in which patient utilization or the number of facilities is growing, it is reasonable to assume that medicine consumption will increase. In such situations, calculated quantities can be increased by a percentage corresponding to the estimated rate of growth. In systems where there is measured impact of other successful interventions, it is reasonable to assume that medicine consumption will decrease. In such situations calculated quantities can be decreased by a percentage corresponding to the estimated decline in malaria incidence.

4.1.2. Cross-checking estimates produced by quantification

Since there will be some imprecision in the estimates no matter how rigorously the appropriate quantification methods are followed, it is always useful to check the estimates with a different quantification method. The two sets of data can then be compared to see which appears to be more realistic, considering the reliability of source data used for the two estimates.

To resolve inconsistencies between the consumption and morbidity results, the following steps can be taken—

- Verify the data.
- Consider whether the results appear reasonable.
- If you are confident of the quality of both morbidity and consumption data used, then—
 - When consumption data has an over 70% reporting rate by facility then use consumption-based estimate
 - When consumption data reporting rate is very low (<30%) then compare both morbidity and consumption results over the last 3 years to get a good estimate.

Cross checking is a fundamental step to reconcile procurement quantities with available funds. It is also useful to cross-check consumption with theoretical need to get an idea of the rationality of drug therapy in the system. For example, if the supply system usually bases purchases on past consumption, cross-checking for high-volume, high-cost drugs using another method may reveal targets for interventions to promote more rational drug use.

4.1.3. Estimating total procurement costs

When estimating the cost of medicines on a quantified list, the critical issue is determining the next purchase prices. It is not adequate to use the last purchase prices because doing so results in an under or overestimate of the actual next purchase prices, leading to insufficient/excess funds when it comes time to place orders.

There are two basic ways to estimate the next purchase price of a drug; both are usually needed to estimate the cost for full list of drugs. The first option is to obtain data on current drug prices in the market where the drugs will be purchased. The other option for estimating next purchase price is to adjust the last purchase price for factors such as

- International inflation for products bought internationally;
- Local inflation for products purchased on the market, adding the appropriate percentage based on the current local situation.

Once price estimates are obtained, it is necessary to add percentages for shipping and insurance for drugs obtained from international sources, and any known fees, such as those paid to a tender board or for local customs duties.

4.2 Dissemination of the Quantification Report

The quantities and costs of antimalarial medicines to be procured should be documented in a National Malaria quantification report. The drugs, quantities and cost shall be listed in the following order: 1st line treatment for malaria; 2nd line treatment for malaria; treatment for severe malaria; IPT in pregnancy.

The Quantification findings should be presented to the Drug Policy Technical Working group and a report provided to the DOMC for dissemination to key stake holders. The stake holders should include the Ministry of Public Health and Sanitation, Ministry of Medical Services, KEMSA, MEDS, the procurement agent and development partners.

4.3 Tracking system for Post Quantification

To ensure an uninterrupted supply of antimalarials it will be important to institute a tracking system to prevent stock outs and over stocking. The Drug Supply Management subcommittee (DSMSC) will be responsible for developing a call down delivery schedule based on projected Average Monthly Consumptions, Maximum stock at central level and Stock on Hand. This schedule will be communicated to the supplier by the procurement agency. The DSMSC will periodically carry out a situational analysis to inform stakeholders on the existing stock position in the country. The DOMC in collaboration with the procurement consortium shall monitor and

evaluate the performance of the supplier with regard to quantities requested and timeliness of delivery while the contract is in force.

4.2. Evaluation of the Quantification Process

A short period after the annual quantification, it is important to review the preparations, the process, the actual activity, the results of the quantification, and the use of the results, to obtain a better result in the following year.

Tools that can be used include:

- Questionnaire to cross check on the various processes and activities.
- Qualitative reviews can be given by stakeholders who took part in the exercise or to whom the results were disseminated.

Of greater importance is the need to compare quantity procured for the year vis a vis total country requirement. To do this one needs to evaluate the magnitude of stock outs and expiries against quantities consumed. Alternatively a comparison of reported malaria cases against procured quantities can be carried out.

A conscious effort to improve the quality of the preparations, processes and outcome will have multiple snowball effects on product flow and stability of malaria management efforts.