ROLE OF A PROCUREMENT OFFICER IN PREVENTING PROCUREMENT OF COUNTERFEIT MEDICATIONS

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A DESSERTATION SUBMITTED TO THE DEPARTMENT OF BUILDING TECHNOLOGY OF THE KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF MASTER OF SCIENCE HONORS DEGREE IN PROCUREMENT MANAGEMENT

SEPTEMBER, 2014

DECLARATION

I declare that I have wholly undertaken the study and reported herein under supervision and the project report entitled **"ROLE OF A PROCUREMENT OFFICER IN PREVENTING PROCUREMENT OF COUNTERFEIT MEDICATION"** is the result of my own research except the literature whose sources have been explicitly stated.

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ACKNOWLEDGEMENT

I am grateful to God Almighty for giving me good health and strength to embark on this academic exercise successfully. I am also thankful to my supervisor Mr. Yaw Kush whose directions, critique and mentorship has helped me tremendously to enable me produce this dissertation. The cordial relationship encouraged me to discuss my opinions freely and helped to boost my academic confidence. I would also like to thank the entire lecturers of the Department of Building Technology for their supervision, constructive criticisms, useful suggestions, and encouragements.

God bless you.

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DEDICATION

This research project is dedicated to God Almighty, my lovely wife Emma Ida Pekyiand our three adorable children; Anthony Quaicoe, Nana Aba Twento Quaicoe and Curtis Kwabena Nyametease Quaicoe.

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ABSTRACT

The deadly implications of counterfeit medicines/drugs are well understood to be a central challenge to the integrity of public health systems around the globe, as well as a direct threat to our individual health and welfare. What is less understood is that the profits from this sinister crime are increasingly being co-opted by an array of organized criminal groups and terrorist entities as a means by which to fund their nefarious operations around the world. As such, counterfeit pharmaceuticals pose a direct threat to national and international security.

The main aim of this research is to explore the role of procurement officers in preventing procurementof counterfeit medicines into our public hospital and the following specific objectives were identified to help attain the stated aim;

1. To identify procurement processes (of medicines) within Ghana Health Service.
2. To identify the role of procurement officer in the procurement of medicines.
3. To identify the tools procurement officers use to ensure that the medicines they procure are counterfeit free.

Methodology: The research processes that were adopted were quantitative and qualitative. The data sources were primary and secondary and a purposive approach of sampling selection was used since the population of procurement officers responsible for the procurement of medicines are very small. Both closed and open ended questionnaire were used to collect data and the data was analysed using Microsoft Excel statistical tool and content analysis respectively.

Study outcome/findings:

Objective 1: To identify the procurement processes (of medicines) withinGhana Health Service.

Content analysis was used to analyse the data. It was identified that procurement of medicines starts from when the user department issues requisition and it ends when the products are delivered and paid for.

It resulted that documents requested by 80% of the respondents during prequalification were inadequate to ensure that the medicines procured were of good quality. Secondly the excessive use of price quotation by 80% of the respondents in the procurement of medicines accounts for the high cost of medicines in our public hospitals.

Objective 2: Identify the role procurement officers play during medicine procurement.

The outcome of the research resulted that the procurement officer plays four (4) strategic roles;

- Procuring the most cost-effective medicines in the right quantities
- Coordinating the selection of reliable suppliers of high-quality products and keeping database of themin order to assure the procurement of quality medicines.
- Ensuring proper logistic management and timely delivery of medicine.
- Achieving the lowest possible total cost.

Objective 3: Identify the tools procurement officers use to ensure they procure quality medicines.

It resulted that only 20% of the respondents do request for all the tools WHO and Standard tender documents for the procurement of medicines by the Public Procurement Authority require that every procurement officer should request to prevent the procurement of counterfeit medicines.

Conclusion

Once a fake or counterfeit medicine slips through the supply chain system and enter the health institution or pharmacy, the harm has already been done. For that matter the role procurement officers play in preventing the procurement of counterfeit medications into our public hospitals cannot be over emphasised. The recommendations below can help to achieve the objective of ensuring counterfeit-free medicines into our hospitals.

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Recommendations

Based on the findings of the research, the following recommendations were proposed:

- Since the first point of call for all medicines by public health facility is the Regional Medical Stores, they should be well stocked to prevent hospital from procuring from the open market.
- Regional Medical Stores should be well equipped with a mini-lab to help undertake certain basic quality control test and a management information system to help track the medicines to ensure they are of good quality.
- Certificate of analysis during quality control testing and other relevant documents as stated by WHO and the PPA should be requested by all procurement officers no matter the mode of procurement method being used.
- FDA must have a database of all registered medicines in the country where procurement officers can verify the authenticity of the medicine they intent to procure.

Recommendation for further research

- Further research into the role of Information Communication Technology in the fight against counterfeit medicines.
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CHAPTER ONE

1.0 INTRODUCTION

1.1 STUDY BACKGROUND

Medicines counterfeiting is often referred to as the second oldest profession'(Lybecker,2008). Its history dates back to the first century in Greece when Dioscorides first classified drugs by their therapeutic use and warned of the dangers of adulterated drugs as well as howthey could be detected (WHO, 1999a cited in Newton et al, 2006a). The mid 19th-centurywitnessed a widespread adulteration of medicines especially quinine which led to theestablishment of the Code of Ethics for Pharmacists and guides on the detection ofcounterfeits in the United States of America (Newton et al. 2006a). Since then there has been anecdotal reports of tragedies resulting from the use of poor quality medicines.

InNigeria for instance, medicines counterfeiting was first observed in 1968 when there was aderegulation of Crown Agents as sole distributors of medicines (Akunyili, 2007). This led tothe promulgation of the Food and Drug Decree No. 35 in 1974. Owing to the globaleconomic recession at the time and the consequent devaluation of the Nigerian currency(Naira); most drugs became unaffordable to the majority of the population leading to theissuance of import license for medicines/drugs (NAFDAC, 2002).

WHO (2003) cited in Morris and Stevens (2006) showed that a survey by the WHO on the quality of anti-malarias in seven African countries (Gabon, Ghana, Kenya, Mali,
Mozambique, Sudan, and Zimbabwe) revealed that about 50% of the products failed quality testing. This included Artermether based syrup/suspension and tablets with failure rates ranging

from 23% to 38% and about 90% of the sulphadoxine/pyrimethamine tablets were found to be substandard (Maponga and Ondari, 2003). Between 1991 and 1993, 519 samples were collected from private, public and nongovernmental drug outlets and illegal markets inthree African countries (Ghana, Nigeria and Togo) by the WHO; 429 of the samples were tested in independent laboratories; out of which 77 (18%) were discovered to be substandard (WHO,1995 cited in WHO, 1999b). Sixteen of the samples that failed quality tests did not contain any active ingredient, and were therefore deemed counterfeit (WHO 1995 cited in WHO, 1999b).

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Counterfeit pharmaceutical are fraudulently produced or mislabeled medicines purchased by consumers who believe them to be legitimate. These drugs/medicines can cause a range of serious health concerns. Fake pills may look nearly identical to their genuine counterparts, but may be incorrectly formulated and produced in substandard conditions. They are, by definition, not subject to the same regulatory scrutiny as legitimate medications. The drugs often have incorrect amounts of active ingredients, if those ingredients are present at all, and are illegal in developed countries.

Pharmaceuticals are also considered counterfeit if the genuine products are stolen or repurposed and "up-labeled "a process in which pills of one dosage are placed in bottles listing higher dosages. For example, counterfeiters may use legitimate capsules with 10mg of active ingredient and sell them in bottles with labeled dosages of 40mg. Even individual components of pharmaceuticals can be counterfeit, requiring both companies and regulators to scrutinize suppliers to avoid illicit compounds entering legitimate facilities through their supply chain.

Both brand-name and generic pharmaceuticals are susceptible to counterfeiting; posing problems for any corporation producing legitimate drugs/medicines. According to a report by the WHO, in

addition to pharmaceuticals, medical devices and medical-related products have also been counterfeited, including blood glucose test strips, contact lenses, surgical instruments, and even condoms.

Nearly a third (33.3 %) of reported counterfeits contained no active ingredient, according to an analysis done by the WHO in 2000. Another 20.2 % had incorrect quantities of active ingredients; 21.4 % contained the wrong ingredients; 15.6 % had the correct ingredients, but fake packaging; 8.5 % contained high levels of impurities; and 1 % was copies of an original product.

Counterfeit and substandard medicines have been an issue in both developed and developingeconomies (Ibrahim & Ali, 2013, Yankus, 2009, Bird, 2008, Lybecker, 2007 and Liang, 2006). This has been a worry for governments, health practitioners, policy makers, marketers and economists. The problem according to the literatures is more severe in thelow income economies or developing economy where few empirical works have beendone on the demand side of attitude towards counterfeit drugs.

Aside the health implications of counterfeit drugs/medicines local manufacturers are affected withthe influx of counterfeit drugs in loss of revenue. The government also loose in taxrevenue while as citizens also loose as a results of inadequate jobs. According to some researchers there is a huge profit forthe producer of counterfeit drugs in an economy since it is not easy to distinguishcounterfeit drugs from genuine (Kontnik, 2004).

According to Dondorp et al. (2004), 53% out of the 188 tablet packs purchased in Southeast Asia under the label of artesunate drug for the treatment of malaria did not contain anyartesunate.

Newton et al. (2001) in earlier studies established that 38% of 108 drugsamples were counterfeit drugs. World Health Organisation (WHO) in 2009 using a sample of 491 anti-malaria drugsfrom Africa found high failure rates in all of the three sample countries in the study. These results indicate an increase in the problem of counterfeit.

According to Harris (2008) counterfeit drugs/medicines cause the death of 700, 000 people in the treatment ofmalaria and tuberculosis every year in Africa. According to researchers (Bate et al., 2011; Marcketti & Shelley, 2009; Liang, 2006; Bang et al., 2000) what makes the problem serious is the fact that consumers are not ableat all times to identify the counterfeit and substandard drugs. Bate et al. (2011) indicatesthat consumers use price and the look of the pharmacy to determinethe quality of drugs but that does not guarantee their safety at all times.

Despite the importance of tackling medicines counterfeiting, it was not given internationalrecognition until 24 years ago when it was first discussed at an international health meeting; the WHO Conference of Experts on Rational Drug Use (WHO, 2006). In 1988, the WorldHealth Assembly issued a resolution (WHA41.16) against counterfeit and substandardpharmaceuticals requiring initiation of programmes to prevent and detect poor quality drugs(Newton et al, 2006a). In 1992, the first international meeting on counterfeiting was held in Geneva which recommended a collaborative effort to help curb the problem and defining acounterfeit drug.

In a bid to crack counterfeiting, WHO held a conference in Romein 2006 which led to the Declaration of Rome and the formation of International MedicalProducts Anti-counterfeiting

Taskforce (IMPACT) which is aimed at forming a collaborativeeffort among a range of stakeholders in order to curb medicines counterfeiting. IMPACT focuses on major technical areas which have been identified as needing action nationally andinternationally; legislative and regulatory infrastructure, regulatory implementation,enforcement, technology development for detection of counterfeits and technology transferto developing countries as well as communication of risk and innovations/strategies aimed atcurbing counterfeiting (WHO, 2010a).

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What is now unique about medicines counterfeiting when compared to what was reportedprior to the 20th Century is the international nature and scope of the problem as well as thesophisticated technology and strategies employed in this crime (Forzley, 2005).

Medicines counterfeiting is increasingly becoming like the worldwide narcotic trade in that in majority of the cases, the raw materials are obtained from one country, formulated into tablets or capsules in another country, packaged in a different country and then shipped through several countries before arriving at its final destination (Lybecker, 2007). In Egypt for instance where about 10% of medicines sold are believed to be counterfeit, following a warehouse raids, a large amount of counterfeit medicines purporting to treat all kinds of illness were confiscated (CNN Money, 2009). These medicines were thought to originate from China and passed through Syria before arriving in Egypt (Egypt today, 2009).

1.2 STATEMENT OF THE PROBLEM

Imagine that a patient is prescribed chemotherapy to treat a life-threatening tumor. A pharmacist dispenses the prescribed medication and counsels the patient without realizing that the tablets did not contain an active ingredient. In this scenario, not only is the patient not receiving the prescribed medication, but the physician and pharmacist are evaluating treatment outcomes based on the patient's response to a placebo.

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Counterfeit medications have been defined as "products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. Examples include medications that contain no active ingredient, an incorrect amount of active ingredient, an inferior-quality active ingredient, a wrong active ingredient, contaminants, and repackaged expired products.

A new report from the International Policy Network and sponsored by IMANI center of policy and education details the shocking burden of fake drugs in less developed countries. Fake tuberculosis and malaria drugs alone are estimated to kill 700,000 people a year (IMANI, 2011).

The report lays bare the ballooning problem of counterfeit and substandard drugs, which can constitute one third of the drug supply in certain African countries. These deceitful drugs result in unnecessary death and increased levels of drug resistance.

The report highlights more shocking evidence, such as:

- Nearly half the drugs sold in Ghana, Nigeria, Angola, Burundi, and the Congo is substandard.
- Most fake drugs originate from China and India.

Current attempts to deal with the problem through tougher regulation and criminal penalties do not address the root causes of counterfeiting.

The impact of counterfeit medications on the legitimate global pharmaceutical market has been estimated to reach $75 billion and the profit margin is reportedly greater than illicit drug trafficking (WHO 2009). Counterfeit medications have been distributed via complex global networks that have been traced to terrorists and organized crime. Estimates indicate that less than 1% of prescription medications sold in the United States and Europe and 30% sold in developing nations are counterfeit, and the problem is likely growing rather than receding (WHO 2010).

Although 1% may seem low, if a pharmacy dispenses 200 to 300 prescriptions per day, that means that two or three of them could be counterfeit. Pfizer reported discovering 14 counterfeit Pfizer products in at least 36 countries, including the United States, in the first 9 months of 2009 and reportedly seized more than 11 million counterfeit tablets, capsules, and vials in 2009.

A U.S. Immigration and Customs Enforcement official reported at least weekly seizures of counterfeit medications on the U.S. border. Placebo products initially dominated, but a recent trend is for counterfeiters to substitute less expensive active ingredients in hopes of securing repeat business. The problem of counterfeit drugs is known to exist in both developed and developing countries. However, the true extent of the problem is not really known since no global study has been carried out.

The appearance of counterfeit medicines in international commerce was first mentioned as a problem at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya, in 1985. Since then, public awareness of the problem of counterfeit drugs has grown. Both government

authorities and manufacturers have been concerned with efforts aimed at preventing the problem, and WHO has received reports related to counterfeit drugs from some of its member states on a voluntary basis. According to this information, the problem is known to involve both developed and developing countries. The data also reflects that only a few countries are willing to provide information about cases detected. The drugs most counterfeited included antibiotics, hormones, analgesics, steroids, and antihistamines. These drugs form almost 60% of medicines world -wide.

In February 2013, Ghana's Food and Drugs Authority (GFDA) and the United States Pharmacopeia Convention (USP), supported by the United States Agency for International Development (USAID), published a study on maternal-health products sold in Ghana. The GFDA and USP procured samples of oxytocin and ergometrine, used to treat potentially lethal post-partum hemorrhage. While Western hospitals routinely use such products to lower the risk of hemorrhagic, Anna Adjoa, an obstetric nurse in Accra, explains that she uses them "mainly in emergency situations." She said that, when these drugs don't work, the chances are "far higher" that a new mother will bleed out during delivery and can result to the demise of the mother (FDA 2012).

The GFDA study found that, of 303 samples, 220 (or 72 percent) were not registered in Ghana and all of those that were not registered failed basic quality tests, making them unfit for patients. Moreover, roughly 95 percent of the 83 samples that were subjected to all methods of quality and sterility testing failed. The companies that registered the products they sold (a legal requirement fulfilled by only three of the 16 companies examined) performed somewhat better, but most of their products failed, too. For example, Ciron, an Indian generics firm, registered its product Ergogen, but half of its samples failed and as a result the products were rejected (FDA, 2012).

All these could have been averted if the procurement officers have requested for the right documentations as specified by the World Health Organisation and the standard Tender document for the procurement of medicines by the Public Procurement Authority. For instance if certificate of analysis of the quality control procedures from both the Food and Drugs Authority and the manufacturer were requested the quality or otherwise of these product could have been ascertained but instead they relied on the credibility of the suppliers.

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1.3 RESEARCH QUESTIONS

- What processes does procurement of medicines go through in Ghana Health Service?
- What role does a procurement officer play in the procurement of medicine?
- What tools or documents do procurement officers use to assess the quality or otherwise of the medicines they procure?

1.4 AIM AND OBJECTIVES

1.4.1 Aim of Research

To explore the role of procurement officers in preventing procurementof counterfeit medicines into our public health institutions.

1.4.2 Objectives of Research

- To identify the processes for procurement of medicines in Ghana Health Service institutions.
- To identify the role of a procurement officer during procurement of medicines.
- To identify the tools or documents used by procurement officers to assess the quality or otherwise of the medicines procured.

1.5 SIGNIFICANCE OF STUDY

Counterfeit medicines are dangerous by their very nature because they are not produced under safe manufacturing conditions (WHO, 2009).There are no reliable data on the mortality and morbidity arising from the use of counterfeit pharmaceutical products in Ghana and other developing countries. The effects go unnoticed except when it causes easily observable mass tragedies (Erhun et al. 2001). When data on extent and impact of counterfeiting are available, they are often limited as only 5-15% of the 191 WHO member states report cases of counterfeiting and generalisations made from such reports may not be accurate (Newton et al, 2010).

Only three journal articles were found to describe the impact of counterfeit and substandard medicines; Morris and Stevens (2006), Fenoff and Wilson (2009) and Newton et al. (2006a). While these articles focused on mass tragedies in the form of death attributed to the use of poor quality medicines, Morris and Stevens (2006) and Newton et al. (2006a) also included other consequences such as development of drug resistance.

Medicines counterfeiting is partly responsible for the doubling of malaria deaths over the last 20 years in Ghana and Nigeria according to Dora Akunyili, (Morris and Stevens, 2006). This is evidenced by the fact that 8 out of the 12 major anti-malaria drugs in use in these countries have been reported to have been counterfeited (Newton et al, 2006a).

It appears that until the distribution of counterfeit (poor quality) medicines is tackled, the efforts of new drug discovery and development will continually be rendered futile. This also means that resistance at the population level renders legitimate drugs less effective, even amongst patients

who have not used fake and/or poor-quality medicines (Bate at al. 2009a) causing a switch to second or third line medicines which are usually more expensive and more toxic (Centre for Global Development, 2010).

Although it is a difficult task to trace illness and death to counterfeit or substandard medicines, evidence show that poor quality medicines pose significant threats to consumers as they cause adverse reactions, lack of successful treatment and possibly death (Nsimba, 2008). Evidence of this can be seen from previous experiences in some developing countries such as the death of about 100 children in Nigeria in 1990 following the ingestion of a cough mixture which was diluted with a poisonous solvent, diethylene glycol (DEG) (Morris and Stevens, 2006). Eighty-four more children died in Nigeria between late 2008 and early 2009 due to the consumption of diethylene glycol-contaminated teething medicine (My Pikin Baby Teething Mixture), distributed by the NAFDAC-licensed Barewa Pharmaceuticals (Polgreen, 2009; Eboh, 2008, Harris, 2008, Mbachu, 2009 cited in Milissa2010).

Another catastrophic example is the death of about 2,500 people resulting from the consumption by about 60,000 people of vaccines donated by Nigeria to Niger during a meningitis epidemic which were later found not to contain any active ingredient (Fenoff and Wilson, 2009). Other incidents which have been attributed to the use of poor quality medicines include the report from three Nigerian hospitals of cases of adverse reactions from the use of infusions which were contaminated with micro organisms. Also, 147 out of the 149 water for injections analysed from these hospitals were found to be unsterile (Akunyili, 2006a). Two children were reported to have died as a result of fake adrenaline administered to them during an open-heart surgery at

University of Nigeria Teaching Hospital, Enugu (Akunyili, 2007). Medicines counterfeiting have also been implicated in some cases of liver damage, kidney failure and heart damage in Ghana (Kapp, 2002 cited in Yar, 2008).

The WHO estimates that about 100,000 Africans die annually from the consumption of counterfeit medicines and that about 200,000 deaths per year could be avoided if illnesses are treated with only medicines of high quality (All West Africa, 2009b; International Council of Nurses, 2005).

The recent finding of counterfeit forms of artemisinin derivative in Africa is a serious cause for concern due to fear of development of resistance to artemisinin in the highly malaria endemic Africa (Newton et al, 2006a). In Ghana, 82.4% of artemisinin samples which were obtained from pharmacies in Kumasi did not meet European Pharmacopoeia content requirements (Ofori-Kwakye, 2009). Counterfeit forms of Coartem, Zentel, Vermox and Amoxicillin have also been discovered in Ghana through the help of the medicine quality monitoring programme implemented by the US Agency for international development (Ghana news agency, 2009).

It is evident that the procurement of counterfeit medicines into our public heath institutions poses a significant threat to our clients and the country at large so there is the need for this research to help identify other way procurement officers can use to prevent the procurement of counterfeit medicines into our public health institutions.

1.6 SCOPE OF THE STUDY

The scope of the research will be limited to only Ghana Health Service public hospitals within Kumasi metropolis and Regional Medical Stores. Kumasi has five health districts: Asokwa, Subin, Bantama, Manhyia North and Manhyia South.

The Kumasi South Hospital (KSH) is situated at Chirapatre, within the industrial hub of the metropolis and serves the people of Asokwa, Ahensan, Atonsu, Esreso, Gyenyase and Kaase.

The Manhyia Hospital, located at Ashanti Newtown near the Manhyia Palace, serves Manhyia, Krofrom, Ashanti Newtown, Aboabo and Asawasi communities. The Old Tafo Government Hospital located within the Old Tafo constituency, serves Tafo, Pankrono, Atimatim and the surrounding communities. The Suntreso Government Hospital is located at North Suntreso and serves North and South Suntreso, Patasi Estate, Kwadaso, Adoato, Asuoyeboa, Breman and Suame (columbia.edu/millennium-cities/kumasi-ghana, 2013).

The following health institution will also be included in the research; Children hospital and KMA clinic.

The Regional Medical Store which is located within the Subin health district serves as the central store from which all the public hospitals procure their medicines. In case the medication is out of stock, a certificate of non availability must be issued to the public hospital in question before they can procure the said drug in the open market.

1.7 METHODOLOGY

The purpose of this research is to explore ways that procurement officers can play in preventing the procurement of counterfeit medications into our public health institutions. The outcome of the research may be applied and the research processes that will be adopted are quantitative and qualitative. The data source will be primary and secondary and a purposive approach of sampling selection will be used since the population is very small. Both closed and open ended questionnaire will be use to collect data and the data will be analysed using Microsoft Excel statistical tool and content analysis respectively.

1.8 STRUCTURE OF REPORT

This research is organized into five chapters. Chapter One is the introduction and provides background information for this research. It explains why the research was undertaken and how this research is significant to public health. The research aim and objectives; scope; methodology and limitations are highlighted. Chapter Two consists of the literature review of the study. This chapter builds a theoretical foundation for the research by reviewing literature and previous research. Chapter Three is the methodology and gives an outline of the research methodology adopted for undertaking the research. The data collection process is also detailed in this chapter. Chapter Four is the analysis of data and presents the result of the findings. Finally, Chapter Five consists of the conclusions and recommendations of the research. The possibilities of further research are also highlighted in this chapter. Figure 1.1 below demonstrates the work flow of the study.

CHAPTER TWO

2.0 LITERETURE REVIEW

2.1 INTRODUCTION

According to Buowari (2013), drugs are used to cure or treat disease, relieve symptoms, ease pain, prevent disease or symptoms, eliminate or reduce symptoms and to slow the disease process. Fake/counterfeit means something that is not genuine but is presented as or appears to be genuine to make or produce something and claim it is genuine when it is not. Counterfeit is something made for a dishonest purpose; an act deliberately designed to deceive.

The World Health Organization (2002) defines counterfeit drugs as one which is deliberately and fraudulently mislabelled with respect to identify and/or source. Counterfeiting of commercial products is an age old practice which flourishes in many countries and is motivated mainly by the huge profits to be made. Trade in counterfeit drugs appears to be widespread internationally, affecting both developed and developing countries. According to WHO (2008), the spread of counterfeit drugs is generally more pronounced in those countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak.

Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging with the wrong ingredients, without active ingredients or with insufficient active ingredients (WHO, 2006). Counterfeit medicinal drugs include those with less or none of the stated active ingredients with added sometimes hazardous, adulterated, substituted ingredients, completely misrepresented or sold

with a false brand name otherwise legitimate drugs that have passed their date of expiry are sometimes remarked with false date (Songare and Chauhan, 2011).

A counterfeit medication or pharmaceutical product is produced or sold with the intent to deceptively represent its origin authenticity or effectiveness. According to Songare and Chauhan, (2011), counterfeit drug may contain inappropriate quantities of active ingredients or none may be improperly processed within the body for example absorption by the body, or may contain ingredients that are not on the label. Several technologies may prove helpful in combating the counterfeit drug problem. Fake drugs otherwise called counterfeit drugs are unfit for usage and human consumption and therefore constitute hazard to good health. Drug counterfeiting is a growing danger and not only in developing countries where it can account for up to 40% of the market. Some counterfeiting is difficult to detect, investigate, quantify or stop. The quantity of counterfeit medication is difficult to determine(Songare and Chauhan, 2011).

According to WHO (2012), fake medicines pose a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure and contribute to increased resistance example, in the case of anti-malarial that contains insufficient active ingredients or even death.

Due to worsening economic conditions and poor enforcement of existing pharmaceutical and customs regulations, third world countries are faced with a growing threat from counterfeit and substandard medicines (Videau, 2006). With expansion of illicit markets in urban areas, the sale of medicines of uncertain quality and origin are increased. Most victims of illicit trade are among

the world's poorest populations that cannot afford to buy quality drugs through private sector distribution channels.

2.2 EMERGENCE OF PROCUREMENT IN HEALTH SECTOR

Procurement is still a much-undervalued area in the public sector. This is particularly true for the health sector. In many countries, hospitals or other health service units do not have qualified procurement personnel (Rob, 2002). The financial impact of procurement in health care is significant. In The Netherlands, e.g., this impact has been estimated to amount to 40% of the total costs of a hospital (Lenselink &Telgen, 1998). In developing countries, expenditures for medicines and other items range from 25% to 50% of the total health care cost according to the World Health Organization (Management Sciences for Health, 1997). The World Bank has become the largest single source of finance for health in low and middle-income countries (Falkenberg &Tomson, 2000).

The approach adopted by the Ministry of Health (2003) is to ensure the effectiveness of each cedi spent on health services, and it involves:

- Increased decentralization of health care delivery, especially through expansion of district-based health care networks composed of health centers and first referral hospitals; and
- Improved management of essential inputs to health care, i.e., pharmaceuticals, health sector personnel, infrastructure and equipment (Rob, 2002).

In 1997 the Ministry of Health, in consultation with the World Bank, hired technical assistance to set up a Procurement Unit and to develop a common set of procurement guidelines, procedures, and standard documents. Subsequently, intensive procurement consultancy services were executed by the International Procurement Agency from March 1998 to November 1999, followed-up by ongoing backstopping services in 2000(Rob, 2002).

Procurement guidelines and procedures for all levels were laid down in a Procurement Procedure Manual (Ministry of Health, 1999) for the procurement of goods, civil works and services. The manual covers the organizational structures, planning, selection and quantification, procurement methods (linked to financial thresholds), monitoring and evaluation and ethics. To complement these guidelines and procedures, standard bidding documents were prepared for the execution of tenders (or bids) for:

- Essential medicines/drugs;
- Non-drugs Consumables, such as medical supplies and reagents;
- Health-care Equipment, including spare-parts, installation, maintenance, training and other related services;
- Services; and
- Civil Works. (Rob, 2002).

2.3 THE PUBLIC PROCUREMENT ACT (ACT 663)

The Government of Ghana enacted the Public Procurement Act, 2003, in December, 2003. This Act became operational on 27th August 2004 and Public Procurement in Ghana therefore is subject to the Act and it's implementing Regulations and Administrative Instructions. The Act

and Regulations provide the general rules governing Public Procurement (Public Procurement Law). The overall objective of the public procurement system is to provide value for money to the Government by ensuring that public funds are spent in a transparent, efficient and fair manner (Public Procurement Law).This Manual incorporates policy provisions and procedures to promote transparency, accountability and ethics in the operation, management and reporting of procurement and asset disposal (Procurement Manual).

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The procurement system aims at the procurement of goods, services and works at their right qualities, prices, times and places through an open competitive tendering process. The Government is entrusted with public funds to provide services for them. The use of public funds must be conducted in a transparent manner, allowing stakeholders and the general public access to information on procurement actions by the Government as well as a means to control and audit all procurement cases (Public Procurement Act, 2003).

According to the Public Procurement Manual the government requires that:

- all public officials and practitioners of procurement shall be held accountable and responsible for their actions;
- all suppliers, contractors and consultants will be treated fairly and given equal opportunity to obtain contracts with the Government;
- procurement shall be done in the most efficient manner, upholding the principles of value for money, transparency and fairness
- funds will be used solely for the purposes for which they have been entrusted;
- appropriate procedures of the Government or the Development Partners are applied;

- all transactions are properly authorized and fully supported by written records;
- value for money can be demonstrated by comparison with market rates; and
- an appropriate Code of Ethics is followed by all staff involved in the procurement process.

According to Anvuur et.al (2006), the Public Procurement Authority establishes the five basic pillars of public procurement [World Bank 2003]:

- Comprehensive, transparent legal and institutional framework;
- Clear and standardized procurement procedures and standard tender documents;
- Independent control system;
- Proficient procurement staff; and
- Anti-corruption measures.

These pillars are very important to the procurement officer if they want to procure medicines that are counterfeit free and also demonstrate that value for money is achieved.

2.4 PROCUREMENT STRUCTURES IN GHANA HEALTH SERVICE

Procurement in the health sector is a little different in other sectors of the economy. The Directorate responsible for procurement in the Ghana Health Service (GHS) is Supplies Stores and Drug Management (SSDM)**.** According to GHS (2005), the directorate is mandated to develop comprehensive policies, sustainable plans, programmes and budgets to cover the procurement and supply of medicines, non-medicine consumables and equipment needs of the GHS in accordance with existing regulations and laid down institutional policies.It also has the

responsibility of ensuring that procurement is carried out in a transparent, fair, competitive and efficient manner and in line with the Public Procurement Law, Act 663.

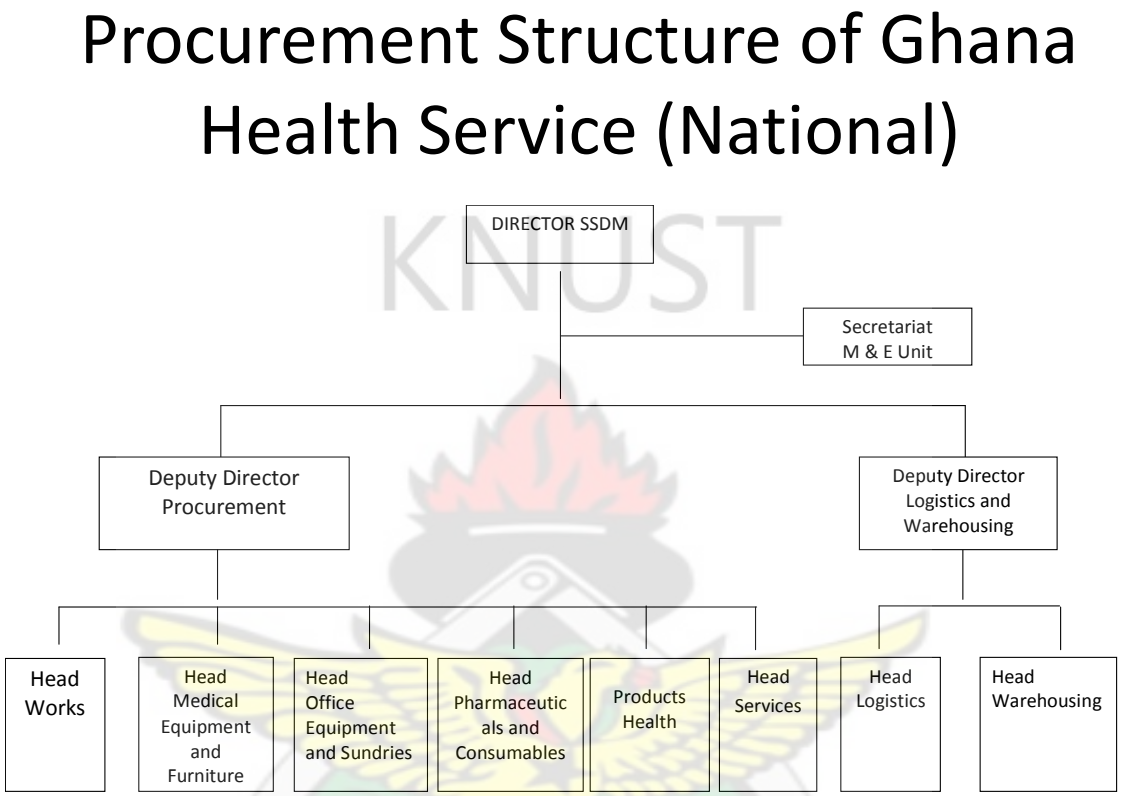

Figure 2.1Ghana Health Service procurement organogram

The core objective of the directorate according to GHS (2005) is to strengthen Procurement Management System throughout GHS by:

- Training Procurement Officers and focal persons within the sector to procure goods (medicines), works and services that are of good quality and also offer value for money.
- Continuous dissemination of the Public Procurement Act (ACT 663)

- Supporting Divisions/ Programs to procure goods, works and services to achieve value for money
- To ensure timely delivery and Port clearance of health commodities.

At the national level procurement is seen to be part of strategic level of management hence it is placed just beneath the director general and its deputy to help develop strategic vision for the service but this is not the case in the regional and district levels of Ghana Health Service.

Regional level

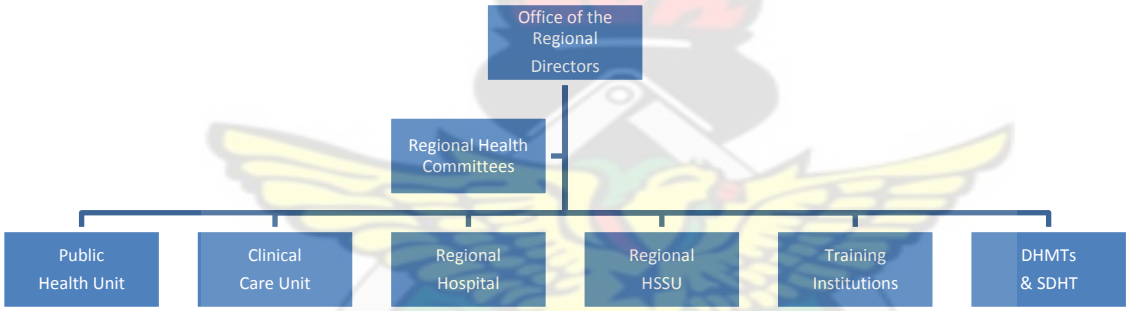

Figure 2.2 Ashanti Regional Health Administration (GHS, 2005)

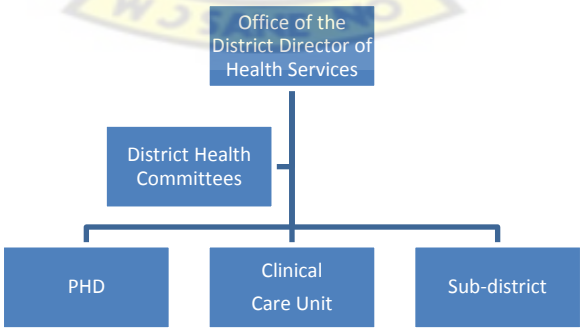

Figure 2.3 District hospital level (GHS, 2005)

Procurement plays a significant role in the running of a hospital and should be part of management to help develop a better strategic vision for all health institutions to enable them attain value for money, efficiency, effectiveness and help serve their clients well.

2.5 PROCUREMENT OF MEDICINES WITHIN GHANA HEALTH SERVICE

Medicine (drug, pharmaceutical product, pharmaceutical) according to WHO (2008), is any substance that is manufactured for sale or distribution, offered for sale, sold, supplied or presented for use in:

(i) The treatment, mitigation, cure, prevention or diagnosis of disease, an abnormal physical state or symptoms thereof in humans or animals

(ii) Normal physiological conditions in humans or animals; or

(iii) The restoration, correction or modification of organic functions in humans or animals or any substance in a pharmaceutical product that is used to modify or explore physiological system or pathological states for the benefit of the recipient.

The Procurement and Supply Division (PSD) works with the program directors from each vertical program to select products, prepare forecasts, and quantify needs. Ghana uses IGFs from a revolving drug fund, World Bank credits, and donor sources to pool financing in a common basket as part of its SWAp to procure essential medicines, including drugs to combat TB, antiretroviral (ARVs), and non-drug consumables (NDCs).

The decision to use basket funding was made because there was no consistency in the procurement process. Ghana received donations from an array of donors that followed different

rules and regulations. To increase efficiency and cost savings, it was necessary to harmonize the procurement process across all sectors in an acceptable way for all donors (PATH, 2005).

For each tender, the MOH develops a World Bank standard bidding document (SBD); the procurement office advertises the tender offer through print and electronic media. The SBD includes the schedule of requirements, the special conditions of tender that refer to products, all rules and procedures for bidding and bid opening, and the criteria for choosing a winning bidder. Additionally, the SBD specifies terms and conditions for the contract between the purchaser and the winning bidder (Rao et al. 2005).

On the day of the bid submission deadline, a public opening of bid documents is held; the names of the bidding companies and their prices are announced. Before the deadline, suppliers submit technical and financial proposals. The bid evaluation committee, made up of members of the Procurement Unit and other MOH staff, reviews the technical proposals first. The committee checks manufacturer/supplier compliance with all regulations set forth in the bidding document (PPA, 2003).

Non compliant bids are discarded. Financial proposals of the remaining bidders are then opened. The contract is usually awarded to the lowest bidder, although the committee must present its final recommendation to the MOH Procurement Committee, which approves the recommendation and formally awards the contract.

The PSD conducts a post-tender evaluation; a committee reviews the commercial characteristics of the supplier to ensure that manufacturers have given valid authorization and that bids are signed properly.

Audits of Ghana's procurement process are conducted annually. In December 2003, Ghana passed a public sector procurement law that translates standard procurement procedures into domestic law.

According to Deliver (2006), routine efficient procurement of medicines requires specialized knowledge of and expertise in essential medicines and the sourcewhere these medicinal products can be obtained and this include the careful selection of products and development of specifications, accurate forecasting, precise tender preparation, and a capacity for testing (equipment, protocols, and procedures). It also involves sustained and adequate financial resources, the willingness and ability to maintain a transparent process, and strong skills in contract management (PATH, 2005).

Efficient procurement is even more complicated to achieve in the absence of supportive national and international public health policies, such as those involving commodity financing; global trade and patent protection issues; the decentralization of health services; national essential medicines policies; and the enforcement of laws and regulations that support transparency and accountability (Deliver, 2006). Within this context, the procurement of pharmaceuticals by and for public sector health programs has become an inherently complex process that involves the coordination of numerous government agencies, international funding sources, suppliers, and manufacturers (Rao et al. 2005).

The procurement of medicines and non-medicinal consumables and other goods is the obligation of Ghana Health Service (all public health institutions) and that may be determined from time to time by the Minister of Health and the Budget Management Centres (BMCs). All public health

institutions are to first source their requirement from the Regional Medical Stores or Central Medical Stores as appropriate (GHS, 2005). Budget Management Centres may only buy the said items from the open market (i.e. outside the Medical Stores system) when such items are not available at the Medical Stores and when this is confirmed by the issuance of a 'certificate of unavailability' from the Medical Stores (MOH, 2003).

The procurement of pharmaceuticals is unique when compared with procurement of other commodities or capital goods. Pharmaceuticals, which provide both therapeutic and curative value, contribute to decreased morbidity and mortality (Rao et al. 2005).

Pharmaceutical supply systems are also susceptible to corruption becausethey are highly regulated. Powerful government regulatory authorities can make discretionary decisions in selecting products and suppliers that circumvent statutory regulations (Cohen, 2006).

2.6 ROLE OF PROCUREMENT OFFICER IN MEDICINE PROCUREMENT

According to BGiLPharma (2002), pharmaceutical procurement is a complex process which involves many steps, agencies, ministries and manufacturers. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market (Beracochea E., 1995). Market constraints differ from country to country. Public sector drug procurement must take place in the context of both the local pharmaceutical market and the international market. In many countries public health officials have limited experience in designing an optimal procurement system to fit their market context (WHO, 2002). An increasing number of countries have moved, or are moving, away from a pharmaceutical

procurement and distribution system which is totally operated by the public sector, and are investigating various options for involving the private sector in order to enhance public health (Quick J. D et.al, 1997).

According to World Health Organization, Action Programme on Essential Drugs (1997, 2002) and BGIL Pharm (2002), procurement officer plays four strategic roles during medicine procurement;

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- Procuring the most cost-effective medicines in the right quantities.
- Coordinating the selection of reliable suppliers of high-quality products and keeping database of them.
- Ensuring proper logistic management and timely delivery of medicines.
- Achieving the lowest possible total cost.

2.6.1. Procuring the most Cost-effective Medicines in the Right Quantities

According to WHO (2002), no public or private health care facility in the world can afford to procure all medicines circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly procured and is one of the most effective ways to control drug expenditure (WHO, 1999).

The essential drugs concept has been used in Ghana for more than a decade and this allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or national list

allows for concentrating on a limited number of products (WHO, 2002). Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs (Essential Drug List, 2010).

An accurate quantification according to WHO (2002) of procurement requirements is needed to avoid stock-outs of some drugs and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract (WHO, 2002).

According to Dorner G (1982) and as cited in WHO (2002), past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate. Such consumption data must be adjusted in the light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance (WHO, 2002). The downside of basing quantification only on past consumption is that any existing patterns of irrational drug use will be perpetuated.

In many countries consumption data are incomplete or do not reflect real demand because the supply pipeline has not always been full and drug use has not always been rational. In such cases the morbidity-based and extrapolated consumption techniques may be used to estimate procurement requirements (WHO, 2002).These techniques, particularly the morbidity-based method, should also be used periodically to check on the rationality of past consumption, by

comparing actual consumption with the estimated need to treat common diseases based on standard treatment protocols and epidemiological data (Ghana Standard Treatment Guideline, 2010).

When funds are not available to purchase all drugs in the quantities estimated, it is necessary to prioritize the procurement list to match available financial resources (WHO, 2002). According to WHO (2002), various techniques such as VEN (vital, essential and nonessential) Analysis, Therapeutic Category Analysis and ABC Analysis can be used to select priorities and reduce the quantities of less cost-effective drugs.

2.6.2. Co-ordinates the selection of reliable suppliers of high-quality productsand keeping database of them

Different procurement functions and responsibilities such as selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders should be divided among different offices, committees and individuals, each with the appropriate expertise and resources (WHO, 2002). Their activities must be co-ordinated by the procurement officer to achieve the desired result (WHO, 1999). This will ensure that pharmaceutical procurement is carried out effectively, efficiently and in accordance with the country's policies, laws and regulations (Public Procurement Act, 2003, Act 663).

Separation of key functions according to WHO (2002), contributes to professionalism, accountability and an efficient procurement system which hitherto would have lead 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 (WHO, 1999).

According to Hessou and Fargier (1994), fairness and the perception of fairness are essential to attract the best suppliers and achieve the best prices. When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair (WHO, 2002). Whether true or not, such charges are damaging and suppliers, health care providers and the public lose confidence in the procurement system. Unsuccessful suppliers may feel that they have no chance of winning and consequently withdraw from future tenders. As the pool of potential suppliers decreases to a small set, price competition decreases and procurement prices become much higher than necessary (WHO, 2002).

The procurement officer must ensure that proper documentations are attached to the standard tender document. According to the Standard Tender Document for Health Service Goods (PPA, 2003), the following documents must be verified by the procurement office on submission of tender;

- Documentary evidence of the Tenderer's qualifications to perform the Contract if it's tender is accepted.
- Certification of incorporated in the country of manufacture of the Goods
- Is the manufacturer licensed by the regulatory authority in the country of manufacture to supply the Goods;

- That the manufacturer has manufactured and marketed the specific goods covered by this Tender Document, for at least two (2) years, and for similar Goods for at least five (5) years;
- That the manufacturer has received a satisfactory Good Manufacturing Practice (GMP) inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (FDA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to tender submission;
- That the Tenderer has been duly authorized by a manufacturer of the Goods to supply it in the Ghana;
- Statement of installed manufacturing capacity;
- Copies of its audited financial statements for the past three fiscal years;
- Details of on-site quality control laboratory facilities and services and range of tests conducted;
- List of major supply contracts conducted within the last five years.
- Good Distribution Practice (GDP) Certificate where appropriate.
- List of pharmaceuticals being manufactured by the Tenderer with product registration/license number and date.
- Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

2.6.3. Ensuring proper logistics management and timely delivery of medicines

In many developing countries according to WHO (2002), logistics systems for public health facilities have been centralized, with central ministry offices responsible for planning, forecasting, procurement, warehousing and the distribution of essential drugs, contraceptives and vaccines. These systems have been inadequate and in many cases incapable of providing adequate supplies on a timely basis. Experts in logistics have developed new approaches to make these logistics systems more effective and efficient; however, most concentrate on initiatives that retain central control and focus on developing better skills and systems at the central level and assuring that standard methods are used throughout the system (Bates *et al*. 2000).

According to Gyimah et al., (2009) as cited in Frimpong- Manso et al., (2013) one major challenge of national medicines policies is the ability to ensure that their implementation plans include the uninterrupted supply of essential medicines that are safe and efficacious, physically and financially accessible and used nationally. According to them in some countries especially in Sub-Saharan Africa, the medical supply systems are often unreliable and therefore do not guarantee regular supply of these essential medicines. Since medicinal products and other health commodities in general, form the backbone of all health systems all over the world, there is always the need to ensure their quality and regular availability in the right quantities at affordable prices.

In order to ensure regular availability of medicines and health commodities, it is important to integrate all the logistical functions together in order to ensure effective and efficient logistics management (Frimpong- Manso et al., 2013).

Since effective and efficient logistics management plays a key role in the proper function of an organization and its economic activities the supply chain partners must coordinate all activities in logistics management to ensure efficiency(Frimpong- Manso et al., 2013).

Sangeeta and Nadeem, (2004) as cited in (Frimpong- Manso et al., 2013) refer to logistics as the specific functions that need to be carried out by each of the supply chain partners such as selecting products, forecasting demand, ordering and procuring, warehousing and storing, managing inventory, transporting from one level to the next until the commodities reach the clients and managing data in the process.

In health logistics system, the supply chain partners are the manufacturers who are the pharmaceutical companies which supply raw materials, the procurement agents such us the Ministries of Health, Health Administrative Units, United Nations agencies and others. Distributors are composed of the transporters, the central, the regional and the district medical stores (Frimpong- Manso et al., 2013). Financiers are donors or funding agencies. Service providers also constitute NGOs and Service Delivery Points (SDPs) such as hospitals, health centres and pharmacies. The proper coordination of these activities by the supply chain partners plays significant roles in organisations and the economy as a whole(Frimpong- Manso et al., 2013).

The importance of strategic logistics management in the Ghana Health Service system cannot be overemphasized. Poulin (2007) as cited in Frimpong- Manso et al., (2013), argues that logistics

accounts for a sizeable portion of a hospital's operating budget. Studies have shown that from 30% to 46% of hospital expenses are invested in various logistical activities and that almost half of the costs associated with supply chain processes could be eliminated through the use of best practices.

In order to ensure that medicines/drugs are available where and when they are needed drug procurement must be carefully planned. According to WHO (2002),planners should consider factors such as access to suppliers; funding availability and timing; the number of levels in the logistics system; constraints of time and resources affecting procurement functions such as drug selection, quantification, tendering and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport (WHO, 1999).

According to Quick (1997), reliable management information system (MIS) is one of the most important elements in planning and managing procurement and lack of a functioning MIS or the inability to use it appropriately is a key cause of programme failure. The MIS should have the ability to track the status of each order and payment, and compile the information required for supplier monitoring. It is important that the MIS also tracks the number of orders placed, payments made, and quantities actually purchased compared with estimates, purchases from all contract suppliers, and drug purchases from non-contract suppliers(Frimpong-Manso et al., 2013).

In all the procurement information system should be computerized in such a way as to facilitate tracking and reporting on performance by suppliers and by the health facility. The procurement

officer should be required to report regularly on key procurement performance indicators, such as the planned versus actual items and quantities purchased; prices obtained versus average international/market prices; average supplier lead-time and service level; percentage of key drugs in stock at various levels of the supply system; and report on stock-outs and reorder levels (WHO,1999).

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2.6.4. Achieving the lowest possible total cost

The International Non-proprietary name or generic name is widely accepted as the standard for describing drugs on a procurement list or tender request (Essential Drug list, 2010). Although this is most obviously applicable when purchasing drugs which are available from multiple sources, generic description should also be used when purchasing single source products (WHO, 2002). When purchasing products which present potential problems with pharmaceutical equivalence or bio-equivalence the procurement request should specify the quality standards but not mention specific brands (BGiLPharma, 2002).

This does not mean according to WHO (2002) that brand-name suppliers should be barred from tender participation; they may offer the most cost-effective product, and in fact may offer more competitive prices for certain branded drugs than generic competitors. However, all drugs supplied to the public health system should be properly labelled in accordance with standards laid down by law or in accordance with labelling instructions of the Food and Drugs Authority (Ghana National Drug Policy, 2004).

Procurement should be effected in the largest possible quantities in order to achieveeconomies of scale since larger procurement volume makes favourable prices and contract terms morelikely, by increasing suppliers' interest in bidding and by providing them with anincentive to offer a competitive price (Public Procurement Manual, 2003).

According to WHO (2002), higher volume for single items may be achieved through pooling of procurement volume from many facilities by restriction of the drug list or by elimination of duplication within therapeutic categories.

According to Downs (1992), large contract awarded to one supplier by no means implies that the entire volume must be shipped at once. Many procurement services specify, as part of contract terms, divided deliveries over the period of the contract or to multiple delivery points (WHO, 2002). Secondly, procurement volume must negotiate prices centrally for a list of essential drugs and allow various regional medical stores order the drugs as needed from the contract supplier (WHO, 2002). These strategies allow for optimal use of available storage and transport capacity, facilitate inventory management and ease cash flow constraints (WHO, 1999).

According to the Federation of Internationale Pharmaceutique (1997), as long as drug quality and service reliability are assured, competition should be increased to the point at which drug prices are as low as possible. The rule 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.

2.7 EXISTING COUNTERFIET MEDICINE PREVENTIVE MEASURES

The Food and Drugs Authority (FDA) as a national regulatory body that has the responsibility for the regulatory control of the manufacturing, importation, exportation, distribution, sale and advertisement of food, drugs, cosmetics, medical devices and household chemical substances as enshrined in the Public Health Act, 2012 (ACT 851). This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information has very grave consequences on public health and serious implications for healthcare delivery. The FDA, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated in their mandate (FDA, 2013).

The mission statement of the authority is to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy, and quality for all food, drugs, cosmetics, household chemical substances and medical devices (hereinafter referred to as products) locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the law regulating food and drugs in force in Ghana (FDA, 2013).

The Drugs Evaluation and Inspectorate Division contributes to the attainment of the functions of the Food and Drugs Authority for safeguarding public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carried out by regulating all medicines submitted in the registration dossiers, pre-registration inspection, and drug quality analysis reports (FDA, 2013).

The FDA also has a Unit that monitors registered drugs, cosmetics, household chemical substances and medical devices that have been given marketing authorisation or otherwise that is

in distribution on the Ghanaian market to ensure that they are of right quality, safe and efficacious. The Unit therefore undertakes the following activities:

- Inspection of storage facilities of pharmaceutical companies.
- General and targeted market surveillance (conduction of product quality monitoring).
- Collaboration with stakeholders to monitor quality of products on the Ghanaian market.
- Supervision of safe disposal of expired, unwholesome and confiscated products.
- Destination inspection in liaison with the Import and Export Control Department.
- Undertake investigations into consumer and other complaints.
- Undertake random sample products for analysis.
- Public Education
- Training of stakeholders
- Perform gap analysis of the manufacturing industry to identify GMP deficiencies for immediate attention.

The Food and Drug Authority has a role to play when it comes to the fight of counterfeit medicines. WHO (2010), as cited in FDA (2013), list the following activities that the FDA can do to help fight against counterfeit medicines;

- Conduct routine, announced, unannounced Good Manufacturing Practice (GMP) audit inspections in all local licensed pharmaceutical manufacturing facilities for the

production of allopathic and herbal drugs. Drug inspection is a very important tool for monitoring pharmaceutical operation to know if they follow the stipulated standard, this is done by inspectors' physical visits to drug facilities and by use of quality assurance laboratories. Well-qualified inspector with good knowledge of pharmacy adequately trained and having the necessary legal power should be used in order to avoid deception.

- Conduct pre-licensing inspections for new applicants and evaluation of block plans of new manufacturing facilities to assess their GMP compliance.
- Conduct site verification inspections in foreign pharmaceutical manufacturing plants in line with GMP Audit inspections for pharmaceutical companies that sell their products or carry out business in Ghana.
- Conduct industry production capacity monitoring and control of extemporaneous preparations and also undertake quality control tests in accordance with WHO standards (FDA, 2013). Before the issuance of marketing authorization/certificate, the drug products are first sent to the quality assurance laboratory for analysis in order to ensure the quality of drug products before they are sold in the market. In any drug-regulating agency, the importance and adequacy of the laboratory system, the equipments, materials, infrastructure, and work force should be a priority for the success of regulation. (Ratanawijitrasin, 2002).

For instance the FDA conducted foreign Good Manufacturing Practice (GMP) audit in 25 pharmaceutical plants in 2013 as against 20 in 2012 (FDA, 2013). They visited 29 local pharmaceutical plants and 38 local herbal manufacturing plants in 2013 as compared to 31 and 29 plants respectively in 2012(FDA, 2013).

According to World Health Organization, (2007) the prevalence of fake medicines is higher in countries with weak regulations, enforcement, and scarcity of supply of basic medicines, unregulated markets and unaffordable prices. Because of these, the quality, safety and efficacy of drug products especially in developing countries cannot be guaranteed. Drug counterfeiters and their allies aggressively seek to avoid detection and they often disguise their activities.

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According to WHO (2006), the production of fake drugs need not occur in large infrastructures or facilities but in ordinary households, small cottage industries or in backyards. The high demand for medicines and low cost of production prompts counterfeiters to continue because adequate drug deterrent legislation is lacking.

As a result of this World Health Organization in collaboration with other international agencies are supporting developing countries regulating agencies to fight fake drug through the development of drug regulation system (Ratanawijitrasin, 2002) as cited in Chiwendu (2008).

WHO (2003) also made guidelines for drug regulating authorities on what countries can do for effective regulation and enforcement. It state that Drug Regulatory Authority should be competent, independent with strong political backing, they must have a clear mission with sufficient legal power, appropriate organizational structure and facilities, adequate number of qualified staff that are motivated and experienced, adequate financial support and supportive tools such as standards, procedures and guidelines.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter discusses the methodology used for the research. It addresses issues on research strategy, design and process. Some of the specific areas considered were: data collection instruments, population of the study, sampling technique and sample size and data preparation and statistical tools.

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3.2 RESEARCH STRATEGY

The purpose of this research is to explore the roles that procurement officers play in preventing the procurement of counterfeit medications into our public health institutions. An explorative type of research will be adopted for the study. Researchers may conduct explorative research to develop a list of possible causes to the problem. Additional more extensive research may then confirm which possibility or possibilities are most the likely causes. Secondly, exploratory research can uncover possible avenues for reaching decision makers' objectives.

Exploratory research produces both quantitative and qualitative (textual). Although the text is analyzed, the methods of analyses are not statistical; textual data are not numerical and do not lend themselves to statistical analysis. Generally, exploratory research techniques simply involve conversations between a researcher and the people being studied. Although the researcher may guide the conversation across certain issues, the questioning is usually informal and semi-structured.

The outcome of the research may be applied and the research processes that were adopted were quantitative and qualitative. The data source was primary and secondary and a

purposiveapproach of sampling selection was used since the population of procurement officers responsible for the procurement of medicines were very few and their addresses are known. Both closed and open ended questions were used to collect data via questionnaire survey and the data was analysed descriptively using Microsoft Excel statistical tool and content analysis respectively.

3.3 DATA COLLECTION AND INSTRUMENTATION

3.3.1 Questionnaire design

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The strategy adopted for the questionnaire design was to first conduct a literature review which was relevant to the study with much emphasis on the objectives of the research. The questionnaire was designed in simple words and sentences and they were straight to the point. The privacy of the respondents were also taken into consideration in order to allow them answer the questions without fear or intimidation. Enough guidance was provided to aid the respondents in answering the questions.

Some of the questions were closed-ended and provided options for respondents to choose, whereas others were open ended. The first part of the questions was used to identify the demography of the respondents. The second part was used to identify the role that procurement officers play in the procurement of medicines. The last part was used to proffers applicable suggestion to procurement officers in preventing the procurement of counterfeit medicines into our public health facilities.

3.3.2 Sampling technique and sample size

A study population of 85 procurement officers was identified but purposive sampling technique was used to identify 30 officers who are responsible for only procurement of medicines. Purposive sampling is an approach for locating information-rich key informants in a known

address population. Using this approach, a few potential respondents are contacted and asked whether they know anybody with the characteristics being looked for in your research (Fugar, 2010). This technique was adopted to help the researcher to reach hard-to-reach respondents. The officer who was visible and easy to locate was first contacted and gave the lead to others with the same characteristics.

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3.3.3 Instrument administration

The questionnaires were delivered to individual personnel within the public health institutions by the researcher.

3.3.4 Data preparation and statistical tool intended for analysis

The units for the data collection were the individual personnel within the procurement unit who are responsible for the procurement of medicines in their various public health institutions. The individual responses were aggregated to give larger units for analysis. The quantitative data (closed ended questionnaire) were descriptively analysed with Microsoft Excel statistical tool to generate pie chart and tables whereas the open ended questionnaires were contently analysed. In content analysis all the respondents' responses to the opened ended questions were tabulated and coded. The codings were grouped and summarised and quantitative data were generated from it.

CHAPTER FOUR

4.0 RESULTS AND DISCUSSION

4.1 INTRODUCTION

The analysis of primary data collected from thirty (30) respondents is documented in this chapter. The analysis centred on the specific objectives of this study. Tables and pie charts aided the discussions of the results.

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4.2 DEMOGRAPHY OF RESPONDENTS

From the figure below 80% (24) of the respondents were from Ghana Health Service hospitals whereas the rest (20%) came from the Regional Medical Store. There is the likelihood of the responses of respondents to skew towards one direction since the Service has policies and programmes that health institutions should adhere to.

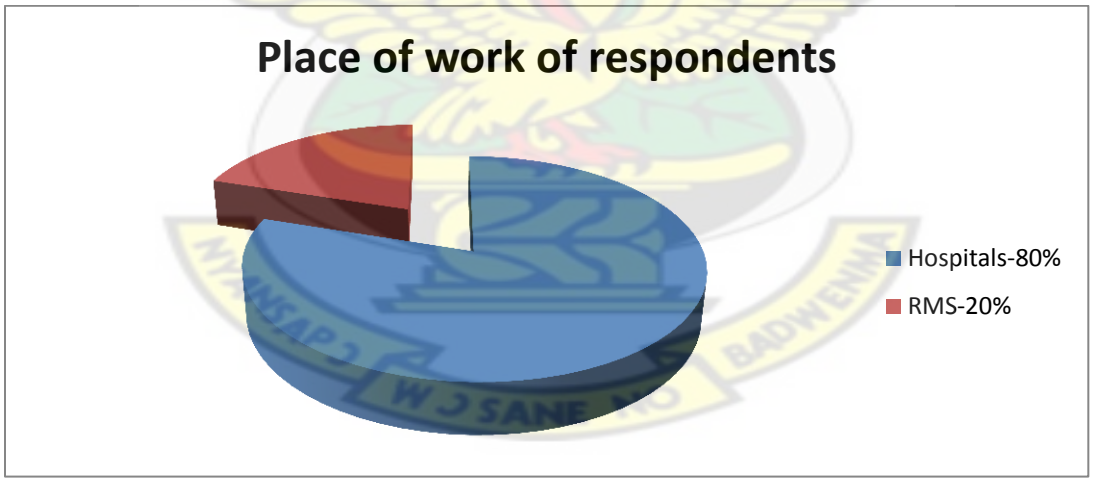

Figure 4.1 Place of work of respondents

From the figure below 30% (9) of the respondents were Supply Chain Practitioners whereas the 70% (21) of the respondents representing majority were Pharmacists. This confirms the fact that

when it comes to the procurement of medicines the Pharmacists and the Supply Chain Practitioners combined can be classified as procurement officers.

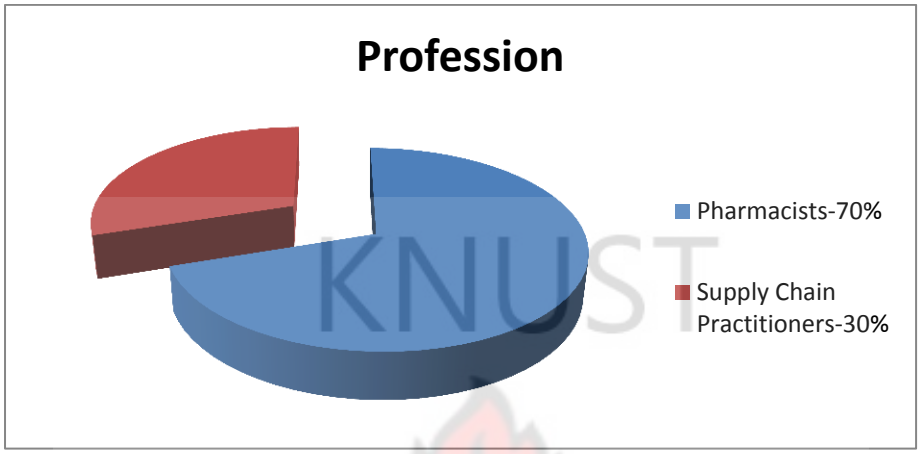

Figure 4.2 Profession of respondents

About 66.67% of the respondents have worked in the procurement area from between 6-10 years, 16.66% of the respondents have worked as procurement officers responsible for the procurement of medicines for over ten years and the rest 16.67% have worked in the procurement area from 3-5 years. The results indicate that 83% of the respondents have worked in the procurement area for more than five years and are in their senior grade or above it. This indicates that majority the respondents have had so many years of experience in the procurement area

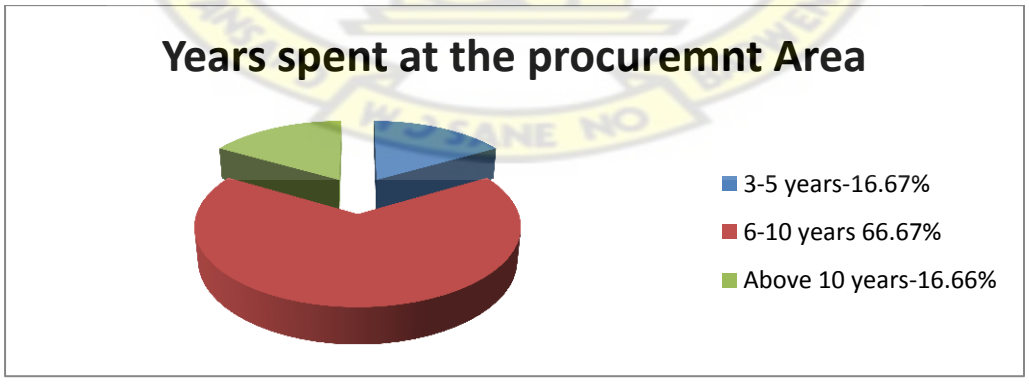

Figure 4.3 Years spent by respondents at the procurement area.

Although all the respondents view procurement as a very strategic and highly professional activity that aims at attaining the best value for money, only one facility(14.3%) out of the seven health institutions has a well-staffed procurement department. But for a proper functioning of the procurement department in the procurement of counterfeit medicines, there should a well-staffed department that will coordinate the activities of the office and help review all the quality assurance information from supplies before the drugs were procured.

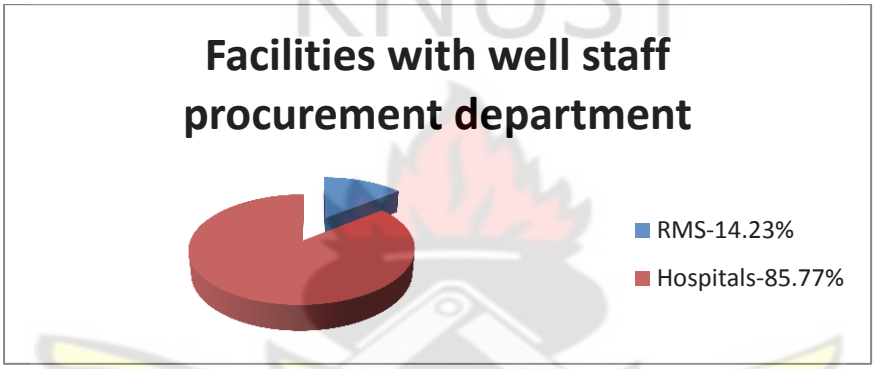

Figure 4.4 Respondents response on facilities with well staff procurement department

4.3 PROCUREMENT PROCESSES (OF MEDICINE) IN GHANA HEALTH SERVICE

Procurement of medicines according to all the 30 respondents starts with the user unit placing a request to the head of entity through the procurement officer.On the question of how the facilities obtain their medicines, 80% of the respondents said they do so through the Regional Medical Stores and Price quotation whereas the rest (20%) of the respondents said they obtain their medicines through the central medical stores and competitive tendering.

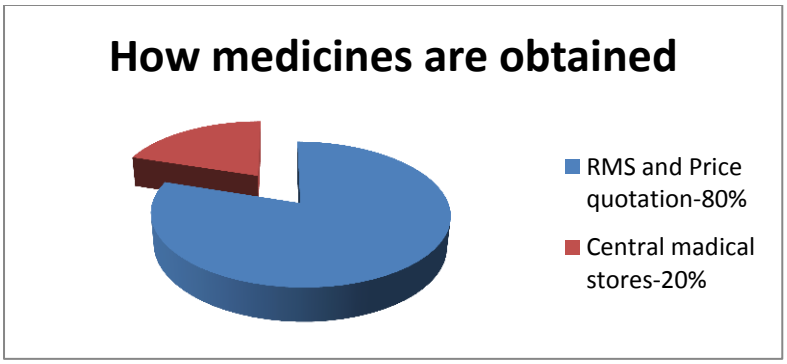

Figure 4.5 Respondents responses on how they obtain their medicines

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Majority of the respondents (80%) said the procurement processes within the Ghana Health Service are in two forms:

1. A request is first sent to the Regional Medical Store for the supply of medicines and when the medicines are not available a certificate of non-availability is given to the health institutions to procure the medicines from the open - market.
2. Upon the receipt of the certificate the second form of procurement process starts.

With the exception of the Regional Medical Stores, all the respondents in the various hospitals said they prequalify their suppliers at the beginning of every year and fall on them to supply the non-available medicines from the medical store through price quotation.

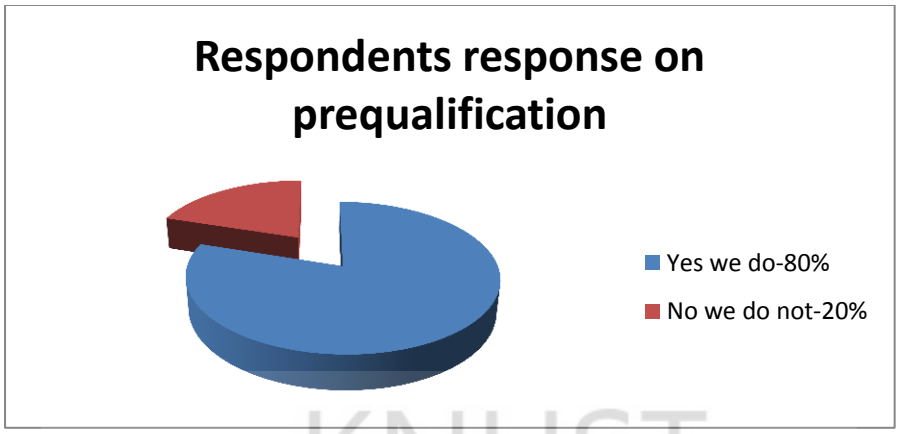

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Figure 4.6 Respondents response on prequalification

The use of price quotation by 80% of the respondents from about six hospitals as a method of procurement from the open-market can account for the high cost of medicines in our public health facilities.The regional medical stores procure all their medicines through a competitive tendering with the exception of some injections and programmed medicines which are received from the central medical stores hence their medications are very affordable.

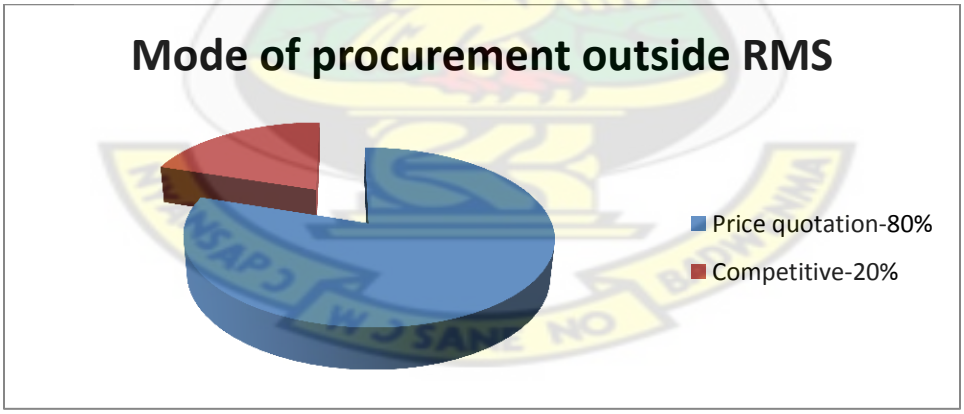

Figure 4.7 Respondents response on the mode of procurement outside Regional Medical Store

On the issue of the procurement plan and who prepares them, all the respondents confirmed that they do have a plan and it was prepared by the procurement officer with the help from the user department.

On the question of who writes the specifications and the quantity estimate of the medicine to procure, 20% of the respondents said they have a standing committee who oversees those activities whereas 80% of the respondents said it is the pharmacist in consultation with SCP and storekeeper does those activities.

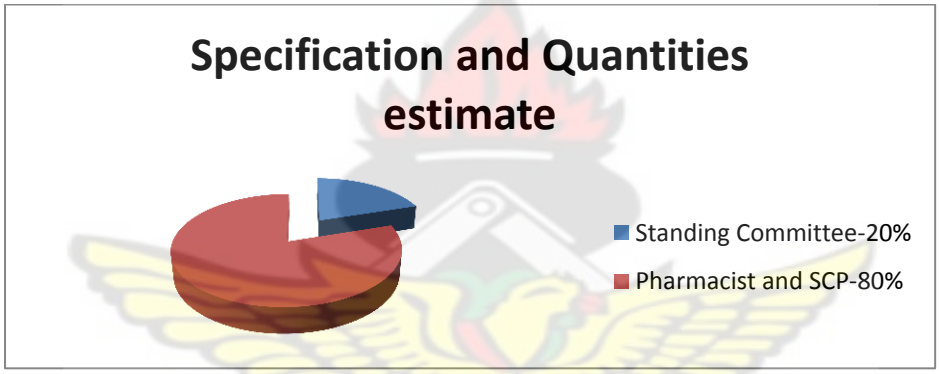

Figure 4.8 Respondents response on who writes specification and quantity estimates

With the exception of the regional medical store that perform post qualification by visiting the manufacturer's production plant to assess their production processes and quality control measures, the rest do not do any post-qualification for the medicines they procure from the open-market.

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Figure 4.9 Respondents response on whether they do post qualification or not

On the evaluation of tenders, quality –cost based selection is used. Here all the medicines that that met the specifications are selected and ranked and the one with the lowest cost but of the same quality is selected.

On the issue of whether or not the trucks that deliver their medicine were tracked to ascertain that the medicine were transported in the stated temperature, all the respondents said they do not track the medicines except for cold chain medicines such as Insulin which they insist it should be in the cold state to prevent them from deteriorating.

All the respondents (30) answered in the affirmative that they do have a standard operating procedure for the receipt of medicine and it was as follows;

1. When the medicines gets into the facility the pharmacist/standing committee is invited to testify as to the quality or otherwise of the medicine
2. An inspection team which includes storekeeper, internal auditor, pharmacist and a representative from administration will check the quantities of the medicines per their descriptions and their expiry dates

3. Visual inspection of at least three (3) packages sampled at randomby the team is undertaking and if the team is satisfied with the medicine supplied it will ask the storekeeper to receive it into the stores.

Procurement officers should have the following in place within their facilities to help prevent them from procuring counterfeit medicines; quality assurance system for procurement, quality assurance for warehousing, quality assurance for product testing, distribution and also ensure that medicines were randomly tested at different point within the supply chain.

When regulatory checks on suppliers and manufacturers are inconsistent, the procurement officer can use the procurement processes and practices such as transparency, accountability and integrity of the supply chain to ensure that the medicines they procure are of good quality.

4.4 ROLE OF PROCUREMENT OFFICER IN MEDICINE PROCUREMENT

The roles that procurement officers play during the procurement of medicines were ranked by the respondents using the likert scale from 1= not applicable to 5= Very important. According to the respondents, procurement officers play four (4) strategic roles and the table 4.1 shows the results.

Table 4.1 Descriptive analysis of the procurement officer's role in co-ordinating procurement processes

ROLE	*Mean*	*Standard Deviation*
Receives memo or request from user department	*5*	*0*
Writes to seek approval from the entity head	*5*	*0*
Upon approval from the entity tender committee writes award letters to various suppliers appropriately	*5*	*0*
Writes to appropriate agencies to authenticate the supporting documents attached to the tender.	*1.8*	*1.6*
Takes appropriate minute during tender evaluation	*5*	*0*
Record the details of all suppliers who procure the tender documents	*5*	*0*
Record the details of all suppliers who are returning the completed tender documents just before it is placed in the tender box.	*5*	*0*
Co-ordinate the tender opening process	*5*	*0*
Record details of suppliers who submitted the tender documents will be compared with the once who procure it and any defect is corrected	*5*	*0*
Takes appropriate minutes during tender opening	*5*	*0*
Prepares a contract document upon the receipt of acceptance letter	*5*	*0*
Write to notify unsuccessful tenderers	*5*	*0*

When the various activities under this role was ranked in their level of importance, 80% of the respondents ranked all very important with the exception of this activity '*Writes to appropriate agencies to authenticate the supporting documents attached to the tender'* which is an activity that is done by only the Regional Medical Store that had a mean of 1.8 and a standard deviation of 1.6. A written approval of the documents from the FDA or a comparable stringent regulatory authority must be given before the procurement officers procure the medicines.It is the responsibility of a procurement officer to ensure that all the document as required by WHO and

PPA are attached to the standard tender document so that the quality or otherwise of the medicine can be ascertain. These confirm the indispensible role that procurement officers play in co-ordinating and documenting procurement activities.

Secondly separation of the key functions such as prequalification of suppliers, product selection and quantification and evaluation of the tenders contribute to transparency, professionalism, accountability and an efficient procurement system and proper coordination of their activities will help the procurement officer quality and counterfeit-free medicines.

Table 4.2 Descriptive analysis of the procurement officers role in achieving the best lowest possible total cost

Role	*Mean*	*Standard Deviation*
Select an appropriate method of procurement depending on the quantities and the thresholds	*5*	*0*
Prepare the tender documents with all the necessary instructions	*5*	*0*
Advertise or invite suppliers to procure tender documents	*5*	*0*
Guides the evaluation panel as to what the law say with respect to such procurement.	*5*	*0*
Writes to request the entity tender committee to approve the outcome of the evaluation	*5*	*0*
Defend the outcome of the evaluation panel when the need arises	*1.8*	*1.6*

Value for money is one of the four pillars of public procurement Act, Act 663 and when the activities performed by the procurement officer in the area of ensuring the best lowest possible total cost were ranked, 80% of the respondents ranked all the activities very important with the exception of '*defend the outcome of the evaluation panel when the need arise'* which is an activity that is performed by only 20% of the respondents.Procurement should be effected in the

largest possible quantities in order to achieveeconomies of scale since larger procurement volume makes favourable prices and contract terms morelikely, by increasing suppliers' interest in bidding and by providing them with anincentive to offer a competitive price.

Secondly, when the requisitions are written in their generic names more suppliers are encouraged to bid and this increases the chances of the procurement officer procuring medicines that are of high quality and affordable.On the issue of pooled procurement, all the respondents said pooling of procurement volumes from many facilities must be encouraged to help eliminate duplication of functions.

Table 4.3 Descriptive analysis of the procurement officer's role in the procurement of medicines in their right quantities

Role	*Mean*	*Standard Deviation*
Help the user units to estimate their quantities to help them take advantage of trade discounts	*5*	*0*
Writes to request for volume of space available from the storekeeper	*5*	*0*
Writes to request for the consumption pattern of the medicine from stores if the quantities were too high	*5*	*0*

When the activities perform by procurement officers under this role were ranked from not important (1) to very important (5), all the thirty respondents ranked the activities very important. Selection of drugs based on a national formulary allow for concentration on a limited number of products and procuring large quantities of medicines in their generic names

encourages competition on both quality and cost. All the respondents said when this role of the procurement officer is performed very well more quality and affordable medicines can be procured from suppliers.

Table 4.4 Descriptive analysis ofthe procurement officer's role in ensuring proper logistics management and timely delivery of medicines

Role	*Mean*	*Standard Deviation*
Manages the contract until the medicines are supplied	*5*	*0*
Writes to the accounts office for the payment of the medicines supplied.	*5*	*0*

When the activities pertaining to the role procurement officers play in ensuring proper contract and logistics management were ranked from not important to very important, all the 30 respondents ranked the activities very important.

In order to ensure that medicines/drugs are available where and when they are needed drug procurement must be carefully planned. During planning procurement officers should consider factors such as access to suppliers; funding availability and timing; the number of levels in the logistics system; constraints of time and resources affecting procurement functions such as drug selection, quantification, tendering and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport.

All the respondents said procurement officers should also take into account the vulnerability of medicines to deteriorate as they are being transferred from the suppliers' warehouse to the health facilities. They should also maintain the chain of custody of the medicines procured until they are delivered especially vaccines. Post shipment testing of the product to ascertain whether or not the medicines are still of good quality was recommended by respondents.

4.4 TOOLS OR DOCUMENTATION USED TO ASSESS THE QUALITY OR OTHERWISE OF MEDICINES PROCURED

Table 4.5 Microsoft Excel statistical tool analysis of thetools or documents used to assess the quality or otherwise of the medicines procured.

What health institutions do to ensure quality medicines	***Mean***	***Standard Deviation***
Credibility of the suppliers	*5*	*0*
Request for certification of incorporation in the country of manufacturing	*1.8*	*1.6*
Certification from the manufacturer's home regulatory authority if medicines are imported	*1.8*	*1.6*
An indication that the manufacturer has been manufacturing and marketing the specified medicines covered by the tender document for the last two years or similar once for the past five years	*1.8*	*1.6*
Request for a satisfactory GMP inspection certificate by WHO from the manufacturer	*1.8*	*1.6*
Manufacturing authorisation for the tenderer to supply the medicines	*1.8*	*1.6*
Pre-shipment batch testing	*1.8*	*1.6*
Under take inspection upon receipt of medicines	*5*	*0*
F D A certification of medicines	*5*	*0*
Pharmacy council certificate	*5*	*0*
Credibility of the Regional Medical stores	*5*	*0*
Certificate of analysis of both the raw materials and finished goods	*1.8*	*1.6*
Credibility of Central Medical Stores	*1.8*	*1.6*

The tools or documents that WHO and the Standard Tender document for the procurement of medicines by the Public Procurement Authority requires that every procurement officer should request to prevent the procurement of counterfeit medicines were ranked by respondents. All the respondents ranked the following tools very important with a mean value of 5 and a standard deviation of zero;

1. Credibility of suppliers
2. Credibility of Regional Medical Stores
3. Food and Drug Authority Certificate
4. Pharmacy Council Certificate
5. Proper inspection upon receipt;

and the rest of the tools were scored one (1) since they were not requested by 80% of the respondents who worked mainly in six out of the seven Ghana Health Service hospitals in Kumasi Metropolis. From the above responds of the respondents it can be inferred that the procurement officers in the six health facilities trust the credibility's of suppliers, Regional Medical stores, Pharmacy council and FDA that they do not request for all the necessary documents that WHO and PPA requires of them. This means that if any of these agencies do not adhere to quality standards counterfeit medicines can slip through the supply chain system and enter into the health facility.

Only 20% of the respondents from the Regional Medical Store do request for all the tools as requested by WHO and PPA standard document as listed in the table above. The responds of the respondents affirm the credibility that 80% of respondents place on the regional medical as the first point of call when it comes to the procurement of quality medicines.

CHAPTER FIVE

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

This research which is on the role of a procurement officer in preventing the procurement of counterfeit medicines into our public health facilities was divided into five chapters. Chapter one talked about the Introduction. Chapter two explored the review of pertinent literature. Chapter three explained the methodology used. Chapter four analysed and discussed the data and results. Chapter five is the conclusion and recommendations for the research.

5.2 ACHIEVING RESEARCH OBJECTIVES

5.2.1 Objective 1: Identify the procurement processes in Ghana Health Service institutions

Content analysis was used to analyse the data. It resulted that documents requested by 80% of the respondents during prequalification were inadequate to ensure that the medicines procured were of good quality but instead really on the credibility of the suppliers, FDA, RMS and the Pharmacy council. Prequalification is a very important tools that procurement officers can use to select credible suppliers who manufacture quality medicines and fall on them to supply when the need arises. Secondly the excessive use of price quotation by 80% of the respondents in the procurement of medicines accounts for the high cost of medicines in our public hospitals and process would not assure quality and value for money.

5.2.2 Objective 2: Identify the role procurement officers play during medicine procurement

Microsoft Excel statistical tool was used to analyse the data. It resulted that the procurement officer plays four (4) strategic roles;

- Procuring the most cost-effective drugs in the right quantities to enhance competition among the suppliers
- Coordinating the selection of reliable suppliers of high-quality products by requesting the right documentations in order to assure the procurement of quality medicines.
- Ensuring proper logistic management and timely delivery of medicine by taking into account the vulnerability of the medicines to deteriorate as they are being transferred from the suppliers' warehouse into the health facilities. Procurement officers must also ensure that there is maintenance in the chain of custody until medicines such as Insulin are delivered to the facility.
- Achieving the lowest possible total cost by writers of the requisition for the medicines to do so in their generic name and that will enhance competition. Pooled procurement volumes from many facilities must be encouraged to eliminate the duplication of functions.

5.2.3 Objective 3: Identify the tools or documents used to assess the quality or otherwise of the medicines procured

Microsoft Excel statistical tool was applied to analyse the data. It resulted that only 20% of the respondents do request for all the tools WHO and Standard tender documents for the procurement of medicines by the Public Procurement Authority require that every procurement officer should request to prevent the procurement of counterfeit medicines. Eighty percent of the respondents in the six health facilities trust the credibility's of suppliers, Regional Medical stores, Pharmacy council and FDA that they do not request for all the necessary documents that WHO and PPA requires of them. This means that if any of these agencies do not adhere to quality standards counterfeit medicines can slip through the supply chain system and enter into

the health facility. Whether a procurement officer is procuring from a prequalified supplier or not all the necessary documents that will prevent the officer from procuring counterfeit medicines must be requested from the supplier and verified from the regulator (FDA).

5.3 CONCLUSION

Gross non-adherence to quality standards permits the intrusion of counterfeit medicines and once a fake or counterfeit medicine slips through the supply chain system and enter the health institution or pharmacy, the harm has already been done. For that matter the role procurement officers play in preventing the procurement of counterfeit medications in our public hospitals cannot be over emphasised. The recommendations below can help to achieve the objective of ensuring counterfeit-free medicines in our hospitals.

5.3 RECOMMENDATIONS

Based on the findings of the research, the following recommendations are proposed:

- Since the first point of call for all medicines by public health facility is the Regional Medical Stores, they should be equipped with a mini-lab to help undertake certain basic quality control test.
- Pooled procurement volumes from many facilities must be encouraged to eliminate the duplication of functions.
- Regional Medical Store should be well stocked to prevent public hospital from procuring medicines from the open-market where its quality cannot be ascertained.
- Certificate of analysis during quality control testing and other relevant documents as stated by WHO should be requested by all public hospitals when they are procuring

medicines from the open-market. This should be made a term and condition of the contract delivery for compliance.

- Procurement officers as part of procuring quality medicines take steps to develop risk mitigating plan to help address the short falls that may arise during the processes.
- Food and Drugs Authority must have a database of all registered medicines in the country where public hospitals can verify the authenticity of the medicine they interned to procure.
- Procurement officers should improve information sharing among themselves to help blacklist suppliers who supply substandard medicines
- Public hospitals must be equipped to undertake basic quality control test as stated in the standard compendia to assure that the samples suppliers provide during prequalification conform to what is stated on the products procured.

5.4 RECOMMENDATIONS FOR FURTHER RESEARCH

- Further research into the role of Information Communication Technology in the fight against counterfeit medicines.

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APPENDIX

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

DEPARTMENT OF BUILDING TECHNOLOGY

QUESTIONNAIRE

ROLE OF A PROCUREMENT OFFICER IN PREVENTING THE PROCUREMENT OF CONTERFEIT MEDICINE

NAME: ENOCH QUAICOE

I am a final year student of the Kwame Nkrumah University of Science and Technology (KNUST) conducting a research on the role of a procurement officer in procurement of counterfeit free medicines.

The aim of this research is to explore the role procurement officers play in preventing procurement of counterfeit medicine in our public health institutions.

This is purely for academic purposes and all information will be treated with strict confidentiality. Your response would be highly appreciated for the success of the research.

Kindly respond to the questions appropriately.

Thank you.

1. Name of institutions…….....
2. Profession…….....
3. Number of years spent at the facility…….....
4. How does your organization view procurement?

   [A] A mere reactive buying activity

   [B] A highly professional activity aiming at the best value for money

   [C] A formality

5. Do you have a well staff procurement department? Yes [] No [ ]
6. Do you have a procurement plan for the procurement of medicines? Yes [] No [ ]
7. If yes, who prepares it?
   ……
8. If no, what guides you in your procurement?

   [A] Rough estimate

   [B] Based on previous consumption

   [C] Work load

   [D] Others.....

10. How is procurement of medicines initiated in your organization?

[A] Recommendation from procurement committee

   [B] Approval from the head of entity

   [C] Storekeeper

   [D] User unit request

   11. Do you pre-qualify your suppliers? Yes [ ] No [ ] Sometimes [ ]

   12. If yes how do you do it?
   ……
   ……
   13. Do you do post-qualification of suppliers? Yes [] No [ ] Sometimes [ ]
   14. If yes, how?
   ……
   ……
   15. Who writes the specifications of the medicines?
   [A] A standing committee
   [B] An ad hoc technical committee
   [C] Pharmacist

16. How are the quantities estimated?
[A] A standing committee
[B] An ad hoc technical committee
[C] Procurement officer
[D] Procurement officer/Pharmacist in consultation with the store keeper.

17. How do you obtain your medicines? (You can choose more than one)

[A] Single source

[B] Regional Medical Stores

[C] Price Quotation

[D] Competitive Tendering

[E] Others.....

18. What role does a procurement officer play in procurement of medicines?

Please indicate the level of importance of the following role that a procurement officer plays during the procurement of medicine using the following Likert scale. **[1=Not applicable; 2=Less important; 3=Moderately Important; 4=Important; 5=Very important]**. Please tick (√) in the space provided.

ROLE	**1**	**2**	**3**	**4**	**5**
A. **Co-ordinate the processes and keeping database of reliable suppliers**					
Receives memo or request from user department					
Writes to seek approval from the entity head					
Upon approval from the entity tender committee writes award letters to various suppliers appropriately					
Writes to appropriate agencies to authenticate the supporting documents attached to the tender.					
Takes appropriate minute during tender evaluation					
Record the details of all suppliers who procure the tender documents					
Make sure that a tender box is placed in a location specified within the tender document					
Record the details of all suppliers who are returning the completed tender documents just before it is placed in the tender box.					
Co-ordinate the tender opening process					
Takes appropriate minutes during tender opening					
Prepares a contract document upon the receipt of					

acceptance letter					
Write to notify unsuccessful tenderers					
B. **Achieving the best lowest possible total cost i.e. value for money**					
Select an appropriate method of procurement depending on the quantities and the thresholds					
Prepare the tender documents with all the necessary instructions					
Advertise or invite suppliers to procure tender documents					
Guides the evaluation panel as to what the law say with respect to such procurement.					
Writes to request the entity tender committee to approve the outcome of the evaluation					
Defend the outcome of the evaluation panel when the need arises					
C. **Procuring medicines in their right quantities**					
Help the user agent to estimate their quantities to help them take advantage of trade discounts					
Writes to request for volume of space available from the storekeeper					
Writes to request for the consumption pattern of the medicine from stores if the quantities were too high					
D. **Ensuring proper logistics management, timely delivery and payment of medicines**					
Manages the contract until the medicines are supplied					
Writes to the accounts office for the payment of the medicines supplied.					

19. Do you have a system/software you use to track your orders? Yes [ ] No [ ]
20. How do you track the medicines prior to their delivery to make sure they are in good condition?.....
    .....
    .....
21. Do you have a standard operating procedure for the receipt of medicines? Yes [] No [ ]
22. If yes, what are the steps?

    ……
    ……
    ……
    ……
    ……..

23. How do you ascertain whether or not the medicines are of good qualityorcounterfeit free?

Please indicate the level of importance of the following on how to ascertain whether or not the medicines procured are of good quality using the following Likert scale. **[1=Not applicable; 2=Less important; 3=Moderately Important; 4=Important; 5=Very important]**. Please tick (√) in the space provided.

What health institutions do to ensure quality medicines	**1**	**2**	**3**	**4**	**5**
Credibility of the suppliers					
Request for certification of incorporation in the country of manufacturing					
Certification from the manufacturer's home regulatory authority if medicines are imported					
An indication that the manufacturer has been manufacturing and marketing the specified medicines covered by the tender document for the last two years or similar once for the past five years					
Request for a satisfactory GMP inspection certificate by WHO from the manufacturer					
Manufacturing authorisation for the tenderer to supply the medicines					
Pre-shipment batch testing					
Under take inspection upon receipt of medicines					
F D A certification of medicines					
Pharmacy council certificate					
Credibility of Regional Medical Stores					

24. In your opinion as a procurement officer/pharmacist what other ways do you think can be used to help procure counterfeit free medicines?

……

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……

……