EFFECTS OF OPERATIONAL MANAGEMENT PRACTICES ON THE PROCUREMENT OF PHARMACEUTICAL PRODUCTS IN DEVELOPING COUNTRIES: A CASE OF KENYA MEDICAL SUPPLIES AGENCY (KEMSA)

BY

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A MANAGEMENT RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF BUSINESS ADMINISTRATION, SCHOOL OF BUSINESS, UNIVERSITY OF NAIROBI.

2010
DECLARATION

This management research project is my original work and has not been presented to any university for examination.


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REGISTRATION NO: D/61/P/8824/2005

This management research project has been submitted for examination with my approval as the university supervisor.

Sign ............................................. 13-11-2010

DR JOHN YABS
DEPARTMENT OF BUSINESS ADMINISTRATION.
UNIVERSITY OF NAIROBI.
I dedicate this project to my parents, beloved husband Dennis and daughter Maya.
I love you all.
ACKNOWLEDGEMENT

The preparation of this project benefited enormously from the support and contribution of various people and institutions. I particularly thank God for life and brains. I also wish to express my sincere thanks to Dr. Yabs for his, guidance and direction through out this piece. I am entirely indebted to my parents Obieros and Mogois for their tireless effort and support towards the completion of this piece and to my dear husband for the unseen support and effort he has channeled to this project. Special gratitude to Dr Odundo for his valuable criticism too.

Thanks to the research staff of the Institute of policy and research (IPAR) and African Medical Research Foundation (AMREF) for their library resources, Kemsa (kenya medical supplies agency) officials, TB( Tuberculosis programme), and Kenyatta National Hospital staff. Special thanks to my brothers and sisters for their motivation and support.
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ABSTRACT

Procurement of drugs and medical supplies is one of the most critical facets in the access and coverage of primary health care. Anti malarials, anti retroviral (ARVs), and therapeautic drugs are constantly needed in developing countries and Kenya is not an exception, yet we experience drug stock outs, expired drugs on the shelf, poor procurement procedures and even counterfeit drugs in the market. This is what this project sort to unfold. Upon discovery is that, amidst this unlimited need for drugs, conflicts of interests arise from the manufacturers who invent new supplies and medicines to the market to counter the rising demand and sudden rise in vast diagnoses. At the same time suppliers of these drugs seek market approval in order to expand sales and their market share, this competition though may be healthy on one side but disadvantageous on the other especially when Key hospitals in the country run stock outs on critical drugs like anti malarials and Arvs. The rise of counterfeited drugs in the pharmaceutical industry is also cause for alarm and leads one to question whether there exists a bureau of standards to streamline quality assurance procedures? Whether there exists an essential medicine list and adherence levels to it? What popular promotion mode is used and if it is inline with the pharmaceutical promotional code of ethics?

This project based itself on the 4 WHO (World Health Organization) operational principles of pharmaceutical management namely efficiency and transparency, drug quantification, procurement, promotion and supplier selection. It is on the above principles that the project sought to examine the managerial implementation on the pharmaceutical products industry. Based on the above, the main objective of this project was to establish the impact of operational management practices on the procurement of pharmaceutical products in developing countries. In this case the practices are the principle framework recommended by the WHO above. The study sought to particularly use a case of KEMSA (Kenya Medical Supplies Agency) which drew a significant representation of drug procurement in a number of developing countries. Particularly procurement methods and key supplier policies on TB (Tuberculosis) drugs, ARVs and Antimalarials played a critical role in the sample determination and analysis thereafter. The document further discusses the options of procurement processes and policies that should be considered when implementing or reforming access to the drugs and medical
supplies in question, which is key information to drug manufacturers, suppliers, competitors and even policy makers.

An empirical analysis was carried out surveying various Kemsa’s key respondents to establish opinions on effective procurement, promotion, efficiency, drug quantification, and supplier selection management. Based on a basic Cobb Douglas function that the project formulated, correlation models and coefficients were drawn to identify relationships and extents of managerial adherence to pharmaceutical procurement principles. Two operational principles appeared to have drawbacks on the management perspective: drug quantification and supplier selection, procurement (irregular supply chain management). The project concluded on one major mechanism that would prove remedial to the managerial inefficiencies in the principles above is decentralization. Whereby management of drugs and supply chain logistics is contained within the facility such that it does its own quantification and supplier selection as per the needs of that particular locality. This will eradicate loopholes in health care access and coverage such as essential drug stock outs, and undeserved supplier selection hence saving lives.
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</thead>
<tbody>
<tr>
<td>ARVs</td>
<td>Antiretrovirals</td>
</tr>
<tr>
<td>ACT</td>
<td>Artemisinin Based combination Therapy</td>
</tr>
<tr>
<td>AL</td>
<td>Artemether Lumefantrine</td>
</tr>
<tr>
<td>ALAFARPE</td>
<td>Peru’s Association of Pharmaceutical Laboratories</td>
</tr>
<tr>
<td>BCT</td>
<td>Blood Safety and Clinical Technology</td>
</tr>
<tr>
<td>CDS</td>
<td>Communicable Diseases</td>
</tr>
<tr>
<td>CHS</td>
<td>Health Systems and Community Health</td>
</tr>
<tr>
<td>DAP</td>
<td>Action Programme on Essential Drugs</td>
</tr>
<tr>
<td>DIGEMID</td>
<td>General Directorate of Medicines, Supplies and Drugs</td>
</tr>
<tr>
<td>EAC</td>
<td>East Africa Community</td>
</tr>
<tr>
<td>ECHO</td>
<td>Equipment for Charity Hospitals Oversean</td>
</tr>
<tr>
<td>EDM</td>
<td>Essential drugs list</td>
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<tr>
<td>EDM</td>
<td>Department of Essential Drugs and Medicines Policy</td>
</tr>
<tr>
<td>EURO</td>
<td>Regional Office for Europe</td>
</tr>
<tr>
<td>FIP</td>
<td>Fédération Internationale Pharmaceutique</td>
</tr>
<tr>
<td>FSHSS</td>
<td>Russia’s Federal Service for Health Sphere Supervision</td>
</tr>
<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>ICRC</td>
<td>International Committee of the Red Cross</td>
</tr>
<tr>
<td>IDA</td>
<td>International Dispensary Association</td>
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<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>INN</td>
<td>International Nonproprietary Name</td>
</tr>
<tr>
<td>INQUIFAR</td>
<td>El Salvador’s Association of Pharmaceutical Companies</td>
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<tr>
<td>IPC</td>
<td>Interagency Pharmaceutical Coordination Group</td>
</tr>
<tr>
<td>IB</td>
<td>Innovator Brand</td>
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<tr>
<td>IPMG</td>
<td>International Pharmaceutical Manufacturers Group</td>
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<tr>
<td>LPG</td>
<td>Lowest Priced Generic</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MIS</td>
<td>Management Information System</td>
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<tr>
<td>MSF</td>
<td>Médecins Sans Frontières</td>
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<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
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<tr>
<td>NQCL</td>
<td>National Quality Control Laboratories</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<td>--------------</td>
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<tr>
<td>NGO</td>
<td>Non Governmental Organization</td>
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<tr>
<td>PPDA</td>
<td>Procurement and Disposal Act</td>
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<tr>
<td>PPDR</td>
<td>Public Procurement and Disposal Regulations</td>
</tr>
<tr>
<td>SEARO</td>
<td>Regional Office for South-East Asia</td>
</tr>
<tr>
<td>SUP</td>
<td>Supply Services</td>
</tr>
<tr>
<td>SP</td>
<td>sulfadoxine-pyrimethamine</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>UNIDO</td>
<td>United Nations Industrial Development Organization</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>VAB</td>
<td>Vaccines and Biologicals</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WPRO</td>
<td>Regional Office for the Western Pacific</td>
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<tr>
<td>GFTAM</td>
<td>Global Fund to Fight Aids, Tuberculosis and Malaria</td>
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<tr>
<td>CCM</td>
<td>Country Coordinating Mechanisms</td>
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<tr>
<td>SRA</td>
<td>Stringent Regulatory Authority</td>
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<tr>
<td>TCM</td>
<td>Technical Co-operation for Essential Medicines</td>
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<tr>
<td>LFA</td>
<td>Local Fund Agents</td>
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<tr>
<td>PMI</td>
<td>Presidential Malaria Initiative</td>
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<td>Ci</td>
<td>Submitted to WHO or SRA for approval but not yet approved</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<tr>
<td>NOC</td>
<td>Notice of Concern</td>
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<tr>
<td>DOMC</td>
<td>Division of Malaria Control</td>
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<tr>
<td>DRH</td>
<td>Division of Reproductive Health</td>
</tr>
<tr>
<td>RPM</td>
<td>Rational Pharmaceutical Management Plus</td>
</tr>
<tr>
<td>IPMG</td>
<td>International Pharmaceutical manufacturers group</td>
</tr>
<tr>
<td>NMRA</td>
<td>National Medicines and Regulatory Authority</td>
</tr>
<tr>
<td>PPB</td>
<td>Pharmaceutical Poisons Board</td>
</tr>
<tr>
<td>VEN</td>
<td>Vital, Essential, Non-essential drugs</td>
</tr>
<tr>
<td>INN</td>
<td>International Non Proprietary name</td>
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<tr>
<td>EML</td>
<td>Essential Medicines List</td>
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**DEFINITION OF SIGNIFICANT TERMS**

**Board of Governors:** Refers to a committee whose members are constitutionally nominated according to Kenya’s medical act, 1970, Cap 211, part 3 to oversee the procurement legalities.

**Procurement:** Refers to purchasing, hiring or obtaining by any other contractual means of goods, construction and services.

**Procurement Plan:** Refers to a documented schedule that specifies the goods and services to be procured over a period of time, spelling out the quantities, estimated cost and a method of procurement, financing arrangement and schedule for processing.

**Procuring Entity:** Refers to any public institution that procures either goods or services from the market.

**Threshold:** Refers to the maximum amount that can be committed by the medical procurement officers without going through the rigorous tendering procedure.

**Value-for-Money:** Refers to the best value that is worth the money spent on goods and services.

**Pharmaceutical Product:** All Pharmaceutical or biological products which are registered by the Pharmacy and Poisons Board as drugs including Part I and Part II poisons.

**Promotion:** Any activity undertaken or organized or sponsored by a company, distributor, or and importer that is promoting the prescription, recommendation, supply, sale or distribution of a Pharmaceutical product.
Health care professionals: Members of the medical, dental, pharmacy and nursing professions and any other persons who may as a result of their legal qualification be able to prescribe, supply or administer medicines.

Pharmaceutical Representative: Those persons whose duties comprise calling upon doctors, dentists, pharmacists, wholesalers or government officials who are involved in the provision of healthcare.
CHAPTER ONE: INTRODUCTION

1.1 Background of the study:
Procurement is an important part of efficient drug management and supply and is critical for all levels of health care institutions. An effective procurement process ensures the availability of the right drugs in the right quantities, available at the right time, for the right patient and at reasonable prices, and at recognizable standards of quality (WHO 2007). Based on this document, are four main operational principles of drug quantification, registration, selection and efficient management. This project drew from the above framework with key emphasis on the management perspective of the above. Thus, procurement is not simply the act of buying but encompasses a complex range of operational, business, information technology, safety and risk management, and legal systems, all designed to address an institution's needs (Ombaka 2009). Specifically, management of medicines procurement determine, accredit, and monitor appropriate supply sources; evaluate suppliers' performance; choose a buying strategy or approach; monitor drug delivery; assess clinical and use outcomes; and evaluate new products and the drug market. Successful hospital procurement is also a collaborative process, involving people with skills in purchasing, finance, management, clinical and nursing specialties, pharmacy, quality control, and even the end user: the patient.

In developing countries initial decentralization of drug procurement was followed by pooled procurement by hospitals or cooperatives. Unbiased market information on product availability, comparative pricing, product quality and supplier performance is difficult to obtain in many countries. Poor access to information is most common in countries where it is most needed in the light of inadequate regulation of the local market. This information deficiency can result in gaps in essential drug availability and in procurement of poor-quality products at unnecessarily high prices hence facilitating undue influence on the procurement process by special interest groups (WHO 2007). Even if appropriate policies and procedures are in place, lack of properly trained staff in key positions can doom any procurement system to failure an example of Ghana, Kenya, Zambia and more especially Nigeria. While effective training programmes can remedy this problem, in many supply systems there is limited access to training in good
procurement practices. Also unattractive public sector salaries and lack of career
development tend to restrict capacity to attract and retain qualified staff.

Information is critical to an effective and efficient procurement process, on the other hand
financing is the engine that drives it. In the case of Kenya for example, (World Bank
2007) ensuring adequate financing for the procurement of pharmaceuticals remains an
important part of medicines procurement. Pharmacists involved in hospital procurement
of medicines, whether directly or indirectly, must be knowledgeable about medicines as
well as the interacting issues and the many stakeholders who can potentially affect the
process or who may have legal responsibility.

Transparent management is another concept, which is closely related to accountability
and Kenya lives a lot to be desired in this facet. The idea behind transparency is that by
actively disclosing information on how decisions are made, as well as measures of
performance, we can improve public deliberation, reinforce accountability and inform
citizen choice. In addition, transparency helps to document and disseminate information
on the scope and consequences of corruption, information which can help build support
for anti-corruption programmes and target enforcement effort (Griffin, 1988). It is
therefore in accordance with the basic operational management principles of efficiency
and transparency, registration of medicines and pharmacies, drug selection and
quantification, supplier selection and quality assurance, promotion and financing of the
procurement process that the chief objective of ensuring access and coverage of primary
health to all is achieved. This study therefore sought to bridge the gap between these
management principles and the health institutions and clientele in question showcasing
developing countries like Ghana, Nigeria, Uganda, and more especially Kenya.
1.1.1 Operational Practices On The Procurement Of Drugs And Medical Supplies:

Pharmaceutical procurement occurs in many contexts (WHO 1999). According to WHO postulated framework from which this document is grounded are 4 main operational principles that pharmaceutical companies should adapt for efficient product procurement. These principles are drug quantification, drug and pharmacy registration, efficient and transparent management and finally finance and promotion. Although the operational principles presented here are in many respects applicable to all procurement settings and for most types of procurement situations, their primary target is pharmaceutical procurement for public sector health systems, hence the choice of Kemsa. It was recognized that public sector procurement may be managed in a variety of ways, ranging from total in-house systems, through various autonomous or semi-autonomous procurement agencies, to total privatization. These principles were applicable to each of those variations.

1.1.1.1 Registration of medicines and pharmacies:

Market approval (or registration) of pharmaceutical products is usually granted on the basis of efficacy, safety and quality. It is a regulatory decision that allows a medicine to be marketed in a given country (Rouselle, 1996). Compliance with regulations affecting drug licensing, accreditation and approvals can be costly for pharmaceutical companies wanting to market their products. Some of them may try to bribe or influence the regulator to get their product registered or simply to speed up the approval process. One form of influence is to offer lucrative industry jobs or consulting assignments to regulatory officials, rewarding them for decisions that are favorable to industry. Such conflict of interest can also affect the setting of user fees for drug registration, which are often set well below true cost. Thus, government is effectively subsidizing costs of private industry for little public benefit (Kaplan and Laing, 2003).

The Pharmacy and Poisons Board in Kenya established under the Pharmacy and Medicines Act Chapter 244 is responsible for the registration of pharmacy professionals, drug registration, and issuance of licenses for manufacturers, wholesalers, and retail pharmacies. The Board is assisted by the Division of Pharmaceutical Services under the Ministry of Health. There is a unit within the Pharmacy Division of the MOH responsible
for registration of drugs. The Technical Evaluation Committee, which is part of the Board, assists in the evaluation and registration of drugs. The Board is responsible for the approval of registration of drugs. Drug registration started in 1982 but the precise number of products on the market is not known. The percentage of pharmaceutical products registered at the time of the mission was 50%. There is also an illicit market.

On the other hand, Cameroon had no written and approved national drug policy (WHO 2005), however elements of a national drug policy such as drug registration, quality control, drug procurement and regulatory control were being implemented. The country had an essential drugs list called Liste nationale des Médicaments essentiels utilisés dans les Formations sanitaires, developed in 1990 which is being used to date. It is being used in the procurement of drugs for the public sector. The list contains 120 products. Guidelines for registration were developed in 1981 and registration started the same year. The Pharmacy Department in the Ministry of Health is responsible for drug registration, inspection and drug legislation activities. About 90% of the products were registered at the time of the assessment. The figure does not include drugs imported into the country illegally. It was therefore observed that the Scheme was not used in drug procurement in the public and private sector nor in drug registration and Quality testing of pharmaceuticals was found to be inadequate.

According to WHO publication 2005, in less developed countries especially, Pharmacies and drug stores also require approvals to operate. The process of licensing pharmacies for operation has been corrupted by bribes, leading to unfair decisions (favoring kin or political contacts of government agents), geographic inequities, and facilities that do not adhere to government regulations implying unethical drug dispensations, under and over prescriptions, fake and substandard drug circulation in the market too. As with the registration process, conflict of interest is also a concern if national experts receive compensation from pharmaceutical companies that could influence their judgement. In Peru the sale of counterfeit drugs has risen from an estimated US$ 40 million in 2002 to a current US$ 66 million, according to Peru’s Association of Pharmaceutical Laboratories (ALAFARPE). These figures include medicines that entered the country as contraband, expired, counterfeit, adulterated, with altered or missing labels and those stolen from the warehouses of the Ministry of Health, the armed forces, and the police. In Lima alone the
number of illegal pharmacies devoted to counterfeit medicines has increased from an estimated 200 in 2002 to a current number of 1,800 stores. The General Directorate of Medicines, Supplies and Drugs (DIGEMID) of the Department of Health seized around 460,000 adulterated and expired medicines in 2005 alone.

In 2006, Russia’s Federal Service for Health Sphere Supervision (FSHSS) reported that 10% of all drugs on the Russian market were counterfeit. However, other sources estimate that the real figure could be much higher. The Dominican Republic’s Public Health Department reported that 50% of the country’s pharmacies operated illegally and 10% of the medicines that arrived in the country were counterfeit. For example, some of the medicines found had expired over 10 years before.

El Salvador’s Association of Pharmaceutical Companies (INQUIFAR) reports that there is a widespread availability of counterfeit drugs on the domestic market. According to the local manufacturer Gamma Laboratorios, the commercialization of counterfeit medicines generated economic losses of around $40 million to the country’s pharmaceutical industry that year. Indonesia’s International Pharmaceutical Manufacturers Group (IPMG) estimated that pirated drugs constituted 25% of Indonesia’s $2 billion pharmaceutical market. According to IPMG, the fake drugs hit foreign pharmaceutical companies’ bottom lines and posed a potential serious public health threat.

In Kenya, a random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found that almost 30% of the drugs in Kenya were counterfeit. Some of the drugs were no more than just chalk or water marketed as legitimate pharmaceutical products. According to figures from the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical products account for approximately $130 million annually in sales in the country all these could be avoided if medicine registration and pharmaceuticals management is efficiently undertaken.

1.1.1.2 Drug Selection and Quantification:

Once a pharmaceutical product has received market approval, public procurement systems have mechanisms to limit procurement or reimbursement of medicines, based on comparison between various medicines and on considerations of value for money. This step leads to a "national list of essential medicines, (World Health Organization, 2002).
The selection of essential medicines in a given country uses defined criteria and consultative and transparent process. The inclusion of any pharmaceutical on this list will lead to increased market share and if the process is not transparent, special interest groups may offer bribes to the selection committee members to get their product on the list.

Drug Quantification is the process of estimating the quantities of a specific drug or medical supply item needed for procurement for a specific period. Malaria is among the most important global health problems in Africa, accounting for more than a million deaths each year. About 90 percent of cases occur in tropical Africa, where malaria is the leading cause of mortality in children below the age of five years. A key component of the global malaria strategy is early diagnosis and treatment. In recent years, mounting resistance to commonly used pharmaceutical therapies, such as chloroquine and sulfadoxine-pyrimethamine (SP), has rendered them ineffective (DoMC1998). As a result, the World Health Organization (WHO) recommended that all countries changing antimalarial treatment policies should change to ACTs (WHO 2005). Early diagnosis and treatment as well as the provision of effective antimalarials to all levels of the delivery target require that antimalarials be available in the right quantities and used appropriately at the right time. This recommendation highlights the responsibility of pharmacists and program managers at all levels to ensure that an uninterrupted supply of antimalarials is available while minimizing waste and costs and ensuring the antimalarials are used rationally.

In 2006, Kenya implemented a change in malaria treatment policy in all public facilities from SP to the ACT artemetherlumefantrine (AL), largely supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Two years after AL introduction, a cross-sectional survey by the WHO was carried out to investigate AL availability in government facilities. From August 18 through October 2, 2008, 164 facilities (115 dispensaries, 30 health centers, and 19 hospitals) were assessed in seven districts in Nyanza, Western, and Coast Provinces, Kenya, that were highly endemic for malaria. At each facility, information was collected on the availability of AL packs for the four patient weight groups either through direct review of stock cards or through phone interviews. Health workers were also asked what they prescribed in the absence of AL.
One (25.6%) of four of the surveyed facilities had none of the four AL weight-specific treatment packs in stock, with such complete stock-outs more common in dispensaries. It was particularly worrying that packs for the youngest age group, the group most at risk of malaria mortality, were absent in nearly two-thirds (61.0%) of facilities. The median duration of current stock-outs was substantial, ranging from 35 days (interquartile range [IQR] = 12–83 days) for the 12-tablet pack to 52 days (IQR = 22–99 days) for the 24-tablet pack of the facilities out of stock of all packs, they had been in this state for a median of 52 days (IQR = 16–76 days).

Quantification also involves the financial requirements needed to purchase the items. Good quantification provides for appropriate allocations of the pharmaceutical budget and results in enough antimalarial stock to meet the demand for different malaria control situations, including emergency or epidemic needs, but the knowledge and skills for quantification are largely unavailable or insufficient. The current lack of capability within malaria programs in Kenya (Tetteh G, C. Adegoke, W.Kabuya, F Nyane 2005) and to determine the appropriate method of quantification to use, as well as ways of meeting the big challenges faced by program managers in obtaining accurate and reliable data, was an area of immediate intervention in the management of pharmaceutical procurement.

1.1.1.3 Procurement process:
Providing health facilities with drug and medical supplies is a complex process involving both the private and public sectors. Governments and health ministries often lack the management skills required to write technical specifications, supervise competitive bidding, and monitor and evaluate the contract performance (Ombaka 2003). Financial malpractices also could occur at any stage of the process and influence decisions on the model of procurement (direct rather than competitive), on the type and volume of procured supplies, and on specifications and selection criteria ultimately compromising access to essential quality medicines. An example of Kenya and Uganda who reportedly implemented the AL switch which gave the tender to a local firm the (The Standard 2009), Confusion in communicating this decision delayed the start of the tendering process to late 2007, and the opening of the tender until February 2008. Further delays
arose because of the difficulty in obtaining compliant tender bids. Finally, evaluating the tender bids took longer than expected because the Kenyan tender committee was being investigated for allegations of corruption. The tender was finally awarded in May 2008 to the Indian firm Ajanta Pharma Limited. The first AL consignment was promised in October 2008, but had not arrived by the end of the year.

This delay was reportedly partly due to the slow process of quality assurance testing procedures, which had to be carried out on each batch of AL before its supply. Although the drugs were approximately half the cost of those obtained by direct sourcing, their arrival was late. This chain of events left Kenya with disastrously low AL stocks. Similar availability problems have been experienced elsewhere in sub-Saharan Africa. The international community responded promptly to calls to replace failing medicines but now has turned its attention to failures in supply to fix problems of access and effectiveness of ACT policies in Africa. Common malpractices in the procurement process include collusion among bidders resulting in higher prices for purchased medicine, kickbacks from suppliers and contractors to reduce competition and influence the selection process, and bribes to public officials monitoring the winning contractor's performance all of these practices led to cost overruns and low quality. Other forms of abuse, fraud and mismanagement can occur due to insufficient management and monitoring capacity. In Nigeria for example the anti malarial supplies do not meet the expected standards, and are only partially delivered or not delivered at all (USAID 2005).

In a context where quality controls are difficult to exercise, an increasing lack of funds results in opportunities to sell low quality, expired, counterfeit and harmful drugs at cheaper prices. Corrupt procurement officers can also purchase sub-standard drugs in place of quality medicines and pocket the difference.

Moreover due to under-financed and badly managed systems, poor record-keeping and ineffective monitoring and accounting mechanisms, large quantities of drugs and medical supplies are stolen from central stores and individual facilities, and diverted for resale for personal gain in private practices or on the black market (Lerberghe M.V. 2004). This involves a variety of practices such as record falsification, dispensing drugs to "ghost patients", or simply pocketing the patient's payment. Patients are directly affected in this
process as they are forced to supply their own medications or, in the case of hospital inpatient stays, linens and food. These resulted in considerable leakage of public resources. Distributing medical supplies to the healthcare facilities also involved managing an effective transportation system and preventing misappropriation of fuel and vehicles for private or non-health related uses.

1.1.1.4 Promotion, financing and competition:
Promotion and marketing of pharmaceuticals follows the code for pharmaceutical promotion in Kenya. The Code sets out standards for the ethical promotion and conduct of Pharmaceutical Representatives in their interactions with healthcare professionals to ensure that they are appropriate and perceived as such. The relationship of the Pharmaceutical industry with healthcare professionals is intended to benefit patients and to enhance the practice of medicines. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and, supporting medical research and education. (Code for pharmaceutical promotion in Kenya 1999)

No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting, contracts or educational or practice related items) may be provided or offered to healthcare professionals in exchange for prescribing, recommending, purchasing, supply or administering products or a commitment to continue to do so. Nothing may be offered or provided in a manner or conditions that would have an inappropriate influence on a healthcare professional’s prescribing practices. Promotion should encourage the appropriate use of Pharmaceutical products by presenting them objectively and without exaggerating their properties. Promotion should not be disguised. Clinical assessments, post-marketing surveillance, experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Material relating to Pharmaceutical products and their uses, whether promotional in nature or not, which sponsored by a company or distributor/importer should clearly indicate by whom it has been sponsored. No Pharmaceutical product shall be promoted for use unless it has been registered by the
Promotion should be consistent with the approved product information.

Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the Pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as ‘safe’ or ‘no side effects’ should generally be avoided and should always be adequately qualified. Promotion should be capable of substantiation either by reference or reference to approved labelling or by scientific evidence. Such evidence should be made available on request to healthcare professionals.

1.1.1.5 Promotion and Competition in the Pharmaceutical Sector:

Aggressive marketing strategies have led to the unethical promotion of medicines and to conflicts of interest that influence a physician's judgement. A range of practices are commonly used by pharmaceutical companies in Kenya as incentives to encourage the use of their product such as distributing free samples, gifts, sponsored trips or training courses (The Standard 2008). Although it is sometimes delicate to draw the line between marketing and corruption, such practices are likely to generate conflict of interest whereby a decision on treatment is no longer made in the patient's best interest. Interactions between physicians and the Pharmaceutical industry can lead to non-rational prescribing and increased spending on medicines with little or no additional health benefit (Alfred A. Knopf; 2004). A recent case of an ailing child in Mombasa who used a drug consistently with no effect only to test it and find it has no medicinal content. The management aspect in the promotion department is left to be questioned on this matter considering a lost life and many more endangered. Perverse incentives and "money warped behavior" can endanger patients' health, as doctors enroll unqualified patients in trials or prescribe unnecessary and potentially harmful treatments, in order to maximize profit. Some countries have banned,
procurement decisions be made by user representatives (WHO 2007). Larger procurement volume makes favourable prices and contract terms more likely, by increasing suppliers' interest in bidding and by providing them with an incentive to offer a competitive price. A higher volume for single items may be achieved through pooling of procurement volume from many facilities or from several States or countries, by restriction of the drug list or by elimination of duplication within therapeutic categories. Procurement in the public health sector is based on competitive procurement methods, except for very small or emergency orders. There are four main methods for purchasing drugs (Ombaka 2009). Three of them are competitive: restricted tenders, open tenders and competitive negotiations. The fourth method is direct negotiation with a single supplier.

Since inducing supplier competition is a primary key to obtaining favourable pricing, the public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed. As discussed above, drugs that are available from multiple sources should be competitively purchased under their generic (INN) name. As long as drug quality and service reliability are assured, competition is increased to the point at which drug prices are as low as possible. The “rule-of-five” for pharmaceutical pricing holds that generic prices generally reach their minimum when there are at least five generic alternatives on the market and that prices in tendering systems are at their lowest where there are at least five bids per item; adding more bids generally does not result in further lowering of prices.

In situations where most or all of the products in a therapeutic category are single-source or branded products, the number of different drugs in a therapeutic category can be reduced through cost-effectiveness analysis (Di Tella and Savedoff 2001). Competition can be induced by therapeutic class tendering. For example, among the newer antibiotics there may be several which are therapeutically similar, at least for specific indications. Therapeutic class tendering means that offer are requested on two, three or more therapeutically similar but generically different products. The selection of the most cost-effective drugs within a therapeutic category should be done by the national essential drugs committee, not by the procurement office. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract (Di
Tella and Savedoff 2001). Except in those systems where each health facility negotiates prices and purchases drugs individually, public pharmaceutical procurement systems are seen as purchasing groups. Normally, group purchasing achieves lower prices than would be available to the same group of health facilities if they purchased individually. These discounts are based on the fact that facilities which are part of the purchasing group will purchase contract items only from the selected contract supplier, as long as that supplier is able to perform. This is called sole-source commitment. If group members are free to make separate deals for contract items with other suppliers at will, the suppliers who participate in tenders will have little incentive to offer the best possible discounts to the purchasing group.

1.1.1.6 Efficient and Transparent Management

Expensive hospital construction, high tech equipment and the increase in drugs needed for treatment, combined with a powerful market of vendors and pharmaceutical companies, present risks of bribery and conflict of interest in the health sector (Lantham 2001; Kassirer 2006). Government officials use discretion to license and accredit health facilities, providers, services and products, opening risk of abuse of power and use of resources. The patient-provider relationship is also marked by risks stemming from imbalances in information and inelastic demand for services. Resulting corruption problems include, among others, inappropriate ordering of tests and procedures to increase financial gain; under-the-table payments for care; absenteeism; and use of government resources for private practice (Di Tella and Savedoff 2001).

Clinical care providers also exercise discretion by making decisions about the amount and types of health care services a patient should have. High amounts of discretion without adequate controls can create opportunities for corruption. For example, a department head can choose to hire an unqualified relative, or a procurement agent can decide to procure a new, high priced drug in quantities that greatly exceed need, in order to obtain a promised kickback. The goal of anti-corruption strategies is to increase appropriate control on discretion without creating dysfunctional bureaucracy. Strategies can include dividing tasks between individuals to create checks and balances; clarifying the decision-making process through standard operating policies and procedures; and strengthening information systems such as personnel management, drug inventory control and internal
financial control systems. To control discretion in drug warehouses, for example, one South African distribution agency strictly segregates duties for order fulfillment, order checking and transport; staff working in each area has access only to the information needed to fulfil their own task, thus minimizing chances for collusion and drug diversion (Vian 2006).

Reforms to improve control on discretion may not be possible if there are so few health workers available that tasks cannot be separated and there is no time for control, and it is of limited use when there is extensive collusion among health workers at different levels in the hierarchy. Accountability is government's obligation to demonstrate effectiveness in carrying out goals and producing the types of services that the public wants and needs (Segal and Summers 2002). Lack of accountability creates opportunities for corruption. Brinkerhoff (2004) identifies three key components of accountability, including the measurement of goals and results, the justification or explanation of those results to internal or external monitors, and punishment or sanctions for non-performance or corrupt behaviour. Strategies to help increase accountability include information systems which measure how inputs are used to produce outputs; watchdog organizations, health boards or other civic organizations to demand explanation of results; performance incentives to reward good performance; and sanctions for poor performance. In South Africa, a district health planning and reporting system was used to improve management control and hold government agents accountable for their decisions. By combining financial and service data, the reporting system drew attention to clinics and programmes that had unusual indicators, and helped officials to explore root causes for performance differences, including possible corruption (Vian and Collins 2006).

Based on Kenya's experience, it would be preferable for donors to instead issue clear procurement guidelines, giving guidance on considerations of price and logistics. Such a system should also be accompanied by a global audit of GFATM tenders and procurement. Given the fact that global taxpayer funds are used to support such tenders, a fully transparent and public audit of drug tendering and procurement should be instituted. Furthermore, in order to ensure improved tendering, tenders and details of procurement decisions, including drug prices, should be more transparent. Currently, some companies, with good intentions, publicize their product prices prior to the issuance of tenders, which
allows other companies to benefit from this information when submitting their own confidential bids. A system that is more consistent with the principles of fair competition would discourage companies from publicizing prices ahead of tenders and would insist on full transparency of these tenders once awarded. Lastly, to achieve improved accountability for awarded tenders, penalties for suppliers, PRs and LFAs should be instituted.

1.1.2 Kenya Medical Supplies Agency (KEMSA)

Kemsa is a specialized medical logistics provider for Ministries of Medical Services/Public Health-supported health facilities and programmes. The Agency was formed on 11th February 2000 as a result of recommendations of a health stakeholders’ forum dubbed “Strategies for Reforming the Drug and Medical Supplies Systems in Kenya” held between June 7 and 10, 1998. A State Corporation established by a legal notice issued under CAP 466 of the Laws of Kenya, KEMSA replaced successive medical stores administrations that had existed since 1901 under various names. KEMSA works to support the National Health Strategic Plan and the Kenya Health Package for Health in providing public health facilities with the “right quantity and quality of drugs and medical supplies” at the best market value”. To fulfil its mandate, the KEMSA Board and Management seeks to Develop and implement a distribution system that effectively and efficiently deliver medical commodities to all public health facilities, Develop a harmonized national procurement system in collaboration with the MoH and other stakeholders.

Developing countries have undertaken the pool system of procurement of medical supplies. As discussed later in the literature review, Nigeria, Zambia, Ghana not with standing the East African community have embraced the same such that, an agency is appointed by the government to undertake the distribution and procurement of drugs and medical supplies to ministerial health institutions. This project therefore takes up KEMSA as a case with the argument that it is a representation for most developing countries in the procurement of pharmaceuticals. It is with this regard that as a medical logistics provider with the widest national coverage of 4,100 facilities: KEMSA works closely with the Government of Kenya (Ministries of Medical Services, Public Health & Sanitation and Finance), multi- and bi-lateral aid organizations who finance healthcare
such as: World Health Organisation; Unicef; Global Fund; USAid; Danida; Clinton Foundation; PEPFAR; Etc that this management project dims it fit and suitable to ground it as a case study for Kenya’s medical supplies docket.

1.1.3 Kemsa’s procurement function:
Kemsa’s procurement is governed by the Public Procurement and Disposal Act (PPDA) and Public Procurement and Disposal Regulations (PPDR) and has as such set up a Tender committee, Procurement committee, Evaluation committee and Receiving and Acceptance committee to foster transparency and accountability in procurement processes. KEMSA’s procurement process is mandated to demonstrate a significant degree of efficiency and effectiveness and in compliance with the provisions in procurements legislations, particularly the Public Procurement and Disposal Act. Therefore it is expected that, the process be open and transparent, Furthermore a critical role and mission is it seeks to offer a more competitive procurement price for medical commodities compared to those of other procurement agencies.

1.1.4 Kemsa’s Distribution Function:
KEMSA Logistics function aims to deliver medical supplies direct to all health facilities in Kenya consistently and efficiently. In partnership with experienced third party transport service providers, KEMSA set up a distribution structure with the capacity and aim to reach all public Hospitals, Rural Health Centres and Dispensaries throughout the country. By making timely deliveries against hospital orders with regular deliveries to rural health facilities based on a mutually agreed schedule, KEMSA Logistics has tried to adhere to and remain versatile and responsive to public customer requirements. Currently, a process has started aimed at integrating parallel programmes such as Reproductive Health commodities, TB/Leprosy and ARV’s into KEMSA’s overall distribution process. Ultimately, it has so far cut down on distribution costs and has ensured medical commodities are managed within one supply chain resulting in greater reach and efficiencies whilst utilizing limited available resources despite pending loopholes to be discussed later in the proposal.
1.2 Statement of the Problem
Given the impact of procurement activities on the operation and effectiveness of hospitals in Kenya among many other developing countries, it is essential that these activities be performed by qualified staff with high professional and ethical standards and using sound procedures anchored in appropriate policies and regulations. Experience has shown that an effective procurement process is one in which efforts are made at all times to have a transparent and corruption-free process and use good procurement practices. Efforts must also be made to contain costs through regular review of procurement models and approaches, monitor prices, and keep records of sourcing, and use a variety of information to make informed decisions. Attention must be paid to safety, the quality of products and processes, the monitoring of external and internal environment, and the use of appropriate technology and available tools.

In situations when the procurement system cannot guarantee access to funds at the time they are needed, drug shortages and procurement inefficiencies are inevitable. Government funds for procurement are, in some countries, released irregularly during the financial year. In some countries government regulations specify that funds must be spent in the year for which they are allocated or be returned to the treasury; this compounds the problem. Where this combination exists (Hartford, CT; 1997) it compromises procurement planning and execution. Limited or irregular funding which leads to delays in payments worsens procurement problems as suppliers deny credit or insist on advance payments. A degree of financial autonomy for the health system, while providing flexibility, requires proper accountability and efficient management.

Moreover, without mechanisms to monitor local performance and to ensure adherence to good procurement practice in developing countries, in the facet of drug quantification in Kenya for example, cases of drug stock outs of critical drugs like Coartem and ACTs in Nyanza, western and Coast provinces respectively are an implication of mismanagement. Inefficient management is also replicated in drug selection such that for drugs to be approved they have to be efficable and have a high value for money. However this is not the case in the Kenyan pharmaceutical industry with the advent of counterfeits, In a context where quality controls are difficult to exercise, an increasing lack of funds results in opportunities to sell low quality, expired, counterfeit and harmful drugs at cheaper
prices moreover, health objectives may not be met and scarce funds may be wasted on inappropriate purchases. Although Contracting out parts of the procurement/distribution function may improve efficiency and reduce costs, impending deaths and poor diagnosis are eminent considering the standard and efficacy of pharmaceutical products and thus inefficient Management.

A lot had been written on drug procurement, its operational principles and constraints but little if not none significantly dwelt on the managerial aspect of operations in the procurement process as from drug quantification, selection, supplier selection, efficient and transparent management and medicine registration, yet it is critical in the timely, cost effective and efficient access to drugs. This management project therefore sought to bridge this gap by establishing the impact of operational management practices on the procurement of drugs and medical supplies in developing countries touching on Uganda, Nigeria and Kenya among many.

1.3 Objectives of the Study;

This management project was guided by one main objective, to establish the impact of management and conformity to the operational principles framework of procurement of drugs and supplies. Moreover the study sought to identify the mechanisms adopted by pharmaceutical firms in addressing challenges in the procurement of drugs and medical supplies. It therefore analyzed the managerial aspect of;

i) Drug quantification

ii) Drug and pharmacy registration and selection.

iii) 3. Finance and promotion.

iv) 4. Efficient and transparent management

1.4 Significance of the study

The main significance of this project was to provide insight in improving pharmaceutical procurement practices in less developed countries. The study also sought to provide an understanding of procurement constraints and remedial measures to;
Pharmaceutical companies: For procurement purposes, all pharmaceutical organizations be it public, private non-profit or private for-profit, need to develop an essential drugs list to ensure that only the most cost-effective drugs are purchased. Procedures must also be in place, that accurately estimate procurement quantities in order to ensure continuous access to the products selected without accumulating excess stock, and that drugs are selected through a transparent bidding process and delivered in rightful quantities, quality and at the right time.

Government institutions: This document will inform Public drug institutions on the need to ensure reliable supply of high-quality products, (pre-) selected, and that active quality assurance programmes involving both surveillance and testing must be implemented.

Hospitals and health facilities: Significant to health practitioners, this project sought to create precedence on procurement and distribution systems ensuring timely delivery of appropriate quantities to central or provincial stores and adequate distribution to health facilities where the products are needed. It also aids in proper medicinal content of drugs and their effectivity on patients, a feedback critical to the pharmaceutical manufacturers.

Health based N.G.Os (non governmental organizations) and Policy makers: This management project will aid and give a clear understanding of the current drug supply chain deficiencies and loopholes, Information critical in developing models to counter and address these deficiencies and also come up with policies and predictions with this regard.
CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction
This section explores theoretical and empirical literature touching on the procurement of drugs and medical supplies with regards to the basic management principles of availability and transparency, drug selection and quantification, pharmacy registration and financing and competition. The purpose of this section is to establish the foundation for the proposed study and identify a framework within which primary data will be contextualized and interpreted. Better still, by exploring the experiences of different countries, literature review will also strengthen findings of the study.

2.2 Procurement within the Public Sector
Sound public procurement policies and practices are among the essential elements of good governance (KIPPRA, 2006; World Bank, 2002). Otieno (2004) notes the irregular procurement activities in public institutions provide the biggest loophole through which public resources are misappropriated. In some cases, tenders are awarded to firms either through single sourcing or manipulation of bids; and worse still, full payments have often been made for projects that fail to take off or are abandoned half way. Still in other cases, tenders are awarded to un-competitive bidders through irregular disqualification of the lower bidders. According to Thai (2001), the basic principles of good procurement practice include accountability, where effective mechanisms must be in place in order to enable procuring entities spend the limited resources carefully, knowing clearly that they are accountable to members of the public; competitive supply, which requires the procurement be carried out by competition unless there are convincing reasons for single sourcing; and consistency, which emphasizes the equal treatment of all bidders irrespective of race, nationality or political affiliation.

An ideal procurement system should also focus on effectiveness, where procuring entities should meet the commercial, regulatory and socio-economic goals of government in a manner that is appropriate to the procurement requirement. Furthermore, a good procurement practice should embrace: efficiency, which requires that procurement processes be carried out as cost effectively as possible; fair-dealing, where suppliers should be treated fairly, without discrimination or prejudice including protection of
commercial confidentiality where necessary. The process should also uphold integrity by ensuring that there are no malpractices; informed decision-making, which requires public bodies to base decisions on accurate information and ensure that requirements are being met. More still, the Procurement practice should be responsive to aspirations, expectations and needs of the target society. Finally, there is need for transparency to enhance openness and clarity on procurement policy and its delivery (World Bank, 2003).

Various studies have shown that procurement and revenue management form the core functions of public financial management, particularly within the Medium Term Expenditure Framework (MTEF). The main objectives of the MTEF include linking policy, planning, budgeting; achieving fiscal discipline through a realistic macro economic framework; resource allocation, efficiency in line with strategic priorities and operational efficiency through delivery of quality managerial services. As illustrated in fig 2.1 public procurement within the MTEF, framework aims at advancing social economic development by improving elements such as economic growth, poverty reduction, decentralization and enterprise development in the private sector. In addition, public procurement within the MTEF, is also closely linked to the export market development as well as foreign direct investment into the country (KIPPRRA 2005).
In most developing countries, public procurement serves a greater role than it does in developed nations. This is because in developing countries, governments are the main buyers of goods and services. In this regard they often influence the size, structure, conduct and performance of national industries (KIPPRRA, 2006).

2.3 Pharmaceutical procurement in Nigeria
In order to ascertain the prices of medicines in Nigeria, a survey was undertaken by the Federal Ministry of Health in collaboration with the World Health Organization and Health Action International in 2004 using an international standardized methodology. A total of 129 medicine outlets in public and private health clinics as well as private pharmacies were randomly sampled from six states representing the six geopolitical zones in the country. The prices of a basket of 34 prescription medicines were measured. Three State Central Medical Stores and one NGO procurement facility were also assessed in terms of prices at which they procure key medicines.
It was found out that Patients paid between 2 to 64 times international reference prices for medicines in various facilities in the public and private sectors of Nigeria. Prices in the public sector were almost identical with those in the private pharmacies and Private
health clinics were shown to charge up to 184% more than the public health facilities and 193% more than private retail pharmacies. Innovator brands were found to cost between 2 to 7 times the lowest priced generic equivalents. There was wide variability of prices of the same medicines between facilities, sectors and different types of the same product.

2.3.1 Procurement Prices and availability

Prices ranged from 2 to 38 times international prices in the three functional state central medical stores surveyed. In the NGO facility, prices were up to 20 times less than those of the state central medical stores. Generic medicines were generally more available in all outlets. The availability of the basket of 34 medicines was low in all sectors but more so in the public and private health clinics (Thai 2001).

2.3.2 Affordability

Medicines were unaffordable to the majority of Nigerians (90.2%) who lived below the income level of US$ 2 a day as well as the government worker that earns a minimum wage of US$1.4 per day. Affordability was largely dependent on choice of therapeutic class, product or sector from which the medicine was purchased. For example: A worker would pay 0.7 days' wages to treat an infection with amoxicillin but would pay an additional 18.8 days' wages when using ceftriaxone injection to treat the same infection. The worker would spend 1.4 days' wages to pay for the lowest priced generic atenolol to treat hypertension but would require 10.2 days' wages to pay for innovator brand atenolol. This means IB atenolol costs 7.3 times more than the LPG (World Bank, 2002). Likewise, amitriptyline obtained from a private health clinic could cost a patient up to 650% more than when it is obtained from either a public health facility or a private pharmacy.
2.3.3 Component of Medicine Prices and Procurement

Government tariffs and taxes as well as mark-up for distribution account for a significant proportion of what patients pay for medicines. Mark-ups by the distributor or retailer were found to be up to 900% of the manufacturers' price. There is need to review procurement policy of the country. Considering the size and complexity of Nigeria, it will be rational to conduct further studies on best procurement methods that would be effective with consideration of methods that have worked in similar developing countries. Policy options include:- National tendering with decentralized contracting and purchasing, Procurement agency with responsibility for national procurement of medicines, Competitive tendering with price transparency. Pooled procurement with national buyers, providing incentives and capacity building in rational procurement-Parallel importation of single source products and price negotiations and also making medicine price information widely available would spearhead quality drug distribution.

2.4 Procurement of drugs and medical supplies, the case of E.A.C

The East African Community (EAC), in January 2007, requested the assistance of the WHO Department of Technical Cooperation for Essential Medicines (TCM) to conduct a situational analysis and feasibility study for implementing Regional Pooled Procurement of Medicines as part of their efforts to address issues of accessibility and availability of essential medicines in the region. Pooled procurement, otherwise known as joint purchasing, is increasingly being regarded globally as an efficient strategy to resolve challenges as high medicines prices, poor quality and other bottlenecks generally associated with Procurement and Supply Chains of Essential Medicines.

The 2 models of pooled procurement in question were the Group Contracting and the Central Contracting. These models are similar as they both involve bulk purchasing of medicines on behalf of a group or countries, with the main difference being the level of collaboration and integration, the administrative infrastructure required to implement the pooled procurement and therefore the technical and financial resources needed.

The situational analysis report identified the similarities in legislative and regulatory framework as well as policies and practices, which were later translated into assets and
strengths of the community, which are therefore regarded as supportive to regional pooled procurement but needs to be maintained through the development and implementation of the system.

Similarly the disparities identified were translated as constraints and challenges which in their current states are not consistent or wholly supportive of regional pooled procurement. However these challenges further provides opportunities to address them either through improvement or harmonization efforts. The findings were further quantified to assess the feasibility of adopting a pooled procurement model, and also identify the appropriate model as follows:

2.4.1 Political Will and Organizational Commitment

The political will and commitment for a harmonized regional economic bloc is strongly evident, and further supported by the existing hierarchical structure of the EAC Policy Organ. The inherent asset for the EAC therefore is that it guarantees political commitment and support from the highest level of government for its approved programmes. The EAC member states are currently involved in a number of pooled procurement related activities, thus confirming the active participation of partner states. The main issues to address is the limited capacity of the EAC Secretariat to implement either of the 2 pooled procurement models, but even more so with the Central Buying Model. The level of awareness on pooled procurement at national level is still limited thus emphasizing the need for more advocacy and further consultations (World Bank, 2003).

2.4.2 Procurement Legislations and Policies

The current procurement legislations and institutional framework in the EAC member states is relatively homogenous, providing the basis for Good Pharmaceutical Procurement Practice for the adoption of regional pooled procurement (www.eac/int).

However as no specific legislation currently exists for regional pooled procurement, the various interpretations on national laws and international obligations might give rise to potential conflicts and needs to be addressed. The main issue to address is the potential
role of local manufacturers in regional pooled procurement of medicines, with the current disparity in the utilization and support of national medicines industry (Soudry, 2007). Two of the EAC member states with the largest number of local manufacturers are strongly supporting the national industry through the local preference clause in their respective legislations, which might be perceived as 'non-competitive' and therefore a challenge at regional level. On the other hand, local production could be dealt with as a potential area for harmonization through improvement of quality and the pooling of local capacity to meet regional needs that will benefit not only the specific countries that produce the medicines but the sub-region as an economic bloc.

2.4.3. Medicines Regulation

The regulatory legislations, institutional framework and capacities to regulate the movement of quality assured medicines within the member countries are relatively diverse. Likewise the varying capacity of the National Medicines Regulatory Authorities (NMRAs) in the region makes it necessary to establish a regional Quality Assurance system to support either model of pooled procurement. It is important to note that the NMRAs are meeting regularly and working towards harmonization of standards and practices for Quality Assurance. As part of the quality assurance system at national level, medicines registration is one of the key criteria for the tendering and importation of medicines in most of the EAC partner states. It therefore poses a challenge towards the implementation of regional pooled procurement, as there is no system of mutual recognition of EAC member states National Medicines Regulatory Authorities (NMRA) decisions on registration of medicines. The harmonization of medicines registration procedures and process needs to be prioritized for regional pooled procurement.

2.4.4 Medicines supply chain

The set up and mode of operation of the National Medical Stores varies considerably, but with most of them operating as semi/autonomous institutions. Apart from the national medical stores, the procurement of medicines for the public sector involves other stakeholders such as development partners and procurement agents with various procurement regulations and methods. This diverse number of players in the procurement
arena might either negatively impact regional pooled procurement or offer opportunities for negotiation for pooled procurement. The inadequate Logistics Management Information System, which impacts on the accuracy and availability of information, has a substantial negative impact of quantification of needs and further limits information sharing. Although Essential Medicines Lists and Standard Treatment Guidelines are not fully harmonized, each of the countries procure similar essential medicines and HIV/AIDS products with which to initiate pooled procurement. However, the lack of harmonization of these essential documents therefore limits the selection of the products that can be successfully pooled together for bulk purchasing.

2.4.5 Financing

The medicines financing environment among EAC member-states is complex as each potential category of target commodities for pooled procurement involves multi-source financing that will require negotiation and revision to the current financing structure for medicines. Political commitment however exists to increase internal resources for medicine procurement. Furthermore all the EAC countries have access to and use convertible currency for international procurement, with 80% of the national medical stores identifying Letter of Credit as the most prevalent method used for procurement which is also the preferred method by international suppliers (Knight, Harland, Telgen and Caldwell, 2007). The EAC regional financial institution, i.e. the East African Development Bank can be utilized to facilitate payment processing for pooled procurement. Other opportunities or potential sources of funding for regional pooled procurement of medicines include household financing of medicines which presents opportunity to capture additional funds, if concerted efforts are made to channel fund for purchases.

2.4.6 Pricing

The primary monetary advantage of pooled procurement is that purchasing higher volumes can reduce unit prices. As a sub-regional bloc, the opportunity to negotiate for lower prices does exist, with monetary savings identified as one of the potential benefits of pooled procurement, and from the simulation of savings conducted for the region it
was found that significant savings could be made at a regional level up to 22% for common essential medicines. The amount of financing necessary to support the procurement of the range of essential medicines to treat HIV in the EAC region is quite substantial in comparison to other essential medicines purchases. There is no question that the support of international donors in partnership and ministries of health will be a vital component in ensuring adequate quantities of medicines can be procured. This scale, however, also provides opportunities for significant savings over current prices both for the 12 products examined in this section and, assumably, for the several dozen, perhaps hundreds of other products not examined in this analysis (Callender and McGuire, 2007).

2.4.6.1 The Kenyan case

GFATM required that Kenya purchase seventy-five percent of its annual order of ALU, the recommended first-line treatment for uncomplicated malaria in Kenya, through an international open tender (Kangwana, Njogu, Wasunna, Kedenge 2007). In line with GFATM policies, in May 2008, the Kenya Medical Supplies Agency—a GFATM sub-recipient—awarded a $12.3 million tender to Ajanta Pharma, the lowest bidder, whose AL was, at the time, registered by GFATM (submitted to WHO or an SRA for approval, but not yet approved). Tender documents were not made available to the authors; however, industry and academic sources indicate that the difference between Ajanta's tendered price and rival tenders was substantial, at around forty percent. The substantial cost savings from the lower bid could mitigate the risk of awarding the tender to a relatively unknown company. On the other hand, procurement agents should have questioned how realistic the pricing was and whether or not the company would be able to deliver at such a low cost. The contract stipulated that Ajanta would supply 13 million doses of Artefan in three phases to begin in October 2008 at the latest, although it was widely expected that delivery would begin earlier. By mid 2008, Kenya was experiencing wide stock-outs of ALU and had to place emergency orders to the President's Malaria Initiative (PMI). While PMI was able to supply the country with nearly 1.3 million doses of Coartem over July and August, Kenya's drug shortage remained.

A delayed and confusing tendering process was partly to blame for the ongoing stock-outs, but these were exacerbated and prolonged by Ajanta Pharma's inability to fulfil its contract and supply Artefan in sufficient quantities. It is possible that Ajanta would have
been able to fulfil its tender for Kenya, had the Kenyan Government not delayed procurement, since Ajanta probably redirected some of its product to fulfil other contracts in the meantime; regardless, it managed its own supply poorly. Additionally, Kenyan sources tell the authors that because the product was a Ci (and hence not WHO prequalified), batch-quality testing was undertaken, which further delayed delivery. Ajanta delivered its first consignment on December 31, 2008—at least three months late. In addition, the amount that arrived was well below the expected monthly requirement, and some of the blister packages were only partially filled. In March 2009, WHO issued a Notice of Concern (NOC) against Ajanta Pharma following an inspection of the company's production plant, which "revealed several major deviations from the WHO GMP [Good Manufacturing Practices] standards". WHO's NOC announced the withholding of prequalification of any new Ajanta products until the deviations were satisfactorily addressed and could also consider suspending Ajanta's products that were currently listed as prequalified. Fortunately for Ajanta, the NOC has since been withdrawn.

2.4.6.2 The Ugandan perspective

Despite Kenya's experience, Ajanta's logistical failures have not influenced GFATM policy in neighbouring Uganda. In early March 2009, Uganda issued an international open tender for its annual ALU supply. Fourteen companies took part, including Novartis, the large Indian generics company Cipla, and Kenya-based Cosmos (with the lowest bid.

With WHO's drug quality concerns still outstanding, Uganda's Ministry of Health announced on May 8th that Ajanta was the "best evaluated bidder". Though Uganda's Health Minister, was "aware of the Kenyan situation," A Ugandan news source indicated that as of early November 2009, the tender was awarded to Ajanta Pharma and Artefan would replace Coartem. As of December 2009, it was unclear whether orders had actually been placed and when Ajanta was scheduled to deliver product. The delays in awarding the tender and issuing the orders have already contributed to greater shortages of ACT in Uganda.
All this leaves lingering questions about Uganda's actions; awarding a contract not to the lowest bidder or to the one with a reliable history. Tender documents on file with the authors reveal that Ajanta's tendered price was approximately four percent below that of Novartis AG, therefore there is little apparent cost mitigation to account for the added risk of procuring from a company with a poor record of delivery and an outstanding NOC at the time the open tender was issued. Furthermore, the extent to which GFATM exercises oversight and demands greater accountability over such tenders is questionable. In its guidelines, GFATM suggests PRs are responsible for oversight along the supply chain, but does not specify if or how GFATM itself is responsible, which may have contributed to the cases presented here. The U.S. Government Accountability Office reported that numerous sources have raised "concerns about the quality of grant monitoring and reporting" provided by GFATM's LFAs, particularly on "their ability to assess and verify recipients' procurement capacity and program implementation." GFATM had limited access to the information it needed to manage and oversee LFAs because it did not require "systematic assessments" of their performance.

In response to queries from the authors concerning the status of medicines on GFATM's procurement list after WHO has issued an NOC, GFATM representatives indicated that they are in 'continued dialogue' with WHO, but would not de-list a medicine as long as it remained on the WHO prequalification list. However, while a WHO NOC reports on drug quality, it does not report on the ability of a manufacturer to deliver drugs, an issue that should be of concern to GFATM. A tender process based primarily on price cannot account for a company's ability to consistently supply sufficient product in time. GFATM and its donors should insist on an assessment of the lives lost and the socioeconomic cost of Kenya's stock-out, including the cost of the emergency procurements made by the PMI. And where possible, assess how Ajanta Pharma's failures contributed to this problem. A possible longer-term solution could be to circumvent national tendering by PRs, and instead have donors issue tenders, manage funds and deliver drugs directly to recipient countries. Such a system, however, is not only patronizing toward disease endemic countries, reducing their level of responsibility for tendering and procurement, but could also limit these countries' long-term ability to manage sustainable disease control programs.
2.5 Contextual framework

Transparency policies may include government-mandated disclosure of information, or may involve external agents such as civil society or the media (Fung et al. 2007). Strategies to increase transparency include public service ‘report cards’, price monitoring and release of government documents or decisions through web sites, public databases,
public meetings and the media (World Bank 2003). Examples of transparency initiatives in Argentina, Morocco and Uganda show the range of interventions possible. The Ministry of Health in Argentina created a price monitoring system that tracked prices paid by 33 public hospitals for common drugs, sharing this data with the reporting hospitals. The effect of the transparency policy was that purchase prices fell immediately by an average of 12%, and stayed below the baseline for over a year (Schargrodsky et al. 2001). In Croatia, regulations have been proposed which will require hospitals to make waiting lists public, to reduce the practice of patients bribing doctors to jump ahead of the queue (Transparency International 2006). In Uganda, an information strategy was used to reduce leakage of central government education grants to local governments (a problem first identified through a Public Expenditure Tracking Survey). Before the grant transfer amounts were publicized in newspapers and posted in schools, only 13% of grant allocations reached the schools; after the reforms, 80–90% of grant funds were reaching recipients (Reinikka and Svensson 2002).

A large government provincial referral hospital in Kenya identified a problem with theft of user fee revenue (the monitor 2008). This problem was seen as serious, both because user fee revenue accounted for about 24% of the hospital's non-personnel expenditure budget, and because patients had complained about the abuse. With donor assistance, the hospital conducted a patient survey and review of control systems to collect more information. They found many systemic weaknesses, including a large number of fee collection points, manual receipt and ledger book system that did not allow timely account reconciliation, unclear policies, and infrequent supervision. The main intervention used to address these abuses was the installation of networked electronic cash registers. To limit discretion, multiple cash collection points were reduced to five, and procedures were put in place to separate the functions of billing and fee collection. The cash registers helped improve internal accountability by speeding the data collection and analysis, producing automated reports which allowed managers to see daily and cumulative monthly revenue, by item, cash collection point, cost centre and by cashier. The system helped to detect corruption by facilitating the comparison of reported revenue with expected revenue, based on prices and number of patients or services provided. The system increased transparency by providing patients with an itemized receipt for the services billed, amount paid and change received. External accountability and citizen
voice were improved by sharing information on user fee system performance with the hospital management committee, which had citizen representation, and with other district and MOH officials. Within 3 months, user fee revenues increased 47% with no effect on service utilization. Over the next 3 years, annual collections increased 400%, due mainly to better revenue controls (though one modest price increase did take place as well during this period).

2.5.1 Efficient and Transparent Management

Senior managers responsible for procurement must ensure that pharmaceutical procurement is carried out effectively, efficiently and in accordance with the country’s policies, laws and regulations. The health system’s procurement office, under various names, is normally responsible for actually managing the procurement function. The procurement office should be responsible for coordinating inputs to achieve the desired result. But in most public sector contexts the reality is that all functions of the drug procurement process are entirely in the hands of one office or official. Without appropriate separation of function and authority the procurement process is much more susceptible to influence by special interests. In that case, procurement personnel may be able to bias drug selection, manipulate orders to increase the quantities of certain drugs, prejudice supplier qualification decisions, manipulate the final award of tender, and slant product specifications to limit competition. Separation of key functions contributes to professionalism, accountability and an efficient procurement system.

According to a recent World Bank report (2007), a number of key procurement functions typically require different expertise and should be separated. Examples include: Drug selection, which should be done by a national formulary or essential drugs list (EDL) committee. Where such a committee does not exist an ad hoc committee should be set up for this purpose. Quantification of drug requirements, which should have inputs from the medical stores and/or from district or health facility managers in decentralized systems. However, the procurement office should draw up the final procurement list. Product specifications, which should be prepared by a standing committee or an ad hoc technical
committee. Pre-selection of suppliers, which should be done by a broad-based procurement committee composed of managers and technical staff, including quality assurance experts.

Adjudication of tenders, which should be reserved for the procurement committee or tenders board (WHO, 2003). Procurement office staff can make technical recommendations but should not have a vote in the contract decision. Pharmaceutical procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists’ expertise all along the pharmaceutical procurement chain.

2.5.2 Cost containment model

There are a number of arguments why developing nations should focus attention on revenue generation and cost containment strategies for pharmaceutical supply systems. After personnel costs, pharmaceuticals are generally the largest item of expenditure within their public sector health budgets, ranging from 40 to 60 per cent of total recurrent costs (World Bank, 2003). With the exception of a few developing countries with large domestic markets and advancing technological capabilities, pharmaceutical manufacturing in the developing world is limited to the end stages of the process: repackaging or turning imported finished compounds into tablets, capsules, or liquids. In one form or another, pharmaceuticals are therefore imported and thus represent the health sector's major requirement for foreign exchange. Pharmaceuticals must compete for scarce foreign exchange, compounding the demand for scarce financial resources in the public health system and contributing to frequent stock-outs and shortages. These shortages, along with chronic public sector administrative problems, demoralize health providers and erode the public's confidence in the health care delivery system. A case study on Jamaica—as one example from the Caribbean—describes the common vicious
cycle in the public sector pharmaceutical supply system of a developing country (Huff-Rousselle, 1996).

From selection of products, to quality assurance and procurement mechanisms, to warehousing and distribution, to prescribing and public sector sales, to patient compliance, public sector supply cycles are often plagued with problems of wastage and irrational use of scarce resources. At the same time, health demand studies in developing countries have shown that even very poor people are willing to pay for pharmaceuticals (Huff-Rousselle 1993). This finding, combined with the drain on foreign exchange and high recurrent costs of pharmaceuticals, has led to: policy recommendations for the introduction of pharmaceutical user fees in the public sector (DeFerranti, 1985); explanations of how to price (Litvick et al., 1989) and to implement cost recovery schemes for pharmaceuticals (Cross et al., 1986; Van der Geest, 1992); major implementation activities, most notably the UNICEF-supported Bamako Initiative which has been launched in a number of African countries (World Bank, 2003).

Critics claim that user fees for pharmaceuticals are not a solution in many situations, that they reduce or divert rational demand for health services (Creese, 1992), that they do not provide needed foreign exchange (Huff-Rousselle 1993), that the private sector is better able to distribute pharmaceuticals (Vogel and Stephens, 1989), and that there are many practical obstacles to implementation from book-keeping to impending elections (Bennett, 1989; Griffin, 1988; Foster, 1991). Some user fee critics argue that cost containment strategies can be more effective than user fees in expanding the buying power of a public health budget and reducing shortages in pharmaceutical supply, thus reducing the negative impact on health care providers, patients, and the credibility of the public sector delivery system. The World Bank 1993 Development Report Investing in Health specifically targets the pharmaceutical sector for reform and describes it as 'the most promising area for efficiency gains in the short run' (World Bank, 2003). This project considered the success of one organization, the Eastern Caribbean Drug Service (ECDS), in implementing improved pharmaceutical procurement as a cost containment strategy. New policies and procedures for pharmaceutical procurement can, in turn, inspire other cost containment strategies. Also, when basic purchase costs are reduced,
the cost of all other wastage in the supply system is automatically reduced, as most supply system costs relate proportionally to the basic purchase price multiplied by the volume of demand. Finally, since procurement is normally centralized, it can be easier to implement than other strategies—assuming there is the necessary political and administrative will.

2.5.3 Model Specification

It is with the above regard of cost containment that this project was based thus deriving the model of efficient procurement as follows. A non-linear functional form is assumed as it is sufficiently tractable to permit derivation of the cost and input demand frontiers as shown in the analytical framework by Firsund, et. al. (1980). The estimation of operational management practices in this paper is based on the familiar regularity condition effective and rational cost containment. The estimation of a short run cost function can be obtained using a translog or a Cobb-Douglas (C-D) functional forms. Even though the former is superior, more flexible, and captures the interactive effects of the explanatory variables, it is nested in the C-D form which is estimated. Based on the framework discussed, the model estimated was given by equation (1).

\[
\text{PROCUREMENT} = F (\text{DRUG QUANTIFICATION}, \text{TRANSPARENT MANAGEMENT}, \text{FINANCING& COMPETETION}, \text{PROMOTION STRATEGY, MEDICINE REGISTRATION}) \ldots (1)
\]

Assuming a non-linear relationship, the Cobb-Douglas form in natural logarithms was used and specified as follows:

\[
\ln \text{COST} = \hat{\alpha}_0 + \hat{\alpha}_1 \ln \text{DRUG QUANTIFICATION} + \hat{\alpha}_2 \ln \text{TRANSPARENT MANAGEMENT} + \hat{\alpha}_3 \ln \text{FINANCING& COMPETETION}, + \hat{\alpha}_4 \ln \text{PROMOTION STRATEGY}, + \hat{\alpha}_5 \ln \text{MEDICINES REGISTRATION} + v-u \ldots (2)
\]

Where \(\hat{\alpha}_1\) defines the parameters to be estimated, while \(v-u\) indicates the composed disturbance term.
CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Research Design

Research design is the general plan of how one goes about answering the research questions. This management project applied both quantitative and qualitative approaches. The quantitative dimension adopted a survey design. According to Bryman and Cramen (1997), survey designs are often called correlational designs since they donate the tendency to reveal relationships between variables. The researcher used an explanatory approach using descriptive survey design which ensured easy understanding of the insight and ideas about the problem. It is important to highlight the two main methods used when investigating and collecting data — quantitative and qualitative. A quantitative approach is strongly linked to deductive testing of theories through hypotheses, while a qualitative approach to research generally is concerned with inductive testing (Saunders et al., 2003). The main focus of this study is quantitative.

This research was an exploratory study carried out to find the effects of operational management practices on the procurement of pharmaceuticals in the developing countries a case of KEMSA. The design was useful in describing the characteristics of the pharmaceuticals and determining the frequency of key attributes of the study. Correlation of the dependant variables was also done using various statistical measures.

3.2 Target Population

The population of the study consisted of procurement officers working with KEMSA and other allied organizations that deal with medical supplies in Kenya. The agency was preferred because it is entrusted with the responsibility of running rational drug use campaign by the government of Kenya and hence the operational management principles are more applicable in the procurement of drugs and medical supplies. Other relevant partners involved in the distribution of drugs and procurement constituting the population of this study include a representation from Kenya bureau of standards for drug selection results, Nairobi Quality Control Laboratories, Universal Laboratories, (Ministries of Medical Services, Public Health & Sanitation and Finance), multi- and bi-lateral aid organizations who finance healthcare such as: World Health Organisation; Unicef; Global Fund; USAid; Danida; Clinton Foundation and PEPFAR firms based in Kenya.
3.3 Sampling

The sampling plan describes how the sampling unit, sampling procedures and the sample size for the study are done. Where external validity is important, one need to carry out random sampling from properly defined population. In this view purposive sampling whose logic lies in selecting a truly random and representative sample that permits confident generalizations from the sample to a larger population will be done (Cooper and Schindler, 2003).

This project applied purposive sampling procedures to obtain a sample of pharmaceutical affiliated companies under the main, Kenya medical supplies agency (KEMSA). Purposive sampling is a non-probability technique that allows a research to use cases that have the required information with respect to the objectives of the study. Such cases are often handpicked because they are informative on posses the required characteristics (Mugenda and Mugenda1999). It is with this regard that this study justified the purposive sampling process.

3.4 Sample Size

Kotler, Armstrong, Saunders and Wong (2001) argued that if well chosen, samples of about 10% of a population can give good reliability. Considering the wide scope of the population, the study applied purposive sampling of 1/10th representation of KEMSA and every other pharmaceutical supplier, bidder and quality assurance company affiliated to it.
<table>
<thead>
<tr>
<th>Section</th>
<th>Frequency</th>
<th>Percentage</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>KEMSA</td>
<td>40</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>Kenya bureau of standards</td>
<td>10</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Nairobi Quality Control Laboratories</td>
<td>15</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Ministry of Health Institutions</td>
<td>126</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>multi- and bi-lateral aid organizations</td>
<td>100</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>291</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

### 3.5 Data Collection

This management project used the questionnaires as the main data collection instrument. According to Sproul (1998), a self administered questionnaire is the only way to elicit self report on people’s opinion, attitudes, beliefs and values. The questionnaires included structured and unstructured questions, with key questions revolving around legalities and procedures to be followed in the procurement process, transparency and accountability measures put in place in the distribution channel, supplier selection and quantification policies and financing and promotional extents of drug companies. The respondents of the study were drawn from top, middle and low level procurement cadres in the pharmaceutical agency, KEMSA. The questionnaire was administered through drop and pick method to respondents. Structured questions were used in an effort to conserve time and money as well as to facilitate in easier analysis as they are in immediate usable form; while the unstructured questions were used so as to encourage the respondent to give an in-depth and felt response without feeling held back in revealing of any information. With unstructured questions, a respondent’s response may give an insight to his feelings, background, hidden motivation, interests and decisions and give as much information as
possible without holding back. At the same time, with the use of structured questions, if
the researcher is after information that he finds easier for administration purposes, he
would use this method since the questionnaires and interviews are followed by alternative
answers.

3.6 Data Analysis
Detailed surveys of pharmaceutical management may be needed to determine efficiency
and possible waste. Data collected during the assessments was adjusted for inflation and
deflation respectively. The Statistical Package for Social Sciences (SPSS) was applied to
run descriptive analyses to produce frequency distributions and percentages while charts
and tables produced using Ms-Excel.

Hypothesis testing was done using Pearson's Correlation Co-efficient with T-test and
cross-tabulations with Chi-square (X2) test. Pearson's Correlation Co-efficient is
denoted by a letter. Further, chi-square (x2) test is a statistical technique which attempts
to establish the relationship between two variables both of which are categorical in
nature. It is often described as a standardized slope whose value does not depend on the
units of measurements and is used to measure the degree of association between interval
scaled variables. Its value lies between 1 and 1. When r= -1 or 1, then the correlation
between two variable is perfect. The larger the absolute value of r the strongest the
degree of linear association. T-test is used along With correlation co-efficient r to
establish the statistical significance of the linear associations between two sets of means.

A null hypothesis (H0) is rejected when the calculated t is greater than the critical t. in the
proposed study, Pearson's correlation co-efficient and t-test was used to test the
following null hypothesis.

H01: There is no significant linear association between transparent, efficient management
and the procurement of drugs and medical supplies.

H02: There is no significant linear association between the levels of financing and
promotion strategy and procurement of medical supplies.

H03: There is no significant linear association between the registration of medicines and
pharmacy and pharmaceutical procurement.
H$_{04}$: There is no significant linear association between drug selection and quantification and procurement of drugs and medical supplies.

H$_{05}$: There is no significant linear association between supplier selection, quality assurance and the procurement of pharmaceuticals.
4.1 Introduction
The main objective of this management research was to determine the effects of operational management practices on the procurement of pharmaceuticals in developing countries, case of Kenya Medical Supplies Agency (KEMSA). The findings were represented in form of graphs and tables.

4.2 General Information:
This section outlays the general information on the summary of the findings and their correlations to enable the researcher make a conclusion on operational management practices in the procurement of pharmaceutical products in Kenya.

4.2.1 Respondents’ Department

Figure 4.1 below is an illustration of the department in which the respondents belong. From the findings, majority of the respondents (64%) were in the Sales and Procurement Department. Only 13% were in the Pharmacy while the remaining (23%) belonged to the Disease Prevention and Control Department.

Figure 4.1: Respondents’ Department
4.2.2 Category of Health Facility in the Pharmaceutical Industry

The researcher found that the most prevalent health facility in the pharmaceutical industry was the agency (40%). Hospitals and laboratory tied at 23% each while pharmacy had only 13%. These results are displayed by table 4.1 below.

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Laboratory</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Agency</td>
<td>12</td>
<td>40.0</td>
</tr>
<tr>
<td>Hospital</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Table 4.1; Category of Health Facility in the Pharmaceutical Industry

4.2.3 Ownership of the Organization

Researcher also wanted to know who exactly owned the respondents' organization. From the findings, majority of the respondents (60%) said that the government owned their organization while the remaining (40%) said their organizations were privately owned. Figure 4.2 is an illustration of the same information.

![Ownership of the Organization](image)

Figure 4.2: Ownership of the Organization
4.3 Drug Quantification and Procurement

In the interest of the researcher information on how drug estimation was done to counter drug stock-outs in disease prone areas and regions in the country was of essence.

4.3.1 Formal National Medicine Policy Document

The researcher was interested in knowing whether there exists a formal national medicine policy document covering both the public and the private sector. Most of the respondents (93%) claimed that there exists such a document while the remaining 7% denied any presence of a formal national medicine policy document covering both the public and the private sector as illustrated by table 4.2 below.

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.2: Presence of a Formal National Medicine Policy Document

4.3.2 Whether there is an Essential Medicine List (EML) Available in the Firm

Regarding the presence of an Essential Medicine List (EML) available in the respondents' firm, an overwhelming majority (93%) agreed that there exists such a system while only 7% disagreed of the availability of the EML in their firms. The pie chart below is an elaboration of the same information.
Whether there is an Essential Medicine List (EML) Available in the Firm

No 7%
Yes 93%

Figure 4.3: Whether there is an Essential Medicine List (EML) Available in the Firm

4.3.3 Whether There Is a Policy for Generic Prescribing or Substitution

Table 4.3 is an illustration of whether there is a policy for generic prescribing or substitution. According to the findings, majority (93%) agreed there is a policy for generic prescribing or substitution while 7% said there are no such policies within their firms.

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>29</td>
<td>96.7</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.3: Whether There Is a Policy for Generic Prescribing or Substitution

4.3.4 Whether There Are Incentives for Generic Prescribing or Substitution

On whether there are incentives for generic prescribing or substitution, the researcher found that majority of the respondents (83%) said no while only a few (17%) said that there existed the incentives. This is shown by figure 4.4 below.
4.3.5 Whether There Are Policies Governing the Procurement Process

Concerning whether there are policies governing the procurement process, 93% said yes while 7% said no as shown by table 4.4 below.

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.4: Whether There Are Policies Governing the Procurement Process

4.4 Institutional Structure

Of great importance is the constitution of the procurement agency’s tender committee in terms of gender and experience to derive scales on efficiency in procurement decisions.

4.4.1 Number of Members in the Institution Committee

The researcher sought to know the number of members in the institution committee. From the findings, majority of the respondents (97%) said the number ranges between 1
and 10 members. Only 3% claimed that the number was beyond 10 members as shown by the figure 4.5 below.

![Figure 4.5: Number of Members in the Institution Committee](image)

4.4.2 Committee Members Appointing Authority

Regarding who appoints the committee members, the researcher found that majority of the respondents (57%) mentioned the Senior Management within the Institution as the appointing authority while 23% said it is the government through ministry of health and Sanitation. Only 20% of the respondents said that it is the government through the appointing board does appoint the committee members. This is illustrated by table 4.5 below

<table>
<thead>
<tr>
<th>Appointment Authority</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government through ministry of health and Sanitation</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Government through Appointed Board</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>Senior Management within the Institution</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Table 4.5: Committee Members Appointing Authority
4.4.3 Prerequisite Factors to Committee Member Appointed

Figure 4.6 illustrates on whether certain factors are prerequisite factors in appointment of committee members. From the findings, experience and education qualifications were highly considered as given by 60% and 100% majority respectively. Nonetheless, personal relations and age were not highly considered as opposed by the majority (100% and 77% respectively).

![Graph showing prerequisite factors to committee member appointed](image)

Figure 4.6: Prerequisite Factors to Committee Member Appointed

4.4.4 Tenure of the Tender Committee

Majority of the respondents (60%) said that the tenure of the tender committee is permanent. The remaining 40% said that the tenure is an annual contract. This is illustrated by table 4.6 below

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent</td>
<td>18</td>
<td>60.0</td>
</tr>
<tr>
<td>Contract</td>
<td>12</td>
<td>40.0</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.6: Tenure of the Tender Committee
4.4.5 Contract of Tender Committee Renewed Subject To

Figure 4.7 shows the bases on which the contract of a tender committee member is renewed. From the findings, qualifications and merits were the major parameters of contract renewal as supported by 40% and 37% of all the respondents respectively. Only 23% attached significance on signatories, as a bases of contract renewal.

Figure 4.7: Contract of Tender Committee Renewed Subject To

4.5 Efficiency and Transparency

The researcher was interested in the respondents opinions on efficiency in the management aspects of drugs supply chain management.

4.5.1 Adherence to some Contents in the Procurement Schedule

Figure 4.8 below illustrates whether certain contents in the procurement schedules are adhered to during the time of procurement. From the findings, date of delivery, name of products and the terms of delivery are adhered to as supported by majority of the respondents (57%, 57% and 53% respectively). However, the quantity procured as well as the supplying given are not adhered to as indicated by a majority of 60%
Adherence to some Contents in the Procurement Schedule

Figure 4.8: Adherence to some Contents in the Procurement Schedule

4.5.2 Representation in terms of transparency and Accountability

Table 4.7 illustrates the extent to which the respondent would rate representations in terms of transparency and accountability. According to the findings, availability of procured information is represented to a moderate extent while drug quantification was represented to a moderate extent.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Little extent</th>
<th>Moderately Extent</th>
<th>Great Extent</th>
<th>Very Great Extent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of procured info</td>
<td>23.3</td>
<td>40.0</td>
<td>36.7</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Bidding decision</td>
<td>20.0</td>
<td>23.3</td>
<td>20.0</td>
<td>20.0</td>
<td>16.7</td>
</tr>
<tr>
<td>Supplier selection</td>
<td>20.0</td>
<td>23.3</td>
<td>20.0</td>
<td>20.0</td>
<td>16.7</td>
</tr>
<tr>
<td>Drug quantification</td>
<td></td>
<td>23.3</td>
<td>40.0</td>
<td>36.7</td>
<td></td>
</tr>
</tbody>
</table>

Table 4.7: Representation in terms of transparency and Accountability
4.6 Supplier Selection and Promotion

This section sought to answer what is the criterion for supplier selection, and generally to gather information on a competitive bidding process.

4.6.1 Tender Rate Method Applied in the respondents’ Organization

According to the findings, the most prevalent tender rate method applied in the respondents organization is contract procurement (37%), slightly higher than open procurement with 35%. 28% of all the respondents mentioned the pool procurement as the main tender rate method. The same information is elaborated by figure 4.9 below.

![Tender rate Method](image)

Figure 4.9: Tender Rate Method Applied in the respondents’ Organization

4.6.2 Most Preferred Media in Advertising and Promotion of Drugs

The researcher was also interested in knowing the most preferred media in advertising and promotion of drugs. From the study, public posters and radios prevails as supported by a majority of 47% and 43% respectively. Internet and intermediary pamphlets had a 40% and 38% majority respectively.
4.6.3 Level of Adherence to Promotion Codes

The research also wanted to know the level of adherence to the promotion codes for their various organizations. High value of money had the highest percentage of adherence as 53% supported them to a very great extent. The table below gives an elaboration of the same.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Less Extent</th>
<th>Moderate Extent</th>
<th>Great Extent</th>
<th>very Great Extent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear and accurate drug information</td>
<td>-</td>
<td>-</td>
<td>43.3</td>
<td>20.0</td>
<td>36.7</td>
</tr>
<tr>
<td>High value for money</td>
<td>23.3</td>
<td>-</td>
<td>-</td>
<td>23.3</td>
<td>53.3</td>
</tr>
<tr>
<td>Standard quality</td>
<td>-</td>
<td>-</td>
<td>23.3</td>
<td>36.7</td>
<td>40.0</td>
</tr>
<tr>
<td>Prompt and efficient delivery</td>
<td>23.3</td>
<td>23.3</td>
<td>16.7</td>
<td>36.7</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 4.8: Level of Adherence to Promotion Codes
4.6.4 Importance of Efficiency

On the importance of efficiency, majority of respondents (100%) agreed that reduction of stock outs, deserved supply selection, timely and standard drug deliveries as well as accountability in supply and chain management were the most important aspects. Table 4.9 elaborates the details.

<table>
<thead>
<tr>
<th>Drug Quantification</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in stock outs</td>
<td>100.0</td>
<td>-</td>
</tr>
<tr>
<td>Scrutiny of counterfeits</td>
<td>76.7</td>
<td>23.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplier Selection and Procurement</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Deserved supply selection</td>
<td>100.0</td>
<td>-</td>
</tr>
<tr>
<td>Timely and standard drug delivery</td>
<td>100.0</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Registration</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard drug quantity</td>
<td>80.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Accountability in supply chain management</td>
<td>100.0</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 4.9: Importance of Efficiency

4.7 Empirical Analysis

The model for this study is generally specified as

\[
\text{Procurement} = f (\text{Drug Quantification, Transparent Management, Financing & Promotion, Medicine Registration, Supplier Selection})
\]

Assuming a non-linear relationship, the Cobb-Douglas form in natural logarithms is used and is specified as follows:

\[
\ln \text{Cost} = a_0 + a_1 \ln \text{Drug Quantification} + a_2 \ln \text{Transparent Management} + a_3 \ln \text{Financing & Promotion} + a_4 \ln \text{Medicine Registration} + a_5 \ln \text{Supplier Selection} + v - u.
\]
### COEFFICIENTS(A)

<table>
<thead>
<tr>
<th>Model</th>
<th>Unstandardized Coefficients</th>
<th>Standardized Coefficients</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Constant)</td>
<td>1.47</td>
<td>0.38</td>
</tr>
<tr>
<td>Drug quantification</td>
<td>(0.27)</td>
<td>0.10</td>
</tr>
<tr>
<td>Transparent Management</td>
<td>(0.14)</td>
<td>0.50</td>
</tr>
<tr>
<td>Financing &amp; Promotion</td>
<td>(0.36)</td>
<td>0.22</td>
</tr>
<tr>
<td>Medicine Registration</td>
<td>0.37</td>
<td>0.55</td>
</tr>
<tr>
<td>Supplier Selection</td>
<td>0.34</td>
<td>0.30</td>
</tr>
</tbody>
</table>

Table 4.10: Coefficients

\[
\ln \text{Cost} = 1.47 + 0.62 \ln \text{Drug Quantification} + 0.25 \ln \text{Transparent Management} + 0.15 \ln \text{Financing & Promotion}, + 0.65 \ln \text{Medicine Registration}, + 0.17 \ln \text{Supplier Selection} + \nu - u.
\]

From the findings, procurement of medical supplies is positively related to the drug quantification; transparency management, medicine registration; financing and promotion and supplier selection. In addition, change in 1 unit of medicine registration leads to change in 0.65 units of procurement of medical supplies. However, a change in 1 unit of financing promotion only influences a 0.15 change in procurement of medical supplies. This implies that the correlation between medicine registration and procurement of medical supplies is higher than those of quantification; transparency management, financing and promotion as well as supplier selection with procurement of medical supplies.
Table 4.11: Correlation Summary

Adjusted $R^2$ according to the findings shows a positive relationship between all the variables and the procurement of medical supply. From table 4.11, a change in one unit of the entire analytical variables in the model influences change in procurement of drug supply to a tune of 76.2%. This implies that efficiency in execution of the variable indicated will lead to efficiency in drug procurement systems.

From table 4.10, we can either reject or accept the null hypotheses as indicated by t value in the table. When $t > 2$ then we reject null hypothesis and accept alternative hypothesis. From the findings, we accept $H_01$, $H_02$ and $H_05$ but reject $H_03$ and $H_04$. The summary is as indicated against each of the formulated hypothesis below:

$H_01$: There is no significant linear association between transparent, efficient management and the procurement of drugs and medical supplies. - Accept

$H_02$: There is no significant linear association between the levels of financing and promotion strategy and procurement of medical supplies. - Accept

$H_03$: There is no significant linear association between the registration of medicines and pharmacy and pharmaceutical procurement - Reject

$H_04$: There is no significant linear association between drug selection and quantification and procurement of drugs and medical supplies. - Reject

$H_05$: There is no significant linear association between supplier selection, quality assurance and the procurement of pharmaceuticals. - Accept
CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1 Summary of Findings

From the study, majority of the respondents (64%) were in the Sales and Procurement Department. Only 13% were in the Pharmacy while the remaining (23%) belonged to the Disease Prevention and Control Department. Majority of the respondents (60%) said that the government owned their organization while the remaining (40%) said their organizations were privately owned. On whether there exists a formal national medicine policy document covering both the public and the private sector majority of the respondents (93%) claimed that there exists such a document while the remaining 7% denied any presence of a formal national medicine policy document covering both the public and the private sector.

Regarding the presence of an Essential Medicine List (EML) available in the respondents’ firm, an overwhelming majority (93%) agreed that there exists such a system while only 7% disagreed of the availability of the EML in their firms. On whether there are policies governing the procurement process, 93% said yes while 7% said no.

The researcher also sought to know the number of members in the institution committee. From the findings, majority of the respondents (97%) said the number ranges between 1 and 10 members. Only 3% claimed that the number was beyond 10 members.

Regarding who appoints the committee members, the researcher found that majority of the respondents (57%) mentioned the Senior Management within the Institution as the appointing authority while 23% said it is the government through ministry of health and Sanitation. Only 20% of the respondents said that it is the government through the appointing board does appoint the committee members. From the findings, experience and education qualifications were highly considered as given by 60% and 100% majority respectively. Nonetheless, personal relations and age were not highly considered as opposed by the majority. In addition, qualifications and merits were the major parameters of contract renewal as supported by 40% and 37% of all the respondents respectively. Only 23% attached significance on signatories, as a bases of contact renewal.
From the findings, date of delivery, name of products and the terms of delivery are adhered to as supported by majority of the respondents (57%, 57% and 53% respectively). However, the quantity procured as well as the supplying given is not adhered to as indicated by a majority of 60%. The researcher was also interested in knowing the most preferred media in advertising and promotion of drugs. From the study, public posters and radios prevails as supported by a majority of 47% and 43% respectively. Internet and intermediary pamphlets had a 40% and 38% majority respectively. On the important of efficiency, majority of respondents (100%) agreed that reduction of stock outs, deserved supply selection, timely and standard drug deliveries as well as accountability in supply and chain management were the most important aspects.

From the empirical results, loopholes were evident especially when it came to drug quantification, rightful estimates were not quantified hence leading to stock outs and overstock as experienced in a section of the respondents. Professional procurement skill also left a lot to be desired in Kemsa’s recipients and this implies poor estimations, low quality drugs on shelves, sale of counterfeits and sluggish procurement procedures. Moreover, although the researcher noted a small percentage acknowledging incentives before bidding, which would have dimmed subjective to the procurement principles, they offer motivation to the personnel for strict adherence to the operational practices.

5.2 Conclusion
From the findings we can conclude that:
The mechanisms adopted by the pharmaceutical firms in addressing challenges in the procurement of drugs and medical supplies are not efficient. This is manifest on the fact that, availability of procured information as well as drug quantification are represented to a moderate extent in the findings. Despite the positive response from Kemsa, on timely deliveries, quality assurance and efficient management, its Key players and recipients denote contrary.

This paints a picture of undying drug stock outs let alone free market for counterfeits and adulterated drugs to continue bustling in the market at the expense of user fees and consumer health. This raises questions on efficiency of drug quantification and whether there is deserved supplier selection for better, timely and quality drugs in government health Institutions for all.
5.3 Recommendations

From the findings, the researcher recommends KEMSA to come up with a turn around programme to enhance the efficiency of operational management practices on the procurement of pharmaceuticals. This will counter the deficiencies of counterfeits, expired drugs, avoidable deaths and most of all will enable decentralization to trickle down to health centers within and without the city centres. The government should also develop policies to ensure that the action program is well developed by the relevant regulatory bodies, motivated and acquitted with professional follow ups for efficient procurement to stream to the end user-the patient. Besides the Decentralization policy, the government should also follow up with the DHMTs for effective and timely feedback on drug supply chain management.

Implementation of operational principles of good pharmaceutical procurement

The main aim of efficient procurement and distribution procedures are to select the most cost-effective essential drugs to treat commonly encountered diseases, quantify an institution’s needs, pre-select potential suppliers, manage procurement and delivery, ensure good product quality, and monitor the performance of suppliers and the procurement system. If procurement is conducted without a systematic process, it can lead to a lack of access to appropriate drugs, wastage of resources (e.g., overstocked items expiring on the shelves), the purchase of low-quality products, or failure to achieve intended clinical outcomes as indicate in the analysis section. To ensure this systematic approach, hospitals should review, adapt, and adopt the available tools for their own internal procurement procedures. To ensure that all those involved in procurement are aware of these principles, standard operating procedures must be developed, accompanied by emphasis on accurate record keeping and regular reviews.

1. Purchasing for safety

Patient safety is recognized as a priority for health care organizations and is receiving more and more attention. Purchasing for safety should therefore be a guiding principle (i.e., procuring presentations and formulations of medicines that are approved for use in the formulary and designed to promote safe practices). The strategy involves learning from medication errors that are or may be associated with labeling and packaging and developing risk management criteria that may be used during the purchasing process.
There are many situations that are likely to lead to high medication errors and which the products would need to undergo risk assessment as part of the procurement process. They include products whose manufacturer is unknown or have poor history, new generic products, a product known to be associated with problems, parallel import products, injections requiring specialized labeling, and products in a high-risk therapeutic category (e.g., anticoagulants). A more complete list and tools and procedures for assessing inherent risk potentials of products have been developed in the United Kingdom and Canada and why not we the developing world?

2. Adhering to an appropriately selected drug list

Procurement must be informed by drug selection. The pharmacy and therapeutics committee must identify the drugs to be purchased by making decisions based on most up-to-date evidence. Pharmacists’ role in the committee is crucial. The process of drug selection is also facilitated in many cases by the availability of a national essential drugs list (which 80% of the respondents acknowledge) or the use of the WHO model list of essential medicines or more-specific lists, such as those for reproductive health and for children. In addition, systematic management and assessment of drug expenditures (and hence the procurement budget) must be ensured by regular study of the Kenyan local drug market and the various factors affecting it, such as drug development, drug utilization, drug costs, new drug entry into the market, entry of generics products, and other trends in health care as they occur both locally and internationally. These factors can affect the current clinical judgment and therefore the selection process. Control must also be exercised to eliminate seductive strategies, such as donations and seeding trials, which may not only introduce unselected drugs on the list but also disturb the transparent procurement processes.

3. Timely, accurate, and accessible information

Information is the lifeblood of procurement and is needed at every stage if the procurement process is to be optimal. Costs and procurement inaccuracies are reduced by timely and accurate information exchange among the staff of the institution and between staff and the supplier (i.e., the procurement trading partners). Keeping accurate records and documentation of all activities provides the basis for this information. In this way, the pharmacy staff and the administration have information necessary for decision-making. Access to quality data is also necessary for the quantification process, the outcome of
which is used for the hospital and the national health information system. Experience has shown that proper drug inventory, monitoring, and control can identify bottlenecks in the hospital system beyond the pharmacy. The data can be stored in a number of ways, ranging from simple paper forms to electronic forms. Human error can be reduced and data processing improved by the use of new telecommunication technologies, including electronic systems, which should be investigated and introduced in the procurement process when available and appropriate to the situation.

4. Ensuring quality products

Although quality is one of the key components in the operational principles of good pharmaceutical procurement, it is highlighted here because of the increasing problem of counterfeit and substandard medicines on the market. Although the extent of counterfeiting is difficult to quantify, WHO reported an average detection of more than four incidents daily for 2007, a 10-fold increase from 2006. Other reports estimated a global prevalence of 1% in developed countries, up to 30% in developing countries, and as much as 50% for Internet-based sales. Substandard, counterfeit, and contaminated drugs cause wastage of resources and can pose serious health risks. Quality assurance in procurement is therefore an integral part of all key activities (i.e., prequalification of products and suppliers during purchasing, storage, and distribution). But more can be done. Each hospital should develop and implement its own internal quality-assurance system, guided by guidelines and technical details specified in national or international agencies, such as WHO’s interagency guidelines. Depending on the level of sophistication, personnel training, and resources available, a number of methods to check on drug quality are available for use at the hospital level. These include visual inspection, colorimetry, refractometry, thin-layer chromatography, and the use of minilabs. Hospitals can also "link up" with centers with the ability to check quality with high-performance liquid chromatography and other forensic techniques.

5. Proper budgeting and financing

Adequate financing is necessary for successful procurement. Drug-financing mechanisms include public financing (i.e., government budget), health insurance, user fees, donor financing, and development loans. Each of these has limitations and, depending on how the hospital is funded, will affect pharmaceutical procurement. The drug procurement
managers should therefore be familiar with funding mechanisms. Revolving drug funds (RDFs) or earmarked or designated funds have been used in drug procurement, sometimes with success. Unfortunately, experience has shown that RDFs face a number of problems, which leads to insufficient recovery of funds to replenish the supplies. All these point to the importance of addressing drug procurement financing using business principles, careful quantification and planning, and an agreed-upon mechanism to ensure that funds are available when needed.
REFERENCES


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Firsund, et. al. (1980), Phase-remapping attack in practical quantum-key-distribution systems


Kangwana, Njogu, Wasunna, Kedenge (2007), Kenya purchase seventy-five percent of its annual order of ALU, the recommended first-line treatment for uncomplicated malaria in Kenya, through an international open tender.


Otieno (2004), procurement activities in public institutions.


World Bank report (2007), Key procurement functions typically and expertise requirement.

Appendix I: Introduction Letter

Dear Sir/Madam,

REF: REQUEST TO CARRY OUT RESEARCH ON THE IMPACT OF OPERATIONAL MANAGEMENT PRACTICES ON THE PROCUREMENT OF DRUGS AND MEDICAL SUPPLIES IN DEVELOPING COUNTRIES.

I am a student at the University of Nairobi, Department of Business pursuing a master’s degree in Business Administration. As a requirement in fulfillment of this degree, I wish to carry out a study on the impact of operational management practices on the procurement of drugs and medical supplies in developing countries.

I have chosen your facility because it is an epitome of drug and medical supplies dispensation and is a main channel of procurement processes to various health institutions let alone individuals. I intend to research the above with a bias on the various managerial practices and how effective they are in enhancing efficiency in the timely, cost effective access to drugs and other medical supplies. Possible constraints to reaching the above will also be considered in the study. I, therefore, humbly request for license to carry out research on your facility by way of questionnaires.

Any assistance accorded to me in my noble cause and information given shall be treated as confidential and will be used purely for the purpose of this research and a final copy of the document shall be availed to you upon request. Your cooperation will be highly appreciated and thank you in anticipation.

Yours faithfully,

Mogoi Sheila Osebe
Appendix II: Research Instruments

Kindly answer the following questions by ticking in the appropriate box or filling the spaces provided.

PART A: GENERAL INFORMATION

1. Name of the firm (optional):

..............................................................................................................................................

2. Department:

..............................................................................................................................................

3. Which is the category of this health facility in the pharmaceutical industry?

   Pharmacy [ ]
   Laboratory [ ]
   Agency [ ]

4. Ownership

   Government [ ]
   Private [ ]

PART B: DRUG QUANTIFICATION AND PROCUREMENT

5. Is there a formal National Medicines Policy document covering both the public and private sectors?
   Yes [ ] No [ ]

6. Is an Essential Medicines List (EML) available in this firm?
   Yes [ ] No [ ]

If yes, state total number of medicines on national EML

   National [ ]
   Regional [ ]

7. Is there a policy for generic prescribing or substitution?
   Yes [ ] No [ ]

If yes, how are the policies reviewed?

   Quarterly [ ]
   Half yearly [ ]
8. Are there incentives for generic prescribing or substitution?
   Yes [ ]    No [ ]

9. Are there policies governing the procurement process?
   Yes [ ]    No [ ]

10. If yes does your firm follow them?
    Yes [ ]    No [ ]

11. In the case of violation of the drug quantification, what measures are taken to counter the loopholes encountered?

12. Are there incentives awarded before the bidding process?
    Yes [ ]    No [ ]

13. Which are the various sources of such incentives?
    Government [ ]
    NGOs [ ]
    Private investors [ ]
    Individuals [ ]

14. Do this incentives influence the decisions below
    Yes  No
    Procurement [ ] [ ]
    Delivery [ ] [ ]
    Drug selection [ ] [ ]
    Drug Quantification [ ] [ ]
    Official Management [ ] [ ]

15. Explain the answer above.................................................................

.................................................................

PART C: INSTITUTIONAL STRUCTURE

16. What gender percentage constitutes your institution’s tender committee?
    Male [ ]    Female [ ]

17. How many members are in your institution’s tender committee?
    1-10 [ ]    11-20 [ ]
18. Who appoints the committee members?
- The government through ministry of health and sanitation
- The government through appointed board
- The senior management within the institution
- The board members within the institution
- The professional bodies concerned with pharmaceuticals
- Others (specify...........................................)

19. Indicate prerequisite factors to committee member appointment:

<table>
<thead>
<tr>
<th>Factor</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Age</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Personal Relations</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>Education Qualification</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

20. What is the tenure of the tender committee?
- Permanent
- Contract
- Casual
- Others (specify............)

21. How are your contracts renewable?
- Quarterly
- semi quarterly
- Randomly

22. Renewable subject to?
- Qualification
- Merit
- Signatory
- Personal Relations

PART D: EFFICIENCY AND TRANSPARENCY MANAGEMENT

23. Indicate the adherence to the following contentys in the procurement schedule:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
24. How would you rate their representation in terms of transparency and accountability? In a scale of 1-5, 5 being the highest efficient.

<table>
<thead>
<tr>
<th>Availability of procured information</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bidding decisions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier selection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug quantification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(specify..........................................................)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Elaborate and explain your rating above..........................................................

25. Are the above measures followed? (YES) (NO)

26. If (NO) why?

27. In the case of violation what corrective measures are undertaken?

PART E: SUPPLIER SELECTION AND PROMOTION

28. Which tender rate methods apply to your

- Pooled procurement [ ]
- Open procurement [ ]
- Contract procurement [ ]
- Random procurement [ ]

29. Is the choice above preferred and efficient in drug supply:

- YES [ ]
- NO [ ]

30. How often does your committee advertise tenders?
31. Select the most preferred media in advertising and promotion of drugs in your facility?

- Television channels [ ]
- Public posters [ ]
- Radio [ ]
- Intermediaries pamphlets [ ]
- Internet [ ]

32. Is the promotion venture rewarding in terms of YES NO

- Market share [ ] [ ]
- Drug popularity [ ] [ ]
- Quality Assurance [ ] [ ]
- Profit Markup [ ] [ ]

33. Rate in a scale of 1-5, your organization's adherence to the promotion codes below:

<table>
<thead>
<tr>
<th>Code</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear and accurate drug information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High value for money</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Standard quality</td>
<td></td>
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<tr>
<td>Prompt and efficient delivery</td>
<td></td>
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<tr>
<td>Others</td>
<td>(specify)</td>
<td></td>
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</tbody>
</table>

34. Which of the deterrent factors below affect efficient drug flow in your organization? Yes No

- Untimely bidding [ ] [ ]
- Financial malpractices [ ] [ ]
- Poor procurement management [ ] [ ]
- Random selection of bids [ ] [ ]
- Unclear supply chain procedures [ ] [ ]
- Procedure violation [ ] [ ]
- Unskilled procurement personnel [ ] [ ]
35. Select the criterion applied in supplier selection?

- Highest bidder [ ]
- Random selection [ ]
- Official arrangements [ ]

36. Procurement management improves cost differentiation towards customers and higher profits than their competitors. Indicate benefits that would accrue to your organization that adopts efficient:

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug quantification</strong></td>
<td></td>
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<tr>
<td>Reduction in stock outs</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td>Scrutiny of counterfeits</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td><strong>Supplier selection</strong></td>
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<tr>
<td>Deserved supplier selection</td>
<td>[ ]</td>
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<tr>
<td>Timely and standard drug delivery</td>
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<td>[ ]</td>
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<tr>
<td><strong>Drug registration</strong></td>
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<tr>
<td>Standard drug quantity</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td>Accountability in supply chain management</td>
<td>[ ]</td>
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</tr>
</tbody>
</table>

37. What measures do you suggest effective in addressing

- Drug stock outs
- Counterfeited and adulterated drugs
- Sale of expired and substandard products
- Untimely delivery of drugs and medical supplies in health institutions

THANK YOU FOR PARTICIPATING!!!!!
DECLARATION

This management research project is my original work and has not been presented to any university for examination.

Sign ..............................................................

MOGOI SHEILA OSEBE
REGISTRATION NO: D/61/P/8824/2005

This management research project has been submitted for examination with my approval as the university supervisor.

Sign ..............................................................

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DEPARTMENT OF BUSINESS ADMINISTRATION.
UNIVERSITY OF NAIROBI.