



**REPUBLIC OF KENYA**

**Ministry of Health**

**Reproductive and Maternal Health Service Unit  
RMHSU**

# **National Guidelines for Quantification, Procurement and Pipeline Monitoring for Family Planning Commodities in Kenya**

**September 2016**



**ISO 9001 :2008  
Certified**



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MINISTRY OF HEALTH**

**Reproductive and Maternal Health Service Unit  
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## Foreword

The Ministry of Health is keen to ensure provision of quality preventive, promotive and curative services to the lowest level of care. This requires strong, efficient and effective health care systems that ensure adequate availability of quality, safe and efficacious health commodities.

Health commodities in all health institutions constitute a large percentage of the budgetary allocation. However, many health facilities either experience shortages for these health commodities or incur substantial losses as a result of overstocking. A number of factors contribute to this occurrence, key among them is sub-optimal forecast of the commodity requirement, a supply plan not aligned to demand, inefficient or delayed procurement, and weak in-country stock level monitoring. Additionally, the push supply systems, unreliable consumption and morbidity data, and lack of necessary knowledge, skills and tools at all levels of health care contribute to weak commodity supply chain management both at national and peripheral levels.

The Ministry of Health has adopted a shift from the wasteful push supply system to the cost effective demand-driven pull system so as to improve access to health commodities particularly in the public health facilities. Successful implementation of the pull system is dependent on proper determination of health commodity requirements at national and sub-national level; efficient supply planning; effective resource mobilization; procurement of commodities according to plan, and close pipeline monitoring to ensure required health commodities are available at all levels in the required quantities and time.

The Reproductive and Maternal Health Services Unit (RMHSU) in collaboration with various partners carries out annual quantification of FP commodities. The end of this process triggers off resource mobilization and procurement of the FP commodities once funds have been secured. Additionally, RMHSU monitors in-county stocks and uses this strategic information to make decisions on distribution and supply. These inter-related processes of quantification, procurement and pipeline monitoring have not been documented and this is being done for the first time. This informative and easy to use document has been designed to provide step by step guidance to FP program officers and managers involved in these processes. The guidelines recognize that accurate forecasts, procurement and stock monitoring as well as collecting and sharing strategic commodity information are key to ensuring FP commodity security in the country. If utilized as intended, this handbook will contribute to ensuring reliable access to adequate contraceptive commodities in all health facilities.

The development of this 1<sup>st</sup> edition of the National Guidelines for Quantification, Procurement and Pipeline Monitoring for FP Commodities has been done through extensive consultation and commendable effort of various partners and stakeholders. Our sincere appreciation goes to USAID and Management Sciences for Health/ Health Commodities and Services Management (MSH/HCSM) program for providing both financial and technical support.



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## ABBREVIATIONS & ACRONYMS

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AMC	Average Monthly Consumption
CDRR	Consumption Data Report and Request form
CSTWG	Commodity Security Technical Working Group
COCs	Combined Oral Contraceptives
CPR	Contraceptive Prevalence Rate
DHIS-2	District Health Information Software, version 2
DMPA	Depot Medroxyprogesterone Acetate
ECP	Emergency Contraceptive Pills
EDA	Estimated Date of Arrival
ESHE	Enabling Sustainable Health Equity for Family Planning
FCDRR	Facility Contraceptives Consumption Data Reporting and Request form
FDA	Food and Drug Authority
FHOK	Family Health Options Kenya
FP	Family Planning
ISO	International Standards Organization
IUCD	Intrauterine Contraceptive Device
KDHS	Kenya Demographic and Health Survey
KEBS	Kenya Bureau of Standards
KEMSA	Kenya Medical Supplies Authority
KfW	Kreditanstalt Für Wiederaufbau
LAM	Lactational Amenorrhea Method
LMIS	Logistics Management Information System
MoH	Ministry of Health
MOS	Months of Stock
MSH/HCSM	Management Sciences for Health/Health Commodities and Services Management (Program)
MSK	Marie Stopes Kenya
NASCOP	National AIDS & STI Control Program
OJT	On-the-Job Training
PPDA	Public Procurement and Disposal Act
POP	Progestin Only Pills
PPB	Pharmacy and Poisons Board (Kenya)
PS Kenya	Population Services Kenya
RH	Reproductive Health
RHCS	Reproductive Health Commodity Security
RMHSU	Reproductive and Maternal Health Services Unit
SCA	Supply Chain Agency
SOH	Stock on Hand
SRAs	Stringent Regulatory Authorities
STIs	Sexually Transmitted Infections
TFR	Total Fertility Rate
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
USD	United States Dollar
WB	The World Bank
WHO	World Health Organization
WRA	Women of Reproductive Age

## SECTION 1: BACKGROUND

### 1.1 Introduction

Effective use of modern contraception saves lives through preventing maternal and infant mortality associated with unintended pregnancies (UNFPA, 2012). Across the world, limited access to family planning commodities has been found to contribute to the unmet need for contraception by over 225 million women of reproductive age (WRA) in developing countries not using effective contraceptive method (UNFPA, 2014). Family planning (FP) is recognized to play a key role in the achievement of the national and international goals, including the Sustainable Development Goals (UNDP, 2015), and FP 2020 objectives.

Kenya has realized significant gains in family planning; the contraception prevalence rate averages about 58% while the Total Fertility Rate is 3.9 (KDHS 2014), an achievement largely driven by use of modern FP methods. However, there is still an unmet need for family planning of 18% (KDHS 2014). For Kenya to build on current gains, cover the last mile for FP and achieve the various goals on reducing maternal and child mortality, investment in contraceptive security is mandatory

*Contraceptive security exists  
when every person can choose,  
obtain, and use high quality  
contraceptives whenever  
needed*

Quality family planning services require continuous supply for contraceptive commodities. The Ministry of Health (MOH) through the Reproductive and Maternal Health Service Unit (RMHSU) works closely with county governments and different partners to increase access to and utilization of quality FP services through various interventions among them, providing efficacious FP methods and strengthening commodity supply chain management. So as to ensure an uninterrupted supply for FP products, the country must carry out an accurate *quantification* to determine annual commodity requirements, *procure* according to plan, and closely *monitor the commodity pipeline* to ensure sufficient stocks are available and avert stock-outs.

The role of quantification, procurement and pipeline monitoring is envisaged to be taken up by the county governments in the near future. In this regard therefore, the National Guidelines for Quantification, Procurement and Pipeline Monitoring for FP commodities aim to provide guidance in all matters related to quantification, procurement and pipeline monitoring at all levels

#### 1.1.1 The National Family Planning Program

The national FP program is implemented through RMHSU which works to promote the reproductive health of all Kenyans by responding comprehensively and effectively to their needs for information and reproductive health services. RMHSU has several programs, namely, Family Planning; Maternal and Newborn Health; Adolescent/Youth Sexual & Reproductive Health Rights; Gender & Reproductive Rights; Infertility, Reproductive Tract cancers; and Reproductive health needs of elderly persons.

The national FP program works closely and in collaboration with various development and implementing partners across the country to achieve her objectives on improving access to quality FP services including expansion of method mix; ensuring there are no missed opportunities; reduction of unmet need; and in addition, sustaining the gains made and increasing numbers of new FP users (National Family Planning Guidelines for Service Providers, 2016).



Some key functions the FP program performs to achieve these objectives include:

- Coordinating FP activities across the country
- Carrying out supportive / facilitative supervision
- Supporting expansion of access and utilization of FP services
- Developing FP policy guidelines.
- Formulate strategies for contraceptive commodity security- they include annual national quantification, initiating procurement, and pipeline monitoring for FP commodities.
- Supporting FP related research.
- Managing FP commodities distribution and logistics.

### 1.1.2 Current context and policy environment

Kenya has various policy documents and strategies that recognize FP as a crucial investment for health and development. The Kenya Health Policy (2014-2030) identifies the need to manage population growth, achievable through utilization of effective FP commodities, as a key pillar in achieving economic growth and sustainability. Other guiding documents such as the National Reproductive Health Strategy (2013-2017), the National Family Planning Costed Implementation Plan (2012-2016), the National Family Planning Guidelines for Service Providers, Vision 2030, National Health Sector Strategic and Investment plan (2013-2017), and Minimum package for RH/HIV and AIDS integration services emphasize the need to create demand for and expand supply of FP services to which FP commodities is a central component.

*The new constitution established two levels of government- the central level (MOH headquarters) tasked with the role of making policy, developing standards, regulation and research, while the 47 County Governments are mandated with health service delivery (except for referral hospitals).*

Additionally, the Kenya Health Policy underscores the importance on need to improve procurement processes to ensure availability of essential medicines and medical supplies which, according to Kenya Essential Medical List, include FP commodities. This public procurement process in Kenya is generally guided by the Public Procurement and Disposal Act (2015).

Since the establishment of the national FP program, the MOH was tasked with the responsibility of determining the national FP commodity requirements, mobilizing resources (internally from national budget and from donors), procuring, distributing and monitoring the in-country stock levels. However, following the promulgation of the new constitution in 2010, there has been a change in governance structures which consequently restructured the way health services are delivered. MOH (headquarters) with support from development partners still coordinates initiatives and formulates strategies for ensuring availability and use of family planning services in the country.

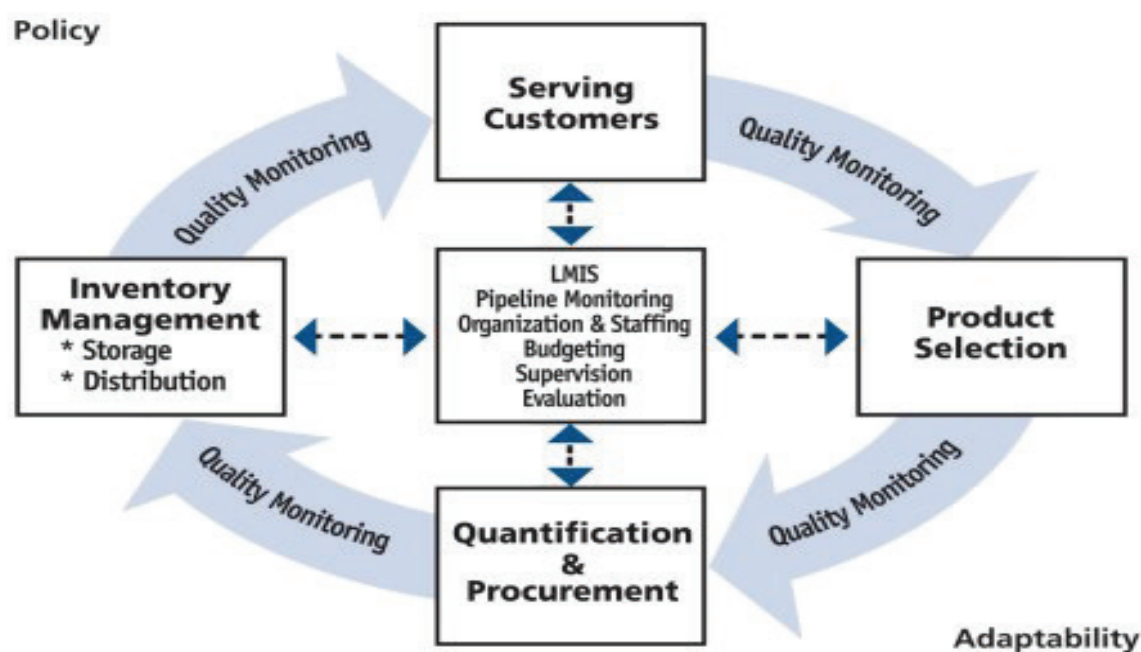
To achieve this, the MOH and development partners have put in substantial efforts to ensure the country achieves FP commodity security. However, inadequate commitment of devolved government leadership in allocating resources for FP commodities and services; weak integration of reproductive health commodities into policies, plans, and budgets; inadequate funding; weak resource mobilization (especially at devolved government level); and sub-optimal skills in FP commodity supply chain management practices remain a threat to such efforts.

## 1.2 Essential Health Products and Technologies Cycle

A successful FP program requires a continuous supply of effective modern FP methods which is only achievable when a country generates accurate forecast of commodity requirements, procures according to plan and monitors in-country stocks to avert shortages. The key relationship of these processes is drawn in the Essential Health Commodities and Products (EHPT) Cycle that has 5 steps: product selection, procurement, distribution, and use. Each activity of EHPT cycle relies on the success of the previous activity and contributes to the effectiveness of the next activity. Every step requires efficient management support.

Quantification is situated as the first activity within the element of procurement. Once the FP program has selected products of priority, it forecasts the requirements for a specified period and generates a supply plan, the last process in quantification that outlines when the products should be delivered, and which triggers off procurement. Delivered commodities are distributed to service delivery points, filling the commodity pipeline. So as to maintain an uninterrupted supply of various options for FP commodities in the country (central level and health facilities), continuous monitoring of in-country stocks is mandatory.

**Figure 1: Health Commodity Supply Cycle (Logistics Cycle)**



Source: *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities*. USAID/DELIVER project, Task Order 1. 2008

## 1.3 Guidelines scope and use

### 1.3.1 Rationale for Guidelines

Various processes are undertaken by the FP program to achieve commodity supply chain management namely, quantification, procurement, distribution and pipeline monitoring with varied levels of efficiency. To standardize some of the process, it was deemed necessary to document and institutionalize the steps through development of guidelines.

These guidelines will cover three key aspects of FP commodity supply chain management:

- i. Quantification
- ii. Procurement
- iii. Pipeline monitoring

It is envisaged that these guidelines shall provide a step by step guide to the FP program and other users on how to carry out the three processes so as to move beyond the emergency mode of responding to stock outs, towards more predictable, planned and sustainable country-driven approaches for ensuring availability and use of essential FP commodities.

### **1.3.2 Goal of the guidelines**

The goal of these guidelines is to standardize, document and institutionalize the processes for quantification, procurement and effective pipeline monitoring for FP commodities in the country.

### **1.3.3 Objectives of the guidelines**

Specific objectives of these guidelines are to describe and document the processes listed below for FP commodities:

- Quantification
- Procurement
- Pipeline monitoring.

It is also anticipated that the guidelines will provide a basis for quality assurance and performance monitoring within the FP commodity supply chain.

### **1.3.4 Scope of the guidelines**

These guidelines cover the following aspects:

1. Forecasting
2. Supply planning
3. Procurement
4. Stock status monitoring and reporting
5. Management of facility orders and distribution planning
6. County level redistribution
7. Commodity information management

This is expected to cover the full range of FP commodity supply chain management activities- from strategic planning (Quantification); through routine operations (procurement and Pipeline monitoring) to information management (Reporting).

### **1.3.5 Commodities covered by the guidelines**

The national FP program has identified key FP commodities recommended for use in Kenya as outlined in the National Family Planning Guidelines for Service Providers (March 2016). These are:

- Combined Oral Contraceptive Pills
- Progestin Only Contraceptive Pills
- Emergency Contraceptive pills

- Injectable Contraceptives (DMPA IM/SC)
- Contraceptive Implants (Etonogestrel and Levonorgestrel implants)
- Intra-Uterine Contraceptive Devices (Copper-T and LNG-IUS)
- Male condoms
- Female Condoms
- Cycle beads.

### 1.3.6 Levels of application of the Guideline

The Reproductive and Maternal Health Services Unit has the mandate to develop policy and guidelines that will guide the FP program. These guidelines will be applicable at national and county levels in line with their respective operational needs. The guidelines will be used by National and County teams involved in quantification, procurement and pipeline monitoring for FP commodities.

Use of this document will benefit the program by providing guidance on the following processes:

- Forecasting national FP commodity requirements and supply planning.
- Planning and executing procurement
- Pipeline monitoring at national and county level.
- Management of distribution and re-distribution of FP commodities.
- Management of FP commodity information.

### 1.3.7 Guidelines development process

The guidelines were developed through the collaboration RMHSU, related MOH national level staff and partners involved in FP commodity management. The initial meetings to define the scope and content of the guidelines were held in January 2016 and were followed by detailed background work involving mapping of the processes involved in quantification, procurement and pipeline monitoring. A workshop was convened in July 2016 to review and harmonize the process maps and develop the guidelines content. The output from the workshop provided the basis for drafting of the guidelines, which was presented to various stakeholders for technical review and input in September 2016. The final draft was thereafter approved for dissemination and use.

### 1.3.8 Guideline Review

The context within which the FP program is run is dynamic and rapidly changing; by extension, the supply chains that support program service delivery must be responsive to the changing context and continuously adapt their processes to achieve continuity of supply for FP commodities. To ensure that these guidelines are relevant and aligned to current practice and processes, the guidelines will be reviewed and updated initially on annual basis – for the first two years – and thereafter every two years. The FP commodity manager will initiate the guidelines review process and coordinate compilation / dissemination of the updated guideline.

## SECTION 2: QUANTIFICATION

### 2.0 Importance of quantification

Quantification is a critical process in ensuring FP commodity security. Through it, the country is able to generate timely forecasts for commodity requirements, determine resource needs and generate a supply plan that will inform the procurement process. Additionally, quantification results are used to advocate for resource mobilization, help maximize use of available resources and inform manufacturer production cycles and supplier shipment schedules. A commodity estimate that is too high could cause excess holding costs, storage-capacity strain, and increased risk of product expiries. Over estimating also has an opportunity cost where limited resources are not used where they are required. On the other hand, a low estimate puts a country at a risk of stock-outs and therefore hampers service provision.

*Quantification has two aspects- forecasting, which is the process of estimating the quantities and costs of the products required for a specific health program (or service), and supply planning, the process of determining when the products should be delivered to ensure an uninterrupted supply of commodities for the program*

Successful quantification requires adequate preparation, access to good data and a team to lead the process and coordinate key stakeholders. The conclusion of quantification triggers the procurement process that turns forecasts and supply plans into purchased products that are then delivered to a point of use.

### 2.1 Coordination and oversight for FP commodity security

The Ministry of Health at the national level provides leadership and coordination for all FP commodity security efforts in the country. It works through an FP Commodities Commodity Security Technical Working Group (CSTWG) that takes the oversight role for FP commodity resource mobilization and quantification. The membership for FP CSTWG is outlined below, while TOR is in appendix 1:

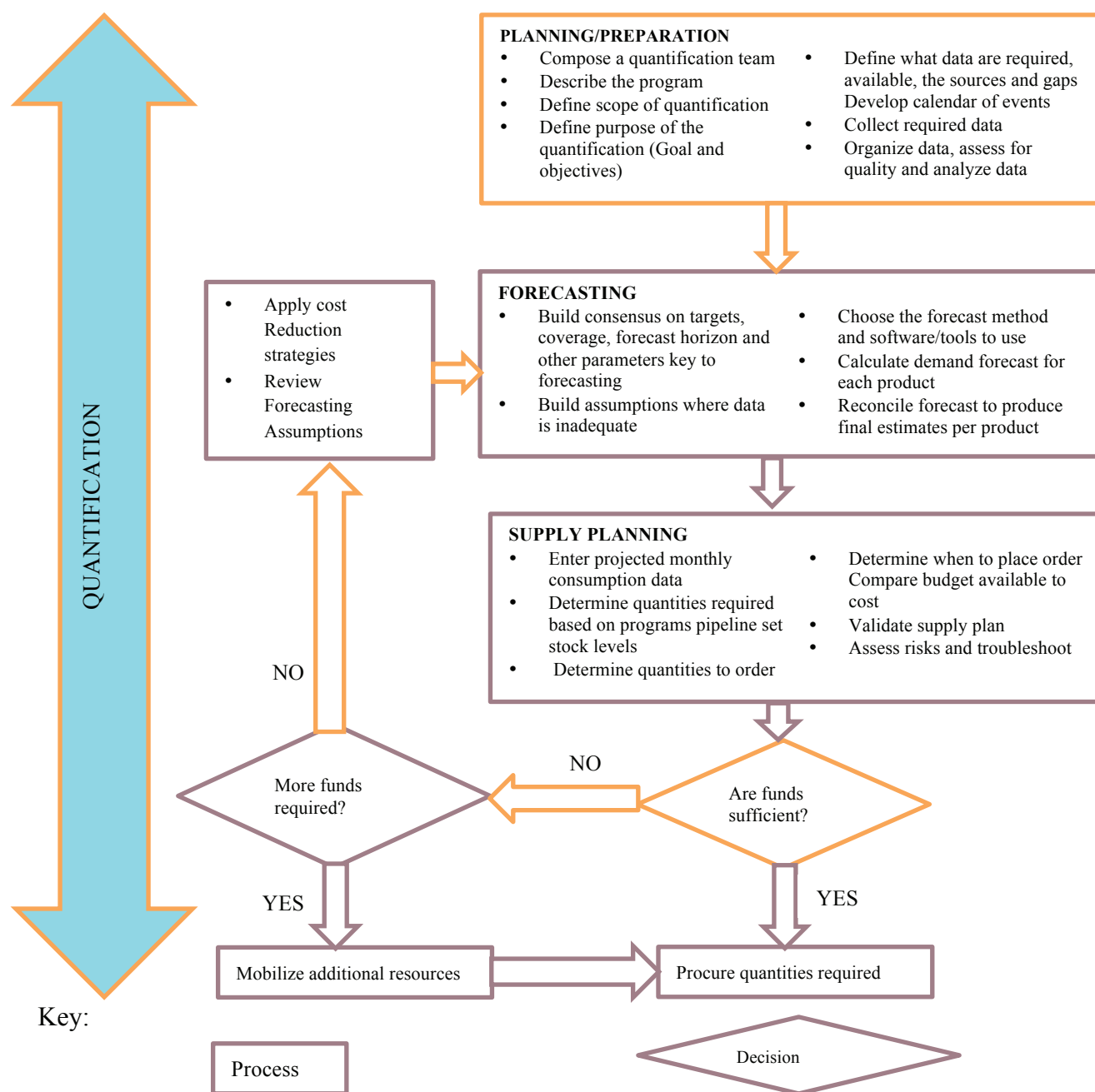
1. Ministry of Health
2. Development partners / donors - USAID, DfID, UNFPA, KfW
3. Implementing partners involved with commodities management
4. Kenya Medical Supplies Authority (KEMSA)
5. Market players such as manufacturers where appropriate
6. Other select co-opted stakeholders.

The CSTWG appoints a Logistics TWG that carries out quantification and executes the routine FP logistics management tasks. The membership and TOR for the logistics TWG is in appendix 2. At the County level, leadership and coordination for FP commodity security should be provided by the County Ministry of Health. FP commodity security should be integrated into the County commodity security forums which should also be a multi sectoral and multi-disciplinary to include all relevant stakeholders in the county.

### 2.2 The process of quantification

Quantification process entails several related steps that must be well coordinated and executed sequentially, starting with formation of the quantification team, through data collection and validation, to forecasting and supply planning as shown in figure 2

**Figure 2: Steps in Quantification Process**



Source: Adapted from *Quantification of Health commodities: USAID/DELIVER project, Task Order 1. 2008*

## 2.3 Quantification Team

A multi-disciplinary quantification team comprising of members with various sets of skills and expertise that will carry out the estimation of annual requirements and generate a supply plan is appointed by the FP CSTWG. The members of the team at the national level are outlined below and a similar composition can be used at the county level.

- MOH/ RMHSU
- Other MOH departments such as NASCOP



- Implementing partners involved in FP commodities management
- Pharmaceutical services unit
- FP program management specialists
- Logistics and supply chain management officers
- Supply chain agencies, e.g. KEMSA
- Private FP commodity players and social marketers
- Any other persons co-opted.

Besides providing the overall leadership for this team, the key roles for FP CSTWG in particular are to:

1. Initiate the formation of quantification team
2. Convene the team as appropriate
3. Liaise with other state agencies and stakeholders involved with procurement of FP commodities
4. Determine commodity requirements and resources needed to procure, warehouse and distribute the commodities
5. Determine any resource gaps and communicate with the relevant stakeholders involved in resource mobilization

The team should have clear terms of reference (appendix 3) and work plan (appendix 4). This team carries out an annual quantification and should meet quarterly at county level and mid-year (6month) at national level to review the quantification plan and the supply plan.

## **2.4 Preparation for quantification**

### **2.4.1 Determine Quantification Scope**

The quantification team should define and communicate to FP CSTWG or the county commodity security forum at the county level and any other stakeholders the scope of the activity which covers three key areas:

1. The objectives of quantification
2. The commodity list- informed by the county needs and the FP service guidelines.
3. The period to be covered by the quantification.

The overall objective for quantification is to determine the quantities of FP commodities needed for the forecast period under consideration.

### **2.4.2 Determine Quantification Method**

The quantification team should choose from the various options (table 1) a suitable quantification method.

**Table 1: Quantification Methods**

	Consumption	Population (Morbidity)	Adjusted Consumption	Service-Level Extrapolation
Use	<ul style="list-style-type: none"> <li>In established supply systems</li> <li>Stable programs</li> <li>Is the method of choice for rapid procurement quantifications (if reliable data available, future consumption can be predicted)</li> <li>Useful for short to medium term forecasts</li> </ul>	<ul style="list-style-type: none"> <li>New programs, Scaling-up programs or for Disaster assistance</li> <li>Disease-specific treatment, based on projections of the incidence of those diseases</li> <li>Developing and justifying budgets (e.g. funding requests to donors)</li> <li>Long-term planning</li> <li>Useful in absence of reliable historical consumption or service data</li> </ul>	<ul style="list-style-type: none"> <li>Procurement quantification when other methods are unreliable</li> <li>Compare use with other supply systems</li> </ul>	<ul style="list-style-type: none"> <li>Estimates budget needs</li> </ul>
Essential Data	<ul style="list-style-type: none"> <li>Inventory records</li> <li>Reliable consumption and stock data (high consistent reporting)</li> <li>Pipeline requirements</li> <li>Unit costs for each commodity (medicine, laboratory, etc)</li> <li>Supplier Lead times</li> <li>Data for Adjustments: Rates for losses / wastage rates; stock-outs, seasonal patterns</li> </ul>	<ul style="list-style-type: none"> <li>Reliable Service population attendance data</li> <li>Reliable data on morbidity and patient attendance</li> <li>Actual / projected Prevalence rates or Disease incidence within defined population group</li> <li>Demographic or population data and growth trends</li> <li>Defined program targets</li> <li>Standard treatment / testing guidelines</li> <li>Health surveys, studies</li> <li>Unit costs for each commodity</li> <li>Supplier Lead times</li> </ul>	<ul style="list-style-type: none"> <li>Comparison area / system with good data (consumption, population, patient attendance, etc)</li> </ul>	<ul style="list-style-type: none"> <li>Use by service levels and facility type</li> <li>Average cost of providing medicines or lab services per attendance</li> </ul>
Limitations / Requirements	<ul style="list-style-type: none"> <li>Assumes that current usage patterns will continue</li> <li>The system must have relatively uninterrupted supply and a full supply pipeline</li> <li>Can perpetuate irrational use</li> </ul>	<ul style="list-style-type: none"> <li>Assumes that service utilization can be projected from past trends; yet may be difficult to predict</li> <li>Computer analysis may be needed for large datasets</li> <li>Most complex and time-consuming method</li> <li>Tends to over-estimate commodity demand</li> <li>Standard treatments/testing protocols may not be used by healthcare workers</li> <li>Morbidity data not available for all diseases</li> </ul>	<ul style="list-style-type: none"> <li>Questionable comparability of the data (Morbidity, consumption, population, patient attendance, treatment/ testing practices, etc)</li> </ul>	<ul style="list-style-type: none"> <li>Variable facility use, attendance, treatment/ testing patterns, supply system efficiency</li> </ul>

Source: MDS-3: Managing Access to Medicines and Health Technologies. Management Sciences for Health

The population-based method is preferred by RMHSU for FP commodities at the national level since it allows a forecast to be made based on program goals (for example, the national CPR target) for a specific period of time and hence determine the number of end users required to



reach these goals. Results from this method should be validated against the service level data and consumption methods.

At the county level forecasting can be done either through population based forecasting or using consumption and service level data. This should be informed by quality and completeness of data available at the county level on FP commodities. Other factors that should be taken into consideration are the planned activities, goals and targets set by the County.

### 2.4.3 Make quantification plan

Actual quantification exercise requires early planning. The quantification team should formulate a clear action plan which details processes to be undertaken for successful quantification and specifically addressing the following key aspects:

- Date(s) for quantification
- Workshop logistics
- Tasks to be done, their timelines and deliverables.
- Assigning of tasks and roles

The action plan (sample in table 2) should outline the specific tasks to be undertaken and by whom for a successful quantification as well as cover the post-quantification activities such as dissemination of the results and the quantification reviews.

**Table 2: Sample action plan**

<b>BASIC ACTION PLAN FOR QUANTIFICATION</b>
<ul style="list-style-type: none"> <li>• FP commodities pharmacist to initiate the activities for the quantification process.</li> <li>• Determine start and end dates for the annual cycle of national quantification activities.</li> <li>• Confirm budget and procurement cycles and timelines for the Ministry of Health and the main FP funding partners</li> <li>• FPCSTWG to convene the FP quantification Team.</li> <li>• The FP Quantification team to develop a quantification work-plan and timeline for quantification</li> <li>• The FP Quantification team to set the objectives, coverage, and list of commodities for the quantification.</li> <li>• Designated members of the FP Quantification team to prepare the list of data needed for the quantification activity.</li> <li>• Fix dates for quantification workshop and draw a program (appendix 5)</li> <li>• Hold the quantification workshop</li> <li>• Communicate and disseminate results of the quantification exercise</li> <li>• Initiate the procurement process.</li> <li>• Hold a quantification review</li> </ul>

## 2.5 Data Collection

A reliable quantification requires accurate, up-to-date, and complete data. The data types required relate to procurement, supply, demand, consumption, service utilization, demographics, stock on hand, unit price and funding for the various FP commodities (table 3).

**Table 3: Data types and sources relevant to quantification**

<b>Commodity Data type</b>	<b>Description</b>	<b>Source</b>
<b>Receipts / shipments</b>	All commodities that have been procured and delivered to Kenya by GOK or partners	KEMSA, MEDS, Other suppliers, Funding partner, RMHSU, NASCOP, PSK, MSK, FHOK
<b>Distribution/Issues</b>	Month by month data on issues.	KEMSA, MEDS, Other suppliers, PSK, FHOK, MSK
<b>Pending procurement</b>	Procurements for which order has been placed but delivery is pending	KEMSA, MEDS, Other suppliers, RMHSU, Funding partner, NASCOP
<b>Planned procurements</b>	Planned, but order processing not started.	KEMSA, MEDS, Other suppliers, Funding partner
<b>Stock on hand</b>	Central/County stock level closing balances for all the commodity at the ended month preceding quantification	KEMSA, MEDS, Other suppliers, PSK, FHOK, MSI
<b>Commodity Consumption</b>	Commodity use as reported in the FCDRR	DHIS2; LMIS reports
<b>FP service utilization</b>	Method up take as recorded in MOH 711 (month by month)	DHIS2
<b>Stock out data</b>	Commodity stock out either at central, sub county or facility level	KEMSA data; MEDS, Other suppliers, facility reports
<b>Reporting Rates</b>	Refers to month by month national and county reporting in DHIS2	DHIS2, LMIS reports
<b>Commodity prices</b>	The cost of each commodity	KEMSA MEDS, Other suppliers,
<b>Demographic data</b>	Population WRA	Census Reports; KDHS; TRAC and PMA 2020 surveys
<b>Funding data</b>	Committed versus actual funding	County Treasury, RMHSU, Funding partner
<b>Previous year forecast</b>	Necessary to compute forecast accuracy	Previous quantification report
<b>Procurement lead times</b>	Time from planning to order to receipt of commodities. Influences pipeline parameters	KEMSA, MEDS, Other suppliers, funding partner

The quantification team should identify the relevant data types needed and the sources. Additionally, the team should prepare data collection templates and send them to select team members with clear timelines.

## 2.6 Data analysis and validation

Collected data should be assessed for quality and accuracy; identify and address any inaccuracies and incompleteness. The steps in data analysis and validation are outlined below:

1. Organize data by type
2. Summarize data into tables and frequencies
3. Clean and identify any outliers
4. Check for quality- accuracy, completeness and relevance
5. Where data quality is lacking or weak, make adjustments through calculations and/ or assumptions to account for the missing on unreliable data.
6. Analyze data trends.
7. Compute previous year's forecast accuracy

A sample data summary is in table 4, sample report for stock on hand (SOH), summary of shipments and commodity prices can be found in appendix 6, 7 & 8

**Table 4: Sample data summary per commodity**

Kenya												
Commodity summary: Implants 1 rod_ 2015												
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Consumption	24,644											
Forecast	14,791	14,791	14,791	14,791	14,791	14,791	14,791	14,791	14,791	14,791	14,791	14,791
KEMSA Issues	9,511	438	83,870	313	400	0	0	0	10,325	5,000	5,000	0
Receipts	0	0	0	0	0	0	0	0	0	230,000	100,000	100,000

Source: DHIS2 FCDRR (2015); KEMSA stock reports; Commodity shipment reports

## 2.7 Executing quantification

### 2.7.1 Run pre-quantification check list

The quantification preparation stage is very critical to a successful forecast. The quantification team can use simple check list to ensure the process has been done right (table 5)

**Table 5: Sample Pre-quantification preparation check list**

QUANTIFICATION PREPARATION CHECK LIST	
<b>Quantification logistics</b>	
•	Are the quantification team/ stakeholders invited?
•	Is quantification workshop dates, venue and funding confirmed?
<b>Quantification tools and models</b>	
•	Are the tools for forecasting and supply planning available and updated?
<b>Data:</b>	
•	Is there data on past consumption and service utilization?
•	Is there method specific data?

- Is the data complete and accurate?
- Is data from the last KDHS available?
- What is the target population for quantification?
- Is there segregation of the female population to specific sub-sets?
- What is the source of mCPR estimates?
- Are latest national/ County/ District mCPR estimates available?
- Is there evidence of adherence to national family planning services guidelines?

#### **Stock status and Procurement arrangements**

- Is there data on stock on hand?
- Who does procurement for MOH and donors? Is procurement agency used?
- Is there information on the different lead times?
- Where are the procured commodities received and warehoused?
- Who supplies/ distributes procured commodities?
- Is there data on procurement, warehousing and distribution?
- Is there data on pending and planned procurements?

## **2.7.2 Quantification Assumptions**

Quantifications assumptions refer to the key considerations taken into account during the quantification and which influence the entire forecasting besides simulating scenarios relevant to the quantification variables. They also provide tenets for accounting for any adjustments done to improve data quality and validity. The quantification team is required to define and document all the assumptions made (table 6).

**Table 6: FP Quantification Assumptions**

<b>Assumption</b>	<b>Rationale/ Importance</b>
<b>A. Forecasting assumptions</b>	
Period of forecasting	Defines period of forecast
Forecast coverage	Defines the sector to be covered by the quantification. Typically, RMHSU forecasts for the whole country but focuses on Public sector requirements. Non public sector requirements (commercial, social marketing) are taken care of by their respective sectors. The county should similarly focus on Public facilities or facilities supported by the county Governments such as faith based institutions.
Forecasting method	Population (demographics) Consumption and services. Consider all methods and compare results.
Population to be covered by services	Women of reproductive age (WRA)
Population figures and growth rates	Refers to the national census estimates for the population selected.
Percentage of WRA that are sexually active	Proportion of WRA that are actually at risk of getting pregnant-target and potential users for FP commodities
Targets for coverage	CPR target that the FP program plans to achieve by a defined period in the future. Analysis on how this target compares with past patterns of past mCPR growth.

<b>Assumption</b>	<b>Rationale/ Importance</b>
Method mix	Refers to the proportion of users using a particular FP method
Estimation for condoms use for FP	Determination of what proportion of sexually active WRA that use condoms (male or female) specifically for birth control
Percentage use of individual products within a method category	This refers to the split between commodities in the same method category e.g. for oral pills would be split between COCs and POPs, for implants, split between 1 rod and 2 rod.
Product mix: public and non- public sector	Estimated split of the annual national requirements between public and non-public sector.
<b>B. Supply plan assumptions</b>	
Days out of stock	Number of days the commodity was not in stock. Necessary in adjusting the overall commodity consumption and forecasting of requirements.
Exchange rate	The equivalent of Kenya shillings to 1 USD used for currency conversion during quantification
Wastage factor	Estimate for proportion of all the commodities that will be wasted during transport, storage and handling. Fixed by the program.
Pipeline parameters	Refers to the minimum and maximum months of stock that the program wants to maintain at different levels of the supply chain. Influenced by lead times, safety stock and order interval period
Order interval	Average period between orders.
Order time	Refers to the time from when an order is planned, placed, shipped and finally received.
Prices for commodities	Refers to the source of prices to be used for quantification and the unit cost of the product.

### 2.7.3 Determine and Prepare quantification models

The quantification team should review the last quantification tools and models and identify any changes needed to improve them. The team should also consider any other new tools before determining what to use. Commonly used tools are in appendix 9. In this section hypothetical examples have been used where appropriate to illustrate further the processes involved in each step of quantification.

### 2.7.4 Forecasting

Forecasting is the process of estimating the quantities and costs of the FP commodities required for a specific period. The assumption formulated during the quantification exercise form a major component for forecasting. Regardless of the quantification model or tools used, forecasting follows basic steps outlined below:

**Step 1:** Define the forecast period, commodities to be quantified and the population coverage (usually for sexually active women of reproductive age, which is a subset of total women of reproductive age). This is set during the assumption and building stage.

**Step 2:** Calculate the method mix – The method mix determines the proportion of clients on the different methods within a given period. The calculated method mix should total to 100%. The data source would be from past service statistics or from survey data if the survey was current. Below is a method mix determined using service data generated from the DHIS-2 at the

national level. This serves as the baseline method mix. Other sources of data can be used as appropriate, for example the facility based service data.

**Table 7: Sample method mix**

FP Method	New Clients	Current (Baseline) method mix
Injectable	642,277	46.1%
Intra-uterine device	83,819	6.0%
Implants	400,581	28.7%
Pills	259,695	18.6%
Sterilization (male and female)	7,988	0.6%
<b>Total</b>	<b>1,394,360</b>	<b>100%</b>

*Source: DHIS2, MOH 711 for 2015.*

**Step 3:** Identify national and county mCPR target for the forecast period then using the current method mix, calculate future method mix and corresponding CPRs across the various method mixes. For example, assume the country Kenya has a target mCPR of 61.94 for year X and 64.82 in year Y, the respective year's method specific CPRs using the method mix in step 2 will be as below:

**Table 8: Sample method mix and future desires CPRs per method**

FP Method	Current (Baseline) method mix	Method mCPR in Year X	Method mCPR in Year Y
Injectable	46.1%	28.53	29.86
Intra-uterine device	6.0%	3.72	3.90
Implants	28.7%	17.79	18.62
Pills	18.6%	11.54	12.07
Sterilization (male and female)	0.6%	0.35	0.37
<b>Total</b>	<b>100%</b>	<b>61.94</b>	<b>64.82</b>

**Step 4:** Calculate the number of projected clients per method for each of the target year. This is derived by first determining the total number of sexually active married women of reproductive age (sMWRA). This is normally a proportion of the women of reproductive age (WRA) - this proportion is already determined during the assumption formulation stage. As a hypothetical example, we assume that in year Y, the WRA is **12,097,262** while the proportion of sMWRA is 71.94%. The sMWRA shall be **8,702,770**.

The generated estimated number of sMWRA is then used to calculate the number of clients on each of the methods for the target year. For example, using the projected method specific mCPR in step 3, to calculate the projected number clients using injectable in year Y, we divide the method specific mCPR (i.e 29.86) by 100 then multiply by the total sMWRA (8,702,770) for the year. This gives a total of **2,597,202**. Repeat this for the other methods.

Thus the projected number of clients per method in Year Y is as shown in table 9

**Table 9: Sample estimation of projected number of clients per method**

FP Method	Current (Baseline) method mix	Projected Method mCPR in Yr Y	No. of clients per method in Yr Y
Injectable	46.1%	29.86	2,598,448
Intra-uterine device	6.0%	3.90	339,105
Implants	28.7%	18.62	1,620,623
Pills	18.6%	12.07	1,050,643
Sterilization (male and female)	0.6%	0.37	32,317
<b>Total</b>	<b>100%</b>	<b>64.82</b>	<b>5,641,136</b>

**Step 5:** Calculate annual commodity requirements - this is determined by multiplying the projected number of clients per method by the number of units of the product required for one user per year. Note that adjustments will have to be made for the discontinuation rates for implants and IUCDs. Also note that at this point a split will have to be made for the implants (1 rod and 2 rod) and the pills (POPS and COCs), based on the assumptions adopted. For this example, a split of 50% is assumed for implants and 70:30 for COCs and POPs. For example, using the clients per method generated for year Y above in step 4 above, the commodities required shall be as indicated in the table 10.

**Table 10: Sample annual FP commodity requirements**

FP Method	No. of clients per method in year Y	No. of commodities per client for year Y	Commodities required for year Y
Injectable	2,598,448	4	10,393,792
Intra-uterine device	112,242*	1	112,242
Implants (1rod)- 50%	418,793*	1	418,793
Implants (2rod)- 50%	418,793*	1	418,793
Pills (COCs)- 70%	735,450	15	11,031,750
Pills (POPs)- 30%	315,193	15	4,727,894
<b>Total</b>	<b>5,641,136</b>		

\*Note that the number of clients on Intra-uterine device and the implants is adjusted for method discontinuations.

**Step 6:** Once the total requirements are determined in step 4 using the population based forecasting we will then determine the public sector requirements. Determine public sector requirements as a proportion of the total national or county requirements using the public and non-public split ratio. Divide annual forecast by twelve to get monthly forecast

**Step 7:** Validate the forecast results - Compare calculated quantities with FP service, commodity consumption and central level distribution data

Before arriving at the final commodity requirements, compare the estimates with a different quantification method using the same set of data to see which appears more realistic. Additionally, make adjustments for commodities lost due to damage; spoilage, expiration, theft or program expansion through increased number of new users.



**Step 8:** Determine cost of annual commodity requirements -multiply the unit cost by the total annual requirements per commodity. Using the commodities determined for year Y in step 5 as an example, the cost of requirements will be as tabulated as below:

**Table 11: Cost of FP commodity requirements**

FP Method	Unit price	Commodities required	Cost
Injectable	1.040	10,393,792	10,809,543
Intra-uterine device	0.512	112,242	57,468
Implants (1rod)- 50%	8.992	418,793	3,765,786
Implants (2rod)- 50%	8.850	418,793	3,706,317
Pills (COCs)- 70%	0.225	10,296,303	2,482,144
Pills (POPs)- 30%	0.323	4,727,894	1,527,110
<b>Total</b>			<b>22,348,368</b>

### 2.7.5 Supply planning

Supply planning, is the last output of quantification process that determines the quantities required to fill the commodity pipeline, their related costs, lead times, and shipments dates to ensure optimal procurement and delivery schedules. The basic steps in supply planning are outlined below:

**Step 1:** Determine the desired pipeline parameters (supplier lead times, reorder period, central and lower level minimum and maximum months of stock)

**Step 2:** Enter data into the supply planning tools/ models:

- Current stock on hand of commodities both at central and lower levels.
- Pending procurements and their estimated times of arrivals.
- Unit prices for procurement of the commodities to be quantified.
- Enter the monthly forecast for each commodity.

**Step 3:** Determine the supply plan requirements and cost- Based on current Stock on Hand (SOH), the pending procurements and monthly forecast for each commodity, plan for new procurements ensuring that stock levels are maintained optimally between minimum and maximum months of stock. Then multiply the supply plan requirements per commodity by the unit cost to determine the cost of the supply plan.

### 2.7.6 Determine commodity commitments and gap

Once the supply plan requirements have been generated, the next step is to determine what commitments from Government of Kenya (GoK) at National and County levels; and partners have been made against individual commodities. Compare supply plan requirements with available funding commitments to determine the gap.

Once cost estimates are obtained, it is necessary to add percentages for shipping, insurance, warehousing and distribution costs for commodities obtained from international sources, and any known applicable fees.



### 2.7.7 Prepare technical specifications

As the quantification team winds up the forecasting and supply planning, it must prepare product technical specifications, one most important elements of procurement (Annex 1). The specifications should cover product information, quality assurance provisions, packaging, and shipping requirements.

### 2.7.8 Quantification reviews and pipeline monitoring

The quantification team should meet quarterly to review commodity forecast and supply plan requirements. This will provide an opportunity to put into consideration any new information received that has the effect of changing the quantification assumptions, and also to identify areas for improvement in the next quantification cycle. So as to ensure an uninterrupted supply of commodities, Logistics TWG or county commodity security will periodically carry out pipeline monitoring and provide a status report to all stakeholders.

### 2.7.9 Quality assurance in forecasting

To ensure that quantification is done rationally and that forecasts remain accurate over time, the quantification team should do periodic checks to compare quantities procured and consumed for the year to the respective forecast quantities. The variance between the quantities procured and consumed and the quantities forecast will not only give a quantitative measure of the accuracy of the quantification process but also highlight the parts of the process that need to be adjusted.

A few monitoring measures should be adopted for both the data and the systems/personnel that generate the data:

- Compile quarterly LMIS data and follow up on the non-reporting levels (national, county sub-county and facility) to ensure accurate and timely reporting/ sharing of data.
- Regularly monitor consumption patterns and follow up on orders to ensure continuous commodity availability.
- Carry out continuous pipeline monitoring to ensure that enough commodities are available given current demand patterns.

## SECTION 3: PROCUREMENT

### 3.0 Introduction

Procurement is the process of turning forecasts and supply plans into purchased products that are delivered to a point of use. The process spans the whole life cycle from identification of the needs through to the final delivery to end use (procuring entity). Proper procurement ensures that the country receives family planning commodities in time to prevent stock outs, avails various contraceptive options at service delivery point to prevent missed opportunities for method uptake, and averts emergency ordering that has the inherent risk of increased costs. Emergency orders can also create additional bottlenecks by preventing the procurement department from filling routine orders, and increase the cost of goods procured.

*Procurement is the step that follows the completion of forecasting of commodity requirements and supply planning, so as to effectively fill the commodity pipeline to within the desired program parameters.*

### 3.1 Policy environment, regulation and public procurement in Kenya

Procurement of FP commodities for Kenya is done by either the Government of Kenya (GoK) through KEMSA or by development partners, in line with the supply plan developed at end of the quantification process. Just like for all other public goods, this process is governed by the Public Procurement and Disposal Act (PPDA) 2015. The act outlines various rules and principles which generally address the following key areas:

- Need to promote integrity, fairness and transparency through effective competition
- Need to maximize economy and efficiency.
- And desire to achieve value for money as a core principle underpinning Kenyan government procurement - government needs to be satisfied that the best possible outcome has been achieved taking into account all relevant costs and benefits over the whole procurement cycle.

A number of other related documents and regulations provide guidance on procurement of FP commodities. The Kenya Essential Medicines List (KEML) identifies essential health commodities, among them, the contraceptives, while the Kenya Health Policy (2014-2013) recognizes the need to improve the procurement processes to ensure availability of essential health commodities. Additionally, the Pharmacy Poisons Board provides import regulation product registration and import clearance for all health commodities.

### 3.2 Coordination for Procurement of FP commodities in Kenya

Procurement is a complex process involving estimating the quantity of commodities required, defining the technical specifications for each product to be procured, and managing the financial transactions between the procuring entity and the supplier. The process requires coordination between different GoK agencies and departments, and the development partners. The end of quantification and dissemination of the report sets in motion resource mobilization to meet the commodity requirements. Ministry of Health mobilizes funds from the national budget to partially meet the commodity costs with development partners providing additional support. Once commitments have been made and funds availed, MOH procures these commodities through KEMSA while development partners may use KEMSA or use their own procurement mechanisms that must be within WHO pre-qualified criteria and MOH standards. For MOH,

process should be carried out within the confines of applicable laws, policies, regulations and good pharmaceutical procurement practices to ensure transparency, accountability and efficiency.

The FP program plays the following key roles to support the procurement process:

- Make procurement request to KEMSA.
- Specify the product and quantities to be procured.
- Provide desired receipt dates.
- Provide product technical specifications (ref 2.7.7)
- Liaise with regulators (PPB) for import clearance permits.
- Make follow ups with MOH and Ministry of Finance for commitment of funds, appropriations, and expenditure authorization.
- Additionally, the Family planning program equally makes follows up on commitments made by development partners to ensure the commodities are procured and delivered according to the supply plan.

### 3.3 Rationale for the procurement guideline

The success of a procurement process depends on many factors that interplay at both international and local levels. These include the time schedule for procurement, quality of the products, the required quantity, availability of the suppliers (lowest priced and technically competent suppliers), and need for best value for money. It is on the premise of the complexity of this process and the need for effective coordination of interdepartmental/ agency relationships that this document has been developed - to provide step by step guidance to the FP program officers on the procurement process.

### 3.4 The procurement process

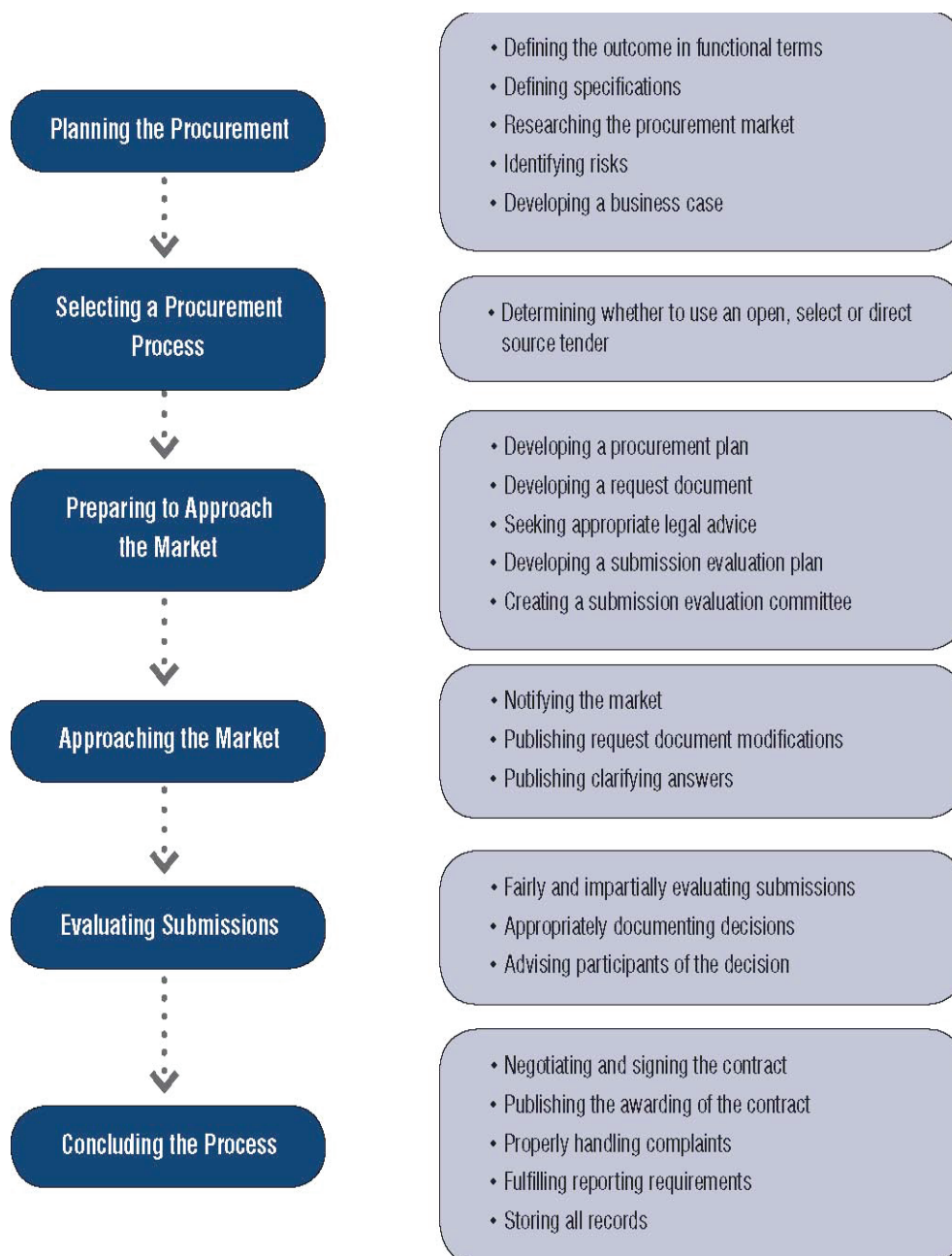
The length of the procurement process for new goods varies significantly and, in many cases, may take more than one year from start to finish. Procurement benefits most from well-defined and accountable processes which work to ensure that commodities are obtained through competitive, fair, consistent, and reliable means. Without efficient mechanisms to manage procurement processes, the acquisition of commodities may easily become disorganized and costly, resulting in stock-outs of products or the placement of emergency orders to fill anticipated supply gaps. Compared to other domains of the in-country supply chain, procurement is most likely to entail significant relationships between processes and activities at the global level.

Successful completion of the procurement process is dependent on a number key components named below that must be fully addressed:

- i) Need to know how much to procure and for what periods (forecasting & quantification).
- ii) Whom to buy from (supplier selection)
- iii) How to buy (procurement methods: local/international tender, pooled procurement etc.)
- iv) How to ensure quality of the products you buy (quality assurance)
- v) Systematic and sequential follow-up of the procurement activity (procurement planning)

Typically, the procurement cycle is divided into several interrelated steps with a focus on managing the tendering, bidding, and contracting process.

**Figure 3: Procurement process**



### 3.4.1 Quantification of the needs

Quantification is the process used to estimate how much of a product is required for the purpose of procurement. Quantification involves estimating the quantities needed of a specific item, the Funding required for purchasing the item, and when the products should be delivered to ensure an uninterrupted supply for the program. This steps involves defining which family planning commodities / products are required, their quality and quantities. The quantities are already generated from the annual forecast, which details requirements per commodity and the associated costs. The quantification process has two parts— forecasting and supply planning (discussed in chapter 2).

### 3.4.2 Reconciliation of needs and funds

The supply plan outlines the total commodity requirements and their costs which informs resource mobilization. For commodities to be procured using GoK funds the FP program manager should identify and secure this source within the national budget, ensure appropriate commitments and appropriations have been made, and place orders that match available funding. In the event that available funds can not cover all the needed quantities, commodities should be prioritized based on stock status and service delivery considerations.

### 3.4.3 Choose procurement method

The choice of procurement method is informed by the size and complexity of the procurement and procurement regulations in PPDA (2015). Other considerations are total value for procurement, procurement thresholds as defined in regulations, delivery timelines, current stock position, and the type of procuring entity. Overall, the method chosen must match the risk and complexity of the transaction.

### 3.4.4 Procurement planning

Procurement planning is the first process undertaken after supply planning and is intended to align the supply plan to actual day to day supply chain operations by matching demand for commodities to supply. Proper procurement planning will ensure the country receives family planning commodities in time to prevent both stock outs and emergency ordering that has the inherent risk of increased costs (refer to section 4.1.1).

### 3.4.5 Locate and select suppliers

At this stage, the procuring entity assesses market for producers and suppliers of these products. Once the decision on the appropriate tender process has been made, the procuring entity carries out the following activities:

- Prepares pre-requisite documents i.e. procurement plan, request document and an evaluation plan.
- Sends out requests/invitations to suppliers through advertising in local and international media with stipulated response period and bidding requirements. Technical and financial bids to be received separately.
- Carries out bid evaluation after closing date against the requirements stipulated in the bid documents. Bids are opened, reviewed, scored and ranked.
- Holds technical and financial evaluation separately.
- Determines and awards the most responsive bidder- the lowest priced but technically compliant supplier.

### 3.4.6 Specify contract terms

Contract terms define the contractual relationship between procuring entity and the supplier. This process entails the formulation of a contract that meets the needs of the procuring entity in terms of pricing, delivery dates, risk mitigation, supplier performance management, part deliveries and contract duration. The contract terms should:

- Stipulate the product specifications to ensure the products being procured are of the highest standards of quality to meet the needs of the user, are made of high quality raw

materials, and meet current good manufacturing practices (cGMP) and good distribution practices.

- Require that bid documents be delivered separately.
- Provide very clear product specifications
- Be general enough and avoid favoring some particular supplier in the brand.

### **3.4.7 Contract approval**

After a supplier has been competitively selected, the process moves to contract approval. The approval panel will:

- Review the procurement process to ensure compliance with the procurement rules and regulations.
- Ensure that supplier selection process and contract awarding are fair and transparent.

### **3.4.8 Monitor order status**

The procurement team prepares a purchase order (PO) / contract which is forwarded for signing by the authorized officer then subsequently send to the supplier. Once the supplier acknowledges receipt of the PO / contract, the procuring entity should start monitoring the order. This includes tracking the supplier's receipt of the order, order fulfillment, and shipping dates.

### **3.4.9 Receive and check commodities**

Delivery of commodities should be done according to the PO / Contract. The procuring entity should:

- Ensure compliance with all import process requirements – Import declaration form, Import permit, pre-shipment inspection / certification.
- Constitute and confirm presence of an inspection and acceptance committee.
- Verify deliveries against contract terms and technical specifications.
- Thoroughly assess the products to ascertain quality, quantity, expiry dates and packaging.
- Quarantine the received products until quality checks have been carried out and completed.
- Check for quality assurance - verify Certificate of Analysis, inspection certificate, sampling procedure and results where applicable, and sample retention by supplier.
- Liaise with Ministry of health officials for customs clearance.
- Confirm that all delivery documents are provided- commercial invoice, delivery note, packaging lists, original freight documents, certificates of analysis and certificates of origin. Attach them on payment documents.
- Confirm commitment of funds for the commodities.

### **3.4.10 Make payment**

Once goods have been received and acknowledged, the procurement team should forward all relevant documents for processing of payment - delivery note, commercial invoice, packaging lists, original freight documents, certificates of analysis and certificates of origin. The team should also confirm the quality, quantity and price of the commodities against contract terms besides verifying availability of funds on the commodity vote.



### 3.4.11 Distribute commodities

Distribution involves the transferring/transporting the FP commodities from the central store to service delivery points and the monitoring and follow-up mechanism during and on completion of the distribution process. The overall objective of distribution is to align the supply of commodities from central level to facility level demand, and the process entails:

- Stock (inventory) control
- Stores management
- Processing of facility orders / requests for commodities
- Delivery to medicines stores and health facilities
- Receipt and management of supplies by facilities

(Refer section 4.1.3)

### 3.4.12 Collect consumption data

Routinely collect commodity consumption data that will reveal stock depletion rates, method preferences and stock levels. The purpose is to ensure continuous monitoring of consumption against forecast, and against actual supply to inform pipeline management decisions and procurement plans.

### 3.4.13 Review commodity selection

The procuring entity should routinely review any changes in commodity specifications locally or globally which would then inform changes in the commodity list.

## 3.5 Supplier Performance Monitoring

The procurement team should routinely assess the supplier performance against the terms defined in the contract with objective of ensuring adherence. The team should collect information relating to the procurement process- from placement of purchase, order placement, order processing and delivery. Supplier performance monitoring for instance will entail comparing actual performance against expected performance as stipulated in the contract agreement. The goal of supplier performance monitoring is to ensure the supplier is meeting the procuring entities expectations in terms of product quality, timeliness, pricing and responsiveness. Some illustrative Key Performance Indicators are:

- Vendor response times compared to contract requirements
- Date of receipts of goods compared to planned delivery dates in PO/Contract.

## 3.6 Quality Assurance

In order to ensure the highest standard of family planning services, it is important to provide commodities of the best quality. The quality of a product is as good as the process it undergoes. To achieve the best quality of products, the Ministry of Health considers each stage in the logistics cycle;

- Selection and procurement – high quality products are selected based on internationally accepted criteria e.g. WHO Pre-qualification (mandatory for family planning commodities in Kenya); approval by SRAs e.g. the US FDA and PPB; and internationally accepted certification e.g. KEBS, CE and TÜV. Products are also selected

from manufacturers who have attained various globally accepted certifications like ISO. Other criteria that should be considered are recommended WHO storage conditions for Kenya – **Zone IV, 30°C/65% RH (relative humidity)**

- Distribution and Storage – product quality can be affected in these two processes even if all necessary measures were taken in selection and procurement. Good distribution and storage practices should be observed to maintain the quality of family planning commodities.

Pharmacovigilance plays an important role in quality assurance. The Pharmacy and Poisons Board in Kenya has set up systems to report suspected poor quality medicines or adverse drug reactions. Suspected poor quality medicines can be reported using the PINK FORM (PV6) or through the PPB website; link: <http://www.pv.pharmacyboardkenya.org/> and <http://pharmacyboardkenya.org/?p=464>.



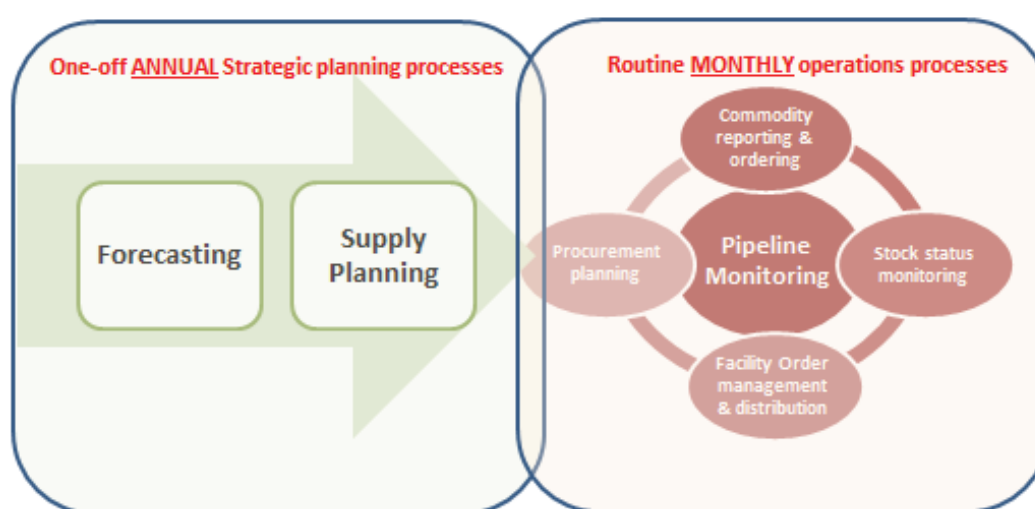
## SECTION 4: PIPELINE MONITORING

### 4.0 Pipeline monitoring

The practice of pipeline monitoring is centered on three key processes: Procurement planning, Stock status monitoring and Facility orders management and distribution planning. Ideally the processes should flow in the preceding sequence, but the sequence may be varied to enhance operational efficiency or address operational constraints. Each process is described in turn below.

Pipeline monitoring facilitates transition from the annual quantification to routine monthly processes as shown in diagram below.

**Figure 4: Strategic and operational supply chain process overlap**



### 4.1 Pipeline Monitoring at National Level

#### 4.1.1 Procurement planning

Procurement planning is the first process undertaken after supply planning, and is intended to align the supply plan to actual day to day supply chain operations by matching demand for commodities to supply through a procurement plan. This section assumes that there is or will be a team or a person who coordinates all the related activities. A full description of the process is appended below.

<b>Supply chain function</b>	Pipeline Monitoring
<b>Process name</b>	<b>Procurement Planning</b>
<b>Process Owner</b>	Person(s) coordinating procurement
<b>Process Executor</b>	Officer in charge of FP commodity management
<b>Process Frequency</b>	Monthly
<b>Process</b>	The Procurement planning process compares commodity demand (as captured

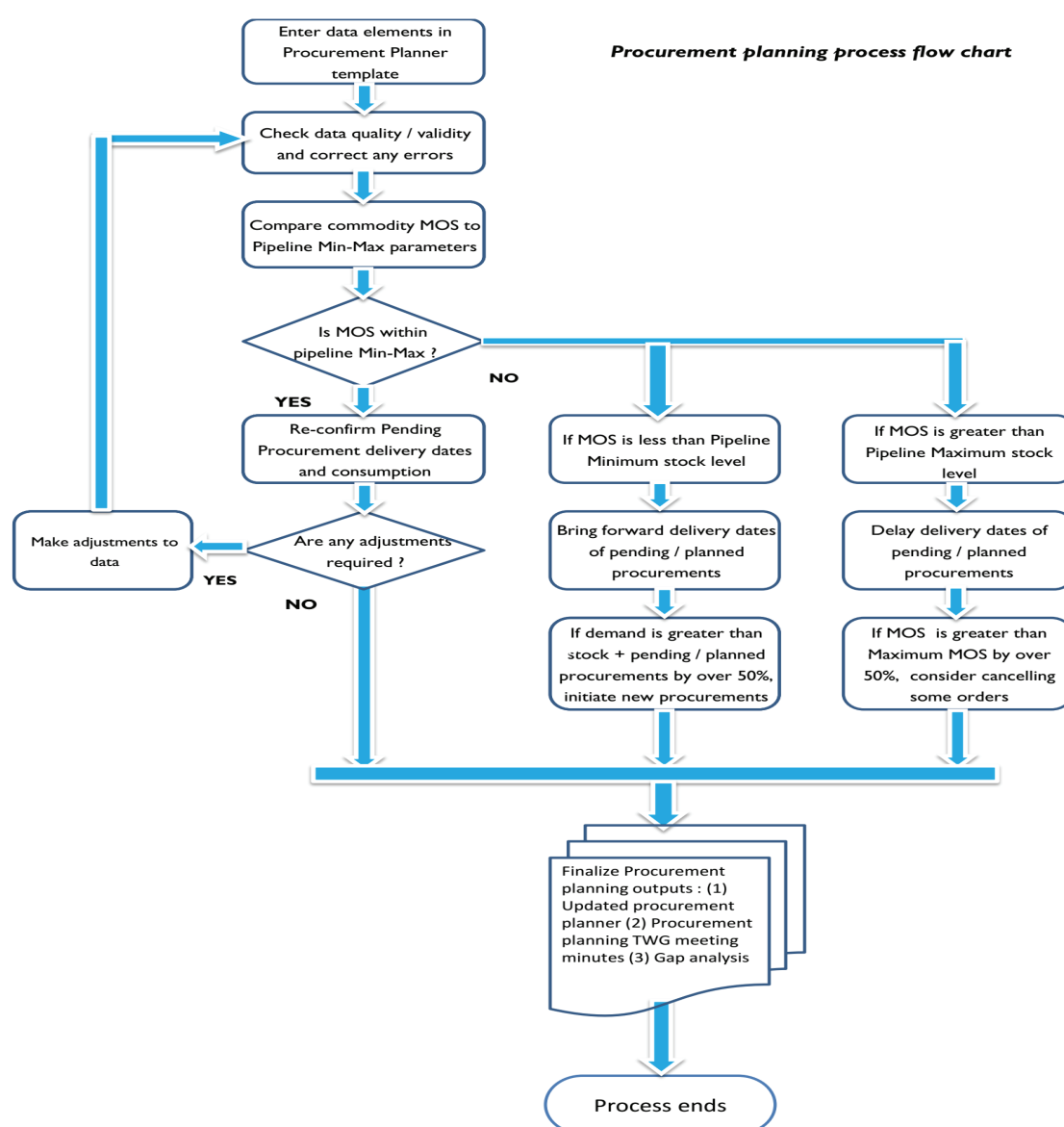
Description	in consumption reports) against commodity held in stock to determine if there is a need to vary planned and pending procurements. The process’ objective is to achieve uninterrupted supply of commodities to health facilities.	
Process Requirements	To carry out procurement planning, the following data is required.	
	Requirement	Source
	1. Procurement planner tool template	FP program /focal/RH coordinator/Commodity Manager
	2. Planned procurements / orders data	program annual supply plan Annual Supply plan as per last Quantification report; quantification for any funding commitments
	3. Calculated program scale-up rate for the commodities in each FP commodity category. National and county CPR targets as applicable	FP 2020, FP strategy, FP program /focal/RH coordinator/Commodity Manager Historical program growth from consumption data over the last 6 to 12 months
	4. Commodity consumption data (for the previous reporting period) Note: If consumption data is not available or reliable, then central level commodity issues data may be used as a proxy for consumption	FP program LMIS databases / reporting platforms. DHIS 2, FP Dashboard
	5. Central warehouses beginning stock balances for the previous reporting period	Supply chain agency (e.g. KEMSA, Warehouse department), Other central level stores managed by FP program and related units / departments
	6. Central warehouses commodity issues data for the previous reporting period	
	7. Central warehouses Commodities closing stock on hand (SOH) for the previous reporting period	
	8. Commodity stock in quarantine for the previous reporting period and expected release dates	Supply chain agency (e.g. KEMSA, QA department, any other supplier or distributor)
	9. Commodity receipts data	Supply chain agency (e.g. KEMSA, County procurement unit Procurement department); FP
	10. Pending purchase orders / contracts	
	11. Pending deliveries data with estimated delivery dates – Procurement status report	
	12. Current commodity unit prices	

	13. Procurement lead time information	program and relevant programs / units / departments					
	14. Program pipeline parameters (min/max) for each level of supply chain	Program quantification report					
	Collection of the above data is done on a monthly basis through engagement with designated contact persons in the supply chain agency – such as KEMSA/County procurement unit. For efficiency a standard data request form should be sent via email to the Agency in the first week of the month (requesting data from the preceding month) to ensure the data is available for the Procurement Planning Team meeting that should be held in the second week of the month.						
Process execution tasks and sequence	<div>1. Create master Procurement planner folder for the current year and within it create folders for each month</div> <div>2. Open Procurement planner template and save in the current month folder, along with related source data as listed above</div> <div>3. Populate the Procurement planner template fields with the data collected:<div>a) Commodity beginning balances, receipts, consumption or issues and SOH</div><div>b) Program CPR targets</div><div>c) Commodity unit prices</div><div>d) Pending and planned procurements and the expected dates when they should be available for distribution</div></div> <div>4. Validate entries in the template and the output numbers:<div>a) Compare the calculated closing stock in the template with the warehouse physical count and make adjustments as necessary for closing stock on hand to reflect actual physical stock</div><div>b) Compare current Months of Stock (MOS) to previous reporting period MOS. The change should correlate to commodity receipts/issues during the month under review.</div><div>c) Investigate any anomalous SOH and MOS figures and correct.</div></div> <div>5. Convene the Procurement Planning Team meeting where the MOS for each commodity is compared to the pipeline Min-Max levels to determine the procurement actions required and prepare updated procurement planner.</div>						
	<div>Likely scenarios and related actions outlined below.</div> <table><tr><th>Scenario #</th><th>Scenario description</th><th>Possible Procurement planning TWG actions</th></tr><tr><td>A</td><td>MOS is below Minimum level (or stocked out)</td><td><div><div>• Review pending and planned orders</div><div>• Review program scale up trend</div><div>• Expedite delivery of pending orders</div><div>• Expedite procurement of planned orders</div></div></td></tr></table>		Scenario #	Scenario description	Possible Procurement planning TWG actions	A	MOS is below Minimum level (or stocked out)
Scenario #	Scenario description	Possible Procurement planning TWG actions					
A	MOS is below Minimum level (or stocked out)	<div><div>• Review pending and planned orders</div><div>• Review program scale up trend</div><div>• Expedite delivery of pending orders</div><div>• Expedite procurement of planned orders</div></div>					

			<ul style="list-style-type: none"> <li>• Inform CSTWG that stock is below minimum level</li> <li>• Review funding commitment to identify any funding gaps</li> <li>• Inform Commodity Security committee to mobilize additional funding if required</li> <li>• Identify alternative commodities that may be used as substitutes until stocks are available and inform service delivery points through the facilities order management team</li> <li>• Inform the facilities order management team to ration supplies to facilities</li> </ul>
	B	MOS is above Maximum level	<ul style="list-style-type: none"> <li>• Review pending and planned orders</li> <li>• Review program scale up trend</li> <li>• Delay delivery of pending orders</li> <li>• Re-schedule procurement of planned orders</li> <li>• Negotiate for roll-over of funding commitments if necessary</li> <li>• Consider facility level demand creation activities</li> <li>• Redistribution at any level that has excess stocks</li> </ul>
	C	MOS is within Min-Max levels	<ul style="list-style-type: none"> <li>• Review pending orders (check for delays / cancellations of orders)</li> <li>• Review program scale-up trend</li> <li>• Monitor MOS trend</li> </ul>
	<p>6. Based on detailed evaluation of each commodity, the Procurement planning team makes decisions on: expediting, delaying, initiating or cancelling procurement orders. The decisions made and related information are documented through the minutes of the team's meeting</p> <p>7. The procurement planning team lead finalizes procurement planner and prepares presentation to Commodity Security Committee meeting</p> <p>8. Procurement planner circulated to relevant program staff and selected stakeholders like KEMSA for action on procurement and funding agencies for action on funding gaps</p> <p>9. Save all working documents and outputs in the current month folder created in step 1 above</p>		

<b>Process Outputs</b>	<p>The procurement planning process has three key outputs:</p> <ol style="list-style-type: none"> <li>Updated Procurement planner – which captures all the adjustments made to procurement orders to reflect the current status of all orders</li> <li>Minutes of procurement planning team meeting – which capture the deliberations of the committee and related action points and recommendations</li> <li>Commodity funding gap analysis over the next 12 months – which shows the gaps in funding and guides the FP commodity security committee in resource mobilization</li> </ol> <p>Details of how the outputs are used provided in the <i>Use of pipeline monitoring information</i> section of this guideline.</p>

**Figure 5: Summary of procurement planning process**



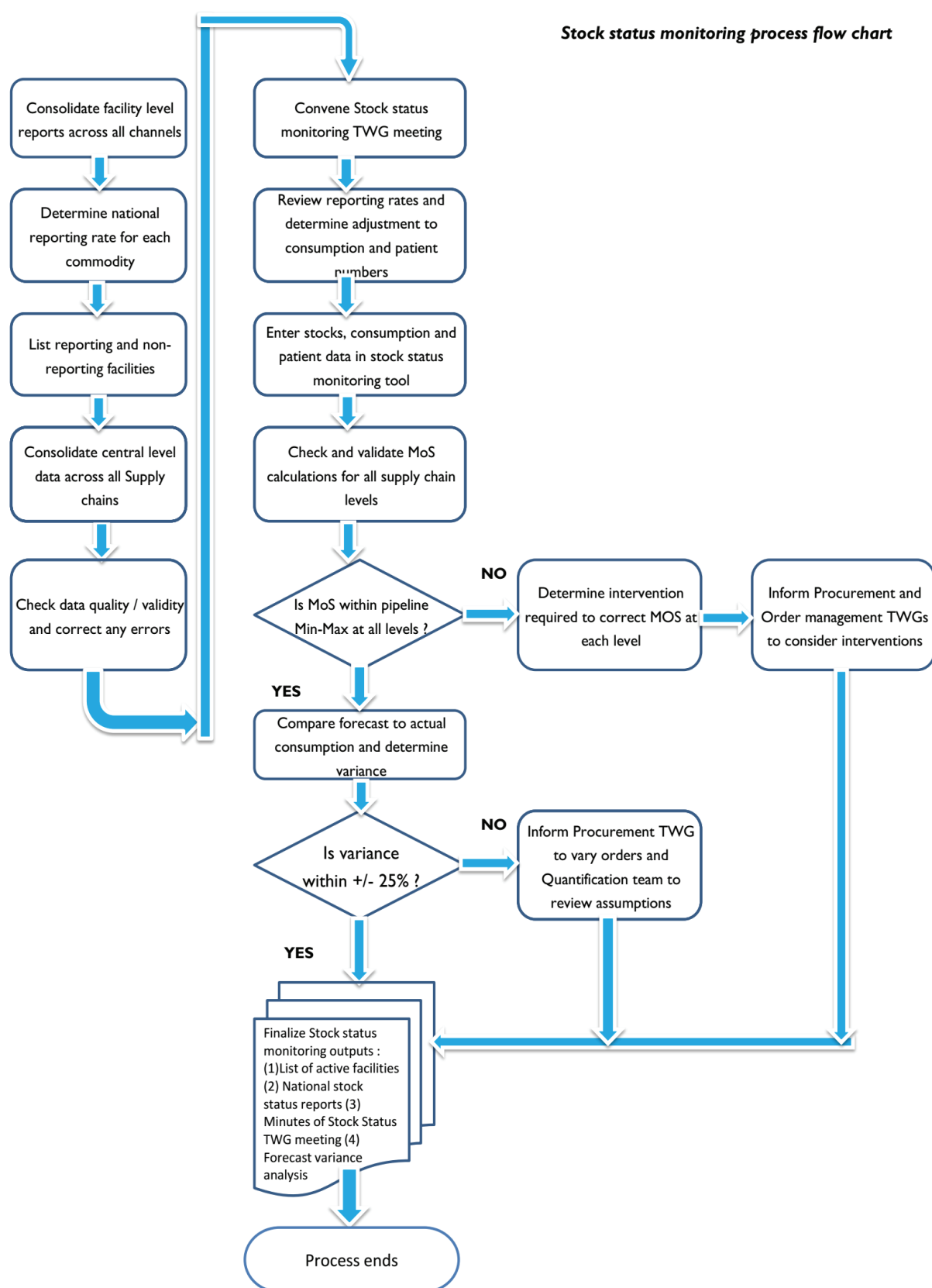
### 4.1.2 Stock status monitoring and reporting

Stock status monitoring and reporting is undertaken on a routine basis to provide end-to-end supply chain visibility and facilitate the decisions that need to be made to ensure that stock at all levels of the system is adequate to sustain health service delivery. A detailed description of the process follows.

<b>Supply chain function</b>	Pipeline Monitoring											
<b>Process name</b>	<b>Stock Status Monitoring and Reporting</b>											
<b>Process Owner</b>	The FP Logistics TWG											
<b>Process Executor</b>	Officer in charge of FP commodities											
<b>Process Frequency</b>	Monthly											
<b>Process Description</b>	The Stock status monitoring and reporting process tracks the trends in service delivery and commodity consumption to determine the adequacy of stock held at different levels (health facility, central warehouses, pending with suppliers) of the supply chain relative to pre-determined min-max stock levels.											
<b>Process Requirements</b>	<p>For all commodities, obtain the data below:</p> <table border="1"> <thead> <tr> <th>Requirement</th><th>Source</th></tr> </thead> <tbody> <tr> <td>1. Aggregated facility data (Stock on Hand (SOH), facility consumption and reporting rates) for the previous reporting periods</td><td>Aggregated LMIS reports e.g. FCDRR reports on DHIS2. Aggregated manual and electronic facility reports from all reporting channels</td></tr> <tr> <td>2. National level data (central warehouse SOH, stock receipts, stock issues, stock transfers)</td><td>Supply Chain Agency Warehouse department, and other central level stores</td></tr> <tr> <td>3. Pending procurements</td><td rowspan="2">Procurement Planner or SCA procurement department</td></tr> <tr> <td>4. Planned procurements</td></tr> <tr> <td>5. Templates – for Stock status analysis, Reporting rate analysis</td><td>FP commodity manager</td></tr> </tbody> </table> <p>Facility level reporting and aggregation is done through the FCDRR. Ensure that all data is collected on a monthly basis and the reporting rate computed.</p> <p>The procurement related data is obtained from the preceding procurement planning process. As such, the stock status monitoring and reporting process has to be scheduled after the procurement planning process has been completed.</p>	Requirement	Source	1. Aggregated facility data (Stock on Hand (SOH), facility consumption and reporting rates) for the previous reporting periods	Aggregated LMIS reports e.g. FCDRR reports on DHIS2. Aggregated manual and electronic facility reports from all reporting channels	2. National level data (central warehouse SOH, stock receipts, stock issues, stock transfers)	Supply Chain Agency Warehouse department, and other central level stores	3. Pending procurements	Procurement Planner or SCA procurement department	4. Planned procurements	5. Templates – for Stock status analysis, Reporting rate analysis	FP commodity manager
Requirement	Source											
1. Aggregated facility data (Stock on Hand (SOH), facility consumption and reporting rates) for the previous reporting periods	Aggregated LMIS reports e.g. FCDRR reports on DHIS2. Aggregated manual and electronic facility reports from all reporting channels											
2. National level data (central warehouse SOH, stock receipts, stock issues, stock transfers)	Supply Chain Agency Warehouse department, and other central level stores											
3. Pending procurements	Procurement Planner or SCA procurement department											
4. Planned procurements												
5. Templates – for Stock status analysis, Reporting rate analysis	FP commodity manager											

<b>Process execution tasks and sequence</b>	<ol style="list-style-type: none"> <li>1. Create master Stock Status Monitoring and Reporting folder for the current year in computer, and within it create folders for each month</li> <li>2. Extract facility reports from multiple reporting channels / systems</li> <li>3. Check facility data quality and validate using historical data</li> <li>4. Check if all facilities have reported, and follow up non-reporting and late reporting facilities as necessary</li> <li>5. Determine reporting rate for each commodity</li> <li>6. Aggregate facility consumption data</li> <li>7. Aggregate facility stock on hand data</li> <li>8. Obtain and validate central level stock data – SOH, Receipts, Issues and Transfers</li> <li>9. Obtain and validate central level procurement data – Planned and Pending procurements</li> <li>10. Convene monthly stock status monitoring and reporting TWG meeting to undertake the following tasks: <ol style="list-style-type: none"> <li>a) Assess commodity reporting rates and determine adjustments to consumption required to cater for non-reporting sites. Adjustment for reporting rate should only be applied to facility consumption (no adjustments should be made to Patient numbers or Stock on Hand)</li> <li>b) Validate central and aggregated facility level stock data</li> <li>c) Calculate Months of stock held at each level of the system and assess adequacy of stocks in relation to trends in patient numbers, consumption and pipeline min-max levels</li> <li>d) Analyze current stock status and provide interpretations and recommendations in relation to commodity security - for each commodity</li> </ol> </li> <li>11. Summarize stock and patient data into stock status reports Logistics TWG lead finalizes the stock status report(s) and sends to the FP commodities focal person for review, approval and circulation to the stake holders via email</li> <li>12. Send final stock status reports to Procurement Planning Team</li> <li>13. Logistics TWG lead Prepares presentation for Commodity Security Committee meeting</li> <li>14. Save all working documents and outputs in the current month folder created in step 1 above</li> </ol>
<b>Process Outputs</b>	<p>The Stock status monitoring and reporting process has three key outputs:</p> <ol style="list-style-type: none"> <li>i. Aggregated facility data – showing patients, consumption, stock on hand and reporting rates</li> <li>ii. Central level data – showing central SOH, Receipts, Pending Procurement, Planned procurement, Issues, stock transfers</li> <li>iii. Graphs, charts, tables – summarizing stocks, patients and reporting data</li> </ol> <p>Details of how the outputs are used provided in the <i>Use of pipeline monitoring information</i> section of this guideline.</p>

**Figure 6: Summary of stock status monitoring**





### 4.1.3 Management of facility orders and distribution planning

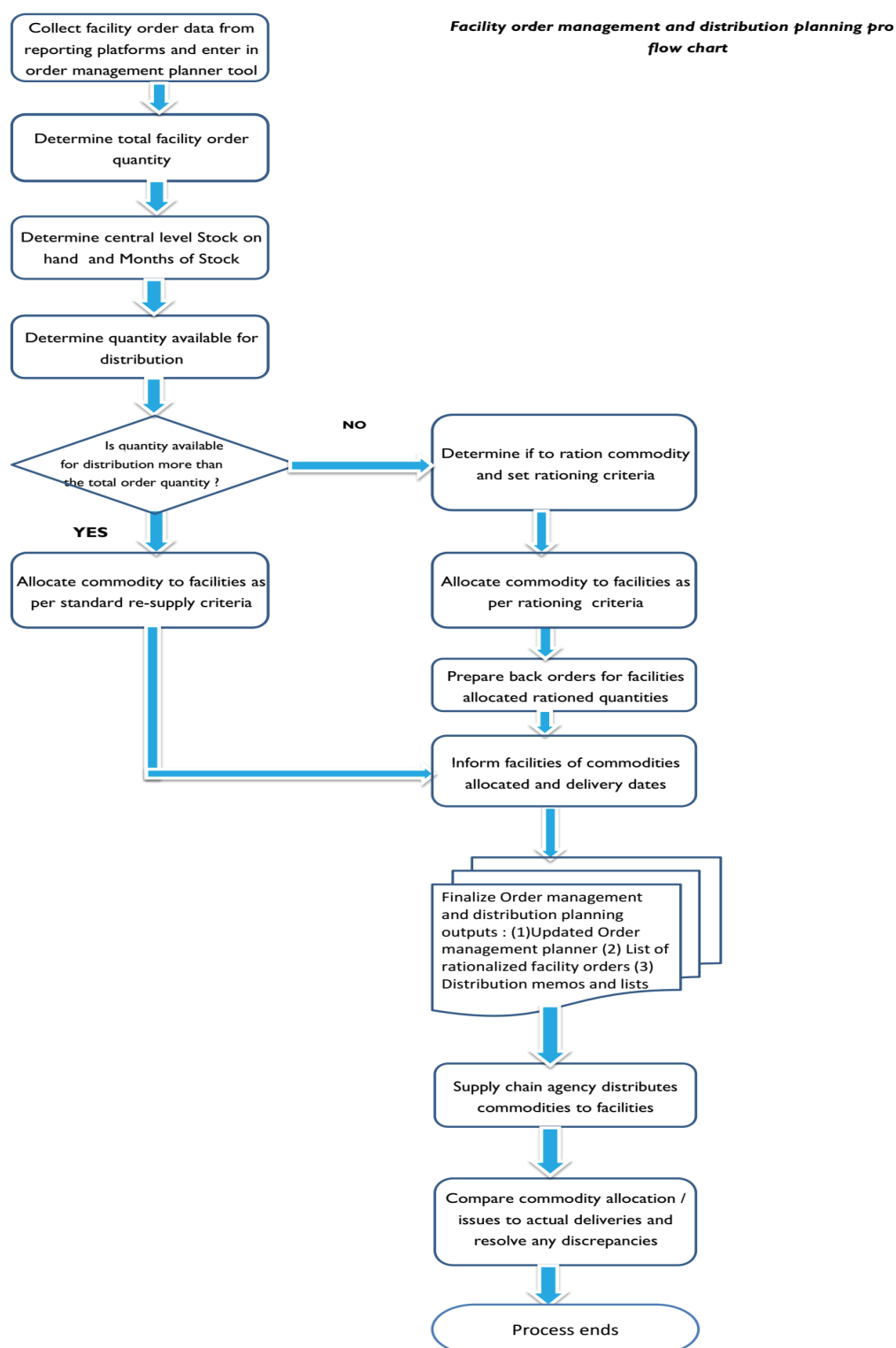
The order management and distribution planning process seeks to ensure that the demand for commodities (as captured in facility orders) is realistic and rational, and that commodities distributed match the demand while taking into account any supply side constraints there may be. The process is detailed below.

<b>Supply chain function</b>	Pipeline Monitoring	
<b>Process name</b>	<b>Order Management and Distribution Planning</b>	
<b>Process Owner</b>	Order Management and Distribution Planning Team	
<b>Process Executor</b>	Program officer in charge of FP commodities	
<b>Process Frequency</b>	Monthly or quarterly (depending on commodity distribution cycle)	
<b>Process Description</b>	Order management and distribution planning is the process of validating health commodity orders from health facilities and allocating commodities for distribution to the facilities in line with stock available for distribution and the established pipeline parameters.	
<b>Process Requirements</b>	For all commodities obtain the data below.	
	<b>Requirement</b>	<b>Source</b>
	1. Central level stock status report – showing: <ul style="list-style-type: none"> <li>Central level SOH and aggregated facility level SOH</li> <li>Pending and planned procurements</li> </ul> Notes on any special issues /actions – e.g. commodities to be rationed or re-distributed	Logistics TWG
	2. Facility reports for last three months – showing: <ul style="list-style-type: none"> <li>Facility commodity consumption data over last three months</li> <li>Stock on hand, as at the end of the last reporting period</li> <li>Facility commodity order quantities (requests) for the next distribution cycle</li> </ul>	Facility Contraceptives Consumption Data Report and Request (F-CDRR) – as reported through DHIS2
The central level data is produced by the Logistics TWG on a monthly basis, while the facility level data is captured monthly through the routine commodity reporting processes and aggregated through DHIS 2		

<b>Process execution tasks and sequence</b>	<ol style="list-style-type: none"> <li>1. Create master Order Management &amp; Distribution Planning folder for the current year in computer, and within it create folders for each month</li> <li>2. Save all source data listed above in the current month folder</li> <li>3. Validate the data and confirm all data elements have been received</li> <li>4. Convene the Order Management &amp; Distribution Planning Team meeting to review the aggregated central warehouses stock on hand (based on stocks after the last distribution cycle) and compare commodity stocks to facility orders received. For each commodity determine the quantity available for distribution in the current cycle and produce the commodity distribution schedule. Some likely scenarios and possible actions are outlined below:</li> </ol>		
	<b>Scenario #</b>	<b>Scenario description</b>	<b>Possible Order management &amp; distribution planning Logistics TWG actions</b>
	A	Stock on hand > Total Facility Orders received	<ul style="list-style-type: none"> <li>• Review pending procurement orders – to see dates for next deliveries</li> <li>• Determine quantity available for distribution in the current period</li> <li>• Distribute to facilities as per validated orders</li> <li>• Recommend delay of pending procurement orders delivery to procurement planning team</li> </ul>
	B	Stock on hand < Total Facility Orders received	<ul style="list-style-type: none"> <li>• Review pending procurement orders – to see dates for next deliveries</li> <li>• Determine quantity available for distribution in the current period</li> <li>• Prioritize and rationalize facility orders based on quantity available for distribution</li> <li>• Recommend to Procurement Team to expedite delivery of pending orders</li> <li>• Consider redistribution of commodities from overstocked facilities</li> </ul>
	<ol style="list-style-type: none"> <li>5. Based on distribution quantities determine in (4) above, the order management team to review facility orders and rationalize them – steps as below:               <ol style="list-style-type: none"> <li>a) Check data quality of facility reports – by comparing historical consumption with current consumption and orders</li> </ol> </li> </ol>		

	<ul style="list-style-type: none"> <li>b) For facilities with anomalies in consumption or order quantities, contact them to validate data and make corrections</li> <li>c) Adjust the validated facility order quantities in line with commodities available for distribution, to produce the rationalized facility orders</li> <li>d) Circulate the rationalized orders list to the Order Management &amp; Distribution Planning Team or FP focal person.</li> </ul> <p>Depending on the number of commodities and facilities, step 5 may take up to two weeks to complete. For commodities on a monthly distribution cycle it is therefore critical to establish and adhere to a monthly schedule of tasks.</p> <ul style="list-style-type: none"> <li>6. After approval of the rationalized orders list by the logistics TWG, prepare the commodity distribution memo(s) and submit for approval and subsequent distribution</li> <li>7. Save all working documents and outputs for steps 4,5 and 6 in the current month folder created in step 1</li> </ul> <p>Submission of the signed distribution memo(s) to the central stores triggers the actual distribution of commodities to facilities. After distribution, the supply chain agency should avail actual issues data showing the quantities delivered to each facility. As a final control check, conduct the two steps below:</p> <ul style="list-style-type: none"> <li>i. Check quantity allocated per facility in distribution memo against quantity delivered per facility as reported in issues data</li> <li>ii. Check quantity delivered per facility against quantity received per facility – as reported in facility monthly reports</li> </ul> <p>The checks may be conducted on a random sample of facilities, and any anomalies identified should be followed up and resolved.</p>
<b>Process Outputs</b>	<p>The order management and distribution planning process has three key outputs:</p> <ul style="list-style-type: none"> <li>i. Order management planner</li> <li>ii. Rationalized facility orders</li> <li>iii. Distribution memos</li> </ul> <p>Details of how the outputs are used provided in the <i>Use of pipeline monitoring information</i> section of this guideline.</p>

**Figure 7: Facility order management & distribution planning**



#### 4.1.4 Use of pipeline monitoring information at national level

The key outputs for each of the three pipeline monitoring processes are listed in table below with their respective uses shown in the last column of the table.

**Table 12: Pipeline Monitoring outputs and uses**

Process	Key outputs	Use of outputs
Procurement planning	Procurement planner	Provides upstream supply chain visibility and shows when future procurements should be ordered and delivered  The planner is also used to inform the wider Commodity Security committee on the status of procurement
	Minutes of procurement committee meeting	Action points provide interventions required to sustain supply - for different teams including procurement, QA, Warehouse, distribution and other TWGs
	Commodity funding gap analysis over the next 12 months	Used to mobilize resources with government and donor agencies. It can also inform re allocation of resources to cover the gap
Stock status monitoring and Reporting	Aggregated facility data - patients, consumption and stock on hand, Reporting rate data	Provides visibility of downstream commodity stock and consumption – used for planning and decision making
	Central level data - Central SOH, Receipts, Pending Procurement, Planned procurement, Issues, stock transfers, expiries / short expiries	Provides visibility of central commodity stock, distribution and expected shipments – used for planning and decision making
	Graphs, charts, tables (Cleaned patient data, Stock report – current MOS, consumption trend, consumption and issues comparison, Reporting rate, Patient trend analysis)	Visual outputs used to prepare stock status reports and presentations  Used to summarize stock status for wider FP commodity security committee and other stakeholders

	National stock status reports for FP commodities	Stock status reports sent to the commodity security committee and stakeholders – used for planning and decision making
Order Management and distribution Planning	Order management planner	Determines MOS available for distribution at central level and provides a basis for facility order rationalization
	Rationalized facility orders	Determines commodity quantities to be allocated to facilities Provides a basis for aligning supply to facility consumption and stock
	Commodity distribution memos	Instructions to supply chain agency on quantities to be distributed to each facility

Overall, the pipeline monitoring outputs constitute a major part of the information flows required to run health commodity supply chains.

#### 4.1.5 Coordination and oversight at National level

Pipeline monitoring is undertaken as one of the activities that contribute towards FP commodity security. It is therefore within the mandate of the FP commodity security committee, with TWGs/ teams reporting to the main committee.

The activities / tasks under pipeline monitoring are conducted by the commodity TWG on a monthly basis and presented to the various stakeholders. The focal person of each TWG is responsible for convening monthly meetings as necessary and ensuring that the routine tasks are carried out on schedule. The detailed TWG membership, Terms of Reference and meeting schedules are attached hereto as appendices 2, 3 and 4.

#### 4.2 Key Performance Indicators in Pipeline Monitoring

Pipeline monitoring processes are major contributors to the availability of FP commodities at all levels of the supply chain. To assess the efficiency and impact of the process, the indicators listed below are tracked at regular intervals and the indicator values are used to inform corrective actions at national and county levels.

**Table 13: Pipeline Monitoring- Key performance indicators**

What to monitor (Indicator)	Indicators Definition	Data Source(s)	Frequency of monitoring	Target	Acceptable result
Commodity Stock Status (stocking according to	Percentage of facilities with current stocks within the nationally set Min-Max level – at end of last reporting	Facility SOH obtained from facility reports (CDRRs) on DHIS2	Monthly	100%	80%

What to monitor (Indicator)	Indicators Definition	Data Source(s)	Frequency of monitoring	Target	Acceptable result
plan)	period <i>Measured at sub-county, county and national levels</i>	and other reporting platforms			
Commodity availability	Percentage of health facilities that did not experience a stock-out of the tracer health commodities* in the last 3 months. <i>Measured at sub-county, county and national levels</i>	Facility SOH obtained from facility reports (CDRRs) on DHIS2 and other reporting platforms	Quarterly	100%	80%
Reporting rate	Percentage of facilities submitting commodity consumption reports on the national LMIS <i>Measured at sub-county, county and national levels</i>	Facility reports (CDRRs) on DHIS2 and other reporting platforms	Monthly	100%	80%
Ensuring FP commodity security / coordination	<u>National level:</u> Existence of an <u>active</u> HIV commodity security committee and its pipeline monitoring TWGs  <u>County level:</u> Existence of an active County commodity management / commodity security committee and relevant pipeline monitoring TWGs	RMHSU  County	Annual	Yes	yes

\*\* Tracer commodities: DMPA

### 4.3 County Level Redistribution of FP Commodities

Re-distribution refers to the movement of commodities from one health facility to another. The need for re-distribution may be identified during the routine pipeline monitoring at the county level. It seeks to address facility level short-expiries, over-stocks and stock outs. The health facilities may be within or across different counties. The process is guided by the following criteria:

- The commodity months of stock (MOS) is greater than 3 months
- The commodity short expiry MOS is greater than 3 months
- Both criteria (a) and (b) are satisfied

### 4.3.1 Steps in Re-distribution

There are six steps involved in re-distribution.

**Step 1:** Conduct County stock status assessment and identify under stocked and overstocked facilities

During county level stock assessment, facilities with overstocks, under stocks, complete stock outs and or expiries for each commodity should be identified. During this assessment, obtain the following data for all health facilities in the county either from DHI2 or other commodity reports:

- Stock on hand (SOH)
- Short-expiry stock on hand (less than 3 months to expiry)
- Average monthly consumption - AMC (over last three months)
- Months of stock (MOS) = SOH/AMC (for normal and short expiry stock)

**Step 2:** Determine donor and recipient facilities. The criteria in the table below can be used.

**Table 14: Criteria for determining donor and recipient facilities**

Recipient (under stocked facilities)	Donor (overstocked facilities)
<ol style="list-style-type: none"> <li>All facilities with MOS &lt;3 months will be considered for receipt of commodities</li> <li>Priority will be given to the facilities with the lowest MOS, i.e. facilities that are stocked out will have the highest priority followed by those with MOS &lt; 1 month etc.</li> </ol>	<ol style="list-style-type: none"> <li>All facilities with MOS &gt; 3 months will be considered for donating of commodities</li> <li>Facilities that have MOS &gt; 3 months <u>and</u> short expiry MOS &gt; 3 months will be considered first</li> <li>Facilities with higher MOS will have their stocks redistributed first</li> <li>Priority will be given to re-distribution of short expiry commodities</li> </ol>

**Table 15: Sample determination for donor health facilities**

**Overstocked - Donor Health Facilities**

Name of Commodity: Combined Oral contraceptive Pills

Name of HF	MFL Code	Long Expiry SOH	Short Expiry SOH	Latest 3 months consumption	AMC	Long Expiry MOS	Short Expiry MOS	Subtract 6 MOS from Short expiry MOS	Quantity available for re-distribution		Quantity to be left in facility	
									Short expiry stock available for redistribution (Quantity)	Long Expiry stock available for redistribution (Quantity)	Long expiry stock left at facility (Quantity)	Short expiry stock left at facility (Quantity)
Health Center 3	24722	10,000	6,000	1,500	500	20	12	3,000	3,000	10,000	0	3,000
Health Center 4	13375	2,400	2,000	387	129	19	16	1,226	1,226	2,400	0	774
Hospital 4	13310	1,500	0	390	130	12	0	-780	0	720	780	0
Hospital 1	16826	2,000	1,500	600	200	10	8	300	300	2,000	0	1,200
County RH	12172	1,000	500	300	100	10	5	-100	0	900	100	500
<b>Total</b>		<b>16,900</b>	<b>10,000</b>	<b>3,177</b>	<b>1,059</b>	<b>16</b>	<b>9</b>		<b>4,526</b>	<b>16,020</b>		



**Table 16: Sample determination of an under stocked health facility**

**Under-stocked – Recipient Health Facilities**

**Name of Commodity:** Combined Oral contraceptive Pills

Name of HF	MFL Code	Long Expiry SOH	Short Expiry SOH	Latest 3 months consumption	AMC	Long Expiry MOS	Short Expiry MOS	Quantity* required
Hospital 5	17203	25	0	1,350	450	0.1	0.0	1,755
Health Center 2	15615	340	50	1,020	340	1.0	0.1	1,054
Health Center 1	19536	200	0	336	112	1.8	0.0	247
Hospital 3	17456	500	200	630	210	2.4	1.0	546
Hospital 1	10075	1,300	0	1,137	379	3.4	0.0	228
<b>Total</b>		<b>2,365</b>	<b>250</b>	<b>4,473</b>	<b>1,491</b>	<b>1.6</b>	<b>0.2</b>	<b>3,830</b>

\* Quantity required to top up to 4 MOS

**Step 3: Prepare the redistribution schedules**

For intra-county re-distribution – apply process below in sequence (aim to minimize transport and other costs):

1. Match donors with recipients within the same locality
2. Match donors with recipients within the same sub county
3. Match donors with recipients in adjacent sub counties
4. Match donors with recipients in non-adjacent sub counties

For inter-county re-distribution – apply process below in sequence (aim to minimize transport and other costs).

1. Match donors with recipients in adjacent counties
2. Match donors with recipients in the same administrative region (e.g. Nyanza, Western)
3. Match donors with recipients outside the administrative region

**Step 4: Communicate to affected health facilities**

The County pharmacist will communicate the proposed redistribution schedule to the identified facilities via e-mail. The relevant National FP program officials should be copied in this correspondence.

**Step 5: Mobilize resources at County level**

The county pharmacist will compile a list of all the costs to be incurred during redistribution (including packaging and transportation) and mobilize resources from the County government or partners where relevant.

**Step 6: Carry out redistribution and document the Process**

The guidance below applies:

- The donor health facilities will prepare excess commodities for redistribution, update their inventory records and fill out the related documentation: S11, delivery notes.
- The recipient health facilities shall receive the commodities and acknowledge receipt on the S11 and delivery note.

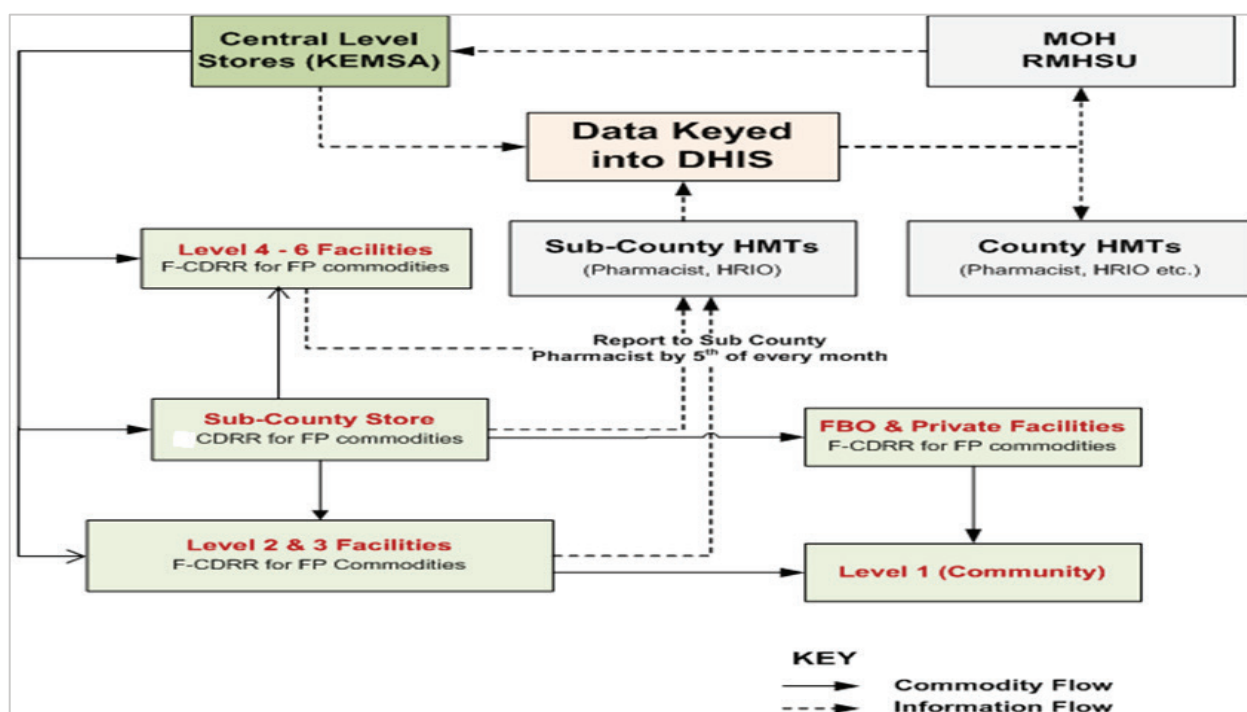
### 4.3.2 Concluding and documenting the re-distribution process.

The re-distribution process is essential in addressing commodities not stocked according to plan and expiries. It needs effective coordination and collaboration intra and inter- county. The County pharmacist shall compile a summary report outlining the redistribution process and share this with the relevant stakeholders (County authorities, FP program, partners etc.)

### 4.4 FP Logistics Management Information System.

Timely and accurate logistics data is critical to effective FP supply chain management. These data is useful in pipeline monitoring, planning distribution and informing procurement processes. Additional, commodity consumption patterns and service utilization provide information useful in quantification. The national and county FP commodity management teams should ensure timely and accurate reporting for all FP commodity data.

Figure 8: FP logistics data flow



## References

Kenya National Bureau of Statistics (2014). Kenya Demographic Health Survey

MDS-3: Managing Access to Medicines and Health Technologies. Management Sciences for Health

Ministry of Health: The Kenya Health Policy (2014-2030)

Ministry of Health: National Reproductive Health Strategy (2013-2017)

Ministry of Health: National Family Planning Costed Implementation Plan (2012-2016),

Ministry of Health (2016). National Family Planning Guidelines for Service Providers (2016)

Ministry of Health: National Health Sector Strategic and Investment plan (2013-2017)

Ministry of Health: Kenya Essential Medical List, include FP commodities.

Ministry of Health: Minimum package for RH/HIV and AIDS integration

Public Procurement and Disposal Act (2015).

The Constitution of Kenya (2010).

The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. USAID/DELIVER project, Task Order 1. 2008

Quantification of Health commodities: USAID/DELIVER project, Task Order 1. 2008  
UNDP (2015). Sustainable Development Goals.

UNFPA (2012). CONTRACEPTIVES SAVE LIVES Updated with technical feedback  
December, 2014.

UNFPA (2014). Adding It Up: Investing in Sexual and Reproductive Health

## Appendices

### Appendix 1: Terms of Reference for the FP Commodity Security Technical Working Group (CSTWG)

#### **Purpose**

The purpose of the FP Commodity Security TWG is to provide overall oversight and coordinate all the FP commodity security related activities, including quantification and resource mobilization.

#### **Membership**

1. RMHSU program managers and commodity focal persons
2. KEMSA
3. Development partners (e.g. USAID, UNFPA, DfID, KfW)
4. Implementing partners (e.g. PS/Kenya, MSK, FHOK, ESHE, CHAI, MSH/HCSM)
5. Private sector (e.g. Bayer, MSD)

#### **Goal**

To coordinate the national efforts of handling FP commodities, in achieving commodity security in line with the health sector policies and FP program objectives.

#### **Overall Objective**

To promote effective and efficient quantification, forecasting, procurement, distribution and use of FP commodities.

#### **Specific Objectives**

These include: -

- To conduct an annual quantification of FP commodities jointly with all the relevant government departments, development and implementing partners.
- To manage the national supply chain thereby assuring adequate availability at all times and forestalling any impending over-stock or stock-outs
- To provide justification and advocate for increased resource allocation for commodity security
- To coordinate the various donors and partners involved in the FP commodity security.

#### **Terms of Reference**

1. Provide a forum for monitoring and coordination of key FP commodity stakeholders
2. Plan, develop and oversee implementation of commodity management and supply chain systems and strategies to increase availability, access and accountability
3. Develop and implement a monitoring and evaluation framework for health commodities, including data quality and related supply chain audit processes
4. Strengthen commodity information systems to efficiently and effectively collect, analyze and provide strategic information and feedback reports on FP commodity management,
5. Provide feedback to senior policymakers and other key stakeholders on priority issues related to FP commodity security and to support decision making at national, regional and peripheral levels.
6. Plan for, undertake and disseminate the national forecasting and quantification as well as procurement planning and pipeline monitoring processes
7. Advocate for resource allocation as well as manage the resources availed through various initiatives for commodity management, including procurement, warehousing and distribution
8. Spearhead human and institutional capacity building for commodity management
9. Plan for, guide and implement supportive supervision to support commodity management at regional and peripheral levels, and disseminate results for follow-up
10. Plan for and conduct operational research on FP commodity security and supply chain management issues.
11. Liaise with the relevant regulatory bodies to monitor quality assurance of FP commodities and adverse drug reactions.

## Appendix 2: Terms of reference (TORs) for the FP Logistics TWG

### **Purpose**

To coordinate the national efforts of determining the stock status FP commodities, gaps and potential procurement needs, and interventions at facility and national level required to achieve FP commodity security in line with the health sector policies and plans, guidelines and FP program objectives, hence improving access to, availability of and accountability for these medicines.

### **Membership**

### **Overall Objective**

To ensure and promote end-to-end supply chain visibility through routine stock status monitoring at national and county levels for FP commodities.

### **Specific Objectives**

These include: -

- To conduct a monthly National stock status review for FP commodities jointly with all the relevant government departments, development and implementing partners; and identify relevant stock interventions
- To ensure adequate stock status at different levels of the supply chain relative to pre-determined Min-Max stock levels for FP commodities.
- To generate a monthly National FP stock status report that is disseminated to relevant stakeholders and to provide any other relevant strategic information as per RMHSU's needs, e.g. for national quantification.

### **Terms of Reference**

- Plan, develop and monitor implementation of FP supply chain and commodity management systems and strategies that have been ratified by the FP Commodity Security Committee to increase availability, access and accountability
- Develop and maintain the national standardized data collection and reporting tools for FP-related commodities' LMIS; and organize for dissemination / provision to counties, with appropriate orientation materials. These LMIS tools should be aligned to the current national FP guidelines.
- Develop/review a monitoring and evaluation (M&E) framework for FP-related health commodities, including relevant commodity management indicators, data quality assessment (DQA) and related supply chain audit processes to FP CSTWG from time to time. Disseminate results from these DQA or supply chain audit exercises.
- Collect and analyze relevant downstream data (consumption and service data) and upstream data (stocks at central level warehouses, issues, receipts, procurements); and provide relevant Quantification exercise inputs, strategic information and feedback reports to FP CSTWG and relevant stakeholders
- Develop/review and disseminate appropriate materials for use in orientation of healthcare workers on FP commodity management and supportive supervision
- Advise the FP CSTWG on relevant regulatory matters in the country to monitor quality assurance of FP commodities

### **Deliverables**

- Minutes of the Logistics TWG meeting
- The FP Stock status monitoring TWG should provide monthly reports to the FP CSTWG

## Appendix 3: Terms or reference for the Quantification team

### **Purpose**

The purpose of the quantification team is to coordinate the quantification process for HIV commodities, offer leadership and ensure timely completion of the quantification.

### **Membership**

1. RMHSU program managers and commodity focal persons
2. KEMSA
3. Pharmaceutical Services Unit
4. Development partners (e.g. USAID, UNFPA, DfID, KfW)
5. Implementing partners (e.g. PS/Kenya, MSK, FHOK, ESHE, CHAI, MSH/HCSM)
6. Other ad hoc members to be identified by the CSTWG

### **Roles and responsibilities**

- Develop a plan for quantification
- Identify relevant key stakeholders
- Plan for stakeholders meeting, working group meetings and any other relevant meeting for quantification
- Participates in the planning
- Attend the planning, stakeholders and working group meetings
- Identify and gather data required, gaps and provide guidance on how the gaps can be filled where feasible
- Analyze data for trends and past performance
- Lead in consensus building on inputs for quantifications as well as assumptions
- Document consensus building process
- Lead in estimation of commodity requirements (forecast) and supply planning for the FP commodities
- Write a report for forecast and supply planning process
- Members should be consistently available for during the quantification process

### **Deliverables**

- Aggregation of data required in forecasting and supply planning
- Analysis of past period data
- List of stakeholders for participation in quantification process
- Report for consensus building on targets, coverage and assumptions
- Quantification report (forecasting and supply planning process and output)
- Technical report on quantification process

## Appendix 4: Quantification calendar

Activity/Sub-activity	Responsible	Timelines
1.Establishment of annual cycle for national quantification activities	RMHSU	May
2. Announcement for quantification process by the official(s) or office that will manage the process	RMHSU	May
3.The Unit defines the objectives, coverage and scope of the quantification and informs the CSTWG/quantification committee	RMHSU	May
4. Distribute / Collect/ Collate data collection forms / templates	RMHSU	May
5. Undertake Data Collection/Collation/Analysis activities	RMHSU, KEMSA,	Early June
6. Arrange a 2 to 4-day National Quantification Exercise for the Quantification committee and stakeholders <ul style="list-style-type: none"> <li>Calculate quantities of RMHSU commodities needed using appropriate methods for quantification</li> <li>Review quantities, adjust estimated quantities as needed</li> <li>Establish final quantities and values of RMHSU commodities as outputs to be included in the quantification report</li> </ul>	RMHSU	June
7. Prepare quantification draft report and circulate to CSTWG	Quantification committee	June
8. Develop plans for dissemination / communication of the FP quantification report to stakeholders	RMHSU	July
9. Identify funding gaps and initiate resource mobilization discussions with partners	CSTWG	July
10. Review the just concluded quantification process, with recommendations and plans to improve and to resolve problems encountered	Quantification committee	July
11.Establish tracking system for post- quantification activities, including procurement and funding re- arrangements	Logistics TWG	Continuous
12. Conduct a semi-annual review of the forecast and supply plans and make necessary adjustments	CSTWG/quantification committee	December

## Appendix 5: Draft Quantification Program



### MINISTRY OF HEALTH

#### Reproductive and Maternal Health Services Unit SIX MONTH REVIEW FOR FP COMMODITIES QUANTIFICATION & SUPPLY PLANNING 2015-2017

Date:

Venue:

**DAY 1:**

**SESSION CHAIR:**

TIME	ACTIVITY/SESSION	FACILITATOR
08.30 – 09:00	Registration	Rapporteur(MSH HCSM)
09:00 – 09:30	Introduction, opening remarks and objectives of the meeting	Head RMHSU
09:30 – 10:00	FP Program Commodity stock status and procurement update	RMHSU
<b>10:00-10:30</b>	Central level stocks, distribution trends and ongoing procurements	KEMSA
10:00-11:00	Tea Break	All
11:00-11:30	Partner commodity / stock status updates-	All partners
11:30-12:30	Review of F&Q results & Supply Plan	RMHSU/ MSH HCSM
12:30-13:00	Discussions	RMHSU/ MSH HCSM
13:00-14:00	Lunch Break	All
14:00 – 16:00	Review of assumptions for FY 2015-2017	RMHSU/ MSH HCSM
16:00 – 17:00	<b>Review of Requirements for 2015-2016 and Forecast for 2016-2017</b>	RMHSU/ MSH HCSM

**DAY 2:**

**SESSION CHAIR:**

TIME	ACTIVITY/SESSION	FACILITATOR
08.30 – 09:00	Recap of Day 1	RMHSU
09:00 – 10.30	Supply planning	RMHSU
10.30– 11:00	TEA BREAK	All
11:00 –13:00	Report Compilation	RMHSU/ MSH HCSM
13:00 – 14:00	LUNCH	All
14:00 – 16:00	Updating of the RH Dashboard	CHAI/RHMSU
16:00 – 17:00	Wrap-up and Closure	Head RMHSU
17:00-18:00	<b>TEA BREAK</b>	<b>ALL</b>



## Appendix 6: Sample summary for Stock on Hand at Central Level (KEMSA and PS Kenya)

Stock status as at 31<sup>st</sup> Jan 2016

Product	Unit Size	Available Quantity
DMPA	Vials	16,605,000
POPs	Cycles	841,542
COCs	Cycles	1,951,215
Male Condoms	Pieces	39,706,320
Jadelle	Sets	149,040
Implanon NXT	Set	396,819
Female Condoms	Pieces	0
IUCD (Copper T)	Pieces	0
Emergency Pills	Doses	35,995
Cycle beads	Pieces	5,277

## Appendix 7: Shipment summary

Commodity	Quantity Required	Estimated Cost (USD)	Shipment Received			
			No.	Quantity	EDA	Agency
DMPA	510,000	530,400	1	510,000	Jun-16	KfW
Jadelle	341,300	2,901,050	1	156,000	Jul-15	USAID
			2	88,300	Jan-16	USAID
			1	50,000	Dec-15	DfID
			1	47,000	Apr-16	UNFPA
Implanon NXT	430,000	3,866,560	1	140,000	Oct-15	UNFPA
			1	90,000	Oct-15	DfID
			2	100,000	Nov-15	DfID
			3	100,000	Dec-15	DfID
POP	607,680	196,281	1	270,000	Jul-15	USAID
			2	337,680	Sep-15	USAID
IUCD	117,244	60,029	1	40,800	Sep-15	USAID
			2	76,444	May-16	USAID

## Appendix 8: Sample Prices of Products for estimation of costs list

Product	Unit Size	Unit Price (USD)
DMPA	Vials	1.044
POPs	Cycles	0.323
COCs	Cycles	0.225
Male Condoms	Pieces	0.037
Jadelle	Sets	8.850
Implanon NXT	Sets	8.992
IUCD	Sets	0.512
Female Condoms	Pieces	0.539
Cycle Beads	Sets	2.325
Emergency Pills	Doses	0.914

*Source: KEMSA, as at 11<sup>th</sup> June 2014*

## Appendix 9: Quantification tools

- *Reality Check* tool (including a population calculator, method mix calculator)
- Spreadsheets e.g. *Excel* worksheets for summaries
- Other tools - *PipeLine®* tool

## Appendix 10: Sample outline for quantification report

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## Annex1: Technical specifications for contraceptives

SPECIFICATIONS FOR DEPOT-MEDROXYPROGESTERONE ACETATE (DMPA)	
<b>Active ingredient/generics name and strength</b>	150mg of Medroxyprogesterone acetate
<b>Pharmacopoeia standards (for preparation and container including the closures and labeling)</b>	USP, Ph.Eur./EP, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.  Should be WHO pre-qualified as per the WHO pre-qualification of medicinal products.
<b>Additives</b>	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
<b>Formulation, dosage form</b>	Each vial containing 1ml sterile aqueous injectable suspension for intramuscular (IM) depot injection.
<b>Description</b>	1ml of sterile aqueous single suspension of 150mg of Medroxyprogesterone acetate in water for injection for intra-muscular (IM) use. Packed in an aseptically closed glass container (vial) with rubber stopper protected with aluminum foil.
<b>Period of action</b>	3 months; for this time period the serum level of  Medroxyprogesterone acetate should be continuously above 0.1 microgram /L (0.025nM/L) in order to inhibit ovulation.
<b>Contraception efficacy</b>	6% (average pregnancy rates per 100 women-years).
<b>Quality assurance requirement</b>	The preparation must be sterile, complies with endotoxin test, pH and osmotic pressure adjusted. Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good clinical practice/Good manufacturing practice) and should be certified/registered as a three-monthly injectable contraceptive in the country of manufacture and in KENYA (PPB).  Any sediment formed during the storage must easily be re-dispersed through shaking. The suspension must be stable enough to allow measurement of proper dose. The particle size should be monitored during the production and appropriate for the kind of application.
<b>Shelf life</b>	At least 60 months, of which at least 80% left at the time of arrival of the medicine at destination
<b>Stability at room temperature</b>	The product should be stable at tropical room temperature of up to  30 degree Celsius and relative humidity of 65% as per the WHO requirements for zone C, through its entire shelf life period.
<b>Special Labeling Instruction</b>	Labeling of vial shall be in accordance with instruction provided below. Each unit should indicate <b>‘GOK-MOH - NOT FOR SALE’</b>
<b>Packing specifications</b>	One primary box should contain 100 vials packed in 25's in sealed boxes, 100 sterile syringes with needles G22, 100 sterile alcohol swabs, 100 pairs of non-sterile gloves size 7.5, 1 safety box and 100 client leaflets in English/Kiswahili.

SPECIFICATIONS FOR COMBINED ORAL CONTRACEPTIVE PILLS	
<b>Active ingredients/generic name and strength</b>	Levonorgestrel 0.15mg and Ethinylestradiol 0.03mg per tablet
<b>Pharmacopoeia standards (for preparation and container including the closures and labeling)</b>	USP, Ph.Eur./EP, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.  Should be WHO pre-qualified as per the WHO pre-qualification of medicinal products.
<b>Additives</b>	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
<b>Formulation, dosage form</b>	Coated tablet containing Levonorgestrel 0.15mg and Ethinylestradiol 0.03mg.
<b>Description</b>	One cycle containing 21 pills packed in a PVC/Aluminium blister pack.
<b>Period of action</b>	21 days; for this time period the serum level of  Levonorgestrel/Ethinylestradiol should sufficiently high in order to inhibit ovulation.
<b>Contraception efficacy</b>	9% (average pregnancy rates per 100 women-years).
<b>Quality assurance requirement</b>	Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good clinical practice/Good manufacturing practice) and should be certified/registered in the country of manufacture and in KENYA (PPB).
<b>Shelf life</b>	At least 60 months, of which at least 80% left at the time of arrival of the medicine at destination.
<b>Stability at room temperature</b>	The product should be stable at tropical room temperature of up to 30 degree Celsius and relative humidity of 65% as per the WHO requirements for zone C, through its entire shelf life period.
<b>Special Labeling Instruction</b>	Labeling of cycles and boxes shall be in accordance with instruction provided as follows; The cycles and box should be branded MY CHOICE/CHAGUO LANGU in the prescribed colors and accompanying art-work ( <i>see below</i> ). Each cycle and the box should indicate ‘GOK-MOH - NOT FOR SALE’
<b>Packing specifications</b>	One box should contain 3 pill cycles with 1 client leaflet and in English/Kiswahili.

SPECIFICATIONS FOR PROGESTIN-ONLY PILLS	
Active ingredients/generic name and strength	Levonorgestrel 0.03mg per tablet
Pharmacopoeia standards (for preparation and container including the closures and labeling)	USP, Ph.Eur./EP, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.
Additives	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
Formulation, dosage form	Sugar-coated tablet containing Levonorgestrel 0.03mg.
Description	One cycle containing 35 pills packed in a PVC/Aluminium blister pack.
Period of action	35 days; for this time period the serum level of  Levonorgestrel should be sufficiently high in order to inhibit ovulation.
Contraception efficacy	9% (average pregnancy rates per 100 women-years).
Quality assurance requirement	Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good clinical practice/Good manufacturing practice) and should be certified/registered in the country of manufacture and in KENYA (PPB).
Shelf life	At least 60 months, of which at least 80% left at the time of arrival of the medicine at destination.
Stability at room temperature	The product should be stable at tropical room temperature of up to 30 degree Celsius and relative humidity of 65% as per the WHO requirements for zone C, through its entire shelf life period.
Special Labeling Instruction	Labeling of cycles and boxes shall be in accordance with instruction provided as follows; Clear labeling of the days of the week in English on the blister. Each cycle and the box should indicate ' <b>GOK-MOH - NOT FOR SALE</b> '
Packing specifications	One box should contain 3 pill cycles with 1 client leaflet and in English/Kiswahili.

SPECIFICATIONS FOR EMERGENCY CONTRACEPTIVE PILLS	
<b>Active ingredients/generic name and strength</b>	Levonorgestrel 0.75mg per tablet
<b>Pharmacopoeia standards (for preparation and container including the closures and labeling)</b>	USP, Ph.Eur./EP, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.
<b>Additives</b>	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
<b>Formulation, dosage form</b>	Coated tablet containing Levonorgestrel 0.75mg.
<b>Description</b>	One dose containing 2 pills packed in a PVC/Aluminium blister pack.
<b>Period of action</b>	Immediate; The formulation should release Levonorgestrel in sufficient amount in order to inhibit ovulation/form a mucus plug.
<b>Contraception efficacy</b>	Not Applicable
<b>Quality assurance requirement</b>	Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good clinical practice/Good manufacturing practice) and should be certified/registered in the country of manufacture and in KENYA (PPB).
<b>Shelf life</b>	At least 60 months, of which at least 80% left at the time of arrival of the medicine at destination.
<b>Stability at room temperature</b>	The product should be stable at tropical room temperature of up to 30 degree Celsius and relative humidity of 65% as per the WHO requirements for zone C, through its entire shelf life period.
<b>Special Labeling Instruction</b>	Labeling of cycles and boxes shall be in accordance with instruction provided as follows; Each blister and the box should indicate <b>‘GOK-MOH - NOT FOR SALE’</b>
<b>Packing specifications</b>	One box should contain a blister of 2 pills with 1 client leaflet and in English/Kiswahili.

SPECIFICATIONS FOR ETONOGESTREL IMPLANT 68MG	
Active ingredient/generic name and strength	Each rod must contain 68mg of the progestin Etonogestrel
Pharmacopoeia standards (for preparation and container including the closures and labeling)	USP, PhEur, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.  Should be WHO pre-qualified as per the WHO pre-qualification of medicinal products.
Additives	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
Formulation, dosage form	Each rod consists of an ethylene vinylacetate (EVA) copolymer core, containing 68 mg of the synthetic progestin Etonogestrel (ENG), surrounded by an EVA copolymer skin and should be 40mm long x 2mm diameter.
Description	1 implant in the cannula of a disposable sterile applicator in a blister pack (polyethyleneterephthalate glycol sealed with coated paper)
Period of action	3 years; The release rate is 60 to 70 mcg/day in Week 5 to 6 and decreases to approximately 35 to 45 mcg/day at the end of the first year, to approximately 30 to 40 mcg/day at the end of the second year, and then to approximately 25 to 30 mcg/day at the end of the third year.
Contraception efficacy	Unintended pregnancy rate of 0.05% within the first year of typical use
Quality assurance requirement	The preparation must be sterile. Complies with total degradation products $\leq 2.0\%$ and an in-vitro release rate of $\leq 450\mu\text{g/unit}$ . Components must be situated correctly and implant is present in the needle of applicator.  Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good Clinical Practice/Good Manufacturing Practice) and should be certified/registered as a 3 year contraceptive implant in the country of manufacture and in KENYA (Pharmacy & Poisons Board)
Shelf life	60 months ( <i>*plus up to 3 years insertion life</i> ), of which at least 80% left at the time of arrival of the medicine at destination
Stability at room temperature	The product should be stable at tropical room temperature of up to  30 degree Celsius and relative humidity of 65% as per the WHO requirements for Zone IV, through its entire shelf life period.
Special Labeling Instruction	Labeling shall be in accordance with instruction provided below. Each unit should indicate ' <b>GOK-MOH - NOT FOR SALE</b> '
Packing specifications	Each box contains 1 implant pre-loaded in a disposable trocar with 1 client leaflet and card (in English), 1 physician's insert and 1 set of insertion and removal instructions.

SPECIFICATIONS FOR LEVONORGESTREL IMPLANT 75MG	
<b>Active ingredient/generic name and strength</b>	Each rod must contain 75mg of the progestin Levonorgestrel
<b>Pharmacopoeia standards (for preparation and container including the closures and labeling)</b>	USP, PhEur, BP or other standard pharmacopoeias as recognized by the Pharmacy & Poisons Board and Kenya Bureau of Standards.  Should be WHO pre-qualified as per the WHO pre-qualification of medicinal products.
<b>Additives</b>	Various additives as required for the formulation of the preparation. Additives must not influence the medical effect of the drug nor be toxic in the used concentration or cause local irritations.
<b>Formulation, dosage form</b>	The core of each rod is a mixture, half of Levonorgestrel; half of elastomer and the rod is sealed with polydimethylsiloxane adhesive and sterilized. Each rod must contain 75 mg of the progestin Levonorgestrel and should be 43mm long x 2.5mm diameter.
<b>Description</b>	Each set is two flexible cylindrical implants, consisting of a dimethylsiloxane/methylvinylsiloxane copolymer core enclosed in thin-walled silicone tubing, and packed in a PE bag manufactured from spun-bonded PE film and a PET/PE film. A disposable trocar must be included for each set.
<b>Period of action</b>	5 years; The calculated mean daily in vivo release rate of Levonorgestrel provided by the implants is about 100 µg/day at month 1 followed by a decline to about 40 µg/day at 12 months and to about 30 µg/day at 24 months with a stabilization thereafter at about 30 µg/day
<b>Contraception efficacy</b>	Unintended pregnancy rate of 0.05% within the first year of typical use
<b>Quality assurance requirement</b>	The preparation must be sterile.  Complies with; Bacterial Endotoxin test ( $\leq 120$ EU/implant), residual Cyclohexane ( $\leq 3$ µg/implant), residual Ethylene Oxide ( $\leq 5$ ppm) and release rate in 24h (67-118µg).  Manufactured and tested in accordance with manufacturing instructions, testing standards, GCP/GMP (Good Clinical Practice/Good Manufacturing Practice) and should be certified/registered as a 5-year contraceptive implant in the country of manufacture and in KENYA (Pharmacy & Poisons Board)
<b>Shelf life</b>	At least 60 months ( <i>*plus up to 5 years' insertion life</i> ), of which at least 80% left at the time of arrival of the medicine at destination
<b>Stability at room temperature</b>	The product should be stable at tropical room temperature of up to 30 degree Celsius and relative humidity of 65% as per the WHO requirements for Zone IV, through its entire shelf life period.
<b>Special Labeling Instruction</b>	Labeling shall be in accordance with instruction provided below. Each unit should indicate ' <b>GOK-MOH - NOT FOR SALE</b> '
<b>Packing specifications</b>	Each primary box contains 10 sets of implants and 10 disposable trocars with 10 client leaflets and cards (in English), 10 physicians' inserts, 10 sets of insertion and removal instructions.





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