PUBLIC

PROCUREMENT MANUAL

FOR

HEALTH SECTOR

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July 2009

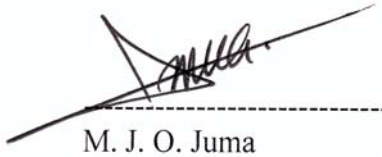
PUBLIC PROCUREMENT MANUAL FOR HEALTH SECTOR

PREFACE

The public procurement reforms in Kenya have culminated in promulgation of the Public Procurement and Disposal Act 2005 and the Public Procurement and Disposal Regulations 2006 that provide a legal framework for regulating public procurement, with oversight functions carried out by the Public Procurement Oversight Authority (PPOA). A Public Procurement and Disposal General Manual has also been prepared. It provides detailed guidance on general issues in procurement that are not adequately covered by the Act and Regulations. Other manuals have been prepared for specific procurement sectors.

This Manual has been prepared to address the specific procurement requirements of the health sector. The procurement processes set out in this Manual have reference to the salient provisions of the Act, the Public Procurement and Disposal Regulations and the General Manual which should be read together with this Manual. Some of the important general steps leading to effective procurement of health requirements have been incorporated into this Manual. Persons responsible for the procurement of health requirements should therefore familiarise themselves with the guidelines provided in this Manual and adhere to them.

This Manual has been prepared by e-sokoni Consulting as part of the Millennium Challenge Corporation Project for strengthening the public procurement system in Kenya. Oversight of the project was undertaken by ARD, Inc and finance was provided by USAID. This Manual has been approved by PPOA as a guide to the systems and procedures that should govern the procurement of health-related items and services.



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July 2009

ACRONYMS

BCF	Bio-Concentration Factor
CDF	Constituency Development Fund
CMI	Customer Managed Inventory
EDL	Essential Drugs List
EOQ	Economic Order Quantity
EPI	Expanded Program of Immunization
EMMS	Essential Medicines and Medical Supplies
FIFO	First In First Out
GMP	Good Manufacturing Practice
GRN	Goods Received Note
INN	International Non-Proprietary Name
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
NEMA	National Environmental Management Authority
NQCL	National Quality Control Laboratory
NRA	National Regulatory Authority
PE	Procuring Entity
PHF	Public Health Facilities
PPDA	Public Procurement and Disposal Act 2005
PPDR	Public Procurement and Disposal Regulations 2006
PPOA	Public Procurement Oversight Authority
RIV	Requisition and Invoice Voucher
ROL	Re-Order Level
SOP	Standard Operating Procedure
VMI	Vendor Managed Inventory
WHO	World Health Organization

1.0 INTRODUCTION

1.1 This Manual serves as a guide to implementation of the Public Procurement and Disposal Act and the Regulations with special reference to the health sector and aims to promote effective and efficient performance of the procurement function in the health institutions and health commodities procuring agencies.

1.2 This Manual sets out the functional relationships and internal controls that promote transparency and accountability in the procurement process.

2.0 THE SCOPE OF THE MANUAL

2.1 The procedures in this Manual should be applied in acquisition, receiving, storage, distribution and disposal of pharmaceuticals, non-pharmaceuticals and medical equipment in the public health sector in Kenya.

2.2 These procedures shall remain effective until announced otherwise by the Public Procurement Oversight Authority.

2.3 This Manual covers:

2.3.1 The generic and specific steps in health sector procurement;
2.3.2 Institutional arrangements for provision of oversight functions within the Health Sector;
2.3.3 Procurement planning and its linkage to budgeting process and implementation;
2.3.4 Administration of the complete procurement cycle up to and after the receipt and acceptance of items procured;
2.3 5 Warehousing and inventory management;
2.3.6 The disposal of unserviceable, obsolete or surplus stores, other assets and equipment;
2.3.7 Framework contracts; and
2.3.8 Supplier performance measurement.

3.0 HEALTH SECTOR PROCUREMENT OBJECTIVES

3.1 Realization of the lowest possible total cost and/or best value

Procurement should be carried out with a view to realizing the lowest possible total cost and/or best value. This should include practical justification, the actual purchase price, associated maintenance costs, and inventory holding costs at various levels of the supply chain. Reference should be made to the average price list for common-user items which is found on the PPOA website, www.ppoa.go.ke.

3.2 Ensuring timely delivery

Logistics systems should ensure timely delivery of appropriate quantities to central or provincial or district health facilities where the products are needed.

3.3 Separation of procurement functions and authorizations to enable checks and balances in the procurement process

Procurement functions and responsibilities such as selection, quantification and product specification, selection of suppliers and evaluation of tenders should be divided among different offices, committees and individuals, each with the appropriate expertise and resources in line with PPD Act Section 26(3) (c).

3.4 Preparation of product specifications should be a multi-functional activity

The specifications should take into account the characteristics of the medical requirements. This should be a multi-functional activity undertaken by a standing committee or ad hoc technical committee in order to incorporate all the necessary professional inputs. The specifications should be as generic as possible.

3.5 Suppliers' performance to be evaluated and measured and feedback given to the suppliers

Systematic evaluation and measurement of suppliers' performance should be undertaken to ensure compliance with the terms and conditions of contract as set out in section 19.0 of this Manual on Procurement Performance Evaluation and Measurement.

3.6 Automation of the procurement process

Procurement processes are to be computerized to the maximum extent possible to integrate the operations between Procurement Units and other departments with a view to speeding-up routine transactions and communication.

3.7 Maintaining optimal inventory levels

Inventory levels should be maintained in accordance with the inventory management procedures set out in this Manual to ensure the best possible services to users at the lowest cost. Replenishment should be undertaken by taking into account the actual and anticipated use based on inventory management procedures in place.

For example, the inputs from the medical stores and/ or from district or health facilities in case of centrally procured products are to be considered to avoid pushing of requirements to the Provincial and District levels that may either be excessive or inadequate. Replenishment of stocks should be carried out in accordance with the procedures in section 17.0 of this Manual.

3.8 Observing ethical practices in procurement

The highest standard of ethical practices should be observed in all procurement transactions. The code of ethics that may from time to time be specified by the Authority shall be strictly observed.

4.0 HEALTH SECTOR PROCUREMENT STRATEGIES

4.1 Procurement should be planned to enable prudent management of budgets and to ensure achievement of best value for public funds.

4.2 The procuring entities (PE) within the public health sector should aim to acquire medical supplies and services at optimum terms by taking into account the acquisition price, payment terms, product and service quality, availability, supplier support and track record.

4.3 Qualified suppliers shall be given equal opportunity to bid for supply of medical products and services.

4.4 The highest ethical, professional and legal standards in procurement should always be observed in establishing a mutually beneficial relationship with suppliers and customers.

4.5 All procurement of medical requirements shall be done through open competitive public bidding unless an alternative procurement method is justified in accordance with the relevant provisions in the Public Procurement and Disposal Act 2005, Public Procurement and Disposal Regulations 2006, the Public Procurement and Disposal General Manual or this Health Sector Procurement Manual.

4.6 There should be a continuous improvement of procurement processes by procuring entities to ensure that the processes are simple, efficient and cost effective.

4.7 PEs should endeavour to realize benefits of economies of scale by consolidating orders and purchasing routine medical requirements through framework contracts where feasible. Such framework contracts should be set-up at national, provincial and district level where aggregation of volumes for potential purchases can take place for clusters of PEs.

4.8 PEs should keep abreast of best practices for acquisition of medical products and services through benchmarking with similar entities to facilitate continuous improvement of the procedures.

4.9 The procurement should be undertaken in compliance with the PE's approved Standard Operating Procedures (SOP) which should not conflict with the Act, Regulations, the Public Procurement and Disposal General Manual and this Manual.

5.0 INSTITUTIONAL ARRANGEMENTS FOR OVERSIGHT AND REGULATORY FUNCTIONS

5.1 Introduction

Oversight and regulatory functions are the prerogatives of the PPOA at the macro level on matters of public sector procurement. However the medical sector procuring entities should also monitor and evaluate procurement activities to ensure compliance with legal provisions of the Act and the Regulations as well as international medical or related conventions propagated by the WHO.

5.2 Institutional arrangements for procurement

Procurement by institutions in the public health sector is undertaken by PEs which have their own funds either allocated by the Exchequer or generated through any other Appropriation in Aid (A-in-A) such as money from cost sharing and from development partners. By far the bulk of the procurement currently takes place at the Health Ministries Headquarters and Kenya Medical Supplies Agency (KEMSA).

5.3 The Role of KEMSA in Procurement of Medical Supplies

The availability of Essential Medicines and Medical Supplies (EMMS) is critical to the success of health care programs. The National Development Plan of 2002-2008 stated that the health care system in its current form (at the time of the National Plan's preparation) does not operate efficiently. Some of the areas targeted for improvement in the plan include drugs and facility utilization. EMMS supplies are one of the key areas earmarked for reform.

A key output of the reform program was the establishment of Kenya Medical Supplies Agency (KEMSA) in 2000.

The broad objectives of KEMSA as stipulated in the legal notice were:

- To develop and operate a viable commercial service for the procurement and sale of drugs and other medical supplies;
- To provide a secure source of drugs and other medical supplies to public health institutions; and
- To advise Health Management Boards and the general public on matters relating to the procurement, cost effectiveness and rational use of drugs and other medical supplies.

The Health Ministries and Health Sector Development Partners have increasingly been channelling significant funds for procurement, warehousing and distribution of EMMS and medical equipment though KEMSA. Under this arrangement, KEMSA acts as a centralised specialised agency which procures EMMS and medical equipment and distributes the same to Public Health Facilities (PHF) countrywide. The distribution is from any of KEMSA's countrywide warehouse locations (presently in Nairobi, Mombasa, Nakuru, Nyeri, Garissa, Eldoret, Kisumu and Kakamega and Meru). PHFs either regularly request for products from KEMSA or KEMSA provides products to these facilities according to an allocation ratio.

The KEMSA supply chain has been targeted for continuous improvements so that it can achieve its mandate more efficiently. PHFs need to be alert to any policy developments and instructions from the Health Ministries which could indicate the most appropriate direction for procurement of EMMS and medical equipment from time to time.

5.4 The Role of Health Ministries in procurement of medical supplies

The Health Ministries negotiate with Treasury for budgetary allocation for procurement of EMMS and medical equipment. The Health Ministries then apportion the allocated budgets between KEMSA and the Health Ministries for the purpose of procurement of EMMS and medical equipment. For the bulk purchases made by the Health Ministries, they mandate KEMSA to distribute to the PHFs according to an allocation ratio.

The Health Ministries may also negotiate for additional funds for procurement of EMMS and medical equipment from various development partners who have an interest in the health sector. Funds from development partners may be used for targeted procurement either through KEMSA or MOH procurement systems for onward distribution to the PHFs. On some occasions, development partners in agreement with MOH may procure directly certain categories of EMMS and medical equipment through selected Procurement Agents and transfer the products to KEMSA for distribution to PHFs through its supply chain according to an allocation ratio.

For PHFs the only significance of noting the originating source of the procurement is for traceability and product recall if and when there is a problem with the products. Product recall for medicines and supplies procured through KEMSA, MOH or an Agent of a Development Partner will be channelled though KEMSA and MOH respectively to the suppliers from where they were sourced.

5.5 Officers in Charge in medical sector procuring entities

For the different categories of procuring entities in the medical sector, there are designated officers who are held accountable for ensuring the Public Procurement and Disposal Act and Regulations are properly implemented. These include:

5.5.1 The Accounting Officer at the Ministerial level;
5.5.2 The Medical Superintendent at the Provincial Hospital and District hospital;
5.5.3 The Medical Officers of Health at the District Hospital and Sub-District level;
5.5.4 Officer in charge of Health Centres and Dispensaries;
5.5.5 Chief Executive of Kenyatta National Hospital;
5.5.6 Chief Executive of Moi Referral Hospital; and
5.5.7 Chief Executive Officer at the Kenya Medical Supplies Agency.

5.6 The Responsibilities of Heads of Procuring Entities

5.6.1 The Accounting Officer

The Accounting Officer is a person appointed by the PS or PSC with responsibilities set out in the Public Procurement and Disposal Act 2005 and Article 7, First Schedule (Threshold Matrix) and Second Schedule (the Composition of Tender Committee) of the Public Procurement and Disposal Regulations 2006.

5.6.2 Heads of procuring entities (as identified in 5.5)

The responsibilities of the heads of procuring entities under sub-sections (5.5) above are the same as those of the Accounting Officer set out in the Public Procurement and Disposal Act 2005 and Article 7; First Schedule (Threshold Matrix) and Second Schedule (The Composition of Tender Committee) of the Public Procurement and Disposal Regulations 2006.

5.7 The Roles of health sector oversight bodies in public procurement

5.7.1 The Pharmacy and Poisons Board

The Pharmacy and Poisons Board is the drug regulatory authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the practice of pharmacy and the manufacture and trade in drugs and poisons.

5.7.2 Kenya Medical Research Institute (KEMRI)

KEMRI is a research institute of international repute with branches across Kenya and has the capacity to undertake research and testing on the effectiveness on human treatment programs. Where PEs are in doubt and need reassurance on advice on the effectiveness of such medicines or treatment regimes, they can contact KEMRI for relevant advice.

5.7.3 National Quality Control Laboratory (NQCL)

NQCL is the body responsible for testing the quality of pharmaceutical products in Kenya. A PE that requires to have verified the quality of any pharmaceutical product can call NQCL which will advise on sampling, handling and submitting product samples to NQCL for testing. NQCL charges a fee for any testing for products it conducts at the request of any PE.

NQCL ensures that the drugs available in the Kenyan market are safe, efficacious and of high quality by appropriate testing of drugs before the Pharmacy and Poisons Board register them. This is aimed at ensuring that consumers and patients receive products that meet established specification and standards of quality, safety and efficacy. PEs should ensure that products to be offered by potential suppliers for purposes of supplier registration or for evaluation for supply are NQCL certified. On receipt of products, PEs may chose to confirm compliance of the supplied products with the specification by seeking sample testing by NQCL.

5.7.4 Kenya Bureau of Standards (KEBS)

The Kenya Bureau of Standards (KEBS) is a statutory organization of the Government established by the Act of Parliament Chapter 496 in 1974. KEBS is a national standards body equipped with laboratories for testing product samples to ensure specifications are realistic and attainable in the Kenyan environment.

KEBS, through appropriate testing, ensures that the quality of products imported or manufactured in Kenya, including non pharmaceutical products, are safe and of acceptable quality.

PEs should ensure that products to be offered by potential suppliers for purposes of supplier registration or for evaluation for supply are correctly certified.

On receipt of products, PEs may chose to confirm quality of the supplied products by seeking sample testing by KEBS.

6.0 CLASSIFICATION OF HEALTH SECTOR PROCURING ENTITIES

Class A procuring Entities	Class B procuring entities	Class C procuring Entities
a) State Corporations (Health Sector) b) Ministries of Health Headquarters	Provincial Hospitals	a) District Hospitals, b) Sub-District Hospitals c) Health Centres / Dispensaries d) CDF Health Centres e) Voluntary Organizations (Health)

Note: Health Centres and Dispensaries under Local Authorities are governed by the classification of various categories of the Local Authorities according the Legal Notice No 719 of January 2007.

7.0 HEALTH SECTOR PROCUREMENT PLANNING

7.1 Introduction

7.1.1 The procurement plan is an instrument for implementation of the budget and should be prepared by the user departments with a view to avoiding or minimizing urgent procurements that do not enable realization of value for money.

7.1.2 The procurement plan must be integrated into the budgetary processes based on the indicative or approved budget, as stipulated in Regulation 20(2) of the PPD Regulations 2006.

7.1.3 The budget as well as the procurement plan are to be based on realistic cost estimates derived from the market research database which is to be compiled and updated regularly by the procurement unit in line with Regulation 8 (3) (z) of the PP&D Regulations 2006.

7.1.4 The departmental/sectional procurement plans shall be consolidated by the Head of Procurement Unit to produce the institution's corporate procurement plan.

7.1.5 The Procurement Unit should verify the departmental/sectional procurement plans to ensure that they are representative of the operational requirements of the institution and subsequently forward the same to the Head of the Procuring Entity for approval.

7.1.6 The plan must not be implemented before approval by the Head of the Procuring Entity.

7.1.7 The contents of a procurement plan should be in line with the format provided in the Appendix (B) of this Manual.

7.2 Procurement planning procedures

7.2.1 The plan is to be integrated in the applicable budgetary processes and based on indicative and approved budget as appropriate.

7.2.2 Where appropriate multi-year procurement plans may be prepared and shall be integrated into the Medium Term Expenditure (budgetary) Framework (MTEF).

7.2.3 The plan should be supported by the inventory plan for operational and project or specific program requirements.

7.2.4 Procurement plans should include the following information:

a) A breakdown of goods, works or services;
b) A schedule of planned delivery, implementation or completion dates;
c) An indication and justification for whether a procurement shall be undertaken within a single year or under a multi-year arrangement;

d) An indication of which items can be aggregated for procurement as a single package or for procurement through any applicable arrangement for common user items, such as a Health Centre Kit with a specified range of products;
e) An indication of which items will be packaged into lots;
f) An estimate of the value of each package of goods, works or services;
g) The budgets available and sources of funds; and
h) The proposed procurement method for each purchase.

7.2.5 The profile for past procurements validated by the latest market research information provided by the Head of the Procurement Unit should be used to enhance preparation of a realistic procurement plan.

7.2.6 The procurement profile should include, but not be limited to the following information:
a) Goods and services purchased and how much was spent on them;
b) How goods and services were purchased;
c) Current sources of supply and their geographical location; and
d) Criticality of the goods and services to the organisation.

7.2.7 Market research information should include but not be limited to the following information:
a) Suppliers' market shares;
b) Availability of alternative or substitute products;
c) Degree and type of competition between suppliers;
d) Technology trends;
e) Price indices; and
f) Environmental factors that affect the supply market.

7.2.8 The procurement method should be selected in accordance with the information contained in the market research data bank and the Threshold Matrix in the PPD Regulations 2006.

7.3 Total cost factor for Pharmaceutical and Consumable Products in a Procurement Plan

7.3.1 The total costs of acquisition should be factored into the procurement plan to avoid delays in clearing of imported products arising from lack of projection for port and inland transportation costs.

7.3.2 In case of medical capital equipment, the costs should include installation, commissioning, testing, maintenance, training and operational cost such as energy and consumables (if necessary).

7.3.3 The Procurement Unit should provide market information such as prices, technology, logistics rates to be used in preparation of the budget and procurement plan.

7.3.4 Forecasting should be undertaken by the Procurement Unit in order to improve or adjust the past process.

7.3.5 Example 1: (Pursuant to sub-section 5.4.1 above)
Procurement of pharmaceutical products and consumables (International Procurement based on CIF Terms)

Cost factors:

Price of a product (CIF) -including insurance and freight up to specified port of entry		
Port charges, custom duty (if applicable) ……	Ksh	10,000,000
Handling charges, warehousing based on statutory rates from KPA or KAA as the case may be (Approximately 5%) ……	Ksh	500,000
Inland transportation (based on Railways or known road transportation rates-Approximately 2%)	Ksh	200,000
Total procurement cost	**Ksh**	**10,700,000**

Example 2: Procurement of an X-Ray Machine (International Procurement) (Based of CIP terms including installation

Cost elements;

Price of the machine (CIP) -including insurance and Freight/Carriage up to specified installation point, including port charges…… .	Ksh	40,000,000
Installation testing and commissioning approximately 1%.....	Ksh	400,000
Training of staff on operating the machine approximately 0.5 %.....	Ksh	200,000
Total Procurement cost	**Ksh**	**40,600,000**

7.4 Total cost factor for programmes in a Procurement Plan

7.4.1 Health sector programmes cover procurement of consultancy services, construction (works), supply of materials and other non-consultancy services and logistical services. These purchases should be classified under various components to enhance effective procurement planning.

7.4.2 Once the categorization is done, the timeframe for accomplishment of each category should be carefully determined. It may be necessary to apply the project network techniques for effective management of all the associated activities within the time lines set.

7.5 Total cost factor for capital equipment in a procurement plan

7.5.1 For high value capital equipment the current prices should be obtained through market research to avoid substantial variances in the budget and the procurement plan.

7.5.2 Capital items typically have a life of many years and hence have a number of costs associated with them beyond the purchase price, for example the operational cost of X- ray machines. The total cost of ownership should be calculated by applying life cycle costing.

7.5.3 The components of Life Cycle Cost for capital equipment

Life cycle cost = Cost of Acquisition + Cost of ownership over the equipment's useful life

Equipment to be bought should have the lowest Life Cycle Cost, as opposed to resorting to the lowest purchase price which may result in high cost of ownership. The calculation of Life Cycle Cost must take account of all relevant information.

The Cost of Acquisition includes design, specifying, purchasing, receiving, storage, and payment.

The Costs of Ownership include installation, commissioning, operation, maintenance, servicing, upgrading, disposal (un-serviceability, trade-in, obsolescence).

7.6 Planning for equipment maintenance and repairs

7.6.1 In order to take account of costs of ownership, provision should be made in the procurement plan and the budget for maintenance and repairs.

7.6.2 The procurement contract may include maintenance with clearly set out service level agreements for a period of time after the expiry of the warranty period.

7.6.3 All medical capital equipment should be subject to a preventive maintenance programme as well as provision for repairs to ensure continued operational efficiency of the equipment.

7.6.4 In case an existing procurement contract does not cater for maintenance and servicing, the procuring entity should appraise and register service providers in order to establish in advance that they have proven technical expertise to maintain the equipment.

7.6.5 The service providers should preferably be authorized agents for the relevant equipment.

7.6.6 Proof of agency may be demonstrated by producing the manufacturer's letter of authorization for any local agent.

7.6.7 The procuring entity should plan for disposal and subsequent replacement of such equipment once they have become old and expensive to run or have become technologically obsolete.

7.6.8 The Heads of Departments should submit their plans to the Head of the Procurement Unit, who should study and consolidate them and compile a master plan for approval by the Head of the Procuring Entity.

7.6.9 The plan should be submitted at least 30 days before the end of the financial year.

7.6.10 The procurement plan should be prepared in accordance with the format provided under Appendix B of this Manual.

7.7 Implementation of procurement Plan

7.7.1 Unplanned requirements that arise out of unforeseen operational needs or changes to the user's annual procurement plans should be communicated to the Head of the Procurement Unit immediately such changes occur.

7.7.2 Regular reports on implementation of the plan should be prepared by the Procurement Unit. The report is to include compliance or variances, if any, from the plan and the implications of such variances, for remedial action.

7.7.3 The report referred to under section 7.7.2 should be prepared by the Head of the Procuring Unit and copied to the Heads of Departments including the Heads of Finance or Accounts Department where budgetary variances, if any, will be analysed for prompt remedial actions.

7.7.4 As far as practicable any existing suitable substitutes or alternative products should be considered before initiating procurement of products not in the plan.

7.7.5 PEs should be aware that health sector financing at the national level is a shared responsibility that is discussed and agreed upon between Government of Kenya and various Development Partners under various Joint Funding Agreements. Although this may not affect individual PEs at an operational level, it is important to understand the sources of medical supplies. However, efforts are constantly being made at the ministry level to harmonise supply options for medical commodities to PEs where this is applicable.

8.0 SPECIFICATION OF MEDICAL SUPPLIES

Specifying pharmaceutical products can be complex when the product is outside the Essential Drugs List. The guidelines below provide an outline for possible consideration and are by no means prescriptive or exhaustive.

8.1 General guideline on preparation of specifications

8.1.1 A committee of specialists

Medical products should be specified by an ad hoc committee of at least two specialists including a representative of the Procurement Unit who will provide commercial information.

8.1.2 Generic specifications

The specifications should be as generic as possible to encourage adequate responses from potential suppliers. The greater the numbers of respondents, the greater are the prospects for obtaining competitive bids.

8.1.3 Scope of specifications

The specifications should be initiated by users and be prepared in a clear and unambiguous manner covering product descriptions and supporting services such as delivery requirements and service responsiveness required of a supplier, where necessary. The specifications should be perused by the Procurement Unit to ensure that they are clear, complete and are based on functional and performance requirements.

8.1.4 Product specifications

Specifications are to address functions and performance in order to avoid elements that restrict competition, such as brand, trade names, origin, and patent, design or type and producer or service provider, except where such items are unavoidable in accordance with the criteria in Section 34 (4) of the PPD Act.

8.1.5 Use of brand names and patents

The PPD Act under Section 34 (4) does not permit specification by brand names or patents. However, due to prevalence of identification and prescription of specific drugs for particular ailments by medical practitioners, such special references may be used when procuring the drugs from potential suppliers, provided the words “or equivalent” are used in order to avoid restriction of competition.

8.1.6 Demonstration and samples

a) When it is difficult to specify consumables such as disinfectants and laboratory chemicals adequately and clearly, potential suppliers may be asked to demonstrate performance of a product. Otherwise the samples should be accompanied by a certificate of conformance to specifications from an

authorized laboratory e.g. the Government Chemist, Kenya Bureau of Standards and National Quality Control Laboratory.

b) Where appropriate, items such as hospital disinfectants may be subjected to testing by bidders to demonstrate effectiveness or appropriate method of use at the procuring entity's premises.
c) Once a sample has been approved, all the supplied products must conform to the sample.

8.1.7 Technical specifications for non-pharmaceutical products

Specifications for medical equipment and other non-pharmaceutical products should be directed to ensuring that they are suitable for the functions to which they will be put. They may include a combination of the following:

a) Physical characteristics (dimensions, strength, etc);
b) Essential features of design;
c) Tolerances;
d) Materials used, where these are relevant to performance;
e) Processes/ methods involved in production, where these are relevant to quality control; and
f) Maintenance requirements.

8.1.8 Composition specifications for medical products

Composition specifications are generally stated in terms of physical as well as chemical characteristics such as weight, volume, level of purity, density, ingredients, additives etc. This type of specification is often used for raw materials, commodities, foods, liquids and pharmaceuticals.

8.1.9 Service specifications for health sector

The specifications for services which are routine such as maintenance, transport publicity, security training information technology, catering, among other services, should be in terms of output which should be measurable and time-bound. Reference should also be made to the guidelines provided in the Manual for Procurement of Non Intellectual Services.

8.1.10 Specifying testing and inspections

In addition to specifying performance of an equipment or product for the health sector, it is prudent to specify the following testing and inspection requirements:

a) In-process testing and inspection at the manufacturing stage, including assessment of quality assurance documentation in place at the end of production or pre-shipment inspection (PSI);
b) Acceptance testing at the time of receipt, installation and /or commissioning; and
c) The party to meet the cost of testing and inspection should be explicitly stated in the bid document and the contract, for avoidance of any doubt.

8.1.11 National and International Standards

When existing standards do not meet users' needs, for example, due to new technological advances or practices, the relevant national or international

standards should be used to enhance testing, inspection and suppliers responsiveness.

8.1.12 Use of the Essential Drugs List (EDL)

In the first instance, all drugs and medical supplies specified for procurement should be checked against the current EDL. The EDL contains the names and specifications of most of the essential drugs and medical supplies recommended for purchase by the public sector health institutions to treat most of the ailments prevalent in Kenya. The Procuring Units in the health sector should refer to this list for specifications before developing alternative specifications.

8.2 Specific Guidelines for Preparing Pharmaceutical Products Specifications

8.2.1 Product Package

The required packaging standards and labelling must meet the latest requirements of the "Good Practices in the Manufacture and Quality Control of Drugs" compiled by the World Health Organization (WHO).

a) Specifications for products such as tablet, capsules, dry syrup, liquid, ointment, vaccine and other injectable, emulsion, suspension, etc. should contain dosage and content (exact number of mg or international units [IU] or % v/v, w/w or v/w acceptable range);
b) The products should conform to standards specified in the acceptable pharmacopoeia standard;
c) In case the pharmaceutical product is not included in the specified pharmacopoeia, but is included in the Ministry of Health's national essential drug list, the procuring entity should clearly indicate acceptable limits and the supplier, upon award of the contract, must provide the reference standards and testing protocols to allow for quality control testing;
d) The packaging and labelling components (e.g., bottles, closures, and labelling) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the purchaser;
e) All packaging must be properly sealed and made tamper-proof and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (NRA). The procuring entity should specify any additional special requirements;
f) All labelling and packaging inserts should be in the language requested by the purchaser or English if not otherwise stated;
g) Goods requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry; and
h) Upon award, the successful supplier should, on demand, provide a translated version in the language of the bid, information for any specific goods the procuring entity may request.

8.2.2 Labelling Instructions

The label of the primary container for each pharmaceutical and vaccine products shall meet the latest standard and include:

a) The international non-proprietary name (INN) or generic name prominently displayed above the brand name, where a brand name has been given;
b) Dosage form, e.g. tablet, ampoule, syrup, etc.;
c) The active ingredient "per unit, dose, tablet or capsule, etc";
d) The applicable pharmacopoeia standard;
e) The purchaser's logo and code number and any specific colour coding if required;
f) Content per pack;
g) Instructions for use;
h) Special storage requirements;
i) Batch number;
j) Date of manufacture and date of expiry (in clear language, not code);
k) Name and address of manufacture;
l) Any additional cautionary statement; and
m) The outer case or carton should also display the above information.

8.2.3 Case (carton) Identification

The following guidelines may be referred to by the procuring entities in identifying cases carrying medical products:

a) No case should contain pharmaceutical products from more than one batch.
b) All cases should prominently indicate the following:
    i. Purchaser's line and code numbers;
    ii. The generic name of the product;
    iii. The dosage form (tablet, ampoule, syrup);
    iv. Date of manufacture and expiry (in clear language not code);
    v. Batch number;
    vi. Quantity per case;
    vii. Special instructions for storage;
    viii. Name and address of manufacturer; and
    ix. Any additional cautionary statements.

8.2.4 Unique Identifiers for Medical Products for Public Entities

The purchaser should request the supplier to imprint a logo, if appropriate, on the labels of the containers used for packaging and in certain dosage forms such as tablets and ampoules. Any such requirement should be stated in the Technical Specifications. The design and detail should be clearly indicated at the time of bidding, and confirmation of the design of such logo should be provided to the supplier at the time of contract award. These unique identifiers are essential to discourage the diversion of products procured by the public entities for illegal distribution and sale through unauthorized outlets.

8.2.5 Standards of Quality Control for Supply

Suppliers should be required to furnish to the purchaser:

a) WHO certificate (where appropriate, for each consignment, and for each item) of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the product being supplied and the manufacturer's certificate of analysis;
b) Assay methodology of any or all tests if requested;

c) Evidence of bio-availability and/or bio-equivalence for certain critical products upon request;
d) Expiration dating and other stability data concerning the commercial final package upon request; and
e) Access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms should the purchaser so desire.

8.2.6 Specifications for Vaccines

8.2.6.1 General Specifications for Vaccines

The following general specifications for vaccines will be useful in preparing the bid documents:
a) The vaccines to be supplied under the contract must be licensed both in the country of manufacture and in Kenya and an assurance that the requirements as defined by WHO are observed;
b) A certified copy of a licence from the country of manufacture stating that the bidder is licensed to manufacture or distribute the vaccines;
c) A certificate confirming that the vaccine offered specifically complies with the requirements for vaccines; and
d) The vaccines must be produced under the control of a recognized, well-functioning national control authority (NCA) which performs the following six critical functions as defined by the World Health Organization (WHO):

i. Licensing based on published set of requirements;
ii. Surveillance of vaccine field performance;
iii. System of lot release for vaccines;
iv. Use of laboratory when needed;
v. Regular inspections for good manufacturing practices (GMP); and
vi. Evaluation of clinical performance.

8.2.6.2 Specific Specifications for Vaccines

The purchaser may find the following specifications for vaccines useful in preparing the bid documents:
a) Dosage form (e.g.: oral or injectable; liquid or freeze dried with sterile diluents packed separately, etc;
b) Type (e.g.: "live attenuated," "manufactured from human plasma or manufactured using recombinant DNA technology";
c) Administration (e.g.: "intended for intramuscular injection," etc.);
d) Description of intended use (e.g.: "immunization of newborn infants," etc.);
e) Dosage size (if not restrictive), or expected immunogenic reaction (e.g.: each dose shall contain that amount of protein with micrograms/ml specified by the manufacturer for newborn dosage, that when given as part of a primary immunization series [3 doses] is capable of producing specific humeral antibody [anti hbs] at a level of at least 10 Mille International Units in ≥ 90 % percent of recipients," etc.);
f) Dose package (e.g.: "5 infant dose sterile glass vials," etc.);
g) Filling volume (e.g.: "final product should contain 15% overfill," etc.);
h) Closures (e.g.: "vaccine vials shall be fitted with closures that conform to ISO standard 8362-2 storage temperature (e.g.: "2–8 degrees C. Do not freeze," or as appropriate, etc;

i) The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature standards (e.g.: "the vaccine should conform to standards established by the Pharmacy and Poisons Board" or, where no standard has been adopted, meet current requirements published by the WHO expert committee on biological standardization, or requirements of an established body of equivalent stature).

8.2.7 Labelling Requirements

a) Each vial or ampoule shall carry the manufacturer's standard label in the English language.

Each vial or ampoule label shall include the following information:

i. Name of the vaccine;
ii. Name of the manufacturer and place of manufacture;
iii. Lot/batch number;
iv. Composition;
v. Concentration;
vi. Dose mode for administration;
vii. Expiration date;
viii. Storage Temperature; and
ix. Any other information that is appropriate.

All labelling shall withstand immersion in water and remain intact

8.2.8 Packing requirements

a) Inner boxes shall:
   i. State the number of individual vials/ampoules they contain;
   ii. Contain a specified manufacturer's standard package printed inserts in the English language;
   iii. Be sufficiently packed so that the vaccine remains refrigerated. The packaging must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) manual on international packaging and shipping of vaccines, including all measures needed;
   iv. Have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above specified limit during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination; and
   v. Have additional cushioning sufficient to protect the vials/ampoules from breakage during transit and handling.
b) Exterior shipping cartons shall:
   i. Have printed materials, packaged as described above;
   ii. Be packed in weather-resistant, triple-wall corrugated fibreboard cartons with a bursting test strength of not less than 1,900 kPa;
   iii. Have overall dimensions such that the product does not become damaged during transportation and storage; and
   iv. Not contain vaccine from more than one lot.
c) Cold chain monitor cards:
   i. Each insulated shipping container must include appropriate temperature monitoring devices designated by the purchaser;

ii. At least two suitable cold chain monitor cards, as approved by the purchaser, shall be packed in each transport case of vaccine; and
iii. Freeze watch indicators shall be included in each transport case at the direction of purchaser.
i. Information Requirements on containers and invoices: The name of the vaccine;
ii. Expiration date of the vaccine;

8.2.9 Appropriate storage temperature

a) Inner boxes**:** The inner boxes containing vaccine vials or ampoules shall be marked with the following information in a clearly legible manner that is acceptable to the purchaser:
   i. Generic name and trade name of the vaccine;
   ii. Manufacturer's name and trade registered address;
   iii. Manufacturer's national registration number;
   iv. Lot or batch number;
   v. Composition and concentration;
   vi. Number of vials contained in box;
   vii. Expiration date (month and year in clear language, not code);
   viii. Instructions for storage and handling; and
   ix. Place of manufacture.
b) Exterior Shipping Cartons: The following information shall be stencilled or labelled on the exterior shipping cartons on two opposing sides in bold letters at least 30mm high with waterproof ink in a clearly legible manner that is acceptable to the purchaser:
   i. Generic name and trade name of the vaccine;
   ii. Lot or batch number;
   iii. Expiration date (month and year in clear language, not code);
   iv. Manufacturer's name and registered address;
   v. Manufacturer's national registration number;
   vi. Destination airport and routing;
   vii. Consignee's name and address in full;
   viii. Consignee contact name and telephone number;
   ix. Number of vials or ampoules contained in the carton;
   x. Gross weight of each carton (in kg);
   xi. Carton #____ of _____;
   xii. Instructions for storage and handling;
   xiii. Contract number;
   xiv. Place of manufacture.

8.2.10 Quality Control for Supply

a) All goods must:
   i. Meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;
   ii. Meet internationally recognized standards for safety, efficacy, and quality;
   iii. Conform to all the specifications and related documents contained herein;
   iv. Be fit for the purposes expressly made known to the supplier by the purchaser;
   v. Be free from defects in workmanship and materials and be certified by a competent authority in the manufacturer's country;

vi. Be accompanied by evidence that each consignment conforms to the WHO release certificate;
vii. State assay methodology of any or all tests if required; and
viii. Contain evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

b) Quality control and test results should include:

i. Pre-shipment inspection and testing: The supplier will be required to provide the purchaser or his representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.
ii. Provision for the purchaser to inspect and sample, or cause to be sampled, such products and may cause independent laboratory testing to be performed as deemed necessary to ensure that the goods conform to prescribed requirements. The testing laboratory shall be of the purchaser's choice and suitably equipped with staff that are qualified to conduct the tests.

8.3 Specifications for Condoms

8.3.1 Product and Package Specifications

a) The goods must conform to the manufacturer's current standards for condoms as specified in line with the ISO 4074 standard for latex rubber condoms;
b) The specifications for the goods shall indicate critical factors, e.g., bursting volume and pressure, freedom from holes, width and length, thickness, lubricant quality, and viscosity;
c) The goods, packaging and labelling components shall meet the standards specified in the latest WHO specification, including batch-by-batch independent quality control laboratory test;
d) Condoms should be shipped in special containers to ensure stability in transit from point of shipment to port/ air port of entry and point of destination for CIP deliveries. Any special temperature requirements must be designed to meet the climatic conditions prevailing in the procuring country; and
e) The procuring entity should advise the supplier of any particular requirements.

8.3.2 Labelling

a) The primary pack

The packs should be labelled in accordance with the latest WHO specifications and should include:

i. Manufacturer's name;
ii. Batch number (printed at the time of packaging); and
iii. Month and year of expiry.
iv. **The secondary packing**, i.e., the inner box, should be labelled in accordance with the latest WHO specifications and include:

i) Batch number;

ii) Month and year of manufacture (including the words: Date of Manufacture/month/year);
iii) Manufacturer's name and registered address;
iv) Nominal width expressed in millimetres;
v) Number of condoms in box;
vi) Instructions for storage; and
vii) Month and year of expiry.

8.3.3 Packaging specification

All exterior shipping cartons and packaging must comply with the latest WHO specification for packaging of condoms.

8.3.4 Case identification

All cases should prominently indicate the following:

i. Nominal width expressed in millimetres;
ii. Number contained in the carton;
iii. Instructions for storage and handling; and
iv. Month and year of expiry.

8.3.5 Lot traceability

a) All exterior shipping cartons for each batch should be assembled and shipped together to facilitate the monitoring of batch quality during shipping and storage.
b) Both codes should be used on exterior shipping cartons, colour coded for ease of identification if requested by the purchaser.

8.3.6 Unique identifiers

The purchaser will have the right to request the supplier to imprint a logo on the package of the condoms so long as the quantity justifies it. The design and details will be clearly indicated at the time of bidding and shall be provided to the supplier at the time of contract award. The objective of unique identifiers is to discourage illegal diversions of condoms from the public entities.

8.3.7 Standards of quality control

The supplier will be required to provide the purchaser with access to its manufacturing facilities to inspect compliance with the requirements and quality control mechanisms, should the purchaser so demand.

8.3.8 Quality control testing

a) The supplier should be required to carry out testing of a proposed shipment in line with the WHO specification and the size of sample will be calculated by reference to ISO 2859-1.
b) For each consignment the supplier must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature, as necessary.

9.0 CHOICE OF PROCUREMENT METHODS

9.1 Open tendering

The preferred procurement method is by open tendering, according to section 29 of the PP&D Act 2005. The details for how open tender should be conducted are contained in Part V of the PP& D Act 2005. However, where open tendering is not the appropriate method, the Act provides for use of alternative procurement methods subject to fulfilling the conditions provided in Part VI of the PP&D Act 2005.

9.2 Alternative procurement methods

These alternative methods are used where open tendering is not feasible or justified under Part VI of the PP&D Act 2005 and should be included in the procurement plan. A procuring entity may use any of the following alternative procurement methods pursuant to the provisions of the PPD Act and the Regulations:

a) Restricted tendering;
b) Direct procurement;
c) Request for Proposal;
d) Request for quotation;
e) Low level procurement; and
f) Specially permitted procurement.

Further guidance on the use of open and alternative procurement methods can be found in the Public Procurement and Disposal General Manual.

9.3 Review of selection of procurement method other than open tender

The tender committee shall review the selection of procurement method other than open tendering, pursuant to Regulation 10 (2) (h) of the PPD Regulations.

10.0 EMERGENCY PROCUREMENT

10.1 Introduction

From time to time, there may be interruption of business operations due to disaster or emergency arising from either internal or external failures. Procurement procedures applied in such circumstances may be different from business as usual.

10.1.1 Disaster preparedness through procurement contracting

Unanticipated disasters may occur. Each procuring entity should therefore prepare a Disaster Recovery Policy which should outline how a Disaster Recovery Plan may be put in place to respond to any disaster. A disaster shall be considered in the context of the definition of 'urgent needs' as defined in the PP&D Act 2005, Section 3(1).

10.2 Emergency procurement procedure

10.2.1 The term 'emergency' shall mean any circumstance caused by fire, flood, explosion, storm, earthquake, an epidemic, riot, insurrection or inherent defects or failure in key equipment or any other unforeseen circumstances so as to threaten the ordinary flow of the business of an institution or any other occurrences that can create situations similar to the foregoing.

10.2.2 A contract may be awarded under emergency conditions provided that an emergency procurement is justified under the circumstances.

10.2.3 Departments or a section of the procuring entity responding to an emergency should exercise appropriate controls when making emergency procurements.

10.2.4 Emergency procurement shall be limited to those goods and services necessary to meet the emergency.

10.3 Business continuity plan as criteria for registration and/ or pre-qualification of potential suppliers

10.3.1 One of the criteria for appraising potential suppliers should be their preparedness to respond to emergencies when approached by the procuring entity. This ability will be evidenced by the existence of a business continuity plan which should enable the suppliers to respond to inquiries or requests promptly.

10.3.2 Other criteria may be an established relationship with their own suppliers, readiness to allow exchange of proprietary information with the procuring entity, inventory policy that would enable emergency inventory back-up and the firm's own emergency response procedures.

10.4 Procurement of goods and services covered by framework contracts

10.4.1 Framework contracts should be formulated to cater for procurement of requirements such as drugs and consumables to run for durations of one to two years. Framework contracts should be in accordance with guidance issued by the PPOA. They should include:

a) A realistic estimate of the expected quantities to be purchased based on monitoring of past purchases and research of users' requirements; and
b) A minimal contractual quantity.

10.4.2 Once the framework contract is in place prompt acquisition of supplies in case of emergencies and disasters by directly issuing LPOs without resorting to invitation and processing of quotations would be feasible.

10.4.3 The framework contracting arrangement should reduce circumstances where it is necessary to resort to emergency procurement.

10.4.4 Commitments made under 10.4.3 above should be formalized through issuance of a covering LPO as soon as possible thereafter, but in any case not later that two working days after the emergency procurement was executed.

10.4.5 The procedures under 10.4.1 and 10.4.2 above entail distributing a summary of framework contracts to user departments who may use the same in case of emergency.

10.4.6 The users are however cautioned against miss-use of the emergency procedures. Emergencies shall be fully justified by whoever takes the action. The approving authority reserves the right to approve or reject such procurement initiatives.

10.5 Procurement of goods and services not covered by framework contracts

10.5.1 In case an emergency procurement involves goods and services not covered by the framework contracts, a quotation may be obtained through fax or e-mail from a known or registered firm in line with the Direct Procurement method as is stipulated in Part VI (b) of PPD Act.

10.5.2 In case the value of the procurement is in excess of the low level procurement threshold, the relevant user department may in consultation with the Head of the Procurement Unit and the Head of the Procuring Entity initiate transfer of an emergency requirement from the nearest institution. Items transferred from another institution should be replaced as soon as possible.

10.5.3 The bids so received are to be evaluated by at least two responsible officers appointed by the relevant Head of Department. The committee will select the lowest evaluated price among responsive bids.

10.5.4 A comprehensive report shall be prepared by the relevant head of department where the disaster occurred and forwarded to the head of the procuring entity for information.

11.0 BIDS EVALUATION PROCEDURE

11.1 The evaluation criteria

The following factors should be taken into account during bid evaluation:

a) Delivery/lead times;
b) Suppliers' economic standing;
c) Suppliers' legal standing – whether qualified to operate as a supplier/vendor of the proposed goods or services;
d) Suppliers' relevant experience;
e) Suppliers' technical capacity to perform the proposed contract;
f) Suppliers' responsiveness to the tender technical requirements;
g) Suppliers' price for delivering the goods or performing the services;
h) Total cost for delivering the services;
i) Reliability, integrity and reputation;
j) Quality, production capacity and flexibility;
k) Credit terms; and
l) Delivery period and ability to meet required deadlines.

11.2 Consistent application of evaluation criteria

No evaluation criteria other than those stated in the bid document shall be used in the evaluation of the tender for responsiveness.

11.3 Recommendation of the lowest evaluated bidder

11.3.1 There shall be a preliminary evaluation of all the bids in accordance with Regulation 47 (1) of the PPD Regulations.

11.3.2 All the bids which pass the preliminary evaluation stage shall be subjected to technical evaluation to determine the substantially responsive offers against the technical criteria set out in the tender documents.

11.3.3 Those bids which are determined to be substantially responsive are then subject to financial evaluation to determine the lowest evaluated price.

a) All other factors being equal, the bid offering the lowest total cost of supply (inclusive of relevant taxes, freight and custom duty, etc) will be accepted, subject to the product conformation to all mandatory technical specifications.
b) If the award is not made to the lowest bidder, a full and complete statement of the reasons for not awarding the lowest evaluated bidder shall be prepared.
c) Sample evaluation templates for some of the pharmaceutical products are at the Appendix C of this Manual.

11.4 The Financial Evaluation Committee

The Financial Evaluation Committee should carry out the evaluation in accordance with the directives in the Regulations 50 (1) to 50(3) of the PPD Regulations to determine the lowest priced offer among those that are substantially responsive to the technical specifications following the technical evaluation stage.

12.0 SUPPLIER SELECTION

12.1 Introduction

The Procurement Unit shall appraise potential suppliers in order to compile and maintain a suppliers' database or for award of contracts for supply of specific goods and services.

12.2 Supplier selection

12.2.1 Registration of suppliers

Registration of suppliers is to be preceded by appraisal of potential suppliers through analysis of responses to questionnaires for registration in accordance with Regulation 8 (3) (a) of the PPD Regulations 2006.

12.2.2 Pre-qualification of suppliers

The pre-qualification of suppliers shall be undertaken in accordance with Regulation 23 of the PPD Regulations 2006 to enhance short listing of suppliers for specific procurements. The standard document for pre-qualification shall be used or modified as appropriate.

12.2.3 Sourcing of offers by procurement methods other than open tendering

Solicitation for offers through alternative procurement methods pursuant to Part VI of the Public Procurement and Disposal Act 2005 may be carried out from the database of pre-qualified and or registered suppliers.

13.0 BIDS ADJUDICATION AND CONTRACT AWARD

13.1 Contract Award

13.1.1 Following completion of tender evaluation, an evaluation report shall be prepared in accordance with Regulation 51 (1) of the PPD Regulations, for consideration by the tender committee, which determines who has submitted the successful tender.

13.1.2 The procuring entity should then notify the person submitting the successful tender that his tender has been accepted. At the same time, all other persons who have submitted tenders shall be notified that their tenders were not successful.

13.1.3. The procuring entity shall before expiry of the period during which tenders must remain valid enter into a written contract based on the tender documents with the person submitting the successful tender. The contract will specify the contractual obligations between the bidder and the PE including the expected deliverables from the full performance of the contract.

13.1.4 This written contract must not be entered into until at least 14 days have elapsed from the giving of notification to the successful tenderer and to the unsuccessful tenderers.

13.1.5. An unsuccessful tenderer may seek an administrative review of the procurement proceedings in accordance with Part VII of the PPD Act. In this event, the secretary to the Review Board shall notify the procuring entity of the pending review and the suspension of the procurement proceedings.

14.0 CONTRACT ADMINISTRATION

14.1 The Purpose of Contract Administration

Managing a contract after its award is important to ensure that a procuring entity gets best value for money. Sound contract administration enhances supplier relationships that guarantee effective contractual undertakings and dispute avoidance.

14.2 Formation of Contract Teams

14.2.1 Significant purchase contracts may require formation of formal Contract Management Teams.

14.2.2 Low value spot (one off) purchases and framework contracts may not entail such formal contract management arrangements. However, careful monitoring and evaluation of the performance of these engaged suppliers is important.

14.2.3 A procuring entity should form a team of senior representatives from relevant departments or sections. Other individuals who would have significant input in the management of such contracts may be co-opted as needs arise.

14.3 Preparation of contract management plan

14.3.1 A contract management plan should be prepared by a team headed by the Head of the Procurement Unit in collaboration with other relevant departments or sections.

14.3.2 Background information on the contract capturing key points may be useful as a quick reference guide.

14.3.3 There should be clear definition of roles and responsibilities of those involved in managing the contract and the policies and procedures to be complied with.

14.3.4 Highlights of timelines, costs and quality risks and how performance will be measured should be provided.

14.4 Preparation of contract quality plan

The contract quality plan will include but not be limited to the following**:**

a) Quality assurance policy;
b) How quality functions are organized and individual responsibilities;
c) What quality control checks are to be carried out; and
d) What quality documentation is to be produced

14.5 Preparation of contract budget

The contract budget will include but not be limited to the following:

a) Planned payment to a supplier for a number of staged payments (or as per terms of payment). This will ensure availably of funds to meet payments and take into account any approved variation;
b) Contingency allowance to cater for unavoidable risks that have cost implications; and

c) Personnel man-hours budget that should cover the time a procuring entity's personnel need to spend on management of the contract based on the existing Government "personnel-hour rate".

14.6 Risk management register

A risk management register should be prepared and maintained by the contract management team to reflect the changes in risks and the mitigating measures recommended as the contract progresses. The register should be annotated with scheduled (time) risks, quality risks, and costs risks, commercial and other risks.

14.7 Measuring and controlling performance

Measuring and controlling performance of the contract should be carried out by the contract management team with a view to monitoring deviations, if any, from the contract management plan. The deviation or risk of deviation in the process should be identified by measuring performance against key performance indicators and communicating the findings at the contract- review meetings, which should take remedial action.

14.8 Contract review

Contract reviews should take place throughout the performance of the contract to ensure that requirements are being met satisfactorily and that remedial measures can be put in place at the appropriate time. In addition, there should be a formal review of the contract after the contract has been completed. It should consider:

a) The time, cost and quality performance;
b) Risk analysis;
c) Organization and operational effectiveness and appropriateness of the procedures used and controls in place; and
d) Review of supplier's performance.

The contract reviews are an important source of information and organizational learning which should be used to improve the management of future contracts.

15.0 SPECIFIC HEALTH SECTOR PROCUREMENT ISSUES

15.1 Value and range of procurements greater than thresholds in Public Procurement and Disposal Act 2005

15.1.1 When values are in excess of those stipulated in the threshold matrix, various procurement methods may be used subject to fulfilling the conditions stipulated in Parts V and VI of the PPD Act 2005, depending on a procuring entity's class.

15.1.2 In case procurement through quotations is the preferred method in view of the prevailing circumstances but the value is in excess of the quotation threshold, the restricted tendering method may be used provided that the stipulated documentation is observed in the categories stated below:

a) The restricted tendering procedure pursuant to Section 73 (2) (a) of the PPD Act – use of suppliers pre-qualified in accordance with Regulation 23 of the Regulations for value in the Threshold Matrix; or
b) Pursuant to Section 73 (2) (b) of the PPD Act - use of suppliers registered in accordance with Regulation 8 (3) (a) of the PPD Regulations 2006, to save time and cost that would be spent by using Open Tendering or Restricted Tendering through a pre-qualification process; or
c) Use of any known suppliers that may not have either been pre-qualified or registered pursuant to Section 73 (2) (c) of the PPD Act.

15.1.3 To simplify the above decisions and to minimize urgent procurement, the above options should be considered in advance and be included in the procurement plan.

15.2 Procurement of specialised products with limited international sources of supply

15.2.1 Items with limited international sources of supply may be obtained through international quotations or international open or restricted tenders depending on the preferred delivery time period and relevant threshold stipulated in the Threshold Matrix in the First Schedule of the PP&D Regulations 2006.

15.2.2 An international tender has no lower limit and the upper limit is as provided for in the budget. However for quotations, though there is no lower limit, the upper limits vary according to the class of a procuring entity according to the Threshold Matrix.

15.2.3 However, to minimize the cost of frequent urgent and fragmented international orders small quantities and or low value items should be consolidated or aggregated in order to realize economies of scale.

15.3 Specification of products by use of patents or brands leading to Direct Procurement method

15.3.1 Specifications for pharmaceutical or non–pharmaceutical products with established similarities in efficacy should be maintained in separate registers or catalogues such as Essential Drugs List, or any other officially approved list to enhance comparability of prices and quality between the patented and the generally specified products.

Every procuring entity should maintain its own list for comparison and cross referencing.

15.3.2 The specifications by using a patent should be supplemented by the technical characteristics of the product or by adding the words "or equivalent".

15.3.3 Fair prices for patented or branded products are to be ascertained by maintaining market pricing data bank right from the manufacturer with estimates of logistics and statutory charges as a basis for determining reasonable and fair prices.

15.4 Quality control Considerations

15.4.1 To be assured of quality, a supplier should demonstrate that he/she has established quality assurance systems in his/her production processes. Quality assurance is among the criteria for registration with the Pharmacy and Poisons Board of Kenya and/or WHO. Pre-qualification of a supplier, award of contract to a supplier and acceptance of delivery of supplies must be premised on an assurance of conformance with specified product quality.

15.4.2 Process quality control through collaboration with key suppliers is a defect avoidance strategy that may be suitable for procuring entities that want to ensure that documented quality control steps are followed in the course of production.

15.4.3 Alternatively, the supply contract should stipulate that pre-shipment inspection be carried out by an approved pre-shipment inspection company and a certificate issued. The certificate should accompany the goods.

15.4.4 Past performance evaluation criteria with regard to quality systems and compliance should be one of the evaluation criteria and be include in the bidding document.

15.4.5 On receipt, inspection by sample testing at the National Quality Control Laboratory or KEBS may be adopted as appropriate.

15.4.6 The suppliers should be made aware in the bid documents of the required options for confirming and demonstrating adherence to quality standards. The bid document will show how the quality risk and responsibilities will be shared between the procuring entity and the suppliers.

15.4.7 Suppliers should also be made aware in the bid documents of contractual remedies the procuring entity may resort to in case of hidden defects or non compliance with specifications which are discovered at any stage of distribution after the medical products have been delivered to the procuring entity.

15.5 Emergencies arising from natural disasters and epidemics that give rise to unplanned requirements that change budgetary priorities.

Emergency procurement is to be carried out in line with the Emergency Procurement procedures set out in Section 10 of this Manual.

15.6 Drug rationalization and use of the Essential Drugs List published by the Ministries of Health

15.6.1 The drugs in the essential list may be ranked as critical and be prioritized while undertaking procurement. However the list may be supplemented by an approved list of other items if the circumstances so warrant.

15.6.2 The essential drugs list should serve as a means for reducing the variety of drugs and hence help to minimize expiry of drugs.

15.7 Procurement of donor/consortium funded products

15.7.1 Donor/consortium funded products should be procured in accordance with Sections (5), (6) and (7) of the PPD Act 2005 unless the procurement provisions in such agreement stipulates an alternative procedure to be used.

15.7.2 The quantities negotiated with the donors should be rationalized with the normal projections made for normal stock replenishment according to the inventory plans, procurement plan and the budget to avoid overstocking and eventual expiry of drugs.

15.8 Stock management and avoidance of expiry

15.8.1 Stock management procedures set out in Section 17.0 (Stock Replenishment) of this Manual are to be followed to avoid overstocking that leads to expiry of pharmaceuticals and non-pharmaceutical products.

15.8.2 Vendor managed inventories where the suppliers deliver consignments according to the negotiated delivery schedules should be used. This delivery arrangement is to be factored in the framework contracts.

15.8.3 Installation of inventory management software should be considered by the procuring entities to enable efficient and effective monitoring of consumption and timely replenishment. Manual inventory management systems may be adequate for small procuring entities with few products and little volume. However for large procuring entities with hundreds of product lines and huge volumes of high value products, manual systems have proven ineffective.

15.8.4 Regular monthly stock checks should be carried out to enable detection of products that expire within 6 months. Such products may be disposed off through exchange between PHFs or transfer to other needy health institutions.

15.8.5 Annual stocktaking should be carried out by support of officials from other organizations to encourage impartiality in the process. The stocktaking findings should be analyzed with a view to identifying over and under-stocking and other warehousing issues.

15.8.6 In the purchase specifications, efforts should be made to demand that the suppliers deliver products with 75% of shelf life remaining.

15.9 Procurement of specialized medical equipment

15.9.1 Specifications should be prepared by an appropriate specialist who should take into account technology and life cycle costing which cover the total cost of acquisition, maintenance and repair.

15.9.2 The required period of warranty should be included in the specifications. The detailed guidelines on equipment specifications area provided in Section 8 of this Manual.

16.0 ENVIRONMENTAL FACTORS IN HEATH SECTOR PROCUREMENT

16.1 Products with chemical composition should be specified by taking into account the economic and environmental performance of a product through-out its life cycle, namely production, distribution, use and final disposal. Care must be taken to ensure that guidelines issued by National Environmental Management Authority (NEMA) are followed.

16.2 Since most of the medical products have some level of chemical composition the following examples present a check list of essential attributes for chemical products including laboratory reagents:

Checklist of Essential Attributes for Chemical products	
Substitution	Possibility to satisfy the need without the use of a chemical or with a chemical that has a lower environmental impact.
Composition & concentration	Extent of compatibility with the required application in terms of composition, concentration, and expiry date.
Product labelling	Conformity with requirements of international standards and regional regulations.
Handling and use instructions	Whether the supplier provides sufficient information on handling and use including the optimum dosage for effective utilization.
Hazard factor	The comparative measure of the toxicity, flammability, corrosively and explosively of the chemical: - the potential hazard factor of the chemical compared to others.
Safety	Availability of Materials Safety Data Sheet that covers potential hazards that may arise during handling and use of the chemical. It should state the necessary steps to be taken to avoid the occurrence of hazard or accidents.
Chronic Health Risks	The level of chronic health risks to humans from skin and inhalation exposure to chemical product.
Bio degradability	The degree and rapidity of degradability by micro-organisms in the natural environment. The faster the chemical degrades the lower is its exposure potential. Persistent chemicals (e.g., those that contain heavy metal such as cyanide, mercury, chrome) are to be avoided as much as possible.
Bio-accumulation	Bio-concentration factor (BCF) is a measure of the rate of accumulation of chemicals in the food chain. The higher the BCF, the higher the potential of toxicity of the chemical through the food chain.
Packaging	Extent to which packaging optimally satisfies the requirements for transportation and materials handling. If the chemical as well as end-use or disposal of the packaging material is bio-degradable.

NB: The above attributes have more or less the same characteristics for the pharmaceutical and non-pharmaceuticals and should be considered appropriately when specifying such items.

17.0 MANAGEMENT OF INVENTORY

17.1 Stores Coding and Classification

17.1.1 Introduction

Stores Codes are suitable for identifying items to minimize ambiguity and misinterpretations that arise when items are only referred to by descriptive titles. Ideally, such codes should be developed centrally by KEMSA and published for adoption by PEs. The codes should also be used for location of stores where a random allocation system is applicable.

17.1.2 Procedures

a) The alpha-numeric structured coding should normally be used. A series of defined classes and sub-groups are determined and incorporated in the stores catalogues containing stock items code number.

b) A stores catalogue contains the items that have hitherto been approved for stock holding and should be used by user departments for description of requirements on the counter requisition and issue voucher.

c) Users should requisition for items in the catalogue unless such items are not suitable for the intended purposes.

d) For efficient stores location, the code numbers should be used to enable prompt order picking when processing stores requisitions.

e) Numeric coding structure should be used to enhance efficient inventory automation as shown in the following example.

17.1.3 Example: Drugs Injectable in various packs

A	Product Group	Pharmaceuticals
A.01	Product Sub-Group	Drug
A.01.01	Individual Product	Injectable
A.01.01.01	1st Variant of Individual Product	Pack of 100 vials
A.01.01.02	2nd Variant of Individual Product	Pack of 200 vials

17.2 Stock Replenishment

17.2.1 Replenishment

a) Stock replenishment is part of the inventory and distribution referred to in section 4(1) of the PPD Act 2005.

b) Inventory replenishment operations are fundamental to achieving the desired service level and to meet the immediate day-to-day requirements taking into account the changes to value and level of inventory which might have substantial impact on the overall operation of procuring entity.

c) The foregoing notwithstanding, replenishment of inventory should take cognizance of need to avoid tying working capital in high inventory since holding excess inventory can lead to obsolescence of such stocks.

17.2.2 Methods

The following are some of the commonly used replenishment methods which would apply for different categories of requirements determined in line with inventory categorization in the stores catalogue:

a) Re-order Level System (fixed order quantity, variable order intervals);
b) Periodic Review System (fixed order interval, variable order quantity);
c) Demand Driven Lean Supply Systems (orders placed in the precise quantity and time required for a specific projects or assignments); and
d) Economic Order Quantity (order what is economical to produce or deliver).

NB: See alternative strategies under 17.2.9 and 17.2.10 below.

17.2.3 Re-order Level System-(Fixed Quantity, Variable Interval)

a) The decision to re-order will be triggered when the level of physical stock plus inventory already on order falls to an established re-order level.
b) The re-order level is calculated by adding the best estimate of demand to cover the lead time duration **to** safety stock quantity.
c) The re-order Level System calculation is to be done by applying the following formula where manual operating systems are in use by applying the following formula:

ROL = (Rd X L) + S

Where: Rd = Rate of demand/usage (per day/per week)
L= lead time (in days/week)
S = safety level of stock

Example:

For instance the ROL, where the rate of demand is 100 units per week, the lead time is 3 weeks and safety stock is 170 units will be:
(Demand/usage rate x 3 weeks) (lead time) + 170 (safety stock)

ROL = 100 x 3 + 170 = 500 units

17.2.4 Periodic Review Systems

a) Ordering is for a fixed quantity at a fixed period cycle, e.g. weekly or monthly. On the average the amount ordered will be equal to the demand over the review period. The longer the review period the larger the order size. The system will apply in categories with small volumes of requirements.

b) The re-order quantity will be based on the following formula**:-**

Order Size = (Anticipated demand over the period + lead time) – (Actual stock) - (pipeline stock) + (safety stock)

17.2.5 Dependent Demands

Dependent Demands fall under the non-stock items categories where the demand is based on a specific activity or project or non recurrent activity.

17.2.6 How Much To Order

a) Order quantities will be determined with economy in view, that is by taking into account:
   i. Cost of placing an order;
   ii. Price discount costs, i.e. where supplier may impose extra costs on small order;
   iii. Stock out costs;
   iv. Costs of tying working capital in inventory;
   v. Storage costs; and
   vi. Obsolescence costs.

b) Computation of the most economic order quantity.

17.2.7 Economic Order Quantity

a) To balance the above stock holding and the acquisition costs mentioned under sub-section 17.2.6 above an economic order quantity (EOQ) should be computed by applying the following formula:

$$EOQ = \sqrt{\frac{2\,CoD}{Pi}}$$

Where:

EOQ = The Economic Order Quantity

Co = The cost per order (including administrative and communication costs)

D = The demand (Quantity required) over the period in units – meters, litres, vials, dozens, pieces, etc

P = The purchase cost per unit (including price, transported)

I = The inventory carrying cost (including the financial and physical costs of inventory, expressed as a percentage of the average value of inventory

NB: *For the inventory carrying cost, it advised that the procuring entities should use*

20% of the average value of inventory

b) The EOQ assumptions

The EOQ formula is based on the following assumption:

i. Demand for requirements is stable;
ii. Existence of a fixed and identifiable ordering cost; and
iii. Identifiable stock out cost.

These assumptions vary considerably. However the computation would provide approximate quantities to work with.

Secondly, it is inevitable that procuring entities ensure that costs which form the basis for the EOQ computation are done and regularly updated.

c) Automated computation of EOQ

For the sake of accuracy and speed of computation of the EOQ, it's advisable that procuring entities computerize their inventory management in line with the guidelines in section 17.2.11 of this Manual.

17.2.8 Determining the Desired Level of Safety Stock

a) Variability of both lead time and rate of demand cause either lower or higher than average levels of stock when the next order arrives. Safety stock level determination may however be inevitable to limit the risk of stock outs.
b) Safety level (that is the average amount that remains in stock at the time fresh deliveries arrive) is to be determined by applying the following formula:

Average Safety Level = Maximum Demand - {Average Usage over the Review Interval + Lead Time}

17.2.9 Managing Lead Time

a) Orders that arrive too early or too late result in either excessive inventory or stock-out. However, whereas short lead-times reduce the length of forecast, long lead-times result in increase of safety stock, which ironically may result in overstocking, with all the attendant problems.
b) To ensure that required customer service levels are met, it is important that internal systems are in place to manage lead time.

17.2.10 Customer Managed Inventory (CMI) [also known as Consignment Stocking]

a) In order to minimize holding of large stocks at any one time, consignment stocking arrangements may be made with suppliers, to enhance acquisition of such stocks by the institution as and when required.
b) Based on terms and conditions of a framework contract for specialized supplies such as medical gases, the supplier may supply a consignment of stocks that would be drawn down as and when required for delivery to the institution's premises.
c) The usage will be verified within the agreed intervals to determine used quantities for which the supplier will issue an invoice in accordance with the terms and conditions stipulated in the relevant framework contact.
d) An example of supplies suitable for CMI is a medical gas that is held in the supplier's metered bulk cylinder from which the procuring entity would draw the gas and only pay for the amount a recorded on the meter.

17.2.11 Vender Managed Inventory (VMI)

a) Procuring entities should minimise overstocking of medical products in order to avoid expiry and loss of funds by adopting VMI concepts for managing stocks.
b) In VMI, the vendor has visibility of stocks of his products within the inventory system of the procuring entity and has the authority and

responsibility to manage the inventory level and replenish stock at the appropriate time to avoid stock-outs.

c) This proactive involvement of the vendor requires crafting of a contract that clearly spells out duties and responsibilities for each party to avoid confusion and blame games. Needless to say, both the vendor and supplier need high degree of competence for them to successfully benefit from VMI relationships.

17.2.12 Automation of Inventory Management

a) For most big organisations with large inventories of medical supplies, it is not efficient to manage and operate them with manual systems. Computerisation and automation of inventory management systems has proven beneficial in improving efficiency in management of large inventories.

b) Computerisation gives a number of demonstrated benefits including the ability to identify the stock position instantaneously, automatic notification of stock levels for all the product lines in the inventory, flagging of products that are about to expire, preparing automated goods receipt notes and goods dispatch notes and schedules, showing product locations within the warehouse, computing reorder quantities and preparing re-order schedules etc.

c) Given the above benefits, computerisation and automation of inventory management is a desirable capability that operators of large inventory systems should seek to acquire. However there are a number of challenges to acquiring, implementing and maintaining a fully functioning automated inventory management system. These include high investment costs for the project, the need for training or recruiting skilled systems operators, need for data and systems discipline, long project implementation time lines, need for change of working attitudes and styles etc. These challenges have often deterred some organisations from fully embracing computerisation and automation of their inventories.

d) There are today many successfully automated inventory management systems in Kenya, both in the private and public sectors for medical supplies. Other organizations may learn from their experience.

e) In Kenya today, there are a number of ICT vendors who supply inventory automation systems that are suitable for both small and large inventory operators. These vendors should also be contacted for demonstration and education on how automated inventory systems work.

f) Based on the learning acquired, the procuring entity is in a better position to decide at what stage they could embark on the inventory automation process.

17.3 Receipts of Goods

17.3.1 Preparation of planned delivery schedule

On receipt of a copy of the purchase order and an acknowledgement of receipt of the same by the supplier, the Stores Controller should prepare a planned delivery schedule. The schedule is important as it enables the stores personnel to arrange for storage and handling and to give feedback to the users of the delivery status.

17.3.2 Preparation of Goods Received Note

a) After delivery has been checked to ensure that the correct item and quantity has been delivered as per the terms of a contact, a Goods Received Note (GRN) should be raised.

b) The GRN will show the item code number, the items received, the order reference number, the quantity, unit of issues, the supplier's name and the value.

17.3.3 Inspection

a) Inspection of goods received shall be carried out by the Inspection and Acceptance Committee and a certificate to the effect attached to the GRN. Goods pending completion of inspection and acceptance should be quarantined till then.

b) In case goods are delivered by a transport company where delays to the delivering vehicles may result in waiting charges being levied on the procuring entity, the inspection may be carried out later. In this case the GRN must be endorsed **"Certified Received [Quantity and Quality Awaiting Inspection]"** and the supplier notified accordingly.

c) Following issuance of the GRN and completion of inspection, the delivered goods should be moved to the storage location which will either be Fixed or Random as the case may be. The stores record should be posted accordingly, stock value calculated and entry made in the stock value column of the ledger.

d) A copy of the GRN should be sent to the buying office for updating the Outstanding Purchase Order Record.

17.3.4 Certification of Invoices for Payment

The suppliers invoice certified by the Procurement Officer (Stores) accompanied by a copy of GRN, purchase order, inspection certificate should be sent to Accounts Section for payment after the goods have been received as per section 17.3 above.

17.3.5 Handling and Storage of Pharmaceutical and Non-Pharmaceutical Supplies

The procuring entity should develop and apply procedures for handling and storage of all medical supplies and equipment in line with the WHO and Pharmacy and Poisons Board guidelines. The overall objective of such procedures and their application is to ensure that handling and storage of medical supplies and equipment keeps them safe and secure free from any contamination or damage. The handling and storage conditions must also be of pharmaceutical grade standards as outlined in Kenya by the PPB or WHO.

17.4 Requisitioning and Issuance of Stores

17.4.1 Requisitioning Procedures

a) All requests to purchase and/or issuance of goods from stock should be covered by the Requisition and Issue Voucher (RIV) form as the official document designed for this purpose and is pre-numbered for monitoring purposes.

b) All requests for acquisition or issuance of medical requirements should be made by the user departments and approved in accordance with the

approving authority concerned as prescribed by each institution for effecting internal controls.

c) The approving officers are expected to exercise their best judgment and observe prudence in reviewing the requisition taking into consideration implications or consequences of their decisions. Thus, the justification or rationale for the need must be clearly established.

d) In case of non-stock requirements meant for procurement, the RIV shall contain all relevant data necessary for making a rational procurement decision such as quality and quantity schedules accompanied with an approved Certificate of Availability of Funds. These will include:

   i. Budgetary provision reference by the Accounts or Finance Department. The absence of the budget reference number will mean that the item is not budgeted for and would therefore require senior management approval.
   ii. Incomplete RIVs should not be processed and should be returned to the requisitioner.
   iii. Specifications should be generic in nature and not refer to any brand name unless this has been earlier agreed upon by the parties concerned for the purpose of standardization or continuity of an on-going treatment or activity.
   iv. The RIV should also include the date the request is required. However, the requisitioner should give the Procurement Units ample time to process the procurement except in case of emergency.

17.4.2 Issuing Procedures

a) Verification of Requisition by Procurement Officer (Stores)

Based on the identified needs specified in the requisition, the Stores Controller should verify the requisition to ensure that it is duly authorized by the relevant head of department/ section and that the requisition is properly completed.

b) Issuance of products in line with First In First Out (FIFO) principle

All issuance procedures should, as far as practicable, observe the First-in-First Out (FIFO) principle. Products with shorter shelf life must also be issued ahead of those with longer shelf life even if this violates the FIFO principle to reduce risk of expiry of products while in the store.

c) Collection of issued items from the stores

Once the order picking is completed the requisitioner should be notified to collect the items from the issuing officer. It is important that the collecting official provides proof of collection authorization from the head of department/section. In some instances, product may be delivered to the facility, in which case proper records of delivery and receipt must be fully observed and documented.

d) Adjusting stock records

After the issuance process is completed, the transactions should be entered in the inventory records and the balances reduced accurately and promptly.

18.0 INSPECTION AND ACCEPTANCE COMMITTEE

18.1 Compliance with Regulation 17 of the PPD Regulations 2006

The Inspection and Acceptance Committee shall carry out its functions in accordance with Regulation 17 of the Public Procurement and Disposal Regulations. The essence of this committee's work is to confirm that what is being delivered by the supplier conforms to the specifications of what was ordered by the organisation and meets conditions to be accepted for pharmaceutical warehousing and distribution for use by patients.

18.2 Testing of pharmaceutical products

Pharmaceuticals should be sample tested where a consignment is large and it would take a considerable amount of time to carry out 100% inspection. PEs should note that not all pharmaceutical products are suitable for testing each time they are purchased e.g. rare drugs. Instead such products must be obtained only from manufacturers who have certified quality assurance procedures in place.

The emphasis however should be on ensuring that the manufacturer has followed appropriate quality control procedures and international standards e.g. those approved by WHO are followed throughout the manufacturing process. Manufacturers should also apply to relevant authorities in their countries of operation or apply to WHO to be awarded Good Manufacturing Practice (GMP) certificate. GMP is a recognised award in the medical supplies sector as an indicator of adherence to high standards of manufacturing, likely to yield good quality products.

The NQCL is the recognised authority in Kenya for testing pharmaceutical products for both manufacturers and PEs. However, PEs who may have small laboratories may conduct some limited and quick tests to verify simple pharmacopeia properties such as solubility of tablets and capsules before sending samples to NQCL for complex tests.

19.0 PROCUREMENT PERFORMANCE EVALUATION AND MEASUREMENT

19.1 The purpose of performance evaluation and measurement of procurement

Performance evaluation and measurement of procurement as a function is recommended with a view to ensuring that procurement services are continuously improved and that value for money is being achieved.

19.2 Key evaluation indicators

Performance evaluation and measurement should focus on understanding to what extent the internal customers are satisfied, understanding different factors that may be causing problems, focusing attention on priority areas when seeking solutions to problems and identifying new approaches to improving performance.

19.3 Performance measures and targets setting

a) The realistic and measurable targets for key performance indicators are to be developed by the Head of Procuring Entity.
b) The targets should be reviewed from time to time whenever circumstances warrant such reviews.
c) The areas to be covered when measuring the procurement units performance should be based on customer satisfaction in terms of:
    i. Timeliness;
    ii. Availability of supplies in terms of supply range, quality, continuity of supply;
    iii. Reduction of lead time in the procurement process;
    iv. Quality in terms of appropriateness to requirements; that is avoidance of deviations from quality;
    v. Cost reduction and cost avoidance; and
    vi. Customer service in terms of provision of information and technical support to customers and problem solving.

19.4 Evaluating and measuring supplier's performance

a) The supplier's performance may have a positive or negative impact on the Procurement Unit's overall performance. The same must therefore be incorporated into the performance management programme.
b) Performance gaps if identified will be communicated to the supplier(s) as feedback in order to improve performance by addressing and eliminating weaknesses. The aim should be to develop capable and reliable suppliers.
c) Suppliers who have not improved on their performance over time should be removed from the register of suppliers. Where suppliers breach a procurement contract or commit another serious malpractice, a PE should make a recommendation to the PPOA that the Director General should exercise his powers under section 115 of the PPD Act to debar such suppliers from future participation in procurement proceedings.
d) The Authority will maintain and make available to PEs a list of persons debarred from participating in procurement proceedings. PEs should not allow such persons or companies to put forward offers in response to tender opportunities.

20.0 DISPOSALS OF MEDICAL COMMODITIES

20.1 Compliance with the PPD Act and the Regulations

Disposal of Stores and Equipment that have been rendered unserviceable, obsolete and surplus is to be carried out in accordance with the provisions of Part X of the PPD Act 2005 and the Regulation 92 and 93 of the PPD Regulations 2006.

20.2 Other legal and regulatory requirements for disposal of medical commodities

20.2.1 The Health Sector PEs are required to follow the WHO guidelines and procedures for health care waste management which includes incineration as one of the alternative means of disposal to reduce the spread of diseases. The NEMA should be consulted to advice on limitation of the resultant environmental pollution arising from emission of dioxins and furans through incineration. For more details access the WHO website http://www.who.int/mediacentre.

20.2.2 Disposal of medical stores and equipment warrant special consideration on account of the broad spectrum of national and international statutory and regulatory requirements that govern packaging, handling, usage and eventual disposal of medical stores and consumables.

20.2.3 The relevant environmental laws and regulations on health and safety must be considered when choosing the method of disposal.

20.2.4 Although disposal by dumping and destruction maybe considered, incineration would be the preferred method for some types of hazardous materials to avoid contribution to environmental contamination in the course of the disposal.

20.2.5 Precaution should be taken to prevent or reduce any adverse effects likely to be experienced by the personnel handling the destruction and disposal process. The choice of a disposal method should take cognizance of the likely disposal risks and mitigate against them.

20.2.6 In case the decision of disposal by dumping or destruction is to be implemented by a third party, or another PE, clear instructions on handling of hazardous materials must be provided with the service contract. These instructions should include a requirement that all NEMA guidelines for safe disposal be adhered to.

20.3 Medical consumables and Equipment

20.3.1 The disposal procedures stated in this Manual do not include disposal of medical supplies classified as “disposables” which are subject to disposal after a single use such as surgical sterile and non sterile medical consumables.

20.3.2 If such medical consumable are rendered surplus, unserviceable or obsolete prior to their usage, due to expiry or due to changes in technology or deletion from approved medical products lists, the disposal decision making process shall be in accordance with the procedures set out in the Act and the Regulations.

20.3.3 For major medical equipment which can be disposed of through sale by open tender, auction, transfer to other public institution or trade-in, a valuation should be carried out to determine a realistic reserve price to ensure that the PE secures value for money. The procedures set out in the Act and the Regulations shall accordingly apply.

20.4 Disposal plan

20.4.1 A disposal plan shall be prepared by the PE as required in Regulation 7 (3) (w) of the PPD Regulations and be linked with the annual stocktaking program, procurement plan and the budget for disposals that would entail direct replacement.

20.4.2 The disposal plan should consolidate departmental disposal projections to reduce administrative costs. The accumulation should not encourage undue delay in disposal of items and should be within the Disposal Committee's frequency of meetings of at least once every quarter, as stated in Regulation 92 (3) of the PPD Regulations 2006.

20.5 Disposal Certificate

After implementation of the approved disposal method, a disposal certificate should be prepared and signed by members of the Disposal Committee.

21.0 REVISION OF THIS MANUAL

21.1 This Manual will be amended from time to time by PPOA to embrace emerging procurement best practices and major policy changes.

21.2 Any user of this Manual who has suggestions on areas which may need to be reviewed will notify the Head of the Procuring Entity in his/her organization.

21.3 The Head of the Procuring Entity should on a regular basis analyze emerging issues in the course of the implementation of the guidelines and procedures in this Manual and notify PPOA of any areas which may be considered for review.

21.4 PPOA will approve and control all amendments to this Manual and will indicate any changes to this Manual on its website (www.ppoa.go.ke).

21.5 The PPOA will from time to time issue the latest revised versions of this Manual for use by PEs.

22.0 APPENDICES

Appendix A: Stock Replenishment Requisition Form

Appendix B: Procurement Planning Template

Appendix C: Sample Bid Evaluation Templates for Pharmaceutical Products

C/1: Cream Ointments

C/2: Tablets

C/3: Capsules

Appendix D: Sample Supplier Appraisal Questionnaire

Appendix E: Tender /Quotation Opening Form

Appendix F: Price Comparison Schedule (Major Procurements)

Appendix G: Price Comparison Schedule (Simple Procurements)

Appendix H: Procurement Authorization Levels

Appendix I: The Threshold Matrix (For use of particular procedures and Segmentation of duties)

APPENDIX A: STOCK REPLENISHMENT REQUISITION FORM

No…….

To: Chief Procurement Officer Storehouse ……

Item No	Item Code No	Item Description	Unit of Issue	Re-Order Qty	Est. Unit Price	Estimated Amount	Monthly Usage Rate	Stock Balance	Procurement Action

Prepared by…….Designation…….Signed……..…Date……..……

Checked by…… Designation ……..Signed…….Date……...….

Approved by …… Designation …….Signed……Date……..….

APPENDIX B: PROCUREMENT PLANNING TEMPLATE

PART I: PRELIMINARY DOCUMENTATION

Ref No	Item	Priority	No of Units	Unit Price/ Cost	Total Cost	Procurement Method	Single/ Multi-Year	Aggregation	Budget Availability	Source of Funds
1.1 Planned										
1.1 Actual										
2.1 Planned										
2.1 Actual										

PROCUREMENT PLAN TEMPLATE
PART II: THE PROCUREMENT PROCESS TIMEFRAME

Ref No	Date Procurement Process must Start	Pre-Qualification	Bid documents preparation	Invitation of Bid	Bid Opening	Tender/ Proc Committee/ Award Notification	Contract Signed	Delivery/ Completion
1.1Planned								
1.1 Actual								
2.1Planned								
2.1 Actual								

APPENDIX C: BIDS EVALUATION TEMPLATES

(PHARMACEUTICALS AND CONSUMABLES)

C/1 CREAM OINTMENTS

No	ITEM NO.				
	PRODUCT DESCRIPTION				
	Product Evaluation	**Bidders Codes**			
1	Manufacturer				
2	Country of Origin				
3	Brand				
a)	**Organoleptic Properties**				
1	Sample Provided matches tender description, Dosage form is correct,				
2	Strength is correct				
3	Creams/ointment show smooth flow and consistency				
4	Creams/ointment have good rub in properties				
5	The cap has a piercing tip and easily penetrates the tamper seal				
6	Cream/Ointment has been packed in leak-proof, tamper proof collapsible metallic or plastic tube				
b)	**Labelling Evaluation**				
1	Batch number clearly show				
2	Date of manufacture is shown in clear language, not code				
3	Date of expiry is shown in clear language, not code				
4	All labelling and packaging inserts is in English.				
5	The INN or generic name is prominently displayed and above				

	the brand name, where a brand name has been given.				
6	The active ingredient "per unit dose, gram, volume ,etc." is given				
7	Applicable Pharmacopoeia or Compendia standards have been stated (State whether BP, Eur, USP, or IP)				
8	Instructions for use given on the label				
9	The phrase " Keep out of the reach of children" appears on the label				
10	The phrase " For External Use" appears on the label Address of manufacturer is shown				
11	Storage requirements have been specified on the label				
	Markings for batch number				
12	Expiry Date and Date of Manufacture cannot be easily erased from the primary pack				
13	Expiry Date and Date of Manufacture cannot be easily erased from the secondary pack				
14	Package insert/ Patient Information Leaflet has been provided				
	Registration status				
1	Product is registered with the Pharmacy and Poisons Board(PPB)				
	RECOMMENDATIONS				
	EVALUATION TEAM				
	Name	**Designation**	**Signature**	**Date**	
1					

2				
3				
4				

C/2 TABLETS

ITEM NO.

PRODUCT DESCRIPTION

1. Product Evaluation					
		Sample Codes			
	Evaluation Criteria				
1	Manufacturer				
2	Brand				
3	Country of Origin				
a. Organoleptic Properties					
4	Sample Provided matches tender description, Dosage form is correct, Strength is correct				
5	Tablets do not have an uncharacteristic odour				
6	Tablets are identical in size				
7	Tablets are identical in shape				
8	Tablets are identical in colour				
9	There are no defects on the tablet (spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)				
10	Tablet markings are identical (scoring, lettering, numbering)				
11	Tablets have a conventional colour				
12	Tablets are of conventional size				
Maximum Score					
Total Score					
% Score					
b. Packaging Evaluation					
1	Tablets are be packed in suitable polythene bags or blister pack laminated aluminium strips, packed in well closed and light resistant containers of appropriate size.				
2	The containers are tamper-proof and sealed.				
c. Labelling Evaluation					
1	Batch number clearly shown				
2	Date of manufacture is shown in clear language, not code				
3	Date of expiry is shown in clear				

	language, not code			
4	Name of manufacturer is shown			
5	Address of manufacturer is shown			
6	All labelling and packaging inserts is in English.			
7	The INN or generic name is prominently displayed and above the brand name, where a brand name has been given.			
8	The active ingredient “per unit tablet" is given			
9	Applicable Pharmacopoeia of Compendia standards have been stated (State whether BP, Eur, USP, or IP)			
10	Instructions for use given on the label			
11	For drugs, the phrase “ Keep out of the reach of children” appears on the label			
12	Special storage requirements have been stated on the label			
13	Markings for batch number, Expiry Date and Date of Manufacture cannot be easily erased from the primary pack			
14	Markings for batch number, Expiry Date and Date of Manufacture cannot be easily erased from the secondary pack			
15	Package/patient information insert has been provided			

Maximum Score

Total Packaging & Labelling Score

% Score

Weighted Score

4. RECOMMENDATION

5. EVALUATION TEAM

	Name	**Designation**	**Signature**	**Date**
1				
2				
3				
4				

C3 / CAPSULES:

TECHNICAL EVALUATION

ITEM NO.

PRODUCT DESCRIPTION

1. Product Evaluation					
1	Manufacturer				
2	Brand				
3	Country of Origin				
4	Sample Provided matches tender description, Dosage form is correct, Strength is correct				
5	Capsules are identical in size				
6	Capsules are identical in shape				
7	Capsules are identical in colour				
8	There are no defects on the Capsule (spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)				
9	There are no empty capsules				
10	There are no open or broken capsules				
11	Capsule markings are identical (lettering, numbering)				
1. b Product Evaluation					
12	Capsules have a conventional colour				
13	Capsules are of conventional size				
2. Packaging Evaluation					
1	Capsules are be packed in suitable polythene bags or blister pack laminated aluminium strips, packed in well closed and light resistant containers of appropriate size.				
2	The containers are tamper-proof and sealed.				
3. Labelling Evaluation					
1	Batch number clearly shown				
2	Date of manufacture is shown in clear language, not code				
3	Date of expiry is shown in clear language, not code				
4	Name of manufacturer is shown				
5	Address of manufacturer is shown				

6	All labelling and packaging inserts is in English.				
7	The INN or generic name is prominently displayed and above the brand name, where a brand name has been given.				
8	The active ingredient “per unit Capsule" is given				
9	Applicable Pharmacopoeia of Compendia standards have been stated (State whether BP, Eur, USP, or IP)				
10	Instructions for use given on the label				
11	The phrase “ Keep out of the reach of children” appears on the label				
12	Markings for batch number, Expiry Date and Date of Manufacture cannot be easily erased from the primary pack				
13	Markings for batch number, Expiry Date and Date of Manufacture cannot be easily erased from the secondary pack				
14	Storage requirements have been specified on the label				
15	Package/patient information insert has been provided				

4. RECOMMENDATION

5. EVALUATION TEAM

	Name	**Designation**	**Signature**	**Date**
1				
2				
3				
4				

APPENDIX D: SAMPLE SUPPLIER APPRAISAL AUDIT QUESTIONNAIRE

NB: To be reviewed from time to time to address characteristics of various purchases

A	**COMPANY CONTACT DATA**		RATING
1	Company Name		
2	Nature of business		
3	Address		
4	Office telephone No.		
5	Office fax No		
6	Plant/Factory		
B	**GENERAL INFORMATION AND STRATEGIC CONSIDERATIONS**		
1	Date established		
2	Types of activities		
3	Owners etc		
C	**STRATEGIC CONSIDERATION**		
1	Strategic Vision		
2	Business Plan or programme		
3	Short-term objectives		
4	Medium-term objectives		
5	Long-term objectives		
6	Has corporate strategy been communicated to staff etc.?		
D	**FINANCIAL ANALYSIS**		
	D1. General financial information		
1.	Which is the company's financial year?		
2.	Which has been the companies turnover during the last 5 financial years		
3.	Are the company's financial statements given and attached to this audit?		
4.	Which are the company's financial objectives?		
	D2 Financial Ratio		
	D2.1 Profitability		
1.	What is gross profit as a percentage of turnover	$\frac{\text{Gross profit} \times 100}{\text{Turnover}}$	
2.	What is the Net profit as a percentage of turnover	$\frac{\text{Net profit} \times 100}{\text{Turnover}}$	
3.	What is turnover as a percentage of capital employed?	$\frac{\text{Turnover} \times 100}{\text{Capital employed}}$	
	D 2.2: Solvency		
1.	What is the current ratio?	$\frac{\text{Current Assets}}{\text{Current liabilities}}$	
2.	What is acid ratio?	$\frac{\text{Current asset – stock}}{\text{Current Liability}}$	
3.	What it the gearing ratio?	$\frac{\text{Long tern loans} \times 100}{\text{Capital employed}}$	
4.	What is stock turnover?	$\frac{\text{Cost of sales}}{\text{Average stocks}}$	
5.	What is the debtors' collection period?	$\frac{\text{Debtors} \times 365}{\text{Turnover}}$	
6	Cost control		
	Does the company undertake regular review of the cost and cost factors?		
	What cost factors are reviewed? Etc		
E	**PRODUCT DEVELOPMENT/R & D**		

1	E1 General information on product development R & D		
	Is there a department or team in charge of suggesting new products ideas or improvement of existing product? Give details etc.		
2	E2: Design Control		
	Is there an established procedure for verifying design to ensure that the relevant technical specifications are met?		
.	How are designs requirements identified, documented and reviewed for adequacy?		
F	**PROCUREMENTAND GOODS INWARD**		
1	Procurement & Supply Management		
2.	What are the company's total expenditure in Procurement of goods and services in the last financial year		
2	Does the company have a Procurement policy		
3	Is there Procurement Manual outlining relevant procedures?		
G	**PRODUCTION**		
1.	Is there a documented production procedures		
2.	What are the types of production machinery		
3.	What manufacturing system and procedures are in place for production processes		
4.	Give an account of in process inspection and quality control		
5.	What procedure is available for handling, storing and preservation of finished products?		
6.	Is there packing and shipping procedures? Explain.		
H	**SALES AND CUSTOMER SUPPORT**		
	General sales information		
	Provide the following information		
1	Sales turnover		
2	Competitions		
3	Main market segments		
4	Sales infrastructure and arrangements		
5	After sales services and customer support		
I	**QUALITY MANAGEMENT SYSTEM**		
	Give an account of the following		
1	Continuous improvement quality system in place		
2	Quality certification and accreditation		
3	Documentation control		
4	Does the company have laboratory facilities for testing products?		
5	How are these facilities allocated to different product? Etc.		
6	Is there an environmental policy? Give details		
J	**GOVERNANCE ISSUES**		
1	What is the social policy practice in force?		
2.	Is there an ethics policy and practices guideline in place?		

APPENDIX E: TENDERS/ QUOTATIONS OPENING FORM

TENDER /REQUEST FOR PROPOSALS (RFP)//EXPRESSIONS OF INTEREST/ QUOTATION NO……. (Delete as appropriate)

FOR SUPPLY OF……

Bidders identification			Prices as read out		Modification or Comments
Names	Address	Country/ Town	Currency(ies)	Amount	

Names of Opening Committee members

Name……Designation…….Signature……
Name……Designation…….Signature……
Name……Designation…….Signature …….
Name……Designation…….Signature…….

Date…… Time ……

APPENDIX F: PRICE COMPARISON SCHEDULE (MAJOR PROCUREMENTS)

TENDER/RFP/QUOTATION NO……FOR SUPPLY OF…….

ITEM NO……..DESCRIPTION……QUANTITY…….....

Bidders No	Unit Price as read out	Corrections		Corrected Bid Prices	Unconditional Discount		Corrected/ Discounted Bid Unit Price	Amount {Qty x Coln.(h)}
(a)	(b)	Computation Error (Amount) (c)	Provisional Sum (d)	(e) (e)=(b)+/- (c)-(d)	% (f)	Amount(s) (g)	(h) (h)=(e)-(g)	

Scheduled by……Signature……..Date……

Checked by…….Signature……...Date…….

APPENDIX G: PRICE COMPARISON SCHEDULE (SIMPLE PROCUREMENTS)

TENDER/RFP/QUOTATION NO …… FOR SUPPLY OF……

Item No	Item Description	Qty	Bidder No1		Bidder No2		Bidder No3		Bidder No4		Bidder No5	
			Net Price	Amt	Net Price	Amt	Net Price	Amt	Net Price	Amt	Net Price	Am

Scheduled by……Signature……..Date……

Checked by……..Signature…….Date…….

APPENDIX H: THRESHOLDS GOVERNING PROCUREMENT METHODS

(*AS PER SECTIONS THRESHOLD MATRIX IN THE PPD REGULATIONS)*

The Threshold Matrix in First Schedule of the Public Procurement and Disposal Regulations 2006 which spells out the minimum and maximum levels of expenditure for use of particular procurement and segmentation of duties for different officers and committees in the procurement cycle under Section 26(3) (c) of the PPD Act 2005 shall be used as stipulated by different classes of procuring entities.

This document was produced with assistance from the American people