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PHARMACEUTICALS FUND AND SUPPLY AGENCY

Comprehensive Manual for Quantification of Pharmaceuticals in Ethiopia.

PHARMACEUTICALS FUND AND SUPPLY AGENCY (PFSA)

CLINTON HEALTH ACCESS INITIATIVE

June, 2016

Addis Ababa, Ethiopia

Comprehensive Manual for Quantification of Pharmaceuticals in Ethiopia.

First Edition

PHARMACEUTICALS FUND AND SUPPLY AGENCY (PFSA)

June, 2016

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FOREWORD

Pharmaceuticals Fund and Supply Agency (PFSA) is coordinating sector wide efforts aimed at significantly improving the sustainable availability of quality assured pharmaceuticals at an affordable price to the public and promote rational use of medicines. As part of this effort, the Agency in collaboration with CHAI, MSH/Heal-TB, JSI, USAID/DELIVER Project and UNFPA has developed the first edition of Comprehensive Manual for Quantification of Pharmaceuticals (Health Program and Revolving Fund Pharmaceuticals) in Ethiopia with a view to standardize work processes and to make clear the role and responsibilities.

Quantification is a critical supply chain activity that links information on services and commodities from the facility level with program policies and plans at the national level, and is then used to inform higher level decision making on the financing and procurement of commodities. The results of quantification can be used to help maximize the use of available resources for procurement, advocate for mobilization of additional resources when needed, and inform manufacturer production cycles and supplier shipment schedules.

This manual for quantification of health commodities is developed to assist technical advisors, program managers, warehouse managers, quantification experts, procurement officers, and service providers in (1) estimating the total commodity needs and costs for successful implementation of national health program strategies and goals, (2) identifying the funding needs and gaps for procurement of the required commodities, and (3) planning procurements and shipment delivery schedules to be able to ensure a sustained and effective supply of health commodities. It can also be used as a reference material for health stream students and faculty at Universities.

I would like to take this opportunity to thank all who participated in the development of this Manual. I would also like to encourage users of the Manual to send their comments regarding the Manual to the Agency via mail (Pharmaceuticals Fund and Supply Agency (PFSA), P. O. Box 21904, Addis Ababa, Ethiopia)

Meskele Lera

Director General, Pharmaceuticals Fund and Supply Agency (PFSA)

ACRONMYS

ARVs	Antiretrovirals
CCERP	Cold Chain Expansion and Rehabilitation Plan
CHAI	Clinton Health Access Initiative
CPR	Contraceptive Prevalence Rate
CMYP	Comprehensive Multi-Year Plan
CYP	Couple Years of Protection
DBS	Dried Blood Sample
DHS	Demographic and Health Survey
PCR	Polymerase Chain Reaction
EPHI	Ethiopian Public Health Institute
EPI	Expanded Programme on Immunization
FDA	Food and Drug Authority
FDCs	Fixed Dose Combinations
FMHACA	Food, Medicines and Healthcare Administration and Control Authority
FMOH	Federal Ministry of Health
GAVI	Global Alliance for Vaccination and Immunization
GF	Global Fund
GTP	Growth and Transformation Plan
HAPCO	HIV/AIDS Prevention and Control Office
HMIS	Health Management Information System
HSTP	Health Sector Transformation Plan
ICC	Interagency Coordination Committee
IT	Information Technology
IUD	Intra-uterine Device
LMIS	Logistics Management Information System
MCH	Maternal and Child Health
MCHL-TWG	Maternal and Child Health Logistics Technical Working Group
MDR TB	Multi-Drug Resistant Tuberculosis
MWRA	Married Women in Reproductive Age
NQT	National Quantification Team
NTP SP	National TB Programme Strategic Plan
OI	Opportunistic Infections
PFSA	Pharmaceutical Fund and Supply Agency
PLHIV/AIDS	People living with HIV/AIDS
PLITS	Pharmaceutical Logistics Information Tracking System
PSM	Pharmaceutical Supply Management
PSTP	Pharmaceutical Supply Transformation Plan
RDF	Revolving Drug Fund
RIIP	Routine EPI Improvement Plan
RTK	Rapid Test Kit
SDPs	Service Delivery Points
SOH	Stock on Hand
STGs	Standard Treatment Guidelines
TB	Tuberculosis
TFR	Total Fertility Rate
TWG	Technical Working Groups
VL	Viral Load
WHO	World Health Organization
WRA	Women of Reproductive Age
XDR	Extensive Drug Resistance

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Pharmaceuticals Fund and Supply Agency (PFSA) would like to acknowledge; Clinton health Access Initiative (CHAI), JSI, USAID/DELIVER and UNFPA for their unreserved contribution in developing this Comprehensive Manual for Quantification of health program and RDF pharmaceuticals in Ethiopia,. We would also like to extend our gratitude to CHAI for its financial assistance in the development and printing of this SOP Manual. We are grateful to the following individuals for their contribution in the development of this Quantification Manual:

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Furthermore, we would like to acknowledge the individuals and their organizations (Annex 1) who participated in the workshop organized to review the draft Manual for their feedbacks.

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Pharmaceuticals Fund and Supply Agency, 2016. Comprehensive Manual for Quantification of Pharmaceuticals in Ethiopia, 1st edition, Addis Ababa, Ethiopia.

About the manual

This Manual describes the overall pharmaceutical quantification process from start to finish, provides instructions for each key considerations in quantification, steps in the quantification process, and commonly encountered challenges, how to make use of quantification results and updating quantification.

Who can use this manual?

This manual is developed to be used as a working document for National Quantification Team responsible for the quantification of national pharmaceuticals requirement such as: ARVs, OI drugs and Laboratory Commodities; Quantification of first and second line Anti-TB medicines, Ancillary Medicines; Laboratory Commodities; Quantification of Malaria products; Quantification of Family Planning Commodities; Qunatification of Maternal and Child Health Program; Quantification of Vaccines and Related Supplies, for national commodity requirement.

In addition, program managers, technical advisors, procurement officers, warehouse managers, service providers, and academicians and trainers can use it as a reference. Specifically,

- A multidisciplinary team of pharmacists, physicians, administrators and epidemiologists and others who are involved in pharmaceutical supply chain management can use this manual.
- Individual members of the quantification team who are responsible for program planning, budgeting, and mobilizing resources for procurement of commodities will also benefit from using this manual to understand how to use the outputs of the quantification to support these activities.

Scope of the manual

This manual is designed for the quantification of national pharmaceutical requirement for: ART, TB, Malaria, Family Planning, MCH, EPI Programmes and RDF. These commodities include: ARVs, OI medicines and Laboratory Commodities; Anti-TB medicines, Ancillary medicines, Laboratory Commodities; Anti-malaria products; Family Planning Commodities; Maternal and Child Health products, Vaccines and Related Supplies and products managed through RDF.

Objectives of the Manual

General Objective

This Manual is designed to assist users in applying a systematic, step-by-step approach for quantifying pharmaceutical requirements at all levels.

Specific objectives

The step-by-step approach to quantification of pharmaceuticals presented in this manual will enable users to:

- Choose the most appropriate quantification method(s) based on available data
- Identify the data needed and data sources;;
- Collect and analyze data;
- Identify, obtain consensus on, and apply assumptions that may be needed for quantification, including those for missing data;
- Estimate the effect of any programmatic factors (e.g., service expansions, scale-ups, etc) or

geographic/environmental factors (e.g., disease epidemiology, seasonality) that may influence demand;

- Identify the unique characteristics of quantification of specific pharmaceuticals and special considerations to be applied
- Use the forecasting data and assumptions to calculate the quantities needed for the specific quantification period;
- Interpret the estimates obtained;
- Identify the key supply chain parameters required to estimate the total pharmaceuticals requirements and cost;;
- Calculate the total pharmaceuticals requirements and costs for each year of the quantification;
- Plan budget allocations and reconcile estimated quantities to fit within the available budget;;
- Identify the funding needs and gaps for procurement of the required pharmaceuticals;;
- Develop supply schedules to ensure uninterrupted supply of pharmaceuticals;
- Implement a process for reviewing and updating the results of the quantification to maintain and improve the validity, accuracy, and usefulness of current and future quantifications;;
- Compare the amounts and timing of funding commitments for procurement with the total
- Commodity costs and required shipment delivery dates as the final step in the quantification

Using the Manual

The manual has 10 chapters. Chapter 1 contains Overview of Quantification including quantification methods, related predictive accuracy of quantification method and key considerations in quantification. Chapter 2 through 10 describes the quantification exercise for different programmer medicines accounting for their peculiar characteristics and. Chapter 2 presents step by step procedure followed during quantification of ARVs, OI medicines and Laboratory reagents. In Chapter 3, a step-by-step procedure for quantification of first and second line Anti-TB medicines, Ancillary medicines for MDR patients, Laboratory Products and supplies; followed by Malaria and Family Planning Commodities in Chapter 4 and 5. In Chapter 6, methods and procedures for quantification of Vaccines and Related Supplies are described. Chapter 7 is describing key considerations and the quantification process to go through in producing Maternal and Child Health (MCH) products requirement. And Chapter 8 is about step by step procedure for quantification of Medicine, Medical supplies and Laboratory product managed through Revolving Drug Fund. The final two chapters, chapter 9 and 10, describe how to make use of quantification results and how to update the outputs of the quantification process, respectively.

CHAPTER ONE

Overview of Quantification

1.1. Introduction

The main components of supply chain system are:

1	**SELECTION**	Deciding what drugs are needed.
2	**QUANTIFICATION**	Estimating how much of each drug is needed.
3	**PROCUREMENT**	Selecting suppliers, placing and monitoring orders, checking delivery quantities and quality, and paying suppliers.
4	**Inventory management: storage & distribution.**	Reception, storage, stock control, transportation, and record keeping for monitoring and control.
5	**USE**	Prescription, dispensing and use of drugs, and patients' compliance with prescriptions.

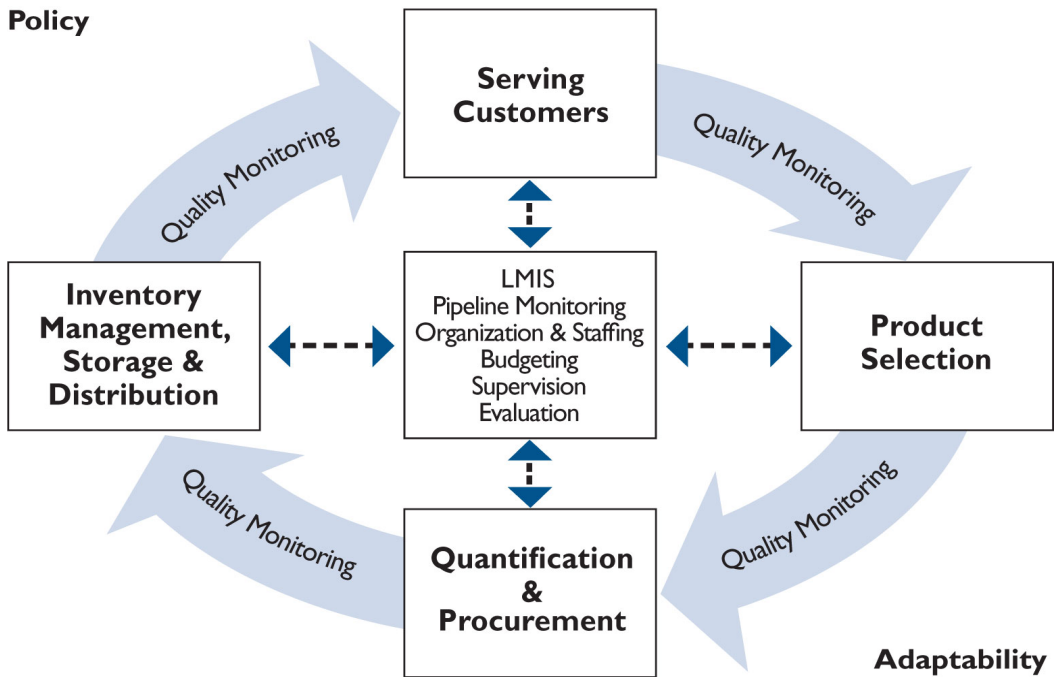

Figure 1: The Logistics cycle

Each activity—serving customers, product selection, quantification and procurement, and inventory management—depends on and is affected by the other activities.

After products have been selected, the required quantity and cost of each product must be determined. Quantification is the process of estimating the quantity and cost of the products required for a specific health program (or service), and, to ensure an uninterrupted supply for the program, determining when the products should be procured and distributed. The ultimate goal of quantifying drug requirements is to ensure that appropriate drugs are available sustainably to treat; promote and maintain the rational and economic use of drugs.

Quantification links information on services and commodities from the facility level with program policies and plans at the national level, and is then used to inform higher level decision-making on the financing and procurement of pharmaceuticals. The results of quantification can be used to help maximize the use of available resources for procurement, advocate for mobilization of additional resources when needed, and inform manufacturer and supplier shipment schedules. Quantification is not a one-time, annual exercise that ends when the final quantities and costs of the pharmaceuticals have been determined. It is an iterative process with reviews and updates required year-round.

Quantification is a critical supply chain management activity that, once the outputs have been produced as a result of the exercise, should drive an iterative process of reviewing and updating the quantification data and assumptions, and recalculating the total commodity requirements and costs to reflect actual service delivery and consumption of commodities, as well as changes in program policies and plans over time. The results of a quantification should be reviewed and updated at least every six months, and more frequently for rapidly growing or changing programs. Quantification is important for informing supply chain decisions on product selection, financing, procurement, and delivery.

The results of a quantification exercise help program managers:

- Identify the funding needs and gaps for procurement of the required pharmaceuticals;
- Leverage the sources, amounts, and timing of funding commitments to maximize the use of available resources;
- Advocate for additional resources, when needed, and develop a supply plan to coordinate procurements and shipment delivery schedules to ensure a continuous supply of pharmaceuticals.

1.2 Methods of Quantification

Pharmaceutical needs can be quantified by using one or a combination of four standard methods. The four general quantification methods are:

a) Consumption method (including proxy consumption)
b) Morbidity method (including Service-Level Projection of Budget Requirements)
c) Demographic/population based methods (or target population methods for vaccines)
d) Forecasting using service statistics (including size of immunization session for vaccines)

a) Consumption Method:- uses records of past consumption of individual pharmaceuticals (adjusted for stock outs and projected changes in pharmaceuticals use) to project future need.

Proxy Consumption Method:- uses data on disease incidence, medicine consumption, demand, or use, and/or pharmaceutical expenditures from a "standard" supply system and extrapolates the consumption or use rates to the target supply system, based on population coverage or service level to be provided.

b) Morbidity Method:- estimates the need for specific pharmaceuticals based on the expected number of attendances, the incidence of common diseases, and standard treatment patterns for the diseases considered. This method starts from two sets of data: the number of episodes of each health problem and average standard treatment schedules..

The quantity of drugs given as a standard treatment for each health problem, multiplied by the number of treatment episodes of that problem, gives the total quantity of drugs required for it.

Quantity of the drug specified for a standard course of treatment	×	*Number of treatment episodes of the health problem*	=	*Total quantity of a drug required for a given health problem*

This calculation is repeated for each health problem and its corresponding drugs. Where a drug is used for more than one health problem, the respective totals are added together to obtain the total quantity required.

An average drug treatment schedule contains six items of information:

1. The name of the **health problem**, and the International Classification of Diseases (ICD) number or numbers of the diagnoses it includes.
2. The **generic name** of **dosage form and strength** of each drug to be used in the treatment.
3. The **average dose**.
4. The **average number of doses per day**.
5. The **average number of days** these doses are to be given.
6. The **total average quantity** of each drug used for a **standard course of treatment;** or in the case of chronic conditions, where treatment is long term, the **total quantity usually given per prescription**.

c) Demographic/population based methods (or target population methods for vaccines) - This method of quantification uses demographic data to forecast commodity requirements.

Demographic data are data on the proportion of a specific population estimated to be affected by a specific disease or health condition that requires a specific treatment. In some cases, these population-based figures are further refined to estimate a more segmented population that may actually have access to a health facility where the services are provided. Demographic and morbidity-based estimates are often used to estimate the total unmet need for a service or treatment in a program or country, and therefore would represent the uppermost bounds of the potential drug requirements for a program.

Target population: is the number of people who are eligible for vaccination with a particular vaccine. The Target Population includes both the Host and Refugee population.

d) Forecasting using service statistics (including: Service-level projection of budget requirements, size of immunization session for vaccines, etc) – This method of quantification uses service related data such as: the number of visits, number of services provided, lab tests conducted, treatment episodes, or number of patients on treatment over defined time period (usually the past 12-month period).

Service data are historical program-level or facility-level data on the number of patient visits to facilities, the number of services provided, the number of fever episodes, or the number of people who received a specific service or treatment within a given period. Service statistics data can

be found in program monitoring reports, HMIS data, facility-level data on service utilization and attendance rates, or patient records

Service-Level Projection of Budget Requirements:- uses the average medicine cost per attendance or bed-day in different types of health facilities in a standard system to project pharmaceuticals costs in similar types of facilities in the target system. This method does not estimate quantities of individual medicines.

Vaccines forecast using Size of Immunization Session primarily requires data/information on: the number of immunization posts for the target catchment, number of immunization weeks per year, number of immunization sessions per week, average number of vaccine vials opened per session, and the number of doses per vial of vaccines are required.

1.3 Relative Predictive accuracy of quantification methods

Quantification of pharmaceutical requirements is inherently imprecise because of the many variables involved. Different quantification methods available may provide distinct advantage over the others based on the context within which they are used. Thus, the choice of specific method over the other should be done based on the level of supply chain at which the forecasting exercise is conducted, and in light of the resources and/or data/information available.

Consumption method:

In many instances, the most precise method for quantifying pharmaceutical usage is the consumption-based approach, provided the source data are complete, accurate, and properly adjusted for stock out periods and the anticipated changes in demand and use.

Large, well-established pharmaceutical supply systems rely primarily on the consumption method. To be reliable, the consumption data must come from a stable supply system with a relatively lower supply interruption and better managed pipelines. Consumption method gives reliable forecast when used in stable programs with sufficient funding, good supply chain management, and where good prescribing practices are exercised. It is also the simplest method to use in hospital contexts where greater variety of health problems are managed and more complex treatment protocols are rendered.

It is good to note that consumption data may or may not reflect rational prescribing and use of medicines or actual demand for medicines at the facilities. It does not normally address the appropriateness of past consumption patterns, which may or may not correspond with public health priorities and needs. Thus, irrational medicine use may be perpetuated by total reliance on the consumption method. If stock-outs have been widespread for long periods, applying consumption method accurately may be impossible, which is why capturing actual demand is the most accurate approach

Proxy consumption method is generally used if neither the consumption-based nor the morbidity-based method is feasible. This method would likely yield accurate projection when used to extrapolate/project consumption profiles from one set of standard (well-established) facilities to another set that serves the same type of population in the same type of geographic and climatic environment.

If the Proxy consumption method is applied by drawing standard data from another facility, the results will be only a rough estimate of the eventual needs. Even when target and standard facilities are closely matched, quantification estimates should be scrutinized (because of the assumption taken for similarity in disease incidence, prescribing habits, and medication utilization patterns in both settings). Still, this method may be the best alternative in the absence of suitable data required for the consumption- or morbidity-based method. The proxy consumption method is also useful for cross-checking projections made with other methods. The proxy consumption method is flexible enough to apply to various situations and can be either population or service based.

Morbidity-based quantification:

The morbidity method uses data on patient use (attendances at health facilities) and morbidity (the frequency of common health problems) to project the need for drugs based on assumptions about how the problems will be treated. It is appropriate for calculating needs for new therapies and for other situations where accurate consumption data are not available.

Morbidity-based quantification is the most complex and time-consuming method.

Collecting valid morbidity data for range of diseases for which the quantification exercise shall be conducted is often challenging, thus resulting in imprecise estimation of requirement. Data on patient attendance are often incomplete and inaccurate, and predicting what percentage of prescribers will actually follow the standard treatment regimens used for quantification is difficult.

Despite these constraints, morbidity-based quantification method remains the best alternative for planning for procurement or for estimating budget needs in a supply system or facility in which a limited range of health problems accounts for virtually all medicine consumption, such as a small primary care system; a special-purpose hospital; a new program with no previous consumption history.

Morbidity-based quantification method is generally better for new or rapidly changing services, or where services are being substantially reorganized. It is also better if prescribing practices are irrational because it provides a systematic basis for improvement. Finally, it is well adapted to the development of the kit system of drug supply. Nevertheless, this method is useful for new and expanding programs and may be the most convincing approach for justifying a budget request.

- **Demographic/population based methods (or target population methods for vaccines)**
  - *Demographic/population based methods*
  - *Target population methods for vaccines*
- **Forecasting using service statistics (including: Service-level projection of budget requirements, size of immunization session for vaccines, etc)**

Service-level projection of budget requirements: produces a rough estimate of financial needs for pharmaceutical procurement and not the quantity of products. The method relies on two assumptions: that the "standard" system (used for comparison) and the target system are comparable in terms of patient attendance and bed-days per type of facility, and that the patterns of medicine use are roughly the same in both systems. Despite its limitations, this method can be useful in predicting medicine costs in a new system or in a system in which no data are readily available.

Quantification estimates can be cross-checked by combining different methods. No matter which method is used, a gap may exist between the initial estimates of medicine needs and the allocated budget. The quantification process itself may help justify an increase in the budget, but often the quantification estimates must be adjusted and reconciled to match available funds. The choice between manual and computerized quantification may be dictated by circumstances, but the process is much easier with computer assistance. Quantification can be centralized, or it can be decentralized to staff of peripheral warehouses and health facilities. The personnel and time requirements depend on the quality and accessibility of source data and on the type and scope of quantification.

1.4 Key Consideration in Quantification

Issues that must be considered in quantification process are:

a) Preparing an action plan for quantification

Essential points in planning for quantification include:-

- Naming the official or office that will manage the process and define roles and responsibility
- Forming a working group to coordinate activities of the office departments and facilities involved
- Defining the objective and coverage of the quantification
- Examining the availability of data and choosing the best quantification method according to objectives and available data and resource (personnel, funding & computer capacity).
- Developing medicines lists and data collection forms.
- Determining standard treatments used in quantification.
- Training staff members in the applicable quantification methods.
- Developing a work plan time line for quantification
- Managing quantification according to plan (adjusting for inevitable delays and unexpected constraints
- Communicating results to relevant committees or managers to determine final assumptions and quantities
- Adjusting estimated quantities as needed.
- Evaluating the quantification process and planning improvements to resolve problems encountered.

b) Using centralized or decentralized quantification

If managed properly, decentralized quantification increases responsibility and creates ownership of the results of quantification. RDF product quantification is done in decentralized fashion, where health facilities quantify and send their forecasted requirements to PFSA hubs. PFSA Hubs aggregate and

report to the central PFSA based on the common preprinted list of pharmaceuticals approved from the central level

A centralized approach is more efficient when the supply system is in equilibrium, with adequate supply to all levels. Program pharmaceutical quantification is managed in centralized way.

c) Using manual or computerized methods of quantification.

Computerized quantification is preferred due to the accuracy, speed and flexibility.

d) Estimating the time required for developing and organizing list of medicines

Quantification is a lengthy and often time consuming process. Setting time frame for quantification process is therefore important. The time to be assigned should account the number of tiers in the supply chain system, and the quality and type of data available. In a multi-level system in which available data is inaccurate/incomplete, several months may be required to produce a useful quantification result.

Medicines list is the main component of any quantification process. The list should contain description of the medicines (generic), dosage form, and strength/concentration, basic unit, package size in basic units, and projected purchase price for the medicine per basic unit or per package.

e) Filling the supply pipeline

Supply pipeline refers to stock level in the supply system and number of supply points at each level. The number of levels, the frequency of requisition and delivery, and the amount of safety stock at each level all influence the amount of pharmaceutical needed to fill the pipeline and the amount that must be procured when a program is started or expanded. Underestimation of stock in the pipeline is a common cause of program failure. So, quantification for a depleted pipeline should include the safety stock level required at each level of distribution (including PFSA Hubs), not only central PFSA level.

f) Estimating the procurement period

The procurement period covers the duration of time (months, years) between the moments when one places an order to the time the next regular order shall be placed. The sum of the quantity ordered and safety stock must cover the time until next order is received; which is procurement time plus lead time. The length of procurement period may be influenced by funding and storage space availability, as well as by expiry and availability of the stocks being ordered.

g) Considering the effect of lead time

Lead time is the time period (waiting period) from the moment an order is placed until it the supply arrives and gets ready for distribution. Lead time can vary from product to product as well as from supplier to supplier. When the lead time is underestimated, the likely results are risks of shortage and more expensive emergency purchases.

When quantifying for a program that is undergoing scale up, the quantity required to cover the lead time period should account for changes due to scaling up process.

h) Estimating safety stock

Safety stock is the amount of stock that is kept in reserve to cushion for unexpected changes in consumption, sudden increase in demands or uncertainty in the supply process from the suppliers. When quantifying for a program that is scale-up, the quantity required for safety stock will also need to be scaled-up.

When quantifying for a program that is undergoing scale up, the quantity required for the safety stock should account for changes due to scaling up process.

i) Adjusting for losses and other changes

Some medicines may be lost due to damage, expiry, spoilage or theft. If such loses are not considered in quantification and procurement, stock outs are likely to result. To prevent such conditions, a defined level of adjustment (addition of certain percentage level corresponding to the wastage rates) should be made so as to allow for losses when quantifying requirements.

In a supply system in which the number of users/patients or health facilities is growing, account for a reasonable level of increment in consumption of the medicines. Under such circumstances, estimated quantities can be increased by percentage that corresponds to the rate of growth.

j) Cross-checking the results of quantification

No matter how rigorously procedures for selected quantification methods are followed, checking the estimate with different quantification methods is always useful.

Cross-checking also is a fundamental step in reconciling forecasted quantities against available funds.

k) Estimating total procurement cost

When estimating the cost of medicines on a list of forecasted products, the critical issue is determining the next purchase prices. Using the previous (last) purchase prices is often inadequate as such efforts most often result in underestimation of the purchase prices, and leads insufficiency in funding levels by the time orders are to be placed.

To estimate the next purchase price of medicine, the first option is obtaining current medicine price on market. The other option is to adjust the last purchase price for factors such as inflation rate. After this, percentage price for shipping and insurance for pharmaceuticals and other fees should be added

l) Adjusting and reconciling final quantities

Difficult decisions are often made to readjust the final quantification output: by reducing quantities or eliminating selected medicines from the forecast list, so as to reconcile the quantities and total cost of the forecasts with the level of funding available.

Organizational policy decisions are required for such undertaking accounting priority diseases, priority age groups, and priority facilities to be supplied, and/or by selecting less expensive therapeutic alternatives, and eventually changing the treatment guidelines.

CHAPTER TWO

Quantification of ARVs, OI Medicines and Laboratory Products

2.1 Activity Planning

2.1.1 Program Description

Policy

The Pharmaceutical Fund and Supply Agency (PFSA), coordinating the quantification activity, should have information on the country's current and upto-dated HIV/AIDS care and treatment policy. These can be:

- National guidelines for PLHIV/AIDS care and treatment
- National guidelines for HIV testing
- National guidelines for PLHIV/AIDS biological follow up
- National strategic plans and documents (Investment case, HSTP, PSTP…)
- Program Implementation manuals, SOPs and related documents (Testing Algorithms, Scale up plan,
- Program and logistics performance reports
- Reputable international and local price references (CHAI ceiling price, International price guide, recent procurement price…)
- Government and Donor procurement guidelines (Host procurement guideline, GF procurement guide…)
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information sources and system

The Agency should provide any information in particular to data related to procurement and supply management. Moreover information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained officially from FMOH (HAPCO and HIV Program) through the Agency. National HIV/AIDS targets for prevention, care and treatment should be defined in line with those agreed upon in the national strategic plan and should hence be sent to the Quantification team through the Agency.

Inventory control System

Max - Min inventory control system, ordering and reporting periods established in the country will be used to describe required stock levels at central warehouse and downstream members of the supply chain i.e. PFSA hubs and health facilities. PFSA shall provide this information to the NQT as per the Logistic Management Information System (LMIS) for currently used ARVs, OI medicines and laboratory products.

Available acquisition funds

Information on available funding (government dedicated budget and partners funding) and the periods in which these budgets are adopted should be obtained from FHAPCO/FMOH, PFSA and other organizations, as appropriate.

Information on products

Get recent standard treatment guidelines for HIV/AIDS and the essential medicines list. Prepare the list of medicines to be quantified. The compiled list should then be sorted into the order that will best facilitate data collection.

Make sure that the list of products to be quantified are registered in Ethiopia and their pre-qualification status from reliable sources (WHO, FDA, Donor pre-qualification list or other sources) have been obtained.

Moreover, get updated information related to the type of equipments, laboratory commodities from PFSA, FMOH, FMHACA and EPHI.

Coordination

The coordination of all these activities related to the quantification of ARVs, OI medicines and laboratory products is done by National Quantification Team (NQT) under the supervision of National Procurement and Supply Management (PSM) Committee led by HAPCO/FMOH.

2 .1.2 Definition of the quantification methodology

The National Quantification Team will define the methods to be used according to available data and other information related to the program.

2 .1.3 Activity timeline

A precise timeline dedicated to the quantification activities should be setup by the National PSM Committee and may be revised as necessary.

The quantification exercise will be done every 2 years and updated annually.

The process will start in March and end up in May in order to be in line with the national and donors budget approval.

- Pre-quantification/preparation phase; 2 months
- Quantification (consultative workshop, Forecasting and supply planning exercise, and report preparation) Phase: 1 months
- Validation workshop and dissemination of the quantification result will be executed by June

2 .2 Preparatory phase

In this phase, the national PSM committee will assign representative National quantification team (NQT) with the right-mix that may include pharmacists, medical laboratory technologists, service providers, program managers/officers, LMIS experts, and Procurement officers, warehouse managers, clinicians and other relevant experts and the team will be led by representative from Forecasting and Capacity Directorate of the Agency. The PSM will also define the scope and forecasting period for the quantification exercise. The NQT will define the type and source of data required, develop data collection tools, collect the required data, and organize and analyze the data collected. The team will also review and summarize different documents such as national policies, strategic documents, plans and targets, technical documents and reports,

any epidemiological surveillance data, demographic health surveys, census data, or special survey studies. After making the necessary preparation for consultative workshop (analyze and adjust data, comparison of data from different source and propose assumption), the team will conduct the quantification consultative workshop. The participants of the consultative workshop may include program managers, policymakers, donors and implementing partner organizations, procurement officers, warehouse managers, and service providers.

For this section, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data and information's with the consultation of actors involved in the information system (PFSA, FMOH, and HAPCO, supporting partners…).
- Validate data(usually by comparing the result of different sources, performing trend analysis…etc)

2 .2 . 1 Data Collection and data sources

The importance of available and quality of data cannot be underestimated. The required data may include service data on the number and type of health services being provided and logistics data on the consumption and stock levels of commodities. A well-functioning health management information system (HMIS) and logistics management information system (LMIS) are central in improving the accuracy and usefulness of health commodity quantifications. In addition, morbidity data, demographic data, and information on national program policies, strategies, and expansion plans should be used to inform the assumptions in the forecasting step of the quantification.

The data and information can be collected through interviews and consultative meetings with key stakeholders, including program managers, policymakers, donors and implementing partner organizations, procurement officers, warehouse managers, and clinical and other technical experts, as well as from direct service providers.

Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical documents and reports, and any epidemiological surveillance data, demographic health surveys, census data, or special survey studies should be reviewed to collect morbidity and demographic data that can be used in the quantification.

Data generated from investigations, studies and researches will possibly help consolidating and/or complete data collected in a routine way. Exceptionally an active field data collection may be done.

I. Data necessary for forecasting of ARVs and OI medicines

- **Morbidity data, Service Statistics, and Demographic data:**
  - ART clients categorized by age as adults and children
  - Recent and updated regimens data according to line of treatment (1st and 2nd

line) and regimen proportion .

- Average number of new monthly inclusions into ART and proportions/number of adults and children being included
- Changing rates from 1st to 2nd line (treatment failure rates) or proportion of client to be on 2nd line
- Proportion of children by age and weight bands
- Lost to follow-up rate and death rate
- Co-morbidity rates (e.g. TB/HIV and HIV/Hepatitis)
- Number of post-exposed cases per month
- Number of children born from HIV infected women
- Prevalence and incidence of commonly occurring OI cases

➢ **Logistics data :** Products related Logistic data are the following:

- List and description of all products to be quantified (Generic name, dosage form, strength, basic unit of measure, pack size, etc)
- Estimated product unit prices per pack
- Consumption rate of FDCs, loose ARVs and OI medicines
- Consumption rate of liquid dosages and solid dosage forms for children
- List of pre-qualified and registered Manufacturers/Suppliers and products registration status in Ethiopia
- Monthly consumption per product for the last 12 months
- Annual consumption for the last 12 months
- Days of stock shortages/out per product for the last 12 months
- Shortage periods and durations during the last 12 months, as well as information on substitution products
- Information on all atypical consumptions, ie. Exceptional epidemics, treatment policy over the period, etc.

➢ **Information on current program performance, plans, strategies, and priorities, including specific program targets for each year of the quantification.**

II. Data necessary for forecasting laboratory products

➢ **Data related to HIV early infant Diagnosis/testing**

- Number of DBS samples collected
- Number of children tested through DNA PCR by the type of machines (eg. Roch or Abbot)
- Testing capacity and utilization rate for each infant testing machines
- Number of children tested positive through DNA PCR
- Number of children born from HIV infected women or No. of HIV+ pregnant women who gave birth within the same period
- No. of HIV+ve pregnant women planned to be on care and treatment

➢ **Data related to HIV testing**

- Number of HIV/AIDS tested individuals
- Number of individuals tested HIV/AIDS positive or prevalence of HIV
- Available and usable product stocks for HIV testing by the end of the defined

period, all over the country
- Consumption related to each testing products
- Monthly consumption or annual consumption per testing product for the last 12 months
- Days of stock shortages/out per testing product for the last 12 months

➢ **Data related to ART follow up**

- Number of patients under ART
- Number of patients awaiting treatment or on Pre-ART
- Number of tests done
- Number of initial immunological tests per client
- Number of follow up tests performed over the review period
- List of functioning lab equipment, their characteristics(Open or Closed) and usage rates
- List of reference centers for CD4/Viral Load samples
- Annual migration from pre-therapeutic phase to treatment phase
- Annual attrition of patients under ART and in pre-therapeutic phase
- Out of protocol tests
- Reagent lost/wastage rates
- Control reagent usage rates

III. Data for supply planning of both ARVs and Laboratory products

- National-or program-level stock on hand (preferably from physical inventory) of each product to be quantified (should include losses and adjustments)
- Expiration dates for the products in stock
- Quantity on order: any shipment quantities of product(s) already on order, but not yet received
- Established shipment intervals and current shipment delivery schedule
- Established national-or program-level maximum and minimum stock levels
- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information: (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (all procurement mechanisms—e.g., competitive international bidding/tendering, donor procurement, or local procurement—for all products to be quantified and procurement lead time for each procurement mechanism).
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

2 . 2 . 2 Data quality control (describe the system of quality control setup at the national level)

This very important step will assess data quality. This is done in order to reduce risks of errors. Organizations in charge of making data available will process databases (HCMIS, PLITS, HMIS and other data sources), harmonize and organize them.

Therefore the following operations will be done:

- Verification of data exhaustively
- Coherence control: this is aiming at verifying that when a figure is shown in a section, an equivalent figure will be sown in another section ;
- Data imputation or database adjustment: this consists in verifying and exaggerated processing data ;
- Verification in comparison with historical data: this allows comparing with other previously collected data (i.e. detect any important changes compared to previous report). Therefore any gap that does not respect established limitations is mentioned and subject to further analysis.
- Possible reconciliation with data from other sources (investigation and research data…)

2.2.3 Definition of assumptions

I. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

1. Assumptions on adjustments made to historical program data, when data are missing, unreliable, outdated, or incomplete
2. Assumptions on future program performance, based on factors influencing demand for services and commodities

Most often, complete data are not available for a particular quantification. The most critical point in making assumptions is to document clearly and specifically which assumptions were made, and on what basis. If there are few or no data, the forecast will rely heavily on assumptions.

Assumptions may include issues such as a change in STGs, products, program strategies, priorities, expansion plans, or service capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

Note: Standard Treatment schedules and options are usually dynamic and therefore it is important to conduct a consultative workshop in collaboration with stakeholder and partners (composed of national experts) to draw and get common consensus on the assumptions to be used for the quantification.

II. Assumption building during supply planning

As previously mentioned, the most critical point in the assumptions building process is to document clearly and specifically the sources of information and the key informant inputs on the assumptions.

And as in the forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning step, assumptions may need to be reached **on the timing of available funds, lead times for each supplier, exact amounts of funding available,** and estimates **on arrival dates of fund**

The quantification team will also need to make assumptions about national and facility stock levels, if the data are not available and to make assumptions about the minimum and maximum stock levels at each level of the logistics system (facility and central levels, for example).

2.2.4 Data Validation

This is an important step in making sure those data/information used in the process are reliable and quality enough for using them in determining products requirement. For this purpose, the validation usually done either by comparing the result obtained from different source or performing trend analysis. Results of data available at PFSA and at FMOH/HAPCO will be reconciled with data available with supporting partners.

2.3 QUANTIFICATION

2.3.1 Quantification tools

The quantification exercise is currently performed using the following tools:

- Quantimed® and Pipeline ®(ARV and OI)
- Excel and ForLab® for laboratory products
- Excel for Nutritional commodities

2.3.2 Forecasting (Need estimation)

The quantification of ARVs, OI drugs and laboratory programs is done in two separate phase:

- The first phase, the entire National Quantification Team members meet together, this will allow formatting data to be used during the quantification exercise.
- The second phase, NQT members divided into 2 groups: one group in charge of the quantification of ARVs and OI drugs and the other group in charge of the quantification of laboratory products.

By the end of the quantification exercise, a report is written by NQT.

Note: The quantification exercise will involve technical staff from different organizations previously trained in related IT programs. Session facilitations will be the role of PFSA, FMOH and HAPCO.

2.3.3 Supply Plan

Following needs specifications, a national supply plan for ARVs, OI medicines and laboratory commodities is designed by NQT members. These plans will take in account available and usable stocks at the national level and ongoing orders.

This activity will be done after exporting quantification results from Quantimed to Excel/Pipeline.

Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Excel/Pipeline® will generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by product quantities to be purchased by each donor according to its promised contribution, with required delivery period in order to guarantee adequate stock levels.

Supply plans hence budgeted will allow organizing donors' meetings in order to confirm available funds.

Thus, if available funds cover needs over the period, results will then be presented and validated by the Ministry of Health. If funding on the contrary do not cover estimate needs and if it is possible to get additional funding after resource mobilization, PFSA should request data and target adjustments and the quantification should be reviewed a new before validation. If the quantification exercise should be revised, this should be done the latest one month after the end of the initial quantification. If the available funds cover the needs over the forecasted period, then results will be presented to and validated by the FMOH. On the contrary, if the available fund does not cover the estimated forecasted needs, the FMOH should either find a way to raise additional funding source or else should request an adjustment on the data and targets; and the quantification should be reviewed again before validation. If need arises to revise the quantification exercise, then it should be done a month after the end of the initial quantification.

Supply plans, once validated will be communicated by the FMOH to each contributor, according to their contribution and budget

CHAPTER THREE

Quantification of Anti TB Medicines, Ancillary Medicines, Laboratory products

3.1 Activity Planning

3.1.1 Program Description

Policy

Information on the country's current and up to date anti TB treatment and prevention policy has to be available. These can be:

- Guideline for clinical and programmatic management of TB
- Guideline on programmatic management of drug resistant tuberculosis
- National guidelines for testing TB
- National strategic plans and documents (HSTP, NTP SP, ...)
- Annual national performance report on TB program implementation
- TB Global report by WHO
- Program Implementation manuals, SOPs and related documents (Testing Algorithms, scale up plan, ...)
- Program and logistics performance reports
- Reputable international and local price references (CHAI ceiling price, International price guide, recent procurement price...)
- Government and Donor procurement guidelines (Host procurement guideline, GF procurement guide...)
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information sources and systems

Information on supply management and procurement of pharmaceuticals can be obtained from PFSA. Moreover information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained from FMOH. National targets for prevention and treatment of TB should be defined in line with those agreed upon in the national strategic plan and should hence be sent to the quantification team through the national TB Program and/or TB Logistics TWG which led by PFSA.

Inventory Control System

The inventory control system dictate stock levels by type and level of organization. According to the health pyramid, as well as the ordering and reporting periods. This information should be provided to the National Quantification Team by PFSA in accordance with the Logistic Management Information System (LMIS) designed for anti TB first line and second line medicines, ancillary medicines and lab products

Available acquisition funds

Information on available funding (government dedicated budget and partners funding) and the periods in which these budgets are adopted should be obtained from FHAPCO/FMOH, PFSA and other organizations, as appropriate. The Agency, in relation with the FMOH, should make sure they have all information on available funding (government dedicated budget, partners' funding) and the periods in which these budgets are adopted.

Information on products

Get recent guidelines for clinical and programmatic management of TB and MDR TB in Ethiopia and the essential medicines list. Prepare the list of medicines to be quantified. The compiled list should then be sorted into the order that will best facilitate data collection. The list of products for anti TB FLD, MDR TB drugs, ancillary drugs, laboratory reagents and supplies for TB program is annexed at the back of the manual.

Make sure that the list of products to be quantified, are registration in Ethiopia and their pre-qualification status from reliable sources (WHO, FDA, Donor pre-qualification list or other sources) have been obtained.

Moreover get updated information related to the type of equipment, reagents and consumables from PFSA, FMHACA and EPHI.

Coordination

The NTP/FMOH and PFSA will be responsible for the coordination of all these activities related to the quantification of anti TB medicines and laboratory products.

3.1.2 Definition of the quantification methodology

The National Quantification Team will define the methods to be used according to available data and other information on the program.

3.1.3 Activity timeline

A precise timeline dedicated to the quantification activities should be setup by the National TB program and may be revised as necessary.

The quantification exercise will be done every 2 years and updated annually.

The process will start in June and end up in August

- Pre-quantification/preparation phase; 2 months,
- Quantification(Forecasting, supply planning and report preparation) Phase: 1 months
- Validation workshop and final quantification result dissemination will be executed in August

3.2 Preparatory phase

In this phase, the National TB Logistics TWG which is led by will assign representative National Quantification Team (NQT) with the right-mix of experts that may include pharmacists, medical laboratory technologists, physicians, program managers(from FMOH/NTP), LMIS experts,

and experts from implementing partner organization and the team will led by representative from Forecasting and Capacity Directorate of the Agency/TB forecasting team leader. The TB Logistics TWG will also define the scope and forecasting period for the quantification exercise. The NQT will define the type and source of data required, develop data collection tools, collect the required data, and organize and analyze the data collected. The team will also review and summarize different documents such as national policies, strategic documents, plans and targets, technical documents and reports, any epidemiological surveillance data, demographic health surveys, census data, or special survey studies After collecting, organizing, and analyzing data from all possible sources, the team will organize the quantification consultative workshop. The participants of the consultative workshop may include program managers, policymakers, donors and implementing partner organizations, procurement officers, warehouse managers, and service providers.

For this section, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data with all the actors involved in the information system (PFSA, FMOH, and supporting partners…).
- Validate data(usually by comparing the result of different sources, performing trend analysis…etc)

3.2.1 Data Collection and Sources

Different types of data and information will be required at each step in the quantification. The importance of available and quality data cannot be underestimated. These data may include services data on the number and type of health services being provided and logistics data on the consumption and stock levels of commodities for informing the quantification. A well-functioning health management information system (HMIS) and logistics management information system (LMIS) are central to improving the accuracy and usefulness of health commodity quantifications. In addition, morbidity data, demographic data, and information on national program policies, strategies, and expansion plans should be used to inform the assumptions in the forecasting step of the quantification.

Different types of data and information will be required at each step in the quantification. The data and information can be collected through interviews and consultative meetings with key stakeholders, including program managers, policymakers, donors, and implementing partner organizations, procurement officers, warehousing managers, and clinical and other technical experts, as well as from direct service providers.

Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical documents and reports, and any epidemiological surveillance data, demographic health surveys, census data, or special survey studies should be reviewed to collect morbidity and demographic data that can be used in the quantification.

Data generated from investigations, studies and researches will possibly help consolidating and/or complete data collected in a routine way. Exceptionally an active field data collection may be done.

I. Data necessary for forecasting of Anti TB and ancillary medicines

- **Morbidity data:** Patients' related data are the following:
  - The trend for morbidity data of the past years (new TB cases & Retreatment for both adult and pediatrics, MDR TB case and XDR cases)
  - The observed adult new TB cases for the past years
  - The observed adult retreatment cases for the past years
  - The observed new TB cases of pediatric for the past years
  - The observed retreatment cases for pediatrics
  - The observed cases of adult MDR TB and XDR TB cases
  - Target set by NTP strategic plan
  - The national population based Prevalence of all forms of TB case in the country
  - The national incidence of new TB cases
  - Type and incidence of ADR

- **Service data:**
  - Facility level and number
  - Service statistics data

- **Demographic and population data:**
  - Population number and growth rate
  - The proportion of children in the population

- **Information on current program performance, plans, strategies, and priorities, including specific program targets for each year of the quantification.**

- **Logistic data :** Products related Logistic data are the following:
  - List of all products to be quantified, with dosage, packing unit and unit prices per pack
  - Monthly consumption per product for the last 12 months
  - Annual consumption for the last 12 months
  - Days of stock shortages/out per product for the last 12 months
  - Information on all atypical consumptions, ie. Exceptional epidemics, treatment policy over the period, etc.

II. Data necessary for forecasting laboratory products

- **Data related to AFB microscopic test**
  - The national population based Prevalence of all forms of TB case in the country
  - Incidence of TB cases
  - Targets set by NTP strategic plan
  - Number of sites giving the service

- Testing Algorithm
- reagents and supplies list
- Usage rates
- Wastage rate and other contingencies such as training

➢ **Data related to fluorescent microscopic test**

- The national population based Prevalence of all forms of TB case in the country
- Incidence of new TB cases
- Target set by NTP strategic plan
- Test Algorism
- reagent and supplies list
- Number of sites giving the service
- Usage rates
- Wastage rate and other contingencies such as training

➢ **Data related to culture test**

- The national population based Prevalence of all forms of TB case in the country and incidence of new TB case.
- Target set by NTP strategic plan
- Test Algorism
- Reagent and supplies list
- Number of sites giving the service
- Usage rates
- Wastage rate and other contingencies such as training

➢ **Data related to gene expert**

- The national population based Prevalence of all forms of TB case in the country and incidence of new TB cases
- Target set by NTP strategic plan for 2015-2020
- Test Algorism
- reagent and supplies list
- Number of sites giving the service
- Usage rates
- Wastage rate and other contingencies such as training

III. Data for supply planning of both Anti TB medicines and Laboratory products

- National-or program-level stock on hand (preferably from physical inventory) of each product to be quantified (considering losses and adjustments)
- Expiration dates for the products in stock
- Quantity on order: any shipment quantities of product(s) already on order, but not yet received.
- Established shipment intervals and current shipment delivery schedule
- Established national-or program-level maximum and minimum stock levels
- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List, specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others).

- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (all procurement mechanisms—e.g., competitive international bidding/tendering, donor procurement, or local procurement—for all products to be quantified and procurement lead time for each procurement mechanism).
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

3.2.2 Data quality control (describe the system of quality control setup at the national level)

This very important step will assess data quality. This is done in order to reduce risks of errors.

Organizations in charge of making data available will process databases (HCMIS, HMIS and other data sources), harmonize and organize them.

Therefore the following operations will be undertaken:

- Verification of data exhaustively
- Coherence control: this is aiming at verifying that when a figure is shown in a section, an equivalent figure will be shown in another section;
- Data imputation or database adjustment: this consists in verifying and processing data;
- Verification in comparison with historical data: this allows comparing with other previously collected data (i.e. detect any important changes compared to previous report). Therefore any gap that does not respect established limitations is mentioned and subject to further analysis.
- Possible reconciliation with data from other sources (investigation and research data)

3.2.3 Definition of assumptions

I. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

1. Assumptions on adjustments made to historical program data, when data are missing, unreliable, outdated, or incomplete
2. Assumptions on future program performance, based on factors influencing demand for services and commodities

Most often, complete data are not available for a particular quantification. The most critical point in making assumptions is to document clearly and specifically which assumptions were made, and on what basis. If there are few or no data, the forecast will rely heavily on assumptions.

Assumptions may include issues such as a change in Standard Treatment Guidelines, test protocols, products, program strategies, priorities, expansion plans, or service capacity

(infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

Note: Standard Treatment schedules and options are usually dynamic and therefore it is important to conduct a consultative workshop in collaboration with stakeholders and partners composed of l experts to draw and get common consensus on the assumptions to be used for the quantification.

II. Assumption building during supply planning

As previously mentioned, the most critical point in the assumptions building process is to document clearly and specifically the sources of information and the key informant inputs on the assumptions.

And as in the forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning step, assumptions may need to be reached **on the timing of available funds, lead times for each supplier, exact amounts of funding available,** and estimates **on arrival dates of fund.**

The quantification team will also need to make assumptions about national and facility stock levels, if the data are not available, and also make assumptions about the minimum and maximum stock levels at each level of the logistics system (facility and central levels, for example).

3.2.4 Data Validation

Results of data available at PFSA and at FMOH will be reconciled with data available with relevant stakeholders.

3.3 QUANTIFICATION

1.3.1 Quantification tools

The quantification exercise will be done with the following tools:

- QuanTB® and Pipeline ®(Anti TB drugs)
- Excel and ForLab® for laboratory products

3.3.2 Forecasting (Need estimation)

The quantification of Anti TB first line and second line drugs, ancillary drugs, laboratory reagent and supplies is done in two separate phase:

- The first phase, the entire National Quantification Team members meet together, this will allow formatting data to be used during the quantification exercise.
- The second phase, NQT members divided into 3 groups: one group in charge of the quantification of Anti TB first line, the second group for anti TB second line drug and ancillary drugs and the other group in charge of the quantification of laboratory reagents and supplies.

By the end of the quantification exercise, a report is written by NQT.

Note: The quantification exercise will involve technical staff from different organizations previously trained in related IT programs. Session facilitations will be the role of FMOH/PFSA.

3.3.3 Supply Plan

Following needs specifications, a national supply plan for Anti TB drugs, ancillary drugs, laboratory reagent and supplies is designed by NQT members. These plans will take in account to available and usable stocks at the national level and ongoing orders.

This activity will be done after exporting quantification results from QuanTB to Excel/Pipeline.

Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Excel/Pipeline® will generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by product quantities to be purchased by each donor according to its promised contribution, with required delivery period in order to guarantee adequate stock levels.

Thus, if available funds cover needs over the period, results will then be presented and validated by the Ministry of Health. If funding on the contrary do not cover estimate needs and if it is possible to get additional funding after resource mobilization, PFSA should request data and target adjustments and the quantification should be reviewed a new before validation. If the quantification exercise should be revised, this should be done the latest one month after the end of the initial quantification.

Supply plans, once validated will be communicated by the FMOH to each contributor, according to their contribution and budget.

CHAPTER FOUR

Quantification of Anti- Malaria commodities

4.1 Activity Planning

4.1.1 Program Description

Policy

The Pharmaceutical Fund and Supply Agency (PFSA), coordinating the quantification activity, should have information on the country's current and up-to-dated malaria care, prevention and treatment policy. These can be:

- National Strategic Plan for Malaria Prevention, Control and Elimination
- Malaria Treatment Guideline of Ethiopia
- Standard Treatment Guideline
- National strategic plans and documents (Investment case, HSTP, PSTP…)
- Program Implementation manuals, SOPs and related documents (testing algorithms, scale up plan),
- Program and logistics performance reports
- Previous quantification reports.
- Reputable international and local price references (International price guide, recent procurement price…)
- Government and donor procurement guidelines (host procurement guideline, Global Fund procurement guide…)
- Demographic and Health Surveys
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information sources and systems

The Agency, as a coordinator of the quantification activity, should provide any information/data related to supply management and procurement. Moreover, information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained officially from FMOH (National malaria case report from EPHI) through the Agency. National Malaria targets for prevention, care and treatment should be adopted from what has been defined in the national strategic plan and should hence be sent to the Quantification Team through the Agency.

Inventory control system

It can be described as the required stock levels by type of organization according to the health pyramid, as well as the ordering and reporting periods for products currently used in malaria prevention, diagnosis & treatment. This information should be provided to the national quantification team by PFSA as per the Logistic Management Information System (LMIS)

Funding

FMOH and the Agency shall collaborate to make sure all funding information from all sources (government dedicated budget, donor funding) are identified, including the: amount, source and the period with in which the funds shall be available, and communicated to the national quantification team.

Product information

Obtain recent standard treatment guidelines for malaria and the national medicines list. Prepare the list of medicines and other commodities to be quantified for diagnosis and prevention. Then, sort the compiled list into an order that will best facilitate data collection.

Make sure that the lists of products to be quantified are registered in Ethiopia and/or check pre-qualification status from reliable organizations (WHO, FDA, Donor pre-qualification list or other sources). Moreover, obtain updated information related to equipment, reagents, test kits and consumables from appropriate bodies such as FMHACA and EPHI.

Coordination

PFSA leads and coordinates the national quantification committee established with relevant stakeholders for quantification of anti-malaria commodities.

4.1.2 Definition of the quantification methodology

The national quantification team shall define the methods to be used based on available data and program specific information.

4.1.3 Activity timelines

A precise timelines dedicated to the quantification activities should be setup by the national quantification committee and may be revised as necessary.

The quantification exercise will be done every 2 years and updated annually. The quantification process shall start in March and ends in May so as to align with the national budget year plan.

- Pre-quantification (preparatory) phase: 1 months
- Quantification phase (forecasting, supply planning, report preparation and validation): 2 months

4.2 Preparatory phase

During preparatory phase, the national malaria logistics TWG will assign representative National Quantification Team (NQT) with the right-mix and define the scope and forecasting period for the exercise. The assigned team will define the data requirement and source of data; develop data collection tools, collects data (demographic, morbidity, service and logistics). In addition, the team shall review relevant documents (national strategic plans, policies, targets, surveys, reports and census data) and prepare a summarized data inputs for the quantification exercise.

The quantification team shall organize national consultative workshop by inviting the right participant with the right expertise by involving all relevant stakeholders (program managers, policymakers, donors and implementing partner organizations, procurement officers, warehousing managers, and clinicians).

During preparatory phase for quantification exercise, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data with all the actors involved in the information system (PFSA, FMOH, RHBs, EPHI, Partners…).
- Validate data

4.2.1 Data Collection

The importance of quality and complete data for quantification is paramount. Important data sets include service data (by number and type of services provided), logistics data (consumption and stock level information), and demographic data.

A well-functioning health management information system (HMIS) and logistics management information system (LMIS) are central to improving the accuracy and usefulness of health commodity quantifications. In addition, morbidity data, demographic data, and information on national program policies, strategies, and service expansion plans should be used to inform assumption building in the forecasting step of the quantification.

Data can be collected through interviews and consultative meetings with key stakeholders as well as from service providers. Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical documents, reports, epidemiological surveillance data, demographic health surveys, census data, or special survey studies can be reviewed to collect morbidity and demographic data that can be used in the quantification. Data generated from investigations, studies and researches may augment data collected through routine reporting. Exceptionally an active field data collection may be done.

IV. Data necessary for forecasting of anti-malaria commodities

- **Morbidity data:**

  Patient related data that are useful for anti-malaria commodities forecasting are:
  - Rates of occurrence of fever episodes per person per year
  - Data on program plans, strategies, priorities, targets, and performance
  - Health seeking behavior
  - Proportions of diagnosis by method: RDT, microscopy and clinical diagnosis; changes in the diagnostic criteria.
  - Positivity rate for each diagnosis method
  - Patients by Malaria Parasite Type (p. falciparem, p. vivax & mixed)
  - Standard Malaria Treatment Guidelines
  - Uncomplicated and complicated malaria cases.
  - Proportions of age groups treated by different formulations/ patient packs and dosages.

- Public Health Emergency Management (PHEM) malaria case reports.
- Facility reporting rate.
- Changes in malaria epidemiology over years/period (seasonality of malaria, changes in rainfall patterns and epidemics)

➢ **Demographic data:**

Demographic data that are useful for anti-malaria commodities forecasting are:

- Population at risk of malaria (free, low risk, medium risk and high risk)
- Population figures and proportions by age from demographic health survey, malaria indicator surveys or population projections
- Percentage of pregnant from the total population
- Migratory population to malariaus area per year.
- Refugee population.
- The target numbers of houses to be sprayed with Indoor Residual Spray (IRS)
- The target woredas found in the malarious areas targeted to larvicide
- Total population targeted for Long Lasting Insecticide-treated Nets (LLIN) distribution

➢ **Logistics data :**

Logistics data that are useful for anti-malaria commodities forecasting are:

- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- Prescribing/dispensing rate of dispersible Artemether-Lumefantrine (AL) forms, especially for children
- Monthly consumption per product for the review period
- Stock out per product for the review period
- Wastage rate
- Durability of protective supplies and LLIN

V. Data necessary for forecasting laboratory products

➢ **Data related to malaria testing**

- Number of health facilities by type/level and population tested
- Proportion of health facilities that use RDT for malaria diagnosis
- Proportion of health facilities that use microscopy for malaria diagnosis
- Proportion of health facilities that use clinical examination for malaria diagnosis
- List of all reagents, chemicals and supplies (with specification & pack size) used for microscopy testing

VI. Data for supply planning of anti-malaria commodities.

- National or program level stock status (SOH, stock on shipment and order) of each product to be quantified
- Expiration dates for the products in stock
- Established shipment intervals and current shipment delivery schedule
- Established national or program-level maximum and minimum stock levels

- Seasonality of malaria cases
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (all procurement mechanisms for all products to be quantified and procurement lead time for each procurement mechanism).
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

4.2.2. Data quality control (system of quality control setup at the national level)

The reliability of data source depends on design of the information system, and accuracy of the data and completeness of the data. The appropriateness, accuracy and completeness of data should be evaluated before using it for quantification purposes.

The following activities should be performed so as to improve the data quality:

- Verification of data exhaustively
- Coherence control: this is aiming at verifying when a figure is shown in a section, an equivalent figure will be sown in another section
- Compensate through extrapolation and interpolation for incomplete data
- Do not rely on the data, if it is more than five or six years old
- Crosschecked dispensed-to-client records with stock records; stock records with actual stock levels; records from to validate reliability
- Use established guidelines regarding program growth.
- Possible reconciliation with data from other sources (investigation and research data…)

4.2.4 Definition of assumptions

I. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

1. Assumptions on adjustments made to historical program data: when data are missing, unreliable, outdated, or incomplete
2. Assumptions on future program targets: based on factors influencing demand for services and commodities

Most often complete data are not available for quantification. If there are few or no data, the forecast will rely heavily on assumptions. Thus, assumption building is critical activity in forecasting exercise. The most critical point in making assumptions is to document, clearly and specifically, what assumptions were made and the basis for making the assumptions.

Assumptions may include issues such as a change in products, program strategies, priorities, scale up, or service capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

I. Assumption building during supply planning

Similar to the practices indicated in forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning, assumptions may need to be reached on the timing of available funds, lead times for each supplier, exact amounts of funding available, and estimates on arrival dates of fund.

4.2.4 Data Validation

Data available at different sources (health facilities report, HDS data, National census data, logistic data from inventory and records) needs to be reconciled

4.3 QUANTIFICATION

4.3.1 Quantification tools

The following tools will be used to conduct the quantification exercise:

- Pipeline 5
- Quantimed
- Excel

4.3.2 Forecasting

The quantification team usually follows the following steps during forecasting:

- Organize and analyze data
- Select the forecasting method
- Build forecasting assumptions (structure a forecasting tree)
- Calculate forecasted need for each product
- Compare and reconcile forecasts prepared with different types of data to determine the final forecast

4.3.3 Supply Plan

Following needs specifications, a national supply plan for anti-malaria commodities is designed by NQT members. The plans will take in account available and usable stocks at the national level and ongoing orders. The activity can be accomplished using pipeline software designed for this purpose. Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Pipeline® will generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by product quantities to be purchased by each donor according to its promised contribution, with required delivery period in order to guarantee adequate stock levels.

Supply plans hence budgeted will allow organizing donors' meetings in order to confirm available funds.

Thus, if available funds cover needs over the period, results will then be presented and validated by the Ministry of Health. If funding on the contrary do not cover estimate needs and if it is possible to get additional funding after resource mobilization, PFSA should request data and target adjustments and the quantification should be reviewed a new before validation. If the quantification exercise should be revised, this should be done the latest one month after the end of the initial quantification. Supply plans, once validated will be communicated by the MOH, to each donor, according to their contribution and budget.

CHAPTER FIVE

Quantification of Family Planning Commodities

5.1 Activity Planning

5.1.1 Program Description

Policy

The Pharmaceutical Fund and Supply Agency (PFSA), coordinating the quantification activity, should have information on the country's current and up to dated polices relevant with family planning.

- National guidelines for family planning services in Ethiopia
- National Reproductive Health Strategy
- Universal Condom strategy
- National strategic plans and documents (Investment case, HSTP, PSTP…)
- Program Implementation manuals, SOPs and related documents
- Program and logistics performance reports
- Demographic and Health Surveys
- Reputable international and local price references (price index, International price guide, recent procurement price…)
- Previous quantification reports
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information tools and system

The Agency, as a coordinator of the quantification activities, should provide any information/ data related to supply management and procurement. Moreover, information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained officially from FMOH through the Agency. National Family planning targets should be adopted from what has been defined in the national strategic plan and should hence be sent to the Quantification Team through the Agency.

Inventory control System

This can be described as the required stock levels by type of organization according to the health pyramid, as well as the ordering and reporting periods. This information should be provided to the National Quantification Team by PFSA according to the Logistic Management Information System (LMIS) for currently used family planning products.

It can be described as the required stock levels by type of organization according to the health pyramid, as well as the ordering and reporting periods. This information should be provided to the national quantification team by PFSA as per the Logistic Management Information System (LMIS) for products currently used for family planning purposes.

Funding

FMOH and the Agency shall collaborate to make sure all funding information from all sources (government dedicated budget, donor funding) are identified, including the: amount, source and the period with in which the funds shall be available, and communicated to the national quantification team.

Product information

Obtain national guidelines for family planning services in Ethiopia and the national medicines list. Prepare list of medicines and other commodities to be quantified for family planning services. Then, sort the compiled list into an order that will best facilitate data collection.

Make sure that the list of products to be quantified are registered in Ethiopia and/or check pre-qualification status from reliable organizations (WHO, FDA, Donor pre-qualification list or other sources). Moreover, obtain updated information related to family planning commodities from appropriate bodies such as FMHACA.

Coordination

PFSA leads and coordinates the national quantification committee assembled from relevant stakeholders for quantification of Family planning commodities.

5.1.2 Quantification methodology

The national quantification team shall define the methods to be used based on available data and program specific information.

5.1.3 Activity timelines

A precise timelines dedicated to the quantification activities should be setup by the national quantification committee and may be revised as necessary.

The quantification exercise will be done every 2 years and updated annually. The quantification process shall start in April and ends in June so as to align with the national budget year plan.

- Pre-quantification (preparatory) phase: 1 months
- Quantification phase (forecasting, supply planning, report preparation and validation): 2 months

5.2 Preparatory phase

During preparatory phase, PFSA and FMOH will assign/invite representative National Quantification Team (NQT) with the right-mix and define the scope and forecasting period for the exercise. The assigned team will define the data requirement and source of data; develop data collection tools, collects data (demographic, service and logistics). In addition, the team shall review relevant documents (national strategic plans, policies, targets, surveys, reports and census data) and prepare a summarized data inputs for the quantification exercise.

The quantification team shall organize national consultative workshop by inviting the right participant with the right expertise which involves all relevant stakeholders (program managers,

policymakers, donors and implementing partner organizations, procurement officers, warehousing managers, and service providers).

During preparatory phase for quantification exercise, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data with all the actors involved in the information system (PFSA, FMOH, RHBs, Partners ...).
- Validate data
- Build assumptions

5.2.1 Data Collection

The importance of quality and complete data for quantification is paramount. Important data sets include service data (new acceptors or new clients, revisits, users or current users), logistics data (consumption and stock level information), and demographic/population data.

A well-functioning health management information system (HMIS) and logistics management information system (LMIS) are central to improving the accuracy and usefulness of health commodity quantifications. In addition, service data, demographic data, and information on national program policies, strategies, and expansion plans should be used to inform assumption building in the forecasting step of the quantification.

Data can be collected through interviews and consultative meetings with key stakeholders as well as from service providers. Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical reports, and epidemiological surveillance data, demographic health surveys, census data, or special survey studies can be reviewed to collect service statistics and demographic data that can be used in the quantification. Data generated from investigations, studies and researches may augment data collected through routine reporting.

I. Data necessary for forecasting of Family planning commodities

- **Service statistics:** Service data are taken from regular management reports at service delivery sites. The most commonly counted service statistics are:
    - **New acceptors or new clients**: The number of persons visiting a program and accepting a method for the first time. There are many variations for this indicator. It includes clients that are new to: modern contraception, particular facility, and/or particular contraceptive method.
    - **Revisits:** the number of repeated visits made by clients during a particular time period.
    - **Users or current users:** The number of individuals served by the program that are using a particular method at a particular point in time, whether or not they have actually made a visit during the reporting period.
- **Population data (demographic data):** Population and family planning data could be results obtained from survey, census, or operational researches in a given geographical area or in specific population group. The key demographic and

program data required for contraceptive forecasting are:

- **Number of Women of Reproductive Age (WRA):** Number of women in their reproductive years (15–49 yrs).
- **Percentage of WRA married (MWRA) or in union:** An estimate of the percentage of WRA who are potentially at risk of pregnancy.
- **Contraceptive Prevalence Rate (CPR):** Percentage of the base population (WRA or MWRA) using a contraceptive method, frequently disaggregated by modern versus traditional methods and by individual contraceptive methods.
- **Method mix:** Mix of contraceptive methods used by the population expressed as the percentage that each method constitutes of all contraceptives used.
- **Total Fertility Rate (TFR):** Average number of live births a woman would have if she survived to age 49 and had births at the prevailing age-specific rates.
- **Source mix:** Source of supply for contraceptives, as reported in the DHS. This is needed because most prevalence surveys report on all national use, whereas most forecasts are prepared for a specific program, such as a ministry of health (public sector) program.
- **Population growth rate:** Annual rate of population growth, measured as births minus deaths plus/minus migration, or the more commonly available rate of natural increase, which is simply births minus deaths. It should be noted that these rates measure the growth of an entire population and may differ somewhat from the rate of growth for MWRA.

These population data are typically available from one of several sources—

- **Demographic and Health Surveys (DHS):** A regular series of surveys, including such indicators as total fertility rate (TFR), percent of women in union, Contraceptive Prevalence Rate (CPR), source of family planning services, and method mix. Reproductive Health and Family Planning Surveys. A series of national surveys, similar to the DHS
- **National censuses:** Complete population counts taken by Central Statistics Agency every 10 years. Details of age and sex structure of a national population and various subpopulations, providing figures for women of reproductive age (WRA) and percent married (MWRA) or in union.

➢ **Logistic data:**

- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- List of all products to be quantified, with dosage, packing unit and unit prices per pack
- Monthly consumption per product for the review period
- Wastage rates
- Annual consumption for the last 12 months
- Stock out per product for the review period

I. Data for supply planning of Family planning commodities and consumables

- National or program level stock status (SOH, stock on shipment and stock on order) of each product to be quantified
- Expiration dates for the products in stock
- Established national or program-level maximum and minimum stock levels
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (all procurement mechanisms for all products to be quantified and procurement lead time for each procurement mechanism).
- Distribution information (custom clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

5.2.2 Data quality control (system of quality control at national level)

Accurate and quality data is very crucial at all level of the supply chain for the appropriate forecasting and supply planning. The reliability of any data source depends on design of the information system, accuracy of records and completeness of the data.

The appropriateness, accuracy and completeness of data should be evaluated before using for quantification purposes.

The following activities should be performed so as to improve the data quality:

- Verification of data exhaustively
- Coherence control: this is aiming at verifying when a figure is shown in a section, an equivalent figure will be sown in another section
- Compensate through extrapolation and interpolation for incomplete data
- Do not rely on the data, if it is more than five or six years old
- Crosschecked dispensed-to-client records with stock records; stock records with actual stock levels; records from to validate reliability
- Use established guidelines regarding program growth.
- Possible reconciliation with data from other sources (investigation and research data...)

5.2.3 Definition of assumptions

II. Assumption building for forecasting steps

Two kinds of assumptions need to be made during the forecasting step:

3. Assumptions on adjustments made to historical program data: when data are missing, unreliable, outdated, or incomplete
4. Assumptions on future program targets: based on factors influencing demand for services and commodities

Most often complete data are not available for quantification. If there are few or no data, the forecast will rely heavily on assumptions. Thus, assumption building is critical activity in forecasting exercise. The most critical point in making assumptions is to document, clearly and specifically, what assumptions were made and the basis for making the assumptions.

Assumptions may include issues such as a change in products, program strategies, priorities, scale up, or service delivery capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

III. Assumption building during supply planning

Similar to the practices indicated in forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning, assumptions may need to be reached on the timing of available funds, lead times for each supplier, exact amounts of funding available, and estimates on arrival dates of fund.

5.2.4 Data Validation

Data available at different sources such as census, DHS, Performance Monitoring and Accountability (PMA) needs to be reconciled

5.3 QUANTIFICATION

5.3.1 Quantification tools

The following tools will be used to conduct the quantification exercise:

- Pipeline 5
- Quantimed
- Family Planning Reality check
- Excel

5.3.2 Forecasting

The quantification team usually follows the following steps during forecasting:

- Organize and analyze data
- Select the forecasting method
- Build forecasting assumptions (structure a forecasting tree)
- Calculate forecasted consumption for each product
- Compare/reconcile forecasts prepared with different types of data to determine the final forecast

5.3.3 Supply Plan

Following needs specifications, a national supply plan for family planning commodities is designed by NQT members. The plans will take in account available and usable stocks at the national level and ongoing orders. The activity can be accomplished using pipeline software designed for this purpose. Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Pipeline® will generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by product quantities to be purchased by each donor according to its promised contribution, with required delivery period in order to guarantee adequate stock levels.

Budget supply plans will allow organizing donors' meetings in order to confirm available funds.

Thus, if available funds cover needs over the period, results will then be presented and validated by the Ministry of Health. If funding on the contrary do not cover estimate needs and if it is possible to get additional funding after resource mobilization, PFSA should request data and target adjustments and the quantification should be reviewed a new before validation. If the quantification exercise should be revised, this should be done the latest one month after the end of the initial quantification. Supply plans, once validated will be communicated by the MOH, to each donor, according to their contribution and budget.

CHAPTER SIX

Quantification of Vaccines and Related Supplies

6.1. Activity Planning

6.1.1. Program Description

Policy

The primary objective of forecasting is to estimate the routine immunization program, planned supplementary immunization activities and the outbreak responses vaccines and devices requirement with the funding sources and supply plans.

The FMOH/PFSA, as coordinating entities for the quantification exercise, needs to have an up-to-date policy direction and strategies pertaining to EPI in Ethiopia in general and EPI Logistics in specific. Accordingly, the following are important policy and/or strategy tools:

- Health Policy of Ethiopia
- Health Sector Transformation Plan (HSTP)
- Pharmaceutical Supply Transformation Plan (PSTP)
- Ethiopia EPI Cumulative Multi-Year Plan (CYMP)
- Routine EPI Improvement Plan (RIIP)
- Cold Chain Expansion and Rehabilitation Plan (CCERP)
- Joint ICC member organizations plans
- Other National strategic plans and documents
- Program and logistics performance reports
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information tools and system

PFSA/FMOH, as coordinators for quantification activity, should provide any information/data related to supply managementof EPI products. Moreover, information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained officially from Procurement Organizations, Funders, etc, through FMOH/PFSA.

National EPI targets should be defined in line with those agreed upon in the EPI programme related strategic plans (CMYP, RIIP, etc) and should hence be availed for the quantification team through FMOH/ the Agency.

Inventory control System

This can be described as the required stock levels by type of organization according to the health system pyramid, as well as the ordering and reporting periods. This information should be provided to the National Quantification Team by FMOH/PFSA as per the Logistic Management Information System (LMIS) currently in use for EPI commodities (vaccines and related dry supplies).

Funding

FMOH and the Agency shall collaborate to ensure that all information related to available funds (from GAVI, co-financing by Government of Ethiopia, contribution from development partners, specific support from UNICEF/WHO and bi-lateral partners) are identified, including the: amount, source and the period with in which the funds shall be available, and communicated same to the National Quantification Team.

Products information

Obtain recent guidelines and the national medicines list. Prepare the list of vaccines and related supplies to be quantified. The compiled list should then be sorted into the order that will best facilitate data collection. The product list shall be prepared in line with the list of vaccines and related dry supplies identified by the EPI Programme.

Make sure that the lists of products to be quantified are registered in Ethiopia and/or status of pre-qualification from reliable organizations (WHO, FDA, Donor pre-qualification list or other sources). Moreover, obtain updated information related to equipment, reagents, test kits and consumables from appropriate bodies such as FMHACA.

Coordination

FMOH and PFSA shall lead and coordinate the quantification process for vaccines and related dry supplies.

6.1.2. Quantification Methodology

The National Quantification Team will select which method of quantification shall be used based on the scope of the quantification, level of available data and other program related information.

6.1.3. Activity timelines

Timeline for the quantification exercise shall be identified by the National quantification team and may be revised as necessary. The quantification exercise shall be conducted every three years and is updated annually.

This process will have two consecutive phases:

- Pre-quantification/preparatory phase – 2 months (September & October);
- Quantification exercise phase – 1 months (November & December)
    - Forecasting, supply planning and preliminary Report Preparation: 2 months (November)
    - Review, validation and endorsement of quantification output document by PFSA/ FMOH management, ICC, and UNICEF SD (December)
- Request for procurement service from UNICEF SD (January)

6.2. Preparatory phase

During preparatory phase,the National Vaccine and Cold Chain Logistics TWG which is led by PFSA will assign/invite representative National Quantification Team (NQT) with the right-mix and define the scope and forecasting period for the exercise. The assigned team will define the data requirement and source of data; develop data collection tools, collects data (target population, size of immunization session and/or previous consumption). In addition, the team shall review relevant documents (national strategic plans, policies, targets, surveys, reports and census data) and prepare a summarized data inputs for the quantification exercise.

The quantification team shall organize national consultative workshop by inviting the right participant with the right expertise which involves all relevant stakeholders (program managers, policymakers, donors and implementing partner organizations, procurement officers, warehousing managers, and service providers).

During preparatory phase for quantification exercise, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data with all the actors involved in the information system (PFSA, FMOH, RHBs, Partners ...).
- Validate data
- Build assumptions

6.2.1. Data Collection

Availability of a complete and quality data is important in vaccine quantification exercise. Different types of data may be used based on the type of quantification method selected. Whenever Target Population method is used, the size of target population, the planned/ expected immunization coverage, number of doses per child, and wastage multiplier factors are important. When using Size of Immunization Session method is used, the number of immunization posts for the target catchment, number of immunization weeks per year, number of immunization sessions per week, average number of vaccine vials opened per session, and the number of doses per vial of vaccines are required. When using Previous Consumption method, stock related information such as the beginning balance, quantity received, ending balance and numbers of vials discarded in a given period are important.

A well-functioning health management information system (HMIS), Logistics Management Information System (LMIS) and good stock management practice are central to improving the accuracy and usefulness of vaccines quantification. In addition, demographic data and information on national programmes, policies, strategies, and expansion plans should be used to formulate the assumptions in the forecasting step of the quantification.

Data can be collected through interviews and consultative meetings with key stakeholders as well as from service providers. Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels

of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical reports, and epidemiological surveillance data, demographic health surveys, census data, or special survey studies can be reviewed to collect service statistics and demographic data that can be used in the quantification. Data generated from investigations, studies and researches may augment data collected through routine reporting.

I. Data necessary for forecasting of vaccines and related commodities

a. Target population: is the number of people who are eligible for vaccination with a particular vaccine. The Target Population includes both the host and refugee population.

- For tetanus toxoid (TT) vaccine the target population is the total number of pregnant and non-pregnant women in the childbearing age-group (15–49 years).
- For BCG vaccine, the target population is all live births (i.e. complete expulsion from the mother, regardless of duration of pregnancy, showing any evidence of life).
- For all other vaccines in the Expanded Programme on Immunization (EPI), the target population is all surviving infants (i.e. survive to their first birthday).

The accuracy with which the target population is measured or estimated is as critical in vaccine forecasting as it is in calculating coverage. To increase accuracy, target population figures should be adjusted annually, especially in urban areas where populations constantly change and in rural areas subject to high migration. Woreda based population figures gathered through Plan and Policy Directorate in FMOH can be used to estimate total population, birth and surviving infants, under five, and under fifteen children. In addition, data shared from ARRA/UNHCR is used to estimate under one, under five and under fifteen children in refugee population.

Due to reliability and completeness of available data, demographic data are preferred for forecasting exercise.

In addition, the following data/information is critical when using Target Population method:

- ✓ **Immunization Coverage**: targeted National Immunization coverage by individual vaccine by year can be obtained from the Comprehensive Multi-Year Plan (cMYP) for the intended time period.

- ✓ **Immunization schedules/Number of doses required per child**: data/information regarding the number of doses of vaccines required to fully immunize a child is also important during vaccine forecasting. The immunization schedule is in line with the national EPI policy of Ethiopia

- ✓ **Wastage Rate:** Since there is no documented study on wastage factors, WHO's wastage rate indicators adjusted slightly based on field vaccine wastage level experience shall be used for vaccine forecasting. Annex XX shows wastage rate of the different vaccine used in Ethiopia.

b. Size of Immunization Session: Even if this method of vaccine forecasting yields more accurate result at lower levels (woreda and health facilities), it can also be presented as an alternative vaccine forecasting method. It may be an appropriate method if you cannot determine the rates of vaccine wastage, or if vaccine stock management is not good.

Forecast using Size of Immunization Session primarily requires data/information on: the number of immunization posts for the target catchment, number of immunization weeks per year, number of immunization sessions per week, average number of vaccine vials opened per session, and the number of doses per vial of vaccines are required.

Annual vaccine needs = posts x weeks x sessions x vials x doses, where:

- posts = number of immunization sites
- weeks = number of weeks the service is delivered during the year
- sessions = number of immunization sessions per week
- vials = number of vials opened per immunization session
- doses = number of doses per vial.

c. Consumption method: This method is based on the consumption of vaccines during the previous reporting period (usually the previous year). Some adjustment may be necessary if you believe that there has been any increase in the population size since the previous vaccine consumption was recorded. This method is useful for a health facility where the stock management is good, but there is insufficient information on immunization objectives and targets for the next action plan. It is also useful when placing short-term orders.

For this calculation, we use an equation based on the stock of vaccine at the beginning and end of a particular period, the vaccines received during that period, and the vaccines lost, destroyed or thrown away during that period.

- ✓ Beginning balance – initial stock at the beginning of the given period;
- ✓ Quantity received – stock received during the period;
- ✓ Ending Balance – stock remaining at the end of the review period, and
- ✓ Discarded quantity – number of unopened vaccines vials lost (destroyed, frozen or affected by high temperature or expired during the same period).

d. Forecasting Dry Supplies

Bundling refers to the practice of organizing related stock all together in 'bundles' consisting of the correct numbers of all the items you need during an immunization session:

- good quality vaccines and diluents
- mixing syringes
- auto-disable (AD) syringes, and
- safety boxes.

The permissible wastage rate, wastage multiplier factor and the formula used for forecasting dry supplies is presented **below**

Vaccines	No of doses	Wast-age factor	Presentation/no of dose per vial
BCG(Bacille-Calmette-Guérin)	1	2	20
IPV	1	1.11	10
PCV(Pneumococcal Conjugated Vaccine)	3	1.05	2
Measles	1	1.25	10
Penta	3	1.05	1
Rota	1	1.05	1
bOPV(bivalent Oral Polio Vaccine)	4	1.11	10
TT(Tetanus toxoid)	2	1.11	10

II. Data for supply planning of vaccines and related commodities

The annual estimate for vaccines and devises is projected taking into account various factors such as target population and aspired coverage, and is prepared for each year in advance. Various data sets are used to prepare the supply plans. These include:

- National or program level stock status (SOH, stock on shipment and stock on order) of each product to be quantified
- Expiration dates and/or VVM stages for the products in stock
- Established shipment intervals and current shipment delivery schedule
- Established national or program-level maximum and minimum stock levels
- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (procurement methods used, procurement lead time).
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).
- Cold chain storage capacity available

6.2.2. Data quality control (system of quality control at national level)

Accurate and quality data is very crucial at all level of the supply chain for the appropriate forecasting and supply planning. The reliability of any data source depends on design of the information system, accuracy of records and completeness of the data.

The appropriateness, accuracy and completeness of data should be evaluated before using for quantification purposes.

Therefore the following activities shall be performed so as to improve the data quality:

- Exhaustive verification of data
- Review of coherence: this aims at verifying that data from different sources show equivalent or corresponding figures.
- Make use of extrapolation and/or interpolation to compensate for incomplete data
- Make use of recent data. Minimize the use of data if it is more than **five or six years** old.
- Crosscheck different data sets – target population based estimates, immunization session estimates and/or consumption based data.
- Use established guidelines regarding program growth, target coverage levels, etc.
- Possible reconciliation with data from other sources (investigation and research data…)

6.2.3. Definition of assumptions

II. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

5. Assumptions on adjustments made to historical program data: when data are missing, unreliable, outdated, or incomplete
6. Assumptions on future program targets: based on factors influencing demand for services and commodities

Most often complete data are not available for quantification. If there are few or no data, the forecast will rely heavily on assumptions. Thus, assumption building is critical activity in forecasting exercise. The most critical point in making assumptions is to document, clearly and specifically, what assumptions were made and the basis for making the assumptions.

Assumptions may include issues such as a change in products, program strategies, priorities, scale up, or service capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

III. Assumption building during supply planning

Similar to the practices indicated in forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning, assumptions may need to be reached on the timing of available funds, lead times for each supplier, exact amounts of funding available, and estimates on arrival dates of fund.

6.2.4. Data Validation

Data available at different sources such as CSA, updated woreda based population data collected through PPD/FMOH, ARRA/UNHCR, and DHS needs to be reconciled

6.3. QUANTIFICATION

6.3.1. Quantification tools

The following tools will be used to conduct the quantification exercise:

- Pipeline
- Vaccine forecast spreadsheet
- Reality check
- Excel

6.3.2. Forecasting

The quantification team usually follows the following steps during forecasting:

- Organize and analyze data
- Select the forecasting method
- Build forecasting assumptions (structure a forecasting tree)
- Calculate forecasted consumption for the vaccines and devices
- Compare and reconcile forecasts prepared with different types of data to determine the final forecast

6.3.3. Supply Plan

Following needs specifications, a national supply plan for vaccines and related supplies is designed by NQT members. The supply planning process is a critical step in ensuring that products are continuously available for the EPI program. The supply plan provides information on volume of antigens expected including costs and their shipment schedules. This ensures that stock levels are maintained between the desired inventory control levels.

In supply planning, the program takes into consideration the forecasted requirements, stock on hand, and leads time of the suppliers and the stock on order.

Supply planning can be prepared using software tools designed for this purpose, such as pipeline. Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Pipeline® can generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by forecasted quantity of products to be purchased by level of donor's commitment for funding. Once supply plan is finalized, it allows facilitation of donors meeting so as to confirm availability of committed funds. If the confirmed level of available fund can cover the needs over the intended time period, the final result shall be presented to PFSA/FMOH for review and validation.

In the contrary, if the level of funding falls short of the required level, additional resource mobilization would be required through PFSA/FMOH to fill funding gaps. If attempt to fill funding gaps fails to completely bridge these gaps, the quantification process shall be reviewed again to adjust any of the assumptions or targets until the estimated requirement can be addressed with the means of the available fund. This should be done one month after the end of the initial quantification. The updated quantification output shall be presented to PFSA/FMOH for review and validation. Once the supply plans is approved, FMOH shall communicate all stakeholders/donors.

CHAPTER SEVEN

Quantification of Maternal and Child Health Products in Ethiopia

7.1 Activity Planning

7.1.1 Program Description

Policy

The Pharmaceutical Fund and Supply Agency (PFSA), coordinating the quantification activity, should have information on the country's current and upto-dated Plices and guilding documents related with maternal and child health, these can be:

- National Standard treatment Guidelines
- National Newborn and Child Survival Strategies
- Maternal and Child Health Package
- ICCM and IMNCI strategies and guidelines
- National strategic plans and documents (HSTP, PSTP…)
- Program Implementation manuals, SOPs and related documents (Testing Algorithms, Scale up plan,
- Strategy to Increase Access to Treatment of Childhood Diarrhea, Malaria and Pneumonia in Ethiopia
- Program and logistics performance reports
- Ethiopian Demographic Health Survey, recent edition.
- Delivery service pharmaceuticals in-kind reimbursement protocol
- Reputable international and local price references (CHAI ceiling price, International price guide, recent procurement price…)
- Government and Donor procurement guidelines (Host procurement guideline, GF procurement guide…)
- And other related documents that potentially influence the program performance through altering demand for service and products.

Information sources and system

The Agency, coordinating the quantification activities, should provide any information in particular to data related to procurement and supply management. Moreover information reflecting the current performance of the program, future program plan, strategic documents and any information that may influence product demand during the forecasting period should be obtained officially from FMOH (Maternal and Child Health Directorate) through the Agency. National Maternal and Child Health targets should be defined in line with those agreed upon in the national strategic plan and should hence be sent to the Quantification team through the Agency.

Inventory control System

The inventory control system established in the country will be utilized as the main source of inventory data that describes required stock levels by type and level of organization according to the health pyramid, as well as the ordering and reporting periods. This information should be provided to the National Quantification Team by PFSA in accordance with the Logistic Management Information System (LMIS) designed for maternal and child health products.

Available acquisition funds

Information on available funding (government dedicated budget and partners/doner funding) and the periods in which these budgets are adopted should be obtained from FMOH, PFSA and other organizations, as appropriate.

Information on products

Get recent standard treatment guidelines and the essential medicines list. Prepare the list of medicines to be quantified. The compiled list should then be sorted into the order that will best facilitate data collection.

Make sure that the list of products to be quantified is registered in Ethiopia and their pre-qualification status from reliable sources (WHO, FDA, Donor pre-qualification list or other sources) have been obtained.

Moreover, get updated information related to the type of equipment's and laboratory commodities from PFSA, FMOH, FMHACA and EPHI.

Coordination

The coordination of all these activities related to the quantification of MCH commodities is done by National Quantification Team (NQT) under the supervision of National Maternal and Child Health Logistics Technical Working Group (MCHL-TWG) led by PFSA and FMOH.

7.1.2 Definition of the quantification methodology

The National Quantification Team will define the methods to be used according to available data and other information related to the program.

7.1.3 Activity timeline

A precise timeline dedicated to the quantification activities should be setup by the National MCHL-TWG and may be revised as necessary.

The quantification exercise will be done every 2 years and updated annually.

The process will start in March and end up in May in order to be in line with the national and donors budget approval.

- Pre-quantification/preparation phase; 2 months
- Quantification (consultative workshop, Forecasting and supply planning exercise, and report preparation) Phase: 1 months
- Validation workshop and dissemination of the quantification result will be executed by June

7.2 Preparatory phase

In this phase, the National MCHL-TWG will assign representative national quantification team (NQT) with the right-mix that may include pharmacists, medical laboratory technologists, service providers, program managers/officers, LMIS experts, and Procurement officers, warehouse managers, clinicians and other relevant experts as necessary and the team will be led by representative from Forecasting and Capacity Directorate of the Agency. The MCHL-TWG will also define the scope and forecasting period for the quantification exercise. The NQT will define the type and source of data required, develop data collection tools, collect the required data, and organize and analyze the data collected. The team will also review and summarize different documents such as national policies, strategic documents, plans and targets, technical documents and reports, any epidemiological surveillance data, demographic health surveys, census data, or special survey studies. After making the necessary preparation for consultative workshop (analyze and adjust data, comparison of data from different source and propose assumption), the team will conduct the quantification consultative workshop. The participants of the consultative workshop may include program managers, policymakers, donors and implementing partner organizations, procurement officers, warehouse managers, and service providers.

For this section, the following activities should be considered:

- Collect and consolidate all necessary data for the quantification exercise.
- Process and analyze all data and information's with the consultation of actors involved in the information system (PFSA, FMOH and supporting partners…).
- Validate data(usually by comparing the result of different sources, performing trend analysis…etc)

7.2.1 Data Collection and data sources

The importance of available and quality of data cannot be underestimated. The required data may include service data on the number and type of health services being provided and logistics data on the consumption and stock levels of commodities. A well-functioning health management information system (HMIS) and logistics management information system (LMIS) are central in improving the accuracy and usefulness of health commodity quantifications. In addition, morbidity data, demographic data, and information on national program policies, strategies, and expansion plans should be used to inform the assumptions in the forecasting step of the quantification.

The data and information can be collected through interviews and consultative meetings with key stakeholders, including program managers, policymakers, donors and implementing partner organizations, procurement officers, warehouse managers, and clinical and other technical experts, as well as from direct service providers.

Specific data on the number and type of health services provided can be collected through the existing HMIS reports; the consumption and stock levels of individual commodities can be collected through the existing LMIS reports. In some cases, it may be necessary to directly collect data at health facilities. In addition, current policy and technical documents and reports, and any epidemiological surveillance data, demographic health surveys, census data, or special survey studies should be reviewed to collect morbidity and demographic data that can be used in the quantification.

Data generated from investigations, studies and researches will possibly help consolidating and/or complete data collected in a routine way. Exceptionally an active field data collection may be done.

I. Data necessary for forecasting of maternal and child health commodities

- **Morbidity data, Service Statistics, and Demographic data,** but not limited to:
  - Prevalence and incidence estimate for maternal and child cases under the scope defined
  - Proportion of children by age and weight bands
  - Proportion of children under five
  - No. of child and maternal per type of service provided
  - Proportion of children and mothers seeking care by sector/type of facility
  - Proportion of facility-based deliveries/births
  - Total number of pregnant women in population
  - Total number of births at facilities
  - Percentage of pregnant women who have severe pre-eclampsia or eclampsia
  - Number/proportion of pregnant women developing PE/E likely to be given magnesium sulfate for prevention and treatment among facility-based births
  - Standard or average treatment regimen, i.e., amount of magnesium sulfate needed to prevent or treat each case of PE/E
  - Expected projected changes in consumption (potential losses or scale-up in use)
- **Logistics data :** Products related Logistic data are the following:
  - List and description of all products to be quantified (Generic name, dosage form, strength, basic unit of measure, pack size, etc)
  - Estimated product unit prices per pack
  - Consumption rate of liquid dosages and solid dosage forms for children
  - List of pre-qualified and registered Manufacturers/Suppliers and products registration status in Ethiopia
  - Monthly consumption per product used to provide maternal and child health service for the last 12 months
  - Annual consumption for the last 12 months
  - Days of stock shortages/out per product for the last 12 months
  - Shortage periods and durations during the last 12 months, as well as information on substitution products
  - Information on all atypical consumptions, ie. Exceptional epidemics, treatment policy over the period, etc.

- **Information on current program performance, plans, strategies, and priorities, including specific program targets for each year of the quantification.**

II. Data for supply planning

- National-or program-level stock on hand (preferably from physical inventory) of each product to be quantified (should include losses and adjustments)
- Expiration dates for the products in stock
- Quantity on order: any shipment quantities of product(s) already on order, but not yet received
- Established shipment intervals and current shipment delivery schedule
- Established national-or program-level maximum and minimum stock levels
- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Funding information: (all funding sources for procurement of commodities, amount and timing of funding commitments and funding disbursement schedules to determine when funding will be available for procurement from each source).
- Procurement information (all procurement mechanisms—e.g., competitive international bidding/tendering, donor procurement, or local procurement—for all products to be quantified and procurement lead time for each procurement mechanism).
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

7.2.2 Data quality control (describe the system of quality control setup at the national level)

This very important step will assess data quality. This is done in order to reduce risks of errors. Organizations in charge of making data available will process databases (HCMIS, PLITS, HMIS and other data sources), harmonize and organize them.

Therefore the following operations will be done:

- Verification of data exhaustively
- Coherence control: this is aiming at verifying that when a figure is shown in a section, an equivalent figure will be sown in another section ;
- Data imputation or database adjustment: this consists in verifying and exaggerated processing data ;
- Verification in comparison with historical data: this allows comparing with other previously collected data (i.e. detect any important changes compared to previous report). Therefore any gap that does not respect established limitations is mentioned and subject to further analysis.
- Possible reconciliation with data from other sources (investigation and research data…)

7.2.3 Definition of assumptions

I. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

3. Assumptions on adjustments made to historical program data, when data are missing, unreliable, outdated, or incomplete
4. Assumptions on future program performance, based on factors influencing demand for services and commodities

Most often, complete data are not available for a particular quantification. The most critical point in making assumptions is to document clearly and specifically which assumptions were made, and on what basis. If there are few or no data, the forecast will rely heavily on assumptions.

Assumptions may include issues such as a change in STGs, products, program strategies, priorities, expansion plans, or service capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

Note: Standard Treatment schedules and options are usually dynamic and therefore it is important to conduct a consultative workshop in collaboration with stakeholder and partners (composed of national experts) to draw and get common consensus on the assumptions to be used for the quantification.

II. Assumption building during supply planning

As previously mentioned, the most critical point in the assumptions building process is to document clearly and specifically the sources of information and the key informant inputs on the assumptions.

And as in the forecasting step, consensus must be reached among the quantification team on the supply planning assumptions. For the supply planning step, assumptions may need to be reached **on the timing of available funds, lead times for each supplier, exact amounts of funding available,** and estimates **on arrival dates of fund**

The quantification team will also need to make assumptions about national and facility stock levels, if the data are not available and to make assumptions about the minimum and maximum stock levels at each level of the logistics system (facility and central levels, for example).

7.2.4 Data Validation

This is an important step in making sure those data/information used in the process are reliable and quality enough for using them in determining products requirement. For this purpose, the validation usually done either by comparing the result obtained from different source or performing trend analysis. Results of data available at PFSA and FMOH will be reconciled with data available with supporting partners.

7.3 QUANTIFICATION

7.3.1 Quantification tools

The quantification exercise is currently performed using the following tools:

- MS Excel for both forecasting and supply Planning or
- Quantimed® to produce forecast result and Pipeline® for supply planning and ongoing stock monitoring

The quantification of Maternal and child Health programs is done in two separate phase:

- The first phase, the entire National Quantification Team members meet together, this will formatting data to be used during the quantification exercise.
- The second phase, NQT members divided into 2 groups: one group in charge of the quantification of Child health products and the other group in charge of the quantification of maternal health products

By the end of the quantification exercise, a report is written by NQT.

Note: The quantification exercise will involve technical staff from different organizations previously trained in related IT programs. Session facilitations will be the role of PFSA, FMOH and Supporting partners.

7.3.2 Supply Plan

Following needs specifications, a national supply plan for Maternal and Child Health commodities is developed by NQT members. These plans will take in account available and usable stocks at the national level and ongoing orders.

Therefore, from available and usable stocks, ongoing orders and data related to the quantification, Excel/Pipeline® will generate future monthly consumptions and especially the national supply plan.

The supply plan is characterized by product quantities to be purchased by each donor according to its promised contribution, with required delivery period in order to guarantee adequate stock levels.

Supply plans hence budgeted will allow organizing donors' meetings in order to confirm available funds.

Thus, If the available funds cover the needs over the forecasted period, then results will be presented to and validated by the FMOH. On the contrary, if the available fund does not cover the estimated forecasted needs, the FMOH should either find a way to raise additional funding source or else should request an adjustment on the data and targets; and the quantification should be reviewed again before validation. If need arises to revise the quantification exercise, then it should be done a month after the end of the initial quantification.

Supply plans, once validated will be communicated by the FMOH to each contributor, according to their contribution and budget.

CHAPTER EIGHT

Quantification of Medicines, Medical Supplies, Medical Equipment and Laboratory Products Managed through Revolving Drug Fund (RDF)

8 .1 Activity Planning

8 .1.1 Program Description

Policy

The Pharmaceutical Fund and Supply Agency (PFSA), coordinating the quantification activity, should have information on the country's current and up to dated polices and guiding documents related with pharmaceutical, these can be:

- Growth and Transformation Plan(GTP),Health Sector Transformation Plan (HSTP) and Pharmaceutical Supply Transformation Plan (PSTP)
- National Health Policy
- Social and Community Insurance Policy
- National Drug Policy
- National drug list, Drug formulary and Treatment Guidelines
- Joint plans with public wings such as local manufactures and associations
- National strategic plans and documents
- Reputable international and local price references (MSH price indicator, International price guide, PFSA recent procurement price etc.)
- Public procurement and property administration directive,

Information tools and system

The Agency, coordinating the quantification activity, should solicit the required tools and information for the quantification activity. National Health Service Expansion Plan, new emerging diseases, newly introduced technology and any information that may influence product demand during the forecasting period should be obtained officially from FMOH and FMHACA.

Inventory control System

The overall RDF quantification activity is based on the existing inventory control system which can be described as the required stock levels by type of organization according to the health pyramid, as well as the ordering and reporting periods. The inventory levels shall be revised by the Agency according to the required lead time, safety stock and the review periods of the existing Logistic Management Information System (LMIS).

Funding

The agency in collaboration with FMOH should make sure the availability of funds for procuring pharmaceuticals through effective and efficient management of the existing revolving fund, additional resources, budget planning and financial management.

Product Information

Obtain recent standard treatment guideline, the national and WHO Pharmaceutical lists. Prepare the list of Pharmaceutical to be quantified. The list should be organized and categorized in the way that will best facilitate data collection.

Make sure that the list of products to be quantified, are registered in Ethiopia and their pre-qualification status from reliable sources (WHO, FDA, Donor pre-qualification list or other sources).

Moreover, obtain updated information related to the type of medicines, equipment's, reagents and consumables from FMHACA.

Coordination

PFSA will coordinate the overall activities related to the quantification of RDF pharmaceuticals.

8.1.2 Quantification methodology

The quantification methodology for quantifying RDF pharmaceuticals would be defined based on the available data.

8.1.3 Activity timelines

A precise timeline dedicated to the quantification activities should be in line with the FCBD guideline. Based on this, the preparatory phase for the RDF quantification will be completed until Nehase 30 of the preceding year before the quantification period. The forecasting phase would be completed on Hidar 30 and the supply planning phase needs to be finalized until the 20th of Tahisas.

Finally, depending on the context, a three years forecast and a one year supply plan will be developed and updated every year.

8.2 Preparatory phase

In this phase, the forecasting team composed of technical experts from different areas depending on the nature of the commodities (Medicine, Medical supplies, and Laboratory reagent and chemicals) will be established. The team then defines the scope of the quantification, methodology, data source and type, and devises data collection mechanisms. The forecasting and inventory control team will revise the list of pharmaceuticals to be quantified based on the level of health facilities. Then the draft list of pharmaceutical will be communicated through email and/or official letter to procurement directorate, storage and distribution directorate and PFSA branches for any comment and concern before final endorsement of the list.

Using the revised list, relevant quantification tools will be developed based on the level of facilities (hospitals, low volume HCs, medium volume HCs and high volume HCs) and communicated officially to PFSA branches. Depending on the context, PFSA branches establish a quantification team composed of branch manager, forecasting and capacity building officers, stock and distribution officers, logistics officers from RHBs/ZHDs and relevant stack holders.

In accordance with the previous experience of the PFSA branches, the team will decide the scope of catchment facilities involvement for the exercise, some PFSA branches may involve all catchment facilities whereas others may sample representative health facilities and extrapolate the result to all catchment facilities. In case of sampling, facility selection process should be a random sampling including representatives from each stratum of hospitals, high volume health centers, medium volume health centers and low volume health centers.

PFSA branches then will officially communicate the quantification tool to respective zonal health departments, woreda health offices and facilities. Following this, the quantification team in close collaboration with administrative units will provide technical support through different means.

8.2.1 Data Collection

Based on the predefined data collection mechanisms, the facilities shall take the necessary steps to duly complete the quantification template and send it to hubs after it gets the approval of the DTC members.

The hub based quantification team will closely work with administrative units for timely submission of quantification result produced by selected health facilities.

I. Data necessary for forecasting of RDF pharmaceuticals

- **Logistic data :**
  - Facility level Consumption data for each pharmaceutical
  - Hub level issue data of each pharmaceutical
  - Days out of stock per product for the defined period
  - Wastage information
- Morbidity data:
  - List and number of specific disease diagnosed or treated in the health facility
  - Treatment and test options used or should be used
  - Service expansion plan or national targets
  - Lab test methodologies
  - Annual attrition and migration rate
- Service statistics data:
  - Number of services provided
  - Number of service visits at which products are dispensed
  - Number of tests conducted
  - Number of episodes of disease or health conditions treated
  - Number of patients on continuous treatment during specified period
  - List of working lab equipment and usage rates
  - Annual attrition and migration rate

II. Data for supply planning of RDF pharmaceuticals

- National stock on hand (preferably from physical inventory) of each product to

be quantified (should include losses and adjustments)
- Expiration dates for the products in stock
- Quantity on order: any shipment quantities of product(s) already on order, but not yet received
- Established shipment intervals and delivery schedule
- Established national-or program-level maximum and minimum stock levels
- Product information (registration status, prequalification status, if applicable status of products on the National Essential Medicines List and specific product characteristics (formulations, dosages, number of units per pack size, unit cost, and others)).
- Supplier information (supplier prices, packaging information, lead times, shipping and handling costs).
- Information on the availability of fund to reconcile with the total cost of pharmaceutical quantified.
- Procurement information (all procurement mechanisms—e.g., competitive international bidding/tendering, donor procurement, or local procurement—for all products to be quantified and procurement lead time for each procurement mechanism).
- Shipment modalities (air, sea, land etc.)
- Distribution information (customs' clearance fees, in-country storage and distribution costs, if applicable and in-country sampling/quality testing costs).

8.2.2 Data quality control (System of quality control at national level)

Accurate and quality data is very crucial at all level of the supply chain for the appropriate forecasting and supply planning. The reliability of any data source depends on design of information system, accuracy of records and completeness of the data. The appropriateness, accuracy and completeness of data should be evaluated before using for the quantification purposes. Therefore the following steps of data auditing can be done:

- Logistics data retrieved from electronic systems (HCMIS, Dash board and others) needs to be triangulated with the manual records and reports to avoid errors.
- Logistic data shall be triangulated with Service data retrieved from HMIS or available service records(patient registration log book, patient chart)
- Verification of data exhaustively
- Verification in comparison with historical data: this allows comparing with other previously collected data (i.e. detect any important changes compared to previous report).Therefore any gap that does not respect established limitations is mentioned and subject to further analysis.
- Possible reconciliation with data from other sources (investigation and research data, etc.)

8.3 Definition of assumptions

III. Assumption building for Forecasting Steps

Two kinds of assumptions need to be made during the forecasting step:

- Assumptions on adjustments made to historical program data, when data are missing, unreliable, outdated, or incomplete.
- Assumptions on future program performance, based on factors influencing demand for services and commodities Most often, complete data are not available for a particular quantification. The most critical point in making assumptions is to document clearly and specifically which assumptions were made, and on what basis. If there are few or no data, the forecast will rely heavily on assumptions.

Assumptions may include issues such as a change in STGs, products, program strategies, priorities, expansion plans, or service capacity (infrastructure, human resources availability, and capacity), client awareness of and access to services, timing and amount of funding commitments for procurement, seasonality, or geographical differences in disease incidence and prevalence.

It is critical for the quantification team to reach consensus on the forecasting assumptions. A quantification workshop is often an effective forum to achieve consensus, and should include dedicated time for clarifying, agreeing upon, and documenting assumptions. This should be a consultative process with a wide range of program implementers (program planners, procurement specialists, clinical experts, pharmacists, warehouse managers). It is important to document the sources of information and input from key informants used in making the forecasting assumptions. The quantification should be revised if any of the forecasting assumptions change.

IV. Assumption building during supply planning

The most critical point in the process of building assumptions for the supply planning of RDF pharmaceuticals is to document clearly and specifically the sources of information and the key informant inputs.

And as in the forecasting step, consensus must be reached among the quantification team on the supply planning assumptions which should take in to consideration the lead times for each supplier, amounts of funding available, and arrival of the ordered pharmaceuticals as per stipulated time. The quantification team will also need to take in to account the established minimum and maximum stock levels for the logistics system

8.4 Quantification

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to ensure an uninterrupted supply. Quantification in principle encompasses forecasting and supply planning of pharmaceuticals. The steps that should be followed during forecasting and supply planning for the RDF pharmaceuticals are pinpointed below.

8.4.1 Forecasting

Forecasting is the process of organizing, analyzing, and adjusting the data collected during the preparation step to estimate the quantity of each product specified quantification period. These quantities are the basis for calculating the total commodity requirements in the supply planning step. The forecasting step in a quantification exercise is a four-part process.

Based on this, the hub based quantification team validates aggregates, analyzes item by item and makes extrapolation as required. Then necessary adjustments will be done based on the assumptions, expert's opinions, and historical trends. The final quantification result will be sent to the central quantification team through email and hardcopy with official letter after it gets the approval of the hub manager.

The central quantification team will validate, organize, aggregate, analyze the hubs forecast output and make necessary adjustments based on the assumptions and historical trends. Right after this, Forecasting and Capacity Building Directorate will conduct RDF pharmaceuticals quantification exercise workshop with the involvement of relevant stakeholders aiming at validating overall quantification process and further refining the forecast output. Finally, the central quantification team will use the refined branch forecast output for the supply planning.

8.4.2 Supply Plan

The supply planning step is used to estimate the commodity requirements and costs for the program. This can be accomplished by considering the forecasted consumption for each product from the forecasting step, the existing stock on hand; any quantities of product already on order, but not yet received; and the established maximum and minimum stock levels. Be sure to include procurement and supplier lead times and provide a buffer stock for unexpected delays. Based on this, a one year supply plan reconciled with available funds and with the required delivery schedule will be developed to guide the procurement process. Once the supply plan is validated, it will be communicated to procurement directorate to initiate the procurement process.

CHAPTER NINE

Using Results of the Quantification

The quantification team should formally present the results of the quantification to stakeholders. This enables the team to receive feedback about the assumptions that were made during the forecasting step, as well as the data sources used. Presenting the results of the quantification is an opportunity for the team to present on national stock status levels for commodities to all stakeholders, and outline the actions required to maintain adequate stock levels.

Through the presentation of the quantification results to policymakers, program managers, procurement managers, funders, and commodity managers, the following decisions and actions can be facilitated:

- Program planning and budgeting decisions
- Mobilization and allocation of funding for commodity procurement
- Coordination of multiple sources of funding for procurement
- Informing procurement actions on which products to procure, how much to procure, and when to procure
- Adjusting timing of procurements and shipment delivery schedules to ensure continuous supply while avoiding stock outs and overstocking

When conducting a presentation, the quantification team should prepare slides explaining each step of the quantification, including

- Summary of the process ;
- Needs for ARVs/OI/Laboratory products, for the defined period ;
- Global supply amounts ;
- Stakeholders' financial engagements ;
- Financial gaps to be mobilized to implement the supply plan ;

These quantification outputs enable program managers, funders, buyers, and suppliers to plan and schedule their inputs, to coordinate available resources, and to advocate for additional resources when funding gaps are identified.

CHAPTER TEN

Reviewing and Updating the Quantification

Quantification does not end when the final quantities and costs have been determined. It is an ongoing process of monitoring, reviewing, and updating the forecasting data and assumptions, which in turn may require a recalculation of the total commodity requirements and costs. For the quantification exercise to be useful and effective, the forecasting assumptions and the supply plan should be reviewed and updated at least every six months, and more frequently for rapidly growing or changing programs. Ongoing monitoring and updating of the quantification is critical to keeping program managers, donors, and other stakeholders informed on the availability of drugs and are a vital precondition for timely decision-making on product selection, financing, and delivery of commodities. Ideally, the same core team of people who conducted the initial quantification should conduct routine updates.

- Reviewing and updating the quantification involves the following activities:
- Reviewing and updating the forecasting data and assumptions
- Calculating or recalculating the forecasted consumption (using Quantimed, Excel spreadsheets, or other software)
- Updating the stock on hand for each product
- Assessing the national stock status for each product (based on product consumption and stock levels)
- Reviewing and updating shipment delivery schedules to ensure continuous supply and maintain desired stock levels
- Updating the amounts and timing of funding commitments
- Recalculating the commodity requirements and costs over time
- Estimating and updating funding needs and gaps for procurement

Knowledge and Skills Required

Ideally, the same core team of people who conducted the initial quantification should conduct routine updates. The knowledge and skills required to complete quantification for health commodities include the following:

- For each commodity category, expertise in the specific program area and knowledge about the commodities and how they are used
- Computer literacy and proficiency in the use of Microsoft Excel spreadsheets or software programs to create and manage databases
- Commitment to conduct ongoing monitoring, data collection, and updating of the forecasting data and assumptions and supply planning data to update the PipeLine database
- Preparation and presentation of quantification data and methodology and final quantification results to key stakeholders and implementers

Quality monitoring of quantification

Quantification is a continuous process that includes regular monitoring and updating. Not only is it important to assess the quality of the data and the assumptions used to calculate the initial forecast; but, to assess the accuracy of your forecast, you should go back periodically and compare actual quantities consumed with your forecasted quantities.

Because forecasting for public health products is more of an art than a science, actual consumption almost always differs from the forecast consumption. by calculating the mean absolute percent error (MAPE)-the absolute difference between the forecasted and actual values, expressed as a percentage of the actual values, you can monitor error rates. If error rates are high, you should revisit your assumptions and try to improve the quality of your data so that your revised forecast will better reflect actual consumption. Over time and with regular monitoring, you can improve the accuracy of your forecasts and the overall quality of your quantifications.

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Annex: List of Partcipants with their respective organization and position in drafted quantification manual enrichment workshop

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