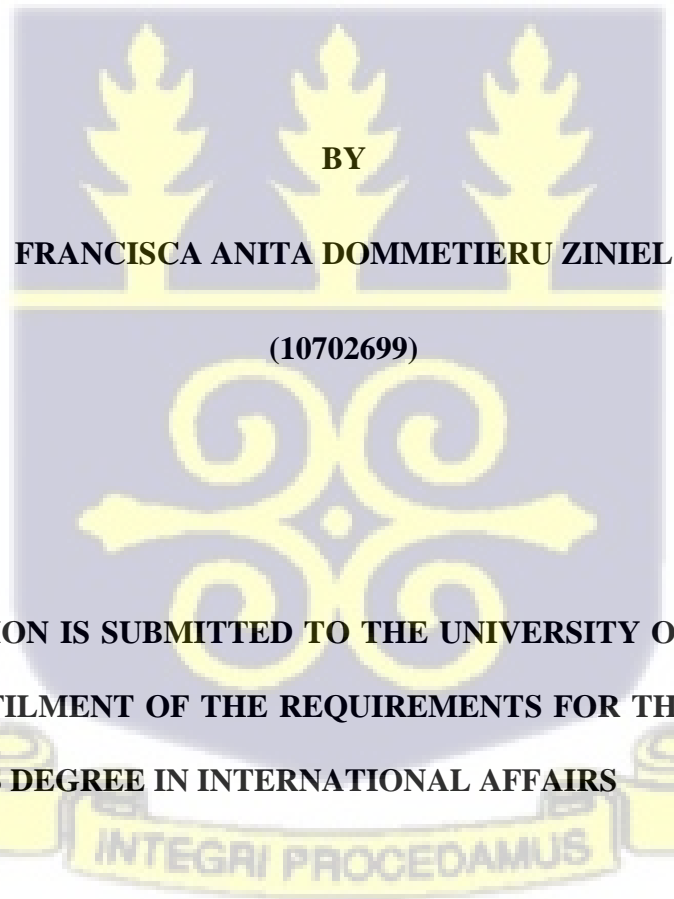


UNIVERSITY OF GHANA

**SOCIO-ECONOMIC IMPACT OF COUNTERFEITMEDICINE/FAKE DRUGS ON
GHANA UNDER SDG 3**

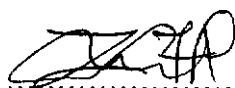


**THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON,
IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE
MASTER OF ARTS DEGREE IN INTERNATIONAL AFFAIRS**

JUNE 2021

DECLARATION

I, FRANCISCA ANITA DOMMETIERU ZINIEL, do hereby declare that apart from references to works of other authors which have been duly acknowledged, this dissertation is the result of my own research work carried out under the supervision of Dr. Mrs. Afua Boatemaa Yakohene. It has not been presented in part or in whole to any institution for the award of a degree.



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(SUPERVISOR)

DATE: 16 October, 2021.

DEDICATION

I dedicate this dissertation to the Almighty for the gift of life, grace, wisdom, guidance and resources to make this dream a reality. I also dedicate this to my husband Ebenezer Ocloo for his unflinching support and to Evans Appiah and Pious for their support when I needed it most.

Finally, to my supervisor Dr. Mrs. Afua Boatemaa Yakohene for her patience, guidance and encouragement without which this work would not have been a reality.

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LIST OF ABBREVIATIONS

ABPI	Association of British Pharmaceutical Industry
ACT	Artemisinin Combination Therapy
ACHAN	Asian Community Health Action Network
AMR	Antimicrobial Resistance
AMRH	African Medicines Regulations Harmonization Initiative
API	Active Pharmaceutical Ingredient
ATM	Access To Medicines
CBTCD	Consumer Behavior Towards Counterfeit Drugs
CEO	Chief Executive Officers
CePAT	Center for Pharmaceutical Advancement and Training
CSOs	Civil Society Organizations
DW	Deutsche Welle
ECOWAS	Economic Community of West Africa
EMLs	Essential Medicine Lists
ENACT	Enhancing Africa's response to transnational organized crime

EU	European Union
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drugs Authority
FIP	International Pharmaceutical Federation
GDP	Gross Domestic Product
GERD	Gross Domestic Expenditure
GFATM	The Global Fund to Fight Aids, TB and Malaria
GMP	Good Manufacturing Practices
HID	Human Development Index
HIV	Human Immune Deficiency Virus
HLTF	High Level Task Force on innovative International Financing for Health System
IFPMA	International Federation of Pharmaceutical Manufacturers and Association
IPR	Protection of Intellectual Property
IRACM	International Institute of Research Against Counterfeit Medicines
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
INTERPOL	International Criminal Police Organization
KAIPC	Kofi Annan International Peace Keeping Training Centre
LMICs	Low and Middle-Income Countries

MDGs	Millennium Development Goals
MSM	Member State Mechanism
MOH	Ministry of Health
NAFDAC	National Agency for Food and Drugs Administration and Control
NEPAD	African Union's technical agency for the implementation of medicines regulatory Harmonization in Africa
NCE	New Chemical Entities
NGOs	Non-Governmental Organizations
NMRAs	National Medicine Regulatory Authorities
NRRA	National or Regional Regulatory Authority
OECD	Organization for Economic Co-operation and Development
OTC	Over-the-Counter Medicines
PHC	Primary Health Care
PMPA	Pharmaceutical Manufacturing Plan for Africa
PSI	Pharmaceutical Security Institute
RAS	Rapid-Alert System
SCMS	Supply Chain Management System
SDGs	Sustainable Development Goals

SF	Substandard and Falsified medicine
SSA	Sub-Saharan Africa
SSFFC	Substandard/Spurious/Falsely labelled/Falsified/Counterfeit Medical Products
TB	Tuberculosis
TOC	Transnational Organised Crime
TRACIT	Transnational Alliance to Combat Illicit Trade
UHC	Universal Health Coverage
UIS	Institute for Statistics
UK	United Kingdom
UN	United Nations
UNDG	United Nations Development Group
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNIDO	United Nation Industrial Development Organization
UNODC	United Nations Office of Drugs and Crime
US	United State
USP	US Pharmacopeia Convention
WAHO	West Africa Health Organization

WHA World Health Assembly

WHO World Health Organization

ABSTRACT

The existence of counterfeit medicines in our world is a known fact to anyone with keen interest. Sadly, the exponential increase in fake drugs' trade is highly rampant in developing countries. In the sub-Saharan, there is a high possibility of finding ten original medicines out of ten. Unfortunately, the drugs that suffer much from this menace are malaria and over the counter pain relievers as these are normally the first point of call in an attempt to manage or relieve pains. Many attribute high levels of poverty, porous borders, weak local and international institutions, inadequate regulatory laws and measures, and illiteracy, among others, to the widespread of counterfeit drugs. This study argued that the overwhelming presence of fake drugs in Ghana is real, and it bears adverse health effects and retards Ghana's socio-economic development. These effects plunge Ghanaians into severe poverty, aside from the many lives lost to fake drugs. To adequately assess the problem and proffer a solution, the study deployed the health security theory. This theory enables the research to evaluate the effectiveness of the nation's measures vis-à-vis the proliferation of counterfeit medicines and health threats and the other resulting consequences. The study employed both qualitative and quantitative research design to enable its use of primary and secondary data using random sampling. To enrich its primary data, it used questionnaires and structured interviews. It randomly selected about fifty respondents in Accra and Tema metropolis and interviewed the representatives of two regulatory agencies and two manufacturing industries. The study also used the Frequency tables, graphs and charts to analyse the data. The study found that the nation had chalked some success in the measures to decrease fake medicines on the market, such as international-local institutional partnerships, FDA's post-market surveillance, improved FDA's Medical Regulatory System, and modern technologies. The study also noted some challenges including inadequate officers for post-market surveillance, and low compliance with the FDA's guidance on GDP.

CHAPTER ONE

INTRODUCTION

1.0 BACKGROUND TO THE RESEARCH PROBLEM

In 1985, the International Conference of Experts on the Ethical Use of Drugs in Nairobi raised the issue of counterfeit medicines for the first time. The meeting concluded by recommending that WHO, in collaboration with other foreign and non-governmental organizations, investigate the feasibility of establishing a clearinghouse to collect data and educate governments about the existence and scope of counterfeitingⁱ. However, the WHO officially condemned the practice in 2006 by producing the Declaration of Rome, which says Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.ⁱⁱ The Declaration of Rome was the first acknowledgment that tackling the issue of counterfeit drugs requires "effective coordination and cooperation at the international level for regional and national strategies to be more effective" (V Li, 2014).ⁱⁱⁱ

Following the Declaration, the WHO member-states pledged to work together to address the global challenge of pharmaceutical counterfeiting by founding the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) on February 18, 2006, in Rome. The IMPACT was the first multilateral partnership set up specifically to tackle this increasingly worldwide issue. It included representatives of 193 national governments and their respective National Medicine Regulatory Authorities (NMRAs), pharmaceutical manufacturers, Non-Governmental Organisations (NGOs), and the International Criminal Police Organization (INTERPOL), the largest global police organisation. IMPACT's founding intention was to eradicate counterfeit drugs from all supply

chains by 2015. To accomplish this mandate, the IMPACT focuses on five specific areas that require international action. They are:

1. Encouraging national governments to establish laws, or strengthen existing legislation, against pharmaceutical counterfeiters;
2. Improving regulation to ensure that suitable agencies (NMRAs) are responsible for monitoring all manufacturers, exporters, distributors and retailers of pharmaceutical;
3. Working with Interpol to break up counterfeit smuggling networks and track the flow of drugs. IMPACT offers courses to national police services on how to tackle the problem and trains 300 law enforcers specialising in anti-drug counterfeiting every year;
4. Offering education on how they can use technology in specific countries for detecting counterfeit drugs; and
5. Raising awareness of the risk of counterfeit pharmaceuticals for both government policymakers and the general public^{iv}.

According to Veronica Li, the WHO has achieved some successes in harmonising and coordinating the fight to eradicate counterfeit pharmaceuticals. As well as universally defining counterfeit medicines and founding IMPACT, they have also taken innovative steps to improve the reporting of counterfeit drugs around the world through the online Rapid-Alert System (RAS), allowing NMRAs to report batches of counterfeit pharmaceuticals quickly. RAS has been piloted successfully in the Western Pacific region, where it is said to have improved up to date monitoring of the situation and promoted the swift follow up of reported cases by the police. A worldwide expansion of RAS will help improve the coordination of the global response against fake drugs (V Li, 2014).

Veronica Li in her research noted that, however, after examining the prevalence of counterfeit pharmaceuticals currently in worldwide circulation, it is fair to say that the WHO's goal of eradicating counterfeit drugs by 2015 was not achieved, even though their representatives still believe it is achievable in the near future and this is because of the increased national and international awareness creation, monitoring and various legislatures and punitive measures to dealing with the problem. Moreover, the international trade lawyer Amanda Chaves argues that the WHO's current focus on improving national awareness and legislation will not alone be effective in eliminating counterfeit drugs from the supply chain.^v Amanda Chaves further claims that a more effective solution would be to enact a multilateral treaty to make pharmaceutical counterfeiting an international crime. Since in legal terms, crimes are escalated to international crimes if they "amount to an offence against the entire international community," and since they increase drug resistance, falsified pharmaceuticals fall under this rubric^{vi}. Aircraft hijackings and narcotics trafficking have been made international crimes by way of international treaties in recent decades, and Attaran argues that drug counterfeiting confers similar dangers to life. The WHO Constitution of 1948 permits the organisation to "propose conventions, regulations and recommendations" on matters of public health, and, if a 'supermajority' of two-thirds of member states agree, a treaty can be adopted (Attaran A., Bate R., Kendall M. (2011)). The WHO has only once exercised its power to make treaties with the Framework Convention on Tobacco Control (FCTC), which included drafting an international law against the illicit trade of tobacco products. This treaty set a public health precedent that the WHO should be able to use in the future to make pharmaceutical counterfeiting an international crime.

International governance is particularly crucial for stopping counterfeits in sub-Saharan Africa (SSA) because Bilateral and multilateral donors and aid agencies import many of the drugs into

the. Many of these philanthropic agents do not ensure that the quality of the medicines they send is reliable (Bate, R. (2008). The Global Fund to Fight AIDS, TB, and Malaria (GFATM) spends millions of pounds every year to distribute essential drugs to Africa, but only 56% of these drugs come through suppliers approved by the WHO.^{vii} Although no studies have examined the quality of the medicines brought into SSA by donors, the lack of regulation may lead to them unknowingly bringing counterfeit drugs into the supply chain. Essentially, WHO and IMPACT hold these aid agencies accountable for the sourcing of their medications. She further observed that according to the World Health Organization (1999) Guidelines for the Development of Measures to Combat Counterfeit Drugs, despite this being a globalised issue, it is over-simplistic to suggest that there is a standard solution applicable to all countries trying to eradicate the problem. Alongside the work done by the international community, every country has its particular role to play in tackling the counterfeit of pharmaceuticals^{viii}. The report suggests that all nations within SSA have different degrees of dependency on domestic and overseas manufacturing of drugs as well as uniquely different supply chains and distributors, which impact the frequency and dissemination of counterfeit medicines within that country. Therefore, each state has to develop policies based on its situation, infrastructure, and resources. The experience of Nigeria provides an instructive case study for SSA. Many usually cite Nigeria as a nation that has gained notoriety for saturating the African pharmaceutical market with fake drugs but has recently attempted to regain its reputation in world markets by implementing innovative policies to thwart counterfeiters (Pete Kingsley, 2014). The researcher pointed out estimating the global market of counterfeit as one major challenge in the study. Although counterfeit pharmaceuticals represent a truly globalised problem, the prevalence of fake drugs in different countries varies widely: counterfeit drugs account for up to half of drug sales in the poorest countries in Sub-Saharan Africa (SSA), but only about 1% in

the developed world. Generally, almost all types of drugs have been counterfeited, but different types are counterfeited in different regions of the world^{ix}. In the developed world, counterfeiters tend to focus on expensive lifestyle medications such as anti-allergic agents and Viagra. However, in the developing world, where there is a huge burden of infectious disease, counterfeiters target life-saving drugs for deadly conditions like malaria, human immune deficiency virus (HIV), and tuberculosis (TB).^x Thus, counterfeit medicines also play a role in magnifying global health inequalities. The high rate of health inequalities, also estimating the prevalence of counterfeit in Sub-Saharan Africa was also noted as a challenge. While the wealthiest countries offer the most lucrative market for counterfeiters, they also have the most advanced techniques for combatting them.^{xi}

In contrast, the lowest third of WHO member states have either no means or minimal means of controlling counterfeit medicines.^{xii} Numerous countries in the sub-Saharan region of Africa, which accommodates 15 poorest countries in the world, according to the Human Development Index (HDI) account for states with limited fake drugs control mechanisms. The WHO estimates that 30% of all medicines in Sub-Saharan Africa (SSA), as opposed to 1% in the developed world, may be counterfeit, suggesting a link between impoverished regions and their inability to restrict counterfeit medicines. Veronica Li further stated that, unfortunately, the sub-Saharan region of Africa offers minimal or no national reporting on seizures of counterfeit drugs. Published data seems to underestimate the prevalence of falsified medicines in SSA. Over 90% of worldwide malaria deaths occur in Africa, creating a vast market for criminals to produce counterfeit antimalarials in the region. Besides, in 2006, the WHO changed its official guidelines for treating malaria to Artemisinin Combination Therapy (ACT) which although more efficacious than chloroquine, costs between five and 23 times as much to manufacture. As a result, this market has

become incredibly lucrative for counterfeiters. Nayyar's survey published in *The Lancet* found that 35% of 2297 antimalarials sampled from across SSA were of sub-therapeutic quality.

The Sustainable Development Goals (SDGs), also known as the Global Goals, were adopted by all members of the United Nations (UN) in 2015 as a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity by 2030. Seventeen integrated sustainable development goals recognise an effort in one area will affect the outcome in another. As such, development must balance social, economic, and environmental sustainability with 167 targets, which must be measurable and applied to both developed and developing countries.

The UN's SDGs place a significant emphasis on populations' health, and SDG 3 aims to 'ensure healthy lives and promote wellbeing for all, at all ages' and sub-target 3.8 access 'to safe, effective, quality and affordable essential medicines and vaccines for all.' Yet, remarkably missing from the discourse around achieving SDG 3 is the need to address the growing phenomenon of counterfeit medicines, which disproportionately affects developing countries.

Universal health coverage (UHC) is the goal of ensuring that everyone has access to the necessary health care they require without facing financial hardship, and it is at the heart of the Sustainable Development Goals' health-related targets (SDGs). As stated in SDG target 3.8, UHC is both a goal in and of itself, as well as the most rational strategy to assure progress toward other health-related SDG targets. ealth coverage (UHC) is the goal of ensuring that everyone has access to the necessary health care they require without facing financial hardship, and it is at the heart of the Sustainable Development Goals' health-related targets (SDGs). As stated in SDG target 3.8, UHC is both a goal in and of itself, as well as the most rational strategy to assure progress toward other

health-related SDG targets.^{xiii} The health goal (SDG 3) comprises nine substantive targets and four extra targets that serve as implementation targets. One of these commitments, achieving universal health coverage (UHC), has been identified as critical to meeting all of the other health goals. According to the SDGs, universal health coverage (UHC) encompasses financial risk protection, access to high-quality essential health-care services, and universal access to safe, effective, high-quality, and affordable necessary medications and vaccinations.^{xiv} In 2015, Secretary-General Ban Ki-moon announced the formation of a High-Level Panel on Innovation and Access to Health Technologies to address inconsistencies and improve health technology research and development (R&D) as well as people's access to essential therapies, whose prices are out of reach for both patients and governments. “Governments should negotiate worldwide agreements on the coordination, financing, and development of health innovations to complement existing innovation models, including a binding R&D Convention that decouples R&D costs from end prices,” the panel suggests. The Panel also emphasizes the harmful impact of lack of openness on both health technology innovation and access, according to Mariana Roldo Santos. The WHO agrees, citing two recent initiatives on health technology R&D incentives: the Global Antibiotic Research and Development Partnership, a joint venture between WHO and the Drugs for Neglected Diseases initiative (DNDi), and the R&D Blueprint for Epidemic Prevention. In the coming year, the Lancet Commission will release a report on essential medications for UHC, recommending changes to the current Intellectual Property (IP) system, the development of new commercial models, and public-private partnerships. She went on to say that assured access to essential and high-quality medicines occurs when there is a) public and private commitment, b) effective and transparent medicine policies, and their appropriate implementation, c) strong health systems and regulatory authorities, d) adequate public financing and human resources, e) efficient supply chain and distribution

systems, f) tax and duty control, and g) ethical promotion and rational use of medicines, as well as control of the pharmaceutical industry. Governments, intergovernmental and multinational organizations, NGOs, private sector enterprises, and academics, among others, must collaborate on this complex collection of activities. Distinct stakeholders have different responsibilities to play in implementing good measures that seek to remove existing hurdles while also creating new opportunities, and their contributions will only be effective if they all work together toward the same goals.

As a result, the study focuses on SDG target 3.8, which is to achieve universal health coverage for all people, including financial risk protection, access to quality essential health-care services, and access to safe, effective, high-quality, and affordable necessary medications and vaccinations.

According to LaKeisha Williams and Ellen McKnight, many have defined counterfeit drugs as *products deliberately and fraudulently produced and or mislabeled concerning identity and or source to make it appear to be a genuine product*. Counterfeit medications include drugs that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products. Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions. Counterfeiting can apply to both branded pharmaceuticals and their less expensive generic counterparts. Fake Drugs is a Public Health Concern, and counterfeiting drugs is not only illegal, but it is also a significant public health concern. Counterfeit drugs often contain the right ingredients in incorrect quantities; however, they may also include either a wrong API, which may even be toxic or no active substance at all. Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and. In extreme cases, counterfeit drugs may even cause death.^{xv}

But the International Institute of Research Against Counterfeit Medicines (IRACM) says there is no proper definition of "fake medicine." The term is occasionally employed and is used in the "Cotonou Appeal" of the Jacques Chirac Foundation^{xvi}. Fake medicine is a drug that is not what it claims to be and which intends to mislead the consumer. Counterfeit medicines put people's lives at risk; finance criminal groups and cause profound public health challenges. The full scale of the challenge in Africa is not fully understood, but some research suggests that the problem and its impacts are severe. If the continent is to make headway in achieving SDG 3, the issue of counterfeit medicines must move higher up on policy agendas (Cartwright and Baric, 2018).

The proliferation of counterfeit medicines in the world and Africa has strongly attracted the attention of many governments to address the canker. The World Health Organization (WHO) has estimated that more than 120,000 people a year die in Africa, Ghana included, as a result of fake antimalarial drugs, not mentioning other drugs. The death is said to be as a result of sub-standard medicines or simply because the drugs contained no active ingredients at all. Fake drugs could contain incorrect doses, wrong ingredients, or no active ingredients at all. At the same time, a worrying number of authorised medicines fail to meet quality standards because of improper storage and other issues. The scale of the problem is hard to quantify precisely, but a WHO pooled analysis of 100 studies from 2007 to 2016, covering more than 48,000 samples, showed 10.5 per cent of drugs in low and middle-income countries to be fake or substandard (LK Williams, 2014). According to LaKeisha Williams and Ellen McKnight, with pharmaceutical sales in such countries running at nearly \$300 billion a year, this implies that trade in fake medicines is a \$30 billion business. WHO commissioned a team from the University of Edinburgh to study the impact of counterfeit drugs. And the team suggest that the human toll is enormous. They calculated that up to 72,000 deaths from childhood pneumonia could be attributed to the use of antibiotics with

reduced activity, increasing to 169,000 deaths if drugs had no activity. The World Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce, or \$21 billion worth, involves counterfeit drugs, drug counterfeiting. However, not a new phenomenon, has provoked more serious concern because it has become so widespread in recent years. A WHO study revealed that nearly one-half (48.7%) of the documented cases of drug counterfeiting was reported in developing countries of the Western Pacific (China, the Philippines, and Vietnam), followed by developing countries grouped within WHO's Regional Office for Africa, with 18.7%. The industrialised areas of WHO's Regional Office for Europe came in third, with 13.6% of reported cases. Many have estimated that approximately 1% of counterfeit medications occurs in the US' pharmaceutical market, but the numbers are increasing annually. Most US counterfeit medications are purchased online; however, others have infiltrated legitimate supply chains. But LaKeisha Williams and Ellen McKnight noted that the growing issue of counterfeit medicines is a concern not only for the patient but also for pharmacists and pharmaceutical companies, as many of them are folding up due to the competition with producers of fake and cheap medicines. Wertheimer et al. state that the magnitude of the drug-counterfeiting problem is difficult to gauge. Since the crimes of producing and selling counterfeit drugs generally become known only when state agencies apprehend the perpetrators, any accurate determination of prevalence is difficult. The World Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce or \$21 billion worth involves counterfeit drugs.

1.1 Statement of Problem

On January 10, 2018, a Deutsche Welle (DW) team from Germany was in Ghana to ascertain from some institutions and residents in Accra about their knowledge of counterfeit drugs. From Stella Oneko's report published in the Mail and Guardian on January 11, 2018, some residents they spoke

to had no clue about counterfeit medicines, and those that did were afraid of buying medication for fear of not being able to buy the correct one. The Food and Drugs Authority (FDA), in collaboration with other bodies, have impounded and arrested various people indulging in the production, importation, and trade of fake medicines. The CEO of the FDA, Delese Darko stated that the production and trafficking of falsified medicines is a multi-billion illegal business, which is primarily sustained by the lure of high financial gains combined with the perceived but low risks of detection. A Pfizer-sponsored study, one of the most extensive investigations conducted in 14 European countries estimated that Western Europeans spend more than US\$ 14 billion a year on illicitly-sourced drugs, many of them counterfeit. Ghana has not been left out in this fight as its Parliament passed a new Public Health law, giving the FDA the full legal backing to prosecute importers, retailers, and other players in the business of this Counterfeit medicine trade from July 11, 2012.^{xvii}

Debates on possible counterfeit medicines' effects on individuals and countries' economy dominate among concerned researchers and agencies/institutions. They are also concerned about governments and the various stakeholders' in curbing the spike in fake drugs, such as the FDA, Chamber of Pharmacy Ghana, Ghana Health Service, and Ghana Drugs' manufacturers.

The 3rd UNs' SDG 3.8 shows the need to "achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all." However, the proliferation of fake/counterfeit drug/medicine poses a severe hazardous implication on the health of citizens, their economic and social life, and that of the country's economic growth. The issue with counterfeit medicines clearly undermines the access of individuals to quality, safe, effective, and affordable medicines and vaccines. It is a dangerous risk to those that consume such drugs due to its fake

branding or alteration, which may include the wrong ingredient which is harmful to the individual. The counterfeit medicine trade leads to a complete revenue loss to the country since they are usually smuggled into the country via unapproved routes. The illegal trade also causes financial loss to companies and individuals who are in the genuine production or marketing of medicines. This research is to investigate the social and economic effects of counterfeit and fake drugs on Ghana under SDG 3.8.

1.2 Research Questions

1. What are counterfeit drugs, and why is the trade booming in Africa?
2. What are the socio-economic effects of counterfeit drugs on Ghanaians, including the economic growth of pharmaceutical and chemical companies?
3. What efforts are being put in place to address the issue of counterfeit drugs to meet SDG 3.8?
4. What are the successes achieved, challenges faced, and the way forward for Ghana?

1.3 Research Objectives

1. To ascertain what counterfeit drugs are and reasons for its trade boom in Africa.
2. To assess the socio-economic effects of counterfeit drugs on Ghanaians, including the economic growth of pharmaceutical and chemical companies.
3. To investigate the efforts to address the issue of counterfeit drugs to meet SDG 3.8.
4. To discuss the successes achieved, challenges faced in the measures undertaken, and the way forward for Ghana.

1.4 Scope of the Study

The period of investigation is from 2009 to 2020, the case study is in Ghana, and it is limited to the city of Accra. The scope of the study is confined to:

- Dwellers within the cities of Accra and Tema;
- Some identified Government agencies in the provision of health;
- Some identified Companies in the production of medicines; and
- Some identified Companies in the distribution chain of drugs.

1.5 Rationale of the Study

The investigation intends to uncover the harmful effects of counterfeit medicine on the individual and the country, bring to light policies that are to help solve the problem, achieved successes and challenges faced. In this regard, the research will contribute to the discourse and scholarship on measures to address the adverse effects of counterfeit medicines on the socio-economic growth of the people in Ghana. The study seeks to discover, to learn, to inform, and educate.

1.6 Thesis Statement

The counterfeit medicines trade has adverse health effects on the socio-economic development of Ghana.

1.7 Conceptual Framework

The study uses health, foreign policy and security as its conceptual framework. The term "health" has several different connotations. The absence of a medically defined and certified disease is the focus of traditional biomedical approaches to health. Health, on the other hand, can be viewed as a comprehensive ideal state, as stated in the preamble of the World Health Organization's Constitution (1946): "Health is a state of complete mental, physical, and social well-being, not only the absence of sickness or infirmity." The way health is defined and applied can have a big impact on policy issues. For example, in the existing literature on global health security (Lee and McInnes 2003), sickness is referred to as health, whether it is actively transmitted through bioterrorism or emerges in the form of acute epidemic diseases. This has resulted in a narrow focus, whereas a broader definition would allow for the inclusion of additional problems on the agenda.

Health security is a major requirement of human security. In the context of global health security, there is also a distinction to be made between clinical medicine and public health. Clinical medicine is concerned with individual health issues, whereas public health is the action taken by society to safeguard and enhance the health of communities. The study used the WHO's broad definition of health, dismissing alternative definitions as being too restrictive to cover the whole spectrum of issues. In its preoccupation with protecting (but possibly not enhancing) population health, the concept of global health security also implies a public health approach as the starting point. For example, the referent object of international security remains a matter of considerable controversy within the academic discipline of International Relations and its sub-discipline security studies. Traditional methods to security studies identify the state as the referent object, as defined by McInnes (2004b). Over the last two decades, this viewpoint has been under sustained

attack, resulting in an expansion of the security studies area to incorporate new types of security and their drivers. While it is impossible to bring all of the many perspectives from the various scholarly and policy sectors concerned with global health security together, this program of work aims to find some common ground. One area of agreement is the need to go beyond a singular focus on the state as a unit of study. While maintaining a central role, it is commonly acknowledged that causes and consequences that cross, and even circumvent, state borders are a significant component of global health security, and that communities inside nations may have global health implications or arouse external actors' concerns. The referent object in foreign policy is unquestionably the state. The national interest, on the other hand, is not simply understood as the promotion of narrow self-interest, but is moderated by other variables. Many people believe that as a result of globalization, countries will be unable to distinguish their own interests from greater global issues. Second, values are important, but they are more important in promoting national ideals than in promoting a more global perspective. Most major foreign policy pronouncements emphasize the importance of the global good, as well as humanitarian commitments that may, on rare occasions, transcend national interests. Although some may contest the existence of a conflict between humanitarianism and national interests, most recognize the possibility for conflict, and the question of when a humanitarian commitment may 'trump' national interests remains unresolved. All of this implies that, while the state remains the major referent object in foreign policy, there is sensitivity to global as well as local (and even individual) issues. (Lee et al., 2015)

According to McInnes (2004a), the foreign policy community evaluates health issues on an ad hoc and pragmatic basis rather than based on a systematic understanding of the subject. Based on the policy statements examined, a number of elements may assist a global health concern in gaining traction on the international agenda. When a global health crisis becomes a humanitarian

catastrophe, or is threatening to become one, when economic development is threatened, when regional stability is challenged, and when health issues are part of trade negotiations are among them. Feldbaum and Lee (2004), however, believe that in these conditions, an issue is deemed a global health security issue within the public health community.

1. Population versus individual health - a global health security concern affects population health (i.e. public health) rather than individual health.
2. Morbidity/mortality (high vs. low) - A global health concern is one that has a high level of morbidity or mortality (i.e., causes a high rate of death and/or sickness).
3. Short-term vs. long-term health consequences - a global health security issue is one that poses a "clear and present danger" to population health. (e.g., a bioterrorist assault using smallpox) rather than a long-term impact (e.g., a bioterrorist strike using smallpox) (e.g. ageing).
4. Intra-border versus cross-border/transborder – a global health security concern is one that has an impact on multiple countries.

In both McInnes (2004a) and Feldbaum and Lee (2004), fake and counterfeit medicines is a global health security concern as it impacts on multiple countries, present clear dangers to population health, can threaten economic development and can also challenge regional stability.^{xviii}

A global dispute has erupted over the best ways to combat the illegal trade in what have historically been referred to as "counterfeit pharmaceuticals." Ideological and economic arguments over public health concerns, intellectual property rights (IPRs), and equitable access to medicines have resulted in a slew of related but disparate terms attempting to define the problem, including: 'spurious,' 'substandard,' 'falsified,' 'falsely-labeled,' 'fraudulent,' 'unregistered,'

'counterfeit,' 'fake,' and (SSFFC)^{xix}. Fake/falsified/fraudulent, poor quality uncontrolled medications, generally known as "counterfeit medicines," are now endemic in the worldwide drug supply chain, posing a significant threat to public health, patient safety, and shared global health security. Counterfeit drugs can be found in a variety of settings, including established healthcare settings and uncontrolled sectors such as the Internet. These lethal medications are spreading in therapeutic and geographic reach, endangering patients' lives, contributing to antimicrobial resistance, and enriching criminals (Mackey TK, Liang BA 2011).^{xx} Despite the numerous, complex, and fractious intersecting political, ideological, and policy issues embedded in the term 'counterfeit medicines,' ongoing arguments over terminology have diverted attention away from the actual global health crisis, namely the continued widespread availability of counterfeit medicines in a variety of settings that are hazardous to public health (Mackey 2013)^{xxi}. At the moment, there is no comprehensive global health governance structure in place to deploy health diplomacy and a wide range of stakeholder resources to confront this significant type of transnational pharmaceutical crime that has a negative impact on public health. Despite apparent global public health hazards, counterfeit pharmaceutical surveillance is severely lacking, with existing data indicating an expanding global illicit trade that has yet to be adequately tackled. Efforts by a range of public and private sector enterprises, national governments, and international organizations have made progress against this illegal activity, but they have been hampered by ineffective governance and competing interests. (Mackey 2013) The World Health Organization, the principal international public health agency, has recently failed to fully incorporate the wide range of stakeholders required to tackle the problem. In order to cover this policy void, other institutions such as the UN Office on Drugs and Crime and Interpol have been tasked with combatting counterfeit pharmaceuticals.

A country's foreign policy is designed to protect and advance its national interests in bilateral and multilateral interactions with other countries. It reflects a country's traditional values and overarching national policy, as well as its goals and self-perception. As a result, foreign policies are the tactics, methods, guidelines, and agreements that are typically used by national governments to achieve their objectives and carry out their actions on a global scale. In today's world, every state establishes diplomatic, economic, trade, educational, cultural, and political ties with other countries, necessitating the maintenance of these ties as well as international relations.

Therefore, using Health Security as a national security and a foreign policy as its conceptual framework

Health security law and legal definitions define health security as the assurance that one's health is excellent, and that if it isn't, there are resources available to help one get back on track. Its goal is to provide the bare minimum of protection against diseases and bad lifestyles. Malnutrition and a lack of access to health services, clean water, and other basic necessities make health security threats more severe for impoverished individuals in rural areas.^{xxii} (Muller and Krawinkle, 2005).

The highlights of responses to the issue of what health security is were provided by various perspectives. "Health security" includes policies, strategies, objectives, and activities that reduce the vulnerability of public health risks such as pandemics, emerging infectious illnesses, bioterrorism, disease outbreaks, malnutrition, and dual-use research, according to Khana. (Bilal Khan, 2016). Hafeez posits that "health security is a collective effort to secure a world free from infectious diseases and other factors which are harmful to human health and life. To achieve this goal, all nations and international organisations must work in conjunction with each other (Saleha Hafeez...).

Iyas thinks that:

Health security deals with addressing all the health issues of the public by implementing policies and preventive measures to eradicate these issues on a national and international level, whether it is an outbreak of some infectious disease or other risks posed by chemical/biological agents harmful to the natural environment and global health. (Sadaf Ilyas ...) ^{xxiii}

From the above different responses to the question of what Health Security is, the challenge of having an acceptable definition and scope is glaring as other researchers have mentioned that many consider Health security as an essential part of human security. But policymakers and health professionals, however, do not share a common definition of health security (YW Chiu 2009). What is 'health security'? Despite the availability of a vast literature on 'human security', 'health security' and 'global public health security', there is no universally agreed definition of health security. Widespread but inconsistent use of the term by global public health stakeholders with widely divergent perceptions, priorities and agendas has created confusion and mistrust (William Aldis, 2008).

The preamble of the 1946 constitution of the WHO refers to "...happiness, harmonious relations and security of all people". The constitution states that "the health of all peoples is fundamental to the attainment of peace and security" (WHO 2005a). Aldis, however, noted that "security" as used here seems to refer to "health and security" (the contribution that health makes to global security) rather than "health security" (securing health itself). He further pointed out the need for a potentially useful distinction between "health and security" and "health security," which he noted some authors used interchangeably.

Aldis noted that because problems around the concept of "health security" occur at the intersection of several fields or disciplines, which do not share a common theoretical approach or academic methodology, it is difficult to proceed from any unified theoretical approach. However, this might be useful to further study of these complex issues. Diverse players in the fields of security studies, foreign policy, and international relations, developing countries themselves, even within the UN system, there appear to be significant differences in understanding and application of the concept of "health security," for example, between the United Nations Development Programme (UNDP) and the World Health Organization (William Aldis, 2008). But Lancet also argues that WHO has not fully addressed the broader questions on the definition, scope, and implementation of 'health security' (Lancet 2007). But Baldwin's questions security borders on Security for whom? Security for which values? How much Security? Security from what threats? And Security by what means? (Baldwin 1997)^{xxiv}.

William Aldis argues that a good point of departure in assessing the proper role of 'health security' concept in today's global public health is to put it into the context of established understandings and approaches. Is the emphasis placed on protection against threats consistent with pre-existing public health approaches, such as those based on primary health care and district health systems? Perhaps because the health security concept originated outside the public health community, very little attention has been given to its added value concerning existing public health concepts. Does health security supplement, replace, or conflict with existing approaches? (Aldis, 2008) Richard Jolly noted that the main difficulty in analysing the place of the health security concept in relation to existing public health approaches is the problem of inconsistency in definition and understanding of the concept, as described above. For those who understand health security the UNDP's 1994 Human Development Report represents it, the concept is not incompatible with a

primary health care approach, emphasising community involvement, self-sufficiency, and protection of vulnerable groups such as pregnant women and the poor. But if health security is defined exclusively in terms of protection of national populations against external threats such as bioterrorism, the concept becomes disengaged from usual public health epidemiologic approaches, which measure and respond to differential levels of risk and disease burden within populations. Several opinion leaders on human and health security understand these contradictions well (Jolly and Ray 2007), but remain unresolved. To the extent that it is not responsive to the particular needs of the most vulnerable, the theoretical and operational underpinnings of 'health security' (and more importantly, the benefits to individuals, families, and communities, especially in developing countries) remain obscure.

Despite the above complications, the WHO has stated unequivocally that 'functioning health systems are the bedrock of health security' (WHO 2007c). The cost of these commitments should not be under-estimated; it is much more expensive to develop and maintain a national health system than to introduce national communicable disease surveillance and outbreak containment alone. But failure to do this may result in a breakdown of health security for rich and poor alike. But health security together with the introduction of a threat protection mentality, foreign policy agendas, military interests, and bioterrorism concerns into global public health, under the concept of global public health security, have subtly altered our understanding of global public health. A re-assignment of policy priorities and re-allocation of resources is underway (Staiti et al. 2003; Feldbaum et al. 2006), without sufficient clarity on definitions of intent (particularly surrounding the concept of 'security'), and without a consensus of the global community (Shashikant 2008). Developing countries are unlikely to accept a 'global health security' justification for international agreements that are not perceived to benefit all countries.

Health security critiques have raised concerns about how a predominantly North America and Europe has used its interpretation of risk and susceptibility to define health security discourse internationally. With substantial financial and political power, many high-income countries can project their foreign policy priorities and state security interests during the design and implementation of large-scale global health and humanitarian programmes. UNDP made no effort to underplay how the infection of people in the USA and Europe with the Ebola virus coincided with a commitment from the international community to respond to this outbreak, many months after the first case was registered. This delay makes a mockery of the shared susceptibility and responsibility discourse, which global health security advocates espouse. Usually, problems around the concept of 'health security' occur at the intersection of several fields or disciplines that do not share a common theoretical approach or academic methodology. The diverse fields or disciplines generate the difficulty to advance a unified theoretical approach regardless of the usefulness of the approach to guide a further study of these complex issues.

Diverse players in the 'health security' game include practitioners in the fields of security studies, foreign policy and international relations, development theory and practice of United Nations (UN) agencies and others, and in health development in developing countries themselves. Even within the UN system, there appear to be significant differences in understanding and application of the concept of 'health security', for example between the United Nations Development Programme (UNDP) and the World Health Organization (WHO). With only a few months remaining before member states of the UN convene in New York to finalise the SDGs, health advocates should question the resurgence of global health security and seek the disentanglement of the perceived vested interests of a minority from the overwhelming needs of the majority as a concept with its different understanding, approach, scope and definition. The fact that health security concept is

still being developed and added on daily make it fit as a conceptual framework for the study also because of its different understanding, approach, definition and scope.

In a number of high-level policy statements, health concerns have been framed as international security threats. Gro Harlem Brundtland, as Director General of the World Health Organization (WHO), argued that health was an underlying determinant of development, security, and global stability, and that the functional separation between domestic and international health policy had lost its meaning in an interdependent world.

1.8 Conceptual Definitions

Counterfeit medicine: The World Health Organization defines a counterfeit medicine as a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source.^{xxv}

Fake drugs: Fake medicine is a drug that is not what it claims to be and which intends to mislead the consumer. (Cartwright and Baric, 2018)

Medicine: Medicine is the science that deals with health and healing. It consists of nurses, doctors, and other specialists. It covers disease diagnosis, treatment, and prevention, as well as medical research and a variety of other topics. (Alana Biggers, 2018)

Pharmaceutical: According to Definitions, Pharmaceutical as a drug or medicine that is prepared or dispenses in pharmacies and used in medical treatment.^{xxvi}

Health security: According to the US Health security and legal definitions, health security is the awareness of being secured that health is good and if not there are ways to obtain care to return to

good health. It aims to guarantee a minimum of protection from diseases and unhealthy lifestyles.

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Bioterrorism: According to the CDC, bioterrorism is defined as the deliberate release of viruses, bacteria or other agents used to cause illness or death in people, and also in animals or plants.^{xxviii}

Public Health: Acheson defines Public Health as "the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society" (Acheson, 1988; WHO).

Human Security: The Commission on Human Security defines human security as protecting "the vital core of all human lives in ways that enhance human freedoms and human fulfilment."^{xxix} (Alkire, S. (2003).)

Foreign policy: Foreign Policies are the strategies, methods, guidelines, agreements that usually national governments use to perform their actions in the international arena (Jesmine Ahmed, 2019).

1.9 Literature Review

This section reviews existing literature in the area of study as it enables me to bring to light the issues that scholars and researchers have already discussed in the area of this study.

Veronica Li stated that due to the underground nature of the counterfeit drug business, it is difficult to get a good figure for the global scale of the trade. Still, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) asks how one can "measure a market, which, by its nature, is illegal"? Therefore, one needs to treat all estimates with caution. This vacuum in data has caused

published estimates of counterfeits to vary from one to 50% of all global pharmaceuticals. Media speculation on the subject is frequently sensationalised. A commonly cited statistic originating from a Chinese state newspaper claims that "192,000 people die every year in China as a result of counterfeit drugs," but this has since been proven to be a mistranslation. The actual statement was that "192,000 people die of irrational drug use every year in China", which includes deaths by inappropriate prescriptions and poor pharmaceutical compliance. Therefore, the figure cannot be used interchangeably with counterfeit pharmaceuticals. Even the data cited by trusted international agencies are based on little more than informed guesswork: the WHO estimates that 10% of the world drug trade is counterfeit and IMPACT put the figure between 10 and 30%, but neither of these organisations based their figures on published scientific research (V Li, 2016).

In addition to the reliability of available research problems, there are also claims that some institutions and agencies keep important data about counterfeit drugs in secret. The WHO does not mandate countries to keep records or report incidences of drug counterfeiting. Thus, nearly all prevalence records in the public domain come from those detected by private pharmaceutical companies. Many have argued that a large amount of data regarding false drugs is being withheld from the public as fake drugs damage the brand image of pharmaceutical companies. A spokesperson for the Association of the British Pharmaceutical Industry (ABPI) who said that it is a challenge to declare a counterfeit drug problem without "damaging legitimate business" highlighted the issue. The researcher mentioned some issues as factors encouraging pharmaceutical counterfeiting, including high prices and low overheads. The researcher noted that pharmaceuticals represent a financially attractive field for counterfeiters because according to the WHO, over 70% of counterfeit drugs contain insufficient or no active pharmaceutical ingredients (API). Hence, ingredient costs are minimal, and some of the more rudimentary fake pills contain

just flour or chalk. Production does not require extensive infrastructure and the necessary technology is readily accessible to many counterfeiters who use only crude facilities to produce drugs: many are made in small cottages or backyards.

Unlike legitimate pharmaceutical producers, counterfeiters do not have to go through quality assurance procedures, meet Good Manufacturing Practices (GMP) standards or have an outlay on future research and development, all of which result in lower overhead costs. They are high-priced vis-a-vis their bulk and have an infinite capacity for demand. High drug prices are the predominant barrier to patients accessing legitimate medicines in the developing world. Because criminals can make fake drugs so cheaply, they can sell them at marked-down prices. Noam Chomsky, one of America's most prominent political commentators, argued that counterfeiting is simply a reaction to the extortionate prices imposed by the pharmaceutical industry. Pharmaceutical companies assert that they are not responsible for the high prices. Others have identified the existence of import tariffs as a major reason why good-quality, legitimate drugs cannot compete with fake ones on price. In an effort to expand their economies, many governments in low-income countries impose tariffs on good-quality, imported drugs, and as a result drive up the costs for the overseas pharmaceutical companies, preventing them in some cases from entering the market at all.

In contrast, the WHO found that 72% of economically developed nations did not impose import tariffs on pharmaceuticals, which helps to prevent counterfeit drugs from entering these markets. Up to 90% of inhabitants in SSA have to pay for essential medicines, so those seeking treatment choose the cheapest medicines available, a position often filled by counterfeits. In addition, many people are oblivious to the danger of buying the cheapest drugs: a qualitative study in Tanzania reported that 96% of people had never heard that medications could contain lower than advertised

amounts of ingredients. Even consumers who are aware of the correlation between reduced costs and increasingly poor-quality pharmaceuticals may be willing to overlook this correlation if the price is low enough. Whilst investigating the 'Consumer Behavior Towards Counterfeit Drugs (CBTCD),' pharmaceutical analyst Dr Abubakr Alfadl invented a scale to empirically quantify CBTCD, which he tested on 100 Sudanese consumers. He concluded that consumers in Sudan may "intentionally buy counterfeits" if they are cheap enough because they are still believed to have some therapeutic qualities. Policymakers have traditionally focused on improving regulation on the supply side of counterfeit drugs. But, this study highlights the need to focus on increasing public awareness of the health risks of fake drugs to reduce their demand (V Li, 2016).

1.9.1 Corruption

Just as the complex, multi-layer structure of the worldwide pharmaceutical system makes it difficult to regulate, this structure also provides many openings for exploitation. According to a senior economist at the World Bank, corruption within the healthcare systems of developing nations is widespread and opens the door for the bribery of customs officials.

Only \$12 of every \$100 spent by the government on pharmaceuticals reaches the Ghanaian patient, according to a report by Charles Allotey of the Health Access Network based on statistics from the WHO and the World Bank in 2011. Inefficiency and corruption account for more than 88 percent of the budget. According to a research conducted by the American Enterprise Institute in 2011, barely two weeks after the Global Fund supplied subsidised drugs to Ghana, some of the medicines, which were supposed to be distributed free of charge to the general people, started surfacing in Togo.^{xxx}

According to Anas Aremeyaw Anas, *The Crusading guide*, It doesn't take a genius to figure out that widespread corruption decreases the availability of medicines and creates loopholes that thieves use to swamp Ghana with counterfeit drugs. According to the Pharmacy Council of Ghana, only 20% of drug stores are inspected annually, but our own survey of pharmacies and licensed chemical shops in Accra found that the majority have not been inspected in several years, and the majority of those that sell prescription medicines do not have a pharmacist on site as required by regulations. Aremeyaw Anas Anas went on to say Over 1000 alerts and announcements on fraudulent drugs have been made by the Food and Drug Administration (FDA) in the last ten years. Despite this, it has not been able to secure even ten convictions in relation to these incidents in the courts. He went on to say that in 2012, the US Promoting the Quality of Medicines (PQM) program collaborated with the Ghana Food and Drugs Authority (FDA) to sample and assess the quality of some critical maternal health products (uterotonics) across the country's ten regions. Samples were collected from a variety of dispensing locations, including private clinics, public polyclinics, pharmacies, pharmacy stores, medical depots, and so on. Only around a tenth of the oxytocin (an important maternal health medication used to prevent dangerous bleeding in mothers after childbirth) on the market was legal. It was unable to determine the provenance of several of the products. All of the ergometrine tablets sampled failed to pass the basic quality tests. Almost all of the oxytocin items tested were found to be incorrectly manufactured.^{xxxii}

One unnamed National Marine Representatives Association (NMRA) within SSA was found guilty of taking bribes to allow the passage of falsified drugs into pharmacies by charging wholesalers \$65 a month to allow their illegal business to continue. The often-unstable economic and political environments in SSA have not only created an opening for corrupt pharmaceutical sellers but also have offered a means of supplementing the meagre incomes of individuals working

in the pharmaceutical sector. A study in Uganda in November 2014 found that 68-77% of pharmaceutical workers had stolen and resold publicly procured drugs at least once and that 80% would be open to the possibility of taking bribes from drug distributors. The unlawful nature of corruption means that empirical evidence rarely exists to prove its presence. However, anecdotal evidence and assumptions from informally published literature suggest that the practice is widespread. Corruption is also present in developed nations, but with more transparent reporting systems, the threat of severe punishments and higher incomes for health professionals the problem is vastly reduced (V Li, 2016).

1.9.2 Lack of Regulation

For the majority of the population in Ghana (like in many other LMICs), private sector retail stores are the principal source of necessary pharmaceuticals. Despite the fact that Ghana's National Health Insurance Scheme (NHIS) was designed to make primary healthcare and essential medicines more accessible, about 60% of the population was uninsured in 2016, forcing them to pay out of pocket for essential medicines sourced primarily from the private sector (Alhassan et al., 2016; Vandam, 2016). Due to drug shortages and stockouts at government health facilities, even people enrolled by the National Health Insurance Program (NHIS) must purchase necessary medicines from private-sector pharmacies, where supply is generally better (Mackintosh and Mujinja, 2010; Palafox et al., 2014; Nicholson, 2013; Seidman and Atun, 2017). Furthermore, particularly in rural areas, the distance and cost of traveling to the next government-run health institution can be prohibitive, and medicines may be unavailable. Ghana has a diverse range of 'private-sector establishments,' all of which operate with varied levels of regulation, legality, and formality. These include everything from huge, up-market licensed pharmacies in city centers to tiny over-the-counter (OTC) medication stores (sometimes known as "drug stores" or "chemical

shops"), grocery stores offering basic medicines, and itinerant peddlers like those in James' town (Hampshire et al., 2011, 2015). Despite the fact that Ghana's informal sector is lower than that of neighboring francophone countries (Baxerres and Le Hesran, 2011), unregulated medications are expected to account for 10–20 percent of all medicines in circulation (Seiter and Gyansa-Lutterodt, 2009). As Baxerres (2014) points out, drugs sold via informal shops are not always of inferior quality, but they are not subject to FDA oversight. Import and distribution channels in Ghana have been described as chaotic, with inadequate distribution networks and fragmented competition (McCabe et al., 2009). Importers, distributors, wholesalers, retailers, sales people, and a slew of other players work at various levels, with substantial vertical consolidation (as one entity manufactures, wholesales, and retails, for example) and horizontal transfer. Medicines have been documented 'leaking' from the public to private sectors, while others travel between the formal and

Manufacturers, importers, wholesalers, prescribers and pharmacists are all part of the pharmaceutical supply chain, and each needs regulation and transparency to ensure that counterfeits cannot enter at their level. To improve pharmaceutical regulation, the WHO stated in its 1999 'Guidelines for the Development of Measures to Combat Counterfeit Drugs' that it was paramount for every country to establish a National Medicine Regulatory Authority (NMRA) to be "accountable for the overall effectiveness of medicine regulation". The core roles of an NMRA include controlling pharmaceutical registration and post-production surveillance as well as governing the licensing and inspection of manufacturers, distributors and sellers of drugs. Despite many countries in SSA having NMRAs, the WHO estimates that many of them are not operating effectively enough to prevent counterfeits from infiltrating the market. Currently, of the 191 WHO member states, only 20% are known to have well-developed drug regulatory bodies, all of which are in the most economically developed nations. A study published by the WHO in 2010 collated

assessments of the effectiveness of NMRAs in 26 Sub-Saharan countries in identifying the problems in pharmaceutical regulation; they found that there was a common lack of sustainable funding and a shortage of qualified staff in all 26 NMRAs. More specifically, 81% of the NMRAs had either inadequate or no quality-monitoring programs in place to detect counterfeit and substandard medicines. Even if they detected poor-quality batches of medicine, only 12% of the NMRAs were able to perform an effective pharmaceutical recall. Lack of official traceability explains how drug counterfeiters often escape unpunished even when seizures are made.

1.9.3 Problem with Jurisdiction

Unlike many other counterfeit products, medicines are almost always destroyed upon ingestion; Wertheimer describes this as the "perfect crime" because the victim eradicates any evidence of wrongdoing. Even on the rare occasions when authorities can catch criminals involved in this industry, they tend to receive lighter penalties than those engaged in other illegal trades, attracting criminals previously involved in narco-trafficking to drug-counterfeiting. As the head of corporate security for the multinational pharmaceutical company, Novartis, puts says "if you get caught with a pound of cocaine, you can expect to do serious time. But if you are found with counterfeit medicines, you might only do six months." The WHO echoed this perspective when they stated that "weak penal sanctions" for counterfeiters was a significant factor in the proliferation of spurious drugs. Attaran says the root of the problem stems from the lack of an international legal framework to punish counterfeiters in what is an increasingly globalised trade. As it stands, if a criminal from one country produces and exports falsified drugs to another country, only the exporting country has the jurisdiction to prosecute the counterfeiter because he committed the crime in that country's territory.

In contrast, the importing country, whose citizens have been harmed by the drugs, can only prosecute the people who have, sometimes unknowingly, let the drugs enter the domestic supply chain. If caught, which is rare, these middlemen are charged with lesser crimes such as fraud, which will not carry a penalty appropriate for the damage caused. The inconsistencies in the national penalties for counterfeiting medicine make internationalising the jurisdiction even more difficult. In some developing nations, where robust judicial and policing systems are not yet in place (e.g. Somalia), counterfeiting pharmaceuticals is not even considered criminal. On the other hand, others have introduced draconian criminal punishments, both China and India have introduced the death penalty for certain offences related to drug counterfeiting, but neither has invoked it. Extradition laws require "dual criminality," in which a person is only extraditable from a country if he or she and the country requesting extradition have comparable penalties for the crime. With such different national penalties for pharmaceutical counterfeiting, criminals often can avoid extradition and hence face the charges. The growing disparity in pharmaceutical access between the "Global North" and "Global South" is one of the most significant factors contributing to global health inequalities. Approximately two billion people lack access to essential medicines worldwide with the majority of these living in SSA and South-East Asia. The higher prevalence of counterfeit drugs within these nations only worsens health inequalities. The most common effect of fake drugs on health is prolonged or unsuccessful treatment, but in the case of malaria, where disease progression is rapid, giving sub-therapeutic drugs is said to be "tantamount to murder". Overall, Harris estimates that 700,000 deaths a year from malaria and TB in SSA are attributable to fake drugs.

The WHO uses the umbrella term, 'Substandard/Spurious/Falsely labelled/Falsified/Counterfeit medical products' (SSFFC sometimes shortened to SFFC, (World Health Organization, 2016a)).

However, there is no universally agreed definition for this. Previously, WHO defined 'counterfeit' medicines as being, 'deliberately and fraudulently mislabeled concerning the identity and or source' (World Health Organization, 2016a). However, others have argued that the causes and solutions of the constituent problems in the SSFFC grouping are different (Newton et al. 2011a; Attaran et al. 2012). Notably, 'counterfeit' should not be conflated with falsified and substandard, as this may shift focus away from public health issues and more towards intellectual property (IP) concerns (Newton et al. 2011a). We use the term 'unregistered generic' to refer to safe and effective medication manufactured without proper IP law authorisation. Employing such a term is a legal and economic problem but does not pose a direct threat to public health.

In contrast, 'substandard' drugs are, 'genuine medicines produced by manufacturers authorised by the National Medicines Regulatory Authority (NMRA) which do not meet quality specifications set for them by National standards' (World Health Organization, 2016a). 'Degraded' medicines were of adequate quality when they left the factory but have subsequently degraded, for example, through inadequate storage or transport conditions (Newton et al. 2009). We use 'falsified' to refer to medicines that have been fraudulently produced and distributed and which do not meet the quality specifications for that drug, these are the primary focus of this review. Lastly, we use the term 'poor quality' to refer collectively to falsified, substandard and degraded medicines, which all pose serious threats to public health.^{xxxii}

Poor-quality medicines directly harm patients by denying them access to potentially life-saving active pharmaceutical ingredients (API) or exposing them to toxins. Researchers have recently estimated that 122,350 deaths in children under five years old in Sub-Saharan Africa were attributable to poor-quality antimalarials in 2013 (Renschler et al. 2015), representing 3.75% of all under-five child deaths in the region. Low-quality medicines also have pernicious consequences

for communities and healthcare systems (Newton et al. 2006b, 2010; Mackey and Liang 2011; Karunamoorthi 2014)), causing lack of faith in healthcare amongst local people and providing a source of funding for organised crime networks. If low-quality medicines contain less than the intended API, pathogens can become exposed to drug concentrations in the 'mutation-selection window' high enough to exert a selection pressure but too low to kill all of the pathogens (Abdul-Aziz et al. (2015)). Many researchers think that low-quality antimalarials are contributing factor to the repeated evolution of antimalarial resistance in *Plasmodium falciparum* in Southeast Asia (Newton et al. 2003, 2006b); Cui et al. (2012); Bharati and Ganguly (2013); (Karunamoorthi 2014), and to effective variable coverage of malaria case management in Africa (Galactionova et al. 2015). Besides, fake medicines damage the pharmaceutical industry by affecting revenue and reputation. Although low-quality and counterfeit medicines have received increasing attention in the academic literature over the last 15 years, their prevalence is difficult to accurately determine. Others have reported poor drug quality for a wide range of anti-infectives, including antimalarials (Cockburn et al. 2005; Lon et al. 2006; Newton et al. 2006b, 2008, 2010, 2011b; Amin and Kokwaro 2007; Bate et al. 2008; (Karunamoorthi 2014), anthelmintics (Khan et al. 2010) and antibiotics (Nair et al. 2011). While many studies have detected falsified drugs through pharmacological testing (World Health Organization 2003, 2009; Dondorp et al. 2004; Atemnkeng et al. 2007; Sengaloundeth et al. 2009; Nayyar et al. 2012; Yoshida et al. 2014), a compilation of these data is challenging due to varying methodologies and inadequate sampling and drug analysis techniques (Taberner et al. 2014).

However, many have suggested that other organisations, such as the UN Office of Drugs and Crime (UNODC) and the International Criminal Police Organization (IN CrimeTERPOL) should take an active role in surveillance and law enforcement (Buckley and Gostin 2013; Mackey and

Liang 2013). The UN Convention against Transnational Organized Crime (UNTOC) could also provide viable enforcement mechanisms and stakeholder engagement (Mackey and Liang 2013). The WHO launched the International Medical Products Anti-Counterfeit Taskforce (IMPACT) in February 2006, to bring together relevant stakeholders including nation-states, the pharmaceutical industry, non-governmental organisations (NGOs) and enforcement agencies, such as INTERPOL to tackle 'counterfeit' medicines (World Health Organization 2016f). IMPACT focused on five policy areas: legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication (World Health Organization 2008). While conceived with good intentions, other institutions have argued that agencies have overemphasised on IP issues rather than addressing public health concerns (Asian Community Health Action Network (ACHAN) et al. 2010). (The Council of Europe's MEDICRIME Convention has faced similar criticism (Bate and Attaran 2010)). The Member State Mechanism (MSM) on SSFFCs was established by WHO in the 65th World Health Assembly (WHA), aiming to: 'promote, through effective collaboration among the Member States and the Secretariat, the prevention and control of SSFFC medical products and associated activities' (World Health Organization 2012). The group has met annually since 2012 (following a 2011 meeting of the 'Working Group of Member States on SSFFC').

One strategy for securing drug quality is to have tight state control over the pharmaceutical supply chain. Rwanda has adopted this approach, a low-income country that has had success in tackling falsified drugs, particularly anti-TB medicines (Bate et al. 2012, 2013; Binagwaho et al. 2013). Rwanda made several changes in the regulation of its pharmaceutical supply chain, detailed in 'Guidelines for pharmacovigilance and medicine information system in Rwanda,' 2011 (Republic of Rwanda Ministry of Health 2011). Binagwaho and colleagues describe a significant focus on pharmacovigilance, with drug quality screening at importation and subsequently along the supply

chain and notification forms supplied for patients and healthcare staff to report suspicious medicines to the National Pharmacovigilance and Medicine Information Center (Binagwaho et al. 2013). The Ministry of Health required manufacturers to have WHO certificates of Good Manufacturing Practices. It permitted private pharmacies to sell anti-TB medication provided they were accredited Centers for Diagnosis and Treatment of Tuberculosis. The Rwandan Medicines Procurement and Planning Division (MPPD) ensure that managers of health centres throughout the country stocked their centres with sufficient drugs. But if this fails, individual facilities can be permitted by the Ministry of Health to procure medicines from private sources (Supply Chain Management System (SCMS) 2013). When this also fails, medicine stock-outs occur (Supply Chain Management System (SCMS) 2013; Nditunze et al. 2015). The Rwandan government is aiming to address these issues as part of its, 'Third Health Sector Strategic Plan' (Government of Rwanda Ministry of Health 2012), active from 2012 to 2018 (WL Hamilton, 2016).

The International Pharmaceutical Federation (FIP) adopted official policies on combating 'counterfeit medicines' in Sydney in 2003 (International Pharmaceutical Federation (FIP) 2003).

Chauve' argues that pharmacists directly involved in distributing falsified drugs should face disciplinary actions (Chauve' 2008). Given that drug falsifying networks involve criminal gangs, such measures require police enforcement. In June 2007, the headquarters of the Conseil National de l'Ordre des Pharmaciens (National Council of the Order of Pharmacists) in Co[^]te d'Ivoire was attacked by gunmen following attempts to limit medicine falsification (Chauve' 2008). In December 2003, the former Director-General of the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria, Dr Dora Akunyili, narrowly escaped an attack by shooters in Kano (Tim Phillips 2007).

Khan et al. have demonstrated the need for improved awareness of, and training in, pharmaceutical authenticity in private retailers (2011a). They found that only 64.5% of drug wholesalers in Cambodia consider drug credibility and quality when accessing their products. Only 56.5% checked that the drug packaging was intact, despite this being a known source of falsified drug infiltration, and proper drug packaging and storage is vital for maintaining drug quality (Khan et al. 2013).

According to William L. Hamilton, the use of drug registration has been mixed. A 2007 joint report by the Kenyan MoH, WHO and Health Action International-Africa found that 42% of antimalarials in Kenya were unregistered (World Health Organization 2007).^{xxxiii}

Recommendations for pharmacy-level interventions Pharmacists should: Purchase medications from known, reliable sources, e.g. confirm drug registration with official NMRA Confirm with distributors that products were purchased from reliable sources; Examine products for suspicious appearance (e.g. using WHO Checklist) Monitor medicine product alerts (e.g. from WHO Medical Product Alert website); Report suspicious medicines to NMRA, the distributor and the manufacturer (hopefully to ultimately be entered on global reporting systems such as WHO Medical Product Alert); Close gaps in pharmaceutical supply, working with NMRA, other relevant agencies and pharmaceutical industry; Use scanning technologies for prescription and drug verification (e.g. barcodes) Educate themselves, co-workers and patients on low-quality medicines (links with pharmacy training and education and raising public awareness); Warn patients of risks of falsified and poor-quality medicines, advise to purchase drugs from reliable sources and warn of risks in internet pharmacy; and Advise patients to report any changes in their medication efficacy or the appearance of drugs, even if they were not purchased in that pharmacy.

1.10 Research Methodology

The study employed the use of questionnaires and interviews to generate and to arrive at the data and conclusions.

1.10.1 Research Design

This study employed both qualitative and quantitative design to help to have access to both primary and secondary data, thereby allowing me to reach out to numerous views of individuals and agencies. The inductive research method was used in this investigation to enable me to gather enough information for the subject under investigation.

1.10.2 Sources of Data

The study used both primary and secondary data. As an investigative study, solicit first-hand information from experts like the producers/manufacturers of medicines. It will then, interview stakeholders in charge or responsible for and ensuring quality and accessible medicine for all. To enrich the study, the researcher will administer questionnaires to some individuals to ascertain and to know their level of awareness of counterfeit drugs. I will also analyse the existing literature on the study's topic.

I contacted the Food and Drugs Authority, Pharmaceutical Society of Ghana, Ghana chamber of Pharmacy, Ghana Medical Association, Danadams, Ernest Chemist, LETAP and Kinapharma because Food and Drugs Authority is the National Regulatory Authority mandated by the Public

Health Act, 2012 (Act 851) to regulate food, drugs, food supplements, herbal and homoeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances tobacco and tobacco products, even though not all were readily available. Pharmaceutical Society of Ghana whose mission is to provide accessible, affordable, sustainable and quality pharmaceutical services to all through professionalism, continuous development, welfare, leadership and collaboration with relevant stakeholders. The Chamber of Pharmacy Ghana collaborates with all industry stakeholders. It can protect and pursue the collective needs and interests of members to create a pharmaceutical industry that supports members and national development. Ghana Medical Association which aim to lead and seek the welfare of its members and provide expert advice and consultancy on quality healthcare delivery of the country.

I also contacted Danadams, Ernest Chemist and LETAP because they are drug manufacturers in Ghana.

1.10.3 Sample Size and Sample Population

The sample size was be Sixty four (64) namely; interview one (1) each from Food and Drugs Authority, Pharmaceutical Society of Ghana, Chamber of Pharmacy Ghana and Danadams with sixty (60) questionnaires for random people in Accra.

1.10.4 Collection of Data

Considering that the work employed both qualitative and quantitative methods of research, two types of data collection instruments was used to solicit primary data from the population of Accra,

who forms the work's unit of analysis. The study deployed structured interview to seek the views of the agents (senior members) of the institutions and agencies mentioned in 1.9.5, here, above. Also, the study sought the perceptions of the general public of Accra through questionnaire administration.

1.10.5 Analysis of Data

The study used frequency tables, bar graphs and pie charts to analyse the primary data gathered through the structured interviews and questionnaires. This was to make the study simple and easy to understand. It also aided the analysis of the relation between the variables of the study's thesis statement.

1.10.6 Ethical considerations

The structured interviews and the questionnaire of respondents were designed to ensure optimum confidentiality of respondents. The aim of the interview and questionnaire was well explained to every respondent and the respondents voluntarily chose to be part of the survey.

1.11 Arrangement of Chapters

Chapter one (1) includes the introduction and background of the study, what has necessitated the study and why it is a problem in the first place. It also looks at the research questions, objectives, scope and rationale of the study. It finally looks at the conceptual framework of the research and literature review of other scholarly works of researchers and various arguments, debates and solutions they presented, followed by the definition of keywords.

Chapter two (2) will investigate why the counterfeit medicine trade is booming in Africa and the efforts being put in place to address the issue of counterfeit drugs to meet SDG 3.

Chapter three (3) assesses successes achieved, challenges faced and the way forward for Ghana, data and data analysis.

Chapter four (4) will discuss the summary of findings, conclusions and recommendations.

Endnotes

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CHAPTER TWO

OVERVIEW OF SOME MEASURES TAKEN TO FORESTALL THE BOOM OF COUNTERFEIT/FAKE MEDICINE TRADE IN AFRICA TO MEET SDG 3

2.0 Introduction

The proliferation of fake medicines in Africa is a public health crisis that can no longer be ignored, according to a UK charity^{xxxiv} (Peter Mwai, 2020). The seriousness of the problem of fake and counterfeit medicines in Africa made seven African countries, Congo, Niger, Senegal, Uganda, Ghana and The Gambia to meet in Togo in January 2020 to discuss measures to combat the problem. But how big a problem is counterfeit medicine in Africa, and what impact does it have?

According to reports by BBC, globally, the trade in counterfeit pharmaceuticals is worth up to \$200bn (£150bn) annually, with Africa among the regions most affected, according to industry estimates. The European Region and the Americas (North and South) accounted for 21% each.

Although the full statistics are hard to pull up as the trade is mostly underground, recent seizures in West African countries show the real magnitude of the problem. According to statistics, Ivory Coast, Guinea-Bissau, Liberia and Sierra Leone seized 19 tonnes of counterfeit medicines in 2018. Law enforcement agents intercepted smugglers in Ivory Coast trying to bring in 12 tonnes of counterfeit pharmaceuticals from Ghana in 2019 (Sharon Chirisa, 2020). An Interpol-led operation in seven West African countries seized more than 420 tonnes of illicit pharmaceutical products in 2017. Mali also confiscated nearly 19.88 tonnes of fake medicines between 2015 to 2018. The accounting firm PwC says the proportion of counterfeit pharmaceuticals in some countries can be as high as 70%, in developing regions such as Africa.^{xxxv}

Sharon Chirisa added that the WHO estimates one out of every ten medical products in low- and middle-income countries, including most of Africa, is sub-standard or fake. London School of Hygiene and Tropical Medicine's analysis for the WHO estimates substandard and fake anti-malaria drugs could be causing 116,000 extra deaths. In 2015, a study published in the American Society of Tropical Medicine and Hygiene estimated more than 122,000 children under the age of five died each year because of sub-standard anti-malarial drugs in sub-Saharan Africa. Fake medicine can often be hard to differentiate from the real products because the packing is almost identical to the original one if not better (Sharon Chirisa, 2020).

The Chapter, therefore, drawing from all the issues mentioned above looks at the causes for the boom in counterfeit and fake medicine trade in Africa and discusses some measures to prevent the boom in counterfeit and fake medicine trade in Africa to meet SDG 3.

2.1. Trade Boom in Counterfeit Medicine in Africa

The WHO defines a counterfeit drug as a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud and then marketing the copied or forged drug as the original. Counterfeit products encompass medicines that may have wrong active ingredients, fraudulent packaging, insufficient active ingredients and absence of active ingredients. The WHO and Interpol both reported that the state of fake pharmaceuticals in Africa was anywhere between 30-60%.

Drug counterfeiting is not just a problem of Africa alone; it is a global phenomenon that threatens global patient safety. The WHO has indicated that in 1999 and 2000, nearly 60% of recorded counterfeit drugs came from developing nations, whereas 40% of such reports came from

developed countries. The British think-tank, International Policy Network (IPN) estimated that globally, fake malaria and tuberculosis medications accounted for 700,000 deaths. While WHO estimated that, about 100,000 deaths per year in Africa have links with counterfeit pharmaceutical products.

Kwame Adjei, in his article, *Counterfeit Drugs: The Relentless War in Africa*, in March 2015 says that Drug counterfeiting is booming in Africa and there are many reasons for that. Many researchers have observed that many substandard and fake pharmaceuticals make their way to Africa from countries such as China and India. A report in 2009 revealed that India and China shipped over 45 million anti-malaria drugs valued at over \$438 million to West Africa.^{xxxvi} Also, Ashifi Gogo, the CEO of Sproxil, a technology aiming at mitigating fake pharmaceuticals, noted that the fake pharmaceutical manufacturers originating from Africa are also adding on to the burden, the proliferation of counterfeit and counterfeit medicines in Africa. Some practitioners and scholars opine that the problem is a multi-billion dollar industry, which means that the fight to halt the problem will remain relentless. Adjei has projected an expected growth rate of 20% in counterfeit drug in the foreseeable future (Adjei, K. H. 2015).^{xxxvii}

2.2 Causes of Trade Boom in counterfeit Medicine in Africa

Some of the causes influencing counterfeiting in drugs in sub-Saharan Africa are mainly due to the rate of corruption, inefficient regulatory system, easy movement in Africa, lack of deterrent sanctions, and meagre punishments not deter people enough from engaging in drug counterfeiting, and inappropriate drug laws. In Africa, one would often find unlicensed and unregulated vendors selling medications on the streets. Such medications are easily accessible to the poor.^{xxxviii} Many

people underscore corruption, bribery and conflict of interest as some of the reasons for drug counterfeiting proliferation in Africa. As the problem continues to propagate, government officials tasked to oversee the importation of medicines in their respective countries continue to engage in unscrupulous behaviours such as taking bribes. And such behaviour ultimately enables fake pharmaceutical products to continue to make their way into their countries. Corruption and conflict of interest have also negatively motivated government officials to fail to enforce laws and subsequently refraining from arresting individuals engaging in drug counterfeiting.

The desperate demand for drugs in many African countries, which is coupled with global drug shortages to meet such demands, possibly incite counterfeit proliferation. The demand for medicines and inadequate drugs supply to satisfy the market creates opportunities for criminals to fill that gap with counterfeit and fake medication with the sole aim of making money. Furthermore, high drug prices and the poverty levels in many African nations provide enough incentives for growing falsified and substandard trade on the continent. Importation cost, such as duties and other taxes lead to high medicines cost. Suppliers, on the other hand, usually forward the price onto consumers making medications too expensive for the poor to buy. Most African countries are also characterised by low salary earners and unemployment, which also makes it very difficult for one to spend such amount of money only on medicines. In a study conducted by Health Action International and WHO, they noted that markups of anywhere between 30-80% of retail prices in licensed and regulated vendors. Patients in need of medication will inevitably ditch buying medicine from licensed and regulated vendors, owing to it to poverty (Adjei K. H., Ohene P, 2015).

2.2.1 Prices of medicines

Finished pharmaceuticals imported into the continent are costly due to high tariffs, taxes and distribution costs (World Health Organization, 2011). Prices of medicines in Africa are not affordable for many because of the poverty levels. The Region imports a large proportion of drugs because they are cheaper compared to locally manufactured medicines. The local manufacturers also use active pharmaceutical ingredients imported mainly from China and India. Thus, fluctuations in the exchange rates of currencies ultimately affect the cost of medicines. Governments in Africa are not legislating prices to lower the cost of medication to make them affordable to poor citizens through the enactment of lower tariffs laws.

Some governments have not instituted any form of price controls because of their inclination to the free-market regime, which Western governments promote. For example, in Cameroon, without price control, a complete treatment dose course for peptic ulcer costs “almost twice the monthly wage of a government employee” (Creese 2003). It is not generally affordable. Criminals are always on the look for gaps in systems to aid their trade. The high cost of medicines in the African continent, which makes it difficult for the citizens to afford leads to the boom in counterfeit and fake medicine trade since the fake ones are usually cheaper. They are less expensive because the traders import these drugs through unapproved routes to avoid detection by law enforcement officers and, also invade tax. Sometimes the low cost of fake medicines results from traders and public officials’ bribery and corruption practices, leading to their smuggling in counterfeit drugs through the borders.

2.2.2 The Financial Returns

The financial returns are very high for the trade in counterfeit and fake medicines because the demand for drugs is high, mainly due to the heavy disease burden in Africa. Also, contributing to this is the enormous financial returns difference between the cost of production of these Substandard and Falsified Medicine (SF) medicines and their selling price (they are usually sold at the same price as the equivalent quality medicines). Prescription drugs are expensive, and there are poverty and economic hardship in the Region, and this provides an excellent opportunity for making money by counterfeiters.

2.2.3 Easy movement in Africa

Counterfeiting is relatively an easy act to commit in Africa because the movement of goods and people across countries is relatively easy because of the regional blocks and the opportunities they provide to trade. The Economic Community of West Africa (ECOWAS), for example, promotes the free-flow of people and goods within member states, leading to easy movement of fake drugs with the Region. Gatekeeping at national boundaries within ECOWAs is porous because, in its bid to facilitate the movement of people and goods among countries, state officials pay little or no attention to inspect goods crossing borders. Therefore, security and law enforcement agents are less likely to detect and arrest counterfeit, once traders introduce such drugs into the medicine-supply chain, since they mix up with the known original medicines. Also, weak medicines regulatory framework and poor communication between National Medicines Regulatory Authorities has immensely contributed to the challenge (World Health Organization 2010). National borders also need to be fortified against corruption to cope with the influx of fake medicine. Even high profile members of governments have been involved in the trafficking,

usually putting regulators in a tight spot. In December 2017, security officers raided the house of a Beninois Member of Parliament, Mr Mohammed Atao Hinnouho and found hundreds of cartons of fake drugs. They arrested him afterwards. Atabong has observed that while some countries have become vigilant at their borders, fake medicine production and smuggling is shifting to the continent (A. B. Atabong, 2020).

2.2.4 Inefficient Regulatory Systems

Inefficient regulatory systems also encourage counterfeiting. Most countries in West Africa either have a body (unit or department), which performs the functions of a National Medicines Regulatory Authority (NMRA), or they have a full-fledge NMRA (World Health Organization 2010). These NMRAs are, however, at different stages of development or maturity. The overall goal or mandate of the various NMRAs is the same as their counterparts in other regions protecting and promoting their citizens' health by ensuring that local industries manufacture only quality, safe and effective medicines. They also see to the importation, promotion, distribution, sales of solely quality, safe and effective medicines, which the populace can access easily, through the enforcement of legislation, rules and principles. According to the Food and Drugs Authority (FDA), the agency that regulates the manufacturing and distribution of food and drugs in Ghana, it reserves the right to recall or cancel an already registered a product, should the manufacturer or distributor fail to put the product on the market after a year. Seth Seaneke, the Deputy Chief Executive (DCE), made this revelation on the legal mandate of the authority to cancel the registration of products at a stakeholders' training workshop on the new and revised guidelines for registration of Allopathathic medicines in Accra. He spelt out the registration process to include submission of application, application review, GMP audit, quality

control analysis and marketing authorisation before registration, approval, differed and rejected.^{xxxix} The “good” companies that come forward to register their products are bogged down with too many inefficient regulatory processes, preventing their quality products reaching the markets on time, thus giving way to counterfeiting. Counterfeiters take advantage of any gap in the supply of medicines to the market. The state regulatory agencies must balance regulatory with quality assurance. When artificial scarcities create mass hysteria, counterfeiters exploit the opportunity to insert their products in the market because desperate people would less likely question the quality of medicines. (A. B. Atabong, 2020)

2.2.5 Weak Legal Structure

All National Medicines Regulatory Authorities (NMRAs) in West Africa, for instance, have some form of legal frameworks. However, some legal frameworks can be compared to an old spider’s web, with unclear definitions of responsibilities, resulting in regulatory gaps and overlaps with other agencies in their respective countries. In many states, NMRAs do not undertake all regulatory functions. For example, in Nigeria, the licensing of medicine manufacturing establishments is done by another regulatory agency in the country, the Pharmaceutical Council of Nigeria. However, in Ghana, the licensing of pharmaceutical manufacturing firms is done by the National Medicines Regulatory Authority (NMRA). The laws or regulations guiding the NMRAs in their regulatory functions require reviews to address global trends in regulatory sciences and adjust the penalties for contravening any of such regulations. For example, there are no regulations on data integrity in the Region and the penalties for contravening existing laws are ridiculously not punitive enough to discourage deviant actions.

2.2.6 Lack of a vibrant local market for the manufacturing of medicines

For Ouattara, the establishment of the pharmaceutical market in several African countries reflected the Region's colonial history. "European manufacturers supplied the colonies, subsequently there was no proactive policy to change the pattern of imports, whereas no country in the world has developed its local market without a protectionist policy," he added. To help the local pharma industry grow, some African states, particularly in North Africa, have relied on measures to protect the pharmaceutical market, such as tax incentives and facilitated funding for local pharmaceutical producers. "In practice, only South Africa and North African countries have managed to develop local pharmaceutical production, as well as Kenya and Senegal to a certain extent," said Mehdi Tanani, coordinator of Proparco's Private Sector and Development review. Proparco is a branch of the French Development Agency. The lack of proactive policies to help grow the local pharmaceutical manufacturing industry in many African countries has helped the trade boom of counterfeit and fake medicines as the continent keep relying on foreign medication for the needs of its citizens.

2.2.7 Flexible Punishments/Penalties

The penalties for counterfeiting are not deterrent enough to deter perpetrators of the counterfeit and fake drug manufacturing and trade. Counterfeiters know this and rationalise and normalise legal liabilities as a routine business' cost. Substandard and counterfeit drugs fail to cure and give expected relief. They also cause actual harm to patients, such as organ damage, resistance to medicines development, long(er) stays at hospitals leading to enormous economic cost, and even death (Blackstone et al. 2014). Unfortunately, due to the endemic institutional weakness in Africa, law enforcement is not sufficiently vigorous. So justice is not speedily done to discourage

counterfeiting as litigations can go on for decades until interests attenuate and the matter goes into obscurity or unresolved.

Substandard and Falsified (SF) products take away a substantial part of the market share of the branded or quality generic drugs and detract their profitability. Most importantly, they can also lead to a total discrediting of the brand and company with a blemish, causing customer paranoia. When patients and health care providers consistently observe treatment failure from the use of unknown counterfeit drugs, they are less likely to prescribe or use that brand or generic in the future. So gradually, the Substandard and Falsified (SF) medicine weakens the legitimate brands and may, eventually drive the brand out of the market. Africa has witnessed many such parasitic symbioses in the industry that drove away iconic brands from the market. (Ekeigwe, A.A, 2019). Togo's president, Gnassingbe, expressed optimism the initiative will raise awareness with other African countries and the international community. "Fake medicine has often been regarded as a violation of intellectual property right, and not a crime." Making it a criminal offence like other crimes, he underscored, will deter traffickers from the malpractice. A review of legal systems of most African states shows criminal legislation against the trafficking of substandard and falsified medicines is either at a low level or absent. In cases where legislation exists, the penalties are weak and not backed by effective enforcement.^{x1} The Lomé Initiative, which shows the political will of the heads of states, will be followed by new legislation criminalising the trafficking and sale of fake medicines which they have realised is one of the factors for the proliferation of counterfeit and counterfeit drugs in Africa. The draft legislation is advancing a minimum 10-year jail term for offenders of fake drug-related crimes. In addition to the introduction of mechanisms to ensure the strict application of the new legislation, the initiative will ramp up calls for the signing of

the Medicrime Convention and the Palermo Convention against transitional organised crime by African countries (A. B. Atabong, 2020).

2.2.8 Inadequate access to Medicines

Many people in Africa do not have access to quality medication because of the high prices. “Medicine is a substantial fraction of health costs, so when we speak of access we also mean financial access,” said Philippe Walfard, deputy head of the Health and Social Security division of the Agence Française de Développement (AFD). “Things are changing. Healthcare demand is on the increase in Africa, and politicians will have to react. The issue of financial access is clearly on the agenda along with the universal health insurance, even if it will take some time,” said Walfard. Making medicine more financially accessible will also involve rationalising the distribution channels, which because of their complexity account for a large part of the price of medicine. “In Africa, there has been a proliferation of intermediaries in recent years which has increased the price of medication,” said Tanani. In Kenya, intermediaries’ margins account for an excessively high 50% of a pharma product’s final price. In contrast, the average in OECD countries varies between 2% to 24% of the total price making medicines inaccessible to the people enabling counterfeiters to fill in the gap leading to the boom n trade of counterfeit and fake drugs in Africa.

2.2.9 Inadequate Human Resources

Most NMRAs do not have the requisite portfolio of competent personnel to execute its mandate. The NMRAs lack adequate competence areas of critical regulatory practice, such as dossier review of New Chemical Entities (NCE), evaluation of bioequivalence data, inspection of facilities,

pharmacovigilance and post-marketing surveillance, monitoring of clinical trials, and quality management systems. A typical scenario in most NMRAs in Africa especially West Africa is that an individual with a science degree in desperate search of job drifts into a medicines regulatory position by being hired into the NMRA, sometimes through political cronyism.

Most regulators at the beginning of their careers do not have any exposure to regulatory practice or pharmaceutical education with even less knowledge about regulations. In many cases, on the job training is lacking, and they stumble their way through learning on the job. Sometimes they may be fortunate to get training from their employers, WHO, USP and other international development partners later. And for the first time, they become conscious of the enormous task they are handling, protecting the lives of people through regulations and informed regulatory decision. These experiences have led to the understanding that hiring and training the right talent is critical for the agenda of the NMRA's. Developing expertise requires extensive and deliberate practice by knowledgeable people (Clark, 2008). In most African countries, the falling standard of education means the knowledge is not being adequately acquired. And because of institutional inefficiencies, employees do not have the right environment to engage in deliberate practice to develop expertise. This is a big problem given that it takes a long time to become an expert (Levitin 2008). The inadequate technical capacities of healthcare systems to detect fake from standard drugs is also giving the fake medicine problem the green light. As Dr Tedros Adhanom Ghebreyesus, WHO Director-General told Quartz Africa, "the response has to be comprehensive" if nations want to end trafficking (A. B. Atabong, 2020).

2.2.10 Low literacy levels among consumers

Consumers on the continent have little or no knowledge about medicines which makes it easy for Counterfeiters in Africa (United Nations Educational, Scientific and Cultural Organization Literacy and Non-Formal Education 2018). UNESCO Institute of Statistics (UIS) in its 2017 report showed that the average literacy rate for adults (above 18 years) in most countries in West Africa is below 50% (UNESCO Institute for Statistics Literacy, 2019). They are about the worst rates in the world. The low literacy level affects the rational use of medicines. It also affects the level of awareness needed to cultivate rational and discriminate receptivity to drugs. Thus, low literacy level negatively impacts the general level of safe medication awareness which in turn affects the capacity for reasonable use of medicines).

2.2.11 Government apathy to crackdown counterfeit drug trade

Overall, there are low investments in the healthcare sector by the governments, which includes lack of government incentives to promote the local manufacture of medicines. Incentives in the form of free land for setting up manufacturing outfits (e.g. Economic Free Trade Zones), funding of research and development, the establishment of technology incubation centres for pharmaceutical manufacturing, tax holidays and rebates, giving of cheap loans to manufacturers, are missing or very few in West Africa (The African Union Commission 2012). Low investments in Research and Development (R&D) are another way of Government apathy. Health researches are very few, and governments are reluctant to implement the outcomes and recommendations of the few health research. Several studies show that the funding of R&D in Africa and West Africa is low (Nwaka et al. 2010; Berger et al. 2010; Defor et al. 2017). African governments are committed to spending 1% of their health budget on research, but only a few are striving to meet

that commitment. Only a few countries in West Africa have R&D expenditure data for some years on the Gross domestic expenditure on R&D (GERD), GERD as a percentage of GDP (Gross Domestic Product), GERD per capita and GERD per researcher in the United Nations Educational, Scientific and Cultural Organization (UNESCO) Institute for Statistics (UIS) database for expenditures in R&D. Inadequate implementation of existing policies and blasé regulatory enforcement.

States reluctance to fully implement the Primary Health Care (PHC) policy in the Region is a notable example of governments apathy to nib fake drug trade. This policy aimed at ensuring equity in access to quality healthcare services has suffered some setbacks due to poor implementation. Most health centres no longer have functional drug revolving schemes, resulting in a shortage of essential and critical medicines and commodities at point of service delivery” (Uzochukwu 2017). Residents of most rural areas travel miles to reach the nearest a health facility, Public Health Centre (PHC), which are barely resourced with qualified personnel, equipment and medicines (Uzochukwu 2017). Insufficient availability of essential drugs, especially in the public sector is a crucial barrier to the access of necessary medicines by the poor, and low-income earners (Dying from lack of medicines (Africa Renewal Online 2019)). Since these medicines are essential for the survival of every country, it becomes easy for counterfeiters to avail themselves through the provision of these essential drugs to the public which is yet another factor leading to the boom in counterfeit and fake drug trade in Africa.

2.2.12 Low Health Financing

Inadequate health care financing by the governments’ National Insurance Schemes account for the schemes’ low coverage and their inaccessibility by the majority. In Countries where they are even

accessible, the ability to access available, safe, and secure medicine remains a challenge. Thus there is high out-of-pocket expenditure by the populace (WHO Regional Office for Africa 2013). Weak public-private partnerships in the health sector (West African Health Organization). In recent years, the need for the establishment of universal health insurance has become priorities on the health agenda of many African countries. While some countries have made more progress than others such as Ghana and Rwanda which set up a national health insurance system in 2003 and 2004, covering about 40% in Ghana^{xli} and more than 80% of its population, all African states seem to seek to establish a health insurance system. The universal health assurance policy is an objective included in the Sustainable Development Goals (SDG). The lack of it is pushing citizens to seek for available, access and affordable healthcare at an affordable cost, which is aiding the boom in counterfeit and fake medicines trade in Africa, as these counterfeiters become providers of available and accessible medicines to the people due to low prices.

2.3 Sustainable Development Goals

The 8th goal of the Millennium Development Goal (MDG) states, “In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries”. The indicator for this goal is “Proportion of population with access to affordable essential drugs on a sustainable basis” (Millennium development goals indicators 2000). Note that these MDGs were agreed to in the year 2000 by the United Nations Millennium Assembly and set out in 2001 as a global framework to shape the planning and monitoring of development efforts, particularly in low income and developing countries. They suggest that such countries should strive to achieve many quantified goals to reduce extreme poverty, disease, and deprivation by 2015. If many countries, including Africa, had fully realised the MDGs, developing economies as in West Africa

would have achieved significant access to quality essential medicines by 2015. The MDG Gap Task Force Report 2015 showed that access to relevant medicines remains a problem for low and lower-middle-income countries (United Nations 2015). However, according to the report, significant efforts were made to increase treatment access, especially for diseases such as HIV/AIDS, malaria, and tuberculosis.

The Sustainable Development Goals (SDGs) is the current program set by the United Nations to help national developments. Adopted by 193 countries, including Ghana, the SDGs came into effect in January 2016, and aim to foster economic growth, ensure social inclusion and protect the environment. The SDGs encourage a spirit of partnership between Governments, private sector, research, academia and Civil Society Organizations (CSOs) with support of the UN. This partnership ensures that nations make the right choices now to improve life, sustainably, for future generations. SDG 3 is “Ensure healthy lives and promote wellbeing for all at all ages” (Sustainable development goals 2018). To achieve this, the SDG targets “access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all” by 2030 (Sustainable development goals 2018). Will this be achieved? Is access to quality, safe and effective medicines a challenge in Africa? How can Africa mitigate these challenges to ensure that the continent accomplishes SDG goal 3 in Africa?

The SDGs are not standalone goals. They are all interconnected, and working to achieve one goal leads to achieving another.^{xlii}

2.3.1 Sustainable Development Goals (SDG) 3

The SDG 3 seeks to ‘Ensure healthy lives and promote wellbeing for all at all ages’. Just as each primary SDG goal contains sub-goals, the SDG 3’s goal – encompasses nine sub-goals/targets, but for purposes of this work, I will focus on SDG3 target 8. The SDG target 3.8 envisages achieving universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all.^{xliii} To achieve this, the SDG targets “access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all” by 2030 (Sustainable development goals 2018).

Most health system strengthening interventions ignore interconnections between systems components. In particular, many nations give insufficient considerations to complex relationships between medicines and health financing, human resources, health information and service delivery. As a consequence, populations' access to medicines (ATM) is addressed mainly through fragmented, often vertical approaches usually focusing on supply, unrelated to the broader issue of access to health services and interventions.

In 1975, the World Health Assembly endorsed the concept of essential medicines, triggering the adoption of essential medicines lists and the implementation of national drug policies in most low- and middle-income countries (LMICs). Estimates of the number of people with access to essential medicines almost doubled between 1977 and the late 1990s through a combination of public and private provision (Quick and Hogerzeil 2002). Despite this success, access to medicines (ATM) remains problematic for poor and vulnerable populations.

The United Nations Development Group (UNDG) defines access as having medicines continuously available and affordable at public or private health facilities or medicine outlets that

are within one hour walk from the homes of the population^{xliv}. The World Health Organization (WHO) characterises access by four (4) cardinal attributes namely; rational selection of essential medicines, sustainable financing, affordable pricing and reliable health and supply system (World Health Organization 2004). Peters *et al.* (2008) also define access as ‘the timely use of services according to needs’. Access barriers can stem from the demand side and the supply side (Ensor and Cooper 2004). The demand side constraints influence individuals', households' and communities' ability to use services. The supply-side constraints, on the other hand, are aspects of health services and the health sector that hinder service uptake. The Region can identify necessary remaining Access to Medicine (ATM) barriers which can be along all dimensions of access – geographical and financial accessibility, availability, acceptability and quality (Peters *et al.* 2008).

According to the WHO, ‘Equitable access to essential medicines framework presents four dimensions of Access to Medicine: rational selection – proposes to rationalise therapeutic choices, consumers use of improved medicines; affordable prices – deals with the supply-side aspect of affordability; sustainable financing – addresses resource mobilisation and pooling as well as reduction of out-of-pocket and catastrophic expenditures; and reliable health and supply system – meant to include all aspects of health system strengthening that the preceding Access dimensions do not cover namely, procurement and supply of medicines, regulation and human resources (WHO, 2004c). Quality assurance and management systems are assumed to underpin all the access components.^{xlv} But, WHO goes into details to explain the rational selection of essential medicines to involve choosing drugs appropriate to a country’s health situation based on their effectiveness, safety and cost. Institutionalising rational choice involves using Essential Medicines Lists (EMLs) based on the best available evidence on local disease burden, efficacy, safety and cost of treatment for those diseases (WHO 2015). Selection for procurement is important in rationalising the scarce

resources for vital products that must always be available at all level of health care. In a study carried out in Tanzania in 2007, only about 52% of surveyed facilities procured medicines within the EML. The government of each country, through the ministry of health, sets up a committee made up of physicians and pharmacist to formulate the EML for that country. For example, the government of Nigeria reviewed the EML using a committee of this nature (Federal Ministry of Health Nigeria 2016). Nigeria's practice has been the practice for many countries in the sub-region to help nations. The WHO published its first model EML in 1977. In this regards, the WHO expected the various states in sub-Saharan Africa to develop national EML using this model to take into consideration the disease gradients and prevalence in their countries (Ekeigwe, 2019).^{xlvi}

Faced with the numerous difficulties with access to medicine in Africa, African states want to organise the market to increase local production, which currently accounts for 3% of world output^{xlvii} (Barbière, 2018). Despite a booming market of trade in counterfeit and fake medicine in Africa, local production of medicine in Africa remains remarkably low since as the Region accounts for only 3% of global pharmaceutical products. The regions low contribution to the production of global medicines/drugs is a weakness that leads to a high dependence on imports from Europe. The WHO advises countries to use their EML as the basis for rational selection of drugs for the treatment; promotion and protection of their citizens' health.

Sustainable financing of medicines is another characteristics of WHO's attribute of access yet an illusion and a remote prospect in many some African countries. According to WHO, Out-of-pocket expenditure on healthcare is a significant indicator used by the WHO to measure the equity of healthcare systems and the extent to which accessing healthcare depends on personal abilities^{xlviii}. Private expenditure on health has impoverished many households in Africa. For some, it has compelled them to sell off their assets, including sometimes their income-generating tools

to offset healthcare bills^{xlix}. Invariably, without such tools to support their trade/economic activity, the families only fall back to abject poverty, and incapable of affording safe and quality medicines.

The 2013 report of the WHO on the African Region states that:

The Member States of the African Region of the WHO are on average, still far from meeting key health financing goals, such as the Abuja Declaration target of allocating 15% of the government budget to health. Out-of-pocket expenditure is still higher than 40% of the total health expenditure in 20 of the 45 countries studied; and in 22 countries, the total health expenditure does not even reach the minimal level of USD 44 per capita defined by the High Level Task Force on innovative International Financing for Health Systems (HLTF). Only three countries have attained the Abuja Declaration and HLTF targets (WHO Regional Office for Africa 2013).

The situation is no different today. The 2018 budgetary allocation to health by Nigeria is 3.9%. The highest allocation to health since the Abuja declaration has been 5.95% (Adepoju, 2017). The 2015 WHO country report, Nigeria, corroborates these statistics. It further observed that Nigeria's health expenditure in 2014 is 3.7% of its GDP (World Health Organization Nigeria 2018). The situation is no different in the Gambia where the budgetary allocation to health is 11% of the total government budget between the year 2010 and 2011. 65% of their healthcare funding is said to be from external sources which are not sustainable (African Health Observatory 2013).

Affordable Pricing

Affordable Pricing is one of the characteristics of access by the WHO. In developing countries, most people have to pay for their medicines out-of-pocket. In contrast to developed countries, there are often mechanisms such as insurance schemes or government provision of drugs. This means

that many people living in developing countries frequently face a choice between buying medicines or buying food or other necessities. Therefore, medicine prices matter. For many years many NGOs have worked on this issue to uncover the reasons for high prices of medicines less developed nation but to no avail. Participants at the WHO's Public Interest NGO Pharmaceutical Roundtable in 1998 also raise the same issue concerning the cost of drugs in developing nations. A working group was formed and began developing a simple but robust method to measure drug prices (A. Creese 2003).¹ Every day, millions of people throughout the world go without treatment because they cannot afford the medicines they need. People in industrialised countries generally have insurance or subsidies that cover most of the price of their drugs, but those in poorer countries with less well-developed health systems, for instance, Africa typically pay the full cost of almost all of their medicines themselves. These are the people who know that medicine prices are a problem. Although prices may vary quite a bit within a country, people usually do not have the information about what costs are, or where to find the best prices. The same is often true of government authorities dealing with medicine. There are dozens of medications and hundreds of prices. The same drug may have different prices, in its originator brand or generic form, in public, charitable agency or private pharmacies, in urban and rural areas. The proliferation of medicines and their variant costs makes it impossible for the public to know what a "best buy" is and where they can get it. Reliable information on what prices are and how sellers arrive at them is the first step to better negotiation, management and policy to make medicines more affordable by bringing costs down. (A. Creese, 2003).

The prices of medicines vary according to several factors. Firstly, the sector from which people purchase them. The cost of medicine is often higher in the private for-profit sector and also the type of procurement agents used. For instance, a public sector purchaser, such as the Ministry of

Health, the health facility that supplies the medicine to the patient, and the individual who purchases the medicine may pay different prices for the same product. Secondly, the distribution route can also affect the prices of medication. A patient who purchases a drug at a public hospital pharmacy might have to pay more if the hospital pharmacy bought the product from a local wholesaler than if the pharmacy had purchased it by tender and supplied through the public health sector distribution system. Thirdly, the patent status of the medicine also accounts for the price. The price of patented drugs is often higher than that of their generic equivalent, at least while the patent is in force. (K. Myhr, 2003). Patent medicines originally referred to medications whose ingredients enjoy government protection for exclusivity^{li} Generic drugs contain the same active ingredients, in the very same strength, as brand-name drugs.^{lii} According to Kirsten Myhr, while the price of medicines is an issue, affordability is yet another whether people can afford the medication regardless of how cheap or expensive they are. One way to find out if people can afford the medicines is to compare the cost of medicine/ treatment with that of the people's income.

According to Antonio Villarreal, the high cost and limited availability of some drugs is the cause of counterfeit and fake medicine in Ghana, and not just Ghana. According to WHO data, global counterfeit medicine trade tripled between 2000 and 2013, accounting for a market worth around 371,000 million euros. A study on anti-malarial and tuberculosis medications was conducted in 2010 by this organization and the United States Pharmacopoeia (USP), a non-profit organization financed by USAID (the US Agency for International Development). The results in East Africa were positive, with only a few medications failing to pass the testing in nations like Kenya and Tanzania. The disease, on the other hand, was spreading westward. Half of the medications audited in Cameroon were found to be fraudulent or substandard, while they accounted for more than 60% in Ghana and Nigeria. Although the percentages of evaluations completed in Ghana varied

substantially, all of the findings were disturbing. In a 2008 trial conducted in Kumasi, Ghana's capital, 14 of 17 boxes of artesunate (another anti-malarial medicine) purchased by researchers did not contain what they claimed^{liii}. Surprisingly, these are commonly purchased medicines for the treatment of malaria, and many individuals fall prey to fake and counterfeit versions, which either extend their illness or result in death.

Reliable Health and Supply System

According to WHO, reliable health supply system will: 1) Integrate supply management into health system development; 2) Develop an efficient mix of public-private partnerships; 3) Maintain medicines quality in distribution channels; and 4) Ultimately increase access to essential drugs.^{liv}

The regulatory capacity and capability in the Region are inadequate – regulators are inexperienced (Moran et al. 2010) and poorly rewarded precise prescriptions for weak enforcement. Besides, there are unclear regulatory requirements for the issuance of marketing authorisation (West African Health Organization 2014); the lack of reciprocal recognition of regulatory processes among Anglophone, Francophone and Lusophone countries putting constraints to human resource mobility and access to quality and affordable medicines in the Region (West African Health Organization 2014); Inadequate cooperation and vulnerable trust among the ECOWAS Member States (West African Health Organization 2014). These unclear regulations affect the potential for the portability of regulation across borders. The medicines distribution and supply channels are chaotic, especially in the private sector. Public sector distribution is through the Ministries of Health. However, the private sector distribution channels are not defined, and it is complicated to track. In these regions, distributors may sell highly regulated prescription drugs in open markets; of which many are Substandard and Falsified (West African Health Organization 2014). In Ghana for instance, it is estimated to have approximately 1600 retail pharmacies and 10 000 chemical

sellers of which 7000 are registered with the Pharmacy Council which is the regulatory body of the Ministry of Health tasked with ensuring the quality, accessibility and equitable distribution of pharmaceutical services, and the Association of Chemical Sellers^{lv} which makes it complicated to monitor and track the sale and quality of medicine.

The proliferation of Substandard and Falsified (SF) medicines, in most cases, is oppressing right products out of the market and further discouraging investments in research and development. The health information systems are weak to non-existing. Thus, communication and knowledge sharing within the Region are low. There is a duplication of efforts and resources contributing to diseconomy in the drug supply chain of the Region. Reliable medicine supply chains have two primal components, namely, procurement and distribution systems^{lvi}. Public procurements done by the government through the Ministries of Health are fraught with many challenges ranging from inadequate quantification, non-transparent contract award processes to inefficient supplies, receipt and storage processes at the Federal medical stores. (Ekeigwe, A.A, 2019). Private pharmaceutical industries and businesses essentially procure medicines as vendors to the government. Reliable health and supply systems are limited, especially in the rural and sub-urban areas of the Region. Ironically, a significant proportion of the population resides in the rural and sub-urban areas (Population, West Africa 2019). Some communities will need to travel for hours before accessing any proper health care facility. Such a situation has led to the proliferation of untrained, unqualified and unregulated providers of healthcare supplies and services. This, in turn, has caused indeterminate undocumented mortalities.

Also, anecdotal evidence abounds that there are no defined distribution channels for medicines in West Africa (The African Union Commission, 2012). Distribution is the system by which drugs get to the ultimate target destinations (the patients) from their origin (the manufacturing site). An

efficient and effective medicines distribution system affects time-to-patient cycle, affecting timely access to essential medicines at all levels of the health system and possible recalls of drugs when necessary. Distribution can be either by the government through Federal medical stores to government-owned health institutions or privately by the importers or manufacturers via their distribution channels to hospitals and pharmacies. A high proportion of medicines distribution use these private channels, and they are highly chaotic and unregulated.

2.3.2 Sustainable Development Goals (SDGs) and Illicit Trade in Pharmaceuticals

According to the Transnational Alliance to Combat Illicit Trade (TRACIT), the global trade in illicit pharmaceuticals extends beyond the generally well-known problem of “fakes” and Counterfeiting to include substandard, falsified, unregistered and unlicensed drugs as well as their theft, fraud, illicit diversion, smuggling and trafficking. The problem of illegal pharmaceuticals applies not only to highly-publicised lifestyle medicines, such as for treating erectile dysfunction and weight loss but also to lifesaving medicines including those used to treat malaria, cancer, heart disease and other serious illnesses. The issue also covers generic versions of prescription drugs and increasingly to over-the-counter (OTC) medicines. This category of illicit trade also includes fake medical devices such as contact lenses, condoms, syringes, surgical instruments, wheelchairs and radiotherapy machines where fake or faulty versions can all present considerable health and safety risks. Illicit trade in medicines is a significant threat to public health, diverts resources from already limited healthcare budgets, creates mistrust in government and presents economic and social challenges to pharmaceutical companies operating in the sector. The World Health Organization (WHO) has thus far generated the most widely-cited statistics, reporting that the share of counterfeit medicines on the market ranges from over 10 per cent of total sales in

developing countries to as little as 1 per cent in developed countries. In terms of value, illicit trade in pharmaceuticals has been estimated at US\$75 – 200 billion annually. INTERPOL reports that falsified medical products could account for as much as 30 per cent of the market in some countries in Asia, Africa and Latin America. In the transitional economies of former Soviet Republics, there are estimates of above 20 per cent of market value.

2.4 Definition of illicit trade in pharmaceuticals

The Transnational Alliance to Combat Illicit Trade (TRACIT) says that it is essential to understand that the problem of illicit trade in pharmaceuticals extends beyond the protection of intellectual property rights (IPR). The World Health Organization (WHO) has at the Seventieth World Health Assembly on May 29 2017, provided some categories to help elucidate the problem. Substandard also called “out of specification,” are authorised medical products that fail to meet either their quality standards or specifications or both. Unregistered/unlicensed are medical products that have not undergone evaluation and or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation. Falsified medical products are products that deliberately/fraudulently misrepresent their identity, composition or source. As such, many use the term “counterfeit” to broadly refer to medicines that are (a) deliberately produced with substandard quality; (b) fraudulently labelled concerning their identity/origin; or (c) otherwise tainted, adulterated, or made ineffective or harmful. Fundamentally, counterfeit medicines are neither regulated or quality controlled and therefore, should be expected to be inferior as they move outside the safety of established, and regulated supply chains.^{lvii}

2.5 Impact of the trade in illicit pharmaceuticals on achieving the UN Sustainable Development Goals

The global trade in illicit pharmaceuticals undermines the achievement of several of the SDGs, but none more so than depriving individuals of good health and wellbeing (SDG 3). As highlighted by the WHO, “the rise in substandard and falsified products on all markets, are hampering efforts to ensure health products’ quality, efficacy and safety.” Moreover, expenditure on an ineffective medicine is a wasted allocation of household income, which hinders progress away from poverty for families where drugs and healthcare can account for a significant share of household spending or when medicines are paid for out-of-pocket. According to the UNCTAD’s Secretary-General, Mukhisa “Counterfeit medicines are just one example of how we simply will not achieve the SDGs without looking after our consumers”. The illicit pharmaceuticals trade impair the achievement of seven SDGs, including SDG 1 – poverty eradication, SDG 3 – good health and wellbeing, SDG 5 – gender equality, SDG 8 – decent work and economic growth, SDG 9 – industry, innovation and infrastructure), SDG 12 – responsible consumption and production, and SDG 16 – Peace, justice and strong institutions.

The fact that good health underpins every development issue is embodied in SDG Target 3.8: “Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.” However, the proliferation of falsified and substandard pharmaceuticals present formidable obstacles to good health when consumers and patients ingest spurious medicines that have little to no medicinal value and frequently result in therapeutic failure.

The severity of their associated health risk can vary greatly, ranging from inconvenience to fatality. Substandard, unregistered and falsified medicines present significant health risks to users. Such

drugs may contain the wrong level or very little of the active ingredient, actually, in some instances, Substandard and Falsified medicines may contain none of the active ingredients, but harmful ingredient intended for a different purpose. Thus, they fail to meet quality standards or regulatory specifications since the SF medicines do not undergo evaluation or approval by regulatory authorities.

In all the scenarios, persons taking such medicine is putting their health at risk, and this is perhaps most troubling in cases when fake or substandard anti-malarial medicines fail to save lives. Estimates show that between 72,000 and 169,000 children may be dying from pneumonia every year after receiving harmful drugs and that fake anti-malaria medication might be responsible for an additional 116,000 deaths. As noted by the Organisation for Economic Co-operation and Development (OECD), “a significant body of work confirms that counterfeit pharmaceuticals are increasingly prevalent and pose a serious and growing threat to public health, especially in developing countries, for instance, Africa. While counterfeit drugs are a less visible barrier to access affordable medicines, they are perhaps a more insidious threat to public health than high drug prices will ever be.”

It is often the poorest and most vulnerable in societies who are tempted by the prospect of cheaper, albeit substandard and falsified medical products. Yet, the increased health care costs of being forced to buy effective treatment a second or third time, when a substandard or falsified product fails to work. Or when faced with extra costs of coping with the potential adverse reactions and drug-resistant infections triggered by substandard and falsified medicines and vaccines can create a vicious cycle of poverty and poor health. Falsified and low-quality drugs also have a worrisome effect on antimicrobial resistance (AMR), which is an issue of growing global concern. Many substandard medicines contain a lower amount of the correct active ingredient, which can fail to

kill bacteria, viruses or parasites properly. Such case is what is happening with some of the world's serious diseases, such as tuberculosis and malaria, where multi-resistant strains are becoming a serious global public health threat. It is estimated that by 2050, 10 million lives a year and a cumulative US\$100 trillion of economic output are at risk due to the rise of drug-resistant infections. The largest proportion of this burden will be borne by low-income countries who are more resource-constrained and slowing down progress towards SDG1 (end poverty).

2.6 The Impact of Illicit Trade on the Sustainable Development Goals in Africa

Progress on SDG 1 (End poverty in all its forms everywhere) and SDG Target 5.6 (Ensure universal access to sexual and reproductive health and reproductive rights) are thus intrinsically linked with achieving SDG 3 (Good health and wellbeing). However, the presence of substandard or falsified contraceptives is a growing concern for women's health. Many people have reported Falsified emergency contraceptives in several countries, including Nigeria, Ghana, Kenya, Angola, South America and the United States. In August 2015, the Uganda National Drug Authority notified the WHO of the seizure of falsified Postinor-2 discovered in Kampala, Uganda. A 2014 survey of emergency contraceptive pills in Peru found that 28 per cent of the batches studied were either of substandard quality or falsified. Many pills released, the active was ingredient too slowly, while others had the wrong active ingredient or no active ingredient at all. Incidents of fake contraceptives in the legitimate supply chain, even in small numbers, can lead to a loss of confidence in government programs and private health care systems. Even mere rumours of it can destroy the credibility and success of health and family planning programs, with lasting damage to the reputation of a country's health system. For example, a lapse in the quality of oral contraceptives in Brazil in 1998, resulting in unplanned pregnancies has contributed to poor public

confidence in the Brazilian health care system. Even with the creation of the Brazilian drugs regulatory authority, Anvisa, to mollify the crisis and address other medicine quality problems, rumours about contraceptive quality linger in Brazil.

2.7 Factors in achieving SDG 3.8 in Africa

Since 2000, programs to improve health across the world have accelerated rapidly. The Millennium Development Goals (MDGs) in particular, have intensified the focus on health, development, and poverty reduction and encouraged the scale-up of investments in interventions worldwide. MDGs have spurred a reduction of the proportion of undernourished people in developing regions from 23 per cent to 13 per cent. It has also led to a dramatic fall of the burdens of human immunodeficiency virus (HIV), tuberculosis (TB), and malaria, meeting global targets. And, finally, child and maternal mortality decreased by 53 per cent and 43 per cent, respectively (WHO, 2015). Despite the overall success of the MDGs in general, healthcare in Africa has been uneven. The MDGs largely overlooked inequalities within nations and placed insufficient emphasis on improving conditions for the most impoverished populations in both low and middle-income countries.

As a successor to the MDGs, in September 2015, the global community adopted a new development agenda, the Sustainable Development Goals (SDGs) - agreed on by 193 countries (UNDP, 2015). The SDGs represent an attempt to address the unfinished agenda of the MDG era, setting forth a comprehensive set of integrated targets through economic, social, and environmental lenses. Of particular relevance to this report, SDG 3 focuses on “ensuring healthy lives and promoting wellbeing for all at all ages” (UN, 2017). The pursuit of equity is at the heart of the SDGs, and Target 3.8 addresses explicitly the achievement of universal health coverage

(UHC), the central pillar of SDG 3 (UN, 2017). The SDG 3.8 also seeks to achieve financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines, and vaccines for all.^{lviii}

2.8 Recent activities of international partners in West Africa to ensure access to quality medicines

The international development partners such as the WHO, USP, UNIDO, World Bank, Bill and Melinda Gates Foundation etc. are involved in many initiatives in Africa to help improve access to safe, quality and effective medicines. Researchers anticipate that the harmonisation efforts among many organisations in Africa, comprising West Africa Health Organization (WAHO), NEPAD (the African Union’s technical agency for the implementation of medicines regulatory harmonisation in Africa), African Union Commission, Pan African Parliament, the United Kingdom Department for International Development, Clinton Health Access Initiatives, and WHO (providing technical support) funded by the World Bank, and the Bill and Melinda Gates Foundation could help to resolve many of the issues West Africa faces as regards medicine regulations.

The overall aim of the African Medicines Regulations Harmonization Initiative (AMRH) is “To improve public health by increasing rapid access to safe and effective medicines of good quality for the treatment of priority diseases” (NEPAD and WHO, 2017) and specifically “To reduce the time taken to register essential medicines” (NEPAD and WHO, 2017). The potential benefits of the African Medicines Regulations Harmonization Initiative (AMRH), include robust regulatory capacity, efficient use of scarce resources, and shortened registration timelines of essential medicines. The AMRH initiative will aide industries to prepare only one set of documents for applying to multiple countries, which will fast-track access to essential drugs among communities

(NEPAD and WHO .2017). It will also help improve access to medicines needed for the Neglected Tropical Diseases and the monitoring of clinical trials for new chemical entities.

The Pharmaceutical Manufacturing Plan for Africa (PMPA) is another laudable venture. The Conference of African Ministers of Health adopted the PMPA in April 2007; and in July that same year, the Heads of State and Government endorsed it in Accra (The African Union Commission, 2012). According to the African Union Commission, the main objectives of the PMPA venture is “to increase access to affordable quality medicines, and to ensure a sustainable supply which will provide improved public health outcomes as well as deliver associated economic development.” (The African Union Commission 2012). Its business plan includes the implementation of a “GMP Road Map” (The African Union Commission 2012). The African Union Commission is working with the United Nations Industrial Development Organization (UNIDO) to implement the GMP road map. The continent hopes that this venture will build the capacity of local Pharmaceutical manufacturing facilities, helping them to meet international standards in the manufacture of medicines and thus alleviate the issue of Substandard medicines in Africa.

The GMP road Map is “a risk-based and phased approach to WHO’s GMP compliance”. The approach involves three steps: Collecting baseline data on existing manufacturing practices, evaluation of gathered information and identification of the significant common technical challenges and Design of a GMP roadmap based on the evaluation results (United Nations Industrial Development Organization 2015). Other initiatives include the training and support of regulators and industry practitioners by the USP.

The journey to sustainable manufacturing and access to safe, quality, and effective medicines in Africa seems long, arduous and risky, and the end seems too far off. However, as the common

saying goes “the journey of a thousand miles always begins with one determined and purposeful step”. Africans and to be specific, West Africans have started the long walk to providing safe, quality and effective medicines for its people. The steps should be progressive and fast because lives are involved. This study has highlighted the challenges, which are numerous and seem mountainous lack of adequate support from the government, human resources issues, relative weak regulatory capacity, medicines manufacturing challenges. With the implementation of the current initiatives of the African Medicines Regulations Harmonization, the PMPA, the Good Manufacturing Practicing (GMP), and the Road Map, nonetheless, the continent can achieve the goal of sustainable manufacturing and access to safe, quality, and effective medicines. All stakeholders the government, National Medicines Regulatory Authorities (NMRAs), manufacturers, regulatory consultants, the patient and development partners must work together in an intricate web of activities to overcome these challenges.

High Demand

According to estimates, there is a high demand for drugs on the continent. Some has speculated that he expected spending on pharmaceuticals should reach \$40 to \$45 billion per year in Africa by 2020, compared to \$14.5 billion in 2010. “The market is very promising, particularly the West African area, as there is a high demand for medicine”, said Ouattara. “There is a market, but there are problems in terms of accessibility, quality and price levels.”

2.8.1 Need for Right Tools

A significant aspect of this problem is that Substandard medicines, whether they contain the wrong levels of active ingredients or are contaminated, are difficult to detect without the right tools

and know-how, especially in low-resource settings. According to Ronald Piervincenzi, the US Pharmacopeia Convention (USP), where he works has been trying to address this issue around the world, including in Africa. Three years ago, the USP opened the Center for Pharmaceutical Advancement and Training (CePAT) in Accra, Ghana, to improve pharmaceutical quality in Ghana and across Africa. The centre serves as a platform to train African professionals and build capacity for domestic and sustainable drug quality systems.

Since 2013, CePAT has helped train 190 professionals from 32 African countries. In addition to training, CePAT has also assisted with drug screening. In 2013, USP through the promotion of Quality of Medicines Program and in collaboration with Ghana Food and Drugs Authority (GFDA) discovered grievous issues with the quality of oxytocin, a drug used to treat excessive blood loss within 24 hours of birth. Data have shown that 90 per cent of the oxytocin tested in Ghana were substandard. Based on these findings, the Ghana FDA met with the ministry of health procurement unit to impress upon them the need to have all government-procured products vetted and registered by the FDA before they import them into the country. The FDA also issued a nation-wide press release informing the public about the low-quality batches and recalled them from the market^{lix}.

2.8.2 Impacts of CePAT

On February 10, 2013, the US Pharmacopeia Convention (USP) and Center for Pharmaceutical Advancement and Training (CePAT) opened a brand new lab to train pharmaceutical and regulatory professionals in microbiology testing. Hopefully, the establishment of this new lab will equip more pharmaceutical professionals across Africa to ably learn to detect medicines that have been contaminated by microorganisms. The improvement in pharmaceutical resources will ensure the safety of citizens through the elimination of harmful/contaminated drugs from the market. What is more, this lab was designed specifically for use in low-resource settings, meaning it could

serve as a model for other countries and national laboratories to replicate. Despite our efforts, millions of people across Africa can still be at risk every time they walk into a pharmacy or drug shop. Given the sheer number of fake and low-quality medicines on the market, we're going to need quite a bit more help building the capacity to detect them.

“And, no matter how many fake and poor quality medicines we detect, our work is fruitless without the partnership of those who can enforce higher standards” (Ronald Piervincenzi, USP). CePAT already offers scholarships to pharmaceutical professionals from across the continent. They believe that with additional resources, they can help bring more people from across Africa to Ghana to learn the skills they need to assess the quality of medicines in their home countries.

2.8.3 Importance of Partnerships

According to CePAT, no matter how many fake and poor quality medicines they detect, their work is fruitless without the partnership of those who can enforce higher standards. National governments must commit to ensuring safe drugs for their citizens. They must adequately staff the regulatory agencies with well-trained professionals since it fosters the efficacy and effectiveness of every agency or organisation. Communities, too, should get involved and hold their governments accountable for ensuring that only quality-assured medicines reach the shelves of local pharmacies, dispensaries or other medicine outlets. Governments across the continent are already making great strides to improve health outcomes in their countries (Ronald Piervincenzi, 2016).

Increased focus on more robust health systems and universal health coverage are pointing us in the right direction, toward a future where all Africans can access the health care and the medicine they

need. A new policy brief titled “The Rise of Counterfeit Pharmaceuticals in Africa” has been launched by ENACT on January 22, 2019, in Accra with a focus on its implications for Ghana and West Africa. The brief embodies essential findings and recommendations of a study conducted by Enhancing Africa’s response to transnational organised crime (ENACT), one of the European Union (EU) funded projects under its Pan-African Programme support agenda. Mr Eric Pelser, the ENACT programme Head of the Institute for Security Studies, at the opening ceremony, said the proliferation of counterfeit medicines in Africa is becoming a challenge to achieving the Sustainable Development Goal 3 (SDG 3). The SDG 3 also places significant emphasis on populations’ health, with its sub-target 3.8, specifying access to safe, effective, quality and affordable essential medicines and vaccines for all. “Yet, remarkably missing from the discourse around achieving this goal is the need to address the growing phenomenon of counterfeit medicines, which disproportionately affects developing countries,” he said. Mr Pelser said counterfeit medicine trade put people’s lives at risk, finances criminal groups, and causes profound public health challenges. Yet, the full scale of the challenge in Africa was not fully understood, but research suggests that the problem and its impact are severe. He said that the growing incidence of the so-called Falsified and Substandard medical products was arguably the most insidious and evil form of illegal trade. Because the incidence leads to widespread loss of lives, accounting for between 64,000 and 158,000 otherwise avoidable deaths annually from malaria alone in sub-Saharan Africa. Although the phenomenon is not specific to Africa, counterfeiters preyed on developing countries more than their wealthier counterparts with up to 30 times greater penetration of fakes in the supply chain compared to the one per cent in the developed world, he said. Mr Pelser opined that agencies and governments must move the issue of counterfeit medicines on top of their policy agenda, so as to facilitate the achievement of the SDG 3.^{lx} He buttressed his

suggestion with evidence elsewhere suggesting that there would be scope for significant positive results if policymakers pay optimum attention to addressing issues of counterfeit medicines' propagation. He furthered that addressing the problem in Africa, may help prevent widespread loss of life, and mitigate other public health and safety risks, and, that the African States must prioritise the issues. Responses should include a substantial overhaul of the analytical, legal, educational, regulatory and enforcement systems around the medical supply chains, to help strengthen the mechanisms for combating medicine fraud.

He continued that Africa needs to coordinate these responses within a global effort, including setting up a database of intelligence on counterfeits, improved awareness-raising campaigns, and recommended that national medicines regulatory authorities be tasked to investigate mass serialisation forms of track-and-trace regularly. Mr Pelser said that the increasing trend of these illicit trading, therefore showed that counterfeiters found Africa an easier target because it has not developed the West's armoury of responses to these fake drugs. He cited the Europe and USA's enviable supply chain regulation, track-and-trace technology and enforcement regimes, as a defence that were wholly lacking in African countries. The paper, he said, sets out the scale and effects of the problem, and recommends a comprehensive programme to awareness creation, as well as measurement, legal, supply chain and enforcement activities, to begin the enormous task of reducing counterfeits in Africa.

Mrs. Martha Gyansa-Ludtterodt, the Director of Pharmaceutical Services at the Ministry of Health and Chief Pharmacist, urged all stakeholders to form a united front to fight against the proliferation of these counterfeit pharmaceuticals on the Ghanaian market. She said the presence of these illicit medications had become an enormous setback to the country's achievement of Universal Health Coverage (UHC). She continued that fake drugs including anti-malaria, dewormers, pain killers,

Tramadol, codeine and aphrodisiac medicines brought into the country by unknown persons, have and continue to be seized by the Food and Drugs Authority (FDA). However, such sporadic seizures would not solve the massive problem of the illicit trading unless stakeholders joined forces to fight the menace. She, therefore, continued that nations must strengthen the capacities of mandated institutions to make them more proactive so that they can ensure the harmonisation of policies and standards of pharmaceuticals. The various institutions in the nation must enhance intelligence sharing as strategies to arrest importers of these counterfeit drugs and trace their source of supplies and manufacturing. Ghana, she said, is currently re-engineering her supply chain mechanism to make it responsive to current challenges both at the national, regional and global level. She supported her claim with the Executive Instruments: Act 167, which bans the importation and use of all Codeine content in cough syrups; and the Act 168, which renders the use of Tramadol drug with active ingredients higher than 50 to 100 milligrams criminal acts. Act 168 stipulates that these medicines must be obtained strictly with prescriptions only.

Brigadier General Robert Affram, the Director of Training at the Kofi Annan International Peace Keeping Training Centre (KAIPTC), added his voice to the dramatic shifts in the conversion around Transnational Organised Crime (TOC) in Africa. He said that while the continent has enjoyed increasing stability and rising economic indices, these have also facilitated cross-border criminal activity across the continent. He said the unprecedented openness in trade, finance, travel and communication has also given rise to enormous opportunities for criminals to engage in their activities like counterfeiting. Highlighting also on the treat such activities pose to governance, peace and development in both developed and developing nations.

Mr Sotirios Bazikanwe, the governance advisor to the EU delegation to Ghana, said that the Union places security in Africa at the forefront of its international agenda. Notably through its Pan-

African Programme, which is the first of its kind to centre on development and cooperation, and covering Africa as a whole, hence its support through the three-year ENACT programme. He called on all partners to accept the recommendations of the study to eliminate counterfeit pharmaceuticals to maintain quality health of Africans and reduce the high rate of preventable deaths (Ghana News Agency January 24, 2019).

2.9 Conclusion

The proliferation of counterfeit and fake medicine trade in Africa is a thorny issues which affects everyone and not only the leaders of Africa and despite the fact there are challenges and already existing efforts to prevent the boom in counterfeit and fake medicine trade in Africa, it is still worth mentioning that if issues of counterfeit medicines are to be moved higher up on the policy agenda, it will help better in addressing the problem in Africa which includes weak and porous borders, corruption, high prices of medicine, non-availability of medicines and easy accesses by popular, adequate training of personnel, communication, information sharing and corporation by law enforcement institutions with each other and governments in the continent, investing in local manufacturing and proper licensing, enforcement and a monitoring regime it may also help prevent widespread loss of life, and mitigate other public health and safety risks, and that African States must prioritise the issues.

Endnotes

^{xxiii} <https://www.bbc.com/news/topics/cp7r8vgl2rgt/reality-check>

^{xxiv} <https://iharare.com/fake-medicines-flood-africathousands-dying-each-year/>

^{xxv} Counterfeit Drugs: The Relentless War in Africa
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CHAPTER THREE

EVALUATION OF THE EFFORTS TO CONTROL AND PREVENT FAKE DRUGS ON THE MARKET: SUCCESSES ACHIEVED, CHALLENGES FACED IN THE FIGHT AND THE WAY FORWARD FOR GHANA

3.0 Introduction

The efforts by many nations in West Africa to foster their citizens' good health and wellbeing have been marred by the proliferation of counterfeit/fake drugs on their markets. And certain factors outlined in the preceding chapters, such as high cost of healthcare, porous borders, lack of medical expertise, etc. have paved the way for the rampant of fake drugs in many West African nations. Nevertheless, many of these nations have not stood aloof to the rate at which the propagation of counterfeit drug trafficking is deteriorating the health of their population. They, through public-private partnership, have raised against the canker counterfeit drug increase. And this chapter unfolds in three subdivisions to evaluate Ghana's fight launched against counterfeit drug trafficking on the Ghanaian market: the successes achieved thus far, the challenges met, and the plausible solutions to those challenges.

3.1 The success of the fight against counterfeit drugs in Ghana

Public-private partnerships have been at the forefront of Ghana's efforts to crack down on the continuous increase in fake drugs in the nation. These concerted efforts include the use of modern technologies, increased routine post-market surveillance, affordable healthcare programmes, Pharmaceutical and expert capacity building, and countering transnational fake drug trafficking.

3.1.1 Modern technologies to detect fake drugs

Among the many available technologies globally deployed to detect fake and substandard drugs, mPedigree, RxAll app and spectrometer, CD-3+, and Raman TruScan are the most popular ones used in Ghana and other West African countries to control and prevent the influx of counterfeit drugs on their markets. The mPedigree uses encrypted/verification codes by the original manufacturers to authenticate their products, which are coded in mPedigree's database. With the help of this code, consumers can easily confirm the authenticity of a drug by sending the verification codes to a short code via GSM phone. mPedigree is linked with about 20 telecommunication networks in Africa, India, and Bangladesh. It has over 10 million packs of medicines registered in its database since February 2013 (USAID MHealth Compendium, Vol. 2, 2013)^{lxi}. The system has almost 70% of Nigeria's medicine, as of 2011 (medicamentalia.org, 2018)^{lxii}. According to Selorm Branttie, the CEO of mPedigree, the use of this technology has reduced fake medicine in Nigeria Market to less than 10% (theguardian.com, 2019). It boasts of already registered 2 billion products, including medicines, seeds, and cosmetics (skoll.com, 2019). The company is said to be one of the foremost private corporations to effectively collaborate with the Ghana Food and Drugs Authority to track down the rising number of counterfeit drugs in Ghana (medicamentalia.org, 2018).

The use of this technology looks very promising to both consumers and drug sellers. With a little patience, consumers and chemical sellers can determine the authenticity of the drug there are buying. It is incredibly essential on the side of the chemical sellers because, for the most part, it is through them that quality, counterfeit and substandard medicines are made available for the consumers. Hence, their ability to detect authentic medications from imitations within seconds

places the consumer in a better place to access quality medication even if the price maybe a little bit expensive. This also assures consumers value for their money, that is, good health because they can have quick and easy access to safe and quality drugs. Other technologies have also immensely contributed to the fight against substandard and counterfeit medicines, such as CD-3+ and Raman TruScan.

Both Raman TruScan and CD-3+ are hand-held devices use mostly by the retailers and the officials of Ghana Food and Drugs Authority. These devices have been the FDA and other CePAT's major field devices for their routine post-market surveillance. These devices enable the officers not only to detect counterfeit drugs but also to assess the quality standard of the products – active ingredients. Mr. Kwasi Boateng, USP's country manager, acknowledge the adoption of these two technologies as part of their field testing, in addition to their three level-approach. He recognizes the contribution of these screening methods to the reduction in fake antimalaria drugs in Ghana's Pharmaceutical market from about 31% in 2009 to about 2% in 2018. He said this in an interview with Fight the Fakes in January 2019 (Fightthefakes.org, 2019)^{lxiii}.

The practice by the USP's Promoting Quality Medicines may not have dealt with all the fake antimalaria drugs in Ghana. Nonetheless, its capacity to reduce the rate at which one is likely to pick a counterfeit or substandard antimalarial drug for treatment is evident. Such collaborative exercise with the FDA of Ghana deters retailers and wholesalers who deliberately purchase fake and substandard drugs because they are cheap. It also might have given chemical sellers and pharmaceutical retailers the technical eye to decipher counterfeit from original medicines through these easy to operate hand-held devices. Adding to these few technologies is FDA's routine post-market surveillance.

3.1.2 FDA's routine post-market surveillance

According to a report by Eunice Menka of Ghana Business News, Drugs retail outlets have been cautioned to be wary of purchasing medical products from unregistered sources, the public has also been advised to patronize genuine medical products by taking time to look at the packages, appearances, and colours of medicines and other products when purchasing these items to enable them use only safe products. Getting to know the batch numbers of drugs printed on drug labels is also important since it provides manufacturing information about a drug and details of production, so it can easily be traced to its source. These are some simple ways in which the public can support the Food and Drugs Authority (FDA) to rid the market of substandard and fake drugs.

Mr. Vigil Prah Eshun, Head of Drug Market Surveillance Department of the FDA, speaking to ghanabusinessnews.com in Accra on October 14, 2019, advised the public to also check for the production and expiry dates of products to ensure that they are fit for purpose and safe. He was responding to questions on what the FDA is doing to ensure that fake and substandard antimalarial drugs and related products such as rapid diagnostic test kits are weeded out of the Ghanaian market. He added that in 2018 due to FDA surveillance work, they were able to track and recall some substandard antimalarials, branded as Coartem. In this particular case he explained that the Coartem was traced to a retail drug outlet which had purchased the drugs from a wholesale outlet. According to him, some of the ways substandard and fake drugs get into the market is when peddlers slip in unregistered drugs while sometimes packing these products and moving them into a vehicle from a wholesale to a retail point of delivery. The FDA has improved on its capacity and structures to ensure that it gets a proper handle on dealing with unwholesome products and protecting the public. The FDA has for the past few years relocated from its small offices at the

ministries in Accra to a bigger office complex as its headquarters located at Shiashie, close to Legon. At the lobby of this office, where visitors are received and seated at the reception is a screen constantly putting out messages and educative information on safety and other related issues on drugs, food and other products. Some of the messages actually warn the public about dangerous items that have identified and made their way into the market. ^{lxiv}

Mr. Vigil Prah Eshun stated that, the FDA has also opened more border posts across the country to filter out unwanted products coming in from outside the country as porous borders or lack of proper supervision at Ghana's borders has been stated as one of the causes of the influx of fake and counterfeit medicines in the country. But this was done with various interventions directed at regulating the system to filter out these fake and counterfeit medicines coming into the country. He added that the task of the FDA is to ensure that all drugs, medical devices and other products regulated by the Authority meet standard requirements and that consumers who patronize all products including antimalarials and are not exposed to harmful products which the institution is working hard to achieving it (Eunice Menka, 2019).

3.1.3 FDA rated high on WHO quality standards

According to a report by Julius K. Satsi in Accra, May 15, GNA, The World Health Organisation (WHO) has benchmarked the Food and Drug Authority (FDA) Ghana to Maturity Level Three of the National Medicine Regulatory System, indicating a well- functioning system to guarantee stable performance. The new status makes the country the second in Africa to achieve this status in the WHO African Region, with Tanzania being the first to attain that level in 2018. The new status is the second-highest in the four-tiered WHO classification of a national medicine regulatory system. Dr Neema Rusbamayila Kumambo, the Acting WHO Country Representative,

made the announcement at a short ceremony said the WHO had four levels of regulatory maturity systems starting from Level One. She said the Level Three, currently attained by Ghana, indicated that the system was well functioning and integrated all required elements to guarantee its stable performance. Dr Kumambo said the country had indeed strengthened its medicines regulatory system to ensure safety, quality, and effectiveness of medical products manufactured, imported, and distributed within the country. The FDA attaining the level three of the WHO regulatory maturity system is in line with SDG 3:8 “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”^{lxv}. This puts Ghana in a better place with the FDA as the lead agency with its new attained status in the fight against Counterfeit/Fake medicines in attaining the SDG 3 by 2030.

Dr Kumambo according to the report continued that the WHO expected that the status attained would be sustained as its confirmed maintenance in the next two years would document further elevation. She added that the WHO was proud of Ghana and would continue to provide technical assistance and training to enable the country to implement global guidelines to meet the specific health needs. Dr Kumambo said the WHO believed that Ghana’s achievement would further catalyse other African countries to invest in strengthening their regulatory systems to ensure availability and access to quality, safe, effective, and affordable medical products to the citizenry. Mrs Delesse A. A. Darko, the Chief Executive Officer of the FDA, said the Authority always benchmarked against the best global practices to ensure that it was comparable to the most effective and best regulators in the world. She said having a strong and effective regulatory system played an important role in assuring the quality, safety and efficacy of all medicines and medical products in any jurisdiction. Mrs Darko said the achievement would better equip the FDA to play

its key role in promoting development in both orthodox and traditional medicine industries. “We will keep working hard to continually improve our systems, products and services, not just as a country but within the African medicines harmonisation initiative to improve public health through support, access to good quality, safe and efficacious medicines,” she added (Julius K. Satsi, 2020) and this is a laudable information in the fight against Counterfeit/Fake medicines which has been a headache for all.

3.2 Challenges of the Fight Against Fake Drugs

A WHO article released during the launch of the WHO’s five-year plan on “Delivering Quality-assured Medical Products for All 2019–2023”, said despite global progress, serious problems with quality and safety persist particularly in lower-and middle-income countries.

Adding that these problems threaten the health of people every day and waste resources. According to the WHO, the quality and safety of medicines, vaccines and other products are compromised when manufacturers, whether by accident or intent, produce substandard products, when the supply chain allows unsafe medical products through, and when systems (usually due to lack of resources) are too slow to respond to adverse events^{lxvi}

3.2.1 Lack/Inability of the Modern Technology

The modern technology mPedigree which uses encrypted/verification codes by the original manufacturers to authenticate their products, which are coded in mPedigree’s database might not have been able to capture all the products of all the manufacturing industry, in view of that, not all are encoded or encrypted to assure buyers of safe and authentic medicine that they are buying.

Again, the modern technology, mPedigree is not being use by all pharmaceutical shops or medicine sellers which still makes it possible for people to buy fake medicines in trusted shops.

Also, there is lack of education and publicity on fake/counterfeit medicine and also the availability and use of a modern technology like the mPedigree in verifying the authenticity of drugs. Therefore, there is the need for awareness creation and education for the population and the necessary bodies and individuals involve in the sale of medicines to people.

It can also be that some pharmaceutical companies by their own desire have not subscribed to the modern technology which has also made it not possible for their data to be captured by the modern technology making such products not on their system for verification purposes.

3.2.2 FDA'S Routine Post - Market Surveillance challeges

According to WHO, the manufacturing of medical products is a heavily regulated process to ensure that products are safe, efficacious and effective. The distribution and supply of medical products is an equally important step in ensuring that patients and consumers are dispensed medical products which remain of good quality, are safe and efficacious. Licensed and regulated distributors, wholesalers and retailers have responsibility to comply with good storage and distribution practices, and should be subject to periodic inspections by the appropriate national regulatory authority. Regulatory policies, procedures and sanctions should be published and applied proportionately and consistently to those knowingly engaged in the trade in Substandard and Falsified (SF) medical products. Distributors and retailers should be able to clearly show regulatory authorities from where they purchased or sourced the medical products they are supplying. Distributors, wholesalers and retailers should remain vigilant for

SF medical products and report suspicions to the National Regulatory Authority.^{lxvii} Counterfeiters are not sitting around waiting for regulators or the authorities to come to inspect and find them out in their trade, they are daily looking for ways of advancing their trades and business and this a challenge for FDA as it is easy getting the Licensed and regulated distributors, wholesalers and retailers to act responsibly and comply with all the regulations. The challenge of being able to fish out all groups and individuals in the sale of medicines irrespective of where they are located or hiding to be able to authenticate what they are selling or doing.

3.2.3 Global concerns

The need to strengthen regulatory bodies to deal with fake and substandard drugs such as antimalarials has become a global issue. Fake medical products do not only pose a serious threat to the population but additionally, have implications for the global call on stakeholders to push for universal health coverage. In July 2019, the World Health Organisation (WHO) in a write up which focused on *why strong regulatory systems are needed to reach universal health coverage*, noted that in recent months, regulators across many countries have recalled dozens of medicines to treat high blood pressure because they were found to contain potentially cancer-causing impurities. It had added that a “little less recently, in 2014, in the Ituri district of the Democratic Republic of the Congo several people, 60% of them children became sick after taking a medicine believed to reduce shivering and fevers from malaria.” “It turned out the medicine contained haloperidol, an antipsychotic substance used to treat schizophrenia. Investigators found that the tablets people had been taking contained 13mg of the drug about 20 times the maximum recommended dose for a

child. By the time the source of the problem was identified, 930 people had been hospitalized and 11 had died,” the report explained.

Also, according to the WHO, health gains can only be achieved if globally, regionally and nationally, health products do what they are meant to do which is to prevent illness and improve people’s health and they can only do that if sound regulatory systems are in place. The report further noted that current regulatory capacity and enforcement are insufficient in most developing countries as the WHO estimates that only 3 out of 10 regulatory authorities globally function according to acceptable standards. It added that the manufacturing of health products has become increasingly globalized with products and the materials that go into them crossing several borders before reaching patients, requiring even greater global vigilance. The global agency added that providing oversight of “health products throughout their lifecycle from laboratory to health facility is the linchpin of effective prevention, diagnosis and treatment and an essential part of WHO’s drive towards universal health coverage.” This global view point of the fight against counterfeit and fake medicine is both a strength and a weakness for countries as working together will bring about a safe globe with safe, quality and effective medicines for the treatment of sickness and diseases and help to meet the SDG 3, but failure will also spell doom for many countries and the inability to meet the SDG 3 by 2030.

3.2.4 FDA Guidelines for Good Distribution Practices (GDP)

The Food and Drugs Authority in 2013, introduced guidelines for Good Distribution Practices (GDP) which is an important activity in the integrated supply-chain management of pharmaceutical products. Various people and entities are generally responsible for the handling, storage and distribution of such products. The objective of these guidelines is to assist in ensuring

the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to, storage, distribution, transportation, documentation and record-keeping practices. This document sets out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits into the marketplace via the distribution chain. The relevant sections should be considered by various participants as applicable to the particular role that they play in the distribution of pharmaceutical products. Counterfeit pharmaceutical products are a real threat to public health and safety.

Consequently, it is essential to protect the pharmaceutical supply chain against the penetration of such products. Nonconformance to Good Distribution Practices (GDP) in the distribution processes of pharmaceutical products provides an avenue for counterfeiting. These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in the trade, supply, distribution and manufacturers of medicines including pharmaceutical, herbal and food supplements in Ghana. The relevant sections of these guidelines should also be considered for implementation by, among others, governments, regulatory bodies, international procurement organizations, donor agencies and certifying bodies, as well as all parties involved in any aspect of the trade and distribution of pharmaceutical products, including health care workers.^{lxviii} Again on 15 March, 2019 FDA adopted the Guidelines for Licensing of Pharmaceutical and Herbal Medicines Manufacturing Facilities. All these development will enable FDA to better function and to help in the fight against Counterfeit/Fake Medicines and to also enable Ghana meet its SDG targets by 2030.

3.2.5 Tightening local controls

Another challenge facing Ghana in the fight against Counterfeit/Fake medicines is tightening local controls. Substandard and fake drugs, especially antimalarials can destroy the gains made in controlling malaria, globally. Apart from impacting on the management and control of the disease, it can contribute to the spread of resistance and the rise of morbidity and mortality cases, and for countries such as Ghana, this can be bad news and this is a challenge.

New data from the *World Malaria Report 2018* shows that progress in the global malaria response has levelled off and, in some countries, the disease is on the rise. WHO sources have stated that approximately 70 per cent of the world's malaria burden is now concentrated in just 11 countries, 10 of them in sub-Saharan Africa (Burkina Faso, Cameroon, Democratic Republic of the Congo, Ghana, Mali, Mozambique, Niger, Nigeria, Uganda and United Republic of Tanzania) and India. These high-burden nations are home to an estimated 151 million cases of malaria and 275 000 deaths ^{lxix}.

“In 2017, all of the 10 highest burden African countries reported increases in malaria cases over the previous year, ranging from an estimated 131 000 more cases in Cameroon to 1.3 million additional cases in Nigeria. Only India marked progress in reducing its disease burden, registering a 24 per cent decrease compared to 2016,” the WHO said.

According to the global body, to get the response to dealing with malaria back on track, its Director-General has called for an aggressive new approach that would jumpstart progress against malaria under a “high burden to high impact” country-led approach that would be supported by WHO, the RBM Partnership to End Malaria and other partners. The WHO High burden to high

impact programme is a targeted malaria response which is contained in a document detailing some principles which should, among others, be country-owned and country-led, characterized by packages of malaria interventions which is optimally delivered through appropriate channels and a strong foundation on primary health care. The global body is calling for a coordinated national malaria response complemented by other sectors, such as environment, education and agriculture. It also added that, aligning partners behind this country-led approach would ensure that scarce resources are used as efficiently as possible. The high burden to high impact programme is therefore expected to demand high-level political leadership, country ownership and commitment from a broad coalition of stakeholders. Despite this challenge, it is gratifying therefore that the FDA in Ghana is on the war path and working with other agencies to protect the public from some of these substandard and fake products including antimalarials. Mr. Prah Eshun said the FDA is part of an interagency committee made up of representatives from various sectors such as the police, the legal profession, Bureau of National Investigations, Customs, Narcotics Control Commission, Pharmacy Council and the Ghana Health Service to ensure that products, drugs, medical devices and foods on the Ghanaian market are meeting the standard requirements put in place by law ^{lxx}.

According to Mr. Prah Eshun, apart from ensuring that all products are registered by the FDA, samples and documents covering drugs and other products are by law to be made available to the FDA. Products have to be registered before they arrive in the country and are taken through evaluation and laboratory test. He further explained that, when products arrive at the ports, FDA officers at the entry points conduct a physical examination of the products including re-testing before allowing them into the market as part of the surveillance processes. Continuous monitoring and surveillance is also done by officers across the country and sometimes these officers move

into the markets and other outlets through undercover means or openly, depending on the situation. Samples of products and drugs are then picked and subjected to laboratory tests just to track the presence of unwanted and dangerous products that may have slipped into the market. According to the news, FDA offices are empowered to go into town to pick up samples and conduct initial test by an equipment they carry along to town, they can then do a follow up confirmatory test at the laboratory for further evaluation. Also, FDA has a legal department which works with the police to prosecute offenders when it becomes necessary. Additionally, the Authority has a safety monitoring department working with doctors, nurses and pharmacists who fill out forms and collect data on adverse drugs reactions among clients they serve, and this provides a reporting system on adverse drug situations.

The system helps the health personnel to gather information when they observe that a particular drug is not working as expected. This is then reported to the FDA for action. All these actions are helping the Authority to carry out its surveillance work to weed out fake and substandard drugs. Accordingly, one other way the FDA works is to also scrutinize the addresses of foreign drug manufacturers outside the country and keep records on these companies, so that the Authority can easily track what and where drugs are coming in from. Mr. Prah Eshun said the FDA also does some travelling by visiting some manufacturing sites outside the country to ensure that these sites have standard drug manufacturing practices in place (Eunice Menka, 2019).

3.3 The Wayforward

Counterfeit/fake drug trade is a major challenge especially for developing countries and in the wake the SDG's and the desire of every government to meet especially SDG 3, although countries, governments and institutions are putting into place notable efforts to help fight the proliferation

of Counterfeit/fake medicines with their visible challenges, there are still steps that can be taken by Ghana to help in the fight against Counterfeit/fake drugs.

3.3.1 Effective Public- Private Sector Partnership/Collaboration

There is the need for Government to partner/collaborate effectively with the private sector and individuals who are already in the business of providing certain services by giving the necessary funding and platform to enable them provide such services on a larger scale with some level of supervision, monitoring and coordination to ensure an accessible, reliable and affordable products and services for the people. For instance, government can offer tax holidays, funding and free market to local pharmaceutical manufacturers which will provide job for the people but also a trusted brand at affordable prices to help not only boost the manufacturing sector but also help the country to export to other countries and to satisfy the need of the people and in an effect helping Ghana in achieving SDG 3 by 2030. Government can also make the modern technology, mPedigree a part of the FDA requirement for every pharmaceutical or manufacturing agency to register their products and get all encrypted into the system. This will make it easy for their operations and dealing with private and state institutions and also helping in the fight against Counterfeit and fake medicines and to achieve SDG 3 by 2030.

3.3.2 Increase Expert Capacity Building

Technical expertise in every field is very important and for Ghana to make serious progress in the fight against Counterfeit/fake drug trade and use, there is the need for government through the FDA to recruit more people to help with their various responsibilities such as border controls, registrations, education and awareness creation, routine post-market surveillance and other mandates of the Authority. There is the need for deliberate and targeted expertise trainings to meet

the changing trends and needs of the Authority for the protection of the Public Health of Ghana by ensuring safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. By increasing the capacity of their workforce and giving them the necessary skills training and expertise for their job it will enable them in the fight against Counterfeit/Fake medicine and help Ghana in achieving SDG 3 by 2030.

Many private sector organizations have been working to support public authorities, International trade organizations, NGOs such as PSI, as well as individual manufacturers contribute their expertise to facilitate the work of the public sector agencies. In addition, for example, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has been involved in this work for nearly three decades. It has provided significant technical support to WHO while facilitating communication from its Geneva Headquarters and at international events and training sponsored by industry^{lxxi}. Ghana through the FDA can type into these available platforms, experience and opportunities to help build up our system.

3.3.3 Enforcement efforts and Collaboration with other Institutions

Despite all the efforts and successes by Ghana in the fight against Counterfeit/Fake medicines, organizations engaged in counterfeiting continued manufacturing and distributing for the past years and there is the need for effective enforcement efforts and collaboration between state institutions and the fight.

According to Kubic, addressing the scourge of counterfeit drugs is tremendously challenging because, the global nature of illicit sellers and willing participants in this crime has extended beyond geopolitical borders and hence, it is imperative that a public and private, international cross-stakeholder efforts be integrated to be best coordinate efforts to identify, nvestigate and

prosecute these crimes. The Pharmaceutical Security Institute (PSI) is one entity that represents a facilitator and collaborator in combatting this key public health issue. Globally, INTERPOL and the Permanent Forum against International Pharmaceutical Crime lead a enforcement action against illegal online pharmacies during October 2010. Notably, this was the third consecutive year enforcement actions have been undertaken on an international basis against well-organized trans-national criminal gangs. In all, 45 countries participated in this operation, using information supplied by private information supplied by PSI member companies. This international effort, known as Pangea III, was conducted within the framework of the WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Initial reports disclosed the seizure of counterfeit pills with an estimated value of USD 2.6 million, as more than 1 million illicit and counterfeit pills were confiscated including antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic pills, as well as weight reduction medications. Increases in web site shutdowns (290 v. 153), inspected packages (268 000 v. 21 000), seized packages (11 000 v. 2356) and arrests (76 v. 59) from the previous collaborative effort shows the growing scope of enforcement and criminal activities (Kubic, 2011). Because of the nature of transnational crimes and how sophisticated they can be, it is important to collaborate with other stakeholders both within and outside your borders for a wider network with available technical expertise, capacity and capabilities beyond what one could have done.

3.4 DATA ANALYSIS AND DISCUSSION OF RESULTS

3.4.1 INTRODUCTION

This aspect provides analyses of the results obtained and discussions. The analyses include Descriptive Statistics, Mean Score and Relative Importance Scale. It was done with the research objectives in mind. After identifying the variables for questionnaires objectives, 1) to ascertain

what counterfeit drugs are and reasons for its trade boom, and 2) to assess the socio-economic effects of counterfeit drugs on Ghanaians, including the economic growth of pharmaceutical and chemical companies, and variables for interviews objectives, 3) to investigate the efforts to address the issue of counterfeit drugs to meet SDG3, and 4) to discuss the successes achieved, challenges faced in the measures undertaken, and the way forward.

The next step of the study was to confirm the variables under each objective 1 and 2 by adopting survey questionnaires, using data from a randomly selected respondents in Accra and Tema and confirmation of objective 3 and 4 by adopting interviews on respondents from pharmaceutical and chemical companies in Accra and Tema.

The questionnaire consisted of five (5) parts for the questionnaires and five (5) sections for the interviews. The purposes of the questionnaires were to, part (I) to determine respondents background information, part (II) to determine the effects of counterfeit medicine on the economic growth of Ghana, part (III) to determine the effects of fake drugs on the growth of pharmaceutical and chemical companies in Ghana, part (IV) to determine the effects of the use of counterfeit medicines on the lives of people, and part (V) to determine the probable causes for choosing/opting for counterfeit/fake drugs knowingly or unknowingly (Appendix A). The purpose of the interview was to, section (1) to determine how Ghana is attracting counterfeit/fake medicines, (2) how Ghana is attacking counterfeit medicines trade, (3) socio-economic impact of fake drugs on Ghana under SDG 3, (4) efforts put in place to address the issues of counterfeit drugs to meet SDG 3 through stakeholders contributions, (5) Success, challenges, and measures undertaken and the way forward (Appendix B).

In the questionnaire, respondents (randomly selected people from Accra and Tema) were asked closed-ended questions and few open-ended questions to respectively rate according to their

agreement, the variables under each of the three objectives. The rating required the respondents to determine which variables best answers the questions by ticking appropriately.

3.4.2 SURVEY RESPONSES

Out of the 60 questionnaires distributed to the study's respondents, only forty-nine (56) valid questionnaires representing ninety three percent (93.3%) were completed, and these were used in the analyses. The high response rate of 93% may be credited to the compliance to the techniques employed in the distribution of the questionnaires and the follow ups to claim the questionnaires through "Google Forms" with persistent personal calls to the respondents. As a result, the entire survey process took almost 3 weeks to complete instead of the anticipated 4 weeks.

3.4.3 DESCRIPTIVE ANALYSIS OF DEMOGRAPHIC DATA

This aspect of the questionnaires was adopted to obtain information on the category of work of the respondents, their ages, gender, civil statuses, guardianship, number of children, highest educational level, employment status, and districts in Accra and Tema. This was to improve the authenticity of gathering the information.

3.4.4 Age of Respondents

Table 4.1 and Figure 4.1 below establish the total number of respondents who responded to the questionnaire with their corresponding ages. This suggests that the total number of valid respondents to the questionnaires were fifty-six (56) from the sixty (60) questionnaires issued out to the respondents, representing 93%. The responses from the 56 valid respondents comprised; 3.6% response from both age ranges 15-20 (A) and 41-45 (F), 10.7% from both 21-25 (B) and 36-

40 (E), 32.1% from both 26-30 (C) and 31-35 (D) which represented as the modal age ranges of respondents. Also, 5.4% responses were from age ranges 46-50 and 1.8% from 61 and above, representing the lowest age range.

Table 4.1: Age of Respondents

AGE	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	2	3.6	3.6
B	6	10.7	14.3
C	18	32.1	46.4
D	18	32.1	78.6
E	6	10.7	89.3
F	2	3.6	92.9
G	3	5.4	98.2
I	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

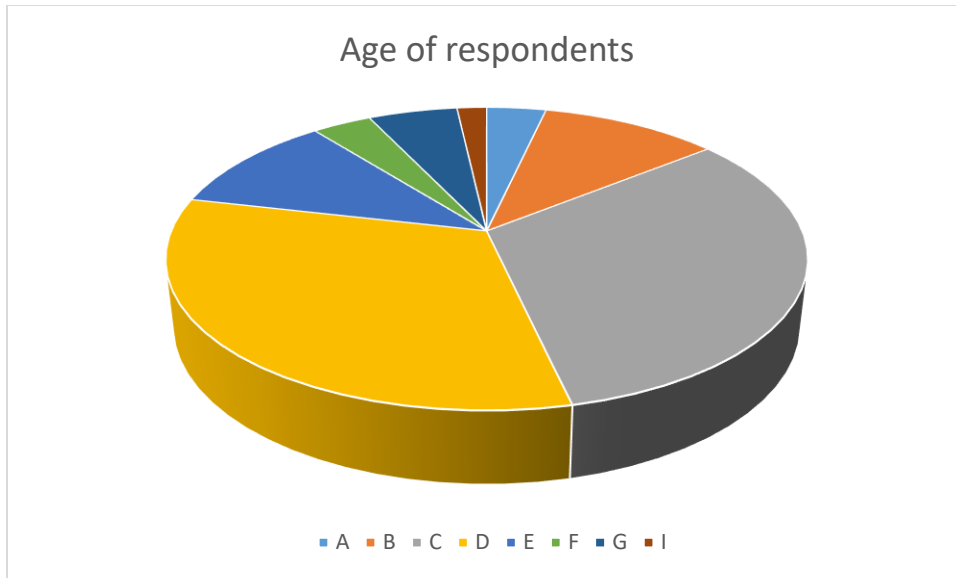


Figure 4.1: A pie chart representing the age range of respondents

Source: (Field Survey, 2020)

3.4.5 Gender of Respondents

The table 4.2 and Figure 4.2 below establish the total number of respondents who responded to the questionnaire with their corresponding genders. This suggests that the total number of valid respondents to the questionnaires were fifty-six (56) from the sixty (60) questionnaires issued out to the respondents, representing 93%. The responses from the 56 valid respondents comprised; a 60.7% response from males and 39.3% being from females.

Table 4.2: Gender of Respondents

GENDER	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	34	60.7	60.7
B	22	39.3	100.0
	56	100.0	

Source: (Field Survey, 2020)

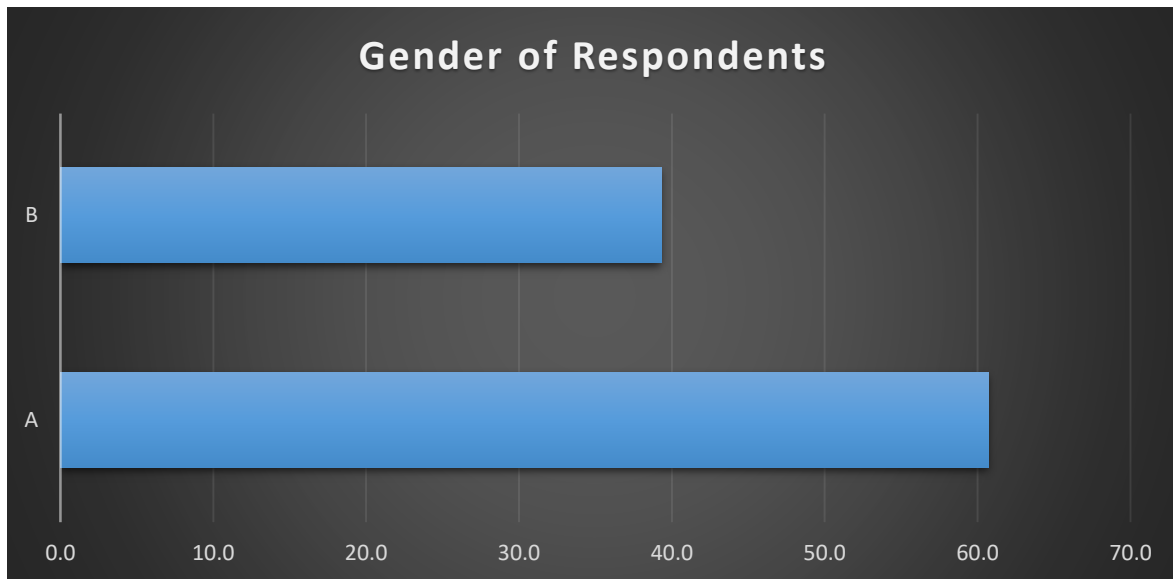


Figure 4.2: A bar chart representing the gender of respondents

Source: (Field Survey, 2020)

3.4.6 Civil Status of Respondents

The table 4.3 and Figure 4.3 below establish the total number of respondents who responded to the questionnaire with their corresponding civil statuses. This suggests that the total number of valid respondents to the questionnaires were fifty-six (56) from the sixty (60) questionnaires issued out to the respondents, representing 93%. The responses from the 56 valid respondents comprised; 42.9% response from married people, 1.8% from divorced, 53.6% representing the modal mark from singles and the rest were did not respond.

Table 4.3: Civil status of respondents

STATUS	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	24	42.9	42.9
B	1	1.8	44.6
C	30	53.6	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

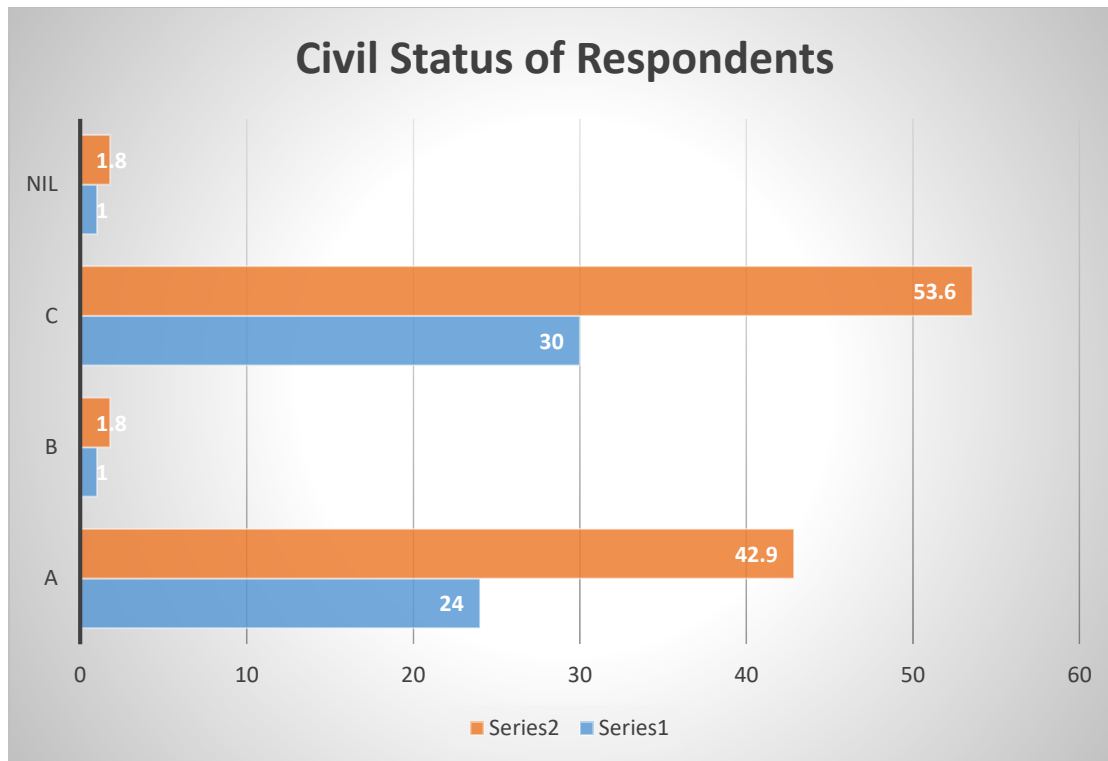


Figure 4.3: A bar chart representing the civil status of respondents

Source: (Field Survey, 2020)

3.4.7 Respondents who are guardians

The table 4.4 and Figure 4.4 below establish the total number of respondents who responded to the questionnaire with their corresponding guardianships. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7%. The responses from the 55 valid respondents comprised; 42.9% responses for “Yes” and 55.4% responses for “No”. Proving that the majority of respondents do not have any children or they are not caregivers to anyone.

Table 4.4: Respondents who are Guardians

PARENT	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	24	42.9	42.9
B	31	55.4	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

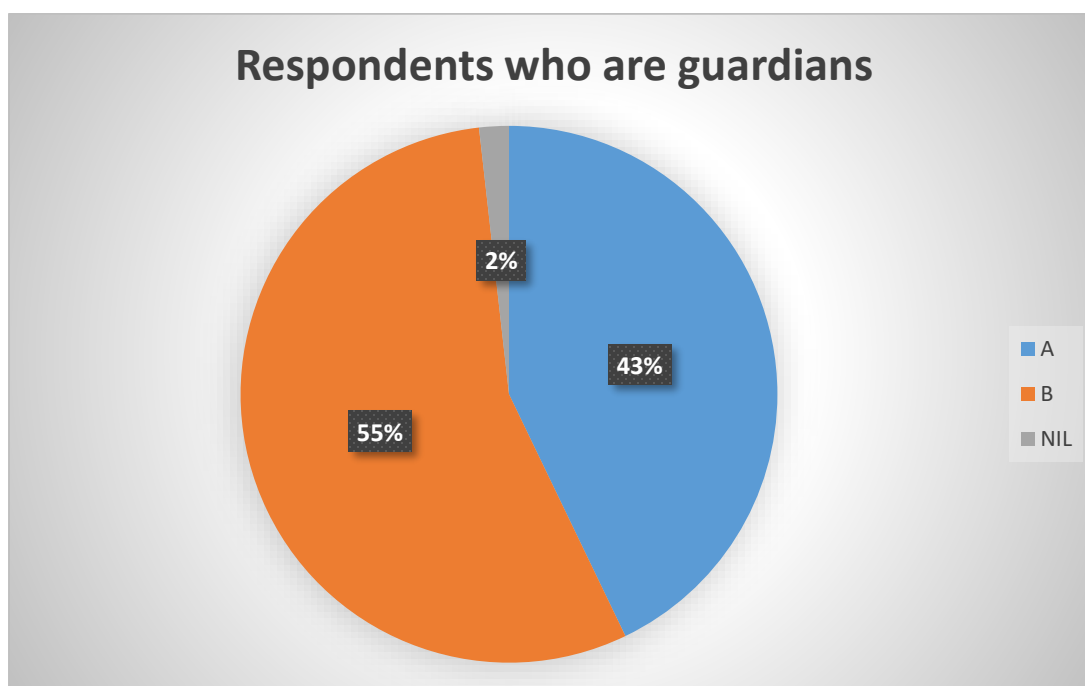


Figure 4.4: A pie chart representing respondents who are Guardians

Source: (Field Survey, 2020)

3.4.8 Number of Children of Respondents

The table 4.5 and Figure 4.5 below establish the total number of respondents who responded to the questionnaire with their corresponding number of children. This suggests that the total number of valid respondents to the questionnaires were thirty (30) from the sixty (60) questionnaires issued out to the respondents, representing 50%. The responses from the 30 valid respondents comprised; 25% response from 1-2 children, 17.9% from 3-4 children, and 3.6% response from 9 and above. The modal respondents have children up to 4, which most probably gives them a wider experience of the subject matter.

Table 4.5: Number of children of respondents

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	14	25	25
B	10	17.9	42.9
E	2	3.6	46.4
NIL	30	53.6	100.0
	56	100	

Source: (Field Survey, 2020)

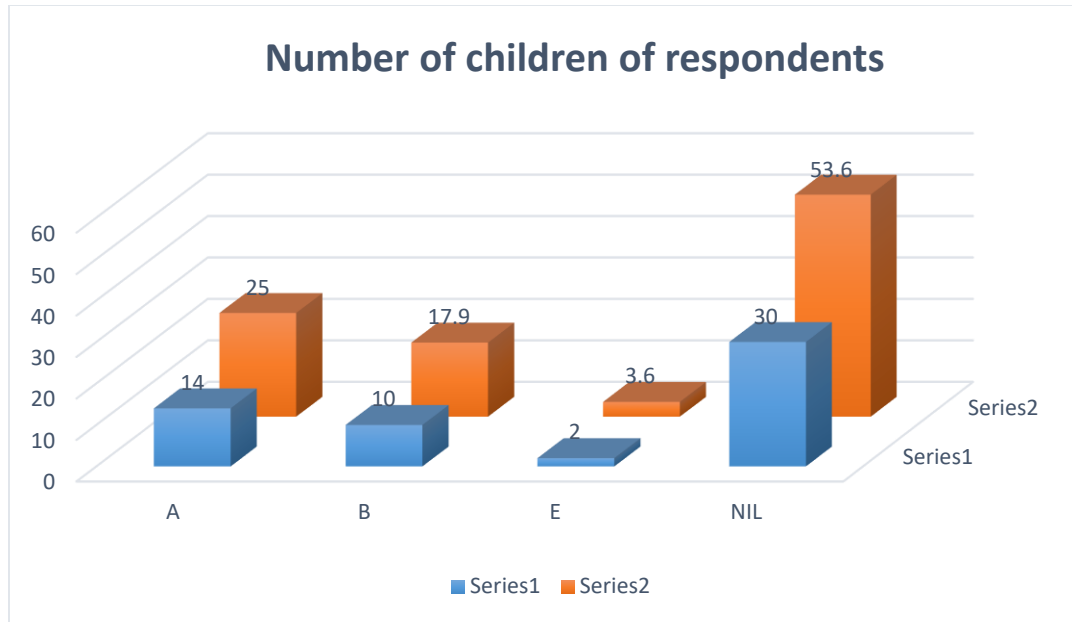


Figure 4.5: A column chart representing Number of children of respondents

Source: (Field Survey, 2020)

3.4.9 Educational Level of Respondents

The table 4.6 and Figure 4.6 below establish the total number of respondents who responded to the questionnaire with their corresponding levels of education. This suggests that the total number of valid respondents to the questionnaires were fifty-two (52) from the sixty (60) questionnaires issued out to the respondents, representing 86.7%. The responses from the 52 valid respondents comprised; 14.3% responses for both SSSCE/WASSCE and Diploma, 10.7% for HND and Post-Graduate degree and 42.9% responses for Graduate Degree, representing the modal educational level.

Table 4.6: Educational Level of Respondents

LEVEL	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
B	8	14.3	14.3
C	8	14.3	28.6
D	6	10.7	39.3
E	24	42.9	82.1
F	6	10.7	92.9
NIL	4	7.1	100.0
	56	100	

Source: (Field Survey, 2020)

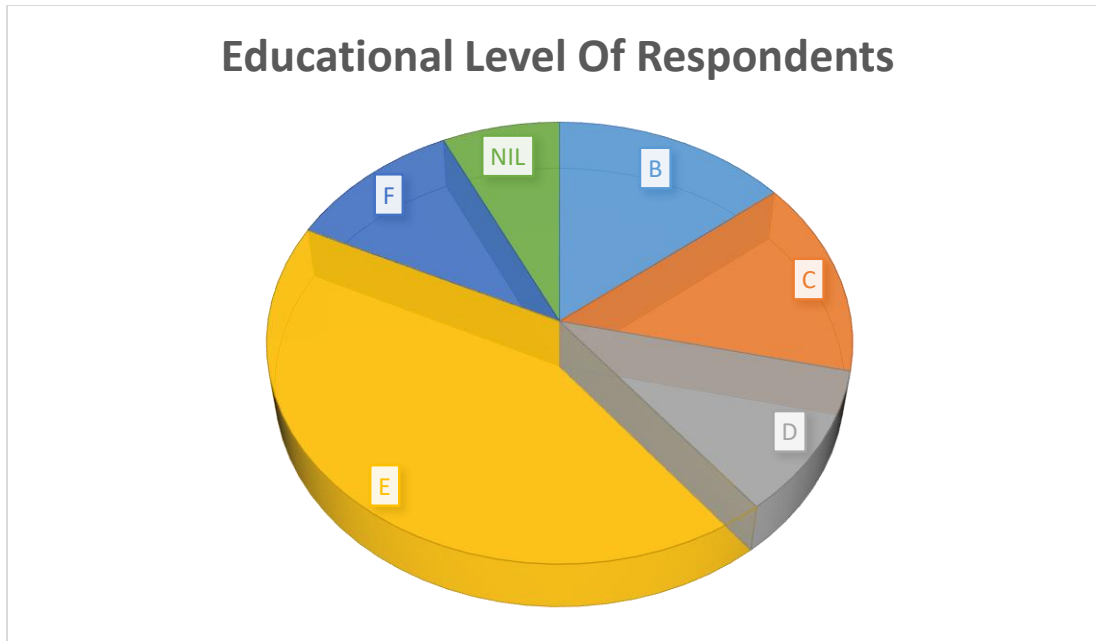


Figure 4.6: A pie chart representing Educational Level of Respondents

Source: (Field Survey, 2020)

3.5 Employment status of Respondents

The table 4.7 and Figure 4.7 below establishes the total number of respondents who responded to the questionnaire with their corresponding employment statuses. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; 62.5% response for “employed”, 16.1% for “self-employed”, 10.7% for students, and 7.1% for others. Clearly the modal respondents were gainfully employed, including the self-employed.

Table 4.7: Employment status of Respondents

EMPLOYMENT	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	35	62.5	62.5
B	9	16.1	78.6
C	6	10.7	89.3
D	4	7.1	96.4
NIL	2	3.6	100.0
	56	100	

Source: (Field Survey, 2020)

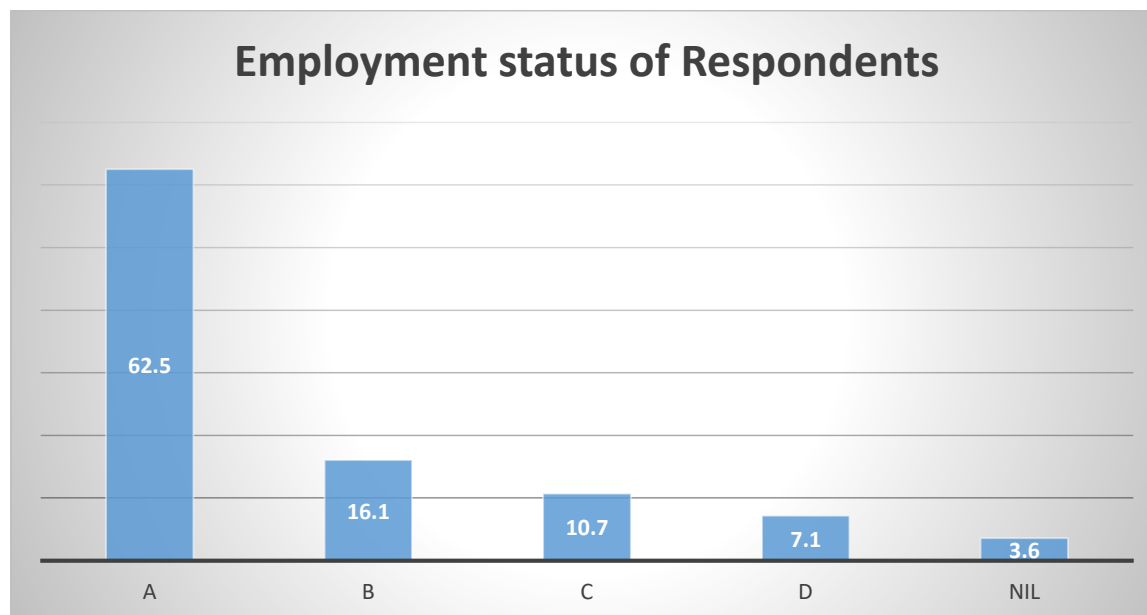


Figure 4.7: A column chart representing Employment status of Respondents

Source: (Field Survey, 2020)

3.5.1 District of Respondents

The table 4.8 and Figure 4.8 below establishes the total number of respondents who responded to the questionnaire with their corresponding districts. This suggests that the total number of valid respondents to the questionnaires were fifty-three (53) from the sixty (60) questionnaires issued out to the respondents, representing 88.3% response rate. The responses from the 53 valid respondents comprised; 69.6% respondents from Accra and 25% respondents from Tema. Though the modal district was Accra, details of the location of respondents showed a representation from across the regional capital from Lashibi through Accra New Town to Weija.

Table 4.8: District of Respondents

DISTRICT	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
ACCRA	39	69.6	69.6
TEMA	14	25.0	94.6
NIL	3	5.4	100.0
	56	100.0	

Source: (Field Survey, 2020)

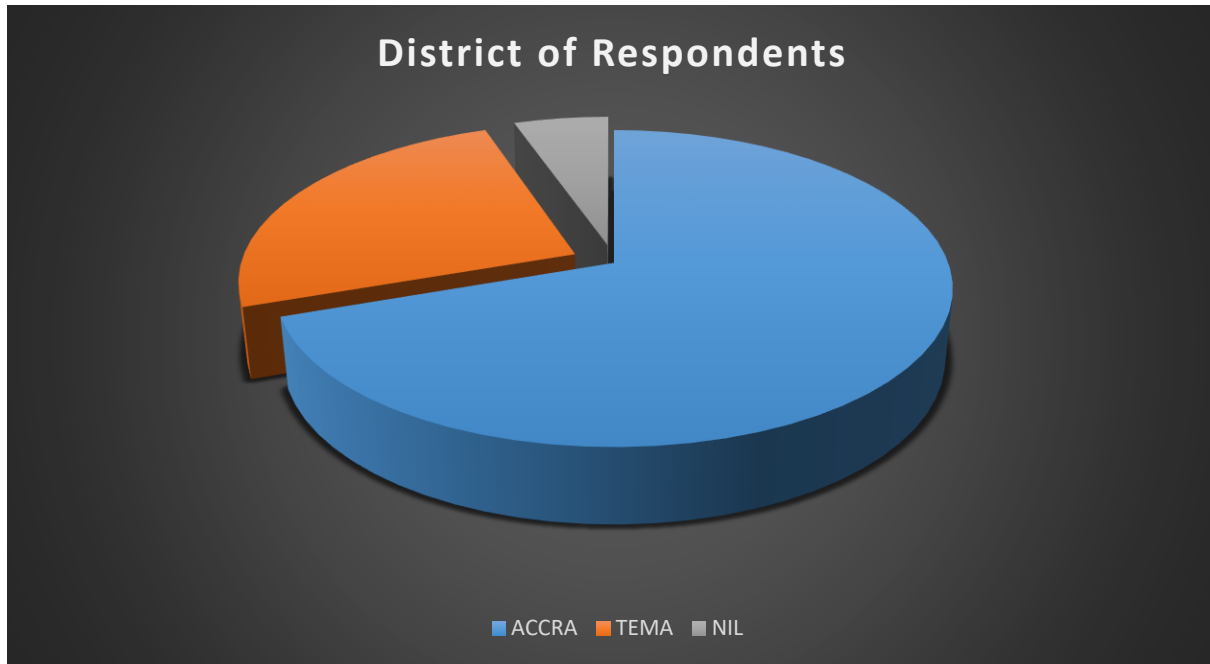


Figure 4.8: A pie chart representing District of Respondents

Source: (Field Survey, 2020)

3.6 DESCRIPTIVE ANALYSIS OF THE EFFECTS OF COUNTERFEIT MEDICINE ON THE ECONOMIC GROWTH OF GHANA

3.6.1 Respondents with idea about counterfeit or fake drugs

The table 4.9 and Figure 4.9 below establishes the total number of respondents who responded to the questionnaire regarding having any with idea about counterfeit or fake drugs. This suggests that the total number of valid respondents to the questionnaires were fifty-six (56) from the sixty (60) questionnaires issued out to the respondents, representing 93.3% response rate. The responses from the 56 valid respondents comprised; 76.8% responded 'Yes' and 23.2% responded 'Noth'. the modal response shows a significant majority who are very aware of the subject matter and can therefore provide the needed responses.

Table 4.9: Respondents with idea about counterfeit or fake drugs

IDEA	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	43	76.8	76.8
B	13	23.2	100.0
	56	100.0	

Source: (Field Survey, 2020)

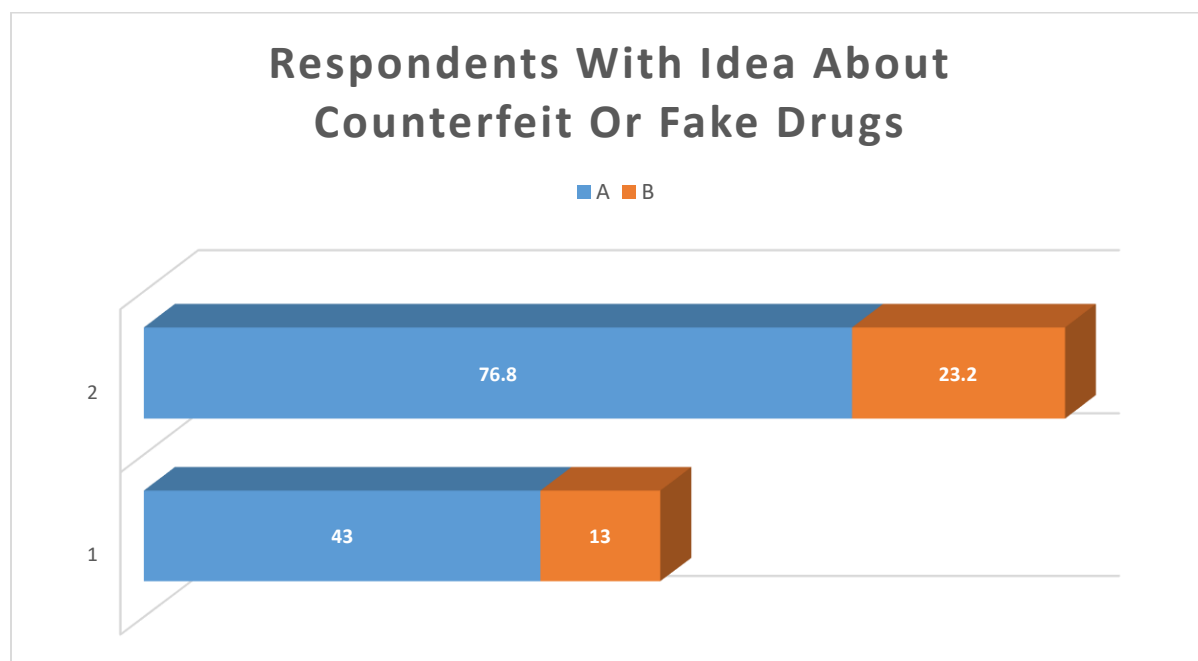


Figure 4.9: A bar chart representing Respondents with Idea about Counterfeit or Fake Drugs

Source: (Field Survey, 2020)

3.6.2 Respondents who described their idea about counterfeit or fake drugs

The table 4.10 and Figure 4.10 below establishes the total number of respondents who responded to the questionnaire describing their idea about counterfeit or fake drugs. This suggests that the total number of valid respondents to the questionnaires were forty-five (45) from the sixty (60) questionnaires issued out to the respondents, representing 75% response rate. Respondents were required to choose as many options that described the knowledge of the subject matter. The responses from the 45 valid respondents comprised; the modal description of 21.4% who responded as ‘the use of unapproved drugs by Ghana Food and Drugs Authority’, 10.7% responded as the former nut include, ‘the use of sub-standard drugs’ and ‘the use of sub-standard drugs sold by licensed pharmacists and chemical sellers’, and the rest also selected either one of multiple choices. Any choice was in fact a description of the various sources and description of counterfeit or fake drugs, and so a choice of one or multiple showed that respondents had a good idea of the subject matter.

Table 4.10: Respondents who described their idea about counterfeit or fake drugs

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	5	8.9	8.9
AB	5	8.9	17.9
ABC	1	1.8	19.6
ABCD	4	7.1	26.8

ABD	6	10.7	37.5
B	12	21.4	58.9
BC	5	8.9	67.9
BCD	1	1.8	69.6
C	5	8.9	78.6
D	1	1.8	80.4
NIL	11	19.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

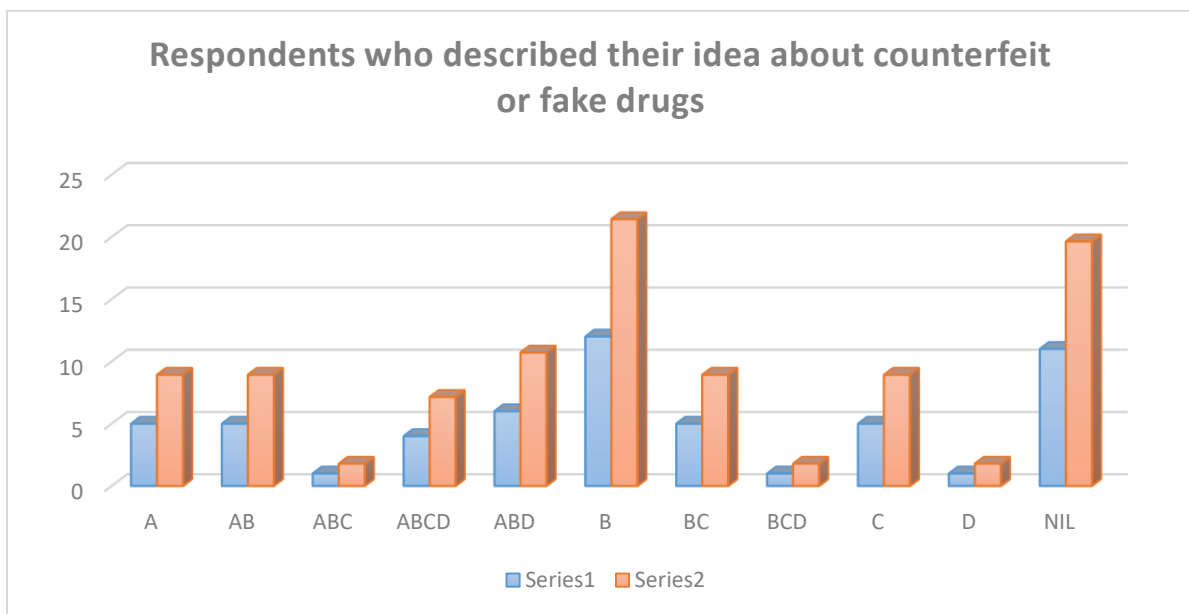


Figure 4.10: A column chart representing Respondents who described their idea about counterfeit or fake drugs

Source: (Field Survey, 2020)

3.6.3 Respondents who had been victims of counterfeit or fake drugs usage

The table 4.11 and Figure 4.11 below establishes the total number of respondents who responded to the questionnaire regarding being victims of counterfeit or fake drugs usage. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate. The responses from the 55 valid respondents comprised; 23.2% responded ‘Yes’ and 75% responded ‘No’. Though the modal response reveal a significant majority who responded in the negativity, some may be ignorant of usage since the literature review showed the difficulty in sometimes differentiating fake drugs from the original. Apart from that, there were other subsequent questions to elicit further knowledge and experiences of the respondents.

Table 4.11: Respondents who had been victims of counterfeit or fake drugs usage

VICTIM	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	13	23.2	23.2
B	42	75.0	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

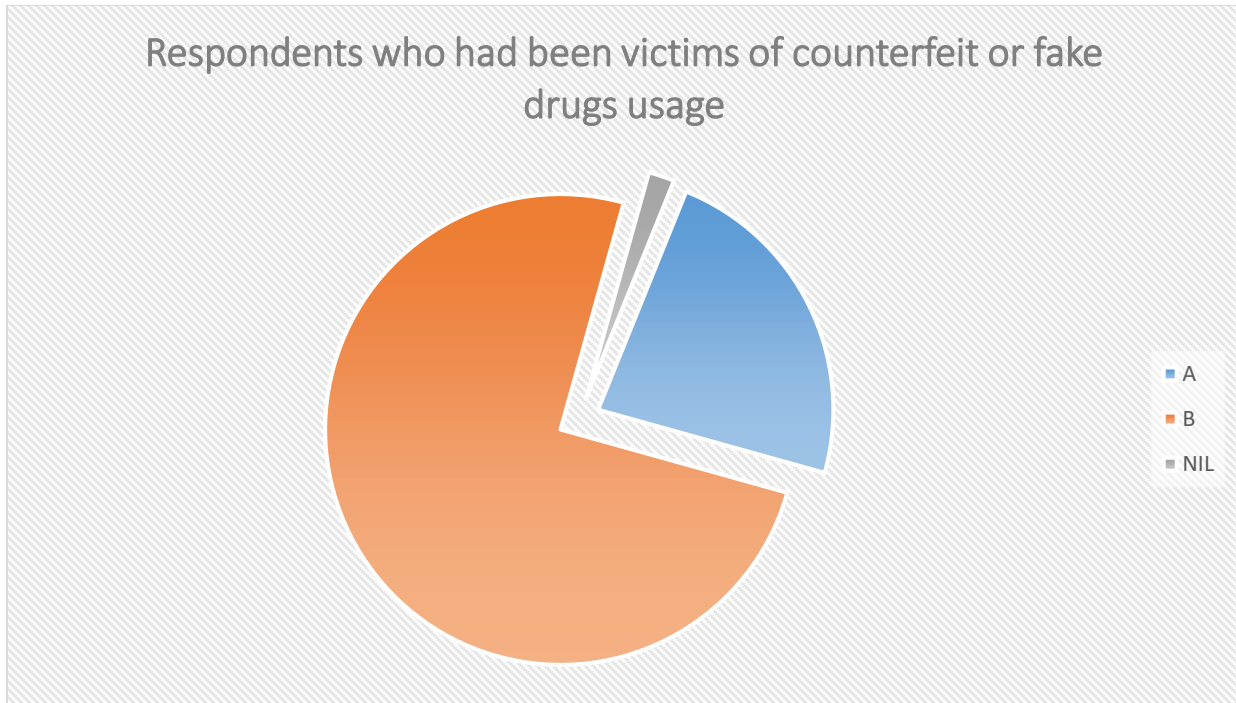


Figure 4.11: A column chart representing Respondents who had been victims of counterfeit or fake drugs usage

Source: (Field Survey, 2020)

3.6.4 Respondents who expressed their view on whether the use of fake drugs can affect the economic situation of users and the nation

The table 4.12 and Figure 4.12 below establishes the total number of respondents who responded to the questionnaire regarding their view on use of fake drugs and its economic impact on users and the nation. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate. The responses from the 55 valid respondents comprised; 83.9% responded ‘Yes’

and 14.3% responded ‘No’. The overwhelming modal affirmation shows that the impact is a generally known fact.

Table 4.12: Respondents who expressed their view on whether use of fake drugs can affect the economic situation of users and the nation

VIEW	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	47	83.9	83.9
B	8	14.3	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

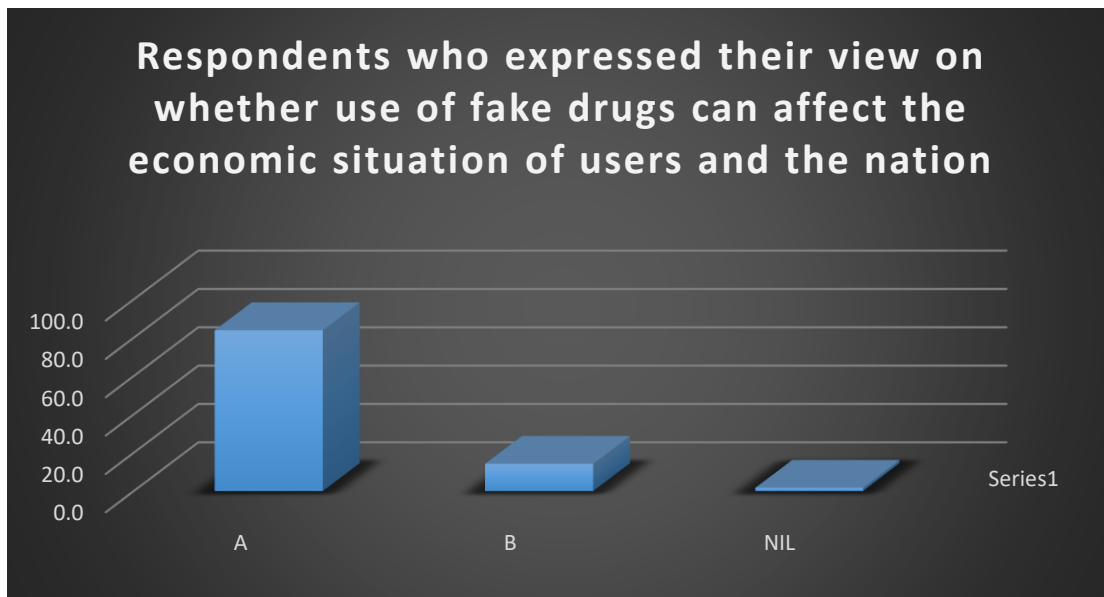


Figure 4.12: A column chart representing Respondents who expressed their view on whether use of fake drugs can affect the economic situation of users and the nation

Source: (Field Survey, 2020)

3.6.5 Respondents who described ways use of fake drugs can have economic impact on users and the nation

The table 4.13 and Figure 4.13 below establishes the total number of respondents who responded to the questionnaire regarding description of ways use of fake drugs can have economic impact on users and the nation. This suggests that the total number of valid respondents to the questionnaires were fifty (50) from the sixty (60) questionnaires issued out to the respondents, representing 83.3% response rate. The responses from the 50 valid respondents comprised; the modal response of 12.5% that included one or more of the following choices, ‘spending more money on treatment of illness’, ‘increase in time for curing illness’, ‘reduction in national import revenue’, ‘reduction in one’s income resulting from long illness’, and ‘reduction in the productivity of individuals.’ A choice of one or more these responses proves adequate knowledge of the economic impact on individuals and the national at large. Indeed the responses covers all the options, though the impact on the individuals are more.

Table 4.13: Respondents who expressed their view on whether use of fake drugs can affect the economic situation of users and the nation

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	4	7.1	7.1
AB	7	12.5	19.6
ABC	1	1.8	21.4
ABCD	2	3.6	25.0
ABCDE	7	12.5	37.5
ABD	7	12.5	50.0
ABDE	5	8.9	58.9
ABE	2	3.6	62.5
ACDE	1	1.8	64.3
ADE	2	3.6	67.9
AE	2	3.6	71.4
B	2	3.6	75.0
BC	2	3.6	78.6
BCE	1	1.8	80.4
BD	2	3.6	83.9
BDC	1	1.8	85.7
C	2	3.6	89.3

NIL	6	10.7	100.0
	56	100.0	

Source: (Field Survey, 2020)

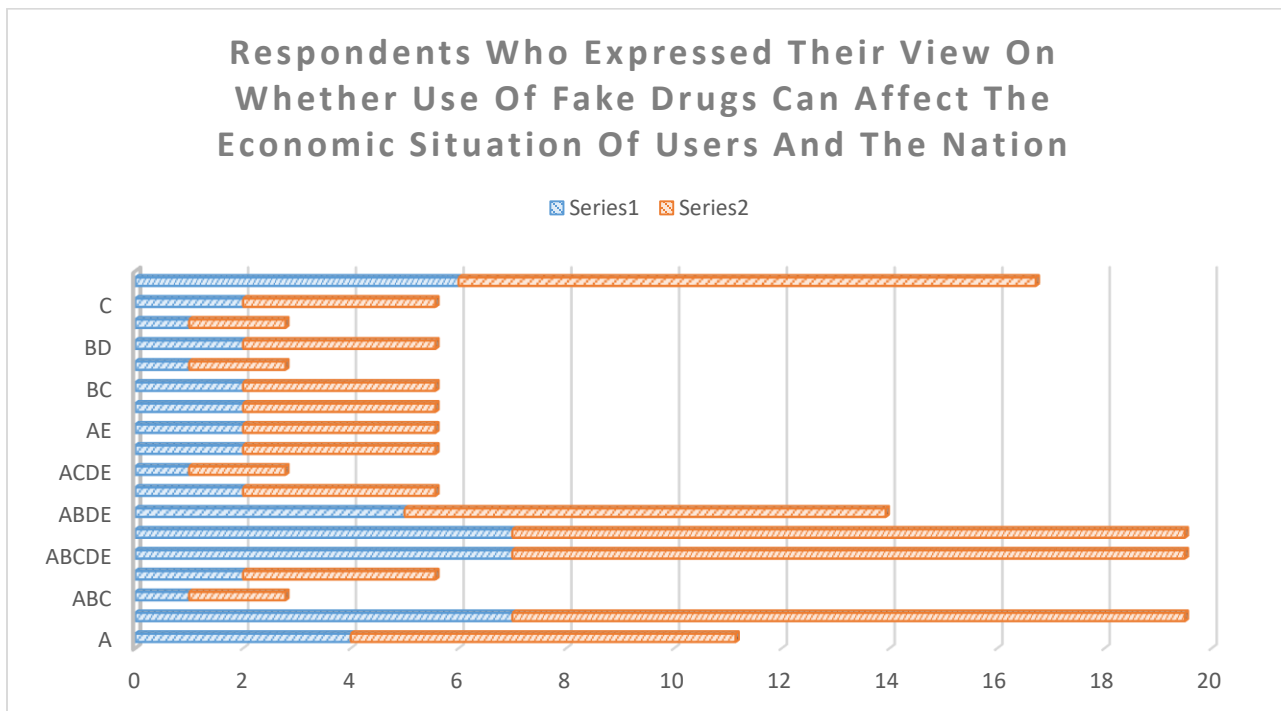


Figure 4.13: A bar chart representing respondents who expressed their view on whether use of fake drugs can affect the economic situation of users and the nation

Source: (Field Survey, 2020)

3.6.6 Respondents who expressed possibility of rise of fake drugs to reduce economic growth of the nation due to illegal importation and sales

The table 4.14 and Figure 4.14 below establishes the total number of respondents who responded to the questionnaire regarding possibility of rise of fake drugs to reduce economic growth of nation

due to illegal importation and sales. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; 83.9% responding ‘yes’ and 12.5% responding ‘no.’ The overwhelming affirmation proves the knowledge of the negative impact of reduced economic growth as a result of rise of illegal importation and sales of fake or counterfeit drugs.

Table 4.14: Respondents who expressed possibility of rise of fake drugs to reduce economic growth of nation due to illegal importation and sales

POSSIBLE	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	47	83.9	83.9
B	7	12.5	96.4
NIL	2	3.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

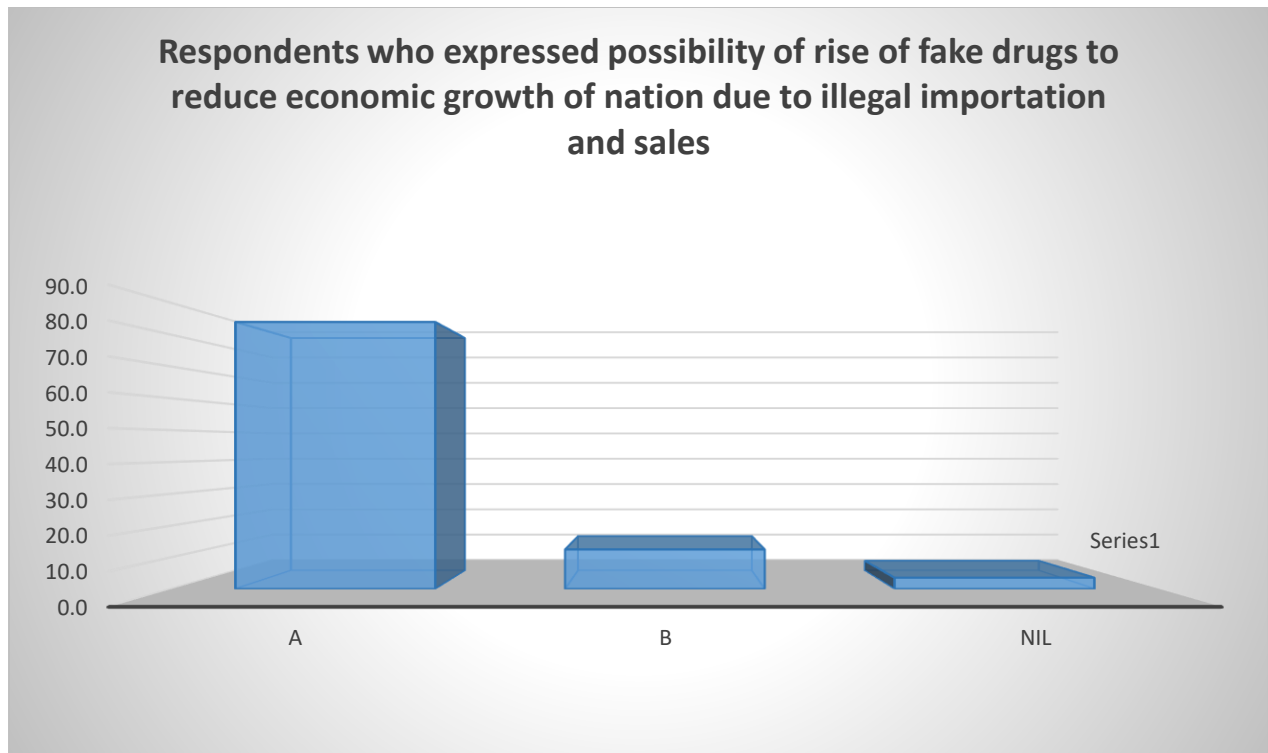


Figure 4.14: A column chart representing Respondents who expressed possibility of rise of fake drugs to reduce economic growth of nation due to illegal importation and sales

Source: (Field Survey, 2020)

3.7 DESCRIPTIVE RESPONSES OF THE EFFECTS OF FAKE DRUGS ON THE GROWTH OF THE PHARMACEUTICAL AND CHEMICAL COMPANIES IN GHANA

3.7.1 Respondents who noticed rise of fake/counterfeit drugs on the market

The table 4.15 and Figure 4.15 below establishes the total number of respondents who noticed rise of fake/counterfeit drugs on the market. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate. The responses from the 55 valid respondents

comprised; 69.6% responding ‘yes’ and 28.6% responding ‘no.’ The affirmative response was significant to prove that indeed respondents are aware of significant rise of fake/counterfeit drugs on the Ghanaian market.

Table 4.15: Respondents who noticed rise of fake/counterfeit drugs on the market

NOTICED	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	39	69.6	69.6
B	16	28.6	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

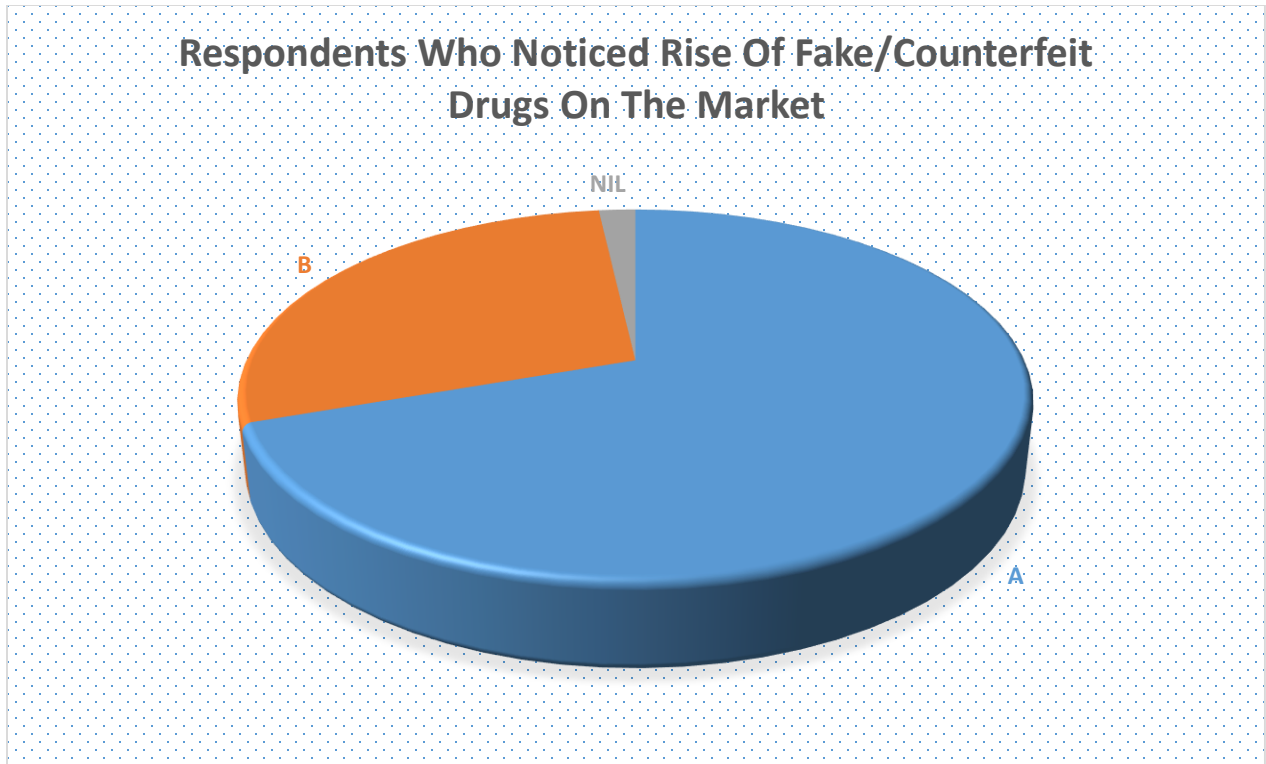


Figure 4.15: A pie chart representing respondents who noticed rise of fake/counterfeit drugs on the market

Source: (Field Survey, 2020)

3.7.2 Respondents who described places where fake/counterfeit drugs are sold

The table 4.16 and Figure 4.16 below establishes the total number of respondents who described places where fake/counterfeit drugs are sold. This suggests that the total number of valid respondents to the questionnaires were forty (40) from the sixty (60) questionnaires issued out to the respondents, representing 66.7% response rate. The responses from the 40 valid respondents comprised; 16.1% responding the modal response of ‘vendors in cars and buses’, followed by 12.5% who included in their responds as ‘at lorry parks’ and ‘hawkers in traffic.’ The rest of the

responses on highlighted similar places or a combination of multiple places. All these confirm that the list of places are all locations for sale of fake or counterfeit drugs though vendors in moving vehicles is most popular.

Table 4.16: Respondents who described places where fake/counterfeit drugs are sold

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	5	8.9	8.9
ABC	7	12.5	21.4
ABCD	2	3.6	25.0
ABD	1	1.8	26.8
AC	6	10.7	37.5
ACD	3	5.4	42.9
B	3	5.4	48.2
BC	2	3.6	51.8
BCD	1	1.8	53.6
C	9	16.1	69.6
D	1	1.8	71.4
NIL	16	28.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

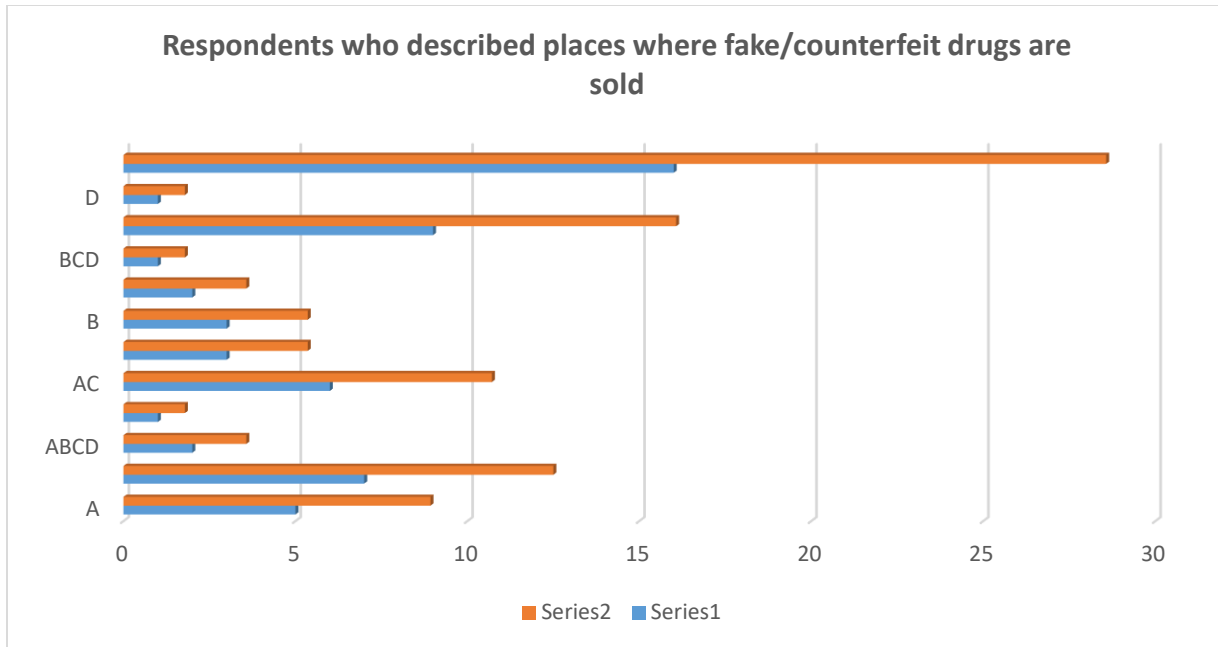


Figure 4.16: A bar chart representing respondents who described places where fake/counterfeit drugs are sold

Source: (Field Survey, 2020)

3.7.3 Respondents who expressed thoughts on whether increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

The table 4.17 and Figure 4.17 below establishes the total number of respondents who expressed thoughts on whether increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate. The responses from the 55 valid respondents comprised; 89.3% responding ‘yes’ and 8.9% who responded ‘no.’ The overwhelming assertion to the questionnaire proves that indeed there is huge threat to the growing pharmaceutical and chemical industry in Ghana.

Table 4.17: Respondents who expressed thoughts on whether increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

THINK	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	50	89.3	89.3
B	5	8.9	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

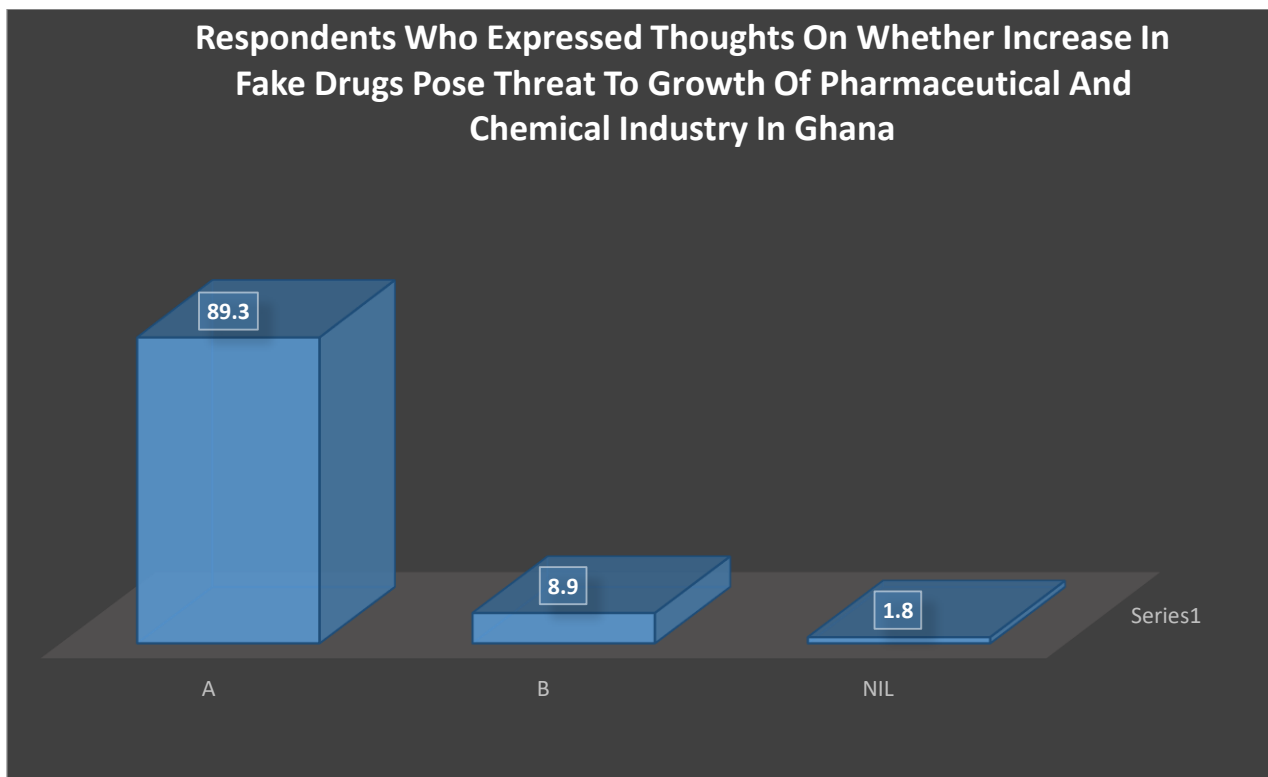


Figure 4.17: A column chart representing respondents who expressed thoughts on whether increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

Source: (Field Survey, 2020)

3.7.4 Respondents who described ways increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

The table 4.18 and Figure 4.18 below establishes the total number of respondents described ways increase in fake drugs on the market pose threat to growth of pharmaceutical and chemical industry in Ghana. This suggests that the total number of valid respondents to the questionnaires were fifty (50) from the sixty (60) questionnaires issued out to the respondents, representing 83.3% response rate. The responses from the 50 valid respondents comprised; a modal response of 21.4% responding as ‘reduction in their daily sales’, ‘discourages investment into research and discovery of new and quality medicines’ and ‘collapse of some pharmaceutical shops’. The remainder of the responses was either a choice of one or multiples of the former.

Table 4.18: Respondents who described ways increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	6	10.7	10.7
AB	7	12.5	23.2
ABC	12	21.4	44.6
AC	10	17.9	62.5
ACD	1	1.8	64.3
B	4	7.1	71.4
BC	6	10.7	82.1
C	5	8.9	91.1
NIL	5	8.9	100.0
	56	100.0	

Source: (Field Survey, 2020)

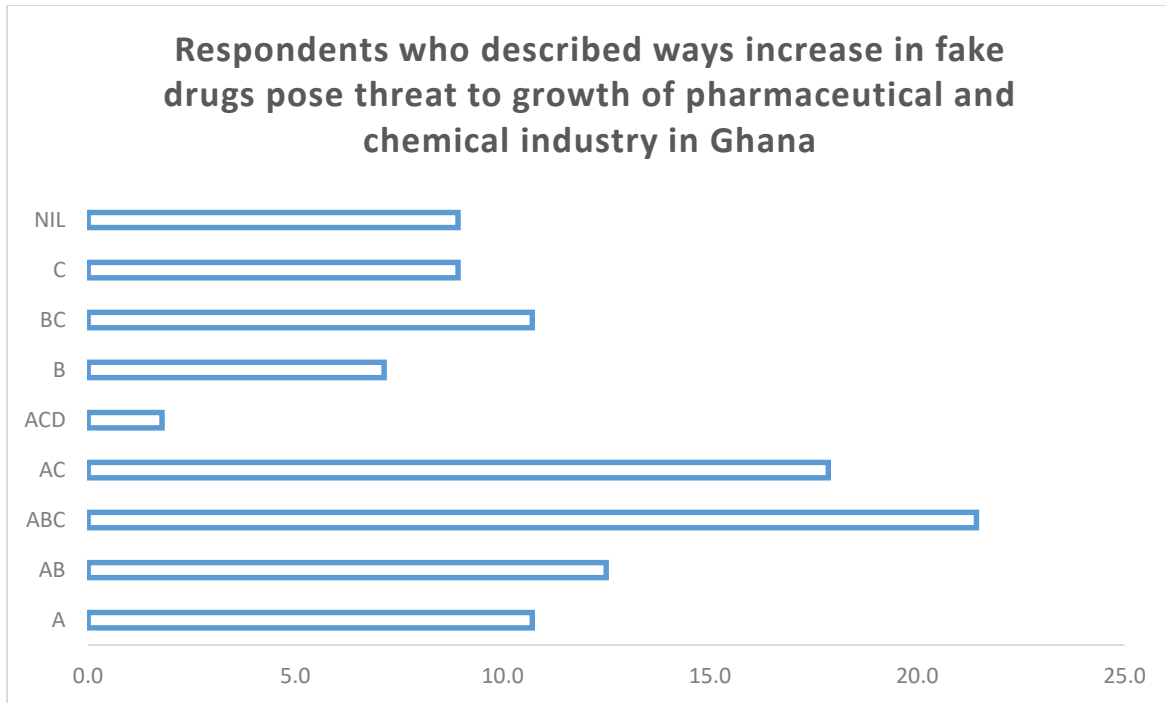


Figure 4.18: A bar chart representing respondents who described ways increase in fake drugs pose threat to growth of pharmaceutical and chemical industry in Ghana

Source: (Field Survey, 2020)

3.8 DESCRIPTIVE RESPONSES OF THE EFFECTS OF THE USE OF COUNTERFEIT MEDICINES ON THE LIVES OF PEOPLE

3.8.1 Respondents who described whether the use of counterfeit medicine have any impact on lives of users

The table 4.19 and Figure 4.19 below establishes the total number of respondents who described whether the use of counterfeit medicine have any impact on lives of users. This suggests that the total number of valid respondents to the questionnaires were fifty-six (56) from the sixty (60) questionnaires issued out to the respondents, representing 93.3% response rate. The responses from

the 56 valid respondents comprised; 94.7% responding ‘yes’ and 5.4 responding ‘no’. This undeniably confirms that respondents are very much aware of the effect such fake drugs have on the human body.

Table 4.19: Respondents who described whether the use of counterfeit medicine have any impact on lives of users

DOES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	53	94.7	94.7
B	3	5.4	100
	56	100	

Source: (Field Survey, 2020)

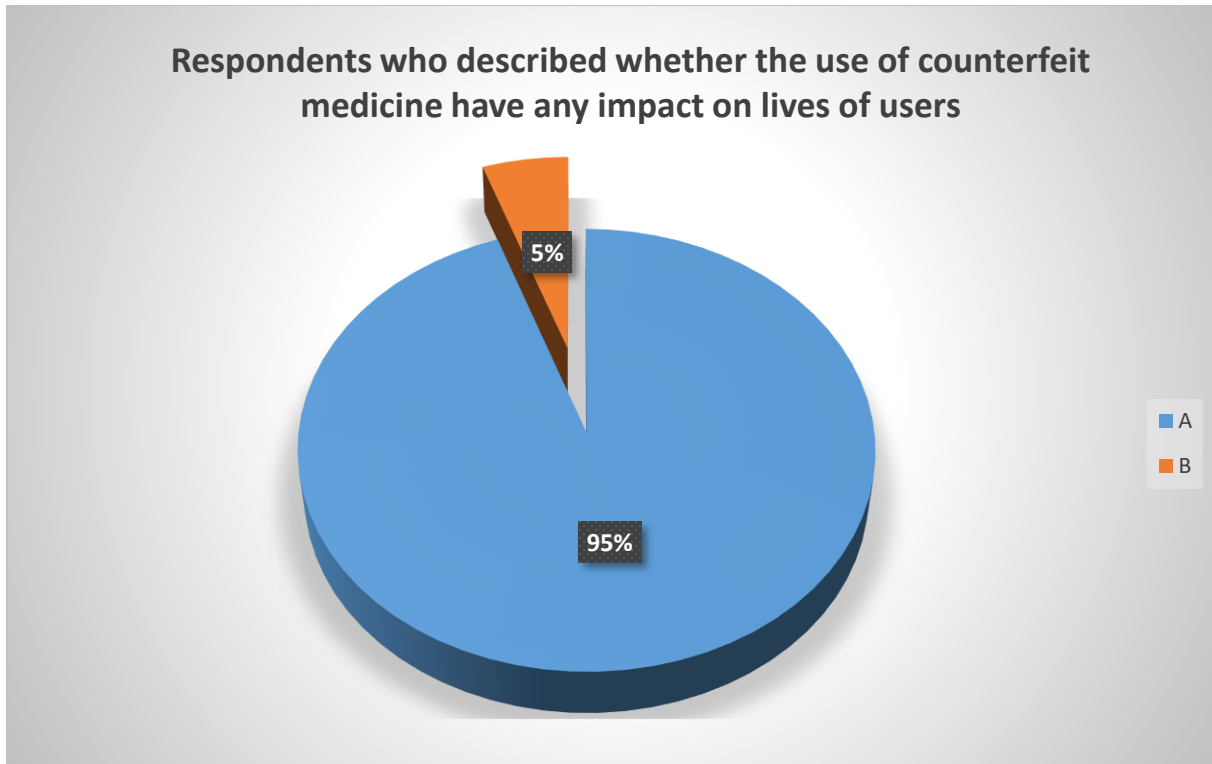


Figure 4.19: A pie chart representing respondents who described whether the use of counterfeit medicine have any impact on lives of users

Source: (Field Survey, 2020)

3.8.2 Respondents who gave details of the kind of impact the use of counterfeit medicine has

The table 4.20 and Figure 4.20 below establishes the total number of respondents who gave details of the kind of impact the use of counterfeit medicine has on the body. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; 3.6% responding as 'positive', 1.8% responding both 'positive

and negative’ and 91.1% responding as ‘negative’. This shows a significant majority who admit the impact is far more harmful & negative than positive for the human body.

Table 4.20: Respondents who gave details of the kind of impact the use of counterfeit medicine has

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	2	3.6	3.6
AB	1	1.8	5.4
B	51	91.1	96.4
NIL	2	3.6	100.0
	56	100.0	

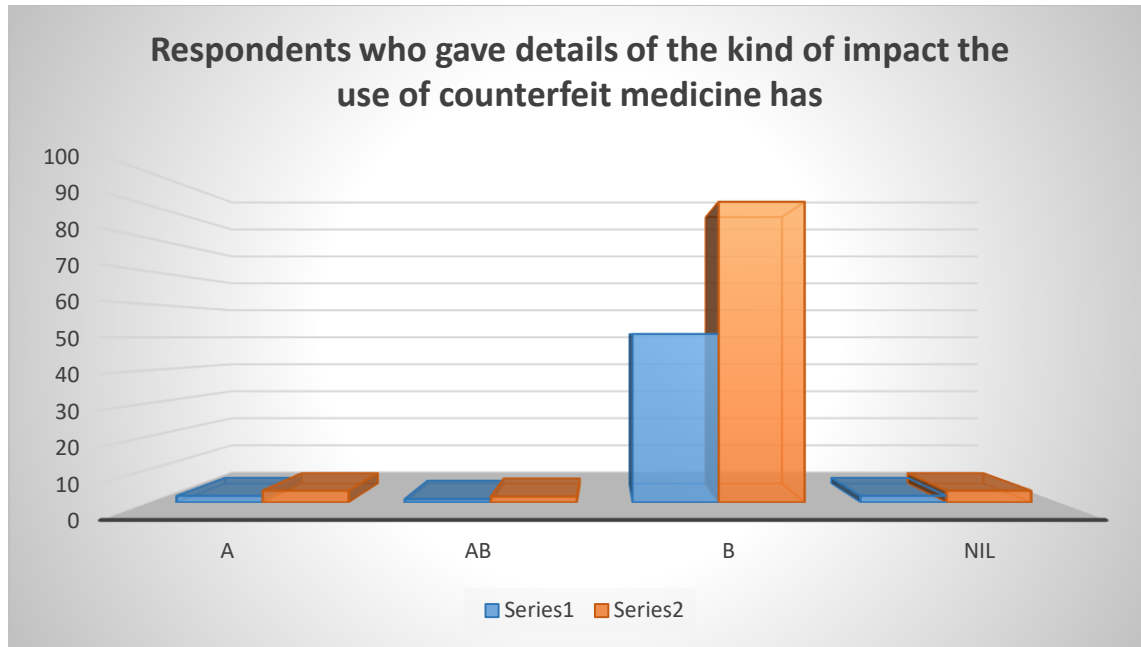


Figure 4.20: A column chart representing respondents who gave details of the kind of impact the use of counterfeit medicine has

Source: (Field Survey, 2020)

3.8.3 Respondents who have witnessed a person negatively affected by a fake/ counterfeit drug

The table 4.21 and Figure 4.21 below establishes the total number of respondents who have witnessed a person negatively affected by a fake/ counterfeit drug. This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate. The responses from the 55 valid respondents comprised; 58.9% responding ‘yes’ and 39.3% responding ‘no’. This reveals that there is an almost equal number of respondents with this experience and those who do not.

Table 4.21: Respondents who have witnessed a person negatively affected by a fake/ counterfeit drug

WITNESSED	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	33	58.9	58.9
B	22	39.3	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

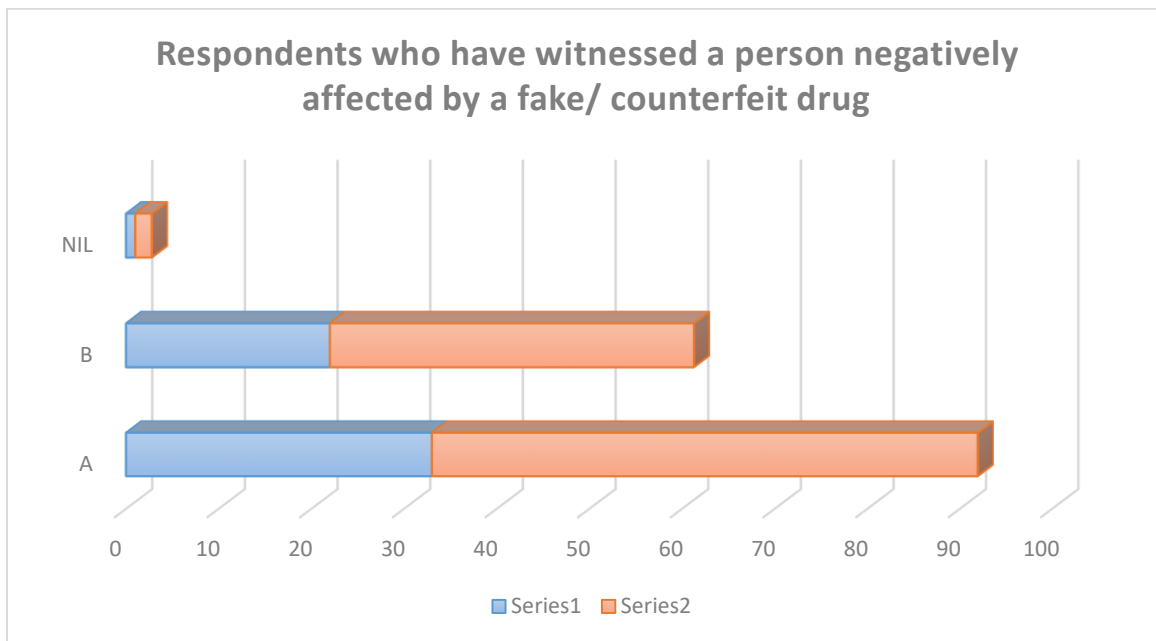


Figure 4.21: A bar chart representing respondents who have witnessed a person negatively affected by a fake/ counterfeit drug

Source: (Field Survey, 2020)

3.8.4 Respondents who expressed their view on ways a person is negatively affected by a fake/ counterfeit drug

The table 4.22 and Figure 4.22 below establishes the total number of respondents who expressed their view on ways a person is negatively affected by a fake/ counterfeit drug. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; a modal response of 25% responding as ‘worsening illness’, ‘psychological effects’, ‘undue increase in financial cost in treatment of illness’, ‘prolong absence from work’ and ‘prolong absence from academic work.’ The remainder of the responses was either a choice of one or multiples of the former. However 10% only responded as ‘worsening illness’, which makes this factor a significant effect of this phenomenon.

Table 4.22: Respondents who expressed their view on ways a person is negatively affected by a fake/ counterfeit drug

VIEW	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	10	17.9	17.9
AB	1	1.8	19.6
ABC	2	3.6	23.2
ABCD	2	3.6	26.8

ABCDE	14	25.0	51.8
ABCE	2	3.6	55.4
AC	6	10.7	66.1
ACDG	1	1.8	67.9
ACE	4	7.1	75.0
ADE	1	1.8	76.8
B	6	10.7	87.5
BC	2	3.6	91.1
BDE	1	1.8	92.9
CD	2	3.6	96.4
NIL	2	3.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

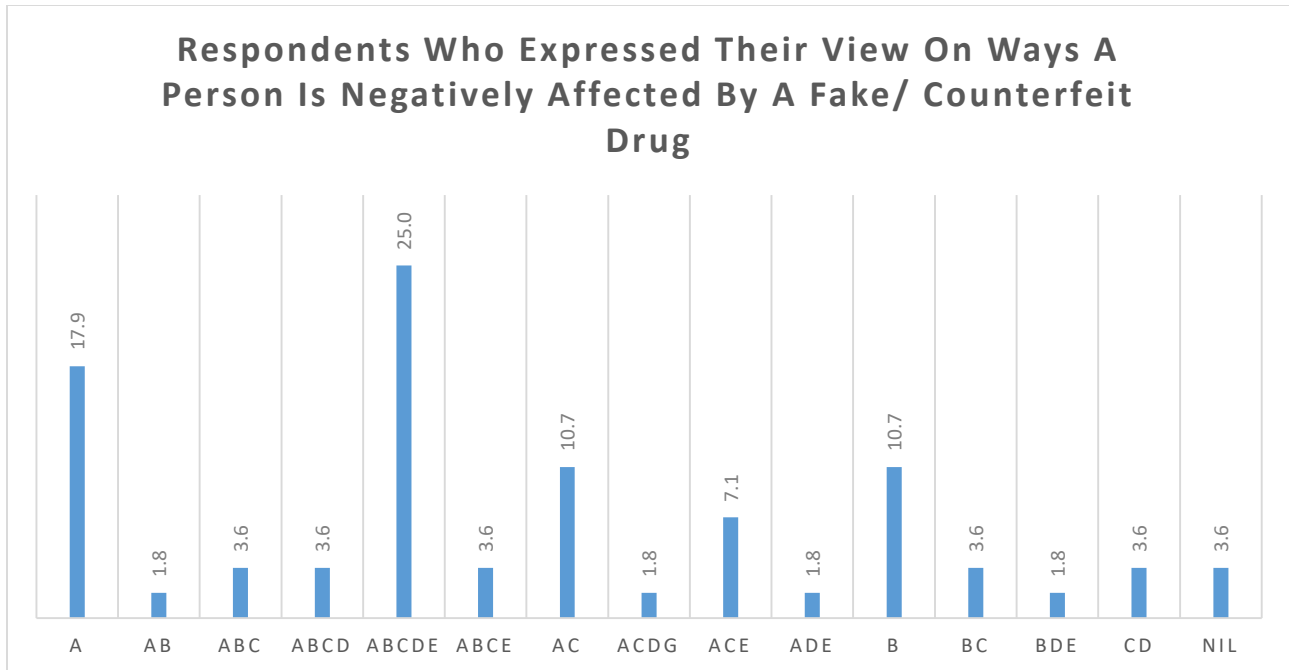


Figure 4.22: A column chart representing respondents who expressed their view on ways a person is negatively affected by a fake/ counterfeit drug

Source: (Field Survey, 2020)

3.8.5 Respondents who explained the negative effect on a family whose bread winner is affected by use of counterfeit/ fake drugs

The table 4.23 and Figure 4.23 below establishes the total number of respondents who explained the negative effect on a family whose bread winner is affected by use of counterfeit/ fake drugs.

This suggests that the total number of valid respondents to the questionnaires were fifty-five (55) from the sixty (60) questionnaires issued out to the respondents, representing 91.7% response rate.

The responses from the 54 valid respondents comprised; 17.9% responding as ‘emotional discomfort’, 33.9% responding as both ‘emotional discomfort and shortage of family income ‘psychological effects’, and 41.1% responded as ‘psychological effects’ only, The modal response

highlights psychological effects as the major effect on families whose bread winner may have to experience this phenomenon.

Table 4.23: Respondents who explained the negative effect on a family whose bread winner is affected by use of counterfeit/ fake drugs

NEGATIVE	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	10	17.9	17.9
AB	19	33.9	51.8
AC	2	3.6	55.4
B	23	41.1	96.4
BC	1	1.8	98.2
NIL	1	1.8	100.0
	56	100.0	

Source: (Field Survey, 2020)

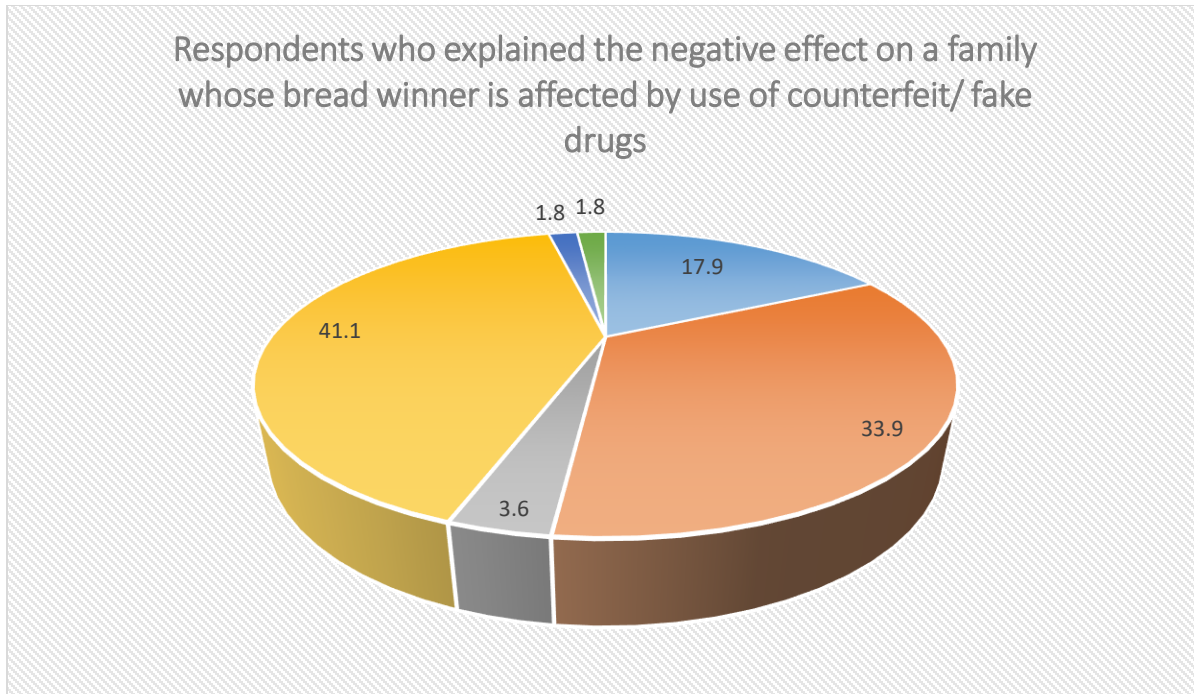


Figure 4.23: A pie chart representing respondents who explained the negative effect on a family whose bread winner is affected by use of counterfeit/ fake drugs

Source: (Field Survey, 2020)

3.9 DESCRIPTIVE RESPONSES OF THE PROBABLE CAUSES FOR CHOOSING/ OPTING FOR COUNTERFEIT/ FAKE DRUGS KNOWINGLY OR UNKNOWINGLY

3.9.1 Respondents who ever bought a fake/ counterfeit drug

The table 4.24 and Figure 4.24 below establishes the total number of respondents who ever bought a fake/ counterfeit drug. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; 30.4% responding 'yes' and 66.1% responded 'no'. Though the modal response was 'no', it is very

possible, inferring from the literature review that some of these respondents may have bought such drugs without knowing.

Table 4.24: Respondents who ever bought a fake/ counterfeit drug

BOUGHT	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	17	30.4	30.4
B	37	66.1	96.4
NIL	2	3.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

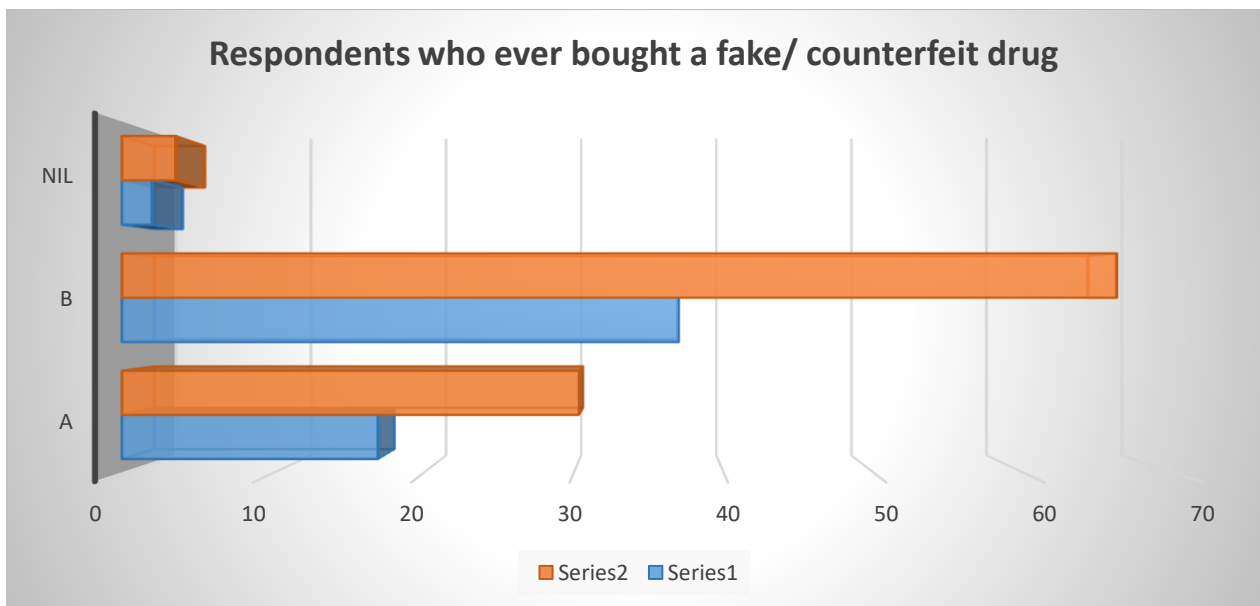


Figure 4.24: A bar chart representing respondents who ever bought a fake/ counterfeit drug

Source: (Field Survey, 2020)

3.9.2 Respondents who shared knowledge of authenticity of fake drug bought

The table 4.25 and Figure 4.25 below establishes the total number of respondents who shared knowledge of authenticity of fake drug bought. This suggests that the total number of valid respondents to the questionnaires were twenty-three (23) from the sixty (60) questionnaires issued out to the respondents, representing 38.3% response rate. The responses from the 23 valid respondents comprised; 7.1% responding ‘yes’ and 33.9% responded ‘no’. Obviously respondents with the modal response were those who thought they were buying the original drug.

Table 4.25: Respondents who ever bought a fake/ counterfeit drug

IF YES	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	4	7.1	7.1
B	19	33.9	41.1
NIL	33	58.9	100.0
	56	100.0	

Source: (Field Survey, 2020)

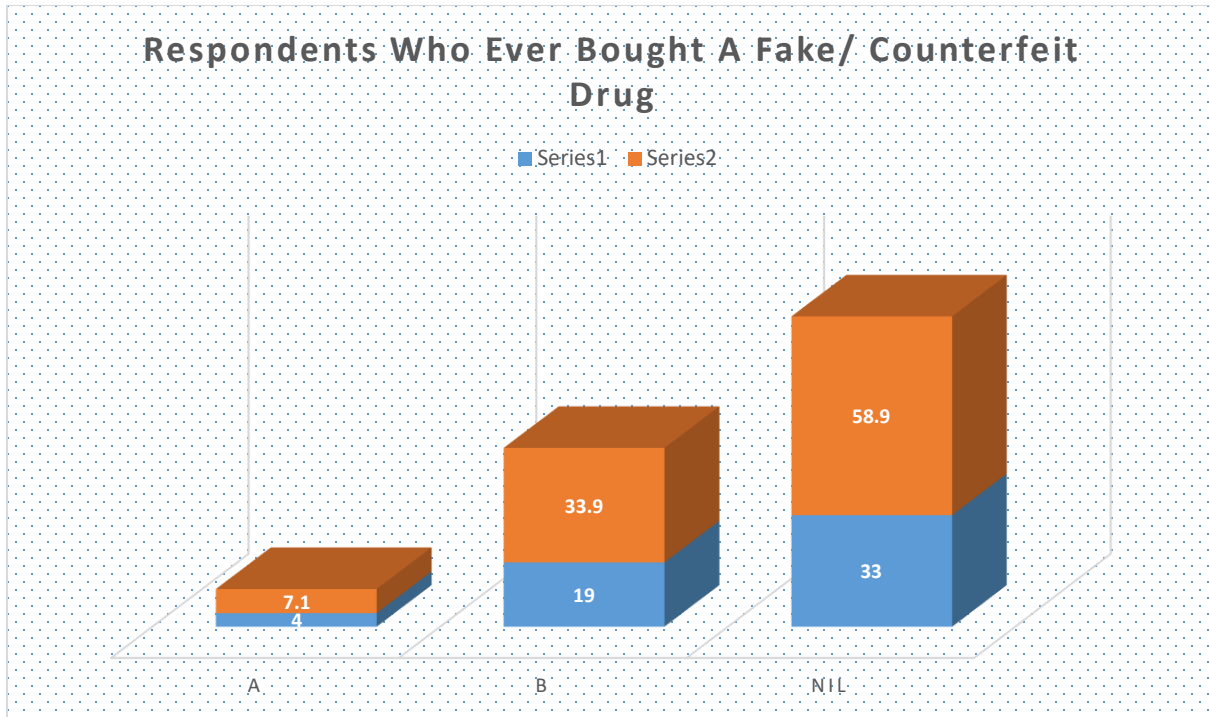


Figure 4.25: A column chart representing respondents who ever bought a fake/ counterfeit drug Source: (Field Survey, 2020)

3.9.3 Respondents who see themselves purchasing fake drugs because of cost

The table 4.26 and Figure 4.26 below establishes the total number of respondents who see themselves purchasing fake drugs because of cost. This suggests that the total number of valid respondents to the questionnaires were forty (40) from the sixty (60) questionnaires issued out to the respondents, representing 66.7% response rate. The responses from the 40 valid respondents comprised; 12.5% responding ‘yes’, 57.1% responded ‘no’ and 1.8% responded ‘maybe’. Though respondents who indicated ‘yes’ were in the minority, this should be of great interest and concern.

Table 4.26: Respondents who see themselves purchasing fake drugs because of cost

IF NO	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
YES	7	12.5	12.5
NO	32	57.1	69.6
MAYBE	1	1.8	71.4
NIL	16	28.6	100.0
	56	100	

(Field Survey, 2020)

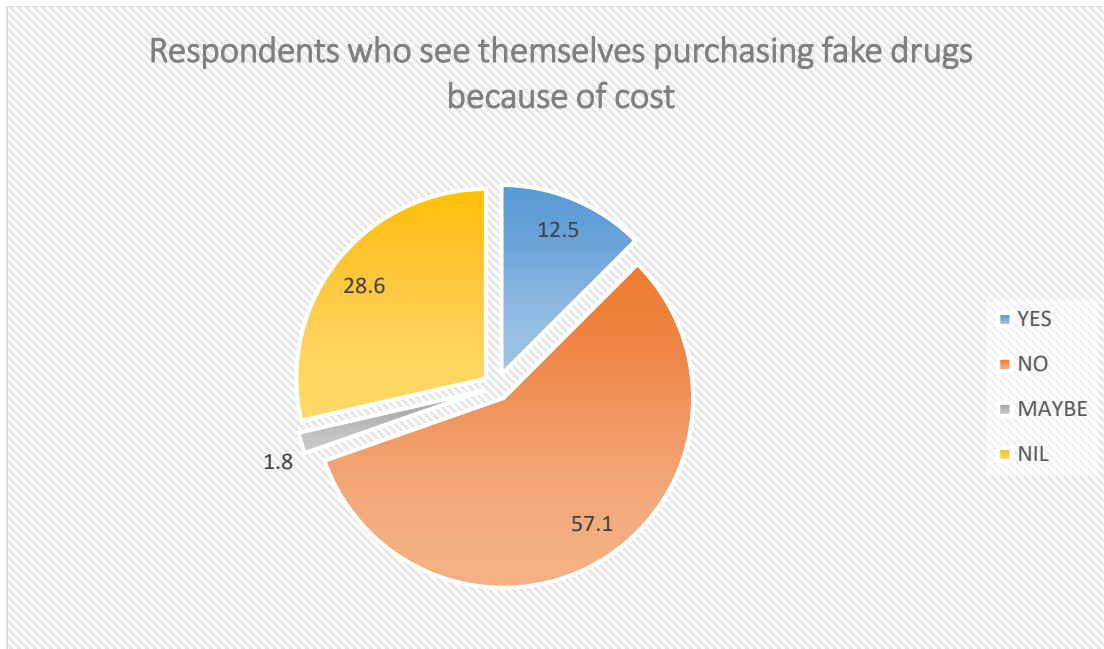


Figure 4.26: A column chart representing respondents who see themselves purchasing fake drugs because of cost drug

Source: (Field Survey, 2020)

3.9.4 Respondents who shared their opinion on why someone will buy counterfeit/fake drug

The table 4.27 and Figure 4.27 below establishes the total number of respondents who shared their opinion on why someone will buy counterfeit/fake drug. This suggests that the total number of valid respondents to the questionnaires were fifty-three (53) from the sixty (60) questionnaires issued out to the respondents, representing 88.3% response rate. The responses from the 53 valid respondents comprised; 8.9% responding as ‘low cost of counterfeit/fake drugs’ being the modal response, 7.1% responded same including ‘ignorance of authenticity of drug’, ‘lack of available quality medicines’, ‘high cost of quality medicines’, ‘lack of knowledge of unapproved medicines by Ghana Foods and Drugs Authority’ and ‘Easy access to fake/ counterfeit drugs’. Others responses also included ‘the overwhelming increase of fake/counterfeit drugs on the market. Though the responses varied, it is interesting to note that cost is a major factor in the proliferation of these counterfeit/ fake drugs on the market.

Table 4.27: Respondents who shared their opinion on why someone will buy counterfeit/fake drug

OPINION	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	3	5.4	5.4
AB	1	1.8	7.1
ABC	2	3.6	10.7
ABCDE	1	1.8	12.5

ABCDEF	4	7.1	19.6
ABCDEFG	2	3.6	23.2
ABCDEFGH	1	1.8	25.0
ABCDFG	2	3.6	28.6
ABD	1	1.8	30.4
ABDE	5	8.9	39.3
ABDEF	1	1.8	41.1
ABDEFG	2	3.6	44.6
ABDEG	1	1.8	46.4
ABDF	1	1.8	48.2
ABDFG	1	1.8	50.0
ABDG	1	1.8	51.8
ABF	1	1.8	53.6
AC	1	1.8	55.4
ACG	1	1.8	57.1
AD	1	1.8	58.9
ADE	1	1.8	60.7
ADEG	1	1.8	62.5
ADG	1	1.8	64.3
AE	1	1.8	66.1
AEG	1	1.8	67.9
B	5	8.9	76.8
BCEF	1	1.8	78.6

BD	1	1.8	80.4
BDEF	1	1.8	82.1
BDFG	1	1.8	83.9
BE	1	1.8	85.7
D	1	1.8	87.5
E	4	7.1	94.6
Nil	3	5.4	100.0
	56	100.0	

(Field Survey, 2020)

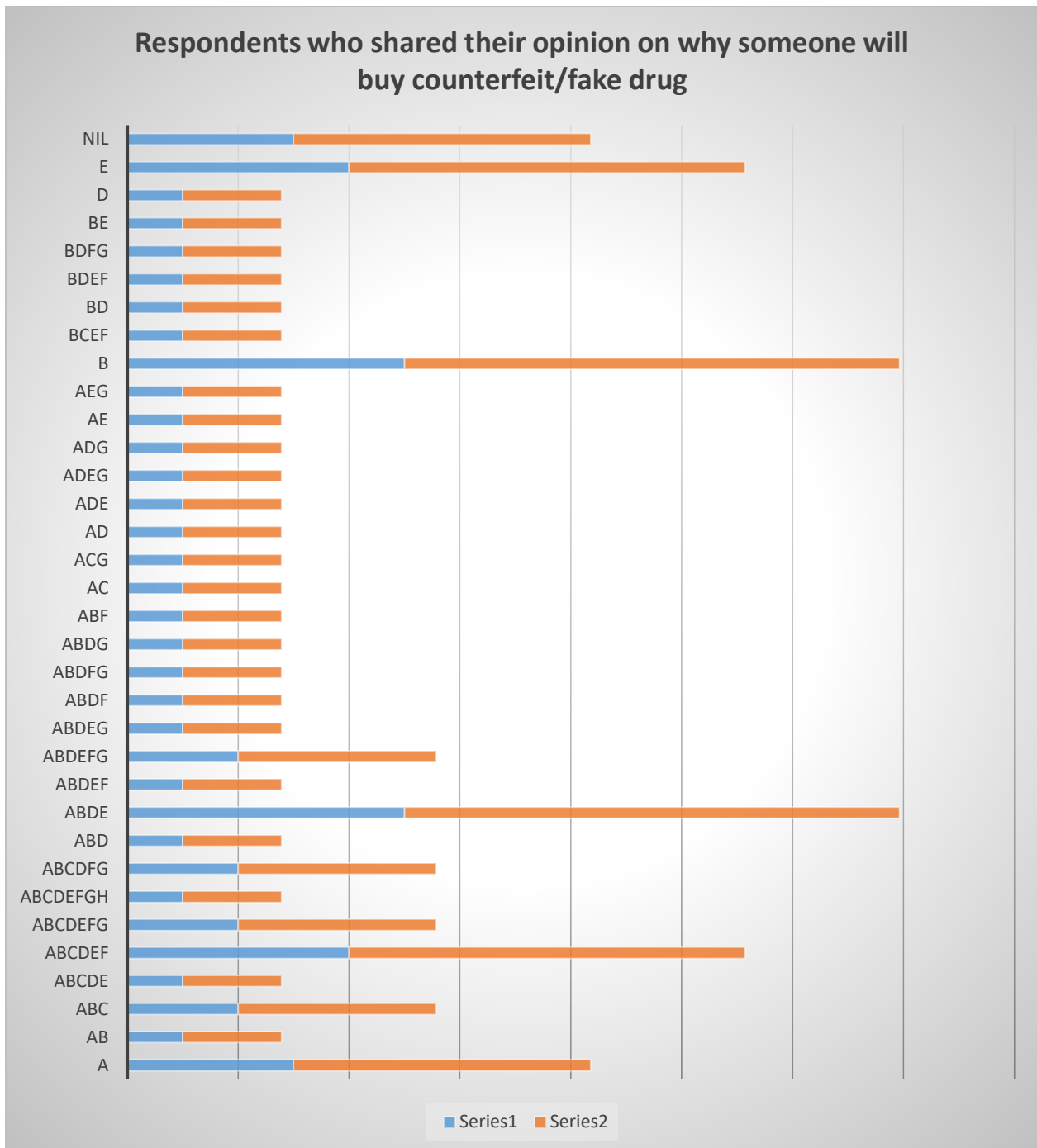


Figure 4.27: A bar chart respondents who shared their opinion on why someone will buy counterfeit/fake drug

Source: (Field Survey, 2020)

3.9.5 Respondents who explained whether it is worth buying fake/counterfeit drugs because they cost less

The table 4.28 and Figure 4.28 below establishes the total number of respondents who shared their opinion on why someone will buy counterfeit/fake drug. This suggests that the total number of valid respondents to the questionnaires were fifty-four (54) from the sixty (60) questionnaires issued out to the respondents, representing 90% response rate. The responses from the 54 valid respondents comprised; 12.5% responding ‘yes’ and 83.9% responding as ‘no’. Though it will be expected that respondents will avoid fake/counterfeit drugs because of their effect on the human body, it is interesting and a concern that quite a significant group will patronize them due to their lower cost to the proper and original version. However this is consistent with the respondents who see themselves buying counterfeit/fake drugs due to cost in 4.7.3 above.

Table 4.28: Respondents who explained whether it is worth buying fake/counterfeit drugs because they cost less

WORTH	FREQUENCY	PERCENTAGE (%)	CUMULATIVE PERCENTAGE (%)
A	7	12.5	12.5
B	47	83.9	96.4
NIL	2	3.6	100.0
	56	100.0	

Source: (Field Survey, 2020)

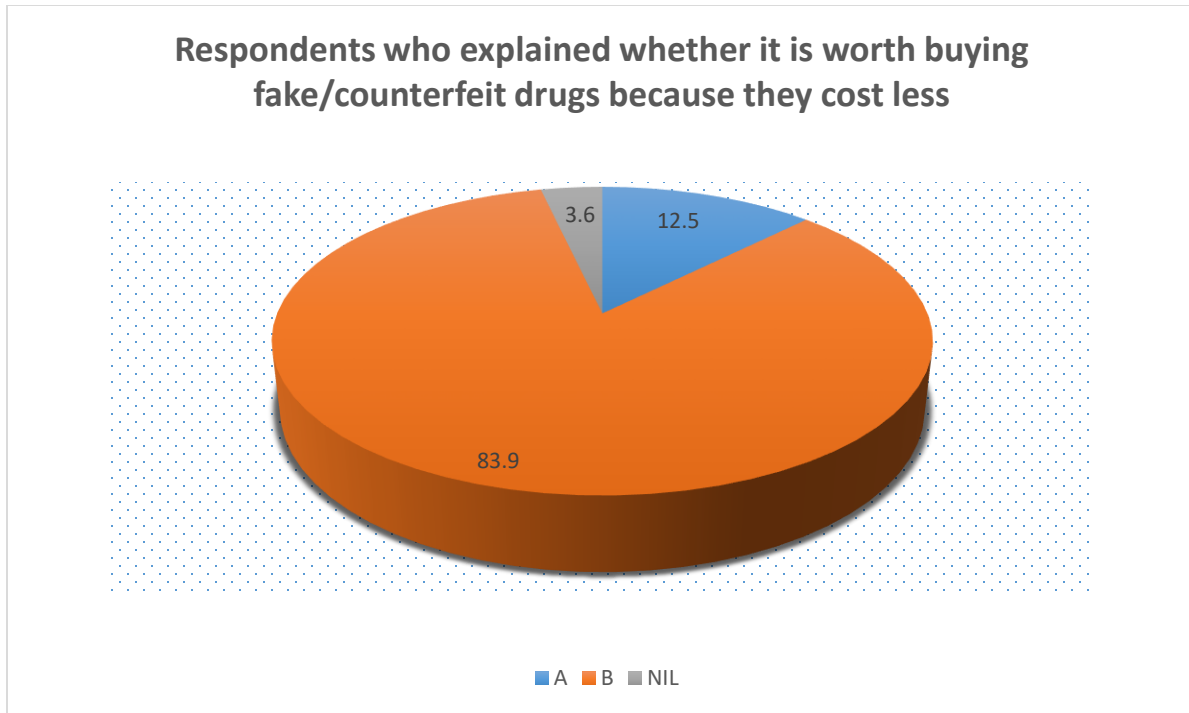


Figure 4.28: A bar chart respondents who explained whether it is worth buying fake/counterfeit drugs because they cost less

Source: (Field Survey, 2020)

3.9.6 Respondents who explained whether it is worth buying fake/counterfeit drugs because they cost less

The table 4.29 below establishes the total number of respondents who shared their opinion on why someone will buy counterfeit/fake drug. This suggests that the total number of valid respondents to the questionnaires were forty-six (46) from the sixty (60) questionnaires issued out to the respondents, representing 76.7% response rate. The responses from the 46 valid respondents comprised varied responses. Details are listed in Table 1.29 below.

What do you say about counterfeit/fake medicines in Ghana
Affects the treatment of chronic diseases
Can lead to loss lives
Can wreck our nation
Causes health issues and financial loss
Causes side effects
Control measures must be put in place
Culprits must be arrested
Death is the final consequence
Deteriorates health
Fake drugs are dangerous to the body in the long term
FDA must ban importation of fake drugs
FDA must create awareness
FDA should deal with culprits
Government must regulate
Harmful to our health so must be combated
Harmful to users
Has to be banned
High cost of quality drugs pushes people to buy fake drugs
Importation of such drugs must be banned
It is collapsing good business and destroying lives
Licensed sellers sell them if demand is high

Makes people lose trust in local medicine
More cost incurred in treating the effect of it
More public information needed about counterfeit drugs
Need to eradicate fake medicines to save Ghana
Nil (10)
Not advisable for use
Not good
Prolongs illness
Reduces individual productivity
Should be banned
Should be banned and culprits arrested
Should be keenly regulated
Should be monitored and regulated
There must be thorough check of imported drugs
They are bad
They are destroying the economy and lives
They are slow killers
They can cause more illness
They cost the nation a great harm
They have cost the nation a lot
They have to be banned
They should be banned
Those who deal in them should face the law

Wastes money
Worsens illnesses
Worsens illnesses

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CHAPTER FOUR

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

4.0 Introduction

The 3rd UNs' SDG 3.8 shows the need to "achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all." However, the proliferation of fake/counterfeit drug/medicine poses a severe hazardous implication on the health of citizens, their economic and social life, and that of the country's economic growth. The issue with counterfeit medicines clearly undermines the access of individuals to quality, safe, effective, and affordable medicines and vaccines. It is a dangerous risk to those that consume such drugs due to its fake branding or alteration, which may include the wrong ingredient which is harmful to the individual. The counterfeit medicine trade leads to a complete revenue loss to the country since they are usually smuggled into the country via unapproved routes. The illegal trade also causes financial loss to companies and individuals who are in the genuine production or marketing of medicines. The study sought to investigate the social and economic effects of counterfeit and fake drugs on Ghana. The study also looked at what counterfeit/fake drugs are, why the trade in counterfeit/drugs drugs is booming in Africa, and the measures put in place to address the problem of counterfeit/fake drugs to meet SDG 3 by 2030. The challenges addressing these problems, successes and way forward.

This chapter presents a summary of the major findings of the study from the data analysis, draws conclusions from the findings and makes recommendations to stop the trade in counterfeit/fake medicines in Ghana in order to meet SDG 3 by 2030.

4.1 Summary of Findings

Summary of Research findings from interviews and data collection are below.

4.1.1 Ascertain what counterfeit drugs are and reasons for its trade boom in Africa

The primary research conducted shows that fake/ counterfeit drugs are fast moving/selling in the market by mimicking or copying the original in order to profit. This is done by changing the batch number, using wrong address of the company or changing the colour coding on the drug. In addition, testing the products in the laboratory also reveal that sometimes there are no active ingredients in the drugs, or they are too low, or other times the quantity may be over what is approved. Apart from that, the product is a different colour from the authentic drug that is known to regulators. Counterfeit/ fake drugs trade is booming because penalties are relatively low as compare to narcotics, high profit margins and the low risk involved.

Further, counterfeit and fake drugs normally come with same packaging, but the content is different as well as the active ingredient. Counterfeit/fake drugs are up to about 50% in Ghana. During inspection, for instance, out of every ten different medicines two might be counterfeit and three fake. Some causes of counterfeit/fake medicines in Ghana are due to porous borders, low standards of enforcement activities, lack of purchasing power for consumers, and convenient to the consumer because drug peddlers are everywhere which make it easily accessible than the authentic medicine. Ghana/Africa is attracting counterfeit/fake medicine trade due to its porous borders, ineffective regulations and a lucrative business to others.

The regulator (Foods and Drugs Authority) in Ghana, like those of Nigeria and South Africa, is doing far more than most other African countries like Togo and Benin, where they only have

Pharmacy Boards, some others have some ad hoc committees which are put in place to grant permission to local manufacturers of medicines as and when necessary.

4.1.2 Assessing the socio-economic effects of counterfeit drugs on Ghanaians and the economic growth of pharmaceutical and chemical companies

The Pharmacy Council of Ghana identified several socio-economic impact of counterfeit/fake drugs on Ghanaians and the industry. The activity is a profit venture for some people albeit it has a negative effect on the public, country, and companies. Counterfeit/fake medicine trade kills innovations, kills business, increases mortality, prolong recover and cure as people keep buying the wrong medicines. It also leads to poverty with the prolong purchasing of counterfeit/fake medicines to cure sickness, results in unemployment as original companies are forced to go out of business to influx of counterfeit/fake medicines. This also affects the suppliers of raw materials to these companies, ultimately impacting the entire industry.

Information from the Foods and Drugs Authority also shows that the effect of these activities result in loss of confidence in the health system, loss of confidence in health professionals, negative impact government and the National Security, and also increases in morbidity of the indigenious. This is due to the residents' perception of health practitioners as inexperienced and incapable of curing diseases that have been passed down to them. They also stop going to the doctor and instead seek healing from traditional sources and homemade remedies. Government, on the other hand, is seen as unconcerned about people's wellbeing due to little/no concern/investment in health-care provision and the resulting problems. National security is seen as unable/incapable of putting a stop to these offenders.

Respondent from Danadams also added some negative impacts such as the inability for the local manufacturing and importers to operate and compete in the market leading to collapse of their businesses. Also, industries are not able to grow to explore and to expand to provide more jobs for people and readily available medicine for the people. He added that the effects of counterfeit/fake medicine are much felt in the border town because they are the first point of sale and also due to their high illiteracy. Though FDA has regional offices, their presence is not felt and they are often unable to stop these illicit trade.

4.1.3 Efforts put in place to address the issue of counterfeit drugs to meet SDG 3

All the policies that government and stakeholders including the manufacturers and regulators are putting in place is towards meeting SDG 3 by the year 2030. Stakeholders contribute to the fight against counterfeit/fake medicines by investing in the pharmaceutical industry to help expand their industry to make medicine easily accessible to all; training more personnel to help in regulating and safe guarding the industry including the porous borders; more collaboration among stakeholders and effective laws. He further explained that uniformity in laws and strict punishments are necessary to help with easy prosecution especially when it comes to dealing with counterfeit/fake medicines which is a cross-border crime/international crime. Inter-country laws should also be made easy for prosecution as the laws regarding these crimes and its punishments are currently different, which makes it difficult to prosecute.

4.1.4 Successes achieved, challenges faced and the way forward for Ghana

Responses from the Pharmacy Council of Ghana highlights some the successes. Respondents explains that Ghana already bought into the SDGs which means it is prepared and ready to do its best to meet all the requirements. It has therefore engaged more training of personnel to be able to have more knowledge to help in the fight against counterfeit/fake medicines. Also, more equipment is being purchased for on sight detection of fake/counterfeit medicines. Finally, Government is investing in the local pharmaceutical industry to enable them produce more and to grow.

Respondent from Danadams identified the positive role of the regulator (Foods and Drugs Authority). He identified some of their successes as engaging in a lot of stake holder consultation, several training of health professionals to create awareness, introducing laws which ban the importation of some drugs, deploying personnel at the borders and other entry points to check. He further added that Government has supported some manufacturers in the past and West African health organization has helped in purchasing some equipment also.

On the other hand, the respondent from Pharmacy Council identified some challenges. He explained that many people do not have money to buy authentic medicine because of the cost, and so they settle on counterfeit/fake medicines which more often cost less. Also, the numbers of professional are not enough in the system to meet the demands of the population. Currently there are about 4,000 pharmacists from Ghana, but not all are resident in Ghana and about 2,500 are active but mostly in the private sector with only a handful in the government sector. He added that the amount of money allocated for the sector is inadequate. Furthermore, the activity is big business for a lot of people, though focus seems to be more on hard drugs and there are stringent punishment for offenders unlike that of counterfeit/fake medicines.

Some measures were suggested as way forward. Respondent from the Pharmacy Council of Ghana suggested that public education is very necessary. Apart from that enforcement activities should be rampant to keep stakeholders vigilant and up to task. Respondent of Danadams also added some measures to include discouraging people from dealing in counterfeit/fake medicines by making medicine affordable and available. He added that Government should support local manufacturers by tax waivers on packaging materials, chemicals and other equipment to help manufacture at a lower rate for affordable medicines. Aside that, the use of technology, by creating and using easy and accessible web applications, which can tell that the product is fake or counterfeit but not substandard unless in a lab. He also said it is important to repeal the laws to make them more stringent in order to deter people from participating in the illicit trade.

4.1.5 Challenges

After thorough analyses of the survey and interviews, the main challenges identified from the results generated include:

- a. Lack of public awareness:** the literature highlights the high proliferation rate of fake/counterfeit drugs on the Ghanaian market. Considering that out of every ten different medicines two might be counterfeit and three fake, even up to 50% on the market. This is rather alarming. With this statistics, the survey revealed that most respondents were certain they have never been victims of counterfeit/ fake drugs. This is evidence of the meticulous efforts by perpetrators to copy the original drugs and so make it difficult for users to differentiate. Apart from that it is also obvious that poor public education has left

Ghanaians unaware of the high of rate of counterfeit/fake drugs on the market, the need to be vigilant, how to detect and report such drugs and its operators.

- b. Socio-economic impact of counterfeit drugs on Ghanaians:** firstly, the high population of middle to low income earners in a developing nation like Ghana has confirmed how many people struggle to buy authentic medicine because of the cost. They would rather settle for counterfeit/fake medicines which more often cost less. The impact to the health of the populace is detrimental. Aside worsening the health conditions of the people who fall victim, they are forced to spend more treating the same ailment, inadvertently resulting in reduction in income and productivity of such Ghanaians.
- c. Economic growth of pharmaceutical and chemical companies:** the activity is big business for a lot of people. This is gradually crippling the pharmaceutical and chemical industry, making Ghanaians lose confidence in the local manufacturers. Also the number of professionals in the system is not enough to meet the demands of the population. Currently there are about 4,000 pharmacists from Ghana, but not all are resident in Ghana. About 2,500 are active but mostly in the private sector with only a handful in the government sector. This wide deficit leaves room and creates the right environment for fake/ counterfeit drug operators to thrive. The proliferation of such counterfeit/ fake drugs operators further encouraged more perpetrators to be involved. This eventually affects the industry in total and loss of revenue to the nation. Furthermore, the inability for the local manufacturing and importers to operate and compete in the market leads to collapse of their

businesses. Also, industries are not able to innovate, grow to explore, to expand to provide more jobs for people and readily available medicine for the people.

d. Porous regulatory structures: Though Ghana is acclaimed to be among countries collaborating to fight the menace of counterfeit/ fake drugs on the continent, much is left to be desired. The mode of operation these perpetrators have largely been discovered and yet their operations keep growing. Focus seems to be more on hard drugs offenders, with stringent punishments unlike that of counterfeit/fake drugs. The borders which serve as entry points for most these drugs are manned by authorities, yet inspection and regulation is a challenge. The Food & Drugs Authority, mandated to regulate these drugs seem unable to deploy their task force to inspect sales points and operators who openly display their wares at the peril of Ghanaian lives.

4.2 Conclusions

Illicit trade in pharmaceuticals undermines the SDGs in many ways: Illegal profits from illicit pharmaceuticals finance organized criminal activity and threaten lives, social stability and peaceful communities.

The proliferation of fake/counterfeit drug/medicine in Ghana also poses severe hazardous implication on the health of citizens, their economic and social life, the country's economic growth and the possible inability of the country to achieve its SDG 3 goals as the issue of counterfeit medicines/fake drugs clearly undermines the access of individuals to quality, safe, effective, and affordable medicines and vaccines. It is a dangerous risk to those that consume such drugs due to its fake branding or alteration, which may include the wrong ingredient which is harmful to the individual. The counterfeit medicine trade leads to a complete revenue loss to the country since

they are usually smuggled into the country via unapproved routes. The illegal trade also causes financial loss to companies and individuals who are in the genuine production or marketing of medicines as the research has clearly highlighted in the data from the survey and interviews which has gone a long way to address the research questions and thereby meeting the objectives which were stated for the study.

In conclusion, the data from the survey and interviews goes a long way to address the research questions and thereby meet the objectives which were stated for the study. Indeed, fifty-six (56) survey respondents and three interviewees who finally helped to answer the data instruments were sufficient to elicit the responses required. It is also important to refer to research questions and objectives the sought to guide the direction of the research. Considering that the research was focused on the socio-economic impact of fake medicine/counterfeit drugs on Ghana under SDG 3, it has meticulously unraveled the various socio-economic scenarios of this menace on the Ghanaian society as guided by the research objectives.

Throughout the research, reviewing literature from other scholars and institutions, primary data from survey and interviews, and the analysis and findings, it was quite clear that these research objectives were critically addressed. The mandate of SDG 3 which aims to 'ensure healthy lives and promote wellbeing for all, at all ages' and sub-target 3.8 access 'to safe, effective, quality and affordable essential medicines and vaccines for all.' Nonetheless the need to address the growing phenomenon of counterfeit medicines, which disproportionately affects developing countries and which seems missing from the global discourse around achieving SDG 3 have been addressed through this research. It is however necessary to pursue this research further to study into happenings in other parts of the country, including other parts of African continent.

4.3 Recommendations

To solve the issue of the proliferation of the trade of counterfeit/fake drugs to be able to meet the SDG 3 by 2030, the following recommendations can be looked at.

Intensify public education and awareness creation

Many people are either ignorant about counterfeit/fake medicines or unaware of them and their effects. There is the need of public education in our schools, churches, mosque and through the print and broadcast media and the internet. This will arm the citizens with some knowledge and keep the vigilant therefore protecting themselves and saving the pharmaceutical companies and the country from various loses. Creating public awareness of this menace is very necessary as it exposes the cunning methods of copying authentic medicines by criminals to the general public. This education must be pervasive on all media platforms including traditional and non-traditional platforms like social media. There must be toll free numbers provided for the general public to report suspicious and fake/ counterfeit drugs.

Targeted Recruitment

Recruiting specific personnel to Mann the various entry and exit points of Ghana based on their experience, geographical location, skills and desires to protect and safeguard the country, market places and borders from criminals using it for their trade in counterfeit/fake drugs. The presence of these personnel will also serve as a deterrent to the people involved in the trade of counterfeit medicines/fake drugs. The personnel manning the various borders of Ghana with prior geographical knowledge and experience serves as a measure to curtail smuggling of counterfeit/fake drugs and to bring to the barest minimum or completely eradicate the trade of counterfeit/fake drugs in Ghana. Increasing the number of personnel special for border patrols,

market surveillance, checks and protection will enable stakeholders to carry out various enforcement activities at random times and places.

Effective training of personnel

Recruiting personnel to safeguard our borders and our country is one thing and training and equipping them to effectively carry out their duties at these border posts and the country is another. When these personnel are recruited, they should be duly trained in safe and secure border patrolling, intelligence gathering, cargo profiling and the examination and identification of counterfeit/fake drugs; these personnel should also be equipped with hand held devices that can easily enable to detect counterfeit/fake drugs, finding its way into our country and its sale too. Training more personnel will also help in regulating and safe guarding the industry including the porous borders; conducting surveillance in the markets, more collaboration among stakeholders and effective laws. It is necessary that the personnel and task force deployed to monitor, inspect and follow up on calls of suspicious and fake/ counterfeit drugs, must be effectively trained to be professionals and also to be beyond compromise. They must be incentivized and motivated so that no perpetrator bribes to look away. The task force, especially at the borders must be resourced with the right tools and materials including patrol vehicles and devices for inspection, in order for them to effectively prevent such perpetrators from crossing the borders with their fake/ counterfeit drugs into the country.

Use of more advanced technology

Manufacturers and traders of such fake/ counterfeit drugs are developing more creative ways to elude check points and maneuver their way into the local market. It is therefore very necessary to

collaborate with advance countries that have gone ahead in combating such menace and learn from them. The use of sophisticated and advance equipment must be adopted for on sight detection of fake/counterfeit medicines. Also, it is necessary to create and use easy and accessible web applications, which can tell that the product is fake or counterfeit.

Role of lawmakers & Enforcement activities

It is important to repeal the laws to make them more stringent in order to deter people from participating in the illicit trade. Whereas punishment for engaging in narcotics and other hard drugs are stringent, it seems the penalty for those who are involved in fake/ counterfeit drugs are far lenient. These penalties are not severing enough to deter perpetrators and others from stopping such illicit trades. The laws must therefore be repealed to correct this. Aside this, enforcement is also very crucial in ensuring the law is working. Law enforcers and special task forces must be motivated to take full charge of these responsibilities to the letter.

Investing in the local pharmaceutical industry

One key means of solving the challenging of costly foreign drugs is to invest in the local industry to research and manufacturing equally effective drugs. Government must support local manufacturers by increasing the budgetary allocations and tax waivers on packaging materials, chemicals and other equipment to help them manufacture at lower rates for affordable medicines. Although the research discovered that government and all stakeholders in the manufacturing/supply of drugs and other essential agencies are doing their best in the fight against the proliferation of counterfeit medicines/fake drugs in Ghana, these recommendations can still be looked at.

Need for Professionals

The research found out that the numbers of professional pharmacists are not enough in the system to meet the demands of the population. Currently there are about 4,000 pharmacists from Ghana, but not all are resident in Ghana and about 2,500 are active but mostly in the private sector with only a handful in the government sector. Government can institute a special scholarship package for people willing to study as professional pharmacists and work for the Country. There should also put in place incentives that will attract more professionals choosing to work with the government than the private sector or abroad.

Lack of attention

From the research it was realized that the trade in counterfeit medicine/fake drugs is a big business for a lot of people in Ghana, but unfortunately, the focus seems to be more on narcotic drugs with stringent punishment for offenders unlike that of the counterfeit/fake medicines. The Socio-economic effects of counterfeit/fake medicine on Ghana is a big problem and the need to give it the needed attention in order to bring it to an end. There is the need to give important attention to both issues of the proliferation and trade of counterfeit/fake medicines and narcotic drugs in the country to be able to arrest and address their attended problems.

All the above recommendation notwithstanding, Ghana/Africa can also fight against counterfeit/fake medicines trade by using the available security measures, enforcing laws to punish offenders, engaging in cross-border collaboration between countries and exchanging intelligence.

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