THE INFLUX OF PHARMACEUTICAL PRODUCTS AS A TRANSNATIONAL SECURITY THREAT TO GHANA

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DECLARATION

I do hereby declare that this work is the result of my own research and has not been presented by anyone for any academic award in this or other university. All references used in the work have been fully acknowledged and I bear sole responsibility for any shortcomings.

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SOPHIA EWURAKUA AMOAH DATE

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CERTIFICATION

I hereby certify that this thesis was supervised in accordance with procedures laid down by the University

…….. ……..

DR. THOMAS BUABENG DATE

(SUPERVISOR)

DEDICATION

This research work is dedicated to my beloved parents Mr. and Mrs. Amoah for the encouragement and support.

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ABSTRACT

The study sought to find out the channels through which counterfeit and sub-standard drugs end up in Ghana and the implications it has on the country. In addition, the study sought to investigate on the procedures used to dispose of counterfeit, expired and sub-standard drug s. This has led to stringent action been taken by the Food and Drugs Authority to individual who are being caught handling these pharmaceutical products (counterfeit and sub-standard drugs).The study involved sample size of 6 respondents who were purposely selected and interviewed. It was found that most of these respondents were aware of counterfeit, sub-standard drugs and expired drugs. The study found that porous borders, inadequate resource and skilled personnel are contributing factors to the influx of these pharmaceutical products to the country. The study established that some of the challenges that lead to the influx include lack of well-planned orderly operations; inadequate allocation of resources by government. There is the need for the government to support these agencies financially to help them execute their strategies in curbing the issue.

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LIST OF ABBREVIATIONS

WHO	World Health Organization
WAHO	West African Health Organization
TFA	Trade Facilitation Agreement
WTO	World Trade Organization
FDA	Food and Drug Authority
GATT	General Agreement on Tariffs and Trade
FTA	Free-Trade Agreement
ESM	European Single Market
IMF	International Monetary Fund
EPA	Environmental Protection Agency
UNDP	United Nations Development Programme
NHIS	National Health Insurance System
NHIA	National Health Insurance Authority
MOH	Ministry of Health
IMPACT	International Medical Anti-Counterfeiting Taskforce
DED	Drug Enforcement Department
WHA	World Health Assembly
DUMP	Disposal of Unused Medicine Programme

APIS	Active Pharmaceutical Ingredients
UNDP	United Nations Development Program
UNODC	United Nations of Drugs and Crime
DEA	Drug Enforcement Agency

CHAPTER ONE

INTRODUCTION

1.0 Background

The influx of pharmaceutical products to a country's market is of great concern to all. Most countries are making serious efforts to draw attention to clean their markets of fake and substandard pharmaceutical products to safeguard the well-being of their citizens. Medicines or drugs are pharmaceutical products which are important element of modern and traditional medicine. Some of these pharmaceutical products are safe, effective and of good quality.

With countries signing and ratifying trade agreements, there are raising concerns over such agreements as there is believe that it will increase the influx of substandard foreign products to the markets, lead to the collapse of indigenous industries and create border problems in terms of movement of goods across borders and security issues. Such cross-border issues are termed as transnational security issues. Transnational security threats are nonmilitary threats that occurs across borders, threatens a country's political and social integrity or the health of the nation's inhabitants. From the human security point of view, transnational security threats do away with lives and undermine the human society.

The signing and ratifying of trade agreements allows countries to be greater participants in the global economy but countries need to put in place risk management systems to help in the movement of goods.

According to the World Health Organization (WHO), health means to support an individual in a wider society.[1] The means to a full life is a healthy lifestyle. All over the world, good health is acknowledged as a key component in socio-economic development[2]. To maintain

good health, pharmaceutical industries are making every effort to produce and deliver medicines to where they are needed to keep people healthy. Pharmaceutical products or medicines are essential component of effective healthcare delivery systems. These products are used in the prevention, treatment, cure and mitigation of diseases. Countries would therefore make every effort to acquire them in order to maintain the health of their citizens. Sub-Sahara Africa has been identified as one of the areas with a high disease burden such as malaria, infant mortality and maternal health. This has led to an influx of all kinds of pharmaceutical products to the sub region.[3]

The idea of security over the past 15 years focuses on the security of nations, this include the security of individuals and communities.[4] The 1994 Human Development Report by the US secretary of state emphasized on the first link concerning human security and the free will from fear and want, outlined in a 1945 San Francisco Conference.[5] The idea of human security began after it reassessed within the United Nations Development Program (UNDP).

The UNDP report provides an inclusive explanation of human security, covering economic, food, health, environmental, personal, community and political security. The conceptualization of security was initiated by a sequence of misfortunes around the world. The genocides in Rwanda (1994) and Bosnia and Herzegovina (1995) proved to the world that the traditional thought of security as the safety of national borders not sufficient to save lives during civil conflict. Human security is an evolving model for understanding worldwide problems that has grown over the past two years from a outmoded view of national security with military readiness and focusing on the security of people.

A health threat in public health aims to toughen, prevent and monitor institutions in a society. Human security also boosts political and economic control on specific health to make an enabling environment for individuals and communities.

Counterfeiting of pharmaceuticals and its related effects on consumers has been detected since 1990 and recently, the problem has escalated in both developed and developing countries.[6] Pharmaceutical and chemical products use for the treatment and improvement of the quality of human life can cause pollution and serious threats to life. Another major situation that aggravates the fight against counterfeit drugs is the definition or interpretation of what comprises a counterfeit drug. Several countries have their own definition or interpretation and there is no consensus. Countries like Pakistan, Nigeria, the United States, Brazil, Portugal, Australia and Japan among others have different interpretations. This situation worsens the problem, as what is considered a counterfeit product in one country will not necessarily be the same in another country.[7]

The World Health Organization (WHO) has distinctively described counterfeit drugs as those, which are "intentionally" mislabeled according to the source and identity. Counterfeiting can be termed as branded and generic products containing the right or wrong amount of ingredients and forged packaging.

Furthermore, free trade and globalization policies, tries to move drugs to where they are required, have also led to the arrival in most developing countries especially various kinds of pharmaceutical products including standard products, sub-standard products and fake products from different parts of the world.

In the West African sub-region, some attempts are being made to remedy the situation. This includes the West African Health Organization agreeing on a protocol to provide protection to their citizens by pooling of resources, co-operation and collective strategies to combat the menace[8]

In addition, Heads of States and officials of the health sector are employing various strategies to address the situation. These strategies include setting up regulatory bodies, law enactments

to guide suppliers; manufacturers and vendors in the health sector and working with major stakeholders.[9] Despite these efforts of co-operation by member states, the existence of porous borders, and the enforcement of pharmaceutical laws regulating the arrival of products in the sub-region remain a challenge.[10]

1.1 Research Problem

In Africa, studies by WHO shows that over 100,000 people die because of intake of counterfeit drug.[11] Empirical observations further shows that counterfeit drugs are of higher purchase than genuine drugs in circulation.[12] The presence and persistence of sub-standard and counterfeit pharmaceuticals products is a potential human security risk to countries mainly in sub-Sahara Africa. For some time now, especially in the last two decades, Ghana has been experiencing an influx of counterfeit drugs and the present situation is alarming mostly in increasing cross-border health issues and the international dimension of trade.[13] Ghana's recent ratification of the Trade Facilitation Agreement (TFA) of the World Trade Organization (WTO) is expected to open the door for Ghana to have greater participation in the global economy. However, this ratification if not well handled could be a potential source of worsening the influx of counterfeit and sub-standard pharmaceutical products to Ghana.

Production of Counterfeit drugs appears to be recorded as a lucrative industry in the world of well thought-out crime.[14] Countries with porous borders, limited technology and poor human resource are therefore vulnerable to the influx of drugs. To fight this menace successfully requires the improvement of these conditions through effective collaboration and carefully thought-out strategies by stakeholders. Current efforts to address the situation include the partnership between security agencies, establishment of regulatory bodies and professional unions.

Troubling questions that exist in limited literature on the topic include how to stop the seemingly organize nature in the production of these drugs. Another interesting question is how to address the differences in the definition by countries or stakeholders what constitutes a counterfeit or fake drug. Also of interest are what stringent measures to put in place to deter people from the production and distribution of fake and counterfeit drugs across and within borders of countries.

The use of counterfeit and sub-standard drug is an international health issue causing numerous deaths in adults and children. The widespread of illicit drugs and extensive use of counterfeit drugs has led to loss of confidence with Ghana's health system, pharmaceutical manufacturers, distributors, and health practitioners.

Counterfeit drugs do not only deny sick people of treatment, but they make most diseases difficult to cure. In West Africa, counterfeit drugs have an increasingly target on antibiotics medicines to fight against malaria and tuberculosis.[15] Pharmaceutical products (counterfeit and sub-standard drugs) brought to Ghana appears to contain small amount of ingredient which are imported from developed countries and other indigenous pharmaceutical industries. Medicines with low levels of active ingredients pose a greater security threat than those with none.

The effect of counterfeit and sub-standard drugs in Africa has resulted to 400,000 children were annually attacked with malaria without treatment due to the use of counterfeit and sub-standard drug.[16] According to Renschler the burden and impact of poor-quality (sub-standard and counterfeit drug estimated to about 200,000-450,000 deaths out of one million malaria-related deaths in Africa are associated with the use of counterfeit and sub-standard drugs.[17]

Africa suffers heavily from the menace of counterfeit drugs, which occurred between 1985 and 2000. Counterfeit drugs sold by unauthorized vendors and chemist have become very

proliferating in the country[18]. In 2008, a study conducted by WHO reveals that antimalarial drug in 14 African countries and shows that percentage of antimalarial drugs in Nigeria constitutes 64% either counterfeit or sub-standard.[19]

According to Deutsche Welle, Isaac Kaledzi merged with agencies in charge of pharmaceutical products in Ghana to pilot a search on a drug trafficking as major issue for the FDA.[20]

According to Clinical Pharmacology & Therapeutics, counterfeit drugs "kill" is a catchphrase by the World Health Organization (WHO), organizations and both developing and developed countries used to guard against anti-counterfeiting. Again, the pharmaceutical industry created an initiative known as International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to sanction successful prohibited industry that gains profits because of selling counterfeit and sub-standard drugs.[21] A study by Newton et al reveals that the challenges posed by counterfeit and substandard medicines are the most urgent global health priorities as they pose a threat to human lives.[22] The rising increase of sub-standard drugs is a challenge, which occurs as a result of different causes. These causes include poor practices from manufacturers, insufficient transport and storage conditions, lack of expertise or falsification with criminal intent. In 2013, the Institute of Medicine discovered areas with high demand of sub-standard and counterfeit drugs as a result of inadequate regulatory.[23]

Akunyili noted "the problems of counterfeit and sub-standard drugs have embarrassed healthcare providers in most developing countries and has doubted nation's healthcare delivery system".[24] The proliferation of sub-standard and counterfeit drugs has led to treatment failures, deterioration of chronic diseases and many deaths. The widespread of counterfeiting and sub-standard drugs affected the treatment of patients due to excess intake of drugs. This affected the curing process of patients when giving quality drugs.

In line with this, stakeholders in other countries gathered in Dakar to curb the menace during the first quarter of 2011 under the international pharmaceutical Pfizer.

Literature shows since 2004, Pfizer has revealed 65 million of counterfeit drugs and active pharmaceutical ingredients to manufacture another 68 million drugs.[25] In addition, viagra is often the recorded as a counterfeited drug.[26] Sub-standard anti-malarial drugs have not been saved with terrible consequences for Africa. Reports indicate that 78% of death cases worldwide and 91% of cases in Africa are attributed to use of sub-standard anti-malarial drugs.[27] In addition, studies conducted in some African countries in 2008 revealed that Ghana, 35% of anti -malarial drugs brought to the country is mostly sub- standard.[28] Additionally, tramadol a pain relief drug is being abused leading to the cause of psychotic problems as well as harming vital body part in the human body.[29] As the abuse of tramadol continues to rise in Ghana, the Food and Drugs Authority (FDA) is in collaboration with other agencies to curtail the prohibited supply and sale of the drug. Latest surveys have indicated some youths, market women, drivers and some students are abusing that tramadol.[30]

This study is to find out how Ghana is coping with the menace of the influx and what the various agencies are doing individually and collectively to address the situation and the way forward. Furthermore, the study seeks to explore the checks and balances in place to reduce the influx of sub-standard and counterfeit medicines into Ghana. The study will also seek to find how expired drugs in hospitals, pharmacies, distribution outlets etc. are handled and the checks and balances in place to reduce the influx of sub-standard and counterfeit drugs to Ghana and highlight strategies to eliminate the threats of counterfeit medicines or sub-standard drugs.

1.2 Research Objectives

The main objective of this proposed study is to find out the security consequences of the influx of pharmaceutical products in Ghana. Specifically the study seeks to achieve four objectives namely;

1. To investigate the channels through which the counterfeit and sub-standard drugs end up in Ghana
2. To find out the security implications of the influx of pharmaceutical products in Ghana
3. To find out how expired drugs, sub-standard and counterfeit pharmaceutical products are disposed of.
4. To find out what sanctions are there to discourage the importation of sub-standard and counterfeit pharmaceutical products

1.3 Research Questions

The following research questions will be addressed in this study:

1. What are the channels through which counterfeit and sub-standard drugs end up in Ghana?
2. What are the security implications of the influx of pharmaceutical products to Ghana?
3. How are the expired drugs, counterfeit and sub-standard drugs disposed of?
4. What sanctions are being used to deter importation of sub-standard and counterfeit drugs?

1.4 Scope of the study

The scope of the study will be limited to Ghana where data will be collected from the Custom and Excise Preventive Service who are in charge of all products inspections at entry points in Ghana, the Food and Drugs Authority, regulators food, drugs herbal and homeopathic

medicines and chemical substances among others. Inputs will also be included from the Environmental Protection Agency, Pharmaceutical Society of Ghana and the Ministry of Health.

1.5 Rationale of the study

The current influx of all kinds of pharmaceutical products to Ghana brings in its wake a number of threatening situations to the health of citizens. It is therefore important that pragmatic and efficient ways be found by relevant authorities to address the situation The findings from the research will not only provide information to guide the development of efficient policies and strategies but also to stem the influx and possibly control it

1.6 Hypothesis

Countries with weak regulations and poor infrastructure to support consumer protection on drug imports, experience influx of substandard and counterfeit pharmaceutical products**.**

1.7 Literature Review

Literature on the influx of pharmaceutical products across the world shows that developing countries commonly experience the problem of circulation of sub-standard drugs. Problems associated with sub-standard drugs include less than or above concentration, contamination and packaging problems.

Newton et al identified artesunate epidemic in southeast Africa as a serious example of counterfeit influx.[31] Behrens et al, also talked about counterfeit drugs being problematic and intimated that poor quality drugs although genuine were sub-standard drugs.[32] According to O'Brien et al sub-standard drugs have severe health consequences[33] and Aldhous explained ineffective treatment and prolonged illness are the result of lack of active ingredients and fatal toxicity.[34]

Sub-standard drugs are frequently described because of counterfeiting; hence, international consideration and action is directed to these drugs. This is for the reason that counterfeit drugs demoralize the markets of pharmaceutical companies who put substantial drive in handling the problem.

The WHO talks about "promoting a global approach to combat the problem of counterfeit medical products through reporting procedures and enhanced access to information, and has launched a taskforce (International Medical Products Anti-Counterfeiting Taskforce) against counterfeit drugs.[35] Counterfeiting is a threat barrier that is less understood and further deceptive than the price of drugs. Also, counterfeiting is undetectable problem, which is difficult to quantify. Pharmaceutical firms now accept counterfeit and sub-standard drug posing a threat to their business, but most agencies openly address their policies and the anti-counterfeiting knowhow and development.

Counterfeiting is an unseen threat caused by nature and industries. Holm, et al define eco-pharmacovigilance as the science and schedules associated to the detection, assessment, and adverse effects of pharmaceuticals in the environment.[36] Pharmacovigilance detection, deterrence and effects of other drug-related problems are important constituent of any health system, safeguarding the menace are quickly identified and resolved.[37] Pharmaceutical companies have found these threats very advantageous. Numerous causes have contributed to change in strategy and among them advancing expertise and the increasing globalization of pharmaceutical markets. Furthermore, counterfeit and sub-standard drugs also decreases the cost-effectiveness of evolving country markets, reduction in the incentives to goal research and developing funds to diseases rampant to deprived countries and making it very difficult to draw foreign investment.

Governments in recent times are becoming more interested and are raising concerns over the influx of sub-standard pharmaceuticals products into their countries. This is seen in their nationwide security plans, which seek to protect their inhabitants against health-based threats like bioterrorism and pandemics. To do away with these threats, governments are not only tackling the issue from preventive and combative approaches but also acquiring and stockpiling display of therapeutic countermeasures such as antivirals, next-generation vaccines, antibiotics and anti-toxins.

A report by WHO in partnership with the governments of Burma and Vietnam make available added information on the quality of a wide array of drugs in South-East Asia.[38] In addition, the researchers deliberated on the problems arising because of counterfeit drugs and in attempt to differentiate between counterfeit and sub-standard products, by meeting with drug regulatory experts in the countries of manufacturing.

The business of counterfeit drugs and sub-standard is a lucrative crime increasing worldwide. The problem of counterfeit is wide spread affecting both developing and developed nations, assumes significance in view of rapid globalization and is assuming a dangerous transnational security threat in most countries. Counterfeiting and sub-standard drugs is the greatest transnational security threat in areas where supervisory and enforcement systems for drugs are weak.

Among other areas of interest in this study is to investigate how unused pharmaceuticals and expired drugs are disposed of, the state in which they come into the country or introduced into the environment and the potential effects they might have.

In Ghana, literature on the subject shows limited studies in the area hence the regulation of pharmaceutical disposal (counterfeit, sub-standard and expired drugs) in Ghana is new and quite technical making the awareness of its practice and ideas not widespread. This study

seeks to attain an in depth knowledge of concepts, practices, benefits, limitations, and challenges related with the disposal of expired, counterfeit and sub-standard drugs in Ghana and the regulation or framework used to govern these procedures. The study will also look at researches piloted in various parts of the world to plan potential and likely effects of the influx and its menace in the country.

Trading in counterfeit drugs seems to be common globally and affects both developing and developed countries; hence, the significance of communication and cross-border cooperation by the governments and industries on the effects of transnational security threat it poses to the environment.

Furthermore, the spread of counterfeit and sub-standard drugs are further distinct in countries where the manufacture, importation, distribution and sale of drugs are less structured and enforced, thereby poses security threats to developing countries.

1.8 Theoretical Framework

Globalization is a term, which is labelled as a long-standing process: the integration of the overall economy began with the introduction of the European colonial years five centuries ago.[39] The practice of globalization enhanced over the past 30 years with the eruption of technology, disassembling of obstacles to the movement of goods and capital, and the increasing political and economic control of transnational corporations. Globalization allows countries to have greater participation in the global economy. However, without proper border coordination between state agencies and risk management system in place, globalization can promote security threats to the disadvantage of countries. The theory of globalization was employed in this study to guard the in the influx of pharmaceutical products.

The theory of globalization is significant in today's world. Globalization started in the late 19th century and has been defined as the formation of diversity of transboundary mechanisms for interaction that affect and reveal the quickening of economic, political and security interdependence as put forward by Fukuda-Parr(.[40] Other definitions of globalization have been attempted by several authors and distinguished presenters without consensus, and therefore has different meanings.

It is generally believed that recent activities have been influenced by globalization. Globalization has several components like economic, political, financial, and cultural military and environmental.

The word 'globalization' has been used in its trade and industry sense as early as 1981, and 1944 respectively.[41] According to Theodore Levitt, globalization is attributed with commercializing the word and taking it into the mainstream business audience in the late half of the 1980's.[42] The concept of globalization has inspired competing definitions and interpretations. The history of globalization dated back to the great movements of trade and empire across Asia and the Indian Ocean from the 15th century onward. Due to the difficulty of the concept, various research projects, articles, and discussions often stay focused on a single aspect of globalization. Globalization is distinguished from modern globalization on the basis of expansionism, the method of managing global trade, and the level of information exchange.

The period is noticeable by such trade arrangements as the East India Company, the move of hegemony to Western Europe, the upsurge of larger-scale encounters between influential nations such as the Thirty Years' War, and the rise of established commodities most particularly slave trade. With regards to triangular trade it was probable for Europe to take lead of resources within the Western Hemisphere. The transfer of animal stocks, plant

crops, and widespread diseases related with Alfred W. Crosby's concept of the Columbian Exchange also played a vital part in this process.[43] European, Muslim, Indian, Southeast Asian, and Chinese traders were all involved in early recent trade and communications, mostly in the Indian Ocean region

Many scholars like Richard Payne and Charles Kegley have written extensively on various types of globalization. Thomas Friedman stresses that globalization is a universal system that substituted the cold war system.[44] Evolutions in technology, communication and transportation, have transformed the global environment.[45] These have powered interaction across borders with increasing movement of goods and people. They have also led to vulnerability of countries to various threats especially developing countries. In the 19th century, industrial revolution resulted as a form of globalization. Through, industrialization standardization of household items with economies of scale while swift population growth formed sustained demand for commodities.[46]

In the 19th century, 1820 and 1850 respectively the mode of international transport was through steamships and railroads, which reduced the cost and fare of transportation. More countries encompassed international trade. During the nineteenth century, globalization was assertively formed by imperialism in Africa and Asia.[47] The discovery of shipping containers in 1956 facilitated improvement in the globalization of commerce. After World War II, the Bretton Woods Conference led by politicians in key governments put down outline for international monetary policy, commerce, and finance, and the establishment of several international institutions projected to facilitate economic growth by lowering trade barriers. In addition, the General Agreement on Tariffs and Trade (GATT) led to a sequence of arrangements to eradicate trade restrictions.

GATT's replacement was the World Trade Organization (WTO), which provided a basis for negotiating and enacting trade agreements and a dispute resolution process. Also, exports approximately doubled from 8.5% to 16.2% in 1970 and 2001 respectively.[48] The method of using global agreements to spread trade stumbled with the letdown of the Doha Development Round of trade negotiation. Several countries then moved to bilateral or minor multilateral agreements such as the 2011 South Korea–United States Free Trade Agreement.[49] Globalization has led to security challenges, which confronts countries. These threats include rapid spread of diseases, illicit drugs, uncontrolled migration, small arms, terrorism, and cybercrime among others.[50] These threats weaken the state security hence creating a transnational threat to Ghana and other developing countries.

Globalization has also led to the expansion of free trade and access to markets all over the world with all kinds of goods and services.[51] It is believed that this expansion in international trade is attributable to trade liberalization that has removed barriers to international economic transactions. It has also facilitated the easy movement and distribution of important pharmaceutical products to-hard-to-reach areas in the world.

Even though globalization has brought about rapid economic growth and international economic integration, it also has impacted adversely on small companies in developing countries whose economies are small and unable to compete in the free trade. This situation has led to the collapse of most small companies /local industries especially sub-Saharan Africa.

The theoretical framework for this study will be based on “economic globalization”. Hence, globalization in this study denotes worldwide economic integration. Economic globalization, which comprises growths in trade, foreign investment and migration, is extensively approved to be arising through an arrangement of developments in technology and lessened

transportation costs, as well as careful policy choices on behalf of various national governments to ease up their economies and partake in the growth of global institutions.[52] However, the policy characteristic of economic globalization is a cumulative result that marks from the choices of several individual countries to surge their integration with the universal economy.[53]

According to Economist Takis Fotopoulos, he well-defined "economic globalization" as the introductory and deregulation of commodity, capital, and labor markets that led concerning present neoliberal globalization.[54] In addition, he used "political globalization" to denote to the occurrence of a multinational leaders and a phasing out of the nation-state. Furthermore, Takis used "cultural globalization" to reference the wide-reaching homogenization of culture.

Further of his procedures included "ideological globalization", "technological globalization", and "social globalization. Economic globalization is the increasing economic interdependence of national economies across the world through a rapid increase in cross-border movement of goods, services, technology, and capital. Whereas the globalization of business is centered around the diminution of international trade regulations as well as tariffs, taxes, and other impediments that suppresses global trade, economic globalization is the process of increasing economic integration between countries, leading to the emergence of a global marketplace or a single world market. Depending on the paradigm, economic globalization can be viewed as either a positive or a negative phenomenon.

Economic globalization includes globalization of production; which refers to the obtaining of goods and services from a particular source from different locations around the globe to benefit from difference in cost and quality. Likewise, it also comprises globalization of markets; which is defined as the union of different and separate markets into

a massive global marketplace. Economic globalization also includes competition, technology, and corporations and industries. Current globalization trends can be largely accounted for by developed economies integrating with less developed economies by means of foreign direct investment, the reduction of trade barriers as well as other economic reforms, and, in many cases, immigration. International standards have made trade in goods and services more efficient. An example of such standard is the intermodal container.

Containerization dramatically reduced transport of its costs, supported the post-war boom in international trade, and was a major element in globalization.

International Organization for Standardization is an international standard-setting body composed of representatives from various national standards organizations. A multinational corporation or worldwide enterprise is an organization that owns or controls production of goods or services in one or more countries other than their home country.

It can also be referred as an international corporation, a transnational corporation, or a stateless corporation. A free-trade area is the region encompassing a trade bloc whose member countries have signed a free-trade agreement (FTA). Such agreements involve cooperation between at least two countries to reduce trade barriers import quota and tariffs– and to increase trade of goods and services with each other. If people are also free to move between the countries, in addition to a free-trade agreement, it would also be considered an open border. The EU has developed European Single Market through a standardized system of laws that apply in all member states. EU policies aim to ensure the free movement of people, goods, services, and capital within the internal market, Trade facilitation looks at how procedures and controls governing the movement of goods across national borders can be improved to reduce associated cost burdens and maximise efficiency while safeguarding legitimate regulatory objectives.

William Robinson's assertion to globalization is a critique of Wallerstein's World Systems Theory. He believes global capital experienced today is due to a new and distinct form of globalization which began in the 1980s. Hence, Robinson argues not only are economic activities expanded across national boundaries but also there is a transnational fragmentation of these activities. One important aspect of Robinson's globalization theory asserts that production of goods is increasingly global. This means that one pair of shoes can be produced by six different countries, each contributing to a part of the production process.

Some scholars have critized on a broader neoliberal policy agenda which argues that globalization is believed to imply. Burtless makes this point when he describes the difference between what economists (typically proponents of globalization) and public health advocates (often critics) mean when they refer to globalization or liberalization. Whereas trade economists interpret liberalization to mean policies that eliminate trade and capital barriers at international borders, public health advocates consider the domestic policy changes that third world governments are obliged to accept in order to become full-fledged members of the IMF–World Bank–Davos club of nations.

1.9 Operational Definitions

Counterfeit drugs/ Fake drugs – contaminated or wrong active ingredient/ illegal/harmful drugs

Sub-standard drugs - do not meet quality standards and specification or product is unacceptable because it is below a required standard

Globalization- Integration of the world’s economy into a single international market rather than many national markets

Free trade- Buyers and sellers from separate economies may trade without the domestic government applying tariffs, quotas, subsidies or prohibitions on their goods and services.

International trade - Exchange of goods and services that takes place between countries

Transnational security threat- Occur across borders and can threaten a country's political and social integrity or the health of the nation's inhabitants

1.10 Ethical Consideration

Ethical consideration is very important for the study. Ethical issues considered by the researcher include confidentiality and anonymity. The information collected from the respondents was withheld for any identification. Confidentiality was consented from participants around related issues. The researcher provided informed consent before the interview and the discussion on the issues were conducted. The researcher consent to respondents was based on the stipulated objectives of the study.

1.11 Limitation of the Study

Regardless of the use of primary and secondary data by the study, the most important limitation was the difficulty in having access to confidential information and drug traffic documents available from relevant offices of state institutions in Ghana. The study therefore utilized relevant materials, books, reports, seminar papers, articles, written documents on the subject matter to mitigate the shortcomings and the validity of the research as well as the findings of the study.

1.12 Research Methodology

1.12.1 Research Design

The study adopted for this research is the case study design since the research focuses on Ghana. The reason for adopting a case study is to have in-depth analysis from specific

respondents on the topic**.** The research design adopted by the researcher is the descriptive research approach. Descriptive research involves describing the characteristics of a given population based on a given data**.**

1.12.2 Unit of Analysis

The study unit was based on institutions such as Food and Drugs Authority, Private Pharmacies and Environmental Protection Agency mandated to address pharmaceutical issues in the country, how they are handling the influx situation and what policies are in place to address menace.

Sources of Data

Primary data was obtained from the following institutions Food and Drug Authority, Customs and Excise Preventive Service in charge of all products inspections at entry point in Ghana, Environmental Protection Agency and some major pharmacies in Accra such as Medi Point, East Cantonment pharmacy and Premier Chemist Care. A face-to-face interview with selected respondents from the above identified institutions in the Greater Accra region was conducted using an interview guide.

Secondary sources of data were derived from the internet, journals, articles, published and unpublished reports, research findings related to the study

Target Population

The target population to provide the needed information for the study was selected individuals in the identified institutions and pharmacy shops in the Greater Accra Region. These individuals were the various heads of department or unit in the organization. Selected respondents in these institutions were persons who are knowledgeable on the topic by virtue of their profession or work experience.

Sample Size

In all, information was collected from 6 selected institutions (Food and Drugs Authority, Customs Excise and Preventive Service, Private Pharmacies and Environmental Protection Agency) and a respondent selected from each institution to be interviewed.

Sampling Procedure

To arrive at the sample size, the study employed the purposive technique. Specific unit and departments in the identified institutions whose functions or activities have direct bearing on the topic were identified and officials from these units randomly selected. The following were selected as respondents for the study: Food and Drug Authority, Customs, Excise and Preventive Services and Private Pharmacies.

Data Collection Instrument

For the purpose of this study, interview guide was the main instrument used for data collection. It was deemed useful because information given by the respondents is normally detailed and follow up questions can be asked for more clarification of responses.

Data Management and Analysis

The interview guide covered the following thematic areas (security, disposal, regulation and sanctions) and analyzed qualitatively. Responses to questions in these thematic areas were grouped from all respondents and analyzed to find if there were any trends, consistencies, major and minor determinants of the issues raised in the various thematic areas. Also, how many respondents have similar or dissenting views of the topics under discussion.

1.12.3 Justification of Study

With the current threat to human life that sub-standard and counterfeit drugs pose to the people it is important that solutions be found to eliminate this threat. Entry points through which these drugs enter the country were identified and secured. Efficient ways were found

to dispose of expired and counterfeit drugs and reduce their influx. Again, the findings of the study will guide in a structural approach for drug regulations in Ghana and design of quality approaches and manufacturing process of continual delivery of genuine drugs that will save money for Ghana to develop other sectors of the economy.

1.13 Arrangement of Chapters

The research comprises four chapters. Chapter one constitutes the Introduction. Chapter Two presents an Overview of Counterfeit and Sub-Standard drugs in West Africa and Ghana. Chapter Three is Evaluation of Data Analysis and Discussion. Chapter Four presents the Summary of Findings, Conclusion and Recommendations.

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CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter analyses scholarly works on influx of pharmaceutical products as a transnational security threat in developing and developed countries. In other words, it present reviews of literature pertaining to key terms on the influx as a transnational security threat and measures to help curb the menace. This chapter has been organized under five themes namely; how expired drugs are handled in Ghana, the strategies and efforts being made to eliminate the threat of counterfeit and sub-standard drug, as well as the theoretical and conceptual framework on the influx of these drugs as a transnational security threat are discussed.

Sub-standard and counterfeit drug is a health challenge worldwide. People across the world mostly come across drug packaging in a form of syrup, tablets, ointment and capsules but do not contain the amount of ingredients needed and could be a poisonous substance [1] Counterfeiting and sub-standard drugs are widely on the increase with high effects in less developed countries.[2]

In the past years, health problems on counterfeit and sub-standard drugs has been a rising issue which is causing mortality and morbidity and reduces good health care delivery particularly in middle-income countries.[3] In several countries including Ghana, quality drug is of great concern especially with the preparations. In these countries the proliferation of counterfeit and substandard products has become a predominant issue to the extent of posing a security threat to the countries.

Generally in middle class countries, counterfeit and sub-standard drugs is measured at 1% whilst in other expanses of the world, for instance the total percentage in Africa and Asia is higher than the average world market (Aria 2008).[4]

A study by Bate et al shows that countries in parts of Africa 35% of samples tested were sub-standard.[5] Tipke et al in their study on substandard antimalarial drugs in Burkina Faso, found 42% of samples tested were of low quality, which and 28% failed the site inspection, 9 samples were sub-standard drugs, and 1% sample do not have any ingredients.[6]

In Cameroun, a study conducted by the American Journal of Tropical Medicine and Hygiene (2004), indicated that 38% of Chloroquine, 74% of quinine, and 12% of anti folates did not have the required or correct ingredient.[7] In countries like Ghana, Kenya, Nigeria, Rwanda, Tanzania and Uganda a study results disclosed that 35% of anti-malarial drug had less amount of ingredient which was not dissolvable and effective.[8] A study was conducted in some African countries on the use antimalarial drugs showed that 38% of drugs sold in the Kenya market were ineffective for treatment.[9]

There is a limited study on counterfeit and substandard antimalarial drugs leading to a situation of scanty information of the subject in Ghana. This notwithstanding, the government of Ghana is interested in fighting to curb the influx by instituting organizations such as the Food and Drugs Authority, Environmental Protection Agency and the Customs Excise and Preventive Service.

2.2 Historical Overview of the Pharmaceutical Societies

Many individuals use therapeutic substances for treatment of themselves. As far back as 4000 BC, the Sumerian population used plants as medicinal purposes. Some of these plants include mustard, myrrh, and liquocie. The Egyptians at the time also prepared and use ointments,

lozenges, lotions pills and infusions for treatment. In preparation of these drugs, people had specific duties from diagnosing and treatment.

In China 2000 BC, Shen Nung composed the first Pen T'sao or natural herbal, which contained accounts of 365 plant-based drugs. History again, shows that there were shops and factories retailing medicinal imports occurred around 1900 B.C. in the town of Sippara on the Euphrates river. In addition, the latest documented shop dealing with transactions of drugs in London was opened in 1345.

The word 'pharmacy' was in well-known in Europe, with different spellings, from the late classical period. In the 17th century, pharmaceutical was used in England to cite a reference to 'good pharmaceutical, botanik and chymicall organizations' completed in 1648. In the 18th century more public usage of the term pharmaceutical chemist often denotes to advocate the French school of chemical based therapeutics. Furthermore, in the mid-19th century, when the new Pharmaceutical Society of Great Britain was adopted, the term 'pharmaceutical chemist' was being more usually applied to those involved in organic chemistry and in the expert compounding of drugs of all descriptions.

In addition, the term chemist in present day is usually used interchangeably with that of pharmacist, references to chemists in past documents occasionally denote to those involved with the learning of science rather than pharmacy. Chemist and Druggist a word used to define chemical and drug merchants and practitioners of the emerging profession of pharmacy in the 18th and 19th century respectively. It is often used in trade handbooks and census returns.

Viable chemical and drug suppliers not involved with the distributing or the sales were not mandatory to register with the society, and persistent to trade after 1868. Legitimately they

could no longer use the name chemist and druggist. The designation master druggist was occasionally used to qualified and unqualified chemists and druggists.

2.3 Ghana's Pharmaceutical Policy Goals

Ghana currently has pharmaceutical policy goals that include accessing drugs for every individual, ensuring quality drugs on the market, having proficient supply of drugs as well as coherent use of drugs by patients, doctors and the pharmacist. In Ghana, the pharmaceutical sector is also responsible for the strengthening of the domestic pharmaceutical industry and outlining the conditions under which the health industry operates. The National Health Insurance System (NHIS) falls under the initiative of the Ministry of Health has improved access to drugs for patients. However, NHIA has the necessary resources and obtaining power to stimulus suppliers and the quality of price on the market.

Furthermore, the pharmaceutical sector is responsible for current information and suggestions for policies, objectives and improves on proper service delivery and quality of drugs In Ghana, the authorized framework for the pharmaceutical sector is established by the Food and drugs law 1992 and in 1996 amended by Act 523. The role of the food and drugs authority controlled of the Ministry of Health (MOH) is to regulate the sector. The Food and Drugs Authority (FDA) is in charge of quality samples from manufacturers, other sources importers and distributors.

2.4 The Food and Drugs Authority and Pharmaceutical Crime

The Food and Drugs Authority' pharmaceutical crime investigations and intelligence gathered to equip participants with skills on modern trends in pharmaceutical crime investigations, intelligence and the handling of evidence.[10] Pharmaceutical crime, which has become a global phenomenon, is selling or promoting a pharmaceutical product for what it is not. It includes falsified, counterfeit, mislabeled and misrepresented medicines and medical

devices. The menace of pharmaceutical crime thus threatens the health of the world's population because treatment failures and drug resistance have become global issues putting patients at risk.[11]

2.5 Definitions of Counterfeit and Sub-standard drugs

Internationally there is no approved description of counterfeit drugs.[12] Many countries and organizations have diverse classifications of sub-standard and counterfeit drugs. In defining these drugs, people have different views or explanation depending on the writer's or speaker point of view. The following are the working definitions which will be used in this research.

The World Health Organization describes counterfeit drugs as deliberately and falsely mislabeled in terms of labelling and its source.[13] A counterfeit drug applies to generic and branded products.[14] A counterfeit drug is termed as a product with correct or wrong ingredients and forged packaging.[15]

A sub-standard drug is a medicine that does not meet specifications. A sub-standard drug that fails laboratory testing in terms of the specification and its classification is termed as a sub-standard drug.[16]

A study by Caudron et al identified certain types of sub-standard drugs: includes high and low concentration of ingredient, contamination, mislabeling difficulties with active ingredient, complications and inactive ingredients used as transporters for active ingredients in drugs, poor protective material problems. This shows several way of tagging a drug as sub-standard.[17]

The distinction between counterfeit and sub-standard drug has a long history. The difference between the sub-standard and counterfeit drug is vital whilst the distribution process is quite different. The difference between counterfeit products from a sub-standard product is quite

difficult to differentiate. A genuine product may turn out to be sub-standard because of its manufacturing problems. However, a counterfeit drug may have the same standards as an authentic product and cannot be called a sub-standard drug. The European Directive in 2011 termed a counterfeit drug as any drug with mislabeled representation of source and identity and errors with manufacturing process and distribution methods.

2.6 Drivers of Widespread of Counterfeit and Sub-standard drugs

Several studies have suggested that, there are certain factors and conditions that motivate the widespread of counterfeit and sub-standard drugs. Furthermore, Chouvy give details on factors include the excessive flow of population and goods from the border, which is because of ineffective border control and the infiltration of prohibited drugs from the regional market.[18] A study by Bhumiratana et al reveals that evident for drug-resistant has been outlined in dangerous border areas like Thailand-Camobodia and Thailand-Myanmar border.[19] Gaps into healthcare systems make patients depend on unqualified private providers. Also, Lon et al, 2006 indicates that the sale of sub-standard drugs in remote communities where access to health facilities or pharmacies is a problem, patients incline to self-diagnosing and medication from unlicensed outlets.[20] The main challenge to pharmaceutical crime, however, is distribution. These illegal distribution channels include courier, door-to-door, social media, internet sales, and the poor handling of cold chain products. Others are diversion of program or subsidized medicines, illegal cross border trade (smuggling), parallel importation and deceptive designation.

A study conducted by Newton et al shows that to guard against sub-standards and counterfeit drugs massive support from regulatory agencies and enforcement authorities should be involved.[21]

Again, inadequate financing of the health sector in Africa is another impediment that creates problem in the sub-region. Weak economies of African countries raise the costs of healthcare, thereby preventing adequate financing in the health sector. Moreover, another setback in the health sector is lack of commitment by the governments.

Drugs used in Africa are as a result of importations from further countries due the insufficient indigenous pharmaceutical manufacturing companies. The availability to these medications is over and done with public sectors like government hospitals and clinics, private hospitals and chemist shops owned by individuals and companies. In Africa, drugs on market do not always originate through the usual networks but are mostly sneaked into the country by avoiding the strict registering levies charged by officials at the border to enable smooth movement of drugs.

The Head of the Drugs Enforcement Department (FDA) Ghana restated that "the individuals who are involved in product falsification and counterfeiting are hugely motivated by the high profit margins and returns they make on their investments". He again indicated that "the falsified and counterfeit drugs create various dangers including threats to vital human organs, drug resistance, therapeutic failure, adverse reaction, and the development of complications, hypersensitivity and a decline of confidence in health systems" [22]

The expansion of internet trading and online retail markets is also a source of the spread of counterfeit and sub-standard drugs.[23] The internet supply of drugs is becoming popular in recent time and a major source of counterfeit and sub-standard drugs. In transacting some pharmaceutical companies are ignorant of the dangers involved in buying lower-priced drugs or purchasing a prescription drugs online without a prescription and end up buying counterfeit or sub-standard products.

2.7 Importation of Counterfeit drugs and Sub-standard drugs to Ghana: Preventive Measures

The World Health Assembly Resolutions WHA41.16 entreats countries to start program for the hindrance and discovery of the exportation, importation and trafficking of products.[24] The WHO's Essential Medicines Program is to offer funding to monitor experts to make sure quality and safety ethics of pharmaceutical products.[25] Furthermore, measures for combating counterfeit drugs also provides methods for examining and analyzing distrusted drugs and training of officials.

Furthermore, the establishment of International Medical Anti-Counterfeiting Taskforce in collaboration with WHO and other stakeholders have been actively seeking a way out to curb the menace and raising awareness to the public.[26]

Counterfeit and sub-standard drugs have flooded the market and government hospitals as a result of the country's drug regulator to control the importation of drugs. This is as a result of the country's Food and Drugs Authority's stringent regulations to the care and management of drugs in Ghana. Counterfeit and sub-standard drugs have found their way to public hospitals as a new brand of drug administered to the patient. This occurs because the smuggling of counterfeit and sub-standard drugs into the country has infiltrated the hospital supply chains. These incidences are not documented to find out the effects it has on patients. In Ghana importation of medicine is allowed through the airport in Accra and the Tema Ports and Habour to ensure quality drugs enter the country and also checks and balances are done to prevent counterfeit and sub-standard product.

According to the Ministry of Health's Director of Pharmaceutical Services Martha Gyansa-Lutterodt stated that most counterfeit and sub-standard drugs found in Ghana are from Nigeria and have found their way into the country because of the porous nature of our land

borders and officials. [27]The issue of counterfeit and sub-standard drugs has been proliferating over the past years. The Food and Drugs Board authority are being forced to intensify raids on pharmacies and distribution outlets to eliminate these products

2.8 Efforts to Address Challenges

In the sub-region several efforts have been made to curb the menace by improving regulatory mechanisms and procedures. Nevertheless, the problem continues to spread, specifically in secluded zones where it is more challenging and unlicensed suppliers are more likely to operate. The trade in counterfeit and sub-standard drugs is known to be widespread in pharmacies throughout the country and some have even found their way onto local market stalls. Hence, it is difficult for consumers to tell the difference between counterfeit and sub-standard drugs. As a result of trade liberalisation, has reduced controls and increase border exchanges which promotes illegal trade in counterfeit and sub-standard drugs.

Efforts to control the proliferation of counterfeit and substandard drugs internationally supply differ extensively through countries. The implementation of regulatory legislation is subject to nationwide governing and enforcement which differs in various countries. [28] The frequent supply of counterfeit and sub-standard drugs cross borders weakens the country's enforcement mechanism due to its corrupt nature. Again, sub-standard and counterfeit drugs have severe health repercussions and are not manufactured by certified companies. Nevertheless, counterfeits could be labelled as a sub-standard drug but it is not inherent in terms of definition.[29]

In manufacturing sub-standard and counterfeit drugs the distinct problem involves effective regulation and enforcement by manufacturers which should be controlled whilst counterfeits are quite difficult to regulate because of its production process which is done in homes, small industries and backyard [30].

The country's pharmacy board in Ghana also ensured that only approved pharmacies sell medication. However, there have been cases where both approved and unapproved pharmacies have been found selling sub-standard and counterfeit drugs. .

.However, Gyansa-Lutterodt said the ministry of health has no data on the extent of sale and use of counterfeit and sub-standard drugs in the country.. Using a World Health Organisation study, estimates that 30 percent of medicines on the market in Ghana are counterfeit and sub-standard drugs.

Gyansa –Lutterodt stated that, the ministry was aware of the problem and that procedures were in place to ensure that "counterfeit and sub-standard drugs do not enter the public system, because we want public access to medicine to be without any taint."

The system, Gyansa-Lutterodt said, was buying from approved sources only, strictly following the procedures, which was not new. According to Charles Allotey of the Health Access Network, emphasized how the ministry had difficulties detecting counterfeit and sub-standard drugs..

"It is a technical problem that is difficult to detect and it would be harsh to say the ministry had not done any work on this issue. Suspicion arises only when a particular medicine is used and produces no result and this must be proved by analysis."

Gyansa-Lutterodt was concerned that the use of counterfeit and sub-standard drugs will have serious implications on people's health, as many believe they are taking the legitimate drugs to treat their illnesses.

According to Thomas Amedzro, head of the FDB's drug post market surveillance, agrees with Gyansa-Lutterodt that the sale and use of fake medicines has a serious impact on the health of Ghanaians..Thomas Amedzro et al found out that some fake antibiotics have found

their way into the country, and any patient that is given them could die because of the poor efficacy of the drug This shows that the country is battling a serious threat and a real problem.

Amedzro stated that, the FDA's duty is to ensure that products are safe for use by the public and ensuring that manufacturers register their products as well as packaging. In the case of importers, officers are sent to the countries of origin to ensure that the manufacturing site really exits. Again, he explained that, it usually happens when suppliers of generic drugs apply to sell medicine in Ghana.

Nevertheless, the Food and Drugs Authority does not have the personnel to patrol our vast land borders and it is this problem that we now encounter," he added, referring to the way counterfeit medication was entering the country.

Furthermore,Amedzro said:

"There is also the need to educate the people first so that they understand what counterfeit and sub-standard drugs mean to their health.

"We also need to encourage the public to stop buying just from any place of sale. In addition, there is the need for the public to report those who sell medicine without registration"

2.9 Harmful Effects of Sub-standard and Counterfeit Drugs

The consumption of counterfeit and sub-standard drugs is a nationwide problem causing deaths in adults and children. Frequent supply and use of counterfeit and sub-standard drugs has led loss of confidence in health professionals and manufacturers.

According to Caudron et al shows that, the end result of consuming sub-standard drug is death . For instance in 1995 and 1998 respectively Haiti and India recorded 89 and 30 infant deaths as a result of contaminated paracetamol cough syrup.[31] The estimation by the WHO

reveals that "of the one million deaths that occur from malaria annually, as many as 200,000 would be avoidable if the medicines available were effective, of good quality and used correctly.[32] Generally, sub-standard drugs have social and economic effects and lessen patients' poise in doctors and pharmacists.[33]

In the less developed world, drugs constitute a large percentage of individual income. Furthermore, the use of sub-standard drugs leads to illness and additional costs incurred on health-care workers.

These extra health-care and regulatory costs include employees costs for health-care workers and regulatory and implementation agents, equipment costs for therapeutic equipment and drug testing laboratories and governmental costs. Also, the spread of sub-standard drugs has political consequences.[34]

Sub-standard and counterfeit drugs undermine governments' investments in health delivery systems. It also wears down trust in the government, capacity to keep and administer regulatory standards. The spread of counterfeit and sub-standard drugs weakens the credibility of quality healthcare of a country.

2.10 Current Disposal Methods of Expired, Counterfeit and Sub-standard Pharmaceutical products in Ghana

2.10.1 Handling of leftover drugs in the country

The regulation of disposal drugs in Ghana is new and quite technical; hence most people do not have in depth knowledge and practice of it. Improper disposal of leftover drugs pose a great challenge to both environmental and health workers globally. Unused pharmaceuticals do not only pose exposure risks for both the environment and humans,

they also reflect lost opportunities for proper therapeutic treatment and wasted healthcare resources.

The disposal of pharmaceutical products in Ghana is structured by the Public Health Act, 2012 Act 851. In Act 851, the disposal of pharmaceutical products is handled by the Food and Drugs Authority under Section132, Closure of Premises and Safe Disposal of Unwholesome products.[35] In Ghana, drugs are distributed in loose form in dispensing envelopes devoid of any information about the expiry date, so that the longer they are kept the likelihood of them going bad without one knowing. This is likely to occur if all the medicines are not taken as prescribed and taken at a later date. Children may easily have access to unused or leftover drugs that are thrown into the trash can, left uncovered. Most medicines look like candies and this can serve as an open invitation to children and other individuals, and this may accidentally and/or purposefully lead to poisonings of infants, children, adults, and pets.

2.10.2 Methods of disposal of Unused Drugs

Leftover drugs include drugs persist when people do not comply with prescriptions given them by the doctor, pharmacist or the chemical seller. These drugs may be suspensions, tablets, capsules, syrups and other formulations. Most patients are not able to finish their medication as a result of unwanted/unbearable adverse effects or generally for the dislike of the drug(s). Drug accrual is taken by the death of a consumer. The drug is purchased in excess and not consumed as directed, which leads unwanted drugs. Drugs may also remain unused when patients feel better and therefore discontinue its use. Leftover drugs also remain as a result of change of medications by doctors. Changes from one drug to another (brand wise or generic wise) without any provision made for retrieving the old ones, leave the patient with no option than hoard these drugs

Unused drugs characterize by misused healthcare assets and opportunities for treatment. The likely factor leading to leftover drugs may be patients are not efficiently counselled about appropriate use of their medication. Another reason may be the lack and or inadequate patient counselling thus leading to non-compliance. Disposal of leftover or unused drugs is an issue of great concern. Wrong disposal of leftover drugs pose a challenge to both environmental and health workers globally.

Furthermore, Ghanaian homes, there is mostly continual usage of left over drugs in one way or the other, consciously or unconsciously. In Ghana, the disposal of unused drugs discovered that majority of Ghanaians in Accra have leftover drugs in their homes. There is no known outlet for the right disposal of unused drugs to the public, thereby the various alarming consequences which has led to the introduction of Disposal of Unused Medicines Programme (DUMP) it is a programme designed to retrieve all unused medicines at some special Hospitals in Ghana.

Disposal of medicines into trash cans has strongly been discouraged. Introduction of Active Pharmaceutical Ingredients (APIS) to sewerage trash, have been found to enter the environment as contaminants, thus posing as threat to humans and environment and humans.

In Ghana much education or awareness has not been created about responsible disposal of medicines. In Ghana, all refuse go to a given dump site and there is no sorting out of unused medicines deposited in the garbage bin. Some hospitals however, burn unwanted drugs in an open air only under the regulation of authorized persons from the Food and Drugs Authority. Ghana, like most third world countries do not have incineration facilities, equipped with adequate emission control, which is mostly found in the industrialized countries.

2.11 Conclusion

Counterfeit and sub-standard drug is a global issue of concern that needs to be dealt properly to prevent the influx of pharmaceutical products in Ghana. Ghana has no nationwide statistics on the quantity of counterfeit and sub-standard drugs within the country. However, the WHO estimates that 30 percent of all drugs on the Ghanaian market could be counterfeit and sub-standard drugs. Silas Agyekum stated one main problem of the influx of pharmaceutical product in the country is as a result of porous borders.[36] Pernette Bourdillon Esteve an analyst of the World Health Organization explains the causes of substandard and falsified drugs in the country include poor governance, short capabilities to deal with the problem and poor access to drug and health facilities. [37] In addition, poor countries are mostly affected by this the influx. Furthermore, persons need be conscious of the risk of sub-standard and counterfeit drugs, and whenever they come across such products they must be reported to state authorities so it could be work on or handled properly. Also, sub-standard and counterfeit drugs occur globally as a result of people wanting to make quick money and the use of weak laws and weak enforcement being a factor to the influx of pharmaceutical products. There are many contributing factors leading to widespread of sub-standard and counterfeit drugs. Counterfeit drug and sub-standard is associated with organized crime, narcotics trade, business welfares of corrupt officials and unregulated pharmaceutical companies.

WHO, identified features influencing frequent use of counterfeit drugs into the country is as a result of weak drug regulatory officials, nonexistence of a legal directive for authorizing of manufacturing and importation of drugs. Nevertheless, the absence of guideline for exporters and within free trade zones, increase of small pharmaceutical industries, high purchase and supply of healthful and precautionary drugs and vaccines, high costs and ineffective

collaboration among stakeholders.[38] Hence, the need to put measures in place to curb the influx menace and sanctions for law breakers of the laws being enacted.

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CHAPTER THREE

DATA ANALYSIS AND INTERPRETATION

3.0 Introduction

This chapter presents the data analysis and interpretation of the study. This research was undertaken by interviewing major players in the regulation and control of pharmaceutical products regarding the importation, distribution and disposal as well as reviewing the legal frameworks governing their operations. Organizations contacted in this research include the Food and Drugs Authority (FDA), Environmental Protection Agency (EPA), the Pharmaceutical Council of Ghana, some selected Pharmacies in Accra and the Customs, Excise and Preventive Service (CEPS). The analysis covered the key objectives of the study namely: channels through which counterfeit and substandard drugs enter Ghana, border security issues, regulation and sanctions and disposal of expired and counterfeit and substandard drugs.

3.1 Channels through which counterfeit and substandard drugs enter Ghana

There has been an increase of unknown or unregistered drugs on the market which have been smuggled into the country. The FDA is not able to trace the source, country of origin and content. The influx of counterfeit and sub-standard drugs to the Ghana occurs frequently as a result of smuggling through the approved and unapproved borders, courier services (door to door delivery) which normally escapes regulatory checks by the FDA, and personal items (being place in the luggage of travelers).

Furthermore, the respondent outlined ways used by the Food and Drugs Authority “To curb the influx of sub-standard and counterfeit drugs, the FDA has come out with measures to address the situation at the entry points by licensing of manufacturer works, legal entity and

facility suit of drug manufacturing companies". The Food and Drug Authority and other agencies have collaboration with Customs in checking the influx at the entry points.

Pharmacies also play a very important part in the supply of healthcare. The license allotted by the FDA indicates that pharmacies are able to supply and administer all kinds of drugs to the public for their use at home and for clinical setting. The pharmacy has become a place for obtaining reliable information on drugs. Three pharmacies in Accra were surveyed with respect to how they obtain their products and precautions against purchase.

Using the interview guide three pharmacies (East Cantonment Pharmacy, Medi Point Pharmacy and Premier Chemist Care Pharmacy) in Accra were surveyed with respect to how they obtain their products, precautions against purchase and importation of products. Also information was sought on methods of disposal of expired drugs, how expired sub-standard and counterfeit drugs are handled when identified in their various outlets. It was observed that, the main sources of drugs purchased are from external pharmaceutical companies and some local companies.

"As a result of the current situation where counterfeit and sub-standard drugs are all over the place, one has to be careful and do proper diligence before acquiring drugs to stock their shops. In this wise we collaborate with the FDA who inspects all drugs imported by us at theentry ports or purchased locally before we distribute to our outlets" the respondent at Medi Point indicated.

"As a licensed pharmacy, it is important we maintain our integrity. This we do by putting in stringent measures to eliminate all possible sources of counterfeit and sub-standard drugs to our shops and outlets" the respondent at Medi Point Pharmacy stated.

"Before we stock our shops we use softwares to check individual products like labelling, manufacture and expiry dates. For example, drugs which are brought to the pharmacies are countered and arranged in order to enable the pharmacist check for the manufacturing date and expiry date and batch numbers".

"Before the drugs are arranged on the shelves, we have softwares for inputting/recording the essential information of the drug. This enables easy identification of when drugs are to expire" – the Premier Chemist indicated.

The respondent at East Cantonment Pharmacy indicated that

"The software alerts us with a popup of expiry dates of drugs to be taken out from ourselves. This notification also helps us to make the necessary arrangements with FDA for disposal of such drugs."

The finding confirms Isaac Kaledzi work that the FDA in Ghana is currently operating a random check in the markets and pharmacies on the authenticity of drugs. . This exercise is also faced by lack of the required staff and equipment to execute this operation efficiently

3.2 Border Security

Porous border was identified as one of the major reasons contributing to the influx of counterfeit and sub-standard drugs to the country. The mandated institution CEP's, however, is not able to monitor all the entry points to the country. This observation is also confirmed by Silas Agyekum who also found that poor security at the border and inadequate provision of resources to officials at the entry points is a major stumbling block to fight against the menace. However, smugglers are able to bring in such drugs easily. Poor security at the border contributes to smugglers conniving with residents at the border communities to

convey pharmaceutical products (counterfeit and sub-standard drugs) in small quantities hidden in their personal belongings into the country.

Another challenge is smuggling where items indicated on documents covering the imported products are different from the real products being brought in. The absence of scanners to verify the contents of vehicles carrying these goods makes it easy for vehicles and individuals to pass through without being detected. Again, lack of data/information and intelligence on vehicles and individuals among the various borders increases illicit drugs to the country.

Respondents from the FDA agreed that corporation from stakeholders at the entry borders and effective measures could curb the influx menace while officials CEPS emphasized that information and intelligence sharing among international, regional and national security groups can significantly help in the fight against the influx of these drugs. Additionally, respondents were of the view that corporation from stakeholders at the entry borders and effective measures could curb the influx menace.

"We are aware that most of these counterfeit and sub-standard drugs come in through our Eastern border with Togo. Our attention has also been drawn to the frequent transportation of drugs to Ghana using the airport and other modes like and our harbors and other cargo land routes from the neighboring countries. With this information we have increased vigilance at these identified points" the CEPS Official indicated.

If the above stated is not tackled or handle, Ghana will face losses in trading with other investors. Furthermore, it will severally affect the health of citizen's in the country. This will make the government invest more money to remedy the situation. This means that more resources such as scanners, well equipped police personnel to patrol the borders and training to update skills of personnel.

3.3 Regulation and Sanctions

Analysis of the responses on security matters from the interviews show that the CEPS who are in charge of monitoring, regulation and inspection of exports into Ghana, are fully aware of the situation and are finding ways and strategies to tighten security to control the entry of counterfeit and sub-standard drugs to the country.

These strategies include creating awareness of the sanctions to be applied when arrested for importing or transporting these drugs at the entry and exit points of the country and in the media.

"We are also collaborating with other agencies such as FDA in embarking on checks especially at the Airport. Also CEPs is collaborating with external agencies like European Union and some manufacturing companies in developed countries, in the fight against the transfer of these drugs through our boarders and at the airports".

The results of this collaboration is seen in publication of Cockburn R where the arrest of suspects dealing with counterfeit and sub-standard drugs at some entry points.[1], counterfeit and sub-standard drugs were detected and stopped at the country's borders through the vigilance of personnel at post.[2] between 2004 and 2005.

The use of sanctions like imprisonment and fines should be enforced to deter persons and manufacturers from patronizing counterfeit and sub-standard drug. This process/ sanctions tarnish the image of the organization and create losses for the organization thereby serving as deterrence for individual and other manufacturing companies, pharmacies and outlets. However, revoking of license, banning of the various products being sold by the organization can also be another strategy for the sanctioning

Also, stiffer penalties should be instituted and implemented. Fines should be increased to deter individuals and organizations from patronizing from the wrong source but there should be cThe fee taken serves as a deterrence for organizations that patronizes counterfeit and sub-standard drug and are required to dispose of their unwanted drugs and expired drugs under the supervision of the FDA consistency with their suppliers and manufacturers to prevent any form of loss and fines

The study result shows that Ghana has comprehensive laws in place to regulate the menace; However, these laws are not enforced as expected. The non-enforcement of the law has made all kinds of people involved themselves in the smuggling of drugs into the country. With this, people will be embolden in dealing with counterfeit and sub-standard drugs

Another observation was stakeholders believed that the laws should be reviewed to address current issues of pharmaceutical products in the country. With such believe, it is hopeful that Ghana can make amends to its regulations without much struggles as done in other EU has where companies continue monitoring drugs safety and its efficacy after approval has been granted.

3.4 Disposal of expired and counterfeit and sub-standard drugs

The Food and Drugs Authority is responsible for the safeguard of health and safety, efficacy, food and security of the citizenry and veterinary drugs by making sure all food items and drugs in the country are of good quality. The interview covered the policies, practices, sanctions and legal and regulatory framework with respect to import, exports and usage of pharmaceutical products including counterfeit and sub-standard drugs to Ghana.

The interview results with FDA show that FDA has four ways of disposing off expired and counterfeit and substandard drugs. Confiscated drugs are crushed and buried in a pit, burning

at the disposal site, pouring liquid formulations into the special drains at the disposal sites. and incineration of vaccines, drugs, oncogenic medicines and steroids.

The results further show that due to time constraints the drugs to be disposed off are most of the time not sorted out before destruction at the dump sites. The disposal sites are not managed by the FDA but are managed by the metropolitan, municipal and district assemblies (MMDAs).

On a typical day when disposal off drugs is to take place, the FDA supervises the packing of the drugs for disposal into vehicles and lead the vehicles to the disposal site. At the disposal site, the method of disposal agreed upon is then implement in the presence of an official or representative of the organization or agency from where the items were seized or collected. At the end of the process, the Food and Drugs Authority (FDA) verifies that the quantities of products stated in the audit report have been damaged on behalf of the organization.

The Environmental Protection Agency (EPA) is accountable for healthy environment in the country. Analysis of their responses show there are two disposal sites in Ghana, Tema and Takoradi. Furthermore, results show that, the bulk of pharmaceutical products that are disposed off at these sites are not made in Ghana but rather imported. The EPA does not carry out the actual disposal but supervises the action to make sure that it is done in ways that do not pollute the environment.

It was also observed that various disposal methods currently in use in the country are mostly rudimental. For seized items that are powders in paper, they are sheared, crushed of shredded before they are buried. Liquid drugs in plastic packaging are first punctured to ensure the liquids are out before buried. Ointments by far are the most difficult to dispose of as they come in inflexible materials and foils. With such products a combustible material such as

petrol is sprayed on them in a dugout and set ablaze. This method is also used for some materials with plastic or paper packaging that cannot be crushed, mostly in the case of tablets. The interviews also revealed that some pharmaceutical companies in the country have their own treatment systems of disposing off of drugs that are not suitable for use.

In terms of modern methods of disposal of counterfeit and substandard drugs such are the use of incinerators, Ghana has five main locations, two in Takoradi and three in Tema . Incidentally, there are all located in the southern parts of Ghana. For quick disposal of seized drugs, therefore Ghana should have some disposal sites in the northern parts of the country where it shares borders with three countries for easy disposal of seized counterfeit and substandard drugs.

Again the country should systematically move away from using rudimentary methods (crushing and burying) for disposal and develop modern disposal sites that does not pollution the environment and endanger people's health. The disposal sites should be relocated from human population centres to prevent exposure to toxic fumes. With regards to the burying of seized and expired drugs, there is a probability of contaminating water bodies and the soil for farming.

"The respondent was of the view that, the burial method of disposing off drugs should be banned" this is because chemicals are generally either solvent based or water based. Solvent based chemicals burn at low temperature leaving behind the active ingredient which is also burnt at high temperature. Also, water based products which burn at 100 degree Celsius leaving behind the active ingredients to burn at a higher temperature. Either ways everything is destroyed.

In order for these plans to be successful, it is necessary to ensure that it is tackled effectively to prevent any chaos. The interview revealed that there are many factors in drug disposal. The

health component (health interest of the people) and the business components (manufacturers seek to make profits). There must be a balance and this is created by the law on both sides where the law protects the interest of both components.

To achieve this balance, all manufacturing companies should seek to register all their products (drugs) in the country to facilitate examination and verification process of the source, batch numbers, dates of production and expiration and quality control.

Public education on the dangers of improper disposal of expired pharmaceutical products by the public should increase encourage persons to return unused and expired drugs in their possession voluntary so that they can be disposed off in a save manner to protect the environment.

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CHAPTER FOUR

SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATIONS

4.1 Introduction

This chapter provides a summary of the research findings draws conclusions and make recommendations to address the research problem. The main objective of the study was to find out the security implications of the influx of pharmaceutical products, how expired drugs, counterfeit and sub-standard drugs are disposed of, the sanctions used to discourage the importation of counterfeit and sub-standard drugs and to investigate the channels through which counterfeit and sub-standard drugs end up in Ghana.

A number of factors contribute to the influx of counterfeit and sub-standard pharmaceutical products Ghana. These include porous borders, inadequate devices or equipment to detect these sub-standard drugs and counterfeit products, inadequate personnel at the border and lack of knowledge and skill and lack of database to track the individual or agency handling the products and non-enforcement of laws. To achieve the objectives of the study, the case study method within the qualitative approach was used. Below are the summary of the main findings of the study

4.2 Summary Findings

Regulations and Sanctions

Ghana has legal frameworks that covers the disposal of unwholesome or unauthorized drugs, related to pharmaceuticals products (Public Health Act, 2012 Act 851) and Environmental Protection Agency Act, 1994 (Act 490). These frameworks however, do not cover expired drugs and damaged drugs. Even though the present practice is for manufacturers, wholesalers and distributors to get FDA's supervision when disposing off their expired

products, there is no legal requisite on how to dispose of unused drugs that have not been classified as contaminated by the FDA. The laws do not provide for disposal of expired and unused drugs which may be found in the public domain. The laws on constant monitoring of approved or cleared drugs are not enforced.

Border Security

- With regards to porous borders, inadequate personnel and qualified personnel to monitor the borders. Also, the issue of smuggling of the products into the country is as a result of the above stated.
- Poor inspection of items brought into the country is a major issue. As a result of this, officials are unable to properly scrutinize all the products brought to the port for assessment.
- Receiving of gifts from persons importing or exporting drugs in to the country.

Channels through which counterfeit and sub-standard drugs end up in Ghana .

- The use of insufficient and sophisticated equipment to validate the huge volume of items arriving at the ports of entry is a worry as the situation put unnecessary pressure on limited personnel working at the entry points.
- Poor altitude of personnel at the various borders are not helping fight the influx menace, this is because they end up receiving gifts from the travelers to fast track the assessment of their goods or products at the border. Hence, there is the need to educate them on the importance of abiding or following the precise process or procedure to avoid any sanctions or fine.

Environmental Impact of Improper Disposal Methods

Poor disposal methods are also a major issue. Expired drugs to be disposed of are dumped directly into the soil without treatment. This action leads to direct contamination of the soil

and groundwater. They are also burnt in the open air leading to release of dangerous gases into the atmosphere.

4.3 Conclusion

This study has provided some answers to why there is an influx of counterfeit and sub-standard drugs into the Ghana by identifying the factors behind the menace. What measures agencies have undertaken measures to curb the counterfeit and sub-standard drug issues in Ghana and the agencies responsible for the implementation of policies, specific roles, prospects and challenges? The findings go to confirm the need to consider strengthening our borders in terms of providing the needed training and equipment or border personnel.

The primary data collected confirms that the major stakeholders that should collaborate to address the influx menace are the FDA, EPA, PC and CEPS who need to be provided with the right training and logistics. Again, government' should be interested in strengthening existing agencies in handling pharmaceutical products as well as cooperating with other agencies and teaming up with foreign agencies. The establishments of sub-regional office in every region in Ghana will enhance the fight against the influx in the country.

Significant challenges like lack of well-planned orderly operations, inadequate allocation of resources by government, lack of knowledge and skill on the part of officials at the border, difficulty in analyzing passengers luggage adequately by the CEPS officials should be tackled with all seriousness including collaboration between local enforcing agencies within the country and inadequate detective devices at the borders.

4.4 Recommendations

Based on the conclusions drawn from the study findings, the study makes four main recommendations. First, the government should include new policy bill, which deals with preventions and support with the agencies by altering the existing laws and examining how

feasible it would be in sentencing defaulters to long prison terms, which will serve us deterrence. Also, the government should frequently revise the legal framework yearly to meet current demands.

Secondly, the FDA and the EPA should collaborate with both local and international scholars in the area of study through workshops and seminars towards developing and improving approaches to curb the border issue. Also, the increment of salary could also deter the officials from receiving bribes to process their product.

Furthermore, there must be a database system used by the FDA and CEPS to track drugs while in circulation. This should help with locating expired drugs, counterfeit and sub-standard drugs in stock or on the market which could be safely disposed of immediately. To ensure that this is feasible, the high rate of mobile phone can be used in the implementation of other policies that needs to be channeled to the urban and rural areas. This could be done via daily or weekly text messages and the media to prompt the public on the harmful drugs on the market. The FDA has put structures in place for the general public to validate the authenticity of drugs which is through a mobile phone platform used in registering point of sale pharmacies and other health facilities in the country

There is also the need to increase public education through the Food and Drugs Authority on the likely risks of inappropriate disposal of unwanted pharmaceutical product. Specific directions should be provided to guide the receiving and disposal of expired drugs to the FDA. Public education on safe disposal of pharmaceutical product should be intensified. Designated locations should be established at the various hospitals to collect expired, counterfeit and sub-standard drugs to be disposed of by the FDA. Again, more sites for disposal of pharmaceutical products should be built far away from communities due to

pollution which may affect the health of people living close to dump sites are mostly centered at known locations like Takoradi and Tema which is close to people

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