Sudanese Medical Specialization Board
Pharmacy Specialization Board

Assessing Blood Bank Items Procurement & Supply Management System In Central Medical Supplies Sudan August- 2008- August 2011

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Chapter One

Dedication

It is a pleasure to me to dedicate this search to my Treasure Mom & Dad , Dear bothers & sister , Mother &Father -in - law & to my small family.

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Also it is a honor to dedicate this humble efforts to my dear CMS.

* * *

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Abbreviations

CMS	Central Medical Supplies
GDP	Gross Domestic Product
NDP	National Drug Policy
BB	Blood Bank
BBI	Blood Bank Item
PSM	procurement and supply management
M&E	Monitoring & evaluation
WHO	world Health Organization
GF	Global Fund
ARV	Anti-Retroviral Drugs
NLED	National List OF Essential Drugs
F	Forecasted
P	Procured
C	Consumed
LTP	Last Tender Price
MLP	Mean Local price
GM	Good Manufacturing Practice
GSP	Good Storage Practice
DRA	Drug Regulatory Authority
AV	Available months
NGO	Nongovernmental Organization
MOH.	Ministry of Health
MOF	Ministry Of Finance
TTS	Transfusion Transmitted Diseases

Abstract

The procurement and supply management (PSM) system is essential in the provision of quality healthcare **.** It should guarantee the timely supply of good quality, affordable medicines . Often when the supply system of the blood bank requirements is not functioning properly , will lead either to serious hazards concerning TTS and blood compatibility problems in case of shortages , or to expired products and waste of funds in case of oversupply **.**

Assessment of the procurement and supply management system is required to measure the performance of all PSM activities. This study was conducted in Central Medical Supplies Sudan to assess the procurement and supply management system of Blood Bank Items for the period August 2008-August 2011 supplied by CMS to the Central Blood Bank .

The study concluded that the procurement and supply management system for BBI was acceptable in 65% of the items , and below the desired in 35% of the items **.** It was found that these items were absent on the WHO model medicines list 2010 , since no medical devices and consumables model list is available that could aid in setting proper specifications . Forecasting was below the required but it was compensated by partial ordering practice , procurement was altered by the shortages in reliable supplier affecting the availability by delaying items arrival in full quantities in time , also shortages in reliable supplier decreased competition and increased procurement price .CMS had an efficient stock keeping record system .Funds supplied by MOH & MOF on behalf of the Blood Bank were insufficient . Current managerial reforms will guarantee future procurement and supply system progress .

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CHAPTER ONE

INTRODUCTION & LITRATURE REVIEW

1.1. Sudan Background Information:-

Sudan, although considered as a country rich in natural resources, is classified as an underdeveloped country**.** In 2003 the Human Development Index for Sudan was 0.503, ranking it at number 138 out of 175 countries. The Human Poverty Index in 2003 is 32**.**7%, ranking Sudan 52 among 94 developing countries (1) . Low commitment of the government to health care services is reflected in the low percentages of GDP spent on health care through the last four fiscal years and the partial execution of the approved budgets (except the 2004 budget, which is still beyond commitment)**.** The per capita spending is below what has been mentioned by the World Bank as the minimum acceptable amount of 6 US$ (2) **.** Despite the relative progress in the growth rate in the health care budget which indicates a promising shift in government attitude towards health care financing (2) **,**although the government in 2004 exceeded the estimated budget**,** the per capita expenditure is still below the targeted one which underlines the weak capacity of the Ministry of Health in estimating the health budget**.** This is clear in the budget allocated to the free medicines program , where the Blood Bank Items were financed**.**

Sudan National Drug Policy (NDP) was established in1983**.**The goals of the NDP is to use available resources to develop pharmaceutical services so as to meet the requirements of all Sudanese in the prevention**,** diagnosis and treatment of diseases using efficacious**,** high quality, safe and cost effective pharmaceutical products (3)**.**The NDP mainly promotes the essential drug concept and rational use to ensure constant availability and affordability of safe and effective drugs to all segments of the population (3) **.**

1.2. CMS:

CMS is responsible for facilitation of the major part of health care in the Sudan**,** by means of availing medical supplies including Blood Bank Items **.** It is the national center for selection**,** procurement**,** storage and distribution of medical supplies **.**CMS was established in 1937**.** In February 1991 CMS became a **"**Public Organization**"** under the Organization Act **.** 1991**"** which allows CMS to exercise the maximum possible autonomy within the framework of the Government of Sudan select, procure, store and distribute medicines and medical equipment

to public and private sector (4). Considering the Free Medicines Programs as top priority medicines for CMS to make available including Blood Bank Items. CMS has the obligation to exercise maximum skill, efficiency and diligence in filling these roles to safeguard that medical supplies reach their destination at the right moment .

1.2.1CMS Goals:

CMS aims to avail, store and distribute drugs, consumables and medical equipments in the right quality, right time and the right price to all the population. To achieve customer satisfaction CMS applied total quality system complying with the international quality requirements ISO 9001, publication 2001. CMS aims to satisfy all parties concerned with the availability of medicines for the population. CMS always assures the sustainable improvement of its employees by continuous technical and managerial training. CMS seeks to improve the quality system by assigning aims and plans and manages to achieve them in the scheduled time.

CMS always comply with laws and regulations dealing with medicines and cosmetics (Translated from CMS Quality Policy).

1.2.2. General Policy:

To fulfill its roles in availing blood bank items , CMS appointed many committees to direct and regulate its operating system. These committees are:

1. Drug committee:

It is headed and appointed by the Director General of CMS, represented by heads of the departments at CMS(4). It is responsible for determining the annual procurement schedules in accordance with the approved budget , determining methods and ways for procurement (Open tender, limited bidding, direct purchase, local procurement, re-ordering from last supplier, etc..) , approval of the specifications and quantities as determined by the blood bank managers , handling of difficulties, problems and non-compliance and claims of any nature in coordination with blood bank representatives at different stages of procurement, supply, delivering, storing and distribution which may be arising by CMS or by the suppliers.

2. Permanent Committee for Tendering of Blood Bank Items : The following members are represented in the committee :

- Different departments in CMS.
- National Drug Quality Control Laboratory.
- Blood Bank Representatives .

- Representative from Ministry of Finance**.**
- Drug authority**.**

It is responsible for selection of the suppliers of blood bank items required for each item separately. This primarily depends on the compliance of the supplier to the all declared conditions of the tender and secondly it depends upon the best price given by the supplier (4) .

1.3. Blood Bank:

Blood bank was constructed for the first time in the sixties, fife decades ago, inside Khartoum Teaching Hospital , until 1999 it was the blood bank for Khartoum state .After that it is upgraded to the National Directorate of Blood Bank which include Blood Transfusion Services section & Hemophilia section as a part of the laboratory directorate .Then in 2003 it was transferred to the National Laboratory which was under the umbrella of General Directorate of Treatment Medicine .In 2005 it was transferred to the General directorate of Treatment Medicine directly & contained the following sections : Voluntary Blood Donation section , Serological section ,Blood Derivatives section ,Blood Transmitted Disease section , Storage Section & Statistics section .

Regional blood banks are fifteen Khartoum , River Nile , White Nile, ,Blue Nile, , El-Gezira , Sinnar , El-Gadarif , Kasala, Red Sea, Dongola, Northern Kordofan , Southern Kordofan, North Darfour, South Darfour, West Darfour. Seven of these regional blood bank units, out of the fifteen, have been constructed as branches for the central blood bank in Khartoum, in North Kordofan, Dongola , EL-Gadarif, El-Gazira , Kasala & The Red Sea . Other branches in other states are going to be constructed. The construction of these branches was aided by donation from WHO -UNDP. Before these regional branches, there were blood bank units in each public regional hospital. All these branches are under the control of the National Central Blood Bank .Supplies are procured centrally and delivered to the states according to their needs.

1.3.1. National blood policy in Sudan & technical recommendations:

The national Blood Transfusion aims to upgrade blood transfusion services as one of the component of the overall health care for the secondary and tertiary level .This policy depended on the national strategic plan for the coming twenty five years .It also depended on the WHO blood transfusion services recommendations (5).

1.3.2. WHO Recommendations on Blood Transfusion:

Blood transfusion is one of the life-saving interventions that have an essential role in patient management within health care systems. WHO recommends the following integrated strategy for the provision of safe blood and blood products and safe, efficacious blood transfusion (6).

1-Establishment of well-organized blood transfusion services that are coordinated at national level and that can provide sufficient and timely supplies of safe blood to meet the transfusion needs of the patient population.

2-Collection of blood from voluntary non-remunerated blood donors at low risk of infections that can be transmitted through blood and blood products, the phasing out of family/replacement donation and the elimination of paid donation.

3- Quality-assured screening of all donated blood for transfusion transmissible infections, including HIV, hepatitis B, hepatitis C. *Treponemapallidum* (syphilis) and, where relevant, other infections that pose a risk to the safety of the blood supply, such as *Trypanosomacruzi* (Chagas disease) and *Plasmodium* species (malaria); as well as testing for blood groups and compatibility.

4-Rational use of blood to reduce unnecessary transfusions and minimize the risks associated with transfusion, the use of alternatives to transfusion , where possible , and safe clinical transfusion procedures.

5- .Implementation of effective quality systems, including quality management , the development and implementation of quality standards, effective documentation systems, training of all staff and regular quality assessment.

6-The establishment of systems to ensure that all donated blood is screened for transfusion transmissible infections is a core component of every national blood program. Globally, however, there are significant variations in the extent to which donated blood is screened, the screening strategies adopted and the overall quality and effectiveness of the blood screening process. As a result, in many countries the recipients of blood and blood products remain at unacceptable risk of acquiring life-threatening infections that could easily be prevented. Each country should formulate a national blood policy and plan, as part of the national health policy, to define how safe blood and blood products will be made available and accessible to address the

transfusion needs of its population, including how blood transfusion services will be organized and managed.

7-National health authorities and blood transfusion services are responsible for ensuring that relevant policies, standards, strategies, systems and infrastructure are in place for the screening of all whole blood and apheresis donations for TTIs prior to their release for clinical or manufacturing use.

1.4. The Procurement and Supply Management (PSM) System:

The procurement and supply management (PSM) system is essential in the provision of quality healthcare (7)**.** It should guarantee the timely supply of good quality, affordable medicines. Often when the supply system of the blood bank requirements is not functioning properly , will lead to serious hazards concerning TTS and blood compatibility problems in case of stock outs and oversupply leading to expired products and waste of funds **.** Assessment of the procurement and supply management system is required to measure the performance of all PSM activities.

The information provided by the Assessment should feed into the decision making process and lead to prevention or correction of (upcoming) problems . There is considerable interest in the development and use of indicators as tools in health care to monitor the quality and performance of health services **.** Use of these tools can assist countries in monitoring progress in program implementation**,** evaluate performance objectively and revise strategies on the basis of systematic assessment**.** Improved assessment can contribute significantly towards better planning and management of the supply chain for BBIs in order to promote efficient and sustainable access to blood transfusion services **.**

The same assessment was applied for the HIV/AIDS pharmaceutical supply management systems by the RTRC (The Regional Technical Resource Collaboration for Pharmaceutical Management) in four countries. The assessments sought to determine the capacity of the health care systems of the four countries to select, quantify**,** distribute and appropriately use ARVs and related commodities; determine the categories of health care workers involved in the supply chain management of HIV/AIDS pharmaceuticals**;** and assess their knowledge, skills and practices**.** The results of the assessments showed that problems with ART commodities-supply management existed widely in Kenya, Rwanda, Tanzania and Uganda. These problems ranged

from the inability of the existing systems to adequately handle scale-up programs due to lack of readiness of the workforce to efficiently use and manage large supplies of antiretroviral**,** including insufficient capacity to quantify needs and distribute the medications and inappropriate medication-distribution practices **.** limited skills were cited as the main reason for the identified problems in all four countries. There was thus a need to build skills in HIV/AIDS pharmaceutical supply management in all four countries**.** Skills-building processes that include local institutions were preferred **,** as these would cover wider geographical areas**.** These were also regarded as more sustainable **.**

Daniel G et al conducted pilot assessment of supply chains for pharmaceuticals and medical commodities for malaria, tuberculosis and HIV infection in Ethiopia .To obtain preliminary data on the drug supply management system in Ethiopia, selected facilities were assessed for the availability of essential drugs and commodities for malaria, TB and HIV. Of the 48 surveyed hospitals and health centers, 9 (19%), 9 (19%) and 10 (21%) did not have malaria, TB or HIV drugs, respectively. Similarly, of 27 health posts, 9 (33%) and 6 (22%) did not have rapid diagnostic tests and anti-malarial drugs, respectively. The findings indicated an inadequate availability of essential drugs and commodities in the surveyed facilities as well as weaknesses in human resources and training. Assessments of commodity supply chains to ensure operational program success and impact are important.

1.4.1. Procurement plan:

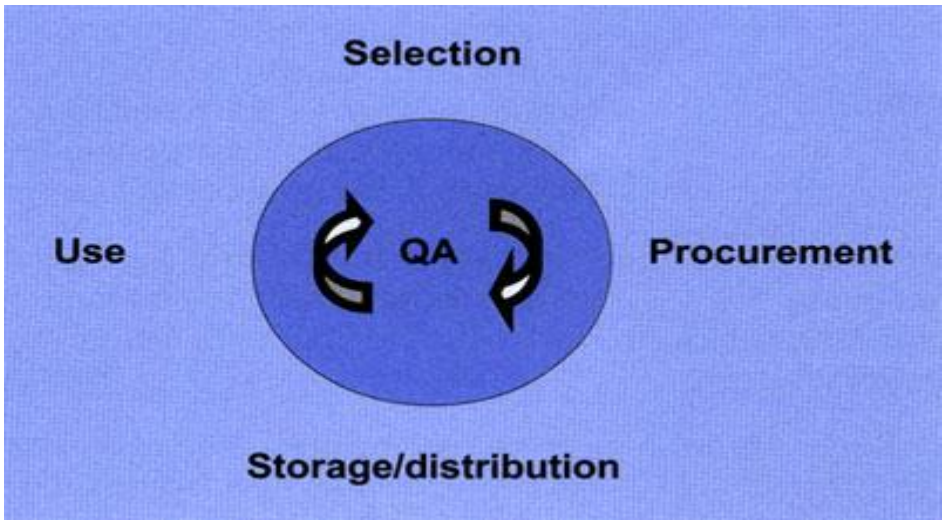
To make good procurement plans**,** it is important that one is familiar with what takes place during procurement planning**.** The following activities are essential: Selection, forecasting/quantification, costs (funding, timing, procurement methods), prioritizing, monitoring and evaluation .

The procurement plan of the blood bank items was started by defining the items with accurate specifications and quantities required by the blood bank , estimating prices for these items to identify total budget required to procure these items . A good Procurement Plan will go one step further by describing the process you will go through to appoint those suppliers contractually (8). Finally, schedule the timeframes for delivery .The plan will also be used to measure performance during implementation (9). .By planning your procurement carefully, you can ensure that you buy the right products for your business, at the right price (9).

1.4.2. Supply cycle:

The supply management cycle has several components that follow each other in a logical manner with the output of the previous element being an input of the next element**.** The cycle is supported by management support system, without which the cycle would collapse. Medicine management functions are performed within a policy and legal framework that establishes and supports public commitment to provide essential medicines to those who need them **.** The national drug policy is a guide for action that contains goals set by the government for the pharmaceutical sector **,** their importance and main strategies for achieving them It is aimed at making essential medicines available and affordable to all who need them**,** ensuring safety**,** efficacy and quality of all medicines in the public domain**.**

Figure(1.1): The Supply Cycle .



From WHO the Practical guidelines on Pharmaceutical Procurement

The Supply cycle include:

1.4.2.1-Selection& Quantification:

Selection of items in the central blood bank involves reviewing World Health organization recommendations on blood safety & the National Blood Policy , identifying medicines and medical supplies of choice, and decide which one will be available. Then identifying accurate required specifications through reviewing pharmacopeias Selection of BBI for optimal use is important not only from a medical point of view but also to optimize use of funds for pharmaceuticals. The possible methods of product quantification include the consumption

method**,** the morbidity method, and the adjusted or extrapolated consumption method**.** The consumption method uses records of past consumption of individual pharmaceutical product and it is the predominate method of quantification in the central blood bank . All requests for products should include quantities and required delivery dates (10) .Larger quantities may encourage competition and lead to more competitive drug prices (11). The latest update of the BBI list was in 16-5-2011 according to the coordinating meeting between CMS need assessment department and blood bank representatives to select & quantify needs for Blood Bank items to be supplied for the coming two years . The selected items include diagnostics like sera for blood grouping ,Rapid tests and confirmatory Elisa tests for HIV, HBV,CV, Syphilis, in addition to drugs used for hemophilia like factor VIII, factor IX**,** tranexamic acid and desmopressin nasal spray . Also include consumables like single blood bags, triple blood bags and blood transfusion sets .There are also laboratory instruments that is supplied by other companies like safety box ,plastic plain container and other instruments which are not included in this study. For blood screening tests (8 items) CMS committed to avail these items in the limited bid held in February 2009 while the study period from august 2008 to august 2011, already availably item have 36 month to be available while the screening kits 30 months ,started on February 2009 to august 2011**.** Other items on the updated list not included in the study because these items have not been supplied on the three previous years and have no data on their supply**.**

1.4.2.2. Procurement:

Procurement is defined here as the process of purchasing supplies directly from national or multinational private or public suppliers(12). Continuity in the supply of the assays, reagents and consumables required for testing depends on reliable procurement and supply systems (6). Strategic objectives of good pharmaceutical procurement are the procurement of most cost effective medicines in the right quantities, selection of reliable supplier of high quality products and ensure timely delivery by using a clear and enforceable contract and achieving the lowest possible total cost .

Procurement is acyclic process whose steps are**:** Collecting information on consumption**,** reviewing drug selections**,** determining quantities**,** reconciling needs and funds**,** choosing the procurement method**,** locating and selecting suppliers, specifying contract terms**,** monitor order status**,** receive and check drugs**,** making payment and finally distributing drugs**.**

CMS was committed to avail all free medicines program for the governmental sector. BBI is a part of this program , since CMS procure these items for the Central Blood Bank where these items are distributed to all regional blood banks all over Sudan .The implementation of centralized bulk procurement with an efficient distribution system is likely to provide significant cost savings, simplify stock management and enable an uninterrupted supply of assays and reagents to be maintained (6). The financial supply for these items is a part of the free medicine program allocated from the ministry of finance and transferred to the ministry of health or directly transferred to CMS from the MOF. It is injected from MOH monthly bypassing blood bank.

The predominant type of purchase is tendering which is done every two years except for certain cases where the awarded company apologizes or increases the price, in this case the direct purchase from other supplier is the only choice to avail these items.

1.4.2.2.1Procurement methods for blood bank items :

1- Restricted tender.
2- Competitive negotiation.
3- Direct procurement.
4- Open tender.
5-Establishment of regional pooled procurement methods under the the supervision of WHO (proposed) .

Table (1.1): Comparison of the procurement method

Method	Effect on Price	Lead Time	Work Load
Restricted Tender	Usually lowest prices	Moderate to long	High
Open Tender	Favorable	Moderate to long	High
Competitive Negotiation	Can be favorable	Short to moderate	Moderate
Direct Procurement	Usually highest prices	Short to moderate	Low

1.4.2.2.2. Characteristics of an Efficient Procurement System

An efficient procurement process is key to health services delivery**.** It is important that indicators are developed and constantly monitored **.** Examples of such indicators include but are

not limited to existence of Standard Operations Procedures (SOP) for all procurement activities, procurement plan, identified procurement process risks and their mitigations procedures .

In addition, always consider the following good procurement practices. Use of generic names ,there is no doubt that if we start from the basis that generic drug is bioequivalent to an innovative one ,and also means a major saving for health system , then it should be the first choice (13).Other important issues in procurement practice are limited to essential drugs list or formulary list , bulk purchases by establishing pooled procurement mechanisms , separation of key functions , formal supplier qualification and monitoring, (using indicators like: tracking lead time, contract compliance , partial shipments, expiry dates, packaging and labeling) , competitive versus sole-source commitment ,ordered quantities based on reliable estimate of actual need, reliable payment and good financial management, transparency and written procedures, product quality assurance program**,** selection of reliable suppliers and drugs, use of existing mechanisms, such as the WHO certification scheme, product problem reporting **,**targeted QA testing, annual audit with published results and Regular reporting on procurement performance**.**

Standards of Procurement

For an effective procurement process, all the stakeholders need to speak the same language and follow the same rules in a give setting. As such, there has to be clear and uniform ;such as definition of words used and stakeholders in the procurement process, standard Terms and conditions and standard instructions to bidders .

1.4.2.2.3 Prequalification

Prequalification is one of the key elements in ensuring purchase and supply of pharmaceutical products of acceptable quality (10) . The prequalification process can be subdivided into two major parts, i.e. product-related assessment and supplier related assessment .

Product-related assessment

An important issue considered as a part of the prequalification which should be requested for products intended for bidding , is the Products Certificates based on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce otherwise known as the WHO Certification Scheme . These certificates confirm that the products have been manufactured according to current GMP standards and that the manufacturer has been inspected by the national DRA and the products are approved for marketing in the country of origin. It further certifies that all written product information has been approved by the national

DRA. For products not approved for marketing in the country of origin, the reason(s) must be given.

Supplier related assessment:

Pharmaceutical products are supplied by:

• Manufacturers

• Trading houses/wholesalers

• Local agents

The advantages and disadvantages of each type of supplier were expressed in the following table:

Table (1.2):Comparison of the Different types of suppliers

Type of supplier	Advantages	Disadvantages
Local agent	Easy and fast communication.	Higher prices, more difficult communication on technical issues.
Wholesaler	Easy and fast communication, stocks on hand.	Higher prices, more difficult communication on technical issues.
Manufacturer	Lower prices, easy communication on technical issues.	

Prequalification of suppliers establishes the profile of pharmaceutical companies(14) . Prequalification is a procedure to qualify products or suppliers and limit consideration of bids or proposals to only those products or suppliers which have been prequalified (15) . Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process that considers product quality, service reliability, delivery time and financial viability (9) . It is important to monitor and evaluate performance of past supplier ,and product quality and supplier reliability for new supplier .New supplies can be evaluated through formal supplier registration ,visual inspection and laboratory analysis , product specifications or bioequivalence study report ,test purchases and informal information.

Before invitations for bids are requested, a system for prequalification of suppliers and monitoring of their performance should be established(14). Prequalification is usually open to any interested supplier (14) . The purpose of the prequalification is to ensure that the company in question is a registered one, that the products offered are manufactured in compliance with Good Manufacturing Practices (GMP) as recommended by WHO and that marketing authorization in the country of origin has been obtained for the products offered.. The manufacturer must be capable of routinely carrying out the activities to the specified standards to ensure batch-to-batch consistency of the product (10) .

Be alert if :

- The company manufactures only for export .
- The company export only to developing countries .
- The company's product list exceeds 200 products.
- The company offers products manufactured only occasionally
- The company has no quality control laboratory .
- Stability studies have not been conducted .

Tools for prequalification of suppliers:-

- Obtaining supplier information through the use of questionnaires (annex2).
- Using the WHO Certification Scheme .
- Seeking information from the drug regulatory authority of the exporting country .
- Using existing networks for information exchange between drug regulatory .Authorities :WHO Electronic Discussion Group for Drug Regulatory Authority (WHODRA) ,Drug Information Exchange for Pacific Island Countries (DIEFPIC) .
- Evaluating product samples .
- Monitoring and recording the performance of the suppliers .

Prequalification does not guarantee that a particular supplier will receive a contract or award, but rather qualifies a supplier to submit a bid or propose a solution for a specific solicitation under agreed-upon terms and conditions (15) .

There are three basic means of locating qualified suppliers, direct inquiry which could be done to local or foreign suppliers and the quickest means of obtaining an offer, another means is the open tender which can be done through both local and international newspaper, notices trade directories and journals, as well as foreign representatives in local diplomatic missions and government agencies responsible for foreign trade .The third one is contracts with international agencies such as world health organization (WHO), world bank (WB) and united nation children's fund (UNICEF) may be helpful in establishing contract with potential international suppliers. These are especially helpful for procurement offices with little international experience.

Comparing quotations is also useful for comparing identical products from different suppliers , not only coated price is considered but also other costs like shipping , transportation, insurance ,storage cost, port clearance, replacement costs and cost of laboratory analysis.

1.4.2.3. Distribution:

Distribution is the process of getting supplies from source (manufacturer, supplier) down to the consumer .The primary distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed while ensuring that resources are used in the most effective way(12) .It is aimed at maintaining a constant supply of medicines, maintaining quality of medicines through the distribution process, minimizing losses (due to expiry, pilferage, damage) ,rationalizing storage points ,efficient use of available transport ,and providing information for forecasting medicine needs. Efficient supply should minimize the risk of stock-outs through effective management of procurement and logistics systems, which should include (but are not limited to) appropriate economic order quantity, buffer stock, procurement period, storage capacity . These procedures should include the establishment and maintenance of reliable inventory management, first-expiry/first-out stock control systems, internal audit systems, and good governance structures. and conditions and product demand.

Distribution is acyclic process whose steps are drug procurement .port clearing, receipt and inspection including quality control ,inventory control ,storage ,requisition of supplies ,delivery and reporting on issued quantities .Distribution can start at any stage depending on who is responsible for which part of the medicines supply cycle. This in turn depends on the source of the medicines and medical supplies and the procurement contract terms.

CMS has reliable cold chain systems. BBI should always be transported and stored in accordance with the manufacturers' instructions. Most test kits and sera require storage within a specific temperature range, usually between +2°C and +8°C. Transportation at ambient temperatures may be acceptable for short periods of time and in moderate climates. In climates with extremes of hot or cold, test kits and sera should be transported under fully controlled conditions at specified temperatures, such as between +2°C and +8°C. Appropriate temperature-controlled storage equipment which conforms to defined specifications should be made available for normal maximum stock of all test kits and reagents (6). Sufficient space should be maintained to permit adequate air circulation (16) .CMS has sufficient capacity to store BBI in good storage conditions since CMS follow GSP. BBIs are only distributed to the central blood bank which on turn distributes them to the blood bank units and branches.

The BBI list include twenty six items all of them were considered unregistered, but they can be imported by permission from the NMPB .Fife of them were drugs and twenty-one were consumables. To ensure that the procured products are safe and effective, certain quality requirement should be submitted for NMPB to give the permission for importation. For drugs this could include license of manufacture, free sale certificate in country of origin, detailed composition formula, detailed method of analysis ,batch certificate of analysis for the finished product, reference standard if needed by the national laboratory & product labeling should include quantity, indication and direction for use, precautions and hazards if any, storage condition, manufacturing & expiry date .Consumables are not registration, but instead the permission of importation is given when the following requirements is availed:

1- Preliminary importation permission requires:- Request from the importing company including the manufacturing company & the country of origin .Performa Invoice containing the items to be imported ,catalogue illustrate the items to be imported ,Free Sale Certificate &License of Manufacture.
2- Port Clearance permission: Request for port clearance from the importing company ,final performa & shipping documents.
3- Packing List ,certificate of origin &certificate of Analysis: The pharmaceutical regulatory and quality assurance processes that should be addressed by county's DRA include (WHO 2004b)-

4- Product registration :assessing and authorizing products for market entry and monitoring their safety and effectiveness after entry.

- Regulation of manufacturing , importation and distribution

- Quality of manufacturing (good manufacturing practices).
- Procurement integrity (assuring the qualifications of suppliers).
- Quality of medicines in the distribution system (including product and premises inspection and product screening and testing).

- Regulation of medicine promotion and information: including post marketing pharmacovigilance and consumer education.

1.4.3 Capacities Required to Conduct PSM:

At the heart of the medicines management cycle, the management support systems for each of the basic functions, without which the cycle would collapse and it represent the quality assurance system for the supply system .

1.4.3.1. Management Capacity:

1.4.3.1.1 Organization Management:

Every organization requires managerial leadership in order to accomplish its objectives. Organization is generally defined as a group of people working together in a unit to achieve certain goals. A manager provides the dynamic force or direction that combines static resources in to a functioning, productive organization. He is the man in charge, the one who is expected to get results and to see that things happen as they should. The manager is not only blamed for failure but also credited with success. The problems of leadership and management have increased in complexity during the recent decades. A number of factors have contributed to this growth in the difficulty of management .One factor is that of size .Due to this complexity and rapid growth in today organizations it becomes difficult for one manager to administer such organization by himself .In this sense participatory managements becomes important and unavoidable. Another reason for the increasing difficulty of management is the more extensive specializations of the labor and greater complexity of work that is involved in the typical modern organizations.

To day managers must manage in a world of accelerating change. The acceleration in the rate of innovation has altered the requirements for managerial success .Managerial awareness of the nature and significance of change is of primary importance.

1.4.3.1.2 Human Resources management

The efficacy and effectiveness of an organization largely depends on the capacity and capability of its human resource .As such human resource managers should possess sufficient knowledge and skills on human resource management to manage employees in their organization as well as exercising their influence in deciding the quality and quantity of human resource at both the entry and operational levels since people are the main key resource for an organization. Therefore there must be adequate number of competent employees with needed skills, abilities, know how and experience to further organizational goals. HRM depends on integrating the importance of human resources into the organization's strategic policy and planning to ensure that all line mangers adopt its principles as part of their every day work.

1.4.3.1.3. Documentation of policies and standards:

Documentation is a critical part of a quality assurance system(10). Policies and standards explain how the organization can achieve its objectives . The procurement agency should have a comprehensive documentation infrastructure, which should include policies, guidelines, norms, standards, manuals, procedures, records and related documents.

1.4.3.1.4. Quality manual

The procurement agency should have a quality manual. The purpose of such a manual is to document the quality policy as defined by management in relation to the various activities undertaken by the procurement agency(10). There should be policy statements and a quality policy in terms of the agency's activities and objectives, as well as documents describing the policy of each section or department with regard to all activities in prequalification and subsequent purchasing, storage and distribution. Once this quality policy is defined, it should be implemented, maintained, reviewed and amended as necessary at regular intervals by the procurement agency(10).

1.4.3.1.5. Standard operating procedures:

The procurement agency should have written, clear and detailed standard operating procedures (SOPs) for all the activities to be performed in the procurement agency.

1.4.3.1.6. Guidelines on conflict of interest

The procurement agency should have a policy on conflict of interest, which all personnel should observe and be sighed.

1.4.3.1.7. List of prequalified products and manufacturers

The procurement agency should have a procedure for drafting and maintaining a list of prequalified products and manufacturers, based on the outcome of the evaluation of product data and information and manufacturing site inspections. The list should be product- and manufacturing site-specific, i.e. sites are prequalified for one or more specified products, and products are prequalified as manufactured at specified sites.

The key person responsible for prequalification should be responsible for addition to and/or deletions from the list. Once the evaluation of a product dossier is complete, and the inspection has been performed to assess compliance with good manufacturing practices, good storage practices and good distribution practices as appropriate, the procurement agency should prepare a list reflecting the status of the prequalified products and manufacturers.

The list should contain at least the following information: name of the procurement agency; authorization signatures; reference number and version of the list ;date of preparation of the list; name and physical address of manufacturer, including the approved site(s) of manufacture linked to each product; contact details, including postal address, telephone, fax number and e-mail address of the manufacturer and supplier .product details, including the brand name, INN, dosage form, strength per dose and pack size; date of original prequalification; date of expiry of the prequalification; and date until which the list is valid.

1.4.3.1.8. Maintenance of records:

Records of all operations should be maintained and kept in a suitably organized manner(10). Sufficient areas for the storage of records, including product information, manufacturers' information and inspection reports, should be available .Access to these areas should be restricted to authorized personnel only, as confidential information may be filed (including records of manufacture, testing and/or storage). Records should be maintained for a defined period of time, in accordance with national legislation. Generally they should be retained for at least one year beyond the expiry date of the finished product.

1.4.3.1.9. Financial management:

The component of the financial sustainability can be brought into better balance by increasing financial resources (13) . The procurement agency should be able to effect national and international financial transactions as required. Funds must be available to ensure continued

operations, whether or not cost recovery mechanisms for key activities, e.g. prequalification, are in place.

Adequate banking facilities must be available. Signatories of bank accounts should be appointed to ensure control on one hand, and continuity of operations during the absence of key personnel on the other hand .An accounting system should be in place. Regular financial audits should be performed.

The Role of the Ministry of Finance:

The Ministry of Finance (MOF) delegates to the CMS the authority to procure and handle medical supplies on behalf of Government Of Sudan/MOH.

The MOF puts upon CMS the obligation to annually present operational budget for its own functioning. MOF authorized CMS to add a margin to the cost of medical supplies. This margin shall cover the expenses of all external and internal operations of CMS.

Blood bank services is one of the free medicine program financed by ministry of finance funds allocated for blood bank is divided into:-

1-Blood transfusion service fund.

2-Blood disease funds. Both are injected in the central medical supplies to avail blood bank items.

3-Donations: in case of screening tests.

4-User fees: It is used in cases of shortages when the allocated budget from MOF &MOH is not sufficient to cover the needs, units and branches buy directly from CMS by the hospital user fee.

5-Elzakat chamber also contribute in financing of these items in cases of BB financial shortages specially for hemophilia patients .

1.4.3.1.10. Management Information System (**MIS**) is a system, that provides information needed to manage organizations effectively. Management information systems involve three primary resources: technology, information, and people. It's important to recognize that while all three resources are key components when studying management information systems , the most important resource is people. Management information systems are regarded to be a subset of the overall internal controls procedures in a business, which cover the application of people, documents technologies, and procedures used by management accountants to solve business problems such as costing a product, service or a business-wide strategy .Management

information systems are distinct from regular information systems in that they are used to analyze other information systems applied in operational activities in the organization (17).

The successful MIS supports a business's long range plans, providing reports based upon performance analysis in areas critical to those plans, with feedback loops that allow for titivation of every aspect of the enterprise, including recruitment and training regimens (17). MIS not only indicate how things are going, but why and where performance is failing to meet the plan (17).

The software selected should be suitable for the intended use. The programs used accurately. They should be user-friendly and staff should be trained adequately in their use. Where possible, different programs used should be compatible so that data can be transferred between them without having to be retyped. Asset Management operations relies heavily on IT to accomplish its core functions and to provide information to management, clients, and other parties (18). Where information is exchanged between the procurement agency and the manufacturer(s) by electronic means, appropriate programs should be in place. Suitable security systems should be in place to prevent unauthorized access or prevent loss of data. A good-quality virus protection program and firewall must be installed, configured, used and updated regularly to prevent unauthorized access and loss of data. Technical support should be available to ensure that software and security systems are kept functional and up to date.

1.4.3.1.11 International & National lows:

Procurement is done in accordance with the national and international lows , since procurement processes is governed by the National Medicines and Poison Board National laws include law of medicines & poison board for 2009 . CMS is also governed by The law of finance and accounting procedures for 2007&2011 ,the law of procurement ,contracts & disposal for 2010 & 2011 . These financial laws govern all tender concerns like supplier payments, contracts …..etc .

.CMS follows international trade terms, the supplier prices and the buyer prices are based on different price terms, and so must not be directly compared. The following incoterms are used to define price types (19).

- CFR (cost and freight): includes transport changes up to the port of destination (sea shipment only).
- CIF (cost, insurance and freight): includes insurance and transport changes up to the port of destination (sea shipment only).

- CPT (carriage paid to): includes transport changes up to the place of destination.
- DDP (delivery duty paid): includes delivery and import duties and unloading costs.
- DDU (delivery duty unpaid: include delivery, but not import duties on unloading costs.
- EXW (ex works):does not include loading ,insurance or freight.
- FC (free carrier): include transport and insurance until the goods are delivered to the carrier.
- FOB (free on board): the price of goods at the point of shipment, but does not include the cost of insurance or freight (transportation).

When calculating and projecting real costs, it is important to consider financing, delivery time, mode of transport (air, sea, in land) and handling charges. In this search all BBI were transported by air except blood bags and transfusion sets.

1.4.3.1.12. Coordination:

PSM of the BBI is always coordinated , since CMS , the only procurement &supply body, & central BB always hold coordinating meetings in scheduled manner to select, specification , quantify needs , supplier selection , and to discuss any bending problem . Financial issues were also coordinated with both ministry of finance and ministry of health .Donations from international organizations to the central blood bank were distributed through CMS .

1.5. Development of indicators:

In 2004, at the request of national PSM managers participating in joint WHO–Global Fund PSM workshops, the AIDS Medicines and Diagnostics Partner Network and the AIDS Medicines and Diagnostics Service in the WHO HIV department concluded that donors providing funding for HIV/AIDS programs should harmonize their requirements for reporting by countries, in order to increase the transparency, productivity and efficiency of programs. Indicators for reporting requirements was developed and tested, 50 indicators that could be used for both continuous program tracking and donor reporting were listed. Guided by feedback at two monitoring and evaluation training workshops, [3WHO] finalized a list of 12 core indicators and designed an Excel tool and a method for data collection and analysis (20).

1.6. Hypothesis or Assumption:

It is assumed that there are some weaknesses on the supply cycle affecting the efficiency of the cycle, or CMS capacity to conduct procurement & the supply system management is

bellow the required. This study will examine the different part of the cycle & the capacities available in managing the supply system.

1.7. General Objective:

To assess the Blood Bank Items Procurement and Supply Management System in CMS Sudan during august 2008-august 2011 according to WHO Global Fund Indicators **,** to assess areas of weaknesses in order to make adequate recommendations for improving the medicine procurement and supply management in the CMS .

1.7.1. Specific Objectives:

To evaluate the performance in the different parts of the supply cycle that can be examined on the central level on CMS:

a) Evaluate selection of Blood Bank Items.
b) Evaluation of quantification &forecasting Blood Bank Items,
c) Evaluation of procurement & ordering of Blood Bank Items
d) Evaluation of distribution of Items procured through quality of drugs, inventory control & availability of items.
e) Funding source and budgeting.
f) Organization and Management.

Sudan represented in Central Medical supplies, the national drug supply system, in strong need for such system assessment . This search studied key aspects of procurement and supply management (PSM) in CMS to take the necessary corrective actions to continuously improve the system's effectiveness. This study was the first of its kind , since no previous study was found in Central Medical Supplies Sudan to assess the supply management system . This research cover 7 core WHO- Global fund monitoring and evaluation core indicators, and a additional 8^{th}& 9^{th} indicator, stock record keeping and availability indicators which were modified from the Inventory Management Assessment Tool (IMAT) which assess the effectiveness of record-keeping and stock management practices in a warehouse and provides suggestions for improvement, and the availability indicator was modified from the routine reports. These indicators represent in put indicator, process indicators and out -put indicators.

Table 1.2 types of indicator

Type of Indicator	**Indicator**
Input indicator	Managerial capacities & financial indicator
Process or activity indicator	Selection, quantification, supplier selection & stock keeping records.
Output outcome indicator	Availability, price and quality.

CHAPTER TWO
METHODOLOGY

The study design was descriptive cross sectional facility- based study based on reviewing tender documents, routine reports and records that reflect the performance in different parts of the supply cycle of Blood Bank Items in CMS during the period from August2008-August2011 using the method modified from WHO-Global fund monitoring and evaluation core indicators, .by applying list of variables according to WHO-Global fund , which include:

A-Selection indicator:

1- "Percentage of procured Blood Bank Items which were listed on the WHO model list Of essential Medicines 16 march 2010" . This is a modified WHO-Global fund monitoring and evaluation core indicators. The modification was using the WHO model list instead of standard treatment guidelines .The WHO Model List (WHO march 2010) (21) is available at the following link:

http://www.who.int/medicines/publications/essentialmedicines/en/index.html

Measures the extent to which Blood Bank Items procured in CMS is in line with the WHO list of essential Medicines .Number of BBI that is listed in the WHO essential list march 2010 . To be considered listed in the WHO list items must be frankly written on the list.

- **Required Information**: WHO List of Essential Medicines 16 march 2010 & Blood Bank Items List.
- **Data Source**: Centrally in CMS, CMS BBI list and WHO Essential Medicines 16 march 2010 (21).
- **Measurements:** Number of BB items present in the WHO list /Total number of BBI *100

Target: 100%.

B-Quantification & Forecasting:

Quantification & Forecast was based on the consumption in the central blood bank .Quantities were estimated for two years 30 month in the coordinating meeting between BB representatives and CMS need assessment department.

2- "Ratio between forecasted item quantities and procured quantities" . Typically a WHO-Global fund monitoring and evaluation core indicators.

The total quantities procured should be as close as possible to quantities forecasted unless there was an evidence that the forecast was not accurate or the budget to order the forecasted quantities and the needs have changed since the last forecast exercise(20) . Forecasted quantities are estimated by BB representatives in the coordinating meeting according to the previous consumption in the blood bank , these quantities were estimated for two years 2009-2011 (forecasted for 30 months) .

- **Required Information:** Forecasted Quantities and Procured Quantities.
- **Data source:** Tender document (2008-2010) and Procurement Follow up reports .
- **Measurements :** Forecasted Quantities \Procured Quantities.
- **Target:** 1 (the ratio from 0.9-1.1 was considered equal to 1) .

3- " Ratio between the Procured Quantities & the Consumed Quantities"

Typically WHO-Global fund monitoring and evaluation core indicators. Measures overestimation of the actual needs, which leads to expiry in several countries. Quantities procured by the central medical stores were overestimated, consumption will be very far below the quantities purchased. Overstock occurs with high risk of expiry. Procured quantities are the quantities arrived to CMS and found complying with quality requirement for drugs and consumables importation . Procurement for the eight blood screening tests were started in march 2009, before this date these items were not available because CMS committed to avail these items in march 2009. Consumed quantities were quantity issued by CMS to the central blood bank were distributed to blood bank units and branches and consumed without expiry.

- **Required Information:** Issued quantities to the Central Blood Bank and the Procured Quantities.
- **Data Source:** Annual Need Assessment Indicator Records for 2008, 2009, 2010, issued
- Quantities in 2011 up to the first of august and procurement follow up report.
- Measurements: Procured Quantities\Consumed Quantities.
- **Target: 1** ((the ratio from 0.9-1.1 was considered equal to 1) .

C-Procurement & Ordering:

Key issues in procurement of pharmaceuticals are product pricing and supplier delivery times. The prices obtained for Blood Bank Items and other commodities have a significant influence on the efficiency of the PSM system .In turn the choice of a procurement method e.g.

competitive bidding or direct procurement has an effect on the obtained prices. An efficient program manages to get the best prices and reliable deliveries from supplier.

4- "Ratio between last tender price paid by the CMS for each item to the median local price" This indicator was modified from the WHO-Global fund monitoring and evaluation core indicators. It compares CMS prices to those paid on the local market and measures the efficiency of Blood Bank items procurement practice.

CMS CIF price was compared with the median local price. Price carries information about the value of the goods or services with the buyer's willingness to pay, defined as demand, and the seller's willingness to produce the goods, being the supply. The market is where the buyers and sellers interact, and the interaction of supply and demand determines price(12) .

Most of these items were consumables and not found in the International price indicator guide for 2009 . The median unit price was found by calculating the mean unit price for higher and lower price in the four selected prices . Therefore median local price was estimated by calculating the median unit CIF price for four different local agents, the mean value is considered to be the local price indicator. Conversion Rate according to *Alri Alaam* (14, mach ,2011) (22).

- **Required Information**: Price paid by CMS & median local price indicator.
- **Data source** : Tender 2011-2013 document to provide tender price & the unit price for each item for many different local agent provided by the National Medicines and Poisons Board , to calculate the median local price indicator .
- **Measurement:** CMS last tender price /local median price indicator.
- **Target: less than 1** (the ratio from 0.9-1.1 was considered equal to 1) **.**

5- "Percentage of non-emergency (regular) orders delivered in full and on time as stated in the procurement agreement for each supplier". O*ne* of the WHO-Global fund monitoring and evaluation core indicators**.** It measure supplier's performance in term of complying with the agreed delivery time and delivery of all quantities ordered.

- **Required Information:** Ordering date, delivery date & scheduled time of delivery.
- **Data Source:** Procurement follow up report.
- **Measurement:** Comparing quantities delivered and time of delivery to quantitative ordered and scheduled time of delivery**.**
- **Target:** Delivery of full quantity in time.

D-Distribution:

Include:

1-Quality Assurance of Drugs:

.**6- "Percentage of Blood Bank items which meet quality requirements stated by National Medicines & poison board excluding registration ",**This was one of the WHO-Global fund monitoring and evaluation core indicators.

Number of BBI that meet quality requirement for drugs and consumables importation stated by the Sudanese National Medicines and Poison Board. Measures the extent to which BBI procured meet the quality requirements .

- **Required Information:** Rejected BBI for 2008, 2009, 2010 & 2011. Data Source: Quality control department annual reports for rejected drugs for 2008, 2009, 2010 and half annual report for 2011 .
- **Measurements:** number of items which meet the quality standards /total number of procured items %
- **Target: 100%:** effectiveness of record –keeping & stock management.

2-Stock Keeping Record:-

This indicator is modified from the Inventory Management Assessment Tool (IMAT) which assess the effectiveness of record-keeping and stock management practices in a warehouse and provides suggestions for improvement.

This tool for improving warehouse performance ; It was developed by the INFORM Program at Management Sciences for Health (MSH) and tested with the help of the Hôpital Universitaired 'Etatd'Haïti (Port-au-Prince), the Family Planning Association of Nepal (Kathmandu), and the Nepal Fertility Care Center (Kathmandu). MSH is a nonprofit organization dedicated to strengthening health programs worldwide.

7- " Percentage of Blood Bank Item that physical stock match stock on follow up card" measure the %effectiveness of record –keeping & stock management" Number of BBI that physical stock match stock on follow up card.

- **Required Information:** physical stock at the end of the years 2008, 2009 & 2010 stock on card for2008, 2009 & 2010.
- **Data Source:** Item follow up card for 2008, 2009 & 2010 .
- **Measurements:** Number of items that physical stock match stock on follow up card /Total number of items*100

- **Target: 100%**

8- Availability of BBI in CMS Stores: "Percentage of items with stock available during all the study period" .This indicator was derived from the routine availability reports, indicate the availability of the items during the study period(36 months for all items except the Rapid and Elisa screening test, the study period was 30 month ,CMS committed to avail these items on February 2009) , items with stock available for 36 month and 30 for the screening Rapid & Elisa or more is considered with 100% availability. Items with stock available for less than 36 months, 30months for the screening rapid & Elisa were considered less than 100%.

- **Required Information:** number of months during which stock was available in CMS.
- **Data Source:** Procured Quantities & Annual Need Assessment indicator records for2008, 2009, 2010, and 2011 to calculate the average monthly consumption.
- **Measurements:** Months with available stock /Total number of months during the study period *100
- **Target: 100%**

9- Funding Source & budgeting: "Ratio between annual budget for these items & the total cost of these items for the same year". Funding of BBI can originate from national and international source which should be used in efficient & transparent manner. Development of the national procurement plan for BBI that has been approved by all partners is the first step in ensuring efficient use of financial recourses& prevent duplication of efforts .This plan should contain the budget, the quantities of items to be procured & the fuddling source .secondly is the budget allocated for these items is enough **.**financial supply for these items from both the MOH & MOF for 2009&2010 and the total cost of these items for both years.

- **Required Information:** The budget allocated to procure BBI for2009 & 2010 & the real cost of these items for the same years.
- **Data Source:** Financial Report for 2009 & 2010.
- **Measurements:**
    1. The budget allocated to procure these items in 2009/Total cost of these items for the same year.
    2. The budget allocated to procure these items in 2010/Total cost of these items for the same year.
- **Target:** 1 for both years.

Assessment of the Capacities Required to Conduct Procurement & Supply management System (represent the quality assurance system for PSM):

Organization and management assessment was done by assessing the presence of documented policies and standards which include:

1- Quality Manual.
2- Standard Operation Procedures.
3- Guidelines on conflict of interest.
4- List of prequalified products and Manufacturers.
5- Maintenance of records.

The assessment of these qualitative managerial data is based on the Model Quality Assurance System for procurement agencies by World Health Organization \PSM \PAR\2007.3, United Nation Children's Fund, United Nation Development Program, United Nation Population Fund & World Bank.

b- Human Resources management:

There should be written job descriptions, with definitions of responsibilities, for all personnel appropriately trained, educated and personnel should be experienced. There should be a sufficient number

c- management information system (MIS)

d- Financial management

e- Follow International & National laws.

f- Coordination.

Studied Population (items):

The study consist of all BBI that is selected in the coordinating meeting dated 13/6/2011 between CMS need assessment department & BB representatives in order to prepare a list for the two coming years. In this meeting the list is updated by addition and deletion. Items included in the study (26 items) are sera for blood grouping , HIV, HBV, HCV, Syphilis Screening Test, single blood bag, triple blood bag, transfusion sets , factor 8, factor 9, tranexamic acid and desmopressin nasal spray .Excluding laboratory instruments, items have not been supplied in the study period , new items added in the coordination meeting which are going to be supplied for the first time.

Sampling:

The study covered all items specified .

Data Collection Tools& Data Analysis:

Data collection tables were structured using excel program by reviewing documents reports, records and interviews. These data was analyzed using SPSS statistical package version 16 & Excel Program.

Study area:

Facility based in CMS.

CHAPTER (3)

RESULTS

Indicator No. 1

Table (3.1) The Blood Bank Items covered by the study and the status of each from listing on the WHO model list of essential medicines .

No	Item Description	Unit of Supply	Being Listed in the WHO model list of essential Medicines 16 march 2010
1	Anti-A sera test 10ml	Vial of 10ml	NO
2	Anti A1lectin sera	Vial of 10ml	NO
3	Anti B sera 10ml	Vial of 10ml	NO
4	Anti-D sera test	Vial of 10ml	NO
5	Anti-C sera 5 ML (big)	Vial of 5ml	NO
6	Anti-c sera 5 ML (small)	Vial of 5ml	NO
7	Anti-E sera test 5ml (big)	Vial of 5ml	NO
8	Anti-e sera test 5ml(small)	Vial of 5ml	NO
9	Anti CDE Sera 10 ml	Vial of 10ml	NO
10	Anti-human globulin(coombs) 5ml.bottle	Vial of 5ml	NO
11	HCV Rapid test	Test	NO
12	HBV Rapit test	Test	NO
13	Syphilis Rapid test	Test	NO
14	HIV Rapid test	Test	NO
15	HIV Elisa test	Test	NO
16	HBV Elisa test	Test	NO
17	HCV Elisa test	Test	NO
18	Syphilis Elisa test	Test	NO
19	Dessmopressin nasal spray	5ml bottle	NO
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	Yes
21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	Yes
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	Yes
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	NO
24	Single Blood Bag 450ml.	Bag	NO
25	Triple Blood Bag 450ml.	Bag	NO
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	NO

***BBI means Blood Bank Item .**

Table (3.2) SPSS Analysis for BBI that is listed on WHO model list

Yes	NO
11.5% (3)	88.5%(23)

***BBI means Blood Bank Item .**

YES= Listed , No=Not listed

Indicator NO 2

Table (3.3) BBI, forecasted Quantity (F), Procured Quantity (P)& the ratio F\P

No	Item Description	Unit of Supply	Forecasted Quantity (F)	Procured Quantity (P)	Ratio F/P
1	Anti-A sera test 10ml	Vial of 10ml	25000	27000	0.9
2	Anti A1lectin sera	Vial of 10ml	2000	1660	1.2
3	Anti B sera 10ml	Vial of 10ml	25000	25000	1
4	Anti-D sera test	Vial of 10ml	25000	22000	1.1
5	Anti-C sera 5 ML (big)	Vial of 5ml	350	350	1
6	Anti-c sera 5 ML (small)	Vial of 5ml	350	500	0.7
7	Anti-E sera test 5ml (big)	Vial of 5ml	150	225	0.7
8	Anti-e sera test 5ml(small)	Vial of 5ml	250	250	1
9	Anti CDE Sera 10 ml	Vial of 10ml	3000	3000	1
10	Anti-human globulin(coombs) 5ml.bottle	Vial of 5ml	10000	14000	0.7
11	HCV Rapid test	Test	400000	330000	1.2
12	HBV Rapit test	Test	400000	370000	1.1
13	Syphilis Rapid test	Test	400000	381280	1
14	HIV Rapid test	Test	400000	470000	0.9
15	HIV Elisa test	Test	2000	3919	0.5
16	HBV Elisa test	Test	2000	3488	0.6
17	HCV Elisa test	Test	2000	4204	0.5
18	Syphilis Elisa test	Test	2000	3089	0.6
19	Dessmopressin nasal spray	5ml bottle	3500	0	
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	2000	2000	1
21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	28000	8000	3.5
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	4000	1700	2.4
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	5000	2500	2
24	Single Blood Bag 450ml.	Bag	300000	375440	0.8
25	Triple Blood Bag 450ml.	Bag	200000	320893	0.6
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	700000	711522	1

***BBI means Blood Bank Item .**

Table (3.4) SPSS analysis of the ratio(F)/(P) Target 1

F\P=1	F\P More than 1	F\P Less than1
42.3%(11)	19.2%(5)	38.4%(10)

When the ratio f\p =1 forecasted quantity =procured quantity

f\p More than 1= forecasted quantities in unit of supply was more than the procured quantities f\p Less than 1= forecasted quantities in terms of unit of supply were less than the procured quantities,

Indicator No. 3

Table (3. 5) BBI Procured Quantity (P), Consumed Quantity (C) & the Ratio P\C

No	Item Description	Unit of Supply	Procured Quantity (P)	Consumed Quantities(C)	Ratio P/C
1	Anti-A sera test 10ml	Vialof 10ml	27000	23000	1.2
2	Anti A1lectin sera	Vialof 10ml	1660	1634	1
3	Anti B sera 10ml	Vialof 10ml	25000	19050	1.3
4	Anti-D sera test	Vialof 10ml	22000	21510	1
5	Anti-C sera 5 ML (big)	Vial of 5ml	350	350	1
6	Anti-c sera 5 ML (small)	Vial of 5ml	500	500	1
7	Anti-E sera test 5ml (big)	Vial of 5ml	225	125	1.8
8	Anti-e sera test 5ml(small)	Vial of 5ml	250	250	1
9	Anti CDE Sera 10 ml	Vialof 10ml	3000	3000	1
10	Antihumanglobulin(coombs) 5ml.bottle	Vial of 5ml	14000	14000	1
11	HCV Rapid test	Test	330000	210540	1.6
12	HBV Rapit test	Test	370000	247060	1.5
13	Syphilis Rapid test	Test	381280	293940	1.1
14	HIV Rapid test	Test	470000	344600	1.3
15	HIV Elisa test	Test	3919	2841	1.4
16	HBV Elisa test	Test	3488	2593	1.3
17	HCV Elisa test	Test	4204	3316	1.3
18	Syphilis Elisa test	Test	3089	2329	1.3
19	Dessmopressin nasal spray	5ml bottle	0	0	0
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	2000	1056	1.9
21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	8000	2425	3.3
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	1700	676	2.5
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	2500	2490	1
24	Single Blood Bag 450ml.	Bag	375440	375350	1
25	Triple Blood Bag 450ml.	Bag	320893	318156	1
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	711522	663048	1.1

*BBI means Blood Bank Item .

Table (3.6) SPSS analysis for the ratio(P)/(C) Target 1

P\C=1	P\C More than 1	P\C Less than1
42.3%(11)	53.8%(14)	3.8%(1)

*BBI means Blood Bank Item.

When the ratio P\C =1 procured quantity =consumed quantity. When P\C More than 1= procured quantities in unit of supply were more than the consumed quantities .When P\C Less than 1=procured quantities in terms of unit of supply were less than the consumed quantities, that means the item has not been procured ,ie zero\zero=zero **.**

Indicator NO 4

Table (3. 7) BBI last Tender Price ,Median local Price and the ratio (TP)/(MP)

No	Item Description	Unit of Supply	Last tender price paid by CMS EURO (TP)	Media-n local price EURO (MP)	CMS price/ median local price
1	Anti-A sera test 10ml	Vial of 10ml	1.106	1.04	1.1
2	Anti A1lectin sera	Vial of 10ml	1.76	1.8	1
3	Anti B sera 10ml	Vial of 10ml	1.106	1.15	1
4	Anti-D sera test	Vial of 10ml	1.61	1.8	0.9
5	Anti-C sera 5 ML (big)	Vial of 5ml	12.68	9	1.4
6	Anti-c sera 5 ML (small)	Vial of 5ml	12.1	9	1.3
7	Anti-E sera test 5ml (big)	Vial of 5ml	7.27	8.2	0.9
8	Anti-e sera test 5ml(small)	Vial of 5ml	19.41	21.2	0.9
9	Anti CDE Sera 10 ml	Vial of 10ml	12.3	12.6	1
10	Anti-human globulin(coombs) 5ml.bottle	Vial of 5ml	1.29	1.6	0.8
11	HCV Rapid test	Test	0.74	0.54	1.3
12	HBV Rapit test	Test	0.63	0.3	2.1
13	Syphilis Rapid test	Test	0.72	0.3	2.4
14	HIV Rapid test	Test	0.74	0.54	1.3
15	HIV Elisa test	Test	0.9	2.72	0.3
16	HBV Elisa test	Test	0.54	2.06	0.3
17	HCV Elisa test	Test	3.7	2.72	1.4
18	Syphilis Elisa test	Test	0.68	2.72	0.3
19	Dessmopressin nasal spray	5ml bottle	0.015	0.015	1
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	47.5	47.5	1
21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	88.97	88.97	1
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	105.15	105.15	1
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	0.383	0.383	1
24	Single Blood Bag 450ml.	Bag	1.364	1.56	0.9
25	Triple Blood Bag 450ml.	Bag	2.897	1.4	2.1
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	0.126	0.295	0.4

*BBI means Blood Bank Item .

Table (3.8) SPSS analysis for the BBI for the ratio (TP)/(MP) Target less than 1

TP\MP Less than1	**TP\MP=1**	**TP\MP More than 1**
19%(5)	53% (14)	27% (7)

*BBI means Blood Bank Item .

When TP\MP =1 CMS price was equal to the local price . When TP\MP less than 1= CMS price was less than the local market price which was desired & when TP\MP more than 1=CMS price was more than the local price .

Indicator NO 5

Table (3.9) Evaluation of Supplier based on the % delivery of orders in time & the % delivery of the full quantities .

No	International company	Agent	Items Supplied by the agent	Total no of orders	Orders delivered in full qt & on time	% of orders deliverd in full	Evalut -ion of supplir
1	Biotec	Shaweesh	Blood Grouping Sera	15	10	67	Bad
2	Clas	Dohia	Blood Grouping Sera	4	0	0	Bad
3	standard diagnostic	Furat	Blood Screening Tests	4	4	100	reliable
4	Turk Lab - Turkey	EANA	Blood Screening Tests	4	4	100	reliable
5	Qualpro diagnostic	Furat	Blood Screening Tests	1	1	100	reliable
6	biorad	Alforat	Blood Screening Tests	3	3	100	reliable
7	Biorex U.K.	Marina Medical	Blood Screening Tests	3	3	100	reliable
8	DioSorin - South Africa* DioPro-Italy	Eana	Blood Screening Tests	1	1	100	reliable
9	Cipla	Marwaco	DessmopreeinNasal Spray	1	0	0	Bad
10	Fering	Hiba	DessmopreeinNasal Spray	5	1	20	Bad
11	Bioproduct	Al-	Factor VIII	1	0	0	Bad

	lab	Hussien	,Factor IX				
12	Hilton Pharma (pvt.) ltd	Raheeg Medical	Tranexamic acid	5	1	20	bad
13	Asia	Desert Star	Single blood bag & triple blood bag	6	2	33	Bad
14	JMS Singaphora	Shaweesh	Single blood bag & triple blood bag	3	1	33	Bad
15	Mais	Lilium	Blood Transfusion Set	2	2	100	reliable
16	Enteplin	Sudanese medical agency	Blood Transfusion Set	2	2	100	reliable

*** analized using excel**

Table (3.10) List of Reliable Suppliers

NO	**International**	**Agent**	**Items Supplied by the agent**
1	Standard diagnostic	Alforat	Blood Screening Tests
2	Biorad	Alforat	Blood Screening Tests
3	Qualpro diagnostic	Alforat	Blood Screening Tests
4	Turk Lab – Turkey	Eana	Blood Screening Tests
5	DioSorin -South Africa* DioPro-Italy	Eana	Blood Screening Tests
6	Biorex U.K.	Marina Medical	Blood Screening Tests
7	MAIS	Lilioum	Blood Transfusion Set
8	Enteplin	Sudanese	Blood Transfusion Set

		Medical Agency	

Indicator NO 6

Table (3.11) Quality Control Assessment of the BBI

NO	Item Description	Unit of Supply	Meeting Quality Standards (certification & testing) excluding Registration
1	Anti-A sera test 10ml	Vial of 10ml	Yes
2	Anti A1lectin sera	Vial of 10ml	Yes
3	Anti B sera 10ml	Vial of 10ml	NO
4	Anti-D sera test	Vial of 10ml	Yes
5	Anti-C sera 5 ML (big)	Vial of 5ml	Yes
6	Anti-c sera 5 ML (small)	Vial of 5ml	Yes
7	Anti-E sera test 5ml (big)	Vial of 5ml	Yes
8	Anti-e sera test 5ml(small)	Vial of 5ml	Yes
9	Anti CDE Sera 10 ml	Vial of 10ml	Yes
10	Anti-humanglobulin(coombs)5ml.bottle	Vial of 5ml	Yes
11	HCV Rapid test	Test	NO
12	HBV Rapit test	Test	Yes
13	Syphilis Rapid test	Test	NO
14	HIV Rapid test	Test	Yes
15	HIV Elisa test	Test	NO
16	HBV Elisa test	Test	NO
17	HCV Elisa test	Test	Yes
18	Syphilis Elisa test	Test	NO
19	Dessmopressin nasal spray	5ml bottle	NO
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	Yes

21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	Yes
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	Yes
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	Yes
24	Single Blood Bag450ml	Bag	NO
25	Triple Blood Bag450ml	Bag	NO
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	Yes

*BBI means Blood Bank Item .

Table (3.12) SPSS analysis of quality control Assessment for BBI

Yes	***NO***
66%(17)	34%(9)

*BBI means Blood Bank Item .

YES= meet quality standards ,NO= did not meet quality standards .

In Indicator NO 7 Target 100% :

It was found that all BBI physical stock found matched with store follow up card the efficiency of stock keeping record was found 100% .

*BBI means Blood Bank Item .

Indicator NO 8

Table 3.13 BBI Availability Assessment

NO	Item Description	Unit of Supply	Procured QT	AMC	Number of months with available stock	%availa-bility
1	Anti-A sera test 10ml	Vial of 10ml	27000	700	36	100
2	Anti A1lectin sera	Vial of 10ml	1660	50	33	92
3	Anti B sera 10ml	Vial of 10ml	25000	700	35	99
4	Anti-D sera test	Vial of 10ml	22000	530	36	100
5	Anti-C sera 5 ML (big)	Vial of 5ml	350	9	36	100
6	Anti-c sera 5 ML (small)	Vial of 5ml	500	8	36	100
7	Anti-E sera test 5ml (big)	Vial of 5ml	225	5	36	100
8	Anti-e sera test 5ml(small)	Vial of 5ml	250	8	31	87
9	Anti CDE Sera 10 ml	Vial of 10ml	3000	17	36	100
10	Anti-human globulin(coombs) 5ml.bottle	Vial of 5ml	14000	400	35	97
11	HCV Rapid test	Test	330000	10500	30	100
12	HBV Rapit test	Test	370000	10500	30	100
13	Syphilis Rapid test	Test	381280	10500	30	100
14	HIV Rapid test	Test	470000	10500	30	100
15	HIV Elisa test	Test	3919	208	18	62
16	HBV Elisa test	Test	3488	208	16	56
17	HCV Elisa test	Test	4204	208	20	67
18	Syphilis Elisa test	Test	3089	208	15	46
19	Dessmopressin nasal spray	5ml bottle	0	30	0	0
20	Human antihaemophilic Factor VIII fraction,dried with set 250 IU	Ampoule	2000	80	25	69
21	Human antihaemophilic Factor VIII fraction,dried with set 500 iu	Ampoule	8000	583	13	38
22	Human antihaemophilic factor IX fraction, dried with set	Ampoule	1700	90	19	52
23	Tranexamic acid 100mg/ml inj. -5ml Amp.	Ampoule	2500	250	10	28

24	Single Blood Bag 450ml.	Bag	375440	12000	31	87
25	Triple Blood Bag 450ml.	Bag	320893		9375	95
26	Blood transfusion set sterile ,non pyrogenic,non oxic	Set	711522		23500	84

*BBI means Blood Bank Item .

Table 3.14 SPSS Analysis for the Availability of BBI

100% availability	***Less than 100%***
54% (14)	46% (12)

*BBI means Blood Bank Item .

100% availability mean available for 36 months, 30 months for the blood screening .

Indicator no 9:

Table (3.15) the allocated budget (B) , the total cost (C) & the ratio B\C

Year	**Allocated budget (B)**	**Total cost (C)**	**Ratio B\C**
2009	7,25149845	11,791,59800	**0.6**
2010	6, 441720.70	10,652,485.20	**0.6**

Table 3.16 the score of each BBI out of the 7 indicators excluding the evaluation of suppliers & indicator no 9.

NO	Item Description	Unit of Supply	Item score out of 7 indicators
1	Anti-D sera test	Vial of 10ml	6
2	Anti CDE Sera	Vial of 5ml	6
3	Anti-A sera test	Vial of 10ml	5
4	Anti A1lectin s	Vial of 10ml	5
5	Anti B sera 10ml	Vial of 10ml	5
6	Anti-C sera 5 ML	Vial of 5ml	5
7	Anti-e sera test	Vial of 5ml	5
8	Dessmopressinna	Bottle	5
9	Anti-c sera 5 ML	Vial of 5ml	4
10	Anti-E sera test	Vial of 5ml	4
11	Anti-human globu	Vial of 10ml	4
12	HBV Rapit test	Test	4
13	HIV Rapid test	Test	4
14	Human antihaemop	Ampoul	4
15	Human antihaemop	Ampoul	4
16	Tranexamic acid	Ampoul	4
17	Blood transfusion sets	Set	4
18	HCV Rapid test	Test	3
19	Syphilis Rapid test	Test	3
20	Human antihaemop	Ampoul	3
21	Triple Blood Bag	Bag	3
22	HIV Elisa test	Test	2
23	HBV Elisa test	Test	2
24	HCV Elisa test	Test	2
25	Single Blood Bag	Bag	2
26	Syphilis Elisa test	Test	1

T able (3.17) SPSS analysis of the score of each BBI

Score 4 &Over	***Score Less than4***
65.4%(17 items)	34.6% (9 items)

*BBI means Blood Bank Item .

Qualitative Data :

Table(3. 18) Assessment of The Managerial Capacity required to conduct PSM in CMS

Organization Management Assessment	
A-Presence of documented policies & standards	**Presence**
1-Quality Manual	✓
2-Standard Operation Procedures .	-
3-Guidelines on conflict of interest .	-
4-List of prequalified products & Manufacturers	✓
5-Maitainance of records .	✓
B- Human Resources management:	
1-There should be written job descriptions, with definitions of responsibilities	-
2-Adequate Staff	✓
3-Qualified	✓
4-Experienced	✓
5-Trained	✓
C- management information system (MIS)	✓
D-Financial management	
1-Can do national and international financial transactions as required	✓
2-Availability of sufficient funds	-
3- Presence of An accounting system	✓
4-Regular financial audits	✓
5-Adequate banking facilities	✓
E-International &National lows.	✓
F-Coordination	✓

CHAPTER FOUR

DISCUSSION

4.1 The WHO model list of essential medicines :

The essential medicines are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms (23). Most of the procurement agencies may find that many of the products they require are on WHO's Model List of Essential Medicines, which contains medicines of proven safety and efficacy and is updated periodically. The selection of pharmaceutical products based on the national formulary or on the essential medicines list is recommended. They will find this list a useful reference for establishing specifications for the medicines needed for their purposes(10). But unfortunately only 11.5% of the BBI were listed on the WHO model list , these items were drugs .88.5 % of the BBI were not listed , these items were considered consumables . The WHO model list do not include laboratory reagents , devices and equipments , but it include the sentence (All plasma fractions should comply with the WHO Requirements for the Collection, Processing and Quality Control of Blood, Blood Components and Plasma Derivatives) (21). Sera for blood grouping, screening tests , blood bags& blood giving sets are essential to fulfill the requirements of the WHO regarding all plasma fractions . On reality most BBI are considered consumables and medical devices which were not included on the WHO medicines list, other list for consumables and medical devices are going to be developed ,as far as the Sudan WHO Pharmaceutical coordinator said.

.When they are listed information about ideal specifications of these items are provided. A national procurement system will require the development of specifications for equipment, test kits, reagents and consumables and assessment of the quantity and types required(6) .

4.2 Quantification and Forecasts:

Accurate quantification of needs is essential to avoid shortages or excess stocks. Shortages could lead to increase mortality and morbidity .Excess stocks could lead to additional storage costs and expiry of products before they are used .In the ratio F/P equal one, the forecast was accurate in less than half of the items 42.2% (eleven items). The ratio F/P was more than one in 19.2% of the items (six items) i.e. the forecasted quantity was more than the procured . One of them, the desmopressin nasal spray, CMS couldn't avail the item at all as in the case of desmopressin nasal spray because it was awarded to unreliable supplier . Also unreliable supplier affected the

procurement of Human antihaemophilic Factor VIII fraction, dried with set 500 iu, Human antihaemophilic factor IX fraction, dried with set 250iu & Tranexamic acid 100mg/ml inj5ml Amp . In the rest of the items, the forecasted quantities were more than the procured as in the case of Anti A1 lectin sera due to the decreased consumption; blood bank did not order additional quantities. For HCV Rapid test there was no sufficient funds allocated to procure this item. For the ratio F/P less than one, the forecasts were less than the actually procured in 34.6% of the items (nine items) due to increased consumption of these items ,this can be justified by the increased awareness of blood transfusion transmitted disease and spreading the culture of voluntary blood donation. Forecasting and quantification depending on consumption data which it is like standing on a moving earth, These items include Anti-c sera 5 ML (small), Anti-E sera 5ml (big), Anti-human globulin(coombs) 5ml.bottle, HIV Elisa test, HBV Elisa test, HCV Elisa test, Single Blood Bag 450ml & the Triple Blood Bag 450ml.

In the ratio P/C was equal to 1 in 42.3 % of the items (eleven items) ie less than half the items, that means the procurement was in the line with the consumption in eleven items .The ratio was more than one in 53.8 % of the items (fourteen item) i.e. more than half the items . That means the procurement was more than the consumed , this due to the fact that data was collected immediately after the arrival of the items this can explain the absence of expired items . That means the total P\C ratio was 96.1% which was considered acceptable .These items include Anti-A sera test 10ml ,Anti B sera 10ml, Anti-E sera test 5ml (big), HCV Rapid test, HBV Rapit test, HIV Rapid test HIV Elisa kits ,HBV Elisa kits, HCV Elisa kits, Syphilis Elisa kits, Human antihaemophilic Factor VIII fraction,dried with set 250 IU &Human antihaemophilic Factor VIII fraction,dried with set 500 iu. The ratio is less than one in 3.8% (one item) this item was desmopressin which was out of stock &has not been procured during the study period .

Both previous indicators F\P &P\C, assess forecasting and quantification. Using F\P achieved the target in 42.2% and P\C 96.1% showing poor forecasting but acceptable ordered quantities . Forecasting in changing consumption is like standing on moving earth, it is out of control of any procurement agency. But it can be minimized by doing forecasts for one year considering up-to-date treatment or laboratory trends.

4.3 Procurement and Evaluation of Supplier :

Pharmaceutical products should be purchased with the aim of procuring effective, good-quality medicines at the lowest possible cost (11).The ideal price was found in 19% of the item (only five items)ie less than half the items**.** in this case CMS failed to achieve its objectives in availing medical supplies with the lowest price. The CMS price/local price indicator was found equal to one in 53% of the items (fourteen items) i.e. more than half the item with price equal to the price of the local market .The CMS price was found more than the local price in 27% of the items (seven items) .The unacceptable price was found in 81% of the items . This high price affect the limited budget allocated to BBI , and consequently limit the service provided by the BB to a limited population .Procurement with high price can be justified by the fact that Blood Bank determine the brands or the suppliers of its items, in most cases the chosen suppliers were un reliable .So there is an oligopolistic competition , limited number of agents providing BBI ,therefore CMS was compelled to procure from a limited number of sources decreasing competition .Scarcity of resources requires that buyers and sellers make choices about how resources will be used, whereas abundance would allow limitless production and consumption(12).

It is intuitive that larger buyers will have strong market positions to negotiate prices, if not by being the sole source of demand, then by the volume of the product they are expected to purchase. However, an association between a large buyer size and low prices does not always hold true. The buyer should be continually aware of the availability of new generic entering the market. In some countries drugs can only be purchased from local agents. Other countries purchase drugs directly from the manufacturer. This method is preferred in as much as dealing through middlemen/agents/wholesalers result in generally higher prices as well as more complicated negotiations(13).

It is important to monitor medicine prices by performing price comparisons, it is critical to determine which price to use for comparison, in many cases the whole seller price is the basis for measurement, and this can be a useful tool to improve procurement practices.

A price survey in Malaysia using the WHO/HAI methodology compared median price ratios of medicines distributed in the private and public sectors with international reference prices .Despite the expectation that the prices of medicines in the public sector would be relatively low, in some cases, public-sector prices were higher than the international reference

price. The study also found that the post manufacture margins charged in the supply chain were significantly driving prices upward in both the public and private sectors. The authors concluded that the lack of coherent government policy to regulate medicine prices allowed excessive profits and reduced medicine affordability (12).

For the supply of blood grouping sera only two suppliers provided CMS with these items where non was reliable for delivering full quantities in time **.**Despite blood screening tests were supplied by six agents**,** all were considered reliable in terms of delivering full quantity in time **.**But in terms of price only three items with price less than one**.** Marwaco and Hiba were the only two suppliers for desmopressin nasal spray for CMS**,** both were found not reliable in terms of delivering full quantities in time & in terms of price **.**For factor VIII & IX which were unregistered drugs, the only supplier was Al-Hussien who was considered bad supplier in terms of delivering full quantities in time**.** CMS is the only supplier for factor VIII and IX which were considered life saving drug for hemophilia patient, CMS was the only supplier for these items in the local market, and since CMS the only supply body who can distribute unregistered medicines**.** For tranexamic acid Raheeg Medical was the only supplier, unfortunately found unreliable supplier .Blood bags were supplied by two agents both were considered unreliable suppliers Blood giving sets were supplied by two agents both considered reliable .Successful purchasing agencies use a formal supplier monitoring system (23). In general, suppliers that have performed poorly should be excluded from the next tender. Some procurement agencies give preapprovals to suppliers that have had a problem, such as too many partial shipments or excessive lead times, but offer high quality products at competitive prices .If problems recur, they are then barred from the next tender .If suppliers problems are sufficiently grave , it can be barred for a two –year period and then forced to go through re-registration .

4.4 Quality control of BBI:

66% (17 items) of these items passed the quality requirements these items are 18 items, 34% (9 items) of the items found noncomplying include HCV Rapid test & Syphilis Rapid test which were rejected because the of the weak sensitivity of the tests to the virus .HIV Elisa test, HBV Elisa test Syphilis Elisa test were rejected because there was no ice bag with these items during delivery ,since the Eliza test must be stored at 2-8C. Desmopressin nasal spray was not complying to the specifications regarding (Content of active ingredient) . Anti B sera 10ml& the

Single Blood Bag 450ml, Triple Blood Bag 450ml.found non complying because the remaining shelf life when receiving these items were below 75% .

The implementation of a quality assurance system in procurement, including systems for prequalification, storage and distribution, may affect costs. However, the benefits of ensuring quality outweigh the cost investment because they reduce the possible losses caused by the purchase and supply of substandard products. Prequalification of products and manufacturers, purchasing, storage and distribution are complex processes that may involve many offices, procurement agencies, sections or departments and several stages of administration, finance and technical decisions. Pharmaceutical products are not ordinary commodities of trade and require special attention. Support from the offices responsible for quality assurance is important. The efficiency of the procedures depends in great part on the use of a proven method in a consistent manner. The use of a standard approach will ensure consistency in all activities involved in procurement of pharmaceutical products of defined acceptable quality .The presence of written SOP can govern all the procurement activity and promote procurement efficiency. The absence of written SOP could be the reason behind the decreased quality of drugs in addition to the absence of qualified supplier.

These results were considered to be not satisfying for a national supply body like CMS. Further studies must be carried out regarding the prequalified products and suppliers to ensure that the prequalification was based on objective evaluations. These evolutions must include technical like evaluation of product documentation, reviewing quality –control laboratory tests, and monitoring product performance .Managerial activities include selecting reliable suppliers, preparing contract terms and monitoring supplier. Poor quality BBI have many undesirable clinical and economical consequences, as well as affect the credibility of the health delivery system . Clinical consequence include transfusion of unmatched blood groups leading to blood hemolytic ,distribution of contaminated blood & blood products and increased risk of bleeding to hemophilia patient & other blood diseased patients .On the economical side , limited financial resources may be wasted on poor –quality medicines .Poor medicine quality may seriously affect health system credibility . Critical elements in quality assurance for pharmaceutical procurement : include products selection, product with longer shelf life, product certification eg , supplier prequalification ,recent GMP inspection reports from national regulatory authority , formal supplier monitoring system , limitation of purchases from new suppliers to non critical

products, certificate of pharmaceutical product (WHO –type) for all new products, new suppliers, batch certificate (WHO-type) for problem drugs only .In addition to contract specifications including acceptable standards ,language , labeling requirements , minimum shelf life ,packaging standards. Inspection of shipments and sampling, targeted laboratory testing & product problem reporting system.

4.5 Efficiency of stock keeping records :

CMS was found to be with 100% efficiency in record keeping and stock management for BBI. Since these items were procured & distributed only to the Central Blood Bank. The stock holding cost was minimized by the withdrawal of these items by the Blood Bank whenever they were availed by the CMS.

4.6 Availability :

The total acceptable availability was found in 54% of the items, 38% of these items scored 100%, 15% of them scored more than 90%. The remaining 46 % of the items scored less than 90%. 46% (12 of the items) was considered unacceptable ,it represented large number of the studied items, these items include Anti-e sera test 5ml(small)HIV Elisa test HBV Elisa test HCV Elisa test ,Syphilis Elisa test, Dessmopressin nasal spray Human antihaemophilic Factor VIII fraction, dried with set 250 IU, Human antihaemophilic Factor VIII fraction, dried with set 500 iu, Human antihaemophilic factor IX fraction, dried with set, Tranexamic acid 100mg/ml inj. -5ml Amp., Single Blood Bag & Blood transfusion set sterile ,nonpyrogenic, nontoxic .. Shortages was detected in these items at CMS level, but blood bank representative said that no shortages at blood bank level . This can only be explained by the fact that direct purchases were done at blood bank level bypassing CMS. Items that could be directly purchased are those which did not require registration, considered consumables imported after permission from the regulatory authorities, like blood grouping sera, blood screening tests, single blood bags & blood transfusion sets .But other items, which are considered drugs , like Dessmopressin nasal spray Human antihaemophilic Factor VIII fraction, dried with set 250 IU , Human antihaemophilic Factor VIII fraction, dried with set 500 iu , Human antihaemophilic factor IX fraction, dried with set, Tranexamic acid 100mg/ml inj, since no agent can export unregistered drug except CMS . So blood bank never purchased these drugs. When BB purchase directly from the supplier, BB uses the hospital user fees to cover the cost of these items, instead of using this money in hospital development. Drugs which BB could not purchase them like Human

antihaemophilic Factor VIII fraction, dried with set 250 IU, Human antihaemophilic Factor VIII fraction, dried with set 500 iu, Human antihaemophilic factor IX fraction, dried with set affect haemophilia patient deeply because these drugs safe lives . Incase of shortages, BB used other sources for factor VIII & factor XI these alternatives like fresh plasma which contain low concentration of these factors, a large quantity of this item is needed to compensate for one dose of these factors. When these items were not available at BB patient use to buy these drugs out of their own buckets , moreover in most cases more than one person in the family were involved with this disease .

4.7 Finance and budgeting :

These shortages can be due to insufficient financial supply injected to CMS to avail these items, considering that these items are expensive. The financial supply was less than the cost of these items for two consecutive years leading to cumulative debts BB awed to CMS. An investment in blood safety measures to prevent transfusion-transmitted infection is more cost-effective than allowing the further spread of TTIs which places additional, avoidable pressures on the healthcare system (6).

Sudan MOH should ensure that sufficient and sustained resources are available for an effective and comprehensive blood screening program that ensures the high quality screening of all donations for TTIs. In order to make optimal use of limited healthcare resources, the screening program should ensure a balance between the application and implementation of good scientific principles and the best use of the resources available. CMS had a limited budget to purchase all its items, including BBI. CMS use displacement policy that means CMS buy the ordered quantity , which was apart from the forecasts when selling a part of what was bought CMS can avail other items .So if the owed money had not been payed this affect CMS ability to avail other items.

BB managers have to find and introduce cost recovery mechanisms as a part of the overall health system economic reform , such as using a system of user fees in public health care .

There were many studies conducted in many African countries examining the application of user fees as a part of economical reform . . Chisada E, et al conducted a study in Zimbabwe 1991 found that the user fees attributed to economic and rational public sector drug procurement .But an observation indicated that a portion of the vulnerable were not effectively protected due to stringent requirements for proof of income .Applying the fees policy indicated the need for

more effective cross-subsidy and better administrative procedures .Fee revenue should be directed towards improvement in quality of service .

4.8 The Score of Each Item :

By assessing the score each item in the seven indicators , it was found that the overall score for the acceptable limits was found in 65% of the items, which was still below the required .This assessment can evaluate the overall supply system in CMS. Many reasons behind these results ,low commitment of the government to health , the Central Bank do not consider health commodities as a top priority to avail foreign currency for and the supplier reliability is a third problem .All these three big issues are out of CMS control

.4.9 Managerial Capacity Assessment:

CMS undergone documentation of policies and procedures .Since CMS follows a system of documentation ISO 9001 .These policies and standards documented contributed in managerial quality assurance , it also help in achieving objectives in monitoring and tracing of policies and standards implementation, for example CMS always set the annual plan for each department ,and assess the implementation of this plan by the end of the year. Other important issue in managerial quality assurance is the written standard operation procedures which set standard for operating each activity. Unfortunately CMS had no written standard operation procedures. This can explain any managerial inefficiency which was explained by the delay in parts of the supply cycle. Other issue is the presence of guidelines for conflict of interest; CMS had no written guidelines for conflict of interest .This may lead to bias in supplier selection or product selection.

CMS had a list of prequalified suppliers for BBI, but this prequalification of suppliers was of low value because CMS had no adequate choices of suppliers. Therefore, CMS was compelled in dealing with unreliable suppliers. This is reflected in the availability of some items. The prequalification of product was very useful in CMS procurement practice since the qualified product consumption were very high compared to others prequalified product resulted in BB satisfaction and its commitment to withdraw the product they selected & quantified.

Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function (24).

Despite the presence of adequate number of personnel, qualified, trained and experienced, but lack of written job description made some managerial confusion about duties and responsibilities for each individual.

Management Information system (MIS) in CMS during the study period was concentrating in managing drug supply with customer satisfaction under a high control of financial procedures starting from procurement accounts (payables) to sales accounts (receivables) .It were consist of the following applications:

-Need assessment application assist in preparing forecasts and quantification depending on consumption data which was taken from the application system developed to assist them how to calculate their equations to forecast and quantify .

-The next application which was capable to safe procurement information entered regarding bank processes .CMS MIS during the study period could give a clear pictures of database integrated views implemented into useful reports that can assist the procurement top managers in their decisions that could reduce medicines gap .

-The inventory module at CMS during the study period worked on how to receive goods which was added to the available stock quantities considering item details like batches, expiration dates, store location, item cost …..etc .Inventory module also have issuing facilities that assist store keeper and inventory control staff to dispatch the goods according to FEFO method to CMS customer .

-The finance module at that time was functioning mainly to run the prices of the items considering all fees and expenses during the Whole supply cycle .The price application was capable to perform the details needed to give the last item cost.

The management information system during the study period was considered satisfying to achieve procurement operations.

CMS established an efficient financial management , since all accountants were from the ministry of finance ,they are qualified and experienced ,implementing efficient accounting procedures ,could perform national and international transactions .The only constraint was the insufficient financial supply for BBI . Additionally the financial supply was continuously monitored and audited .

The procurement practice was governed by national laws like procurement ,contracting & disposal law for 2010 & 2011.Which described all the details of procurement practice giving a

clear pathway for procurement processes .Other important law was the medicines and poison law which deals with quality control for all medicines aspects .CMS was adhered to the International Commercial Terms ,but CIF was the most applicable one in the procurement practice . CMS is the national procurement body for all heath governmental sector therefore coordination is essential for selection & quantification of these sectors .Blood Bank is one of these sectors CMS committed to avail their needs .In addition to excellent intradepartmental coordination represented in weekly and monthly meetings .

CONCLUSION

Item score indicator can assess the overall supply management system .The supply management system was acceptable in 65% of the items , and below the required in 35% of the items .This study shed a light on the blood bank items for the first time . BB consumables and medical devices had no standard reference list .The national consumables and medical devices list is important , it harmonizes medical laboratory trends at the national level .In addition it provides a reference for specifications . Specification of BBI was revised at blood bank level by reviewing pharmacopeias .

Blood Bank had poor forecasting and quantification practice but need assessment department followed partial ordering policy led to good stock management and avoidance of the expiry or overstocking .

BBI procurement practice was altered ,CMS price was equal or higher than the local market price in most items due to the limited number of reliable suppliers , this lead to decreased competition and consequently high procurement price . Moreover the participated supplier did not committed to the scheduled delivery dates and quantities specified in the contract .Other factor was the fact that the arrived quantities might not match quality specifications , and it took a lot of time to manage this tension .

Regarding stock keeping records CMS exercised maximum efficiencies to match physical stock with stock records led to accurate stock information . The acceptable availability was found in 54% of the items and stock out in 46% of the items . Poor forecasts and quantification , insufficient funds , limited number or absence of reliable supplier contributed to decreased availability of these items . Managerial weakness regarding establishment and implementation of standard operation procedures , guidelines on conflict of interest , absence of written job description also contributed to the decreased availability . For the above mentioned reasons CMS could not achieve customer satisfaction (Blood Bank) . Reforms in the PSM like inputs in managerial capacity (increased government commitment to health and availability of sufficient funds, SOPs, conflict of interest & job descriptions) , Process or activities like forecasting and quantification , prequalification of product & supplier , will give better availability , quality and price .

CMS is such a dear place to me ,expressing weaknesses do not mean against or dislike , but it is the first step for improvement .

RECOMMENDATIONS

- Establishment of national medical consumables and devices list that can provide standard specification, this can be done by harmonization and sharing experiences with WHO.
- Doing forecasts for one year considering up-to-date treatment or laboratory trends.
- Development of pricing policies considering fees and charges through the whole supply chain.
- Establishment of government coherent policy to regulate medicines prices that can reduce the profit and increase medicine affordability.
- Strengthening CMS information system to increase the awareness of CMS staff about new suppliers and medical supplies in the national and international level.
- Efforts must be directed toward searching for additional funds to cover the needs for these items , since factor viii
- Governmental mechanisms must be availed to find new reliable suppliers in coordination with national medicines and poison board, and establishment of strong criteria for the suppliers who are willing to supply for CMS.
- Establishment and implementation of pooled regional procurement methods that can overcome problems related to the supplier and excluding registration from tender condition because it limit the number of contributing suppliers .
- Following the updated techniques towards building capable personnel and human resource management.

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قانون الصيدلة والسموم لعام 2009

لائحة الشراء والتعاقد والتخلص من الفائض لعام 2010و2011

قانون الاجراءات المالية والمحاسبية لعام2010

سياسة الجودة بالهيئة العامة للامدادت الطبية

Annex

Attachment 1. Model Questionnaire for Prequalification of Suppliers

PREQUALIFICATION OF SUPPLIERS FOR PHARMACEUTICAL PROCUREMENT

_____
(Country)

This model is intended to facilitate the prequalification of suppliers. Information derived from forms submitted by potential suppliers serve as the basis for evaluating companies and assessing their manufacturing and production capabilities in line with Good Manufacturing Practice and quality standards.

This form contains of four parts:

Part I Business Information
Part II Manufacturing Information
Part III Quality Information
Part IV Product Information

Applicants for prequalification need to fill out one form for Parts I-III. However, Part IV requires that separate forms be filled out for each product being offered for prequalification.

Information provided by potential suppliers seeking prequalification must be regarded as confidential information.

I. BUSINESS INFORMATION

1. Name of company: _____
   Year established: _____
   Form of company: ☐ Individual
   ☐ Partnership
   ☐ Corporation
   ☐ Other (specify)
   Legal status: _____
   Trade register number: _____
   VAT number: _____
   License Number *(attach copy)*: _____
2. Address: _____
   Country: _____
   Telephone: _____ Telefax: _____
   Telex: _____ E-mail: _____

Please attach the company organizational chart

3. Type of activity carried out by the company
   ☐ Manufacturer ☐ Wholesaler
   ☐ Branded products ☐ Branded products

☐ Generic products
☐ Medical supplies
☐ Laboratory reagents
☐ Other products *(specify below)*

☐ Generic products
☐ Medical supplies
☐ Laboratory reagents
☐ Other products *(specify below)*

Indicate % of annual turnover:

Pharmaceutical formulations: _____%
Bulk drugs: _____%
Medical Supplies: _____%

☐ Products manufactured for export
☐ Sold only to the local market
☐ Both

4. Names and addresses of international pharmaceutical companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

Company	Address
_____	_____
_____	_____
_____	_____

5. Employees:

Total: _____
Management: _____
R&D _____
Sales _____
Administrative _____
Others *(specify):* _____

6. Capital value of the company *(specify currency)*
   (a) Authorized capital: _____
   (b) Paid up capital: _____
   (c) Administration: _____

7. Annual sales turnover in the previous three years. Split export and domestic sales. *(specify currency)*

Annual turnover	Domestic sales	Exports	Year
c			
c			
c			
c			
c			

II. MANUFACTURING INFORMATION.

1. Total number of drugs manufactured: _____

(provide list of manufactured products)

2. Are all manufacturing operations (processing, packaging, labeling) carried out internally?

☐ YES ☐ NO

If "No," attach a list of pharmaceuticals and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

3. Provide details if pharmaceutical products and/or raw materials manufactured by your company are exported to other countries

	Pharmaceutical product/raw material	Country	Generic Name	Trade Name
(1)				
(2)				
(3)				

4. State reasons why products manufactured by your company are not marketed in the country of origin

	Generic Name	Trade Name	Reason
(1)			
(2)			
(3)			

5. Does your company have GMP certification?

☐ Yes *(attach a copy of the GMP certificate if any)*
Certified by: _____

☐ No

Indicate if your company has other types of certification

☐ ISO Type of ISO certification: _____

☐ WHO Certification Scheme

☐ Others *(specify)* _____

Attach Certificates of Good Manufacturing Practices (GMP, ISO or Certificates of Pharmaceutical Products according to WHO Certification Scheme covering each item you propose to export.

6. Does your Government carry out inspections and controls on the production of drugs in your country?

☐YES ☐NO

If "Yes", give date of last inspection: _____

7. Has your company been inspected by other governments, organizations or clients?

Inspected by	Year	Outcome

8. Have products manufactured by your company been exported to other countries?

☐YES ☐NO

If "Yes", supply details:

- ☐ Country or (countries): _____
- ☐ By public procurement organization
- ☐ By private importer(s)

9. Date, number and expiry date of current business licence or permit.

Date: _____

Number: _____

Expiry Date: _____

10. Date, number and expiry date of manufacturing licence or permit.

Date: _____

Number: _____

Expiry Date: _____

11. If you are a wholesaler, the following information should be obtained from the manufacturers of product you wish to offer.

A. Give full details on the manufacturer (company name and address), with product lists and brochures of the manufacturing plants, laboratories etc.

Manufacturer: _____

Address: _____

B. Are the products in the product list produced routinely by the company?

☐ YES ☐ NO

C. Or only occasionally on request?

☐ YES ☐ NO

D. Number of specialized personnel involved in the manufacture of pharmaceuticals *(exclude administrative personnel).*

Pharmacists: _____

Chemists: _____

Others: _____

12. A. Are the products manufactured by your company, manufactured under contract by other companies or repackaged?

- ☐ Manufactured
- ☐ Repackaged
- ☐ Manufactured under contract

B. If any products are manufactured under contract, attach a list of such products with the name an address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

C. If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

13. Do other companies package any of the products you manufacture?

☐ YES ☐ NO

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

Provide detailed information on the quality assurance procedures followed.

_____
_____
_____
_____
_____

14. Do you manufacture sterile products?

☐ YES ☐ NO

15. Do you manufacture beta-lactam antibiotics?

☐ YES ☐ NO

If "Yes," are these production facilities in a separate building?

☐ YES ☐ NO

16 Production site

Are the production premises located in the same place as the main office?

☐ Yes ☐ No

If not, state address of the production premises: _____

Address: _____

_____

_____

If there are >1 production site, give description of production site as follows:

	Production site	Address
No. Of products		
Production capacity		
Air treatment system		
Quality of in process water		

List the products from the different production sites:

Production site | Products

(1) (4) (7) (10)
(2) (5) (8) (11)
(3) (6) (9) (12)

III. QUALITY INFORMATION

1. Do you maintain your own quality control laboratory?
   ☐ YES ☐ NO
2. Number of specialized personnel working in your quality control laboratory (excluding administrative personnel).
   Pharmacists: _____
   Chemists: _____
   Others: _____
3. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory.
   _____
   _____
4. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?
   ☐ YES ☐ NO ☐ Certificate of Analysis
5. Quality standards
   ☐ BP Edition ☐ USP Edition ☐ EP Edition ☐ IP Edition
   ☐ JP Edition ☐ CP Edition ☐ Other:

   Are all recommended tests carried out?
   ☐ YES ☐ NO
   If "No," state reason why not
   _____
   _____

   Are additional tests carried out?
   ☐ YES ☐ NO
   If "No," state reason why not
   _____
   _____
6. Are control samples of each batch retained?
   ☐ YES ☐ NO
7. Do you have written cleaning procedures?
   ☐ YES ☐ NO
8. Do you record the training of your employees according to a training programme?
   ☐ YES ☐ NO
9. Do you have a written recall procedure?
   ☐ YES ☐ NO
10. Do you have a written procedure on how to deal with complaints?
    ☐ YES ☐ NO
11. Name and title of the authorized person (s) responsible for batch release:
    Name: _____
    Title: _____
    Experience in pharmaceuticals: _____ years
12. Name and qualification of the head of the Quality Control department:

Name: _____

Qualification: _____

Experience in pharmaceuticals: _____ years

13. Indicate if you perform quality tests conducted routinely:
    - ☐ active starting materials
    - ☐ non-active starting materials
    - ☐ packaging materials
    - ☐ intermediate products
    - ☐ bulk products
    - ☐ finished products
14. Are all quality control tests performed internally?

    ☐ YES ☐ NO

    If "No," list tests performed by external laboratories:

Tests	Laboratories	Address
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

15. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.

    _____

    _____

    _____

    _____

16. Do you conduct tests on each container of the active starting material?

    ☐ YES ☐ NO

    If not, explain your way of sampling: _____

    _____

17. Do you test each container of non-active starting materials?

    ☐ YES ☐ NO

    If "No," describe method of sampling: _____

    _____

18. Are you willing to reveal the sources of starting material? (Information will be deemed confidential)

    ☐ YES ☐ NO

19. Are stability tests routinely conducted for every product?

    ☐ YES c ☐ NO

    If "No," state reason why not: _____

    _____

20. For each batch, check the procedures that are routinely done:
    - ☐ Batch numbers and control numbers of each component
    - ☐ Weighed quantities double checked and signed off for each component
    - ☐ Acceptance record of each component
    - ☐ Date and time of each stage of production
    - ☐ Identification of equipment used

☐ Name of persons in charge at each stage
☐ In-process control results
☐ Environment control results
☐ Remarks on production incidents
☐ Comments on not following the master formula
☐ Yield and reconciliation
☐ Packaging material batch numbers
☐ Line clearance sign off
☐ Result of QC of end product
☐ Inspection checks and test results, dates and signatures of inspecting

21. Explain procedure for releasing batches of finished products:
    c _____
    c _____
    c _____
22. Do you keep samples of each batch?
    ☐ YES ☐ NO
    Indicate how long do you keep the samples: _____ years
23. Are these kept in the original containers?
    ☐ YES ☐ NO
24. Attach a detailed account of the current quality assurance system in your company. A Quality Assurance manual or handbook may be submitted.
25. Do you carry out inspections or quality audits of your own suppliers?
    ☐ YES ☐ NO
    If "Yes," describe audits in detail:
    _____
    _____
    _____
    _____
26. Describe your storage facilities:
    _____
    _____
    _____
    _____
    _____

IV. Product Information (Please fill up one form for each product)

1. Active Pharmaceutical Ingredient(s) _____
   _____
   _____
   Indicate if product has any of the following:
   ☐ Certificate of Suitability to the European Pharmacopoeia (CEP)
   Certificate No.: _____
   ☐ The CEP is in our possession (including annex if any)
   ☐ Drug Master File (DMF)
   registered in *(country)*: _____
   registration no.: _____
   ☐ The full or open part of the DMF is in our possession
   ☐ The full or open part of the DMF is in possession of the manufacturer

Manufacturer: _____

Country: _____

2. Trade Name of the Product: _____

Dosage form: ☐ Tablets ☐ Capsules ☐ Ampoules ☐ Vial ☐ others *(specify)* _____

Strength per dosage unit: _____

Route of administration: ☐ Oral ☐ I.M ☐ I.V ☐ S.C. ☐ other *(specify)* _____

Number of units/volume or weight per container: _____

Type of container: _____

3. Regulatory Status in Country of Origin

☐ Product registered in country of origin and routinely manufactured and marketed

License no: _____ year issued: _____

☐ Product registered in the country of origin but not currently marketed

License no: _____ year issued: _____

☐ Product registered for export only

License no: _____ year issued: _____

☐ Product not registered

4. Regulatory Status in Other Countries

List other countries where the product is registered and currently marketed:

Product	Country	Trade Name
_____	_____	_____
_____	_____	_____
_____	_____	_____

5. Certificate of Pharmaceutical Product According to WHO Certification Scheme (WHO Technical Report-s Series No 863/ http://www.who.int/medecines/team/qsm/certifscheme.htlm)

☐ The Certificate of Pharmaceutical Product (based on the last format recommended by WHO)

☐ The Certificate of Pharmaceutical Product cannot be obtained from the National Drug Regulatory Authorities because:

6. Dosage Forms

Form	Formulation	Dose
Oral		
_____	_____	_____
_____	_____	_____
_____	_____	_____
Injectable		
_____	_____	_____
_____	_____	_____
_____	_____	_____
Fixed-dose combinations		
_____	_____	_____
_____	_____	_____
_____	_____	_____

7. Production Manager

   Name: _____
   Title: _____
   Experience in pharmaceuticals: _____ years

8. Validation

   Are all your production processes validated?

   ☐ Yes ☐ No

9. Do you use an approved manufacturing formula and processing instructions?

   ☐ Yes ☐ No

10. Finished Product Specification

    ☐ CP Edition ☐ BP ☐ USP Edition
    ☐ CP ☐ JP

    Attach a copy of the finished product specifications

    Are you willing to provide necessary information (analytical methods) for the tests to be replicated by another control laboratory?

    ☐ Yes ☐ No

11. Limits in % for the assay in active ingredient(s):

    ☐ 95-105% ☐ 90-110 %
    ☐ Other: _____

    Additional specifications to those in the pharmacopoeia:

    _____
    _____

    Attach a copy of the model certificate of analysis for batch release

12. Stability

    Stability testing data available: ☐ Yes ☐ No

    Type and conditions of satisfactory testing (without significant change):

    ☐ accelerated testing
    ☐ 40°/75% RH/6 months
    ☐ other:
    ☐ in the same packaging as marketed
    ☐ in another packaging:
    ☐ real time testing

    Temperature: ☐ ambient ☐ 25°C ☐ 30°C ☐ other: __
    Relative humidity: ☐ 45% ☐ 60% ☐ 70%
    ☐ not controlled ☐ other: _____
    Period of time: ☐ 1 year ☐ 2 years ☐ 3 years ☐ other: __
    ☐ in the same packaging as marketed
    ☐ in another packaging: _____

13. Label and Insert Information

    Shelf life: ☐ 2 years ☐ 3 years ☐ 4 years
    ☐ 5 years ☐ other: _____

    Storage conditions (e.g. Store below 30°- Protect from light):

    _____
    _____

    Package insert: ☐ Yes ☐ No

    Attach a copy of the label and package insert

14. Therapeutic Equivalence

☐ Bioequivalence Study

Reference: _____
Reference sourced from: _____
Number of volunteers: _____
Year: _____
Institution, country where study was done: _____
Attach a copy of the report on the bioequivalence study.

☐ Clinical Study

Study design: _____
Sample size: _____
Study objective: _____
Results: _____
Year: _____
Institution, country where study was done: _____
Attach a copy of the report on the clinical study

15. Dissolution Tests

☐ Method: _____

☐ Results: _____

_____
_____

16. Normal Batch Size: _____

CERTIFICATION

I, the undersigned (full name of the person responsible)

Name _____

Designation _____

Hereby declare that all the information given above is true, and I take the full responsibility for all consequences that might arise from false or erroneous information. If required, I will cooperate with any official of the Ministry of Health and in (country name) in making personal inspection of manufacturing facilities and records.

Certification by the Ministry of Health or the official authority in charge of the control and inspection of pharmaceutical manufacturing facilities:

We hereby certify that the information given is true and that the company concerned fulfils the requirements of local regulations concerning the manufacturing of pharmaceuticals.

Name _____
Designation _____
Signature _____
Date _____