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PHARMACEUTICAL GOVERNANCE AND ACCESS TO QUALITY MEDICINES IN GHANA

BY

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DECLARATION

I, the undersigned, hereby declare that, apart from authors and institutions, whose works were duly acknowledged in this write-up, this thesis is a product of my endeavour towards the award of a Doctor of Philosophy Degree in Health Policy and Management carried out under supervision. This document has neither been wholly or partly submitted to any higher institution of learning for the award of any degree whatsoever. Any weaknesses found therein solely remain my responsibility.

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CERTIFICATION

We, the undersigned, hereby certify that this thesis was under our supervision and we therefore consider it credible to enter the canon of certified academic research through the award of a Doctor of Philosophy (PhD) degree in Health Policy and Management.

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DEDICATION

This thesis is dedicated to my entire family and friends who have contributed in diverse ways to my PhD journey. However, I specially mention the name of my late father, Alhaji Imam Abdul Salam Abubakar (Alhaji Salinkpang Lana), who laid the foundation of my education but has not lived to witness this level I reach and my mother, Hajia Maimunatu Abdul Salam (Haji Baamunu) who spends her night praying for our success besides her moral and physical guidance.

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ABSTRACT

Medications play a critical role in modern healthcare delivery, serving preventive and curative purposes while mitigating any negative effects caused by drugs. The discovery of medicine has enabled the management and cure of ailments such as sepsis, malaria, and HIV. Access to essential medicines is a cornerstone of achieving Universal Health Coverage, but poor governance poses a significant obstacle to this goal. Ghana has made strides in pharmaceutical governance, but studies have uncovered issues such as inadequate availability of medicines for National Health Insurance Subscribers and the prevalence of substandard and falsified medications. Existing studies that could help explain these problems were found to have some gaps which this study was designed to fill. Therefore, this study aimed to discover how governance of the pharmaceutical life cycle influences access to quality medicines in Ghana.

This study was conducted using institutional theory as its context and guided by the philosophy of pragmatism in its choice of methodology. As a result, a mixed method research approach was employed. The sample size for the quantitative data consisted of 500 healthcare seekers who had visited health facilities within two weeks before data collection. For the qualitative data, 40 participants with significant experience at health facilities were purposefully selected, along with pharmacists of hospitals, managers of community pharmacies, and itinerant medicine sellers. The quantitative data was analysed with descriptive statistics and probit regression. Thematic analysis was used to analyse the qualitative data.

The study discovered that while Municipal hospitals claim that they adhere to prescription regulations, the teaching hospital considered some of the regulations as outdated and unsuitable for a tertiary hospital. Patient involvement in the prescription process was also investigated, which

revealed a moderate level of patient involvement in the prescription process. It was also discovered that prescribers were involved in medicine sales to patients. Overall, the study found that the prescription behaviour of health professionals significantly impacts the affordability of medicines for health seekers. Waiting time at the dispensary, organisation of the dispensary, and information on dosage and side effects were identified as factors that affect the rational use of medicines by patients. Additionally, the study found that Ghana's medicine pricing policies affected the availability of medicines for National Health Insurance subscribers at medicine outlets. Finally, the study assessed the functions of the FDA in regulating medicine quality in Ghana. It was found that the FDA effectively works to eliminate substandard and falsified medicines but struggles with regulating herbal medicines due to social values. It also faces problems due to its collaboration with other state agencies, leading to poor-quality medicines in Ghana. Overall, this study contributes significantly to empirical literature and Institutional theory by demonstrating that applying the elements of good governance can facilitate the isomorphic process explained by the Institutional theory.

CHAPTER ONE

BACKGROUND OF THE STUDY

1.0 Introduction

Medications are crucial in modern healthcare delivery, serving various purposes depending on the patient's condition and needs. In the immediate context, pharmacological interventions are primarily utilised to mitigate acute symptoms or effectuate disease remission, whereas, in the long term, they are utilised to manage and treat chronic conditions. Moreover, medications are increasingly prescribed for primary and secondary prevention, serving as a proactive measure to prevent the onset of diseases or mitigate their effects. Additionally, they counteract any negative effects caused by other medications, ensuring that patients receive the best possible care and treatment. Overall, medications are essential in the healthcare industry, helping individuals maintain their health and well-being (Bennet et al. 2020).

In the history of the World Health Organization (WHO), the provision of essential medicines in an equitable manner has been regarded as a pivotal cornerstone in attaining Universal Health Coverage (UHC) (Mhazo & Maponga, 2022). The availability of crucial medicines is vital in preventing, treating, and managing a wide range of diseases and health conditions. It plays a critical role in decreasing mortality rates, improving the overall quality of life, and promoting economic development in low- and middle–income countries (LMICs) (Mhazo & Maponga, 2022 and Wirtz et al. 2017). The goal of achieving universal access to essential medicines (ATM) has been a major focus in global health discussions, starting from the early Primary Health Care (PHC) concept to the current Universal Health Coverage (UHC) framework (Mhazo & Maponga, 2022). Enabling access to vital medicines is not merely a lofty ambition. Contemporary medicine has remarkably

transformed the trajectory of disease management and alleviated human anguish over the last century. As exemplified by Alexander Fleming's 1928 discovery of penicillin. Pivotal advancements have greatly enhanced sepsis treatment (Pina et al. 2010). Also, the discovery and application of effective medicines for malaria and tuberculosis in the 1940s marked a significant turning point in the battle against these debilitating diseases. Malaria has long been a bane in tropical regions, leading to millions of fatalities annually. On the other hand, tuberculosis devastated communities worldwide, with no viable treatment in sight. The advent of novel drugs like chloroquine for malaria and streptomycin for tuberculosis brought about a remarkable transformation in the trajectory of these conditions (Loeb et al. 1946). In more recent times, the emergence of HIV/AIDS posed an unprecedented and unique challenge. Initially, the disease was regarded as a death sentence with no cure or viable treatments. Nonetheless, the development of antiretroviral therapy (ART) has transformed the management of HIV/AIDS. ART suppresses the virus and enables patients to lead longer healthier lives. HIV/AIDS is no longer an inevitable death sentence but a chronic and manageable ailment (Fosbenner, 2010). Ensuring that medicines are accessible to the vulnerable in society is regarded as a relevant component of ensuring human rights (WHO, 2019). Pharmaceuticals are an integral component of modern healthcare, utilised extensively for the mitigation and management of illnesses and diseases. They represent one of the most frequently employed health technologies in practice.

Access to medicines is key in healthcare delivery. Several studies (Aryeetey et al., 2016; Sarnola & Linnolahti, 2019; Bigdeli et al., 2013) conducted into medicines and healthcare delivery indicate that health delivery is incomplete without access to medicines. According to Aryeetey et al. (2016), ensuring access to high-quality essential medicines is crucial for effective healthcare service delivery. A recent study conducted in Finland by Sarnola & Linnolahti (2019) further highlights

the negative consequences of medicine shortages, such as medical errors, delayed treatments, and eroded patient trust in healthcare providers, ultimately impacting the quality of care received. The study emphasised that the availability and affordability of medicines are core to health service delivery in any community. Bigdeli et al (2013) describe the role of medicine as a "system input that must be available to allow service delivery". The Department for International Development of the United Kingdom (DFID) predicted in 2004 that improving access to medicines and vaccines would save 10 million lives annually, with four million of those being in Africa and Southeast Asia. Unfortunately, nearly one-third of the global population lacks dependable access to medication, with a majority of them residing in the least-developed countries of Africa and Asia, as outlined by Hogerzeil and Mirza (2011). The provision and accessibility of essential medicines is an indispensable element in advancing global health and well-being. Despite its paramount importance, accessing these medicines remains an enormous hurdle, especially in underdeveloped nations and vulnerable communities. As per the estimation of WHO (2007), up to two billion people worldwide lack sufficient access to essential medicines, which are drugs that are fundamental to the treatment of common ailments and health conditions. This shortfall in access can result in escalated mortality rates, diminished quality of life, and heightened vulnerability to epidemics. Tackling this challenge necessitates a cooperative endeavour from administrations, healthcare providers, pharmaceutical firms, and other stakeholders to enhance the availability, affordability, and quality of essential medicines for all (Ahmadiani & Nikfar, 2016 and Bermudez, 2017).

Universal healthcare aims to grant all individuals with high-quality healthcare services, irrespective of their financial status. A crucial aspect of achieving this objective is to guarantee unbiased access to essential medicines. This implies that everyone should have access to the

medications they require to maintain their health and well-being, without considering their financial capability. By prioritising impartial access to essential medicines, the provision of healthy and productive lives can be facilitated for all individuals, without imposing undue financial burden (Wirtz et al. 2017).

However, the current state of affairs can be attributed to a multitude of factors, including patent systems that prioritise financial gain at the expense of public health, leading to a dearth of affordable medication for those in need (Fosbenner, 2011; Castro & Westerhaus, 2007 and Usher, 2020). Furthermore, inadequate healthcare systems exacerbate the issue by hindering the distribution and accessibility of healthcare services and resources (Stevens & Huys, 2017 and Ozawa et al. 2019). Moreover, the prevalence of corruption undermines the integrity of healthcare systems, resulting in limited access to quality care, particularly for marginalised communities (Kohler & Dimancesco, 2020 and Kohler et al. 2014). WHO (2017) implied that the current challenges in accessing essential medicines can be attributed to inadequate pharmaceutical governance. It has been noted that between 20 to 60 per cent of health spending in LMIC is allocated to medications, Cameron et al. (2009) reported. Specifically, a study by Vian & Kohler (2016) found that Ghana, Uganda, and Zambia spent 27.3 per cent, 52.2 per cent, and 18.4 per cent, respectively, of their healthcare budgets on pharmaceuticals. Additionally, WHO (2004) indicated that out-of-pocket expenses for medications made up 50 to 90 per cent of total medication expenditure. The pharmaceutical system is made up of interdependent activities which go through several steps with many partners. Such a complex system functions with a colossal sum of money (SPS, 2011). Due to the huge expenditure in the pharmaceutical sector, it is susceptible to bribery and corruption at every level of the supply chain; that is from clinical trials to prescription and

dispensing (Anello, 2008). It was estimated that, globally, 10 – 25 per cent of the money that is supposed to be spent on medicines is lost through corruption (WHO/GGM, 2008).

Good governance of health systems is what can make improvements in health service delivery sustainable (WHO Maximizing Positive Synergies Collaborative Group, 2009) and ensure access to quality medicines. Governance with leadership has been identified as, possibly, the most salient among the six health system building blocks of WHO (WHO, 2007). The effectiveness of the relationship among stakeholders in the health sector can only be achieved through good governance. This brings about sustained improvement in the performance of the health system and consequently leads to improved health outcomes (WHO, 2007).

Good governance is not universally applicable to all sectors of the health system of every country. Some aspects of good governance may be more suitable in LIMCs which have more complex deficiencies in the national health systems. The governance of such health systems may include maintaining regulatory impartiality, ensuring the safety and quality of medicines in the pharmaceutical supply chain and preventing corruption in the provision of healthcare services (Kohler et al. 2014).

Regarding governance of the pharmaceutical sector, good governance is very important in ensuring the equitable distribution of essential medicines in a society where access to medicines is problematic. It prevents theft of pharmaceuticals and illegal pharmaceutical promotions leading to the elimination of unsafe and falsified medicines (Mackey & Liang, 2011). Therefore, the absence of good governance in the pharmaceutical sector results in an adverse effect on access to and quality of medicines (Kohler & Ovcharenko, 2013).

Also, good governance in the procurement and distribution of medicine tends to have a great impact on medicine prices, availability and accessibility. For instance, Indonesia and South Africa developed procurement policies that led to lower medicine prices. Indonesia set a price ceiling using internal and external reference pricing (Anggriani et al. 2020) and South Africa set up a single body responsible for all medicine purchases (Woutersa et al. 2019). This created competition in the pharmaceutical supply systems that lowered the prices of medicines in those countries.

On the other hand, bad governance has several consequences on the health system in general and the pharmaceutical system in particular. There have been some empirical studies (Jean et al. 2001, DiTella & Savedoff, 2019 and Ferrinho &Van Lerberghe, 2002) that point out the prevalence and the consequence of bad governance on health systems. About two-thirds of hospital workers surveyed in Venezuela knew of the theft of medical supplies and medications (Jean et al. 2001). In the same vein, 83 per cent of nurses and 71 per cent of doctors in Costa Rica complained of theft of equipment or materials in their hospitals (Di Tella & Savedoff, 2019). A study in Uganda similarly indicates that a major source of income for healthcare workers was the resale of drugs (Ferrinho &Van Lerberghe, 2002). These can potentially diminish the availability of medicines, especially to the vulnerable in society. Poor pharmaceutical governance can result in the use of unsafe medicines which can derail the government's effort to make health care accessible to the people (SPS, 2011)

Other possible ramifications of bad governance were shown in Ghana, Kenya, Tanzania and Uganda. In a study of the supply chain of Artemisinin-based Combination Therapy (ACT) [Coartem] in Ghana, Asamoah et al. (2011) found that the production of the medicine was not-for-profit and its price in developing countries was highly subsidised but the price of quality Coartem

in Ghana was very high. In Kenya and Tanzania, there was an erratic supply of medicines from the public sector which compelled a lot of the poor to rely on the private sector for their medicines (Mackintosha et al. 2018). Similar patterns of stock-out were found in Ghana and Uganda (Masters et al. 2014). There is a further indication that, when supplies of medicines were done by the private sector in those countries, there were likely to be low stock-outs (Masters et al. 2014).

Overall, regulating medicine prescription behaviour, responsive dispensing practices, participatory pricing of medicines, and the proper functioning of medicine regulatory bodies are all essential components of functional pharmaceutical governance. By implementing these measures, it can be ensured that patients receive the best possible healthcare outcomes while keeping costs reasonable and affordable for all. Regulating medicine prescription behaviour can prevent prescribers from engaging in self-serving activities that may render medication unaffordable for patients. Adhering to responsive dispensing practices enables patients to comprehend, accept, and rationally use medication to address their healthcare needs. Additionally, involving stakeholders in the pricing of medication can increase its availability within healthcare systems and address issues of medication stockouts. Lastly, ensuring the effective operation of medicine regulatory bodies can eliminate unsafe medication.

A study conducted by Mhazo & Maponga, (2022) concluded that there appears to be a discrepancy between the issues about access to medicines (ATM) that are highlighted in the worldwide dialogue and how they are presented and dealt with in governmental policies and practical implementation at the national levels. Therefore, more comprehensive country studies are necessary to grasp the politics of policy diffusion. This includes comprehending how the interplay of power, ideas, institutions, and interests among different actors affects the priority given to ATM

at the country level and its implications for UHC. That is why this study was designed to find out how pharmaceutical governance affects access to quality medicines in Ghana.

1.1 Problem Statement

In the realm of healthcare, several parties are integral to guaranteeing access to medication. Health professionals are responsible for adhering to the industry's regulations and policies that promote medication affordability and rational use by their patients. The National Health Insurance Authority (NHIA) must offer acceptable prices for medicines to ensure their availability to subscribers and make healthcare affordable for their clients. The Food and Drugs Authority (FDA) is tasked with ensuring medication safety. The coordinated efforts of these various stakeholders, through the application of the principles of good governance, for the provision of accessible, affordable, and effective medication is known as pharmaceutical governance (Anello, 2008 and SPS, 2011).

There are some challenges in ensuring access to safe and effective medicines, especially in LMICs (Kohler et al., 2014). Globally, only 30 per cent of National Medicine Regulatory Agencies are capable of evaluating the efficacy and safety of medicines on the market (Ndomondo-Sigonda et al., 2017). Ghana appears to be doing well with respect to access to safe medicines. Ghana has about 30 per cent of its medicines being manufactured in the country by 30 licensed manufacturers. This makes it the second-largest pharmaceutical manufacturing country in Africa (Hampshire et al., 2022). Besides, Ghana happens to be 'the first in sub-Saharan Africa to introduce a National Health Insurance Scheme (NHIS) in 2003' with a target of extending healthcare coverage (including access to essential medicines) to all segments of the Ghanaian society (Agyepong & Adjei, 2008). Regarding the safety of medicines, Ghana's medicine regulatory system is touted as one of the most effective systems in Africa (PQM, 2016). The FDA of Ghana is the second in

Africa to attain Level 3 Maturity of WHO classifications. The level is an indication of a well-functioning stable regulatory system (WHO, 2021). No African country reached Level 4 as of July 2023.

Despite all these positive indicators, a study conducted in Ashanti, Northern and Central regions of Ghana indicates that 63.2 per cent of insured clients who visited the NHIA accredited health facilities purchased medicines out-of-pocket from the same facilities, 34.9 per cent purchased them from outside the health facilities they visited and 75 per cent paid for consultations (Akweongo et al.,2021). These indicate a refusal to render services to the patients as NHIS-insured clients, perineal medicine stock-outs in the health facilities for the clients or non-coverage of some medicines by the scheme. Also, a study in Ghana indicates that over 66 per cent of sampled antibiotics had more or less active pharmaceutical ingredients than what was embossed on the label. Such antibiotics were distributed by authorised and unauthorised medicine outlets (Bekoe et al., 2020). The relevance of medicine in healthcare delivery and the unique portrait of Ghana in Africa about its efforts to ensure access to medicines and the challenges bedevilling the country's efforts justify its choice for this study. Some studies have been conducted on pharmaceutical governance and access to quality medicines that may help in shaping pharmaceutical governance in Ghana. However, there are some gaps this study is designed to fill. The gaps are shown below.

- **Gap in the link between regulated medicine prescription behaviour and affordability of medicines**

Prescription behaviour of health professionals is noted to be influenced by the promotional activities of pharmaceutical companies or their representatives (Dabboor et al. 2021; Larkin et al. 2017; Kayi et al., 2014; Manchanda & Honka, 2005; Zipkin & Steinman, 2005 and Wazana, 2000). In the United Kingdom and Austria, doctors were found to be prescribing expensive medicines to

patients for financial returns (Goldcare et al., 2019) and when medicine prescribers at the same time served as medicine dispensers, expenditure on drugs increased between 4.5 and 33.2 per cent (Bodnar et al., 2018 and Ahammar & Zilic, 2017). Medicines that were promoted by giving material favours to health professionals were observed to have an increase in their market shares in the USA (Larkin et al. 2017). All these studies were conducted under health systems different from those in sub-Saharan Africa. Besides, those studies have not indicated whether the health seekers were able to afford the medicines. Therefore, there is a dearth of studies in sub-Saharan Africa that explain the relationship between the prescription behaviour of health professionals and the affordability of medicines. This study is designed to fill that gap.

- **Limited studies on responsive dispensing practices and rational use of medicines**

The correct use of medicines is largely determined by how it is dispensed to the health seeker (WHO, 1993). There are a lot of studies regarding the average time used by medicine dispensing personnel to explain medications to patients (Siele et al., 2022; Priyadarshani, 2021; Silva et al., 2018; Gidebo, 2016; Prasad, 2015; Chirwa, 2014; Akl, 2014; Ndukwe et al., 2013 and El Mahalli, 2012). There are also plenty of studies on medicine labelling at the dispensary to provide knowledge of the correct use of medicines (Wendie, 2021, Sisay, 2017 and Chandelkar & Rataboli, 2014). In addition, knowledge of medication dosage has received much attention in the literature (Siele et al. 2022; Sisay, 2017; Chandelkar & Rataboli, 2014; Akl et al. 2014, El Mahalli, 2012 and Awad & Al-Saffar, 2010). Despite all these, there is a dearth of studies on the waiting time at the dispensary, the organisation of the dispensary, the pattern of communication between the dispensary staff and health seekers, and the attitude of the dispensary staff towards health seekers and how they all affect the rational use of medicines. That is the gap this study was designed to fill.

- **Concentration on medicine pricing and affordability of medicines.**

A lot of studies on medicine pricing measure the affordability of medicines as a component of access to medicines (Alefan et al, 2018; Maniadakis et al. 2017; Panteli et al. 2016; Bangalee & Suleman, 2016; Bangalee & Suleman, 2019; Cassar & Suleman, 2019; Fink, et al. 2014 and Tran et al. 2020). Nonetheless, there is one study that links the availability of medicine to pricing in Ghana (Mordi et al, 2015). That study tried to explain how medicine pricing leads to a 'steady decline of availability in the system', but it does not specifically point out where the decline in availability occurs; whether at the Central Medical Store, the pharmaceutical companies or the hospitals. This study will focus on how the medicine pricing policies affect the stocking of medicines at health facilities or how the pricing affects making certain medicines available to NHIS subscribers by health facilities.

- **Lack of recent studies on the functions of regulatory bodies for safe medicines in Ghana**

Some of the major problems with access to medicines are the abundance of substandard and falsified (SF) medicines and the use of antimicrobials without prescriptions. The problem of the proliferation of substandard antibiotics keeps increasing at the medicine outlets (Baxerres & Hesran, 2011 Gullberg et al., 2011).

There have been a lot of studies on the prevalence of substandard and falsified medicines (Baxerres & Hesran, 2011; Gullberg et al., 2011; Bekoe et al., 2020; Usman et al., 2010 and Neyyar et al., 2012), prescription and distribution of antimicrobials by unauthorised persons (Yevutsey et al., 2017; Ahiabu et al., 2018 and Afari-Asiedu et al. 2018), consequences of wrong use of medicines

(Nwokike et al., 2018; Namboodiri et al., 2011; Forson et al., 2011 and Kelesidis et al., 2007) and factors responsible for the abundance of substandard medicines and unapproved distribution of antimicrobials (Afari-Asiedu et al., 2018; Mackintosha et al., 2018; Mackey & Liang, 2013 and Ahiabu et al., 2018). These studies have contributed to enriching knowledge on pharmacovigilance. However, the studies have not included how the regulatory agencies function to ensure the safety of medicines in Ghana. That is the gap this study will fill.

1.2 Objectives

The main objective of the study was to **examine how good governance of the pharmaceutical lifecycle affects access to quality medicines in Ghana**. The following objectives specifically guided the study. The study:

1. Examined the medicine prescription behaviour of health professionals in the context of prescription regulations and how it affects the affordability of medicine in Ghana.
2. Examined medicine dispensing practices in the context of responsiveness and how they affect the rational use of medicines.
3. Found out how medicine pricing in Ghana is participatory and the influence of the pricing on the availability of medicines to the subscribers of the National Health Insurance Scheme at the health facilities.
4. Examined how the medicine regulation authority ensures the safety of medicines in Ghana.

1.3 Research Questions

In a quest to realise the objective of the study, the following research question was answered: **How does good governance of the pharmaceutical lifecycle affect access to medicines in Ghana**? The following were the specific questions that guided the pursuit of the objectives:

- How does the regulated medicines prescription behaviour of health professionals affect the affordability of medicine in Ghana?
- How do responsive medicine dispensing practices affect the rational use of medicines in Ghana?
- How do the participatory medicine pricing policies in Ghana affect the availability of medicines to the subscribers of the National Health Insurance Scheme?
- How does the medicine regulation authority ensure the safety of medicines in Ghana?

1.4 Outline of the Thesis

The thesis is organised into nine chapters. Chapter One explains the rationale for this study. It explains the relevance of medicine in the functioning of a health system for the realisation of UHC. The relevance of governance of governance in enhancing access to essential medicines is also explained in this chapter. The chapter also indicates the existing literature gap in the field of study and came up with research objectives and research questions which guided the study leading to contributions in the literature that cover the literature gap.

Chapter two constitutes a review of the literature on health systems and the relevance of medicines in health systems. The literature reviewed encompasses modern health systems and the idea of essential medicines. It also includes complementary and alternative medical systems which are made of various types of treatments and the kind of medicines used in the treatment process—also,

pharmacovigilance measures on complementary and alternative medicine. The chapter also contains an overview of the Ghana Medical System and the pharmaceutical sector. It explains the structure of the Ghana Medical System and the pharmaceutical industry in Ghana. It further explains the sources of medicines in Ghana, and how medicines are stored and distributed in Ghana.

Chapter Three is the empirical review of the literature in line with the objectives of this study. The literature reviewed elucidates how pharmaceutical pricing affects access to medicines, the influence of medicine advertising on the prescription behaviour of health professionals and how the prescription behaviour affects the cost of medicines. It also contains how medicine dispensary is done to ensure rational use of medicines and finally, the pharmacovigilance measures and quality of medicines. Chapter Four expounds on the concepts of governance, good governance and the concepts of access. It also explains the institutional theory which is the theoretical framework for this study. It goes further to explain the relevance of the theory to this study. It finally presents the conceptual framework which explains this study.

Chapter Five is the research methodology for this study. It explains various philosophical stands in research and ultimately justifies why pragmatism is the suitable research paradigm for this study. It gives further explanation of the method that was used to conduct this study and how the data was analysed. Chapter Six is the presentation of the qualitative data generated by this study. The data is presented in line with the objectives of this study. It points out the relationships that exist between the dependent and the independent variables. Chapter Seven presents the quantitative data and the findings of the document review.

Chapter Eight constitutes a discussion of the findings. The discussion synchronises the import of the quantitative and the qualitative findings and the findings from the document review. It relates

the findings to the previous studies and points out how this study fills the prevailing literature gaps. Chapter Nine presents the conclusion and recommendations of the study. It points out the contributions the study has made in policy formulation and the academic arena.

1.5 Summary of the Chapter

Medicine is one of the important aspects of health technology that enhances the functioning of a health system. WHO has always been functioning to achieve UHC with access to medicine as a bedrock to that goal. The discovery of penicillin for the treatment of sepsis, chloroquine for the treatment of malaria and antiretroviral drugs for boosting the immune system of HIV/AIDS patients exemplifies the relevance of medicines in prolonging life and enhancing well-being of the humans. There are studies indicating that the absence of medicines in health facilities leads to medical errors and even creates distrust in healthcare professionals by patients which adversely affects patients' care. However, access to medicines appears to be a mirage, especially to the vulnerable and the socially excluded who need the medicine most. The prevailing scarcity of medicines can be attributed to problems of governance in the pharmaceutical sector. There is evidence pointing out that, what is been touted regarding the need for ATM leading to UHC at the global level is not reflected in countries' policy formulations and implementations. This calls for a need for studies at various country levels to inform policy formulations that synchronise what is being advocated for at the global level and what is implemented in various countries.

Ghana seems to have made a lot of advances towards the achievement of UHC before it even became a Sustainable Development Goal (SDG) at the global level. A social health insurance scheme was introduced to extend healthcare to every segment of Ghanaian society. Food and Drugs Authority also made a lot of advancements and gained global recognition. These advancements are expected to be reflected in access to quality medicines in Ghana. Unexpectedly,

there are problems related to access to medicines under the health insurance scheme and there is a proliferation of SF medicines in Ghana. There are a lot of studies that give so much knowledge on pharmaceutical governance, however, there are gaps in those studies that will not permit policy formulations to be based on them to deal with the problem of access to medicines. This calls for a study to find out how pharmaceutical governance affects access to medicines in Ghana.

CHAPTER TWO

GOVERNANCE, HEALTH SYSTEMS AND MEDICINES: A BACKGROUND ANALYSIS

2.0 Introduction

This chapter comprises a literature review of the governance of health systems and the role of medicines within the health systems. As a result of a plurality of health systems, the literature reviewed encompasses modern health systems and the idea of essential medicines. It also includes complementary and alternative health systems which are made of various types of treatments and the kind of medicines used in the treatment process. Also, pharmacovigilance measures on complementary and alternative medicine have been discussed in this chapter. The chapter then narrows down to the governance of the medical systems in Ghana. The essence of this chapter is to provide a broader and specific context of pharmaceutical governance within a health system governance.

2.1 Health Systems

A health system comprises people, resources institutions and organisations with the prime aim of improving health. The specific targets are the determinants of health as well as activities of health improvement itself. The actors in a health system are both state and non-state actors. They steer the affairs of a health system to deliver preventive, promotive, curative as well as rehabilitative services. These services are done through public health intervention and a hierarchy of healthcare facilities (World Health Organisation [WHO], 2010).

There are six key components of a health system that must functionally link to each other to ensure health system performance. Those components are named by WHO as health system "building

blocks". The components are leadership/governance, health workforce, service delivery, access to essential medicines, financing, and health information systems. Even though the components of a health system have different ways they contribute to the strengthening of a health system, their robustness must not be mutually exclusive (WHO, 2010). Valesco et al. (2011) and Marmor and Wendt (2012) explicitly named policy in their explanation of a health system at the macro-level. They view health system and policy components as matters about financing model, organizational structure, physical and human resources, and the regulation and planning of the system. Health systems are mostly not limited by geographical boundaries (Pennings et al, 1999).

Health system is also expounded from the premise of system theory which regards a system as a string of inputs, processes and outputs. In this view, the health system is viewed as a sum of the necessary resources which include the human, financial, material and mechanical which are used in formal and informal organisations to provide the needed health of any form to individuals and the society at large (Zakus, 2009). In the same view of system theory, the health system can either be opened to its external environment by being influenced and influencing other health systems or remain self-contained without any influence (Zakus, 2009). However, WHO (2000) advocates the openness of health systems to all who aim at facilitating health and making health systems responsive to the destitute.

The year 2000 Health Report specified the objectives for health systems: health improvement of the population within its jurisdiction; being responsive to the people's needs; and provision of the means to absorb the financial shocks of the sick (WHO, 2000). Healthcare provision may not be mainly done by only the formal healthcare system, however, it has manifold functions that enhance the objectives of general healthcare delivery (Mills, 2002).

The health systems of the developed countries were built within the context of economic stability, robust taxation systems, a non-erratic pace of social change and adequately trained health personnel in numbers to run the health institutions. The situation under which the industrialised countries constructed their health institutions was not the same in the developing countries (Bloom, 2004). The inability of LMICs to expand healthcare coverage to their wider population led to the emergence of other health service providers to meet the healthcare needs of the populace. This brought about plurality in health services provision, the kind that nearly blur the distinction between private and public sectors in the LMIC (Bloom, 2004).

2.2 The Idea of Essential Medicines

The concepts of medicine and medicinal products are synonyms (Aronson & Ferner, 2005). 'A medicinal product is a substance that contains a biologically active compound, as well as excipients, or solely excipients. It may also include impurities. The active compound is typically a drug or prodrug, but could also be a cellular component. Medicinal products are designed for human or animal use, to treat diseases and improve symptoms, among others (Aronson & Ferner, 2005). It can be inferred from the purpose of a medicinal product that, what can be described as medicine could be a synthetic or natural compound. It may be from this angle that medical pluralism is practised in many countries.

However, WHO (1977) came up with an idea of essential medicines that would meet the requirements of various health systems for effective healthcare delivery. Access to essential medicines later became one of the building blocks of health systems. WHO (2010) explained the component of Access to Essential Medicines as a building block of the health system as follows:

- "A medical products regulatory system for marketing authorisation and safety monitoring, supported by relevant legislation, enforcement

mechanisms, an inspectorate and access to a medical products quality control laboratory.

- National lists of essential medical products, national diagnostic and treatment protocols, and standardised equipment per level of care, to guide procurement, reimbursement and training.
- A supply and distribution system to ensure universal access to essential medical products and health technologies through public and private channels, with a focus on the poor and disadvantaged.
- A national medical products availability and price monitoring system.
- A national programme to promote rational prescribing".

Even though health system performance is measured by the performance of the health system building blocks, access to essential quality medicines, vaccines, diagnostics, and other health technologies is regarded as the cradle of universal health coverage (WHO, 2010). Undoubtedly, access to medicines is viewed as an aspect of the right to health (Gover & Citro, 2011). A well-functioning health system is expected to be always stuffed with essential medicine to ensure healthcare delivery equity (WHO, 2013). This implies that the essential medicines are not underdog medicines for the impoverished, they are quality, cost-effective medicines carefully selected based on the health needs of the population.

The Executive Board of WHO (2002) defined Essential Medicines as the medicine that meets the required healthcare needs of the target population. That medicine must always be available in the right amounts and their suitable dosage forms, it must have the right quality and it must be affordable to individuals and the entire community. The foundation of the idea of Essential Medicine by the Executive Board of WHO was earlier laid in 1977 by WHO in the first model list of essential medicine. It was regarded as medicine of "utmost importance, basic, indispensable,

and necessary for the healthcare needs of the population" (WHO, 1977). This definition led to the subsequent classification of access to essential medicine as a requirement for primary health care in the Alma Ata Declaration of 1978. The concept of Essential Medicine was intensified in the international policy agenda when public health advocates guarded the pharmaceutical industry to accept it (Ralyn, 2010).

2.3 Traditional and Complementary Medicines

As a result of the challenges faced by many countries with respect to access to essential medicines, WHO (2013) developed Traditional and Complementary (T&CM) medicine strategies to be implemented from 2014 to 2023. The strategy has the following objectives: 'development of a policy of integrating traditional medicine into the national health systems where possible; ensuring safety, efficacy and quality of traditional medicines; enhancing the affordability and availability of traditional medicine and ensuring rational use of traditional medicine'. Among others, the strategy document wants member states to facilitate UHC through the integration of T&CM in their health systems. Therefore, T&CM is now part of the health systems of many countries including Ghana. The medicines from this health system are equally subject to the regulatory processes just like biomedical medicines.

Traditional and Complementary Medicine (T&CM) is regarded as a traditional and non-conventional group of therapies. It can be used alone or used to support other therapies to treat and prevent diseases (Kayne, 2009). It is also called Complementary and Alternative Medicines (CAM). However, there has been some scepticism from the orthodox medicine community regarding the scientific basis of T&CM. Those who only insist on orthodox medicine reiterate that most T&CM has not emerged from any randomised clinical trials. The aspects of T&CM that went

through such trials have defective methodologies and their conclusions cannot be reliable (Chaplin, 2007 and Schmolz, 2000).

Despite the scepticism, the relevance of T&CM keeps sinking in the health systems of developed and developing countries. A distinction has been made between T&CM which uses medicines and other products and the one that only uses procedures and interventions which are called complementary and alternative therapies (Kayne, 2009).

According to the WHO (2003), traditional medicine is a vast field that comprises diverse health practices, knowledge systems, beliefs, and therapeutic strategies. These practices commonly involve the use of natural resources, including plant, animal, and mineral-based medicines, along with manual techniques, spiritual modalities, and physical exercises. The application of traditional medicine can be either standalone or in combination to prevent, diagnose, treat or maintain overall health and well-being.

Modern biomedicine which is based on germ theory succeeded in eroding a lot of contextual traditional medical practices. The traditional healing systems that survived such erosion are traditional Chinese medicine and the therapies associated with it, the Indian traditional healing system and the African traditional medicine. However, African traditional medicine differs from that of Chinese and Indian systems. African traditional medicine has no written records, it is based on oral tradition whilst that of the two Asian systems have documented philosophies and pharmacopoeias (Kayne, 2010).

The traditional healing that is organised enough to be accepted in the prevailing health systems is what is called complementary and alternative medicine (McCracken & Phillips, 2017b). The Traditional medicine sector is made up of herbalists, divine healers/spiritualists, bone setters and

traditional birth attendants (McCracken & Phillips, 2017a; Twumasi, 1988 and Sato, 2012). Traditional medicine practitioners consider health from human and social, as well as natural and supernatural perspectives (Twumasi, 1988). Due to their extensive experience in indigenous medical practice, some people view traditional healers as professionals (Amegor, 2017).

The traditional medicine sector may be composed of different healers who may be secular, sacred or a combination of both (Buor, 2004). There may be a lot of non-professional healers in the traditional medicine sector in developing countries who may specialise in dealing with certain problems (Kleinman, 1980). Some studies classify traditional healers into two: those who deal with the ailments physically; traditional birth attendants, herbalists and bone setters. The other class is made of those who invoke supernatural powers in their practice such as fetish priests and faith healers ("Mallams" and Pastors) (Sorsdahl et al., 2013). Traditional medicine practitioners in South Africa are grouped into herbalists, diviners and faith healers. The faith healers may have a hybrid form of practice which is a combination of Christian rituals and traditional practices (Peltzer & Mngqundaniso, 2008 and Freeman & Motsei, 1992). Twumasi (1978) and Truter (2007) also classify traditional medicine practitioners into diviners, faith healers, herbalists and traditional birth attendants. Nonetheless, the functions of the categories of traditional medicine practitioners overlap. However, in some cultural contexts, there is no clear distinction between herbalists and spiritualists (Twumasi, 1988). The role of diviners and fetish priests in the treatment process is to diagnose ailments and point out the possible sources of cure. Whilst diviners do that by consulting the oracles or interpreting the messages of the ancestors, fetish priests do it by consulting the deities (Gyasi, 2015 and Tabi et al., 2006).

The investigation of traditional medicine and its production is a significant contribution to the sociocultural analysis of various medical systems (Kleinman, 1978; Nichter, 2008). Medicinal

practices intersect with a wide range of human concerns, including material, social, political, and emotional considerations (Broom and Doron, 2014). Additionally, they serve diverse functions across numerous social and political levels, such as international policies and funding, national politics, and acting as agents of ideology and identity construction (Biehl and Petryna, 2013). Ultimately, these practices have a profound effect on the lives of individual patients, transforming sickness into well-being during healthcare consultations (Kleinman, 1995). The act of purchasing medicine for a loved one can convey a message of compassion and concern (Nichter, 2010). In a religious context, medicinal practices may be regarded as gifts from divine leaders to those who are suffering (Cant and Sharma, 2016).

Besides traditional treatment systems, there is a self-treatment which may include self-medication where advice may be sought from traditional healers and medicine vendors or lay persons like family members, friends, and neighbours who may have previous experience with an ailment (Gyasi, 2015 and Buor, 2004).

The aspect of traditional medicine that solely uses herbs is called medical herbalism. The utilization of herbal products is a common practice in the field of medical herbalism, which aims to alleviate or cure a diverse range of health conditions and ailments. These products, derived from natural plant sources, are often preferred by those seeking a more holistic approach to healthcare (Norfolk, 1999). The practice of medical herbalism involves utilizing products made from herbs to treat various illnesses. Plant-based materials or products containing raw or processed ingredients from one or more plants may provide therapeutic or other health benefits. Some traditional practices may also include inorganic or animal-derived materials (WHO, 1998).

Mills & Bone (1999) explained that herbalists have traditionally taken a holistic approach to treating specific conditions, considering each patient's unique needs. This approach consists of four stages:

1. Eliminate toxins and other harmful substances from the body with diuretics, expectorants, and laxatives.

2. Warming the body with hot spices and other warming medicines to improve circulation, as a disease was traditionally viewed as a "cold" influence on the body.

3. Treating fevers and inflammatory conditions with "cooling medicines" that aid in digestion. This includes anti-inflammatories, antiallergics, and sedatives.

4. Supporting the body's recuperation with tonics such as hawthorn, milk thistle, and St. John's Wort, which help nourish and repair the body after illness.

It's important to note that hot, spicy foods can also help guard against enteric infections in tropical regions. By individualizing treatment and adhering to these stages, herbalists strive to provide the most effective care possible for their patients (Mill & Bone, 1999).

The utilization of herbal source material has been a long-standing practice in the field of medicine, especially in traditional medicine practices (Foster et al., 2002). The extensive history of using herbs for various ailments has shown not only their effectiveness but also their safety for human consumption (Kapoor, 2017). With modern technology, scientists have been able to isolate and extract numerous active compounds found within these herbal sources, which have contributed to the development of modern drugs (Newman and Cragg, 2012). The abundance of plant material available proves to be particularly advantageous for developing countries, where access to expensive pharmaceutical drugs may be limited (WHO, 2002). Additionally, the use of traditional

herbal remedies can also provide cost-effective and natural alternatives for treating common ailments (Saha et al., 2014). Overall, the utilization of herbal sources in modern medicine presents an opportunity for combining traditional knowledge with modern science to improve healthcare outcomes for individuals worldwide (Kamatenesi-Mugisha and Oryem-Origa, 2005).

However, research in the field of clinical pharmacokinetics, pharmacodynamics, and toxicology of herbal medicines reveals that the evaluation process of the safety of herbal medicines can be complex due to the intricate and varied chemical composition of these medicines (Liu et al., 2016). Additionally, identifying the exact ingredient(s) responsible for safety concerns in combined herbal medicines can be quite challenging (Leonti et al., 2010). This is further compounded by the fact that many herbal medicines lack comprehensive documentation of their chemical composition, which can cast doubt on their safety (Bent, Ko, & Shin, 2017). Even for those herbal medicines with established phytochemistry, it can be demanding to pinpoint which specific constituents are accountable for the pharmacological activity, including any adverse effects (Sticher, 2008).

2.4. Pharmacovigilance Practices for Complementary and Alternative Medicines

Pharmacovigilance is a critical scientific discipline that encompasses a broad range of activities to identify, evaluate, comprehend, and mitigate any negative effects or other drug-related concerns (Bate et al., 1998). This comprehensive approach is designed to ensure pharmaceutical products' safety and efficacy and safeguard the health and well-being of patients and consumers alike (Kaplan & Haines, 2015). Whether through proactive monitoring, rigorous testing, or ongoing research and development, pharmacovigilance plays a vital role in helping to prevent and manage any adverse events or other potential risks associated with the use of medications and other therapeutic agents (Edwards & Aronson, 2000).

The practice of pharmacovigilance is of utmost importance, especially in the context of complementary and alternative medicines that can be procured without a prescription (Gavura, 2019). Such medicines are often recommended by close acquaintances or based on information obtained from media sources, rather than through consultation with healthcare professionals. Additionally, some users may refrain from disclosing their use of such medicines to healthcare professionals, and even when patients report possible adverse drug reactions related to traditional medicines, healthcare professionals may not routinely inquire or record such information on patient records (World Health Organization, 2002). This highlights the need for greater vigilance and awareness in the use of alternative medicines, and the importance of open and honest communication between patients and healthcare professionals.

Healthcare experts aver that patients should prioritize their safety by informing their healthcare providers of any complementary medicines they are currently taking, as well as any conventional medicines they may be starting or discontinuing (Cohen, 2019). Similarly, individuals seeking guidance from complementary medicine practitioners should make it a point to disclose their use of conventional medicines, as this can help prevent potential interactions between herbs and drugs, which can pose a significant risk to one's health (National Center for Complementary and Integrative Health, 2021). Maintaining open communication with one's healthcare team is key to promoting and maintaining overall well-being (Cohen, 2019).

2.5 The Medical System of Ghana and the Pharmaceutical Sector

The health system of Ghana has the task of equitably meeting the health needs of the various categories of people in Ghanaian society. Specifically, attention is needed for the poor and the uneducated who may be experiencing certain illnesses because of their economic and social status (Ghana Health Service [GHS], 2021). The challenge of dealing with such problems is compounded

by the growing population, erratic health system financing and the increasing burden of systemic diseases on the health system in addition to the prevailing communicable diseases (WHO, 2018). Succinctly, the health system of Ghana has a heavy burden to ensure the realisation of Universal Health Coverage in the country. This section is an overview of Ghana's medical system and the pharmaceutical sector.

2.6 Healthcare Delivery in Ghana

In the history of Ghana's healthcare delivery, the main healthcare provider was the Ministry of Health (MOH). It was supported by faith-based institutions and the quasi-state institutions' health facilities. The orientation of the health system then was more curative than preventive. The donor community was, largely, the determiner of healthcare programs in Ghana (MOH, 1989). To meet the health sector targets of Vision 2020 which was then a development strategy of Ghana in 1996, MOH also came up with a Medium-Term Health Strategy (MTHS) and a program to implement that strategy within five years, that is from 1997 to 2001. The program was to ensure access to efficient quality health care and foster relationships with the relevant stakeholders for better resource mobilisation.

A well-functioning health system improves the health of various communities and the individuals within the communities. It prevents society from everything that threatens their health. The system does not allow people to experience financial shocks when they seek health care. In addition, the system is responsive and makes the required health needs of the population accessible to them. To make Ghana's healthcare system robust enough to meet the health needs of Ghanaians, "the 1992 Constitution of the Republic of Ghana (Chapter 14) provided for the establishment of the Ghana Health Service (GHS) as part of the Public Services of Ghana. In 1996, Parliament passed the Ghana Health Service and Teaching Hospitals Act 1996, Act 525, to pave the way for establishing

GHS" (Government of Ghana [GoG], 1996). Subsequently, several legislations came up to establish and strengthen various regulatory bodies to facilitate the standardisation of healthcare delivery in Ghana. MOH remains the fulcrum of Ghana's health system and has been mandated to perform its current functions by Act 525. The launching of GHS was done in 2003 and has since been operating under the supervision of MOH. An overview of various components of Ghana's health system is presented below.

2.6.1 Leadership and Governance of Ghana Health System

The legitimacy of MOH and other ministries in Ghana rests on the Civil Service Act (PNDCL 327) and Act 525. The governance structure of Ghana's health system has MOH at the apex (MOH, 2022). The Ministry has several divisions that work together to formulate policies, mobilise and allocate resources, monitor and evaluate the health sector performance, train health personnel, regulate the health sector and engage in health research. The Ministry is in charge of overall leadership in the health sector. It synchronises the operationalisation of the Development Plans in the health sector for achievements of the sector agenda (MOH, 2022). The regulatory function of the Ministry is delegated to 12 agencies, boards and authorities under the Ministry. They include the Food and Drugs Authority, the National Health Insurance Authority, the Pharmacy Council, Traditional Medicine Practice Council among others. The regulatory bodies under the institutions of the Ministry ensure professional standards and quality of health products among others in the country (MOH, 2022).

The Ministry is headed by a Minister who is supported by directors of various divisions of the Ministry to perform his/her functions. The Director General heads GHS at the national level and the Chief Executives head the Teaching Hospitals. There is a health management team at the regional level headed by the regional directors of health. Similar teams are replicated at all the

district and sub-district levels headed by the district health directors. Whilst policies and strategies are formulated at the national level, translation of those policies is done at the regional level to meet the specific regional health needs of the people. Implementation of the policies and strategies is done at the district and sub-district levels to provide Primary Health Care (PHC) to the people (MOH, 2022).

2.6.2. Service Provision

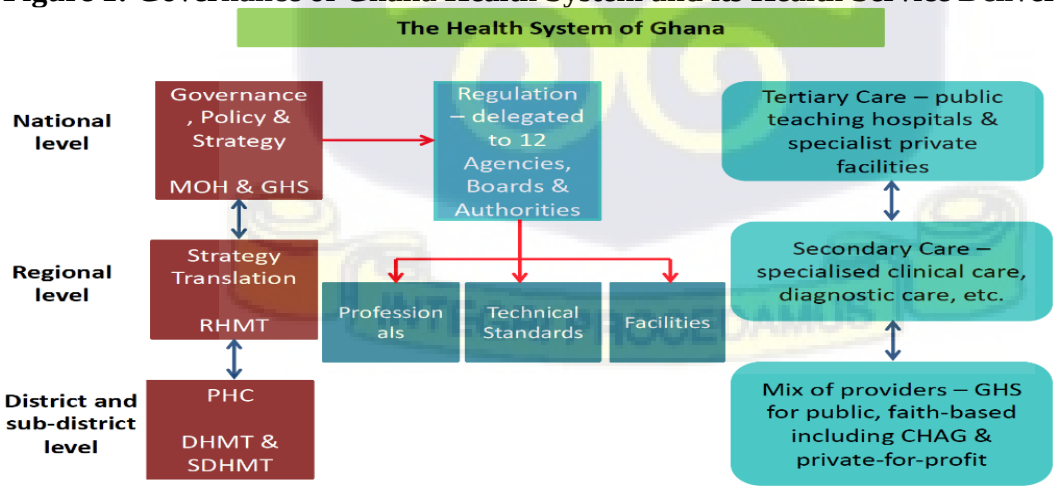
In Ghana, the health system is organised into three tiers consisting of district, regional, and teaching hospital levels, with various entities responsible for providing essential health services to the population. These entities include the GHS, quaternary and tertiary hospitals, profit-oriented private healthcare facilities, mission facilities, and traditional healers (GHS, 2019). The foundation of primary health care (PHC) in Ghana is at the district level which is organised into community-based health planning and services (CHPS) compound at the community level. There are also health centres that deliver PHC services at the sub-district level and district hospitals that render health services at the district level. The interconnection between the CHPS compounds, health centres, maternity homes and district hospitals provides PHC services (GHS, 2019). The goal is to provide essential health services to every community and bridge the access inequity gap by 2030. To achieve this goal, there are strategies designed to ensure the provision of basic services at the CHPS level. Those services include reproductive health services, management of minor ailments, education of people on health issues, issues of personal and environmental hygiene, and other public health services which include nutrition and a healthy lifestyle (Ghana Health Service, 2019).

At the regional level, regional hospitals render clinical health services and function as facilities for the referral of cases from the lower level. There is also provision of public health services at the regional level. The highest level of health services provision has six teaching hospitals, four

university hospitals, and four psychiatric hospitals. These hospitals provide tertiary and specialised care and are also used to train health professionals, and function as referral facilities to the cases from the lower level in the country (Ghana Health Service, 2019).

The health service provision by the state is complemented by the private sector and civil society organisations (CSOs). The services of the private sector are conglomerated in the urban and peri-urban areas. Almost 19 per cent of outpatient department (OPD) services are rendered by the private sector (Ghana Health Service, 2019). Mission health facilities made of Christian and Muslim hospitals and clinics are 302 which also function to complement the government efforts in healthcare delivery. The CSOs make a lot of contributions in ensuring access to service delivery to the deprived and hard-to-reach communities (Ghana Health Service, 2019). Overall, the health system in Ghana is a collaborative effort between various stakeholders, including the government, private sector, and CSOs, to ensure that essential health services are accessible to every community for the attainment of UHC by 2030. It is designed to be responsive to the needs of its population, with a focus on ensuring equitable access to quality healthcare services (WHO, 2018). Figure two below shows the governance and health service delivery structure of Ghana's health system.

Figure 1: Governance of Ghana Health System and its Health Service Delivery Structure



Source: Health Sector Medium Term Development Plan 2022-2025.

Key:
MOH = Ministry of Health
GHS = Ghana Health Service
RHMT = Regional Health Management Team
PHC = Primary Health Care
DHMT = District Health Management Team
SDHMT = Sub-District Health Management Team
CHAG = Christians Health Association of Ghana

2.6.3. Human Resources

One of the components of a health system that facilitates the attainment of Sustainable Development Goal 3 is the extent to which healthcare professionals are available and evenly distributed across the country. This enhances healthcare delivery to achieve better maternal and child health outcomes. According to the 2021 health sector assessment report, there has been consistent improvement in the training and circulation of healthcare professionals from 2018-2021 in the country (GHS, 2021).

The MOH completed the design of a human resource policy and strategy in 2020. Financial clearance was obtained to employ 58,191 health professionals. The human resource policy and strategy document focused on attracting and retaining healthcare professionals in the areas deprived of healthcare personnel. This was targeted at achieving an even distribution of health sector human resources for better healthcare delivery in the country (MOH, 2020).

There has been an improvement in the doctor-to-population ratio from 1:6899 to 1:4,000 from 2019 to 2022. The ratio of nurse-to-population also improved from 1:727 to 1:600 from 2019 to 2022 (MOH, 2022). The WHO standard of 1 nurse to 1000 population ratio has been exceeded by Ghana. However, the ratio of doctors to the population is below the WHO recommendation of 1 doctor to 10,000 people (GHS, 2021). Besides the improvement in the number of general nurses, there has also been an improvement in midwives attending to women of fertility age ratio of 1:720

to 1:387 (Ghana Health Service, 2021). Ghana still faces the challenge of equal workforce distribution. There is a concentration of doctors in the urban areas than the less urbanised areas. Nonetheless, the distribution of nurses and midwives is relatively better (Ghana Health Service, 2021).

A lot of successes have also been attained in the quest to increase the number of specialists in the health sector to improve healthcare delivery. Ghana College of Nurses and Midwives mounted 22 programs in various specialities. As of 2022, the college successfully admitted 643 trainees into those programs. There has also been a decentralization effort to facilitate the training of specialists across the country. As a result, the Ghana College of Physicians and Surgeons agreed with the Ghana Health Service and some private facilities for accreditation for postgraduate training. Besides, Tamale Teaching Hospital also received accreditation from the West African College of Physicians and Surgeons as one of the post-graduate training centres in Ghana.

2.6.4. Health Infrastructure

Investing in health infrastructure is crucial for the development of a comprehensive healthcare system that caters for the needs of the population (World Health Organization, 2020). It is also an essential step towards achieving UHC Goal 3 (United Nations, 2020). As of December 2020, Ghana had a total of 8,825 health facilities. This number is made up of 7,137 public facilities, 280 mission facilities, 1,331 private for-profit facilities, and 79 quasi-government institution facilities (Ghana Health Service, 2020). All these healthcare facilities are classified according to their level of healthcare delivery. There are quaternary and teaching hospitals. There are also regional hospitals which serve as secondary referral hospitals and the are district hospitals which serve as primary referral hospitals. There are also polyclinics, health centres, CHPS, and maternity homes and clinics (Ghana Health Service, 2020). However, despite the impressive number of healthcare

facilities in Ghana, there is still a significant shortage of health infrastructure, including facilities, logistics, and equipment (World Health Organization, 2020).

Generally, it is critical to focus on improving healthcare infrastructure to provide quality care that meets the needs of the population. Additionally, conducting a Service Availability and Readiness Assessment (SARA) will help to identify the gaps and improve service delivery (World Health Organization, 2020). In conclusion, investing in healthcare infrastructure is a necessary step towards achieving a comprehensive healthcare system that caters to the needs of the population and ensures a healthy and prosperous future for the nation.

2.6.5. Health Financing

There are multiple sources of funds the health sector of Ghana relies on. They are the central government funds, the National Health Insurance Scheme, internally generated funds (IGF) obtained from out-of-pocket payment for health services rendered by public healthcare facilities and donor funding (MOH, 2021).

However, the budgetary allocation from the central government dwindled from 12 per cent to 6 per cent from 2012 to 2018. Similarly, donor funding was reduced from 25 per cent to 12 per cent from 2015 to 2018. The funding that emerges to be sustainable is the National Health Insurance Levy of 2.5 per cent of Value Added Tax of which almost 80 per cent is released to the NHIS to serve its main purpose. A larger part of government expenditure on health service delivery is on primary health care (MOH, 2021). Table 2 below shows the budget approval and expenditure patterns between 2020 and 2022.

Table 1: Approved Budget Against Actual Expenditure Trends 2020 - 2022 in GH₵ million

Source of Funds	2020		2021		2022	
	Approved Budget (a)	Actual Expenditure	Approved Budget (b)	Actual Expenditure	Approved Budget (c)	Actual Expenditure @ Sept
GoG	5,870.88	5,405.95	5,291.74	7,661.09	6,461.02	5,454.11
IGF	1,931.08	1,063.91	2,328.14	2,016.73	2,948.13	1,049.44
ABFA	57.40	41.61	32.43	10.59	32.42	0.87
Donor	992.97	859.62	881.29	1,137.22	1,304.22	4.25
Total	**8,852.33**	**7,371.09**	**8,533.59**	**10,825.62**	**10,745.79**	**6,508.67**

Source: Ghana Medium Term Expenditure Framework for 2023-2026

Table 2 above provides a comprehensive overview of the approved budget and actual expenditure trends for the years 2020 to 2022. The columns (a, b and c) represent the annual approved budget for each respective year. The health sector saw a nominal decrease of 4% in the approved budget between 2020 and 2021. However, between 2021 and 2022, there was an 18% increase, primarily due to a 47% increase in donor support. The Government of Ghana (GoG) continues to be the primary financier of the sector, representing 66%, 62%, and 59% of the total approved budgets. The internally generated funds (IGF) approved budget constituted 22%, 27%, and 28%, making it the second-largest source of funds. Donor funding makes up 11%, 10%, and 13% of the approved budgets, respectively. ABFA, which is primarily for capital investment, takes up the smallest share of the total approved budget, representing 0.87%, 0.38%, and 0.28% for the years 2020, 2021, and 2022, respectively (MOH, 2022).

In terms of expenditure, 2020 and 2021 each represents twelve months of expenditure, while 2022 represents only nine months. Budget execution for 2020 and 2021 were 83.27% and 126.86%, respectively, indicating that in 2021, the Ministry overspent its approved budget by 26.86%. However, as of September 2022, the Ministry had spent 60.57% of its approved budget (MOH, 2022). Table 2 below shows 2022 Actual Expenditure by Economic Classification as of September.

Table 2: 2022 Actual Expenditure by Economic Classification as of September in GH₵

Economic Classification	Approved Budget	Actual Expenditure	Execution
Compensation	6,573,021,000	5,572,072,564.00	84.83%
Goods & Service	2,428,116,116	712,888,832.00	31.54%
Capex	1,712,232,600	231,071,044.00	14.01%
Total	10,745,793,716	6,516,032,440.00	62.19%

Source: Ghana Medium Term Expenditure Framework for 2023-2026

Table 2 presents details of the budget execution of the MOH according to economic items, as of September 2022. The Ministry spent 62.19% of the total budget. A closer examination of the expenditure breakdown reveals that compensation expenses make up the largest portion at 84.83%. Goods and services come in second at 31.54%, with capital expenditure trailing at 14.01%. (MOH, 2022).

2.7. Ghana's Pharmaceutical Sector

The pharmaceutical industry of Ghana has been in existence for more than five decades. For instance, Aryton Drug Manufacturing, which is one of the largest manufacturers, was established in 1969 in Ghana. As of 2016, there were 38 pharmaceutical manufacturing units in Ghana, 20 of which were involved in the manufacture of formulations (United Nations Development Program [UNDP], (2016). The domestic pharmaceutical manufacturing companies manufacture only 30 per cent of the pharmaceutical needs of Ghana, the rest are imported. There have been a lot of obstacles that obstruct the efforts of Ghanaian pharmaceutical companies in their quest to increase production. The production cost is said to be high and the state-of-the-art facilities to comply with the WHO standards are also absent.

Ghana has an ambition of being the centre of pharmaceutical investment in West Africa. To realise this ambition, several measures have been put in place to support the growth of the pharmaceutical industry in Ghana. The government of Ghana supported six pharmaceutical manufacturing

companies with US$27 million in 2016 (High Commission of India, 2020) to facilitate their production and increase their market share. The Ghana Export-Import Bank (GEXIM), in line with the government's One District, One Factory (1D1F) policy, has already committed US$60 million to support nine pharmaceutical manufacturing companies in Ghana since 2017. There was promulgation of Value Added Tax (Exemption of Active Ingredients, Selected Inputs and Selected Drugs or Pharmaceuticals) (Amendment) Regulation 2017 (L.I. 2255). This amendment intended to reduce the cost of medicines, most of which are paid for by the National Health Insurance Authority (NHIA) (Parliament of Ghana, 2017). Coupled with these measures, the Ministry of Trade and the Ministry of Foreign Affairs were strategizing to eliminate trade barriers to pave the way for the efficient promotion of pharmaceutical products in the Economic Community of West African States (ECOWAS). In addition, the Ministry of Health started developing a framework to ensure the procurement of more locally manufactured medicines provided the companies meet the required WHO manufacturing standards. Table 3 below shows a sample of pharmaceutical manufacturers in Ghana and their products.

Table 3: Key products manufactured by local firms in Ghana

Company	Key products Manufacture
Ernest Chemist	'Antibiotics, antimalarials, anthelmintics, antihistamines, analgesics, diuretics, antidiabetics, gastrointestinal medicines, vitamins and supplements, cold and cough preparations'
Kinapharma	'Antihypertensives, hypolipidaemic agents, antibiotics, antimalarials, antihistamines, analgesics, vitamins and supplements, cold and flu preparations'
Phyto-Riker	'Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, psychotherapeutics'
Ayrton Drug Manufacturing	'Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, vitamins and supplements, cold and flu preparations'
Kama	'Antibiotics, antimalarials'

Source: UNDP (2016)

The estimation of the size of the pharmaceutical formulations market in Ghana as of 2012 was US$ 329 million. The pharmaceutical market in Ghana was said to be largely a retail market. A major part of the pharmaceutical purchase in Ghana has been out-of-pocket, followed by the reimbursement by the NHIS and those procured publicly by the government and the donor community. However, the purchase by the NHIS has subsequently increased (UNDP, 2016).

In 2019, pharmaceutical imports were estimated at USD 263 million and are projected to increase to USD 312 million by 2024 which indicates a CAGR of 3.5%. This growth in pharmaceutical imports is mainly driven by access to low-cost generic drugs from India and the European Union pharmaceutical markets. The construction of new hospitals in Ghana will certainly ensure geographical proximity to health facilities by many communities. This is likely to boost demand for both imported and locally produced drugs. The government may be able to meet the increase when the fortunes of Ghana's economy turn around. Table 4 below shows the ten top sources of Ghana pharmaceutical imports and their values from 2016 to 2018.

Table 4: Top Ten Importing Partners of Ghana (US$ Million)

Rank	**Country**	**2016**	**2017**	**2018**	**Share%**
1	India	136.37	195.84	87.79	32.09
2	France, Monaco	9.96	18.15	70.98	25.95
3	Belgium	16.23	26.49	24.19	8.84
4	Switzerland, Liechtenstein	13.53	24.20	17.90	6.54
5	United Kingdom	9.52	18.09	12.31	4.50
6	Germany	6.88	12.69	10.05	3.67
7	Denmark	23.59	28.86	6.65	2.43
8	Italy	0.89	1.30	6.42	2.35
9	China	7.59	12.59	5.82	2.13
10	Slovenia	7.81	12.79	5.67	2.07
	World	**274.853259**	**432.830796**	**273.57**	**100**

Source: Pharmaceuticals Export Promotion Council of India (2020)

Table 4 above shows that, India is the leading source of pharmaceutical imports in the country with about 32 per cent of Ghana's pharmaceutical imports. However, Ghana had a net reduction of US$108.05 million in import value from India between 2017 and 2018. The imports value from France experienced a net increase of about US$52.83 million. Generally, there was a reduction in the amount spent on pharmaceutical imports by Ghana from 2016 to 2018.

Exports from Ghana's pharmaceutical industry are expected to increase from USD 3.8 million in 2019 to USD 5.8 million by 2024, with a faster growth rate than imports over the same period. The competitive landscape of Ghana's pharmaceutical market is currently dominated by local firms and Indian companies, but drug manufacturers from other countries are gradually entering the market.

The sales of pharmaceuticals in Ghana in 2019 were US$589 million. The sales value was estimated to reach a compound annual growth rate (CAGR) of 9.8% which then translates to a sales value of UD$941 million. The 2019 pharmaceutical sales and the projected sales in 2024 in Ghana reflect the features of many sub-Saharan African countries' pharmaceutical markets. In those markets, the increased volume of generic medicines consumption drives medicine sales. The governments of those countries put out various economic measures to enable the pharmaceutical companies to increase production to meet the increasing demand for pharmaceuticals. In 2019, per capita expenditure for pharmaceuticals in Ghana was US$20 which is expected to increase to US$41 by 2029.

2.7.1. Pharmaceutical Supply Chain in Ghana

Most of the medicines being distributed in the public health sector in Ghana are procured by the central government (MOH, 2022). However, there is support from donor communities in the

pharmaceutical sector. There are specific health problems some donors target when they procure pharmaceuticals to support Ghana. They are pharmaceuticals for human immunodeficiency virus (HIV), tuberculosis (TB), malaria, diarrhoea, influenza and neglected tropical diseases and for reproductive health. The donor-funded purchase of pharmaceuticals is done through competitive bidding. The bidding is limited to manufacturers who are pre-qualified by the WHO to produce the required pharmaceutical products. Unfortunately, all the manufacturers in Africa have not been prequalified by the WHO to produce the needed pharmaceutical products. The prevailing market for pharmaceuticals in Ghana diminished when the government of Ghana also started purchasing medicines from WHO-pre-qualified manufacturers. An example is the purchase of medicines by the government of Ghana under the 'Affordable Medicines Facility for Malaria' programme (UNDP, 2016). The component of the pharmaceutical market which distributes prescription drugs is 71 per cent. This implies the share of the market for over-the-counter (OTC) medicines is 29 per cent. Local manufacturers concentrate more on the production of OTCs and simple prescription drugs. The portion of the pharmaceutical market for generic prescription medicines in Ghana is 54 per cent, the rest of the market for prescription medicine is for patented medicines (UNDP, 2016).

The chain of pharmaceutical supply in Ghana now has double central levels of storage with many distribution channels. There is a private entity called the Imperial Health Science (IHS) with a pharma-grade warehouse in Tema. That warehouse is where pharmaceuticals donated by Global Fund (GF) and USAID are stored. There is also a Temporary Central Medical Stores (TCMS) in Accra where pharmaceutical products procured by MOH, GHS and other donors are stored. The TCMS and HIS supply the 10 Regional Medical Stores (RMS) and the teaching hospitals. GF and USAID contract Third Party Logistics (3PL) to transport pharmaceuticals from the IHS to the

RMS. 3PL is scheduled to perform this task six times in a year but there are delays sometimes. RMS sometimes mobilise their means to transport medicines from the TCMS to their various regions. While the teaching hospitals are the terminals for the medicines transported to them, the RMS works with Last-mile distribution to send pharmaceuticals to the service delivery points (SDP) monthly or bimonthly (USAID, 2020).

2.8 Summary of the Chapter

There are six components of a health system that must functionally link together to ensure an effective and efficient healthcare delivery. The objectives for health systems: health improvement of the population within its jurisdiction; being responsive to the people's needs; and provision of the means to absorb the financial shocks of the sick. The situation under which the industrialised countries constructed their health institutions was not the same in the developing countries. The inability of LMICs to expand healthcare coverage to their wider population led to the emergence of other health service providers to meet the healthcare needs of the populace. This brought plurality in health services provision, the kind that nearly blur the distinction between private and public sectors in the LMICs. WHO came up with essential medicines. Those medicines must be available, affordable, effective and safe to enhance healthcare delivery. To increase access to medicines, the WHO also advocates for the integration of traditional and complementary medicine in the health systems of all the member countries.

Regarding the medical system of Ghana, the Ministry of Health had solely been on the frontline of healthcare provision. Ghana Health Services was then created to take on the healthcare delivery role but still worked as an agency of the Ministry of Health. Therefore, the structure of Ghana's healthcare delivery system has the Ministry of Health at the apex overseeing the other agencies in the performance of their functions assigned to them by the laws that created them. Healthcare

delivery is in a hierarchy; teaching and specialist hospitals are on top followed by regional hospitals, district hospitals, health centres, clinics and CHPS compounds. Medicines in Ghana are largely imported. They are stored in a privately-owned store and a publicly owned temporary store. There are regional stores that take medicines from the central stores for onward distribution to the districts.

CHAPTER THREE

EMPIRICAL LITERATURE REVIEW ON GOVERNANCE OF THE PHARMACEUTICAL CYCLE AND ACCESS TO MEDICINES

3.0 Introduction

Pharmaceutical production goes through a cycle. It begins with research and development and goes to market authorisation, pricing, distribution and dispensing to the patient. The governance of the various stages of the pharmaceutical cycle has an impact on access to medicine in the larger society (Cylus et al. 2016). This chapter constitutes a review of the empirical literature on how governance of pharmaceutical pricing affects access to medicines, the influence of medicine advertising on the prescription behaviour of health professionals and how regulated prescription behaviour affects the affordability of medicines. It also contains how medicine dispensary is done to ensure rational use of medicine and finally the pharmacovigilance measures and quality of medicines.

3.1 Medicine Advertising, Prescription Behaviour and Affordability of Medicines

The role of healthcare professionals in ensuring patients' well-being is crucial, and the quality of medications prescribed is of utmost importance. A prescription is a written scientific medication order, after diagnosis, intended to treat a patient's health condition. It is a legal document that holds physicians and medication dispensers accountable (Patel et al. 2016). To guarantee the quality of prescriptions, medical practitioners utilize prescription audits. This process is critical in improving prescription precision and elevating patient care. Through this process, medications prescribed are accurate, safe, and effective, leading to benefits for healthcare professionals, managers, patients, and the public at large (Sirisha et al. 2015). It is crucial for healthcare professionals to conduct regular assessments of prescription patterns in order to improve the effectiveness of treatments,

minimize unwanted outcomes, and provide constructive feedback to prescribers (Bismi, 2021). As underscored by Onakomaiya (2022), medication is a crucial component of medical therapy, and those responsible for prescribing drugs should strive to achieve four key objectives: maximizing efficacy, minimizing risks, reducing costs, and respecting patient preferences. These objectives should be taken into account when initially prescribing a medication and monitoring its impact over time. By doing so, healthcare professionals can ensure that patients receive the most optimal care possible (Bismi, 2021).

Pharmaceutical manufacturers make their products known to consumers and health professionals through promotions. As a result, countries have different kinds of ways they regulate pharmaceutical promotions. The regulatory bodies in Denmark and Australia do not prohibit pharmaceutical promotions. The requirement for advertising is that there must be approval from the regulatory bodies. Also, all the relevant information that must inform prescribers and consumers about the quality and side effects of medicines must be included in the promotional message. Direct-to-consumer advertising is limited to over-the-counter (OTC) medicines (Aagaard, 2020 and Paek et al. 2011). Advertising of pharmaceuticals is highly regulated in China. The source of the medicine and whether it has to be taken under the supervision of a professional has to be indicated in the advertising message. Advertising of prescription-only medicine has to be limited to medical or pharmaceutical journals. Direct comparative advertising of medicine is not allowed and no advertising message should undermine the products of others (Zhou, et al. 2021). In the United Arab Emirates (UAE), medicine can be advertised in any form. However, it must not be deceptive and it should be morally sound by UAE customs. It should contain information about its efficacy and side effects. Medical personnel are not permitted to be used to advertise medicines (Gharibyar & Sharif, 2012). Regulations on medicine advertising in India are

not different from many other countries. However, advertising to influence healthcare professionals is not allowed. Also, just like UAE, the names and images of health professionals are not allowed to be used to promote medicines. Also, comparative advertising is allowed but the information must be fair and factual (Handa et al. 2013). Different forms of pharmaceutical promotions go on in the United States of America (USA). There is direct-to-consumer advertising and advertising to medical professionals. As a result, $30 billion is said to be used to advertise medicine in a year by manufacturers. Manufacturers also promote their products in medical and pharmaceutical journals (Kesselheim et al. 2019).

Pharmaceutical promotions take different forms. The intriguing form of pharmaceutical advertising is the one that directly targets medicine prescribers. Pharmaceutical companies do engage in educational sponsorship of medical professionals, finance their research work and its publication, and sometimes there are direct payments of money to the medical professionals (Kesselheim et al. 2019; Grouse, 2014; Grouse, 2008 and DeAngelis, 2014). Agrawal & Brown (2016) analysed the Open Payment Program 2014, it was found that as much as $6.5 billion was paid by 1,444 pharmaceutical companies to teaching hospitals and physicians in the USA. Various studies (Zaki, 2014; Buchman, 2012 and Pham-Kanter et al. 2017) revealed that almost 99.5 per cent of medical professionals in Saudi Arabia, 69 per cent in Canada and 65 per cent in the USA were paid by pharmaceutical manufacturers for promotional reasons. To promote their products, pharmaceutical manufacturers also shower medical professionals with tickets to sporting and other events (DeAngelis, 2014). Pharmaceutical industry payments are not limited to those in the profession, students studying medicine and pharmacy are also targeted. The industry incentivises the students with books, free lunch packs and funds for seminars (DeAngelis, 2014). Besides all, other favours physicians and pharmaceutical representatives mentioned in a study in Lebanon raise

eyebrows. They include sexual advances by female pharmaceutical representatives to male physicians, payments for strip clubs and prostitutes, sponsorship of marriages or honeymoons, and financing of family vacations, boat trips and local retreats (Hajjar, et al. 2017).

There is no doubt the pharmaceutical industry players doll out the incentive for returns as profit from increased sales. Kesselheim et al. (2019) confirm that there is copious documentary evidence that points to the influence of pharmaceutical companies' promotional incentives on prescription decisions of clinicians. Some of the prescriptions do not even emanate from evidence. Pharmaceutical representatives in a study predictably confirmed that certain health professionals could consistently prescribe their medicines. That is why they maintained contact with some of them. Consequently, the pharmaceutical representatives either indirectly monitor how the physicians prescribe their medicines by getting that information from pharmacists or by directly contacting the physicians to give them evidence of the number of medicines from the company they prescribe (Hajjar, et al. 2017). DeJong et al. (2016) found a simple single meal being used by a pharmaceutical company to influence an upsurge in the prescription of their product. The quantum of incentives given to a medical professional was related to the quantity of medicine from the benefactor company they were going to prescribe. That is the more medicines being prescribed from a particular pharmaceutical entity, the more goodies the prescriber will receive from the entity (Hajjar, 2017).

A systematic review conducted by Brax et al. (2017) indicates that there was a measured level of relationship between medical professionals' interactions with pharmaceutical industry players and the patterns and quality of medicine prescriptions by the professionals. Other studies measuring the beliefs and attitudes of clinicians about the interactions they have with pharmaceutical industry players pointed out that, the clinicians did not regard that interaction as being very significant in

their prescription behaviour (Lotfi et al 2016 and Alssageer & Kowalski, 2013). Hammer & Zilic (2017) did not find any influence of monetary inducement on the prescription decision of medical professionals. Also, gifts and other goodies were not found as factors that influence the prescription decision of clinicians. The key factors were textbooks, the internet and the effectiveness of the medicine (Kamuhabwa & Kisoma, 2015).

As a result of the unseemliness of the influence of prescription decisions by pharmaceutical companies, some legislative and ethical measures came up from some angles to check it. Legislation, popularly known as "the Sunshine Act", that is "section 6002 of the Affordable Care Act (ACA) of 2010" in the USA requires all payments made to physicians by pharmaceutical companies to be made public (Kesselheim et al. 2019). From the angle of pharmaceutical companies, an 'ethical code' has been developed and adopted to guide the interaction between the industry players and health professionals to avoid any wrongdoing from both parties (Kamal et al. 2015).

The possibility of pharmaceutical industry players influencing the prescription behaviour of medical professionals raises the question of the impact of prescription behaviour on the cost of medicine. This brings the permission given by the National Health System (NHS) in the United Kingdom (UK) to General Practitioners to dispense medicines to some of their clients into scrutiny. The NHS allows General Practitioners (GP) to dispense medicine to patients who are not within the reach of a pharmacy. While that program may assist the patients, who qualify for it (Kaiser & Schmid 2016; Burkhard et al. 2019 and Bodnar et al. 2021), it may also be exploited by the physicians for monetary gains (Trottmann et al. 2016; Ahammer & Schober 2020 and Bodnar et al. 2021). A study of 12 medical practitioners by Perlis & Perlis (2016) indicates an association between payment received and prescription and dispensing of high-cost medicines most of which

were branded medicines. There are several ways by which dispensing prescribers can raise money through that dual role. They can increase the quantity of drugs they prescribe (Burkhard et al. 2019) or choose drugs that are exorbitant with more profit (Iizuka 2012). A comparison of the prescription of a category of expensive drugs and that of inexpensive ones with the same efficacy by Goldcare (2019) revealed the possibility of a dispensing prescriber prescribing expensive medicine for monetary returns.

An aspect of medicine prescription that is equally key with a strong link to prescription behaviour is rational prescription. The World Health Organization (WHO) released a set of metrics that aim to provide guidelines for assessing the quality of prescriptions in healthcare. These metrics emphasise the significance of utilising generic drugs and medications from a country's essential drug list while advocating for a reduction in the employment of injectable drugs, polypharmacy, and antibiotics. It is noteworthy that non-adherence to these metrics may indicate an irrational prescribing pattern within healthcare. Hence, it is essential to adhere to these guidelines to ensure the quality of healthcare services and promote rational prescribing practices (Birhanu et al. 2015; Berha & Seyoum, 2018 and Lacan et al. 2012). The process of determining the most appropriate course of drug therapy for patients is a complex and nuanced task that draws upon a variety of factors. These may include the physician's own extensive clinical experience and expertise, as well as important considerations such as the unique characteristics of each patient, formulary restrictions, and any relevant cultural factors that may influence treatment decisions. By carefully weighing these factors, physicians are empowered to make informed and well-rounded decisions that are tailored to meet the individual needs and circumstances of each patient (Birhanu et al. 2015; Berha & Seyoum, 2018).

However, Rationality is no longer a priority in prescription by medical professionals, they only put together the names of medicines and dosage instructions (Sirisha, 2015). Globally, there is a widespread of wrong medicines prescription and dispensation which is reflected in an equal measure of wrong use of medicines. The result of these are dangerous therapeutic measures, delayed recuperation by patients and exorbitant costs of treatment which are all harmful to the patient (Bismi, 2021). Several factors lead to irrational prescribing patterns; including demand by patients, imitation of colleagues and incentives from pharmaceutical representatives (Singh, 2019**)**. The prescriptions described as irrational prescriptions are 'polypharmacy, over-prescription, under-prescription, over-prescription of injectables and antibiotics, prescription of medicines outside the essential medicine list and not following the standard treatment guidelines' (Lahry et al. 2017). The issue of irrational drug prescriptions is a global public health challenge, particularly in low-income countries where access to quality-assured medicines may be limited. Prescription patterns can be influenced by a variety of factors, including patient demographics, medicine availability, the quality of health personnel and systems, patient morbidity, age, and reproductive status. With all of these factors in mind, it is clear that proper medication management is critical for the health and well-being of patients worldwide (Rani et al. 2018; Sultan et al. 2015; Bradley et al. 2014 and Pallavi et al. 2016).

Unfortunately, inappropriate or ineffective prescribing can lead to what is known as problematic polypharmacy (Duerden, 2013). This can be especially difficult to avoid in elderly patients, as identifying medications that may have an unfavourable balance between benefit and harm can be challenging. It is important to recognize that medication prescribing and usage can significantly impact a patient's overall health and socioeconomic well-being (Steinman, 2015 and Sharma & Shweta, 2016). When it comes to prescribing multiple medications, it's crucial that certain criteria

are met to ensure that they are both safe and effective. This process involves having clear and specific reasons for each prescription, as well as concrete evidence that the benefits outweigh any potential harm. Additionally, prescribers must also consider the risk of adverse interactions between medications, ensuring that proper dosage is administered and that efficacy is closely monitored (Bennett et al. 2020).

Several studies (Onah, & Idoko, 2022; Singh et al. 2019; Mohammed & Tia, 2019 and Akhtar et al. 2012) conducted in developing countries on rational prescription did not meet the standards of WHO, besides the proportion of prescriptions with injectables. A study at a tertiary hospital in Nigeria indicates non-compliance with the WHO metrics of rational prescription. The study noted the prevalence of polypharmacy among patients with health insurance coverage than those who were on out-of-pocket expenses (Onah, & Idoko, 2022). Also, all the prescriptions analysed in sampled hospitals in Delhi by Singh et al. (2019) had all the required details. However, the prescriptions missed the standard of WHO regarding the number of medicines prescribed which were generic, those from the Essential Medicine List and some of the patients could not remember their prescription schedules. A study conducted in the Tamale metropolis by Mohammed & Tiah (2019) revealed that the average number of drugs prescribed per patient encounter was 3.89, which exceeded the standard set by the WHO of 3. Developing countries like India even had higher averages of 5.6 and 5.2 (Akhtar et al., 2012). Contrary to the other studies, a review of prescribing practices in rural communities in Ghana under the NHIS reported a lower average of 2.9 (Apanga et al. 2014).

3.2 Dispensing of Medicines and Rational Use

Medicine dispensing is a key determinant of the rational use of medicine (WHO, 1993). There are categories of patients who will need serious guidance from the dispensing staff. They are patients

with high-risk medications, patients with medications that need strict adherence to achieve effective therapy, and patients whose medications need devices (Alvarez-Risco, et al. 2018). The WHO (1993) designed guidelines for the prescription and dispensing of medicines to ensure rational use of medicines. Among the indicators, those that are supposed to guard dispensing are found in the patient-care indicators. The metrics specify that the average dispensing time should not be less than 90 seconds. Also, all medicines must be adequately labelled and all patients should have knowledge of the dosage of the medicines dispensed. As a sequel to these guidelines, a lot of studies have been conducted to verify the conformity of prescriptions to those guidelines.

Studies conducted in several countries indicate that the average time taken to dispense medicine fell below the recommended standards set by the World Health Organization (WHO). For instance, in Eritrea, the average dispensing time was only 36.49 seconds (Siele et al., 2022), while in Sri Lanka, it was 40.2 seconds (Priyadarshani, 2021). In Egypt, the average dispensing time was 47.4 seconds (Akl, 2014), and in Brazil, it was a mere 17 seconds (Silva et al., 2018). However, some countries exceeded the WHO's recommended dispensing time. In southern Ethiopia, it took an average of 96.1 seconds to dispense medicine at the counter (Gidebo, 2016). In the Kingdom of Saudi Arabia, it took 100 seconds (El Mahalli, 2012). Furthermore, in Zimbabwe, the average dispensing time was 150 seconds (Chirwa, 2014), in Nigeria, it was 201 seconds (Ndukwe et al., 2013), and in India, it was a staggering 340 seconds (Prasad, 2015). It is essential to note that an extended dispensing time is crucial in improving patient care. A brief dispensing time (less than 90 seconds) is insufficient to provide all the necessary information to patients. Patient adherence and compliance are directly linked to dispensing time, and shorter dispensing times lead to a lack of comprehension of the treatment course (WHO, 1993). Therefore, it is vital to allocate sufficient

time to dispense medication so that patients receive all the necessary information and are encouraged to adhere to their treatment plans.

Also, ensuring that all medicines are properly labelled is an essential aspect of good dispensing practice. According to WHO's (1993) guidelines, appropriate labelling of medicines is a must, but studies have revealed that adherence to this guideline varies widely across different countries. For instance, studies conducted in North-East Ethiopia found that none of the medicines was labelled for patients at the dispensary (Wendie, 2021), while in Eritrea, only 68.24 per cent (Siele et al. 2022) of medicines were labelled. Similarly, in the Kingdom of Saudi Arabia, only 10 per cent (El Mahalli, 2012) of medicines were labelled, while in Eastern Ethiopia, it was 20 per cent (Sisay, 2017), and in Kuwait, it was 66.9 per cent (Awad & Al-Saffar, 2010). However, some countries have achieved a much higher rate of labelling. For instance, Egypt achieved a labelling rate of 95 per cent (Akl et al. 2014) and India achieved a maximum of 100% labelling (Chandelkar & Rataboli, 2014). Proper labelling is essential because it promotes patient awareness and increases treatment adherence. When medicines are labelled correctly, patients are more likely to understand the medication and how to take it properly, leading to better health outcomes and a greater likelihood of successful treatment. The disparity in labelling across different countries could be attributed to several factors, including differences in dispensers' training and workload. In countries where dispensers are well-trained and have a manageable workload, they are more likely to adhere to good dispensing practices, including proper labelling of medicines. On the other hand, in countries where dispensers are overworked or undertrained, they may not have the time or knowledge to ensure that all medicines are labelled correctly. Therefore, it is essential to continue investing in dispensers' training and to increase awareness of good dispensing practices to ensure that patients receive the best possible care.

In addition, understanding the proper dosage of medication is of utmost importance in ensuring that it is both safe and effective for patients. Studies have revealed that Egypt had the highest percentage of patients who possessed knowledge about their medication dosages, with an impressive 94 per cent of patients being aware of the correct dosage (Akl et al. 2014). Following closely behind are Eritrea at 78.88 per cent (Siele et al. 2022), the Kingdom of Saudi Arabia at 79.3 per cent (El Mahalli, 2012), Eastern Ethiopia at 61.88 per cent (Sisay, 2017), and India at 46 per cent (Chandelkar & Rataboli, 2014). On the other end of the spectrum, Kuwait has the lowest percentage at 26.9 (Awad & Al-Saffar, 2010). It cannot be overstated how crucial it is for patients to have a solid grasp of medication dosages, as this knowledge can help them avoid potentially harmful side effects and misuse of drugs. By taking the time to understand the correct dosage, patients can ultimately experience improved care and a better quality of life. This underscores the importance of proper education and awareness campaigns that can help individuals become more knowledgeable and informed about medication dosages, ultimately leading to better health outcomes and safer use of drugs.

Since the WHO has been a leading authority on the safe and effective dispensing of medication since 1993 when they first established guidelines for this important practice, several countries have since adopted and expanded upon these guidelines to ensure that pharmacists assume various responsibilities that guarantee the safe and effective use of medications.

For example, Australia and Lebanon have their dispensing guidelines that are similar in many ways but also differ in some key aspects. In Australia, pharmacists are required to verify that the prescriber is authorized to prescribe the medication, confirm the patient's identity and the type of medication prescribed, ascertain the prescriber's intentions before dispensing the medication, and provide counselling to the patient to ensure adherence to the prescription and dosage instructions.

This comprehensive approach ensures that patients receive the right medication, in the right dosage, at the right time, and with the right guidance to ensure maximum efficacy (Pharmacy Board of Australia, 2015).

In Lebanon, dispensing guidelines recognize pharmacists as independent professionals who conduct further investigations into the patient's condition and the cost of the prescribed medication. These guidelines also permit pharmacists to substitute generic medications for those prescribed by the prescriber, which can help to lower costs and improve patient outcomes. By empowering pharmacists to take a more active role in patient care, the Lebanese guidelines help to ensure that patients receive the best possible care and treatment for their health conditions (Hajj et al. 2020).

Overall, these guidelines and others like them have been instrumental in improving the quality of care that patients receive when it comes to the dispensing of medication. Through careful oversight, clear communication, and a focus on patient safety and efficacy, pharmacists and other healthcare professionals can work together to ensure that patients receive the best possible care and treatment for their health conditions.

3.3 Pharmaceutical Pricing and Access to Medicines

The pharmaceutical pricing policies that are enforced in different countries vary widely based on various factors, such as the patent status of the product, whether it is on or off patent, or a generic version. It has been found in various studies that several pricing policies are commonly followed in the pharmaceutical industry. These include free pricing, internal reference pricing, external or international reference pricing, price negotiations, cost plus pricing, dynamic pricing, state controls, conditional pricing, and price setting through compulsory reductions for off-patent and

generic products (Maniadakis et al. 2017; Panteli et al. 2016; Bangalee & Suleman, 2016; Bangalee & Suleman, 2019; Cassar & Suleman, 2019; Fink, et al. 2014 and Tran et al. 2020).

One of the pricing policies in the pharmaceutical industry is free pricing. Under this policy, pharmaceutical manufacturers are allowed to set prices freely at the time of market entry. However, this approach may lead to higher prices and increased expenditure for the consumers. Therefore, indirect price moderation methods such as rebates, profit or price and cost controls are often used in conjunction with free pricing to ensure that the prices remain reasonable (Maniadakis et al. 2017). Free pricing is used in the USA by manufacturers and prices may even subsequently be increased before the expiration of patents (Kesselheim et al. 2019). In Europe, only a few countries, including Denmark, Germany, and the United Kingdom, have implemented free pricing policies. However, even in these countries, indirect measures such as internal reference pricing, parallel imports, legally mandated discounts and rebates, and individual contract agreements between payers and manufacturers can still affect drug pricing (Panteli et al. 2016). In Germany, the implementation of the AMNOG (German Pharmaceutical Market Reorganisation Act) in 2011 truncated the free pricing policy. The AMNOG required negotiated reimbursement amounts for new drugs with a new active substance or indication expansion, after the first year of marketing authorization (Panteli et al. 2016). The adoption of free pricing is possible among countries where pharmaceutical manufacturing is common. Developing countries, which largely import their pharmaceuticals and whose governments may be striving to achieve universal access to health care, may resort to other pricing policies.

Internal reference pricing (IRP) is another pricing policy that is commonly followed in the pharmaceutical sector. This policy directly establishes the benchmark price by setting prices based on the prices of bioequivalent or therapeutically equivalent products that are already available in

the market (Maniadakis et al. 2017). IRP is adopted to contain costs and stimulate competition (Panteli et al. 2016). Denmark, Germany, the Netherlands, and Sweden have been at the forefront of IRP's increasing popularity over the last 25 years. While IRP is primarily used for the pricing of generics, Italy also employs it for negotiations on the reimbursement prices of new medicines in conjunction with ERP (Panteli et al. 2016). IRP is also used in China, South Korea, Japan and Thailand (Cho et al. 2015; Chan et al. 2016 and Toumi et al. 2014). Overall, IRP is a valuable pricing strategy that has been adopted by several countries to ensure that pharmaceutical prices are affordable and competitive. By comparing similar products within the country, IRP can help control costs and stimulate competition, which ultimately benefits both patients and healthcare systems.

External reference pricing (ERP), on the other hand, benchmarks prices of pharmaceutical products introduced to the market to the price of the same product in other countries. The number and composition of reference countries and the formula for determining prices in the destination country are critical parameters in pricing (Maniadakis et al. 2017). European countries mostly regard it as a primary or secondary criterion to determine pharmaceutical prices, although the strategy varies from country to country. References can range from three to thirty countries (Panteli et al. 2016). The benchmark used can either be the average price of all countries or the lowest price in the basket. A lot of countries use manufacturers' prices for ERP, but Finland uses wholesale prices while the Netherlands uses pharmacy retail prices. In Africa, South Africa is one of the countries that uses ERP in addition to other pricing policies. The ERP resulted in ex-manufacturer prices dwindling between 68 per cent in 2016 and 85 per cent in 2018 in South Africa (Cassar & Suleman, 2019).

Although ERP can have long-term benefits in driving down prices, overpayment is a risk because of the lack of consideration given to confidential discounts and rebates. Additionally, differences in package sizes and dose strengths can complicate arriving at representative results. Therefore, it is recommended to use a weighted referencing approach and exclude all countries using ERP from other ERP baskets to avoid manufacturers' strategic market launches and spillover effects (Cylus et al. 2016).

There was a proposal for a more structured approach called "value-based pricing", which links a product's price to its comparative additional benefit. This approach seeks to reward manufacturers for delivering better value, which is a logical perspective from the payer's standpoint. However, implementation was met with significant challenges, resulting in a critical reception and low adoption rate (Maniadakis et al. 2017). The adoption of value-based pricing has gained momentum in recent years and presents an attractive alternative strategy to traditional pricing methods. However, the concept of "value" lacks a universal definition, leading to a plethora of value-based approaches being considered. Sweden has emerged as an early pioneer in applying a value-based approach in the European context, incorporating a cost-effectiveness threshold since 2002. France and Germany also feature prominently, utilizing demonstrable added benefits to determine prices for newly authorized pharmaceuticals or indications. It is noteworthy that the specific value quantifications adopted by France and Germany were not found in other countries that incorporated value-based elements, such as Belgium, Italy, and the Netherlands. Although value-based elements were not systematically implemented, Italy employs proven added value to support premium pricing, albeit inconsistently applied across all pharmaceuticals. The United Kingdom developed a new approach to value-based pricing in 2014 (Panteli et al. 2016).

“Cost plus” is a pharmaceutical pricing formula that is targeted at embracing other costs in the pharmaceutical production chain. The pricing is extended to cover the cost of research, development and production of the pharmaceuticals with a specified margin of profit. This policy is often used when the costs associated with the production of a particular drug are high (Maniadakis et al. 2017). This pricing formula was implemented in Mali in 2006. It led to the elimination of the monopoly of medicines by some key players in the private sector. The policy led to the fluctuation of the availability of medicines for a while but it stabilised and even increased in the long run. Prices of medicines also reduced significantly (Maiga et al. 2010). In Indonesia and China, “cost plus” was used in conjunction with other price formulae in 2010. In Indonesia, there was a significant drop in generic and innovator medicine prices in both the public and the private sectors. However, the prices were still higher than the ceiling set by the government (Anggriani et al. 2013). In China, the expenses on pharmaceuticals were reduced after the implementation of the assorted policies which included “cost plus”. However, there was more reduction in inpatient expenses than outpatients’ (Zhou et al. 2015).

"State controls" in the pharmaceutical industry refer to the practice of government institutions setting drug prices without input or negotiation from manufacturers. In many countries, however, drug pricing is directly negotiated between governments and manufacturers. The process typically involves evaluating the medical benefits of new products in comparison to existing ones, as well as considering cost-effectiveness and budget impact using a Health Technology Assessment (HTA) methodology (Maniadakis et al. 2017). The use of state controls in many countries happens in the control of mark-ups in the pharmaceutical chain. This scales down profit margins which eventually leads to enhanced access to pharmaceutical products. Studies on the markup policy used in China by Fang et al. (2013) and Han et al. (2013) revealed that there was a drastic

improvement in the availability of essential medicines and the prices of both innovator brand and generic medicines were reduced. In Sudan, the "Pharmacy and Poison Act (2001)" fixed profit margins for wholesale pharmaceuticals at 15 per cent and that of retail shops at 20 per cent. In effect, the wholesale price of medicines went down by 40 per cent and that of retail was down by 47 per cent. These prices were even less than the prices set by the National Medicines and Poisons Board (NMPB). Also, the prices of 11 originator medicines were either less than or equal to the retail prices in Britain (Ali & Yahia, 2012).

A lot of other assorted pharmaceutical pricing policies are adopted by many countries, including LMICs to facilitate universal access to medicine. One of them is the use of tax policy. "Pharmaceuticals are often subject to lower VAT rates compared to other goods and services. Denmark and Germany apply standard VAT rates to pharmaceuticals, which are set at 25% and 19%, respectively. In France, however, reimbursed medicines are taxed at 2.1%, while non-reimbursed medicines are levied at 10%. Meanwhile, Sweden and the United Kingdom have exempted prescription-only medicines from VAT, while over-the-counter (OTC) medicines are still subject to standard rates. In Ireland, oral and non-oral medicines are treated differently under their VAT system. It is worth noting that certain countries have implemented adjustments in their pricing regulations in response to the economic crisis. For example, Belgium, Ireland, and Portugal have made changes to their ERP systems. Greece, on the other hand, introduced lower pharmaceutical VAT rates and internal reference pricing. Other countries like Spain have VAT rates of 4 per cent, and 10 per cent each for Austria, Finland and Italy" (Panteli et al. 2016).

Also, many LMICs use the Revolving Fund model to control access to medicines in their countries. This module simulates monopsony where a Central Medical Store (CMS) remain the main buyer of pharmaceutical products. This gives the CMS the power to tilt pharmaceutical prices in favour

of health seekers. For example, Kenya uses the Revolving Fund Model which is implemented from the tertiary to community healthcare delivery levels. The fund has a minimal markup price to enable replenishment of the medicine stock. As of 2018, there was an improvement in the availability of essential medicines from an average of 40 per cent to more than 90 per cent (Tran et al. 2020). Other pharmaceutical policies widely used to ensure lower pharmaceutical prices are Single Exit Pricing (SEP) and the facilitation of the use of generic medicines. SEP requires all pharmaceutical manufacturers to sell their products at a uniform price. The policy has been blamed for not encouraging competition in the pricing of pharmaceutical products (.Bangalee & Suleman, 2016).

3.4 Pharmacovigilance and Quality of Medicines

Counterfeiting of medicinal products has been in existence since 1500 BC (WHO, 2017). In recent times, the situation that created a chance for those who engage in medicine falsification is the increase in global demand for pharmaceuticals. The situation is exacerbated by constrained access to affordable genuine medical products, poor pharmaceutical governance and corruption at both private and public healthcare facilities (WHO, 2017). The safety of a country's medicines is directly proportional to its level of income. In other words, the higher the income of a country, the safer its medicines are likely to be. This is because countries with higher incomes have the financial resources to invest in research and development, as well as in regulatory bodies that ensure the safety and efficacy of medicines. On the other hand, countries with lower incomes may not have the same resources, which can lead to substandard or counterfeit medicines being produced and distributed (Khan et al. 2023 and Makhene et al. 2023).

Pharmaceutical regulatory bodies are established by legislations. Those legislations contain specific regulations to guide the functions of the regulatory bodies. The regulatory bodies then

develop guidelines and organizational structures to ensure efficient pharmacovigilance (Khan et al. 2023). The main functions of the regulatory bodies are: i) Prevention of the production distribution and consumption of sub-standard and falsified (SF) medicines. ii) Detection of SF medicines already in the system; and iii) responding appropriately to those who have already taken the SF medicines and those engaged in the distribution of those medicines (WHO, 2017).

The globalisation of the pharmaceutical market needs a web of regulations at the global level to curb the menace of SF medicines. Adapting regulatory structures to the current environment is crucial. At the moment, a limited number of nations manufacture a substantial quantity of reasonably priced generic pharmaceuticals. Yet, the regulatory bodies in these countries are solely accountable for upholding the quality of items sold domestically. Consequently, many importing nations have to replicate regulatory processes to guarantee product excellence, leading to a convoluted system (Fadlallah et al. 2016; Dansie et al. 2019 and Habarugira & Figueras, 2021). The globally standardised pharmacovigilance systems are three in number: "the European Union (EU) pharmacovigilance system, the WHO Uppsala Monitoring Center system, and the International Conference on Harmonization (ICH) system" (Khan et al. 2023).

Europe has a very unique network of pharmaceutical regulations. The network is composed of 'the European Commission', (EU) 'the European Medicine Agency' (EMA) and 'National Competent Authorities' in individual member countries. The success of EMA is based on the entire regulatory network. 'Eudravigilance' which was introduced in 2001 by EMA is responsible for data managing data related to medicine safety. Canada has the Food and Drugs Act which requires all Market Authorisation Holders to report the ADR of their products. The report must include ADR on products authorized in Canada that occurred outside Canada. ADR reporting is voluntary for patients and healthcare workers. Cana has seven pharmacovigilant centres that receive ADRs and

forward them to the national vigilant centre. The focus of pharmacovigilance in Australia is Adverse Drug Reaction (ADR) reporting. It is voluntary for patients and healthcare workers to report ADR. However, the pharmaceutical manufacturing industries must report ADR. The reports are sent to the "Adverse Drug Reaction Advisory Committee". The reports are published online by the "Therapeutics Goods Administration (TGA)" which is in charge of publishing medicine safety information (Khan et al. 2023).

The pharmacovigilance scheme of Nigeria has 'National Pharmacovigilance Centre (NPC)' and 'National Agency for Food and Drug Administration and Control (NAFDAC)' as the core institutions. It is overseen by NPC. There are six pharmacovigilance zonal centres which are constituted by the states. The NPC receives adverse drug reaction (ADR) reports from Market Authorisation Holders (MAH), health professionals, NAFDAC coordinators in the states and from the zonal centres. ADR reporting is mandatory for all MAHs but voluntary for health professionals and individuals. The NPC carries out post-marketing surveillance and verifies a significant number of reports using WHO criteria. The verified reports are then managed using 'VigiFlow' software and stored in 'VigiBase', the WHO database for ADR reports, to enhance signal detection (Olowofela, 2016).

Within the African continent, except the Sahrawi Arab Democratic Republic, all African countries have National Medicines Regulatory Authorities (NMRAs) or administrative units that carry out some or all medicine regulation functions (Ndomondo-Sigonda et al. 2017). The countries that constitute the WHO Program for International Drug Monitoring include 46 full members and 4 associate members hailing from the continent of Africa (WHO, 2023). However, as of July 2023, the World Health Organization's Global Benchmarking Tool rated only four African NMRAs as level 3 mature. These distinguished organizations include the Tanzania Medicines and Medical

Devices Authority (TMDA), the Ghana Food and Drug Authority (FDA), the Egyptian Drug Authority (EDA), and the National Agency for Food and Drug Administration and Control of Nigeria (NAFDAC). It's worth noting that none of them have yet attained level 4 (WHO, 2022).

There is a significant variance in the level of pharmacovigilance across different nations. According to a recent report, 11 countries have highlighted some critical hurdles that they experience while executing their pharmacovigilance responsibilities. These challenges encompass inadequate financial resources, substandard reporting mechanisms, an unskilled workforce, and the absence of dedicated laws regulating pharmacovigilance (Ampadu, et al. 2018). Instances of subpar and counterfeit merchandise have resulted in devastating consequences in Africa, such as the tragic loss of 66 young lives in Gambia due to the use of tainted cough syrups (Saied et al. 2023). As such, it is imperative that safety monitoring systems are put in place to address and rectify these gaps in the supply chain.

As per the statistics gathered by VigiBase, a comprehensive database for individual case safety reports (ICSRs), it has been found that African countries have contributed a mere one per cent of all the ICSRs ever since the inception of the WHO Programme on International Drug Monitoring. This data clearly indicates a significant disparity in reporting adverse drug reactions (ADRs) from the African continent in comparison to other regions of the world (Uppsala Monitoring Centre, 2023). A study by Aagaard (2012) indicates that at the time Africa recorded an average of three instances of adverse drug reactions (ADRs) per million people annually, the developed nations reported around 130 cases per million. This suggests a notable underreporting trend in Africa.

Reporting suspected adverse drug reactions (ADRs) through impulsive means and drug-related issues is often unreliable due to its dependence on a limited number of healthcare professionals who are actively working to prevent medicine-related harm. Unfortunately, some healthcare

workers in Africa are often hesitant to report adverse events, particularly medication errors due to possible legal ramifications (Kiguba et al. 2023). Furthermore, some healthcare workers face knowledge gaps and heavy workloads, which can make reporting adverse events seem like an additional burden. To increase participation, some experts suggest incentivizing the reporting process (Kiguba et al. 2015).

In certain African nations, including Ghana, South Africa, and Kenya, inspections to ensure compliance with good Pharmacovigilance practices (GVP) are feasible due to established frameworks and capabilities. Other developing countries, such as Uganda, Sierra Leone, and Nigeria, have also implemented comparable structures. Nonetheless, there remain certain obstacles, particularly in terms of the legal framework and the ability to monitor the efficacy of corrective and preventive measures following inspections (Ndagije et al. 2023).

Some studies (Gore et al. 2017; Pratico, et al. 2018 and Saiyed et al. 2015) were conducted into the use of off-label and unlicensed medicines in developing countries. The studies revealed the prevalence of off-labelled and unlicensed medicines. These studies also discovered suspected corresponding ADRs among those who consumed off-label and unlicensed medicines. A study in Ghana indicates that people were aware of how ineffective falsified medicines were because of their production without active ingredients. The participants who described expired medicines as ‘spoilt medicines’ were also aware of the poisonous nature of such medicines. They claimed to know some features of falsified and expired medicines like the absence of expiry date, soft texture of tablets or wired colour and scent of syrups (Hamill et al. 2019).

Some of the major problems with regard to access to quality medicines are the abundance of substandard and falsified medicines and the use of antimicrobials without prescription. The problem of the proliferation of substandard antibiotics keeps increasing at the medicine outlets

(Baxerres & Hesran, 2011 and Gullberg et al., 2011). A study in Ghana indicates that over 66% of sampled antibiotics had more or less active pharmaceutical ingredients than what was embossed on the label. Such antibiotics were distributed by authorised and unauthorised medicine outlets (Bekoe et al., 2020). Studies conducted on medicines acquired from authorised medicines distributors found a substantial quantity of the medicines being substandard (Usman et al., 2010 and Nayyar et al., 2012). Also, serious medicine falsifications like filling amoxicillin capsules with flour and altering of expiry date of medicines were found in Tanzania (Hamill et al., 2020). However, the unauthorized medicines distribution outlets supplement the authorized ones to increase accessibility to medicines in low- and middle-income countries which includes Ghana (Seiter & Gyansa-Lutterodt, 2009).

The distribution and prescription of antibiotics are supposed to be guarded by regulations. However, some studies in Ghana indicate the presence of antibiotics at unauthorised places which are prescribed by unapproved persons (Yevutsey et al., 2017; Ahiabu et al., 2018 and Afari-Asiedu et al. 2018). Yevustey et al. (2017) indicated that there is no antimicrobial policy to regulate the prescription, dispensing and use of antimicrobials in Ghana. Generally, Giralt et al. (2020) concluded after they studied the quality of medicine distribution in low-and middle-income countries (LMIC) that, LMIC medicine distributors were poorly compliant with the WHO quality standards.

Several studies in Ghana show increasing microbial resistance to the antimicrobials that are used to treat a lot of illnesses (Namboodiri et al., 2011 and Forson et al., 2011). The result of substandard medicine and misuse of antimicrobials is a possibility of serious treatment failure because when microorganisms are exposed to substandard therapeutic doses and wrong use of medicines, they easily become resistant (Nwokike et al., 2018, Kelesidis et al., 2007).

Reasons for the abundance of substandard medicines and unapproved distribution of antimicrobials are poor regulations, reliance on the private sector, poverty and proliferation of online pharmacies (Afari-Asiedu et al., 2018; Mackintosha et al., 2018; Mackey & Liang, 2013 and Ahiabu et al., 2018).

3.5 Summary of the Chapter

There have been a lot of studies on regulations governing advertising in various countries. Also, the effects of promotions of pharmaceutical products on prescription decisions of medical professionals have been widely studied. In addition, how medical professionals who prescribe and dispense medicines at the same time to certain patients take advantage of that to increase their revenue has been studied. Rational prescription in line with the standards established by WHO has been widely explored in many countries.

Medicine dispensing is a key determinant of the rational use of medicine. The WHO designed guidelines for the prescription and dispensing of medicines to ensure the rational use of medicines. Among the indicators, those that are supposed to guard dispensing are found in the patient-care indicators. The metrics specify that the average dispensing time should not be less than 90 seconds. Also, all medicines must be adequately labelled and all patients should have knowledge of the dosage of the medicines dispensed. As a sequel to these guidelines, a lot of studies have been conducted to verify the conformity of prescriptions to those guidelines. Most of the empirical studies on medicine dispensing measure how the dispensing practices fit into the guidelines developed by the WHO.

The pharmaceutical pricing policies that are enforced in different countries vary widely based on various factors, such as the patent status of the product, whether it is on or off patent, or a generic

version. One of the pharmaceutical pricing policies is free pricing. This allows manufacturers to fix their prices after marketing authorisation. Due to the negative effect, it may have on access to medicines, other measures are used by the state to control the pricing of pharmaceuticals. Another pricing policy is Internal Reference Pricing. Pricing of medicine under this policy calls for a comparison of the active ingredients of pre-existing medicine. The pricing is then done based on the price of similar medicines. In external reference pricing, prices of medicines produced in a particular country are determined by the prices of other selected countries. The selection of a country for comparison is based on whether they are located in the same region and the similarity of their health systems. Value-based pricing is another pricing policy that prices medicines based on their benefits. The question regarding this policy is the definition of a value, especially, in the case of multinational pharmaceutical companies. Additionally, cost plus pricing is another pricing policy that determines the price of medicines using the cost of the production process and that of the product plus a markup. Besides, state control is the control of pharmaceutical prices by the state without necessarily negotiating with the manufacturers. This can manifest itself from an extreme to a flexible state control. Other policies that can be used to achieve lower medicine prices are lower VAT rates, the use of single exit price, the use of a Revolving Fund and encouragement of the use of generic medicines. Due to the extreme importance of access to medicine in healthcare delivery, no country uses a single pharmaceutical policy to determine the prices of pharmaceutical products. The policies being used are adopted to strike a balance between making medicines accessible to society and keeping pharmaceutical companies in business.

Falsification of medicines is not new in the history of medicine production. However, globalisation, coupled with problems of access to medicines and poor pharmaceutical governance enhances the spur of pharmaceutical counterfeiting across the world. Legislations have been

promulgated at the international and national levels to curb the proliferation of SF medicines. Those legislations led to the establishment of various regulatory bodies to ensure the elimination of the menace of SF medicines. However, the economic challenges of developing countries are reflected in their ability to effectively protect their society from the vagaries of SF medicines. Several studies show evidence of the proliferation of SF medicines in Low- and middle-income countries, the prevalence of prescription of antibiotics wrongly and the consequences of the wrong use of antibiotics.

Generally, among the studies reviewed on medicine pricing policies, there are no recent studies that point out how the medicine pricing policies facilitated the availability of medicines. This means there is scanty literature that links medicine pricing policy to the availability of medicines especially, under a third-party payer scheme. Also, the studies on the prescription behaviour of medical professionals for revenue generation focus much on situations where there are third-party payers. There have not been studies on how the prescription behaviour of medical professionals is geared towards raising money from out-of-pocket financing health seekers. Besides, all the reviewed studies on medical professionals' prescription behaviour for revenue generation were conducted in the developed world which has health systems different from those of developing countries. In addition, many studies have been conducted on the time used at the counter of dispensaries, the proportion of medicines labelled and the knowledge of patients about medication dosage. However, there are scanty studies on the waiting time at the dispensary, the pattern of communications by the dispensary staff, the organisation of the dispensary and how the attitude of the dispensary staff affect the rational use of medicines. Lastly, there are scanty studies, if some exist at all, that explain the policy capacity of the regulatory bodies in Ghana to control the prevalence of SF medicines. The gaps identified in the literature are the motivations for this study.

CHAPTER FOUR

CONCEPTUAL LITERATURE REVIEW, THEORETICAL FRAMEWORK AND THE CONCEPTUAL FRAMEWORK FOR THE STUDY

4.0 Introduction

This chapter is a review of the literature on concepts that are applicable to this study. It is made up of the concepts of governance, good governance, elements of good governance, the concept of access and the dimension of access. The chapter also reviews access to the medicine's frameworks. In addition, the theoretical underpinning of this study and the conceptual framework for this study are in this chapter.

4.1 Concept of Governance

The terms governance and government refer to targeted behaviour within a system of rules to achieve set goals. However, the activities of government are backed by authority and that of governance is backed by shared goals that may not necessarily emerge from formal legal authority (Rosenau, 1992). This implies there can be governance without government.

Governance constitutes the ways common affairs are managed by individuals and institutions. It is a process by which differences are settled and common actions may be taken. It includes the application of both formal rules and informal arrangements that work to meet the common goal of different segments of society (Commission on Global Governance, 1995 and Dodgson et al. 2002). From a view of governance at the micro level, there is no formal control mechanism that can dictate the relationship among the segments of society (Chhotray & Stoker 2009). This implies that governance is more about negotiations and settlements on the outcome not necessarily a stereotype determination of outcomes. McGuire (2010) noted that laws, statutes and formal constitutions do

not easily make governance attainable, governance is regarded as a concept at the system level (macro level) driven by networks whereby each network constitutes several nodes (organisations) that have many linkages collaborating on different activities.

The view of Brinkerhoff and Bossert (2008) is that governance establishes rules which assign roles and responsibilities to actors in society. The rules go further to shape the interactions among members of society. However, the United Nations Economic and Social Commission for Asia and the Pacific [UNESCAP] (2009) simplify governance as the process of decision-making and implementation. There are two key aspects of governance: i) the intended goal that must be pursued and ii) the process that is best for the achievement of the goal (Grin, 2006). UNDP (2003) further expounded on the focus of governance indicating that, the spectrum of governance encompasses (i) setting the objective (ii) designing rules and regulations accompanied by the provision of the necessary resources to achieve the objectives and (iii) monitoring and evaluating to ensure that the objectives are achieved. Governance operates at every level of human enterprise; from the household to the global level (UNDP, 2004). Blunt (1997) identifies four types of governance: Economic governance, political governance, administrative governance and health system governance. The wider governance framework of a country defines the health system governance of that country (Siddiqi et al. 2009 and Dodgson, 2009).

Health system governance is the establishment of rules that dictate policies, programs, and activities related to health functions within institutional boundaries. These rules clearly outline the roles and responsibilities of societal actors and how they can contribute to achieving health sector objectives. Ultimately, governance in health systems acts as a mechanism for regulating the various actors involved in the process, thereby facilitating the achievement of health goals (Brinkerhoff & Bossert, 2008). Health system governance has three main actors; policymakers,

health service providers and the general public. These actors constitute the health system governance triangle expounded by the World Bank (2007). Siddiqi et al. (2009) and Peters & Muraleedharan (2008) further explain that health system governance involves other stakeholders like communities, civil society organisations, private providers, pharmaceutical companies and development partners that strengthen the regulations in a country.

Besides health system governance, the following forms of governance have close relations with pharmaceutical governance: Clinical governance which concerns the quality of healthcare delivery and safeguarding standards for excellence in clinical care (Starey, 2001). Clinical governance cannot be successful without good pharmaceutical governance which ensures the accessibility and quality of pharmaceutical products. Corporate governance is very relevant in the pharmaceutical sector. This is because the production and distribution of pharmaceuticals are largely done by pharmaceutical companies and their associates who are guarded by the principles of corporate governance (Strengthening Pharmaceutical Systems [SPS], 2011). Therefore, good corporate governance in the pharmaceutical sector will have an impact on pharmaceutical governance. Global health governance is largely concerned with "rules, processes, structures and systems" on health issues across the world (McCoy, 2009). Among others, global health governance ensures the regulation of medicine distribution across the world. Therefore, the illicit circulation of counterfeit medicines is one of the issues addressed at the global level (SPS, 2011).

4.2 Concept of Good Governance

The concept of good governance was introduced by the World Bank in their 1989 report on sustainable growth in sub-Sahara Africa (WB, 1989). Scott et al. (2016) echoed the view that governance is regarded as a web of institutions and rules that determines possibilities but added that good governance keeps the system functioning in the absence of good leaders and even goes

ahead to defend the system against bad leaders. The three main consequences of bad governance are; i) policy failures, ii) adoption of problematic policies, and iii) non-implementation of feasible and well-supported policies (Scott et al., 2016). Plumptre and Graham (1999) believe that the criteria for good governance should be based on the norms, values and the desired outcome of the society that is been evaluated. However, some norms and values happen to be widely accepted in various contexts as elements or dimensions of good governance (Research Matters, 2010).

4.3 Elements of Good Governance

A lot of institutions and scholars have come up with several elements or dimensions of good governance. They include UNDP (1997), WHO (2000), Scott et al. (2016), and Ibrahim &Wertheimer (2018) among others. Below constitutes a discussion of the elements of good governance as explained by various authors.

Participation: Participation is defined in the light of the civic right of people which includes the right to take part in the conduct of public affairs, the right to vote and be voted for and the right to access public services (Speer, 2012). Generally, the meaning of participation is that those who are to be affected by decisions must get access to decision-making and have the power to obtain a meaningful stake in the work of institutions (Woods 1999). Participation is intended to increase the legitimacy of government and prevent the exclusion of some categories of people from public services. A deliberative form of decision-making is achieved and strengthened through participation. Through deliberation and contestation of ideas, better policy outcomes, transparency and equity are realised (Bishop & Davis, 2002; Bucek & Smith, 2000; Weeks, 2000). The implementation of participatory governance aims at allowing citizens to influence the design and implementation of public policy (Andersson et al., 2006; Andersson et al., 2009 and Gibson &

Lehoucq, 2003). Participatory governance is regarded as a promising design because it comes up with governance solutions that are tailored to local needs (Ostrom, 2005).

Participation in pharmaceutical governance is targeted at seeking inputs from traditionally unrepresented voices about drug safety policy (UNESCAP, n.d). Regulators need to strengthen participation because the pharmaceutical industry representatives and the global donors may have more access to the regulators than citizens, especially in developing countries (Moscou &Kohler, 2018). Participation mechanisms are; stakeholder forums, consultations, elections, appointed representatives, legal remedies, choice mechanisms, advisory committees, ad hoc or otherwise and partnerships (Scott et al. 2016).

Responsiveness: Responsiveness requires a timely response to the real needs of people (UNESCAP 2009). It includes tying policies, strategies and programs to people's expectations (Moscou &Kohler, 2018). These require participation from the grassroots (United Nations, 2015). The move by institutions and processes to serve stakeholders within a reasonable timeframe is what responsiveness is about. In pharmaceutical governance, responsiveness is regarded as policies and regulations that address drug safety issues within a reasonable time (Moscou &Kohler, 2018). The main way to achieve responsiveness is by the creation of networks which bring actors together (Cagnin et al. 2012).

Policy Capacity: Policy capacity is explained by Forest et al. (2015) as the ability of an organisation to design a policy to match the resources when trying to achieve a set objective. Specific resources that are available for policy formulation and implementation are what is known as policy capacity (Scott et al. 2016). In every government, there is a small bureaucracy near the hierarchy. That bureaucracy turns raw materials like ideas and political will into policy (Page and

Jenkins, 2005). Mechanisms that can be used to improve policy capacity are intelligence on performance, intelligence on processes, effective research work, staff training and seeking expert support (Scott et al. 2016).

Transparency: In every bureaucracy, professionals will try to escalate their superiority by keeping their knowledge and intentions secret (Weber, 1958). This view does not go well with the modern system of governance, especially when the decisions of those in the position of trust affect others. Transparency requires that decisions that are made and are yet to be made and the processes involved in making those decisions are made known to the public (Woods, 1999). It is the extent to which the most relevant aspect of decision-making by the government is made accessible to the public at the right time and in the form it can be easily understood (IMF, 2000). Transparency requires that citizens are made aware of the reasons behind public policy decisions taken, the procedure involved in making the decision, the arguments for and against the decision and the criteria used to settle on that decision among the alternatives (USAID, 2013 and WHO, 2007). Piotrowski (2010) has outlined five models by which government information is made accessible to the public. They are the proactive model where it is mandatorily required by the state and its agencies to release information appropriately, the requester model; which is when information is requested by members of the public, the request may be backed by law, and open public meeting model, here the government makes its meeting open to those who are willing to attend. The information shared in such meetings can be disseminated by those who attended. The remaining ones are whistle-blower and leak models.

Transparency is the accessibility of information about the decision taken to people who are affected by the decision. Transparency can hold regulatory bodies accountable for their decision about drug safety. Adverse drug reactions (ADR) can remain blared to patients, health professionals and

regulatory bodies when there is no transparency (Moscou & Kohler, 2018). Scott, et al. (2016) outline the following as transparency mechanisms: watchdog committees, inspectorates, regular reporting, freedom of Information legislation and clear and useful public information.

Accountability: Accountability is the obligation of a government to take responsibility for its expected functions and the outcome of its effort in the performance of those functions (Pico et al. 2017). Accountability depends on transparency. Accountability has two dimensions: being answerable to the people and being ready to face the consequences when there is a dissatisfactory performance of the functions (Mulgan, 2003). Accountability has been classified into three main categories by Brinkerhoff (2004). They are financial accountability, performance accountability and political accountability. Accountability prevents the exercise of discretion which makes it a key for drug safety policy (Brandsma & Schillemans, 2012). Accountability has a key function in enhancing checks and balances from internal and external stakeholders. It guides, monitors and evaluates institutions and programs which lead to improvements (United Nations, 2015). Accountability can reduce abuses and ensure compliance with standards and procedures in a health system thereby increasing health system performance (Kaufman & Kraay, 2008). Accountability mechanisms put forward by Scott et al. (2016) are contracts, other financial mechanisms, such as pay for performance, laws that specify objectives, reporting and mechanisms, competitive bidding, organizational separation, and conflict of interest policies and regulations.

Effectiveness and Efficiency: Effectiveness is described as the existence of minimal red tape in the functioning of an organization. The following features are included in the description of effectiveness: stable and credible policies, disciplined budget and efficient expenditure, high quality and depolarized personnel in the organization and small government with formalized structures and rules (Andrews, 2008). Effectiveness and efficiency are regarded as the production

of the expected results by institutions while making reasonable use of resources at their disposal (UNICAP, n.d). In pharmaceutical governance, effectiveness and efficiency are regarded as the capacity to evaluate the relevance of pharmacovigilance policies and monitor the extent to which the pharmaceutical industry complies with the regulations of post-market drug safety (Moscou &Kohler, 2018).

Equity and Inclusiveness: Equity and inclusiveness are a situation where the vulnerable do not feel excluded from mainstream society (UNICAP, n.d). In pharmaceutical governance, equity is regarded as the distribution of safe medicines and other pharmaceuticals to all segments of a society based on their needs. It includes giving every segment of society the capacity to detect and act on drug safety signals (Moscou &Kohler, 2018).

Ethics: Ethics is the practice of fair and impartial implementation of national pharmaceutical and pharmacovigilance policies. Ethics promotes respect for justice, nonmaleficence, and beneficence to safeguard patients' interests, right to medicine and health (Moscou &Kohler, 2018).

Intelligence and Information: Intelligence and information are the data available to the regulators, health professionals and policymakers to aid decision-making. Intelligence and information have consequences on the selection of drugs for the essential medicine list (Lexchin et al. 2013 and Wiktorowicz et al. 2010). The establishment of a system to report ADR is one of the measures of solving the problem of intelligence and information (Moscou &Kohler, 2018).

Stakeholder Coordination: Stakeholder coordination in the pharmaceutical governance domain constitutes domestic and global actors that link up activities to strengthen the national regulatory authority for pharmacovigilance (Moscou &Kohler, 2018). The idea of stakeholder coordination

is emphasised by SDG17 which calls for strengthening multi-stakeholder partnerships to support sustainable development (Mackey et al., 2016).

Integrity: Integrity is where every process of decision-making and representation is specified. In governance with integrity, every process should be predictable, there should be a clear allocation of roles to individuals (Woods, 1999). Integrity mechanisms are: reward of government officials are based on merit, the existence of internal audits, existence of personnel policies among others (Scott et al. 2016).

Strategic Vision: It is when leaders of society have a broader and long-term view of every aspect of human development. That view is grounded on experience, the prevailing culture and the other complexities of society (UNDP, 1997 and Siddiqi et al. 2009).

Rule of law: Existence of a legal framework that is impartial. The law protects individuals against all forms of injustice and ensures accountability and transparency in society (UNDP, 1997 and Siddiqi et al. 2009).

4.4 Concept of Access

Accessibility is regarded as the extent to which there is a balance in terms of the attributes of a population and that of resources in the society (Donabedian, 1973 and Salkever,1976). Access is also regarded as performance relations between the population and healthcare resources where there may be a difference in terms of the factors that inhibit or facilitate healthcare benefits to the population (Bashshur et al., 1971). Aday & Andersen (1974) simply define access as being able to enter into the healthcare system. In another view, access is explained as the capacity of the population to demand and receive health care to obtain the expected health outcome (Frenk, 1992 and Margolis et al., 1995). Andersen (1995) also describes access as the outcome of a process

which passes through predisposing factors, enabling resources, and perceived and evaluated needs to the satisfaction of the health status of an individual. Access to health care may be regarded as the presence and availability of services, the readiness of the services for use and the extent to which services are used by patients and their continued reliance on the services for their effectiveness (Chapman et al., 2002). Also, access is viewed as the ability of a society or its segment to get health goods and services when needed (Khan & Bhardwaj,1994 and Haddad & Mohindra, 2002). Access is the use of health services by a person at the right time and in the right place to get the ultimate possible health needs (Millman, 1993 and Rogers et al., 1999).

Other studies explain access pointing out various dimensions that constitute access to health care. Penchansky & Thomas (1981) explain access as the extent to which the health needs of a population fit into the capacity and readiness of the healthcare provider to supply those services.

4.5 Dimensions of Access

Penchansky & Thomas (1981) view access as a bulky concept being disaggregated into five dimensions: availability, accessibility, affordability, acceptability, and accommodation. Timmreck (1987) also regards access as constituted by the availability and acceptability of health services. Examining the dimensions of access explained in the literature they all fall within the confines of the dimensions explained by Penchansky and Thomas (1981).

Availability: It is the extent of demand for services by clients compared to the existing services ready to be offered to meet the needs of the clients. It is about the adequacy of supply of all categories of healthcare resources to meet the needs of clients (Penchansky & Thomas, 1981). Donabedian (1973) regards availability as a supply side of health service and it is regarded as the capacity of healthcare resources to produce the required services. Availability is the presence of

the required services which are provided to meet the needs of patients (Humphreys et al., 1997 and Gulliford et al., 2002). Availability is the quantity and type of services compared to clients' needs (Young et al., 2000). Penchansky & Thomas (1981) measured satisfaction with availability by questioning clients about their confidence in being able to get medical care for themselves and their family when needed, satisfaction with the knowledge of where to get health care and satisfaction with the ability to get medical care in an emergency.

Accessibility: It is the physical distance a person will travel and the time he/she will use to travel to obtain health services (Aday & Andersen,1974 and Friedman & Basu, 2001). Accessibility is also explained as the geographical location of providers and that of the client. It takes into consideration clients' resources for transportation, transportation cost, the time and the distance to travel (Penchasky and Thomas, 1981; Humphreys et al., 1997 and Young et al., 2000). Satisfaction with accessibility is measured by satisfaction with the distance from home to the physician's office and the difficulty of getting to the physician's office (Penchasky and Thomas, 1981).

Affordability: It is being economically capable of accessing service (Humphreys et al., 1997). Those who are not financially capable to withstand the cost of seeking health care suffer higher rates of morbidity and premature mortality than those who are affluent (Ahmed et al., 2001). Affordability is marred by poverty and the absence of insurance to cushion the poor (Kataoka-Yahiro & Munet-Vilaro, 2002). Young et al., (2000) summarise affordability as the cost of a valued service on the financial prowess of a person to withstand the cost. Affordability is also regarded as the cost of services and deposit or insurance requirements on the client's income, ability to pay and the prevailing health insurance. Other concerns about affordability are the perception of the value of the service rendered, the cost of the service and the knowledge of clients about prices, the total cost of the service and the possible credit arrangement. Affordability is measured by the

client's satisfaction with the health insurance, satisfaction with prices and satisfaction with how soon to pay bills (Penchansky & Thomas, 1981).

Accommodation: It is related to how the provider has organised itself to receive the clients and how the client perceives the propriety of that organisation. It is about the appointment systems, hours of operation, walk-in facilities and telephone services. Also, accommodation is the social and organisational characteristic of a healthcare facility that can either enhance or obstruct clients from getting health care (Aday & Andersen, 1974). It is measured by satisfaction with the waiting time, satisfaction with physician office hours and satisfaction with the ease of getting in touch with a physician (Penchansky and Thomas, 1981).

Acceptability: It is more about the attitudes of the client and the provider. It is about the client's attitude towards the personal and practice characteristics of the provider, the real characteristics of the provider and the provider's attitudes towards acceptable characteristics of the client. It is how clients react to the age, sex, ethnicity, neighbourhood of the facility or religious affiliation of a facility or provider. Providers may not also be willing to serve certain categories of customers because of their financing mechanism (like welfare patients) or their social and personal characteristics. Providers may also make themselves more or less acceptable through accommodation. It is measured by questioning patients about their satisfaction with the office appearance, satisfaction with where the neighbourhood physician's office is located and satisfaction with the other patients one is seeking health care with (Penchansky & Thomas, 1981). The concept of acceptability is similar to that of health beliefs by Anderson (1995). According to Anderson, the knowledge, values and attitudes of people about health and health services are their health beliefs. These beliefs influence the perception of people's health needs and the use of healthcare services. Andrews et al. (2002) concluded in a study that the obstacle to access to the

services of a general practitioner by the Aboriginal population was the general practitioner's awareness of the environment that was discomforting to the Aboriginals in the waiting and consulting rooms.

Rational use: Where there is acceptability, adherence to medicine use will be appropriate. Rational drug use requires that the medications of patients must be the right doses that meet the patients' therapeutic needs within the period of treatment at a reasonable cost to the patient and the community (WHO, 1987). The view of the World Bank on the rational use of medicines is premised on two principles: 1. The use of drugs based on efficacy, safety and compliance which are scientifically proven. 2. Cost-effectiveness involved in the use of drugs based on the prevailing situation of the health system (Almarsdottir & Traulsen, 2005).

The pharmaceutical care process is complex, so there should be a relevant tool to enhance the investigations of the patterns of medicine use in healthcare facilities (Ofori-Asenso & Agyeman, 2016). Rational use of drugs may not mean the same to healthcare personnel and patients. What is regarded as rational use by healthcare personnel may be irrational to the patients and the opposite is true (Brahama et al., 2012). As a result, WHO has given the yardstick for the measurement of rational medicine use at health facilities. The indicators of rational medicine were classified into prescribing indicators, patient care indicators and health facility indicators among others.

> "[*The prescribing indicators are*]: *average number of medicines prescribed per patient encounter, percentage of medicines prescribed by generic name, percentage of encounters with an antibiotic prescribed, percentage of encounters with an injection prescribed, percentage of medicines prescribed from essential medicines list or Formulary*. [*The patient care indicators are*]: *average consultation time, average dispensing time, percentage of medicines dispensed, percentage of medicines adequately labelled, and percentage of patients with knowledge of*

> *correct doses*. [*The facility indicators are*]: *availability of essential medicines list or formulary to practitioners, availability of clinical guidelines and percentage of key medicines available"* (WHO, 1993).

In a simple view, excessive antibiotic use, polypharmacy, injection overuse, prescription without clinical guidelines, over or under-dosage, failure to prescribe by generic names and wrong self-medication are the common types of irrational use of medicines (WHO, 2002). Irrational use of medicine implies that the medicines used by patients are inappropriate for their clinical conditions the required doses for the therapeutic period are not also met and the cost of the drugs is high for the individual or the community (Long & Rybacki, 1995).

In conclusion, Penchansky and Thomas indicated that the dimensions of access are not easily separated. Accessibility and availability are so close that they are almost inseparable. This is because what is available is what is accessible. Also, the other concepts that can easily be merged are acceptability and accommodation. This is because, through accommodation, a provider may not be acceptable to a client. Therefore, the measurement of acceptability in this study includes the dimensions of accommodation. Also, the rational use of drugs is regarded as acceptability in this study. This is because accepting the processes at the dispensary will lead to accepting the medication regimen which leads to rational use.

4.6 Access to Medicines Frameworks

The literature on the concepts of access paved the way for the development of various frameworks of access to essential medicines. The well-known frameworks are the Centre for Pharmaceutical Management (CPM) (2003) framework, the World Health Organisation (WHO) (2004) framework, a framework by Frost & Reich (2010) and the one developed by Bigdeli et al. (2012) after an extensive literature review.

CPM (2003) presented a report, which was access to essential medicine framework, to the WHO The framework was based on the framework developed by Penchansky and Thomas (1981). It has pointed out availability, affordability, acceptability, and accessibility as dimensions of access to essential medicines.

Availability is determined by the supply of medicines; the type and quantity of medicines compared to the type and quantity of medicines demanded. Affordability is the price of medicines and the income and ability of patients to pay for the medicines. Acceptability is related to the characteristics of the medicine and services compared to the attitude and expectation of users about the medicines and the services rendered. Finally, Accessibility is described as the location of medicine supply about the location of a user of the medicines.

World Health Organisation (WHO) (2004) later developed another framework to deal with access to essential medicines. It is composed of rational use of medicines, affordability, sustainable financing and reliable health and supply systems. Rational use concerns developing well-informed national treatment guidelines and the development of an essential medicine list based on the treatment guidelines. The essential medicine list must be used for procurement, donations, training and supervision. Affordable prices are about allowing price competition, use of available impartial pricing, promotion of procurement of medicine in bulk and engaging in effective negotiation for new essential medicines among others. Sustainable financing is mobilising resources and having an efficient insurance scheme to minimise out-of-pocket expenditure on medicines. Reliable health and supply systems concern engaging in partnerships for medicines delivery, including traditional medicine in healthcare delivery and effective regulatory control to ensure the quality of medicines.

Frost & Reich's (2010) framework is generalised on health technology of which medicine is a component. It has four dimensions of access; architecture, availability, affordability and adoption.

Availability is about the manufacturing of the required health technology, forecasting is about the technology needs of the health sector in the near future, effective procurement and distribution of the technology and using the technology for proper healthcare delivery. Affordability concerns how health technology is affordable to the government and non-governmental entities as providers. The affordability of those two entities will certainly reflect how affordable the technology will be to the consumer. Another dimension is the adoption of technology at global and national levels. It includes adoption by providers and clients to ensure wider acceptance of the technology. All the dimensions are coordinated by the structures of the organisation to ensure access to health technology which is called architecture.

The framework by Bigdeli et al (2013) puts the individual and various levels of human grouping in a particular society at the core and deals with the analysis as demand-side obstacles to access. This is made up of individuals, households and communities. Health-seeking behaviour of individuals and households in communities has an impact on the demand for medicines.

The framework also analyses the interconnection of medicines, human resources, health information and health financing as determinants of access to medicine. At the national and international levels, the framework points out donors' agenda and funding, transparency, innovation and market forces as determinants of access to medicine. At the same national and international level, the framework suggests emphasising governance in the health system or even pharmaceutical level, national and international context. The governance is also expected to extend to the private health market.

4.7 Theoretical Framework

Institutional Theory is a framework that places emphasis on the formal and legal components of government structures in the process of policy-making. According to Kraft et al. (2007), it is a perspective that acknowledges the role of institutions in shaping public policy and highlights the importance of how formal rules, regulations, and procedures interact with the broader socio-political context in which they operate. In essence, Institutional Theory seeks to understand how these formal structures and processes shape the behaviour of individuals and organizations within the larger political system, and how they impact the outcomes of policy decisions. Institutional theory regards the social world as the composition of institutions. Institutions are established structures, rules and practices that guard the actions of people in society (Lawrence and Shadnam, 2008).

In order to gain a holistic understanding of institutional theory, it is necessary to take into account the various factors that influence the development of formal organisational structures. These factors include both formal and informal schemes, rules, norms, and routines, which over time become established as authoritative guidelines for social behaviour. This perspective is articulated by Scott (2008), who asserts the significance of these institutional structures in shaping the behaviour of individuals and organizations within a given social context.

When organization theory emerged, institutions were initially overlooked by researchers (Scott, 2008). In 1966, David Selznick emerged as one of the leading figures in the realm of institutionalization theory, a framework that elucidates institutionalisation as a process wherein values permeate organizational structures beyond mere technical requirements. Selznick posits that institutionalization serves as a variable that can be employed to differentiate between organisations that exhibit varying degrees of institutionalisation (Gomes et al. 2012). Selznick's theories posit

that an organization achieves institutionalization once it has reached a certain level of established status. This includes the development of a set of norms and values that are widely accepted and followed by all members of the organization. Institutionalization is a crucial stage in the development of organizations, as it allows them to gain legitimacy and social acceptance, which can enhance their reputation and ensure their long-term survival (Gomes et al. 2012).

In the early days of institutional theory, there was a significant focus on the actors within organizations. Researchers were particularly interested in the role that values and norms play in the institutionalization process. Additionally, there was a strong emphasis on studying micro or local environments, which helped to shed light on the specific factors that influenced the behaviour of organizations. Another key area of investigation was the constraints that organizations faced, which were often the result of political trade-offs and alliances. By exploring these various aspects of institutional theory, researchers were able to gain a more comprehensive understanding of the forces that shape organizational behaviour (Scott, 2008).

In 1977, John W. Meyer - a preeminent sociologist of his time - authored two seminal articles that would significantly impact the field of organisational theory. The first article, "The Effects of Education as an Institution," undertook an in-depth analysis of the role of education as a social institution, exploring how the institutionalisation of education shapes individuals' beliefs, values, and worldviews. The second article, "Institutionalised Organisations: Formal Structure as Myth and Ceremony," examined how formal structures within organisations create myths and symbols that legitimise their existence and activities.

These two articles laid the foundation for New Institutional Theory, a theoretical framework that places great emphasis on the importance of institutional structures and processes in shaping organizational behaviour. New Institutional Theory posits that organizations are embedded in

wider social, cultural, and political contexts and that institutional pressures and norms play a significant role in shaping organizational behaviour and outcomes.

The new institutionalists seek to understand how institutions are formed, sustained, and transformed over time. To achieve this, they draw on cognitive and cultural theories, which help them explore the role of ideas, beliefs, values, and norms in shaping institutional practices and structures. By analysing the complex interactions between individuals, organisations, and society, the new institutionalists provide a nuanced and detailed account of how institutions emerge and evolve, and of the factors that enable or constrain institutional change (Scott, 2008).

The configuration of organisations and their operational procedures are heavily swayed by socially constructed beliefs and rules. These beliefs and rules exercise a significant degree of control over various aspects of organisational behaviour, including their decision-making processes, communication strategies, and overall functionality. Meyer and Rowan's (1977) and Meyer and Scott's (1983) works provide valuable insights into the impact of these beliefs and rules on organisational behaviour and offer a framework to better comprehend how organisations function within a broader social context.

In modern societies, organisations are highly institutionalised in the context of policies, professions and programs which constitute a powerful tradition. Organisations regard the incorporation of their products and services, techniques, programs and policies to make their structures efficient and at the same time gain recognition, resources and stability for survival (Meyer and Rowan,1977).

The context in which organisations find themselves forces them to become similar to each other in form and practice – isomorphism (DiMaggio and Powell,1983). DiMaggio and Powell argue

that there are three isomorphic processes. They are coercive isomorphism, mimetic isomorphism and normative isomorphism.

Coercive isomorphism is a response to pressure from the government, other organisations or the cultural environment to align their structures similar to other organisations. Mimetic isomorphism is where organisations imitate the best practices that make other organisations successful. The imitation is mostly a result of uncertainty in goals, technology or the strategic dynamics of the field. Normative isomorphism is where organisations restructure themselves to meet standards and cognitive frameworks set and controlled by professional bodies. The processes of isomorphism can be reasoned as goal-targeted processes. In a field where certain firms like healthcare organisations have been able to ensure access to medicines whilst others face challenges in that angle, it becomes imperative for the isomorphic process to be triggered to achieve a fit similar to the successful organisations. This does not stifle innovation or flexibility to achieve the set goals.

Whilst DiMaggio and Powell (1983) explain their concepts as isomorphic processes, Scott (2008) expounded similar concepts as pillars of the institutional theory which can be conceived as dimensions of good governance. Those pillars are regulative, cognitive and normative pillars. The regulative component constitutes the prevailing rules and laws of the social environment that restrict certain behaviours and promote others. The implementation mechanisms and the key processes of the laws and rules are generally coercive. The regulative pillar of the institutional theory corresponds to the coercive isomorphism. The cognitive component of social institutions emphasises cognitions and the generally shared perception of actors about what is typical. The cognitive component of a society reflects the cognitive and symbolic structures shared by individuals in the society. The result of the cognitive component of institutions is the isomorphism of activities through processes that enhance the mimicking of activities with strong cultural support

(Scott, 2008). This also matches the mimetic isomorphism. The normative component is made up of the norms, values, assumptions and beliefs of a society that are shared by individuals in the society. An institution's normative component defines the propriety of the conduct of members of society. By this definition, the institutions influence the actions of individuals and organisations even without laws or rules (Scott, 2008). This is same as the normative isomorphism. Simply put, the regulative pillar is founded on rules and regulations, the normative component is guarded by morality and values and the cognitive dimension places emphasis on cultural concessions and shared understanding (Sandhu, 2018). These concepts explained by Scott (2008) and DiMaggio & Powell (1983) may be regarded as adaptable or flexible concepts in institutional theory. There will be codified rules and laws or policies that guide organisations and their members but the organisations will be required to inculcate the perceptions, expectations, norms and values of their clients to fashion out their strategies to achieve the organisational goals.

4.7.1 Application of the Theory in this Study

The institutional theory emphasises adaptation and flexibility of organisations in their environment to achieve the set target. This study is on how pharmaceutical governance influences access to quality medicines in Ghana. The dimensions of good governance used to measure the elements of the pharmaceutical life cycle share the same features as the pillars of institutional theory. The regulative, cognitive, and normative pillars (Scott, 2008) and coercive isomorphism, mimetic isomorphism, and normative isomorphism (DiMggio & Powel, 2008) of institutional theory correspond to the policy capacity, participation, and responsiveness respectively which are the dimensions of good governance in this study.

All healthcare organisations have a target of ensuring that healthcare is accessible to all those who need it. Several targets have been set from the Alma Ata declaration to the recent Sustainable

Development Goals which has one of the targets of ensuring UHC. Access to essential medicine happens to be a strong avenue through which UHC can be achieved. From the view of institutional theory, all healthcare organisations must go through isomorphic processes in their goals, technology and strategy and work towards achieving UHC.

Regarding the regulated prescription behaviour of health professionals and the affordability of medicine, there are policies that guide health professionals to prescribe medicines. Such policies are designed to be implemented to the latter to ensure equitable access to medicines by all categories of health seekers. This brings in the policy capacity of medicine prescription. One of the steps towards ensuring the policy capacity of an organisation is seeking expert support (Scott et al. 2016). The policies are the rules, regulations and guidelines. In this light, policy capacity works with coercive isomorphism (DiMaggio and Powel, 2008) and the regulative component (Scott, 2008) of institutional theory. The healthcare organisations are compelled to work within the policies designed by the government. Besides, there are pharmacists who are experts in the pharmacodynamics and pharmacokinetics of medicines. With coercive isomorphisms, the cultural environment can also compel organisations to draw towards being similar to each other. As a result, the organisational culture of having pharmacists conducting prescription audits has the potential to ensure access to quality medicines. Patients have rights and responsibilities which are christened as the Patient Charter in section 167 of the Public Health Act, 2012 (Act 851). The patients have the right to a 'second medical opinion'. This implies the patient needs to be consulted in the prescription process to know his/her financial muscle to afford certain medicines. The Charter is the guideline on how patients are handled at health facilities. The Patient Charter also reflects the coercive isomorphism (DiMaggio & Powel, 2008) and the regulative component (Scott, 2008) of institutional theory.

Also, in relation to medicine dispensing behaviour and rational use of medicine. There are expectations health seekers may have when they approach the dispensary to obtain their medicines. Most of such expectations are rooted in the culture of the people. The expectations are shaped by the norms, values and customs of the people seeking health care. In other words, the expectations emerge from the social institutions of the health seekers. As a result, good governance for medicine is expected to be responsive to the needs of the people. Responsiveness includes tying policies, strategies and programs to people's expectations (Moscou &Kohler, 2018). This links medicine dispensing practices and rational use of medicines to normative isomorphism (DiMaggio & Powel, 2008 and Scott, 2008) of the institutional theory. It explains that organisations come to be similar to each other based on professional standards or based on the norms, values, beliefs and customs of a society. This implies the pursuit of a goal of ensuring the rational use of medicine to achieve UHC must be guarded by the cultural domain of health seekers.

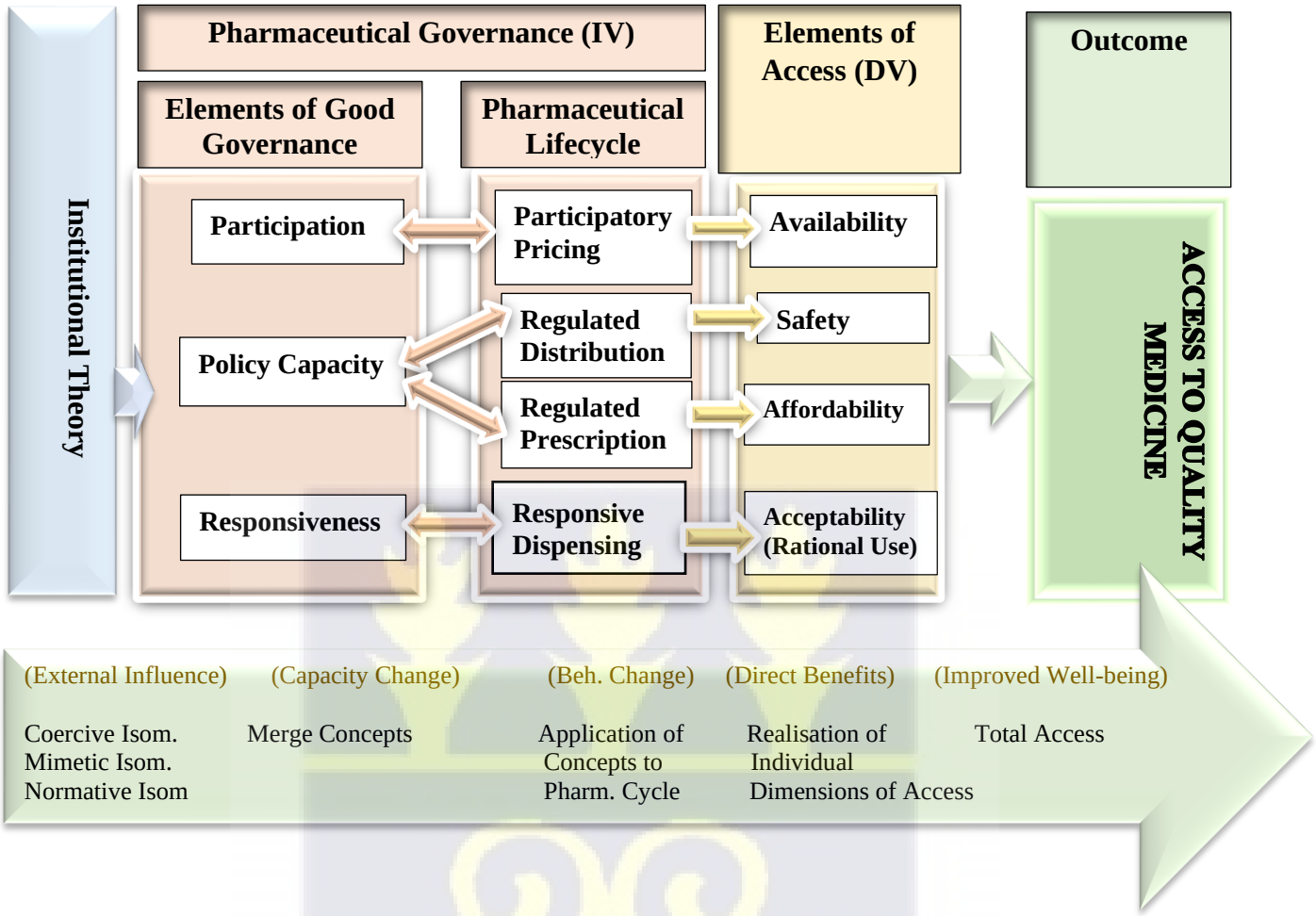
Regarding the objective of the medicine pricing policy and the availability of medicines, there are manufacturers and importers of medicines whose products are priced by a different entity. Also, there are medicine sales points whose prices are determined by another entity. This calls for participation in the pricing of medicines for the NHIS given that participation requires that those who are to be affected by decisions must get access to decision-making and have the power to obtain a meaningful stake in the work of institutions (Woods 1999). This is similar to mimetic isomorphism (DiMaggio and Powel, 2008) and the cognitive component (Scott, 2008) of institutional theory. Medicine manufacturers and distributors are all significant actors in the access to medicines conundrum. Therefore, their cognition about reality will enhance the isomorphism that targets access to essential medicines for UHC achievement.

Lastly, the functions of medicine regulators for the quality of medicines were carved by legislation that created the regulatory bodies themselves. The regulatory bodies are given the authority and prescribed resources to ensure the quality of medicines. That is what policy capacity is about. This is also similar to coercive isomorphism (DiMaggio and Powel, 2008) and the regulative component (Scott, 2008) of the institutional theory. Regulations made by the government are the tools that give regulatory bodies the authority and guidance to clean the pharmaceutical environment of SF medicines. The government equally provides the regulatory bodies with the required resources to function effectively. The isomorphic process to meet regulatory standards is enhanced by the government with laws and resources.

4.8 Conceptual Framework for the Study

The study was conducted within the context of institutional theory. The components of the theory pointed out by DiMaggio & Powel (2008) and Scott (2008) are regarded as being analogous to the **elements of good governance** in this study. Those elements are **responsiveness**, **policy capacity** and **participation**. The model also contains an aspect of the **pharmaceutical lifecycle**. They are **participatory pricing**, **regulated distribution**, **regulated prescription** and **responsive dispensing**. Application of the dimensions of good governance by the health sector stakeholders to the pharmaceutical lifecycle is what is described as **pharmaceutical governance**. This constitutes the **independent variable (IV)** for the study. Also, access to medicine is measured by certain dimensions. The dimensions selected for this study are **availability**, **safety**, **affordability** and **acceptability (rational use)**. Therefore, access to medicines constitutes the **dependent variable (DV)** in this study. Good governance of the pharmaceutical lifecycle will have effects on access to medicine which will then have an **outcome** of **access to quality medicine.** The conceptual framework for the study is shown in Figure 2 below.

Figure 2: Conceptual Framework for the Study with the Flowchart of the Theory of Change



Source: Constructed by the author from the literature review, 2023

In line with the objective of this study, the model explains the relationships between the variables of the study. On the objective of examining the influence of regulated prescription on the affordability of medicines, the model indicates that formulation and implementation of the medicine prescribing regulations, and administrative guidelines (Policy capacity) to regulate medicine prescribing behaviour of healthcare professionals will lead to the affordability of medicines. However, if there are no realistic policies or if such policies are poorly implemented, there will be a challenge of medicine affordability especially among the destitute. These are

examined within the context of coercive isomorphism or regulative components of institutional theory. In explaining the objective of medicine pricing policies and availability of medicines to the subscribers of the NHIS, the model indicates that participation by the stakeholders in the decision-making process of the medicine prices will let there be a convergence pricing which will enhance the availability of the medicines at healthcare facilities for the subscribers of the NHIS. However, if sole conclusive decisions are made in the pricing of medicines, some medicines may not be stocked or made available at healthcare facilities for subscribers of the NHIS. This objective was examined within the context of mimetic isomorphism or the cognitive component of institutional theory. In examining how medicine regulatory authorities function to ensure the safety of medicines in Ghana, the model indicates that formulation and implementation of the right policies on medicine distribution will lead to the safety of medicines in Ghana. If not, unsafe medicines will be abundant in the country which is an affront to the target of access to quality essential medicines. This objective was also examined within the context of coercive isomorphism or the regulative component of the institutional theory. Lastly, with respect to the objective of examining the responsive dispensing behaviour and its influence on the rational use of medicines, the model points out that if there is responsiveness to the expectations of patients at the point of medicine dispensing, people will accept the medicines and use them rationally. If not, there will be an abundance of irrational use of medicines. This objective was examined within the context of normative isomorphism.

4.8.1 Theory of Change

The bottom part of the conceptual framework is a chart flow of the theory of change. Socially constructing reality and COM-B theories of change have been applied to explain the conceptualisation and operationalisation of the concepts in the conceptual model to get the outcome. In the idea of Barrett et al. (1995), all organisations are socially constructed. That is, the discourse between people in a society brings up words that become socially accepted. Those words then become concepts that create real organisations. The creation of words can be viewed as adopting words from other social fields and operationalising them to create the desired outcome. Also, the Mayne (2018) COM-B model has various levels of change; from activities to improved well-being. Those levels are influenced by external factors. The levels suitable for the conceptual framework of this study were those selected.

From the extreme left of the flow chart is **external influence**. The external influences in this study are the postulates of institutional theory. The components of the institutional theory are **coercive isomorphism, mimetic isomorphism and normative isomorphism**. These are external because they are not an integral part of a health system but they can influence activities in the system. The second from the left is **capacity change**. In this study, when the external factors lace with dimensions of good governance in the health sector, it mentally prepares the stakeholders in the health sector to deliver the required services. This implies a change in the capacity of the actors whose functions will yield good results. The third is **behavioural change**. As a result of a change in capacity, there will be a change in how various levels in the **pharmaceutical life cycle** are governed in a positive direction. The fourth is a **direct benefit**. The behaviour change will yield a preliminary result of realising the individual **dimensions of access** which will be benefited directly by health seekers. The last in the chart is **improved well-being**. The ultimate point is getting safe

medicines for health seekers. So, the collective realisation of the individual dimensions of access will lead to **total access to quality medicines**.

4.9 Summary of the Chapter

Table 5: Concept of Governance

Author(s) and Year	Meaning of Governance
Rosenau (1992)	Governance is backed by shared goals that may not necessarily emerge from formal legal authority
Commission on Global Governance (1995) and Dodgson et al. (2002)	Governance constitutes the ways common affairs are managed by individuals and institutions. It is a process by which differences are settled and common actions may be taken. It includes the application of both formal rules and informal arrangements that work to meet the common goal of different segments of society.
Chhotray and Stoker (2009)	Governance is more about negotiations and settlements on the outcome not necessarily a stereotype determination of outcomes.
McGuire (2010)	Governance is regarded as a concept at the system level (macro level) driven by networks whereby each network constitutes several nodes (organisations) that have many linkages collaborating on different activities.
Brinkerhoff and Bossert (2008)	Governance establishes rules which assign roles and responsibilities to actors in the society. The rules go further to shape the interactions among members of a society. Health system governance is the establishment of rules that dictate policies, programs, and activities related to public health functions within institutional boundaries.
United Nations Economic and Social Commission for Asia and the Pacific [UNESCAP] (2009)	Governance is simply the process of decision-making and implementation.
Grin (2006)	There are two key aspects of governance: i) the intended goal that must be pursued and ii) the process that is best for the achievement of the goal
Siddiqi et al. (2009) and Peters & Muraleedharan (2008)	Health system governance involves other stakeholders like communities, civil society organisations, private providers, pharmaceutical companies and development partners that strengthen the regulations in a country.
Anello (2008)	Pharmaceutical governance is an aggregate of the functions of the Ministry of Health, private entities, Medicine Regulatory Agencies, professional organisations and health facilities backed by laws, policies and administrative manuals through the

	pharmaceutical life cycle to ensure access to safe, effective and affordable medicine in a country.

Table 6: Elements of Good Governance

Element	Author(s) and Year	Meaning
Transparency	Woods (1999)	Transparency requires that decisions that are made and are yet to be made and the processes involved in making those decisions must be made known to the public
	USAID (2013) and WHO (2007)	Transparency requires that citizens are made aware of the reasons behind public policy decisions taken, the procedure involved in making the decision, the arguments for and against the decision and the criteria used to settle on that decision among the alternatives
Accountability	Pico et al. 2017	Accountability is the obligation of a government to take responsibility for its expected functions and the outcome of its efforts in the performance of those functions
	Mulgan, 2003	Accountability depends on transparency. Accountability has two dimensions: being answerable to the people and being ready to face the consequences when there is a dissatisfactory performance of the functions
Participation:	Woods (1999)	The meaning of participation is that those who are to be affected by decisions must get access to decision-making and have the power to obtain a meaningful stake in the work of institutions
	Bishop & Davis (2002) Bucek & Smith (2000) Weeks (2000)	A deliberative form of decision-making is achieved and strengthened through participation. Through deliberation and contestation of ideas, better policy outcomes, transparency and equity are realised
Responsiveness	UNESCAP (2009)	Responsiveness requires a timely response to the real needs of people
	Moscou &Kohler, (2018)	Responsiveness is regarded as policies and regulations that address drug safety issues within a reasonable time
Effectiveness and Efficiency	UNICAP (2009)	Effectiveness and efficiency are regarded as the production of the expected results by institutions while making reasonable use of resources at their disposal
	Moscou &Kohler, 2018	effectiveness and efficiency are regarded as the capacity to evaluate the relevance of

		pharmacovigilance policies and monitor the extent to which the pharmaceutical industry complies with the regulations of the post-market drug safety
Policy Capacity	Forest et al. (2015)	The ability of an organisation to design a policy to match the resources when trying to achieve a set objective.
	Scott et al. (2016)	Specific resources that are available for policy formulation and implementation are what is known as policy capacity

Table 7: Concept of Access and Dimensions of Access

Concept	**Author(s) and Year**	**Meaning**
Access	Frenk (1992) and Margolis et al. (1995)	access is explained as the capacity of the population to demand and receive health care in order to obtain the expected health outcome
	Chapman et al. (2002)	Access to health care may be regarded as the presence and availability of services, the readiness of the services for use and the extent to which services are used by patients and their continuous reliance on the services for their effectiveness
	Khan & Bhardwaj (1994) and Haddad & Mohindra (2002)	Access is viewed as the ability of a society or its segment to get health goods and services when needed
	Penchansky & Thomas (1981)	Access is the extent to which the health needs of a population fit into the capacity and readiness of the healthcare provider to supply those services.
Availability	Penchansky & Thomas (1981)	Availability is the extent of demand for services by clients compared to the existing services ready to be offered to meet the needs of the clients. It is about adequacy of supply of all categories of healthcare resources to meet the needs of clients
	Humphreys et al. (1997) and Gulliford et al. (2002)	Availability is when the required services are present and are provided to meet the needs of patients
Accessibility	Penchasky and Thomas, (1981) Humphreys et al., (1997) and Young et al. (2000)	Accessibility is about the geographical location of providers in relation to that of the client. It takes into consideration the client's resources for transportation, transportation cost, the time and the distance to travel.

	Aday & Andersen (1974) and Friedman & Basu (2001)	It is the physical distance a person will travel and the time he/she will use to travel to obtain health services
Accommodation	Penchansky and Thomas (1981)	It is about how the provider has organised itself to receive the clients and how the client perceives the propriety of that organisation. It is about the appointment systems, hours of operation, walk-in facilities and telephone services.
	Aday & Andersen (1974)	It is the social and organisational characteristics of a healthcare facility that can either enhance or obstruct clients from getting health care
Affordability	Humphreys et al. (1997)	It is being economically capable of accessing service
	Penchansky & Thomas (1981)	It is the cost of services and deposit or insurance requirements about the client's income, ability to pay and the prevailing health insurance.
Acceptability (Rational Use)	Penchansky & Thomas (1981)	It is more about the attitudes of the client and the provider
	Anderson (1995)	It is the health beliefs of people which influence their perception of health needs and use of healthcare services.
	WHO (1993)	Indicators of rational use relating to dispensing are average dispensing time, percentage of medicines actually dispensed, percentage of medicines adequately labelled, and percentage of patients with knowledge of correct doses.
	Long & Rybacki, (1995)	Rational use is the appropriate use of medicine by patients for their clinical conditions and the use of required doses of medicines for the therapeutic period.

Table 8: Elements of Institutional Theory

Author (s)	Elements	Meaning
DiMaggio and Powell (1983)	Coercive isomorphism	Organisations respond to pressure from the government, other organisations or the cultural environment to align their structures similar to other organisations.
	Mimetic isomorphism	Organisations imitate the best practices that make other organisations successful.
	Normative isomorphism	Organisations restructure themselves to meet standards

		and cognitive frameworks set and controlled by professional bodies.
Scott (2008)	Regulative Component	The prevailing rules and laws of the social environment restrict certain behaviours and promote others.
	Cognitive Component	Cognitions and the generally shared perception of actors about what is typical
	Normative Component	It is made up of the norms, values, assumptions and beliefs of a society that are shared by individuals in the society

CHAPTER FIVE

Research Methodology

5.0 Introduction

This chapter constitutes the research paradigm which guided the research method used to conduct this study. It also contains the research design for the study, the sampling procedure, the sample size, the data sources, the data collection procedure, data processing and the procedure for data analysis.

5.1 Research Paradigms and Justification

Researchers have their worldviews which are reflected in their assumptions. Therefore, a worldview which is collectively held by a community of researchers is called a paradigm (Su, 2018). A research paradigm sheds light on some investigation areas (O'Sullivan & Irby, 2014). Broom & Willis (2007) regard a paradigm as beliefs and practices which are common among a group of researchers. Research within that group is regulated by those beliefs and practices. In the idea of Kuhn (1996), a paradigm makes provision for a procedure to investigate a designated problem to generate a solution within a period. Aliyu et al. (2015) argue that people associate themselves with paradigms based on their commitment to a particular philosophical stand. It is therefore reasonable to claim that the research paradigms are the atlas that direct researchers in their quest for knowledge.

In management, like other sectors, the research paradigms are categorized into objectivism and subjectivism (O'Sullivan & Irby, 2014). These two major categories have been described as a continuum's opposites with different kinds of philosophical positions between them (Holden & Lynch, 2015). Objectivism is a natural science approach to studying reality in their field. This

approach has been adopted by social sciences to study the social world because of its success in the natural sciences. However, subjectivism developed as a criticism of the position of objectivism (Holden & Lynch, 2015). Different labels have been given to objectivism and subjectivism depending on a particular field of study. They are named positivism and phenomenology by Easterby-Smith et al. (2008). However, Hughes & Sharrock (1997) named them positivism and interpretivism. Whilst positivism is the same as objectivism, interpretivism is the same as subjectivism. Between the two major paradigms are other hybrid paradigms like post-positivism, realism, critical theory and pragmatism which take their touch from the flames of positivism and interpretivism (Holden & Lynch, 2015). Research paradigms emanate from various research philosophies. Those philosophies are about the nature of reality (ontology), how reality can be known (epistemology) and the position of the researcher about societal values in the process of knowing (axiology) (Aliyu, et al 2015).

5.1.1 Positivism

French philosopher Auguste Comte (1798–1857) is regarded as the founder of the idea of positivism (Su, 2018). Comte's work indicates that society has passed through three successive stages: the theological, the metaphysical, and the positive stages. This idea of positivism is broadly explained through various phases by different schools of thought in academic history. A study of human behaviour either in health service management or other social sciences now recognises positivism as one of the research paradigms (Su, 2018).

The ontology of positivism is there is an objective reality. reality is under the control of fixed natural cause-effect laws. Positivists believe that the world is made up of unchangeable pre-existing orders that can be discovered (Tuli, 2010). Positivists also believe that reality is generalisable, independent and external to humans (Aliyu et al., 2015; Tuli, 2010). From the view

of positivists, reality is something that people can use their senses to observe and that observation can be expressed in factual statements by the observers (Weaver & Olson, 2006). Also, positivists assume that the existence of the physical and social world is an external reality and that reality can be understood through generalisations beyond time and context. This kind of generalisation will capture the essence of reality (Krauss, 2005). According to Saunders *et al*. (2009), since objectivism is how social entities exist independent of social actors, health service management can be viewed as being objective.

The position of positivists implies that what is in existence in the world is objective, that is what they call reality. Reality is independent of the human mind; therefore, it is external. Reality is objective in the physical world as well as in the social world. That reality is discoverable by all human beings through their senses and that discovery can be manifested in factual statements.

The epistemology of positivists is that the world can be known, therefore, seeking knowledge must be done in an objective way (Tuli, 2010). Positivists maintain that Knowledge can be described systematically. According to them, knowledge is made up of verified hypotheses that can be regarded as facts and such hypotheses can be proven the same for large groups of people or in many situations. Therefore, knowledge can be said to be accurate and certain in such a situation (Aliyu et al., 2015). According to O'Sullivan & Irby (2014), the positivist paradigm emphasises empirically driven randomized controlled studies.

Positivism assumes that since reality is knowable then it is measurable. It uses the scientific method to develop abstract laws to describe and predict patterns and employs quantitative methodologies to test hypotheses (Broom and Willis, 2007). The positivist research paradigm assumes that reality is ordered, predictable and ultimately knowable through objective measures and rigorous application of the scientific method (Tuli, 2010).

According to Flowers (2009), the position of positivism is a derivative of natural science. Its fundamental feature is the testing of hypotheses developed from existing theory through the measurement of observable social realities. This position of the positivists assumes that the social world exists objectively and externally and what can be valid knowledge is the knowledge based on observations of that external reality. They also hold that there are universal laws or theoretical models that can be developed and those laws or models can explain cause-and-effect relationships which will end up predicting outcomes (Tuli, 2010). According to positivists, their postulates are based on values of reason, truth and validity (Holden & Lynch, 2015). They purely focus on facts which they gather through direct observation and experience and measure empirically using quantitative methods and statistical analysis (Saunders et al., 2007).

The axiology of positivism is that an objective view of society is free from the values, moral judgement and ideological stands of the observer. An objective is that society provides views which are not coloured by the values of the researcher (Haralambos & Holborn, 2004).

Positivists always emphasise that research should be undertaken, as far as possible, in a value-free way (Saunders et al., 2009). The assumption is that 'the researcher is independent of and neither affects nor is affected by the subject of the research' (Mackenzie & Knipe, 2016:9). It is frequently advocated that the positivist researcher will be likely to use a high-structure methodology to facilitate replication (Wahyuni, 2012). Furthermore, the emphasis will be on quantifiable observations that lend themselves to statistical analysis.

Consistent with the dominant, traditional approaches in the natural sciences, objectivist axiology assumes that the phenomenon under investigation and the investigator have an independent relationship (Weaver and Olson, 2006). In the positivist paradigm, the object of study is independent of researchers (Krauss, 2005).

5.1.2 Interpretivism

Whilst positivists believe that reality is objective, interpretivism believes that reality is subjective. Saunders et al. (2009) indicate that interpretivism originated from two sociological traditions: phenomenology and symbolic interactionism. Phenomenology refers to how human being understand their social and physical environment (Haralambos & Holborn, 2004). On the other hand, symbolic interactionism is about the process human beings are involved in interpreting the social world around them. This includes how humans interpret the actions of others whom they interact with which brings about changes in their meaning and actions (Haralambos & Holborn, 2004). According to O'Sullivan & Irby (2014), interpretivism assumes that reality is subjective, for that matter, it keeps changing concerning context and time. As a result of this, there is no ultimate truth. Interpretivists hold that reality is socially constructed. This brings about multiple and varied interpretations of reality (Tuli, 2010). These imply that interpretivism is denying the existence of objective reality.

According to Saunders et al. (2009), interpretivism advocates that one must comprehend the variance among humans in their role as social actors. The phrase 'social actors' is very relevant in this context. Saunders et al. examined human behaviour through the lens of theatre which suggests that humans play their part on the stage called human life. Humans interpret their everyday social roles by the meaning they give to these roles they play in life. Humans also interpret the social roles of others by their own set of meanings.

Blaikie (1993) indicates that there is a fundamental difference between the subject matters of natural and social sciences. According to Blaikie, in the social world, individuals and groups have been able to understand situations based on their exposure, memories and expectations. As a result, meaning is constructed and from time to time, it is constantly re-constructed through experience

which leads to many different interpretations of the social world (Flowers, 2009). The multiple interpretations create a social reality which serves as a basis for people's actions (Flowers, 2009). Therefore, in the idea of interpretivism, it is very important to decipher and understand those meanings and the contexts in which the meanings are formed. These determine and affect the interpretations reached by different individuals. According to Saunders et al. (2009), the subjectivist (interpretivism) view is that social phenomena are created from the perceptions and the resultant actions of social actors. They believe that the creation of social phenomenon is not an event, it is a continuous process. Through the process of social interaction these social phenomena are constantly revised. This view is emphasised by Mackenzie & Knipe (2016) that social constructionism looks at reality as being constructed by human society. They believe that social actors such as clients of a health facility, may place many different interpretations on the situations in which they find themselves. Therefore, individual clients will perceive different situations in different ways as a result of their view of the world. These different interpretations are likely to affect their actions and the nature of their social interaction with others. In this sense, the clients interact with their environment and they also seek to make sense of it through their interpretation of events and the meanings that they draw from these events. In turn, their own actions may be seen by others as being meaningful in the context of these socially constructed interpretations and meanings.

According to Aliyu *et al*. (2015), the world is not simple, it is also dynamic and it is constructed, given meaning and experienced by people in their interactions with each other and with the social world at large. People experience reality in different ways. Aliyu *et al* believe that reality can only be grasped in certain circumstances using language to define what a particular reality is.

The epistemology of interpretivism is that knowledge cannot be obtained by observing human behaviour externally (Mackenzie & Knipe, 2016). According to Haralambos and Holborn (2004), the interpretivist perspective argues that what the social and natural sciences study are different. Consequently, it is inappropriate to use the methods and assumptions of the natural sciences to study humans. Largely, the matter is the focus of the study of natural sciences. Understanding and explaining the behaviour of matter is possible by observing externally. A researcher has no business examining the consciousness of atoms and molecules because they do not have it (Haralambos and Holborn, 2004). Similarly, meanings and purposes that determine behaviour cannot be found in atoms and molecules. External stimuli only make matter simply react unconsciously. Based on that, scientists can examine and give meaning to the behaviour of matter to explain it (Haralambos and Holborn, 2004). There is no need to think of the conscience and logic of matter because it does not exist. Contrary to the features of matter, human are conscious of their environment, they give meaning to what they experience and also have intentions and are aware of their existence. As a result, humans put up meaningful actions. So, human behaviour cannot be understood by externally observing him (Haralambos and Holborn, 2004).

Aliyu et al. (2015) noted that knowledge is based on subjective beliefs, values, reasons, and understandings not only on observable phenomena. Knowledge is constructed. Knowledge is about how people make meaning in their lives. Qualitative research methodology is what interpretive researchers use to study social realities (Cohen et al., 2000). The qualitative research methodology treats people as research participants and not as objects as in the positivist research approach. This emphasis can be an empowering process for participants in qualitative research, as the participants can be seen as the writers of their history rather than objects of research (Chia, 2002).

Interpretivists hold that there cannot be a value-free science in society. They argue that the various theories about society are, in part, influenced by value judgement or the ideological stands of the scientists. They believe human society is shaped more by historical circumstances rather than the objective view of the reality of social life (Haralambos and Holborn, 2004).

Blaikie (2000) contends that there cannot be absolute objectivity in social research. This is because social research involves so many choices. As a result, the opportunity for researchers' values and preferences to influence the process makes it difficult to ultimately achieve true objectivity. Interpretivists also argue that the researcher is a unique individual and that all research is essentially biased by each researcher's perceptions. There is no point in trying to establish validity in any external or objective sense (Saunders et al. 2009).

5.1.3 Pragmatism

Examining the philosophical stands of positivism and interpretivism, the study has adopted pragmatism. The paradigm is distilled from the two polar paradigms which have been the progenitors of the high-breed paradigms.

The ontology of pragmatism is that reality is not stagnant, it is renegotiated and interpreted based on the context of its usefulness (Lincoln et al., 2018). Pragmatism refuses to join the 'paradigm war' between the positivist and interpretivist research philosophies (Tashakkori & Teddlie 1998). A pragmatic approach emphasises critical analysis of facts, applications and outcomes rather than abstraction and verbal solutions (Kelly & Cordeiro, 2020). Pragmatism is not committed to any of the research paradigms. It focuses on the needs of the research problem at hand (Creswell, 2003). Early pragmatists have not accepted the notion that social researchers have to use a single scientific method to access the truth about the real world (Mertens, 2007). As a result, the pragmatic

paradigm regards the research problem as a determinant of the approaches to social research (Mertens, 2007). This approach is further reflected in the data collection and analysis methods without any philosophical loyalty to any alternative paradigm.

Pragmatist supporters start with the research question to determine their research framework instead of questioning ontology and epistemology as the first step (Biesta, 2010). Even though, knowledge is found in the real world in which humans live and experience, it is also constructed through human interactions among themselves and with their environment (Johnson & Onwuegbuzie, 2004). The argument of pragmatism is that experience is needed to attribute meaning to an event (Denzin, 2012). Relying on absolute truths is not the goal of pragmatism. To understand the world, research underpinned by a pragmatic paradigm makes use of the experience of the people as the basic means to construct knowledge to understand the world (Hildebrand, 2011). The view of Dewey is that the construction of knowledge is done by human interactions with their environment, which he names 'transaction realism' (Biesta & Burbules, 2003).

Dewey, from 1927 advocated for micro and macro studies to produce valuable knowledge. A lot of emphasis was placed on studies of people's experiences as well as institutions. Dewey (1927) explained institutionalization as the vital process of integrating something into the established norms, customs, and habits of a group or organization. This involves the development of well-organized and standardized methods and procedures that become an integral part of the group's daily practices. Institutionalization is critical because it enables ideas and beliefs to be transformed into political forms that can be more effectively implemented. Essentially, political experience cannot be fully understood through ideas and beliefs alone; they must be translated into institutional structures to have meaning (Dewey,1927). As Dewey (1941) astutely observed, ideals

that are not embodied in institutions are of little value. This underscores the significance of giving attention to institutions in the knowledge production process.

In his writings, Dewey (1941) emphasizes that institutions that are successful and able to thrive over time are characterized by stability and endurance. This stability is not absolute, but rather relative, since institutions serve as the structural foundation for the processes that take place within them, and are not imposed from external sources. In other words, successful institutions are characterized by an internal coherence that allows them to maintain their stability and adapt to changing circumstances, rather than being subject to external forces that disrupt their functioning. Based on the postulates of Dewey, some pragmatists emphasise that researchers should regard research philosophy as a continuum, instead of a categorical option that stands in opposite positions (Kelemen and Rumens, 2012). Wahyuni (2012) also believes that objectivist and subjectivist perspectives are not mutually exclusive. Hence, a mixture of ontology, epistemology and axiology is not out of place in an attempt to understand social phenomena.

Hughes & Sharrock (1997) stated that several contemporary realists and empiricists are pragmatics; they are not bordered by a particular ontology and epistemology. Their focus is on a particular problem they want to confront in their investigations. If the most important thing to researchers is the appropriate method for a research problem, then a philosophical stance is not relevant. Therefore, there is no need for a researcher to feel bound to any paradigm. Also, there is no doubt that the nature of philosophy and its relationship to other forms of knowledge is itself a matter of philosophical debate. So, there is no need for one to advocate for any position about a paradigm in social research (Hughes & Sharrock, 1997). The longing to pinpoint efforts to deal with practical problems in the physical world using research is what gave birth to the pragmatic paradigm (Feilzer, 2010).

In the process of knowledge production, pragmatism is with the view that research can focus on understanding real-world problems instead of engaging in philosophical debates about the features of reality and truth (Patton, 2005). With pragmatism, researchers can sideline the metaphysical debates and give attention to the exploration and understanding of the interconnectedness between knowledge and action based on the context of the study (Biesta, 2010). The validity and intrinsic value of methods and methodologies are not relevant issues to the pragmatist. Pragmatism puts emphasis on researchers placing value on the relevance of the methodologies and methods to sail society from the world of theory to the world of practice and vice-versa (Kelemen and Rumens, 2012). Contrary to the research philosophies that emphasize the nature of reality, pragmatism emphasizes the nature of experience (Morgan, 2014). Whilst positivism and interpretivism are entrenched in their philosophical underpinnings, pragmatism emerged with an alternative that takes its touch from both polar philosophies. This makes pragmatism a flexible and reflexive chaperone to study design (Feilzer, 2010).

5.1.4 Justification for the Use of Pragmatism

The focus of this study is to find out the influence of pharmaceutical governance on access to medicine. Pragmatism makes a provision for an action-centred research framework. This gives the researcher an impetus to deal with practical issues that emanate from the community by making use of the right methods to find answers to the research questions (Hothersall, 2019). The pragmatists believe that there is a clear link between knowledge and experience (Hildebrand, 2011). That is why pragmatism is chosen for this study.

Besides, pragmatism makes use of a suitable method to study the prevailing real-world problem (Brierley, 2017 and Andrew & Halcomb, 2007). That is, pragmatism permits the usage and mixture of different sources of data in an inquiry to arrive at a dependable conclusion (Hall, 2013). This

makes pragmatism the right paradigm for mixed method research (Creswell, 2015). Access to medicines is one of the key aspects of healthcare delivery and it is a major problem in one way or the other across the world. Therefore, the paradigm that can fit the conduct of a study in that sector is pragmatism. This will permit the use of more than one data source to address the research questions.

Finally, pragmatists believe in the use of the scientific method of enquiry and it is also aligned with the values of a democracy (good governance) (Miller et al., 1996). The physical and social worlds, which include culture, language, institutions and subjective reasoning, are regarded as important in the knowledge construction process by pragmatists (Johnson & Onwuegbuzie, 2004). These attributes of pragmatism are common with that of the institutional theory which is the theoretical context in which this study was conducted. Besides, Dewey (1927) advocates for the study of people's experiences as well as institutions. This indicates that the study of institutions includes how the institutions transform to make an impact on the experiences of individuals. This further explains the rationale for conducting this study in the context of pragmatism paradigm and the theory of institutionalism

5.2. Validity

Validity is the extent to which the tools for data collection measure what the research is designed to measure (de Souza et al., 2017). This implies that a valid instrument is likely to produce the findings the study is designed to find. Validity can be classified into content validity and construct validity. Content validity is the extent to which the study instruments measure the constructs that the study proffers to measure. Construct validity is the extent to which the variables for the study reflect the constructs the study is measuring (Polit, 2015).

The development of the instrument for this study emanates from the variables that constitute the constructs of the study. Therefore, there is no variation between the content of the instrument and the constructs of this study. For example, one of the constructs of this study is the prescription behaviour of medicine prescribers. Some of the questions designed to measure the prescription behaviour of medicine prescribers in the context of this study are: whether the prescriber informed the patient about the price of the medicine, whether the prescriber found out the financial strength of the patient, whether the prescriber directly sold the medicine to the patient and whether the prescriber directed the patient to his or her agent to buy the medicine. The supervisory team which is made of seasoned academics and experts in governance assessed the content validity of the instrument before data collection was done.

Also, the literature was reviewed to come up with the specific variables that measure the constructs of this study. For example, one of the constructs for the study is the acceptability (rational use) of medicine. The variables which came from WHO (1993) and Penchansky and Thomas (1981) to determine acceptability and accommodation (rational use) is knowledge of the patient about the medicine dosage (information about dosage and side effects), waiting time at the dispensary, organisation of the dispensary, attitude of dispensary personnel and communication between the dispensary staff and health seekers.

5.3 Reliability

It is the degree to which the same results will be obtained if the instrument used for a study is used in another space and time. It is about internal consistency (de Souza et al., 2017). The questionnaire was tested and among 30 potential respondents of the study to verify the stability of the study (Keszei et al., 2010). Besides, the respondents to the questionnaire were those who sought healthcare weeks prior to the data collection. This was supposed to avoid recall bias. This sampling

measure will also ensure the reliability of the study. Generally, other statistical measures used in the study to ensure reliability are shown in the data analysis subsection below.

5.4 Trustworthiness

Trustworthiness is related to qualitative study which concerns the credibility, transferability, dependability, and confirmability of a study. It corresponds to the internal validity, external validity/generalisability, and objectivity of quantitative studies.

Regarding credibility, an interview guide was developed from the review of previous studies in the field. However, respondents were not confined to the questions in the interview guide. They were allowed to speak their minds on issues about their experiences at the health facilities they attended. Also, the social environment of the study is not strange to the researcher. The values, norms, and customs of the people being interviewed are very familiar to the researcher. Besides, there were familiarisation visits to the health facilities selected for the studies. The official procedure involved in data collection at the facilities was thoroughly explained to the researcher. All those procedures were followed before the commencement of data collection. Therefore, there was trust between the researcher and the respondents during the data collection. The respondents opened up to discuss their experiences, the institutional procedure, relationships between various stakeholders, and the challenges. Also, there was no bias in the selection of respondents. Even though the selection of health seekers was purposive, the purpose was based on their experience at the health facilities in the process of health seeking. Also, the health facilities selection was based on the experiences of health seekers; where most of the health seekers shared their experiences about the health facilities selected for the study. The respondents at the hospitals were pharmacists. In all the selected hospitals, the directors of pharmacy granted the interviews themselves. No personal relationship determined the selection.

In addition, the data came from three sources. Health seekers and pharmacists were interviewed, and documents on pharmaceutical policies in Ghana were also reviewed. So, there was a triangulation of data where each source checked the other. Participation in the study was voluntary, the essence of the study was explained to the respondents and their consent was sought before commencement of data collection. Therefore, no respondent was forced to fabricate an experience he/she never had. Interestingly, follow-up questions were asked to probe further on the responses given. This was done to ensure the authenticity of the responses given. Also, there was frequent debriefing on the study. There were periodic departmental seminars where the researcher presented proposals. Subsequently, progress reports were presented up to the end of the study. Similar presentations were made to the supervisory committee. All these eliminated most of the potential researcher biases in the study. There was also member checking to eliminate bias. The interviews were recorded with a voice recorder. Transcription was initially done by the researcher. A senior lecturer in a public university was also given the voice recording to transcribe. The two transcriptions emerged as same. All the measures taken to ensure transferability, dependability and confirmability of this study are explained in the research method section below.

5.5 Research Method

The method used for this study is a mixed method. A single study or series of studies that involve quantitative and qualitative data collection, analysis and interpretation of the same underlying phenomenon is called mixed method research (Leech & Onwuegbuzie, 2009). The use of mixed methods indicates the emergence of a new era in social science where the combination of quantitative and qualitative methods was not imagined by the historical controversies (Tashakkori & Teddlie, 2003). Both quantitative and qualitative methods have their strengths and weaknesses.

Therefore, the use of mixed methods will avoid the shared weaknesses of both mono-methods and derive a lot of benefits from their strengths.

When a mixed method is used, findings from the qualitative study can assist in identifying heterogeneity that has not been observed in quantitative data and the explanatory variables that were not earlier on known. Also, improperly understood quantitative findings can be illuminated by results from a qualitative study in a mixed method. Again, the absence of validity in a quantitative measurement can be discovered by qualitative study in a mixed method. This is because there is corroboration of findings from the qualitative and quantitative data when a mixed method is used. In addition, in a mixed method study, the quantitative method can give a wider view of the context of a study and variations at the macro-level. However, the qualitative component of the study will delve into the local knowledge of the society that can give specific explanations for the phenomenon under study (Udo, 2006).

Furthermore, quantitative and qualitative data answer different questions in a study. Whilst quantitative data give information about what the prevailing phenomenon is, qualitative data explain why those phenomena prevail. Therefore, the mixed method produces such informative studies. Ultimately, the small sample size in a qualitative study may lead to hazardous generalization. However, such weakness is compensated by quantitative study in the use of mixed methods with a relatively big sample size (Udo, 2006). Therefore, a mixed method is chosen for this study to derive the advantages of both quantitative and qualitative research methods.

The quantitative and qualitative data are presented in two different chapters but they are mixed in the analysis and discussion chapter for the purpose of triangulation. The logic behind the mixing of the quantitative and qualitative data is corroborative (Jennifer, 2006). This implies the two data sets corroborate each other in the discussion section.

5.5.1 Research Design

The research design for this study is a fully mixed sequential equal status design. This mixed method research design involves the use of both quantitative and qualitative research procedures sequentially in at least one of the following in a single study of a particular phenomenon: (i) the study objective, (ii) the type of data and the procedure involved in the data collection, (iii) the method involved in the data analysis and (iv) the sort of inferences that can be made from the data collected. In such a study, the weight given to the quantitative and qualitative data is equal (Leech & Onwuegbuzie, 2009). The design is a cross-sectional research design.

5.5.2 The Study Population

"A population is a complete group of entities within which a researcher wants to explore, understand or predict a social phenomenon" (Boateng, 2020:142). The study population in this research is the FDA, NHIA, health institutions, itinerant medicine distributors and all those who sought health services from the health institutions. The health institutions include hospitals, clinics, health centres, Community Health-Based Planning Services (CHPS) compounds, community pharmacies and over-the-counter (OTC) medicine retailers.

5.5.3 Sampling and Sampling Techniques

5.5.3.1 *The Research Field*

The study was conducted in the Northern region which is found in the Savanna ecological zone. The Savanna ecological zone leads all the ecological zones in the incidence of poverty in Ghana. The poverty incidence of the urban savanna in 2016/2017 was 24. 9 and that of the rural savanna was 67.7 (Ghana Statistical Service [GSS], 2018). This implies the Savanna ecological zone's poverty incidence was 46.3, almost twice the national average. The rural savanna ecological zone

contributed about 50 per cent to total poverty in Ghana in 2016/2017 (GSS, 2018). It was therefore regarded prudent to conduct this study in that zone since poverty is proven to hurt access to medicines.

The study intended to find out how the governance of the pharmaceutical sector can affect access to quality medicines in Ghana. Even though there are five regions in the Savanna ecological zone, the Northern region was selected for the study due to the following reasons. 1) There was a decline in health insurance coverage in the Northern region from 48.7 per cent in 2020 to 40.77 per cent in 2021. This shows an 8.07 per cent reduction. This reduction is more than that of Bono East which also experienced a decline of 1.51 per cent within the same period (Ministry of Health [MoH], 2022). The health insurance is supposed to make health care and quality medicine accessible to all. So, a decline in its subscription was regarded as a phenomenon that could help enrich the findings of this study. 2) the Northern region remained the only region in the country that did not experience an increase in Outpatient Department (OPD) attendance per person per year from 2018 to 2021. The OPD visits rather declined in the region from 0.64 in 2018 to 0.55 in 2021, the lowest in 2021 (MoH, 2022). This was another phenomenon of interest to a study on pharmaceutical governance and access to medicines which could not be found in any other region of Ghana. 3) The Northern region happens to have one of the teaching hospitals in Ghana, in the context of the decline in the health statistics mentioned above, the experience of health seekers at all levels of healthcare delivery was regarded as important and might provide unique information for policy formulation through recommendations of this study. Those reasons made the region suitable for studies on pharmaceutical governance and access to medicines. Therefore, the sampling technique used to select the zone and the region for this study was purposive. They were

selected because of their special features which have the potential to enrich the findings of this study (Taddlie & Tashakkori, 2009).

The Northern region has 16 districts. The districts were stratified into rural, peri-urban and urban. The rural districts were further stratified into rural municipalities and rural districts. Out of the 16 districts, 12 can be classified as rural districts, 3 as peri-urban districts, and 1 as an urban district based on the population distribution of the districts as presented by GSS (2021). If the population of a district is concentrated more in the rural area of a district, the district is classified as a rural district. If it is concentrated more in the urban area, the district is regarded as a peri-urban district. If a district does not have a rural population at all, that district is regarded as an urban district. This classification was done for this study. Based on the classification, Tamale Metropolis was the only urban district in the Northern region. Therefore, the Metropolis was selected for the study because of its urban status. Out of the 3 peri-urban districts, Yendi Municipality was randomly selected for the study. Finally, Gushegu municipality and Mion districts were also randomly selected for this study as rural districts. Therefore, a stratified sampling technique was used to select the districts for the study.

5.5.3.2 The Quantitative Data

For the quantitative data, those who sought health care not later than two weeks to the day of the data collection constituted respondents for this study. This category of respondents was targeted to avoid recall bias. The sampling technique used to select respondents was cluster sampling. The clusters were Electoral Areas (EAs). Tamale Metropolis had 41 EAs, Yendi Municipality had 30 EAs, Gushegu Municipality had 25 EAs and Mion District had 20 EAs. The total number of EAs in the selected districts was 116.

The 30 by 7 cluster sampling technique used by WHO for immunisation programme evaluation was adopted but modified to suit this study. With this technique, 30 clusters are selected from the region where the evaluation is going to take place and a minimum of 7 respondents are interviewed in every cluster. This means the sample size for the region is 210 which is estimated to be ±10 percentage points of a true population percentage (WHO, 1991). The requirements for the use of this cluster sampling procedure are the following: choosing a specific geographical area for the study, knowing the target population, selecting clusters randomly and selecting the starting point randomly (Milligan et al, 2004). In a situation where the target population may be high, the sample can be made more informative by increasing the number of clusters or by increasing the sample size in the clusters (Singh, 2007). In this study, a 31 by 16 cluster sampling technique was used. As a result, 31 clusters were selected using simple random sampling to allow every cluster to have an equal chance of being selected. Given that the districts had different numbers of EAs, 26 per cent of the EAs were selected in every district to constitute the 31 clusters required. Therefore, 11 clusters were selected in Tamale Metropolis, 8 were selected in Yendi Municipality, 7 were selected in Gushegu Municipality and 5 were selected in Mion District. The data collection started at the centre of each cluster. A residential unit was randomly selected in the centre of the cluster, and anyone in that residential unit within the target population was approached to answer the questionnaire. After that, the data collector then moved to the next residential unit in any chosen direction up to the outskirts of the cluster. In each cluster, 16 respondents were selected. After that one additional respondent was added in every district to get a rounded figure. This made the number of clusters selected in every district proportional to the total number of clusters in the district. Therefore, 177 respondents were selected in Tamale Metropolis. In Yendi Municipality, 129 respondents were selected. In Gushegu Municipality, 113 respondents were selected and 81

respondents were selected in Mion District. The sampling technique used to select the respondents in the selected clusters was convenience sampling.

5.5.3.3 The Qualitative Data

In order to obtain qualitative data from the health seekers, respondents who demonstrated much experience in the process of seeking health care from health facilities were purposely selected for in-depth interviews. Their telephone numbers were taken and arrangements were made and met them later for the interviews. In the Tamale Metropolis, 15 participants were interviewed, in Yendi Municipality, 10 were interviewed, in Gushegu Municipality, 8 and in Mion District, 7 participants were interviewed. The numbers selected were based on the saturation reached during the interviews.

Similarly, Hospital pharmacists and managers of community pharmacies in some hospitals and community pharmacies in the selected districts were also selected as key informants. The selection of the health institutions for the study was based on the outcome of the survey. The hospitals and community pharmacies that most of the respondents shared much experience about were those selected for in-depth interviews of their pharmacists and managers respectively. This means the sampling method used to select those hospital pharmacists and the managers of the community pharmacies was purposive. In Tamale Metropolis, the Teaching Hospital, a private hospital and five community pharmacies were selected. In Yendi municipality, the Municipal hospital, one private hospital and one community pharmacy were selected. In Gushegu Municipality, the Municipal hospital and one community pharmacy in the Municipality were selected for the study. Besides, two itinerant medicine sellers; one in Tamale and one in Yendi were also purposively selected as key informants for in-depth interviews. A summary of the samples selected is shown in **Table 9** below.

Table 9: Samples of Health Seekers and Medicine Outlets

District	Number of Clusters Selected	Sample of Health Seekers		Selected Health Facilities				IMS#
		Quant.	Qual.	Tertiary Hospital	Municipal Hospitals	Private Hospitals	CP*	
Tamale Metropolis	11	176+1	15	1	-	1	5	1
Yendi Municipality	8	128+1	10	-	1	1	1	1
Gushegu Municipality	7	112+1	8	-	1	-	1	-
Mion District	5	80+1	7	-	-	-	-	-
Total	31	500	40	1	2	2	7	2

* Community Pharmacies. # Itinerant Medicine Sellers

Source: ***Compiled by the author from the field data***, 2023

5.5.4 Data Sources

Generally, the sources of data for this study were both primary and secondary. The primary data was obtained from health seekers, pharmacists of hospitals, managers of community pharmacies and itinerant medicine sellers. The secondary data was obtained from a desk review of the FDA guideline for registrations and inspections, FDA 2018 to 2022 annual reports, FDA data on medicine recalls, FDA 2020 to 2023 Drugs Lens, NHIA Medicine List, Public Health Act, 2012 (Act 851) and Koduah et al. (2023).

Specifically, data on prescription behaviour and its influence on the affordability of medicines were obtained from health seekers, pharmacists of hospitals and managers of community pharmacies. The data obtained from the pharmacists were the involvement of pharmacists in the prescription process, the existence and use of the Essential Medicines List and the Standard Treatment Guidelines. The data obtained from the community pharmacies was the role of the community pharmacies in prescribers' medicines sales and the information obtained from the

health seekers was the involvement of medicine prescribers in selling medicines to them and involvement of the patients in the prescription process. Data on the affordability of medicines was obtained from health seekers.

Besides, data on medicine dispensing practices were obtained from the dispensaries of hospitals, community pharmacies and those who sought healthcare from the health facilities. Data on the rational use of medicines was obtained from those who sought healthcare from health facilities. In addition, the source of information for the medicine pricing policy was obtained from the NHIA, the pharmacists of the government hospitals and Koduah et al. (2023). Data on the availability of medicines was obtained from the hospitals' pharmacists, managers of community pharmacies, and those who sought healthcare from the NHIA-accredited health facilities. Also, data on the functions of medicine regulatory authorities to ensure the safety of medicines were obtained from a desk review of the FDA guideline for registrations and inspections, FDA 2018 to 2022 annual reports, FDA data on medicine recalls, and FDA 2020 to 2023 Drugs Lens and the Public Health Act, 2012 (Act 851). The data sources on the safety of medicines were the health seekers and both public and private medicine outlets.

5.5.5 Data Collection

5.5.5.1 *Quantitative Data*

Part of the primary data is quantitative data. As a result, a survey was used to collect it. The use of social surveys is geared at quickly providing data on urgent prevailing problems in a community. Therefore, the necessity of a social survey is paramount when the required accurate and reliable data cannot be obtained anywhere without much expenditure of time, energy and financial

resources (Kumekpor, 2002). On this basis, a survey was chosen to efficiently use the limited time and financial resources available for this study to obtain very accurate and reliable data.

The instrument used for the survey was a questionnaire developed by the researcher from the literature review. Six research assistants who were all teaching assistants at the University for Development Studies (UDS) assisted in the data collection. The questionnaire was converted to a Google form. The form was shared through WhatsApp with selected respondents who could fill it out independently to do so. However, the researcher and the assistants administered the questionnaire to respondents who either did not have the facility or expertise to fill the form on their own. This hastened the data collection and secured the data in the collection process. Pretesting of the questionnaire was done in a peri-urban municipality with 30 respondents before the commencement of the survey.

5.5.5.2 Qualitative Data

In-depth interviews were used to collect the qualitative data. The rationale for the use of Key informants' interviews is that detailed information was needed for clarification and corroboration of the responses in the survey. The tool used for the collection of the qualitative data was an interview guide. The selected participants for the interview were met at their convenience time by the researcher for the interviews. Each interview lasted for an average of 30 minutes. A recording device was used to record the interviews. The interview guides were also tested in one public and one private hospital, a pharmacy and five health seekers in the same peri-urban municipality. A lot of alterations were made to the entire study before the commencement of the data collection in the selected districts.

5.5.6 Data Processing and Analysis

5.5.6.1 *The Quantitative Data*

The quantitative data collected was deposited in Excel and edited. The data was then loaded into SPSS version 21 for analysis. Descriptive statistics were used to explain the proportions of various responses. Probit Regression Model was used to analyse objectives one and two. The Model indicates that the probability of access to medicine, with respect to objectives one (affordability) and two (rational use), is expressed as follows:

$P(y=1/x) = G(\beta_0 + x\beta)$. Where:

$P(y=1/x)$ = The probability of $y=1$ given x

y = The response variables

G = A standard normal cumulative distribution function.

β_0 = Constant

x = A vector of covariates. Regarding objective one the covariates are **prescription behaviour** (involvement in the prescription process and involvement in medicine sales by prescribers) and that of objective two, they are **dispensing practices** (waiting time, organisation, information about medicine dosage, information about potential side effects, attitude and communications).

β = The coefficients to be estimated.

The goal of this study was to explain the influence of x on the response probability $P(y=1/x)$, where $y = 1$ if there was access to medicines and $y = 0$ otherwise. Prior to the Probit Regression estimations, a Spearman Correlation was conducted to find out the relationship between the dependent variables and the independent variables for objectives one and two. In addition, percentages were used to point out the quantum of availability of medicines to the subscribers of

the NHIS. This compared the subscribers who had the medicine in the process of seeking healthcare and those who could not get it but bought the same medicines at the accredited healthcare facilities. In addition, percentages were used to explain the number of those who experienced adverse drug effects (ADE) after medication use, where those medicines were obtained and who advised the health seekers to consume those medicines. This analytical approach was used because all the variables were measured at the nominal level.

5.5.6.1a Dependent Variable: Access to Quality Medicines

Access to quality medicine, which is the dependent variable in this study is measured by several dimensions. The dimensions explained by CPM (2003) are availability, affordability, acceptability accessibility and quality of products. WHO, (2004) also view rational use of medicines, affordability, sustainable financing and reliable health and supply systems as the dimensions of access to medicines. The dimensions pointed out by Frost & Reich (2010) are architecture, availability, affordability and adoption. These dimensions are extensively explained in the concept of access section in chapter four of this thesis. However, the dimensions of access adopted for this study as measurements of the dependent variable are affordability, safety, availability, and acceptability (rational use).

Affordability is when the lowest-paid unskilled government worker does not require extra money to buy a monthly treatment regimen of medicine after taking care of all the basic needs in the month. This is measured by using the wage of the lowest-paid unskilled worker, the sum of the cost of basic needs mentioned in the country's National Poverty Line and the price of the daily dose of medicines (WHO, 2019). It will not be wrong to deduce from the above definition of affordability that, in the case of every individual in society which includes those who are self-employed and the unemployed, affordability is the ability to withstand the cost of medicine for a

treatment regimen without an experience of any form financial shock. That is borrowing, selling an asset or forgoing another important self or household expenditure to acquire the medicine.

Regarding **rational use** of medicine, excessive antibiotic use, polypharmacy, injection overuse, prescription without clinical guidelines, over or under-dosage, failure to prescribe by generic names and wrong self-medication are the common types of irrational use of medicines (WHO, 2002). This definition forms the basis for the description of rational use in this study. Therefore, rational use in this study means completion of the dosage given in the prescription, taking the right dosage, taking the medicine at the time it should be taken and not engaging in self-medication.

With respect to the **safety** of medicines, when drugs are wrongly administered, they produce negative effects. That is called an adverse drug reaction (Alomar, 2014). However, when medicines have not gotten the required scrutiny and get into the market, or are not properly handled in the distribution process, they become unsafe to the consumer (Tauqeer, 2019). In such a situation, unsafe medicine may be toxic and produce an adverse effect (Aronson & Ferner, 2005). This makes it logical to measure the prevalence of unsafe medicine by using the adverse effects of the medicine among those who consumed it. It then follows from the ideas of Tauqeer (2019) and Aronson & Ferner (2005) that **safety** is a dimension of access to medicine. Access is ensured when the right medicine is taken and it serves the purpose for which it was taken. However, if unsafe medicine is taken access is not achieved.

Finally, medicine **availability** is mostly measured from the supply side. Medicine is available if it is found in the facility on the day a data collector visits that facility in question (WHO, 2019). Similarly, this study measures availability by the willingness of the supplier to give out the medicines to the patient. Therefore, availability is when a health seeker obtains a medicine at a

facility after the prescription is done. If the medicine is present in the health facility but has not been dispensed to the health seeker for any reason, the medicine will be declared unavailable.

All the dependent variables were measured at the nominal level. Therefore, they are dummy variables.

i. **Affordability** (*Aff*) is the ability of a person or his/her guardian to withstand the cost of medicines at ease without borrowing, selling an asset or forgoing other important basic needs. If the patient has been able to afford the medicine, *Aff* =1, otherwise 0

ii. **Rational Use** (*RU*) measures the acceptability of medicines. It means completion of the dosage given in the prescription, taking the right dosage, taking the medicine at the time it should be taken and not engaging in self-medication. If there is rational use, *RU* = 1 otherwise 0

iii. **Safety** is the use of medicine that does not end up with **adverse drug effects** (*ADE*) and may solve the health problem for which the medicine was taken. Therefore, *ADE* is the proxy that measures the safety of medicines. If there is an adverse drug effect, *ADE* = 1 otherwise 0

iv. **Availability** is when the medicine is given to a health seeker after the prescription is done.

All the dimensions of the independent variables were measured from the perspective of health seekers.

5.5.6.1b Independent Variable: Pharmaceutical Governance

Studies in the United Kingdom and Austria revealed that when medicine prescribers at the same time served as medicine dispensers, expenditure on drugs increased between 4.5 to 33.2 per cent

(Bodnar et al., 2018 and Ahammar & Zilic, 2017). Also, among the factors being considered in medicine prescription are patient factors. Therefore, prescribers are urged to involve patients in the prescription process (Ofori-Asenso & Agyeman, 2016). The financial strength of a patient may be known and an appropriate prescription can be done to ensure the affordability of the medicine prescribed. Based on these, the prescription of medications based on the established regulations is key. So, the regulated prescription behaviour in this study is made up of involvement in the medicine sales by a prescriber (*InvMS*) and involvement of the patient in the medicine prescription process (*InvP*). It is the independent variable of *Aff*.

Also, WHO (1993) put out a measure of rational use of medicine which includes patient care indicators. The indicators among others are the "percentage of medicines adequately labelled and percentage of patients with knowledge of correct doses". In this case, knowledge of the correct dose may include understanding the expected minor side effects of the medicine. However, drawing from the idea of acceptability and accommodation of a health product by Aday & Andersen (1974) and Penchansky and Thomas (1981), rational use of medicine, from the patient's perspective can be influenced by the dispensary staff being responsive to the waiting time at the dispensary, organisation of the dispensary, attitude of dispensary workers and the communication patterns of the dispensary workers. These form the bases for the selection of waiting time (*SatiWt*), organisation of the dispensary (*Org*), information about medicine use (*InfD*), information about the side effects of the medicine (*InfSE*), the attitude of dispensary workers (*Att*), and communication patterns of the dispensary workers (*Comm*) as the independent variables of *RU*.

Also, the NHIA has the task of coming up with the medicine list and prices of those medicines for the NHIS. Ministry of Health, as an overarching body in the health sector also procures medicines

for use by public sector health facilities. The extent to which the relevant stakeholders participate in the pricing may influence the availability of medicines at health facilities.

Additionally, National Medicine Regulatory Authorities have the responsibility to carry out surveys on the market to evaluate the quality, safety and efficacy of medicines (Ndomondo-Sigonda, 2017). This implies that a well-functioning regulatory system minimizes the prevalence of unsafe and poor-quality medicine in the market. That is why the prevalence of unsafe medicines at the medicine outlets was chosen as the independent variable of ADE.

Regulated prescription behaviour and responsive dispensing practices were both measured at the nominal level; therefore, they are binary variables and their measurements were 1, 0 measurement.

i. ***InvMS*** means involvement of a prescriber in the sale of medicines to the patient. Either the prescriber directly sells the medicine to the patient or has directed the patient to a particular medicine outlet, besides the dispensary of the health facility where the prescription is made, to buy the medicine. This was measured by finding out from the patient or his/her relative how they bought the medicine and whether the prescriber was involved in the sale of the medicine. If a prescriber was involved in medicine sales InvMS = 1 otherwise 0.

ii. ***InvP*** also means consulting the patient to know his financial capacity to buy a particular medicine, which price may be high, before prescribing it. This was measured by finding out from the patient if the prescriber informs him/her about alternative medicines that could be prescribed, the estimated cost of the medicine to be prescribed and if the prescriber asks him/her about his/her ability to purchase certain medicines. So, if the prescriber involves the patient in the prescription process, InvP = 1 otherwise 0.

iii. ***SatiWt*** means the time spent by a health seeker at the dispensary before getting to the counter to collect medicine. This was measured by the patient's satisfaction with the time

they spent at the dispensary before getting to the counter to collect medicines. The independent variables were measured at the nominal level. As a result, they are binary variables. If the patient was satisfied with the waiting time at the dispensary, SatiWt = 1 otherwise 0,

iv. ***Org*** means how the dispensary is organized to receive patients or their relatives whilst waiting to collect their medicines. This includes the appointment systems and availability of seats for the patients and their relatives. This was measured by satisfaction with the reception and procedure involved in the medicine collection process. If the patient was satisfied with the organisation of the dispensary, Org = 1 otherwise 0.

v. ***InfD*** means the depth of information given to the patient or his/her relative about the dosage of the medicine. This was measured by examining the understanding a patient or his/her relatives had about the medicine's dosage and the satisfaction of the patient with the dosage information given to him/her by the dispensary personnel. If the patient was satisfied with the information given to him/her, InfD = 1 otherwise 0,

vi. ***InfSE*** means the extent of information given to the patient or his/her relatives about the expected side effects of the medicine and the consequences the patient will face if the dosage is not strictly followed. This was measured by the understanding of the patient or his/her relatives about the side effects of the prescribed medicine. If the patient/relative was satisfied with the information given by the dispensary personnel about the side effects of the medicine InfSE = 1 otherwise 0.

vii. ***Att*** means the respect accorded to the patient or the patient's relatives by the dispensary personnel. This was measured by the patient or patient's relative satisfaction with the

attitude of those personnel. If the patient/relatives were satisfied with the attitude of the dispensary personnel *Att* = 1 otherwise 0.

viii. Lastly, ***Comm*** means communication patterns by the dispensary personnel to the patient or patient relative. That is whether the dispensary personnel spoke the language the medicine receiver understood, whether the personnel were audible to ensure that the information they were given was properly heard. This was measured by the medicine receiver's satisfaction with how the dispensary personnel communicated to them. If the medicine receiver satisfies with the communication patterns of the dispensary personnel *Comm* = 1 otherwise 0.

5.5.6.1c Control Variables

What eases access to medicine is health insurance coverage. Therefore, the concept of affordability by Penchansky & Thomas (1981) indicates that there is access when clients are satisfied with the health insurance scheme. Besides, affordability is said to be marred by the absence of health insurance coverage to cushion the poor (Kataoka-Yahiro & Munet-Vilaro, 2002). In this light, health insurance coverage is chosen as the control variable because all things being equal, the involvement of the prescriber in medicine sale and the non-involvement of the patient in the prescription process will not influence affordability if the patient obtains the medicine under the NHIS. Therefore, the control variable in *Aff* is obtaining medicines under the NHIS.

This control variable will be measured by finding out from the patient if the medicine obtained was given to him/her as an NHIS subscriber. This means that the variable will be measured at the nominal level. If the patient obtained the medicines as NHIS subscriber Control = 1 otherwise 0.

Also, drugs can be abused. A study in a Nigerian university revealed the prevalence of abuse of drugs by students to withstand academic challenges (Okafor, 2020). Abuse of drugs comes with different kinds of unsafe consequences. Using data from an online medicine distribution platform, Liu & Bharadwaj (2019) found that, there was a 14.9 per cent rise in admissions for treatment of drug abuse, violence resulting from drug abuse also increased by 5.7 per cent and a 6.0 per cent increase in death from an overdose of drugs in United States of America (USA). On these bases, those who intentionally abuse drugs and experience adverse effects are not classified as those who consume unsafe medicines. That category of respondents is in the control group of *ADE*. The control variable will be measured by questioning the respondents to establish whether there was an intentional abuse of drugs or otherwise. If the person intentionally abused drugs, control = 0, otherwise 1.

5.5.7 The Qualitative Data

The interviews were conducted either in Dagbani or English. The researcher translated the interviews conducted in Dagbani into English language. All the voice recordings were transcribed using Microsoft Word. Therefore, the transcribed interviews were saved as Word document. The transcripts were uploaded to Voyant tools. A theoretical thematic analysis approach was adopted as a method of analysing the qualitative data. Specifically, Braun & Clark's (2006) approach was utilised to identify and develop themes from the data set, while keeping the research questions in mind. The identified patterns were subsequently grouped according to the research questions, as the primary objective of the data analysis was to address those questions. Statements in the data that were irrelevant to the research questions were omitted to ensure that the analysis was focused and concise.

The steps outlined by Braun & Clarke (2006) were used for the thematic analysis. The **first** step is familiarisation with the data. After the data was transcribed by the researcher, he went through it several times for a better understanding of the data. The **second** step is the coding of the data. The Voyant tools gives the frequency of the words used in the data. The words and phrases with many frequencies which were relevant to the research questions were selected as codes. The **third** step is theme searching. The codes were used to get the patterns of the data. Braun & Clarke (2006) indicated that there are no specific rules regarding what a theme is. What can be regarded as a theme is its relevance to the research questions. Several codes were examined and some of the statements corresponding to the codes were put together to form themes. At the end of theme searching the codes generated broader patterns which reflected the research questions of the study. The themes identified described patterns of the data which were germane to the research questions. Therefore, the themes can be regarded as descriptive themes. Each code either corresponded to one response or several responses. The **fourth** step is reviewing themes. At this stage, all the data relevant to each theme was put together. The data was examined again to check its relevance to the themes it is associated with. In this step sub-themes were developed. The patterns that constituted the sub-themes either corresponded to one or more codes. For example, the data on regulation of medicine prescription had a theme labelled as *Working with regulations*. This theme came up as a result of the emergence of three sub-themes which are *Standard treatment guidelines, Essential medicine list and prescription audits*. The sub-themes also came from the codes which were repeated words being used in the data. These sub-themes can be described as organising themes for the main theme. The **fifth** step is defining and naming the themes. The themes and the sub-themes were then given labels. In this light, many codes with their corresponding data could

be labelled under a sub-theme which also constituted the themes which were also labelled. Table 10 below is an example of codes and their sub-theme labels and theme labels.

Table 10: Theme Labels, Sub-theme Labels and Codes

Codes	Sub-theme Labels	Theme Labels
Rejection Acceptance	Standard treatment guidelines	Working with Regulations
Relevant Irrelevant	Essential Medicine List	
Utilisation Defiance	Prescription Audits	

Source: Developed by the author from the field data, 2023

The last step is writing up. The write-up was organised based on the themes and the sub-themes which were also organised in line with the objectives and the research questions of this study. Presentation and analysis of the data were done using the themes and the sub-themes.

To enhance the credibility of the qualitative data, **member checking** was done during the data analysis. The respondents were contacted on phone for clarification of some of the statements they made. Interpretations given to their statements by the researcher were also posted to the participants as questions. Where they disagreed with an interpretation, that interpretation was deleted and those analysis they confirmed were those used in this study.

5.5.9 Ethical Concerns

Ethical clearance with protocol number **ERH 072 23-24** was obtained from the Ethics Committee for Humanities (ECH), University of Ghana. During the data collection, oral consent was obtained from the respondents before the commencement of data collection. Respondents were informed of their right to stop the interview when they wished to do so during the interview. The privacy of respondents was protected during the data collection and presentation. Respondents were also

informed that they would not be benefiting directly from this study. However, the study may influence policy amendments or formulation which will trickle to the respondents.

Before the commencement of data collection at the health facilities, a letter was written to the Chief Executive of Tamale Teaching Hospital (TTH) and the Northern Regional Director of Ghana Health Service (GHS). The letter introduced the researcher and requested them to give administrative assistance to the researcher to collect data in their health facilities. The Directorate of Research at TTH and the Northern Regional Director of GHS wrote to the relevant unit and the health facilities respectively informing them of their approval and also requesting them to give the researcher the necessary assistance to collect the data.

5.5.10 Summary of the Chapter

Researchers have their worldviews which are reflected in the way they conduct their studies and interpret their findings. These worldviews are research paradigms. There are two extreme postures regarding research paradigms. There is positivism which is vehemently opposed by interpretivism. Between the two are middle-range paradigms that lit their torch the two paradigms that are opposed to each other. One of those paradigms in the middle is pragmatism. This shares the features of both positivism and interpretivism. This study was conducted within the context of pragmatism. A mixed method was used for the study. The study was conducted in the Northern region because it is found in the Savanna ecological zone which has a very high incidence of poverty. Northern regions also experienced a decline in health insurance coverage and OPD attendance. A cluster sampling procedure was used to select individual respondents and purposive sampling was used to select health facilities for the study. A survey was used to gather the quantitative data and in-depth interviews were used to gather the qualitative data. Pharmaceutical policies and

administrative guidelines were also reviewed. Descriptive statistics was used to analyse the quantitative data and thematic analysis was used to analyse the qualitative data.

CHAPTER SIX

PRESENTATION AND ANALYSIS OF THE QUALITATIVE DATA

6.0 Introduction

This chapter aims to provide a detailed analysis of the qualitative aspect of the data collected during this study. The specific objectives of the study were to: firstly, examine the medicine prescription behaviour of health professionals and how it influences the affordability of medicine in Ghana, secondly, examine medicine dispensing practices and how they influence the rational use of medicines, thirdly find out how medicine pricing in Ghana affects the availability of medicines to the subscribers of the National Health Insurance Scheme at the health facilities and fourthly, examine how the medicine regulation authority ensures the safety of medicines in Ghana. The qualitative data is derived from both primary and secondary sources. It is then presented and analysed per the pre-defined objectives of the study and the research questions formulated to guide the research process. To better understand the data and extract meaningful insights, the data is grouped into themes based on the objectives of the study. The analysis is then conducted using these themes that emerged from the data. This approach helps to provide a more systematic and structured overview of the qualitative data, which is essential to drawing meaningful conclusions and making informed decisions based on the findings of the research.

6.1 Prescription Behaviour and Medicine Affordability

The first specific objective of this study was to analyse the prescription behaviour of healthcare professionals in Ghana and how it influences the affordability of medicines for patients. To gain comprehensive insights, the study examined this behaviour from three key perspectives: Firstly, it examined the policies that serve as guidelines for medicine prescription in Ghana. Secondly, it

focused on the degree of patient involvement in the prescription process and thirdly, it examined the involvement of prescribers in medication sales. The study sought to examine the extent to which the prescribers behaved in conformity to the prescription guidelines and any potential influence these prescription habits may have on the affordability of medication for patients. In order to achieve this objective, the data collected in line with this objective was developed into codes, themes and theme labels. The data analysis was then based on the themes.

6.1.1 Medicine Prescription Regulation

In Ghana's healthcare industry, there are policies in place to regulate healthcare providers in prescribing medicines. One such policy is the Standard Treatment Guidelines (STG). These guidelines are formulated based on scientific evidence and carry a grading system of A, B, and C, which categorizes prescription and treatment choices according to their level of support by evidence. The STG is designed for use in all healthcare delivery settings, including public and private sectors. It is not only intended to guide primary healthcare providers in prescribing medicines but also to help them determine whether a referral is necessary. In this way, the STG serves as a comprehensive tool that ensures optimal patient care is provided at all levels of healthcare delivery.

Pharmacists at the Municipal hospitals have reported that the Standard Treatment Guidelines (STG) are widely used by both prescribers and pharmacists within their facilities. One pharmacist mentioned that:

> *The Standard Treatment Guideline is readily available and every prescriber has access to it and uses it here* (PGMH).

However, a director of pharmacy at the tertiary hospital acknowledged that while the STG plays a significant role in the Ghanaian medical system, those responsible for updating it often fail to fulfil

their responsibilities. The director emphasised the importance of evidence-based medicine and the need for treatment guidelines to be regularly updated to ensure the best possible patient outcomes. He said these:

> *The Standard Treatment Guideline is Ghana's guidelines, but as you know, we live in a very fast-developing world. Look at our Standard Treatment Guidelines, the latest one is the 2017 version but we are in 2023. Medicines are evidence-based; the Standard Treatment Guideline is archaic* (PTTH).

The director of pharmacy compared the treatment guidelines used in other jurisdictions to Ghana's STG. He emphasised that STG is not given sufficient attention, which could lead to some inadequacies in the healthcare system. The director expressed concern that relying solely on STG in a tertiary hospital could be unwise. Instead, the hospital considered incorporating treatment guidelines from other jurisdictions to ensure the best possible care for patients. Overall, the director emphasised the importance of staying up-to-date with global standards and best practices to provide the highest quality healthcare services in Ghana. He had this to say:

> *Our Standard Treatment Guideline is like a textbook. People cannot rely on it in a teaching hospital like ours because every year things change, and people come out with new evidence. If you look at the American College of Cardiology Guidelines, a Guideline for Diabetes Management, the International Hypertension Society, and the European Guideline for Hypertension and Diabetes [these are updated documents]. At the individual units, we deal with the latest (guidelines). (Example) 2023 guideline of managing diabetes. We also have the British National Formulary, that one too they reviewed every six months and Ghana, we are doing it from 2017 to 2023, how many years, six years and you expect us to use that evidence to treat people?* (PTTH).

There was an indication that the STG is not the only guideline being used in Ghana, an example was given as the Malaria Control Program which always has an updated malaria treatment guideline.

In Ghana, the Essential Medicine List (EML) plays a pivotal role in guiding the prescription of medications. It is a carefully curated compilation of medications that are deemed essential for

addressing the prevailing health concerns in the country. The list is created by a team of medical professionals and experts who take into account several factors such as efficacy, safety, and cost-effectiveness of the medications. Accessibility factors such as availability, affordability, and ease of procurement are also taken into consideration while selecting the medications for the list. The EML is considered to be a valuable resource for medical professionals as it provides them with a standardized list of medications that they can rely on. The list is intended to be available in all health facilities, ensuring that medical professionals make informed decisions while prescribing medications. It is a critical tool for ensuring that patients receive the appropriate medication and treatment for their health concerns. Therefore, a pharmacist made a statement regarding the EML:

> *Every hospital has the essential medicine list* (PGMH).

However, according to a pharmacist at a tertiary hospital, the medicines listed in the EML are intended for use at lower levels of healthcare delivery and are generic. While these medicines may be cost-effective and easily accessible, the pharmacist shared that at their hospital, they often opted for branded and original versions of these medicines instead of the generic options listed in the EML. The reason for this is that they believed branded and original medicines are likely to be of higher quality and effective, thereby providing better health outcomes for their patients. It is worth noting, however, that this approach is likely to be more expensive and may not be feasible for all healthcare settings. This is what he said:

> *Drugs in the Essential Medicine List are generic drugs. We deal with the EML but we go beyond them. We stock different brands of medicines in the EML, including the original medicines* (PTTH).

Based on the feedback from the pharmacists, it appears that neither the Standard Treatment Guidelines (STG) nor the Essential Medicines List (EML) are commonly used in tertiary healthcare delivery. These guidelines are perceived as inappropriate for use at this level. The STG

is considered to be outdated and not regularly updated to reflect the latest evidence-based treatments for various ailments. Similarly, the EML is viewed as a list of medicines that are not suitable for stocking at tertiary healthcare facilities. This is because the EML is designed to cater to primary healthcare needs and does not take into account the specific requirements of tertiary patients. As a result, tertiary healthcare providers rely more on their clinical experience and expertise to select the most appropriate treatments for their patients.

The National Health Insurance Authority (NHIA) has also given guidelines for medicine prescription and dispensing for patients who attend hospitals as subscribers to the National Health Insurance Scheme (NHIS), The guidelines are spelt out below:

"All prescriptions should fulfil the following requirements:

- conformity with Ghanaian laws including the Health Professions Regulatory Bodies Act, 2013 (Act 857)
- written legibly in ink or otherwise so as to be indelible
- written by the prescriber and not left for another person to complete
- should be dated
- the full name and address of the patient should be stated
- the age and weight (in the case of children) of the patient being treated should be specified
- the diagnosis being treated should be stated

The prescription should also contain the following:

- Dosage form, generic name of medication, strength, dose and dosage schedule
- Exact quantity of medication to be supplied
- the signature of the prescriber (which should be in ink)

Dispensing Guidelines

- The dispensing of all prescriptions under the NHIS must be carried out either by a pharmacist or under the direct supervision of a pharmacist who can intervene, if necessary. The dispenser should ensure the following:
- that the prescription is legally valid, genuine and has not been altered after issuing
- that the items on the prescription can be prescribed under the NHIS i.e. they are on the NHIS Medicines List.
- Each medicine on the prescription contains the dosage form, generic name, strength, dose, dosage schedule and quantity of medication to be supplied

- the prescription is assessed for validity, safety and clinical appropriateness.
- the dosage form and route of administration are appropriate according to the patient's gender, age and clinical condition" (NHIS, 2023)

As per the dispensing guidelines, pharmacists are entrusted with the responsibility of reviewing prescriptions issued by healthcare practitioners in any medical facility. Although these guidelines are specifically designed for NHIS subscribers, they are largely based on the healthcare regulations currently in place in Ghana. As a result, most of the guidelines are applicable to all medication prescription and dispensing processes in healthcare institutions.

According to this study, pharmacists who work at healthcare facilities are actively involved in conducting prescription audits. These audits are aimed at ensuring that the medication prescribed and dispensed to patients is appropriate and in line with the recommended standards of medical care. The pharmacists carry out a thorough review of the prescriptions to identify any potential errors, such as incorrect dosages, drug interactions, and contraindications. Through this process, they help to promote patient safety by preventing medication-related errors and improving the quality of healthcare services provided. The pharmacist at the tertiary hospital gave a detailed expatiation of how the auditing is done:

> *When a prescription is sent from the consulting room, it lands in the hands of a pharmacist who validates it and gives his authority for them to give out the medicine. If there are gaps, for instance, this particular drug and this drug cannot go together, this condition and this drug cannot go, this patient also has this condition but you did not give anything for that, this patient has been on this drug for all that while but the blood pressure is not coming down, can we substitute for any other one? the pharmacist draws the attention of the prescriber* (PTTH).

According to feedback received from pharmacists who work at Municipal hospitals, prescription audits are carried out cordially and collaboratively with the prescribers. The pharmacists and prescribers generally work well together and there is rarely any disagreement. However, in the event of a disagreement, a third party who holds a superior position would be brought in to act as

an arbiter and provide an objective perspective on the case. This ensures that the prescription process remains fair and transparent, and ultimately, the patient's well-being and health outcomes are prioritized. Below is a narration of one of the pharmacists:

> *It is not allowed for a pharmacist to change a prescription without involving the prescriber. A patient may have an adverse reaction. In that case, the pharmacist has to consult the prescriber before changing the prescription* (PGMH).
>
> *… it is not a confrontational manner; we work hand in hand with each other. But we usually go up to the point of bringing in a third party. … If the person does not agree and his explanation does not conform with what you know, you do not edit and you do not dispense the medicine until you get it resolved by a third party* (PYMH).

Prescription policies and audits are put in place to guarantee that individuals seeking medical treatment have access to safe and effective medications. These policies are designed to ensure that healthcare providers prescribe drugs that are appropriate for the patient's condition and that they are dispensed accurately by the pharmacies. Failure to implement prescription policies can result in significant risks to public health. Furthermore, without proper auditing, it becomes challenging to detect and prevent practices, such as the prescription of expensive medicines and drugs that are not needed. Ultimately, the lack of adherence to prescription policies can endanger the affordability and availability of quality medicines, which can be detrimental to the healthcare system as a whole.

6.1.2 Patient Involvement in the Prescription Process

Section 167 of the Public Health Act, 2012 (Act 851) spelt out the rights and responsibilities of patients. The following are extracts of the Act that give patients the right to be involved in the treatment process which includes prescription of medicines.

- "The Service requires collaboration between health workers, patients, clients and society.
- Respect for the patient as an individual with a right of choice concerning health care plans;

- The patient is entitled to know of the alternative treatments and other health care providers within the Service if these may contribute to improved outcomes.
- The patient has the right to a second medical opinion if the patient so desires" (Government of Ghana, 2012)

In the delivery of health services, patients play a crucial role as partners in the process. They have the right to choose the course of their treatment and are entitled to alternative options in case they are dissatisfied with the current one. Additionally, patients have the right to seek a second medical opinion before making any decisions regarding their health. Therefore, it is safe to assume that patients should be involved in the prescription process. This means that the physician will discuss the medicine to be prescribed, its alternatives, and the cost involved in acquiring the prescribed medicine with the patient, who will ultimately make the final choice. This study aims to examine the extent and nature of such involvement in the prescription process and its impact on the affordability of medicines by patients.

Based on the feedback received from the health seekers, it appears that a few prescribers did not appreciate the active participation of patients in the prescription process. Even when the health seekers tried to provide additional information to aid the prescription process, the prescribers seemed to take offence, which created an unwelcoming environment for the health seekers. This is the experience a female health seeker shared during the data collection:

> *... I explained to him about the medicine that was prescribed for me in my previous visits. I suggested that if there was another medicine he could prescribe that would be affordable and meet my health needs. ... I did not get a pleasant response from him. The way he looked at my face suggested that he was angry with me (FHS1).*

In some cases, there were different types of interactions between some prescribers and their patients during the prescription process. Some of these interactions centred around the medicine that was to be prescribed and the patient's preferences, which can be considered as active participation in the prescription process by the patients. For instance, the prescriber might ask the

patient about their medical history, allergies, and other relevant information to ensure that the prescribed medication is safe, effective and affordable for them. On the other hand, some conversations were focused on traditional medicine, which the hospital did not offer, and personal discussions that were not related to the prescription process. These conversations were not beneficial to the patient's treatment and might be deemed inappropriate. The respondents shared the following:

> *... We had a lot of discussions which included the cost of the medicine and other medicines that he could prescribe. But my focus was more on the medicine that could get me well (MHS3).*
>
> *... He was rather telling me about herbal medicine that could control my blood pressure (FHS4).*
>
> *... our discussion was about our relationships... (MHS2).*

In another case, there was no significant discussion about the medication prescription. The prescriber promptly wrote the prescription without much dialogue or inquiry after the patient relayed their health condition. The prescriber's swift action might have been because the patient's condition was not complicated and required a straightforward solution. Nonetheless, it is crucial for healthcare providers to thoroughly review and discuss medication prescriptions with their patients. Below is the complaint of the health seeker:

> *There was no interaction between us about the medication. After I explained my sickness to him, within 2 minutes he finished writing everything, handed the prescription to me and told me to go to AH place to buy the medicine (FHS1).*

6.1.3 Involvement in Medicine Sales by Medicine Prescribers

All things being equal, healthcare facilities have pharmacy departments that are in charge of dispensing medicines. The regular practice is that a prescriber does the prescription and pharmacists handle the dispensing. If the medicine is not available in the health facility, the

pharmacist then recommends the purchase of the medicine outside the healthcare facility. However, Section 99, subsections 2 (i) and (ii) of the Health Professionals Regulatory Bodies Act, 2013 (Act 857) indicates that health practitioners can supply restricted medicine in urgent situations or upon approval by the board of the Pharmaceutical Council.

Despite the regulatory requirements, some prescribers defied the arranged responsibilities at health facilities and directly sold medicine to health seekers. Below is an extract from the interviews.

> *He had the medicine in his bag. The text on it was written in the Chinese language. He told me it was the only effective medicine I could use. He said it was a herbal medicine. So, he sold that one to me (MHS1).*
>
> *Most of those who went to him earlier came out and said he sold medicine to them. When I went into the consulting room, he told me the medicine he prescribed was not in town, so I had to buy it directly from him (FHS1).*
>
> *He had the medicine in his bag and told me that he had to do me a favour by selling that medicine to me. He said it is an effective but scarce medicine. MHS2.*

This study discovered that certain prescribers were recommending specific pharmacies to patients for purchasing prescribed medicines. This practice raised a red flag and led to suspicions that these prescribers might have been keeping the medicines at these particular pharmacies for sale or may have had some form of agreement with the pharmacies to promote the sale of certain medicines. This finding highlights the possibility of unethical practices in the healthcare industry and the need to ensure that patients receive the best possible care without any attempt by prescribers to make undue financial gains from the situation. These are what the participants of this study narrated.

> *He told me to go to that pharmacy near the filling station and tell them that he directed me to come and buy the medicine. He had written the information about the medicine in small white paper. It was not a prescription form. I sent it there and they sold the medicine to me (MHS3).*
>
> *I suspected that he (The Dr.) was one of the owners of the pharmacy. When he directed me to go to the pharmacy to buy the medicine and I went, I met a number of those who also went to his consulting room to buy the medicine at the pharmacy (FHS3).*

According to the feedback received from a group of health seekers, it was found that there were mixed responses to the involvement of medicine prescribers in medicine sales. While some of them followed the instructions provided by the prescriber and purchased the prescribed medicines, others expressed suspicion regarding the genuineness of the prescription. Such individuals sought further professional advice from pharmacists to ensure the authenticity and effectiveness of the medicine prescribed. Additionally, there were a few individuals who decided to abandon the treatment process altogether and left the hospital. An extract of some of the responses is shown below.

> *… I did not understand why he was directing me to that place. I decided to go to a friend's pharmacy who is also a pharmacist. When I showed the prescription to him, he said I only needed 3 medicines from the list the prescriber had given to me. That the rest of the medicines were duplications. The medicines prescribed for me were 6 (MHS3).*
>
> *I told him that because I came with health insurance, I did not have any money with me. So, he should wait and I go back home for money. When I left, I did not go back to the hospital. I did not believe all that he told me about my sickness (MHS1).*
>
> *I believe he was telling me all that to enable him to sell his medicine to me. I know there is a pharmacy that sells medicines. How come the Dr, was selling medicine himself in a public hospital? Even in private hospitals, doctors don't sell medicines (MHS3).*
>
> *… I became angry and left the hospital. I realised the man was there to extort people but not to treat patients (MHS1).*

On the other hand, some medical professionals adhered strictly to the standard procedure and instructed their patients to obtain their prescribed medications from the hospital pharmacy. This implies that those prescribers believed that obtaining medications from the hospital pharmacy was the safest and most reliable option for their patients, as it ensured that the medications were dispensed accurately and were of the highest quality. By directing their patients to the hospital pharmacy, these medical professionals aimed to provide their patients with the best possible care without any financial inducement. This was echoed by one of the participants below.

> *... he told me to go to the pharmacy. When I went, they gave me all the medicines. I was told I did not need to buy any other medicine* (MHS3).

During the interview with a pharmacist who works in a Municipal hospital, it was disclosed that they had heard about some of the prescribers who worked in the same hospital selling medicines in the consulting rooms. The pharmacist was extremely concerned about this practice and passionately emphasised that it was unequivocally wrong. He went on to express his belief that any individual who was caught engaging in such activities would be swiftly reported to the appropriate authority for appropriate sanctions. This is what he said.

> *... It is against the rules. We have heard about it but you know human institutions, we have not yet caught anyone. If anyone is caught, he will be dragged to management and the appropriate disciplinary procedures will be followed* (PYMH).

It has been confirmed that some prescribers have been writing prescriptions for their patients and advising them to purchase the prescribed medications from outside pharmacies rather than using the hospitals' own pharmacies, even if the prescribed medicines were available in the hospital. This practice is considered inappropriate as it can cause discomfort to the patient and may affect the hospital's internal revenue generation. Such acts are not in line with the hospitals' policies and can lead to negative consequences for both the patients and the hospital. Prescribers need to adhere to the hospitals' guidelines and prioritize the well-being of their patients by providing them with the most convenient and appropriate options for obtaining their medications. A pharmacist at a tertiary hospital stated these:

> *... because human beings are difficult to manage, sometimes you give guidelines they refuse to follow. ... the doctor will write a prescription and say, we don't have this medicine, go and buy it. All that affects the patients' comfort and affect our revenue generation* (PTTH).

An interview with a pharmacist at the tertiary hospital indicated that prescribers were always expected to refer patients to the pharmacy for their medicines. If the medicine was available to be

given out to the patient as an NHIS subscriber, it would be given out without any hassle. However, if the medicine was supposed to be sold to the patient, the hospital would then sell it to the person, which in turn would generate revenue for the hospital. In case the medicine was not available in the hospital, the pharmacist would write a valid prescription for the patient to go out and look for the medicine.

The practice of medicine prescribers keeping medicines in pharmacies for sale to patients was confirmed by the managers of such pharmacies who participated in the study. Below narrations are extracts of the interviews.

> *… sometimes they contact us and ask if we have certain medicines, if we don't have they will give them to us and tell us the price. At a time, people will come with prescriptions and tell us that the doctor directed them to come and buy* (PPHARM2).
>
> *Some of them will contact us with medicine. They explain to us the need to use that medicine to treat some illnesses because the existing ones have become ineffective. For example, we have pyramax here which is a malaria medicine being brought by a doctor. He prescribes it for people and they come to buy it* (PPHARM3).

This study revealed that the length of the supply chain had a direct impact on the cost of medicine for patients. There were indications that when prescribers kept a stock of medicines with pharmacies, the pharmacies tended to make some profit from them. This, in turn, resulted in a marginal increase in the price of the medicines, which eventually affected the cost for the end user. Some of the managers of the private pharmacies who participated in this study had these to say:

> *Certainly, we will not sell it at their price, we will top up something to also gain from that* (PPHARM2).
>
> *They tell us the cost of it and we also add something. We are doing business here* (PPHARM3).
>
> *We also add something to the price they give us. So, we make some profit from their medicines. But the profit will not be like when we are going to sell our product and make a profit* (PPHARM3).

> *When they bring it they give us their price. We find out from them whether we have to adjust the price for our share of the profit or we will have a commission from them. Most of the time they tell us to adjust and take our profit* (PPHARM1)

6.1.4 Affordability of Medicines

In this study, affordability is the ability to withstand the cost of medicine for a treatment regimen without an experience of any form of financial shock. That is borrowing, selling an asset or forgoing another important self or household expenditure to acquire the medicine. This study was geared toward finding out how the prescription behaviour of health professionals may influence the affordability of medicines to health seekers.

Information from the interviews established that some health seekers had no form of difficulty in buying the medicines sold to them either by the prescriber or the pharmacies the prescribers directed to go and buy. Extracts of the interviews are shown below:

> *I did not prepare for the expenditure but I had enough savings to take care of all our health needs. So, I was able to afford the cost of all the medicines (MHS1).*
>
> *The cost of the medication was not all that high. I bought it without any difficulty (MHS3).*
>
> *I was able to buy all the prescribed medicine (FHS2).*

On the contrary, some health seekers were not able to afford the medicines. They had to borrow to be able to buy the medicines. Below is a lamentation of one of the participants in this study:

> *… I could not afford the medicine. I came out from his consulting room confused, I had to finally borrow, went and gave the money to him before he gave me the medicines. I will only be able to pay when I receive my pay* (MHS1).

In a particular case, the health seeker had to sell out an asset to be able to withstand the cost of the medicine. He did that with the hope that he would be able to the asset in future. This is what he had to say:

> *I returned a pack of roofing sheets I had bought earlier to raise money to buy the medicine. So, I went back to him (the prescriber) the next day and gave him money*

> *for the medicine. Even though it will take time I will work and buy those roofing sheets when I fully* recover (MHS3).

In other cases, the health seekers had to forgo another essential need to be able to buy the medicine. Some went as far as calling others far away for support to enable them to withstand the cost of the medicine. These are extracts of the interviews:

> *When he directed me to the pharmacy and I went and heard the cost of the medicine, I had to go back and prepare. All that I kept [all the money] waiting for my boy to gain admission and we used to pay his fees was used to buy medicine. Now I do not know what to do when the boy gets admission* (MHS1).

> *I became a beggar. I left the pharmacy and called my cousin in Accra and pleaded and he sent money to enable me to buy the medication* (FHS2).

The essence of designing policies, legislations and guidelines is to ensure that they are effectively implemented to achieve the desired objectives. In a succinct, the STG, EML and all the legislations and guidelines were designed to streamline issues of prescription that will ultimately ensure unquestionable access to health care. However, reneging to implement those policies encouraged some prescribers to utilise the loopholes to their personal advantage. The experience of some of the health seekers indicates how a lot of health seekers suffer to get medicines when they visit healthcare facilities for attention. They encounter serious financial shocks when they are exposed to improper handling by some prescribers who may want to twist every situation to their advantage.

6.2 Dispensing and Rational Use of Medicines

The second objective of this study was to examine medicine dispensing practices and how they influence the rational use of medicines. This section of the study is focused on that objective and, with qualitative data, answers the research question that emanates from the objective. Dispensing of medicine is a crucial stage in the pharmaceutical cycle, as it can greatly impact a patient's perception of their medication. The interviews conducted focused on the training and guidelines provided to dispensary staff to ensure effective dispensing practices. The dispensing practices

under scrutiny in this study included communication, staff attitude, information given to patients regarding dosage and potential side effects, organization of the dispensary/pharmacy and waiting time within the dispensary. The study also examined aspects of rational medicine use, such as completing prescribed medication, taking medication at the advised time, and avoiding self-medication.

6.2.1 Dispensing Practices

This study explored the prevalent training and guidelines available to the dispensary staff. Through interviews with a pharmacist at the tertiary hospital, it was revealed that there were indeed guidelines at the tertiary level, which were referred to as Standards of Pharmaceutical Practice. However, these guidelines were not documented as a manual, but rather as protocols that were displayed as posters in the dispensaries. The content of the guidelines outlined what dispensary staff should and should not say when dispensing medicines to patients. In addition to the guidelines, it was found that only experienced staff members were allowed to function independently at the dispensaries. Staff who were new to the dispensary had to work in partnership with experienced staff members. This is what the pharmacist said:

> *We have guidelines, we started it not long ago. Just of late, we went to review them, which we call Standards of Pharmaceutical Practice. [It contains] what you should say and what you should not when you are dispensing. We have the manuals as protocols for dispensary staff. They are pasted as posters in the dispensaries. We do not also allow novices to run alone. We try as much as possible to have pharmacists in each schedule guiding the dispensing of medicines (PTTH).*

The study revealed that there were no similar manuals at the municipal hospitals. However, it was discovered that the dispensary staff at those hospitals receive refresher training twice a year to stay up-to-date with policy changes as well as the latest discoveries of new medicines and adverse effects. This training is crucial to ensure that the staff is equipped with the necessary knowledge

and skills to provide safe and effective medicine dispensing services to the patients they serve. One of the pharmacists had this to say:

> *We used to do it quarterly, but now we do it twice a year. New policies come, new drugs come, and research is ongoing. A drug that might have been doing well might be discovered as having an adverse reaction … (PYMH).*

At the community pharmacies, a certificate was not all that important in recruiting the pharmacy assistants who were in charge of dispensing medicines. They employed those who were certificated as pharmacy technicians but they also employed those without the relevant certificates whom they trained on the job. Some managers of the community pharmacies valued the training they gave to those without certificates so much that they did not see the reason they should be looking for those who had formal pharmacy technician training. Some of the managers of the private pharmacies even had a conviction that when those with certificates were employed and they went for further education, they started looking for jobs in the formal sector. The following are extracts from the interviews:

> *We employ people here with certificates in pharmacy assistantship. However, there are others without the certificate whom we train here and they are good to go (PHARM1).*
>
> *The essence of having a qualification is to have the knowledge to work. So, if someone can read and write we can train the person here to work with us (PPHARM2).*
>
> *Some of them go for further education but if they are highly educated, they look for more lucrative appointments (PPHARM3).*

Based on the responses, it appears that the managers of community pharmacies were hesitant about their employees pursuing further education to enhance their expertise. It is possible that they feared losing these employees to government hospitals or larger pharmaceutical companies that may offer better opportunities. Notably, it was observed that the majority of the staff in these pharmacies were relatives of the owners or managers.

Waiting time at health facilities is another aspect of healthcare delivery. The time people spend at the dispensary may have the potential to influence their rational use of medicines. Some participants of the study complained of negligence on the part of the dispensary staff that made them wait for a longer time at the dispensary. Some of the dispensary staff refused to attend to patients because they were supposed to close and those who had to take over from them did report to duty. Consequently, patients were in longer queues whilst the staff were sitting idle waiting for their colleagues to come and take over from them. A patient narrated her ordeal below:

> *I was told one of the medicines prescribed for me was not covered by the health insurance so I should go and pay and come back with the receipt for all the medicines prescribed for me. I joined the long queue and paid the money. When I returned to the dispensary they were not attending to people. I knocked on the window and a lady came and told me that those in the morning shift had closed and that I should wait for those in the afternoon shift to come and serve me* (FHS3).

The actions of the dispensary staff cast doubt on their commitment to the work they were doing. The poor organisation at some of the facilities was the reason for the longer waiting hours in those facilities. Some waited for long because their folders were not in sight. However, in a particular case, the patient waited for a long because he went to obtain the medicine as an NHIS subscriber. As a result, he was told to wait. They attended to him after attending to those who were there to buy the medicine directly. These are the narrations of some of the respondents:

> *I did not know what they were doing, I sat there and people came they called them for their medicines but I was left sitting. I finally went and complained before they took my folder and served me* (MHS4).

> *... when I gave him the prescription, he said the medicine was there but I had to wait. After those who were there buying the medicine left, he then attended to me* (MHS3).

Another aspect of the study was designed to find out health seekers' views and satisfaction about the organisation of the dispensary/pharmacy they went to obtain their medicines. The focus of the organisation of the dispensary was how people were selected to go for their medicines at the

dispensary counter, especially when they were crowded and the availability of seats at the dispensary/pharmacy. This was also examined to find out if patients' views and satisfaction with the organisation of the dispensaries would influence their rational use of medicines. The study found that some of the participants had problems with appointment systems in some of the community pharmacies. They complained of smaller space in some of the pharmacies, as a result, when it was crowded, the pharmacy assistants did not have a way of knowing those who were there earlier. This had the potential to create a chaotic situation in the pharmacy. A participant in the study narrated the situation below:

> *The space in that pharmacy is small, when you are more than five in it you get crowded. So, the attendants get confused as to who was there earlier. You will have to raise your voice before they attend to you. So, those who are not comfortable raising their voice in that circumstance will be delayed because more people will keep coming in* (MHS3).

There were also concerns from the hospital that were using folders. Arranging the folders in such a way that the patients were served on a 'first come first served' basis was problematic. There were times when everything jammed up and patients sat without being invited for their medicines. A participant of this study presented it this way:

> *I have a problem with the organisation of the dispensary. When you present your folder for the medicine, I do not know how they arrange it and call people to go for their medicines. At times some people will be waiting and others come later and collect their medicines and leave* (MHS4).

Some respondents also complained of poor allocation of separate seats for those waiting to be called for their medicines at the dispensary. They complained about how the seats of the dispensary were invaded by other patients going to the hospital's other departments. There were expectations that there could be segregation of patients in terms of the section of the hospital they were going to. This, they believed, could enhance orderliness in the hospitals. Below is an aspect of the interview:

> *The dispensary is not well organised. When you go there the seats are occupied by other patients who are going to other sectors of the hospital. So those of you going to collect the medicines will be hanging around. At times they will call your name to come for the medicines and you are far away; you cannot hear* (FHS2).

In the view of some participants, based on the health facilities they attended, the dispensaries were very well organised. Given that there were several dispensaries in some of the health facilities, people were orderly and organised and the process was very smooth without crowding in any dispensary. Below is the view that was expressed:

> *They have no problem with the organisation of the dispensary. They have several dispensaries and one can get to any one of them for your medicine. You do not even need to sit* (MHS3).

It was observed that most of the community pharmacies did not have much space on their premises. Some of them were rendering laboratory and some clinical services, like wound dressing, malaria testing and pregnancy testing in addition to pharmaceutical services. As a result, most of them were always crowded. Concerning the hospitals and health centres, those who were still using folders were the hospitals with organisation problems at the dispensary.

One of the critical stages of dispensing medicines is educating the patients on medicine dosage. The level of knowledge of patients about medicine dosage may influence the patients' rational use of medicines. This study was in a quest to find out the extent of information given to patients about medicine dosage at the dispensary. The interviews revealed that the dosage information given to the health seekers was very vague. Patients were left to make their own decisions on when and how to take the medicines. The following were some of the information given to health seekers:

> *He told me to take it 3 times daily before or after meals* (FHS3).
>
> *He said I should take it morning and evening* (MHS1).
>
> *He wrote 3 circles on the pack of the medicine and handed it to me without telling me anything. When I asked him how it should be taken, he said that was what he had written on the pack* (FHS2).

In a particular case, the patient was given the wrong information about how to take the medicine. The consequence of taking the medicine wrongly prompted the patient that he had done the wrong thing. The patient was made to understand that eating was not a prerequisite to taking the medicine. This is how the participant narrated his ordeal:

> *The guy nearly killed me. He said there was no need for me to eat before taking the medicine. I was going to drive home so I just bought water and took the medicine instantly. In five minutes, my mouth became dry and I started feeling dizzy. I called someone to get me food instantly. Immediately after eating, I became okay* (MHS3).

There was a case where the quantum of medicine given out was not up to the number of days the patient was required to take the medicine. In such cases, either the dispensary personnel, intentionally or unintentionally, did not give the patient the required quantity of medicine or the wrong timing of the dosage was given to the patient. The participant in this study said this:

> *He wrote 2 caps 3 times daily on the pack. Without any information on the number of days I had to take the medicine. I asked him how many days, he said 7 days. I told him the medicine was not up because the medicine was one pack having 3 seals inside and each seal had 6 capsules. He just told me that if I finish taking and feel okay with my ailment I should not boarder about the rest of the medicine. But if I was not okay then I should come back to the hospital* (MHS1).

However, some of the dispensary staff were very specific with their explanation of the medicine dosage. They gave the exact time intervals the medicine had to be taken and the specific time after meals. In some cases, the health seekers were informed of the consequences they may experience if they either took any other medicine in addition to what was given to them at the hospital or if they failed to eat before taking the medicines. Below is an example of the dosage information given to patients:

> *He said I should take 2 tablets of this one [showing a pack of the medicine] at exactly 10 am and take the next 2 in 6 hours-time. He said I should take it immediately after I finished eating* (MHS3).

> *He told me not to take any other medicine besides what was prescribed for me in the hospital. He said this medicine [showing a medicine in a rubber purse] if combined with certain medicines my health situation would worsen* (MHS1).
>
> *He said I would become drowsy if I did not eat and take this medicine* (MHS2).

As part of the medicine dispensing process, health seekers must receive information regarding potential side effects. Armed with knowledge about the extent of these side effects and when to discontinue use, patients can avoid certain contraindications associated with certain medications. Additionally, patients can confidently continue taking their medication when experiencing normal, anticipated side effects. With this in mind, this study wanted to find out whether patients received information about normal, expected side effects during the dispensing process. The study found that some of the respondents were not given such information at all. This is how a participant expressed it:

> *He did not tell me anything about side effects …* (FHS4).

However, information regarding the potential side effects of the medication was shared with some of the participants. Some of those participants received clear instructions on what to anticipate within the initial 24 hours of taking the medication, as well as guidance on when to discontinue usage and seek medical assistance should any symptoms persist. Others were advised to cease usage immediately and seek medical attention upon experiencing certain side effects. Below are narrations from the participants:

> *He said I may experience headaches and dizziness on the first day of taking the medicine but it would stop in the subsequent days. He said I should not stop taking it if I experience those symptoms. But if those symptoms existed up to the third day, I should stop taking the medicine and come back to the hospital* (FHS3).
>
> *He said if I take it and experience pains in my chest or palpitations, I should stop taking it and come back to the hospital* (MHS3).

Regarding the attitude of the dispensary staff, the study found that some of the health seekers were deeply disappointed with the way they were handled at the dispensary. Some of the dispensary staff were said to have been engaged in the use of their phones or snubbed the health seekers and talking and laughing with colleagues. Some of the dispensary staff even engaged in the use of their phone without explaining the dosage to the patient. These are the experiences some of the health seekers shared with the researcher:

> *The young men there have no time for the patients. The guy was on the phone laughing while serving me. After giving the medicine he did not tell me anything (FHS1).*
>
> *The guy was typing on his phone when I presented my card to him, he checked through the computer and went and brought the medicines, wrote the marks on it and just pushed it to me through the small opening and continued typing on the phone. I waited for about 2 minutes and asked him if that was all, he said yes without even looking at me (FHS3).*
>
> *Their attitude is bad. Whilst he was serving me, one of his colleagues came to him, they were talking and laughing whilst I was standing waiting for him (MHS2).*

Similarly, some of the dispensary staff were seen to be disrespectful because of the way they behaved towards health seekers. Some of the staff were said to be angry when they mentioned someone's name wrongly and the person approached them to verify if he was the one. Others seemed to be making a mockery of the names they could not pronounce correctly. Those attitudes did not go down well with the health seekers. This is the way they complained about such attitude:

> *They had no respect for health seekers. They mentioned my name wrongly, I approached him to verify if I was the one, he was calling, and he became angry* (MHS2).
>
> *They have a problem there. Whilst they struggled to mention some names they kept laughing. It looked like they were mocking people whose names were not familiar to them. I do not expect them to know every name, especially our local names but they should not act as if some names do not deserve to exist* (MHS3).

On the contrary, some of the dispensary staff were regarded as being very respectful. The elderly believed they were given proper recognition by the staff when they approached the dispensary

counter. Some of the staff were also regarded as being very diligent at work. This is how the participants expressed it:

> *The guy gave me proper attention. Immediately I approached him he started calling me his grandfather. He acted as if he knew me already* (MHS3).
>
> *She was very respectful. She was very diligent. So, most of the people in the queue were making all sorts of positive comments about how she was working* (FHS1).

The problem of negative attitude by some of the dispensary staff appears to be due to differences in cultural background between some of the health seekers and some of the dispensary staff. However, the dispensary staff who should have learned the culture of the environment in which they worked to enhance their performance were adamant.

Effective communication is one of the crucial aspects examined in this study, as it directly impacts a patient's understanding and confidence in using medications. It is concerning to note that none of the healthcare facilities had staff who could communicate through sign language or braille. While one pharmacy director believed that individuals with these impairments would always visit hospitals with relatives, another pharmacist hoped that this study's recommendations could assist hospitals in making policymakers assign people with special education to the hospitals to enhance effective communication with disabled individuals. These are what they said:

> *We don't have those who translate into sign language here. Looking at the situation, relatives of people with such disabilities will not allow their people to come here unaccompanied. So, we don't have such people coming here alone (PTTH).*
>
> *We do not have sign language translators. You may be of help to us. When you complete your research, you can make recommendations for us to get those who are specialists in sign language (PYMH).*

The absence of a sign language interpreter is an indication that after relatives accompany a disabled person to the hospital for care, the same people must always be around those patients to give them

their medications. In such a situation, the medicine becomes a source of danger to disabled patients when those accompanied them to the hospitals are not present to give them their medications.

Also, there was only one hospital that had those who could translate the English language to different local languages for patients. There were translators of the English language to only four different local languages. However, those four local languages were the predominant local languages in the municipality. The rest of the workers at dispensaries of the other hospitals could speak only their local languages and English language. A pharmacist said this:

> *We have those who translate into Konkomba. Our area is predominantly Dagomba and Konkomba area. Our problem is the Fulani language. There is one nurse in the emergency who understands Fulani, when it becomes critical, we invite him to do the translation in Fulani and Hausa for us* (PYMH).

Regarding how the dispensary personnel communicated with the health seekers at the time of dispensing medicine to ensure rational use, the study found that there were problems relating to the audibility of some of the dispensing staff. Some of the respondents of this study complained of not hearing what the dispensary personnel was telling them. There was even a complaint of a dispensary staff getting angry when the health seeker was asking questions about the medicine: The complaints are presented below:

> *His voice was very low so, I kept stretching to hear him very well* (MHS3).
>
> *He was not speaking louder, and when I was asking questions about the dosage, he started looking at my face angrily as if I was wasting his time* (FHS3).

In another case, a patient reported an incident where the dispensary staff did not communicate with her and merely handed over the medicine to her. The patient also mentioned that the staff appeared to be angry and visibly upset during the interaction. This lack of communication and unfriendly behaviour from the dispensary staff left the patient feeling uncomfortable and dissatisfied with the service provided. This is a statement from a health seeker:

> *The guy was sounding aggressive. After he pushed the medicine to me through that opening, he called the next person. He did not even wait to answer any question from me* (FHS2).

However, some participants in this study were extolling the professionalism being displayed by some of the dispensary staff. They were said to communicate the dosage of the medicines to their understanding. Some of the staff were even jovial and entertained the health seekers at the time of dispensing the medicines. A staff who was noted as not being a native speaker of the local language was said to have done so well in communicating with the patients. The following are extracts from the interviews:

> *I was okay with the way he communicated with me. He was able to explain the dosage to my understanding* (MHS1).
>
> *She was the sociable type, so she was smiling whilst talking to me. She answered every question I had about the medication* (FHS3).
>
> *He was a communicator. He took time and explained the symptoms I may experience when I start the medication* (MHS3).
>
> *There was every indication that the guy was not a native speaker of our language but he managed to speak to my understanding. He was very responsible in his choice of words* (MHS1).

6.2.2 Rational Use of Medicines

In the context of this study, rational use of medication refers to following the prescribed dosage regimen in its entirety, which includes taking the correct dosage as prescribed by the healthcare provider, adhering to the recommended schedule of administration and avoiding self-medication. It is essential to take the medication at the specified time and not deviate from the prescribed instructions. Additionally, it is crucial to avoid self-medication, which can potentially lead to complications. In summary, rational use of medication involves responsible and conscientious adherence to the healthcare provider's instructions for medication use.

This study revealed that a considerable number of individuals seeking healthcare services failed to complete their prescribed medication regime. A few of them stopped taking specific medicines prescribed to them due to the side effects they experienced. Some participants found the quantity of medication to be overwhelming, which made them feel tired and uninterested in taking it. Additionally, some individuals did not see any improvement in their medical conditions despite taking medication, which made the process of taking medicine a burden for them. As a result, they stopped taking medication altogether. A few others stopped taking their prescribed medicines because of the unpleasant smell of the drugs. These findings reflect the reality that medication adherence can be a challenging aspect of healthcare management and highlight the need for more patient-centred approaches to medication management. The following are extracts from the interviews:

> *I took all but one of the medicines. I was always feeling sleepy when I took that particular medicine. So, I decided to stop taking it* (MHS1).
>
> *The medicine was plenty. So, I took it but when I was feeling well, I stopped taking it. I did not want it to be another source of sickness to me* (FHS1).
>
> *I took the medicine up to the third day but there was no improvement in my health, so I stopped taking it* (MHS4).
>
> *That medicine is also a source of sickness. I felt weak whenever I took it. So, I stopped taking it* (MHS3).
>
> *The scent of the medicine was not pleasant to me. I nauseate when I take it. As a result, I stopped taking it. They do not take us seriously that is why they give people such medicines. Even where to sit when I went for the medicine was a problem*. (FHS3)

During the study, it was observed that some of the participants placed great importance on the prescription and accompanying information about the medicine. They felt that adhering strictly to the dosage instructions provided to them at the dispensary was crucial for their well-being. These participants seemed to have a high level of trust in the healthcare system and the medical professionals who prescribed the medication. They believed that any deviation from the prescribed

dosage could have adverse effects on their health, and therefore, they made sure to follow the instructions meticulously. One of the participants of this study expressed his position this way:

> *I do not joke with my medication. If the Dr. prescribes medicine for me and I am informed how to take it, I must obey them, [because] it is supposed to cure my sickness. So, if I joke with it, I am joking with my health* (MHS3).

Incomplete information about the importance of completing dosages and expected side effects might have caused individuals to discontinue their medications prematurely. Some individuals might have been hesitant to continue taking their medication due to a lack of information about the side effects they were experiencing.

Certain participants of the study appeared more self-assured regarding the timing of their medication intake, as they adhered to the instructions provided by dispensary personnel. Nonetheless, a disconnect existed between health seekers and the dispensary staff, resulting in inconsistent medication schedules. Some individuals failed to establish a consistent routine for taking their medication, while others viewed skipping doses as acceptable. The narrations of the participants are shown below:

> *He said morning and evening before or after meals. So, I take it in the morning immediately after breakfast and in the evening, I take it after supper. I do not have a fixed time to take my food. It can be at 7 am or 10 am and evening it can be at 6 pm or 7 pm* (MHS1).
>
> *He said 3 times daily. So, I took it in the morning afternoon evening* (FHS2).
>
> *There are certain days I do not remember to take it. Since he said it should be taken for seven days, I will take it for seven days but it may not be every day up to the seven days* (MHS3).

Some patients were very particular about the timing of their medication. They followed strict hourly intervals when taking their medicines, as prescribed by their healthcare providers. These patients understood the importance of adhering to their medication schedule to ensure the effectiveness of their treatment and to avoid any potential negative

effects that might have arisen from missing a dose or taking it at the wrong time. Overall, these patients were diligent in managing their health and well-being through responsible medication use. A participant explained how he took his medicine as this:

> *... he told me to take it 6 hours intervals, so I even woke up at midnight to take it* (MHS3).

This study further revealed that some health seekers engaged in self-medication for several reasons. Some participants were not given the medicines they expected, as a result, they went and bought them to supplement what was given to them at the hospital. Some also thought they were given ineffective medicines because they were NHIS subscribers as they believed such category of health seekers were not respected at the health facilities. In other cases, some participants stopped taking what was given to them at the health facilities and engaged in self-medication because there was no improvement in their conditions, and some were experiencing side effects when they were taking the medicines given to them at the health facilities. These were the explanations given during the interviews:

> *There was no cloxacillin in the medicine given to me at the hospital. So, I went and bought it because it is the one that heals my wounds faster. If they are not giving those proper medicines that is how they waste your time.* (FHS1).
>
> *Those medicines are not effective. When you go to a hospital with health insurance, they treat you with disrespect and end up giving you those medicines. If you rely only on that one, you will not recover. So, when they gave me those medicines I went and bought the other medicines I have been using* (MHS1).
>
> *I took the prescribed medicines for up to one week and there were no changes. I went and bought this one to try and see* (MHS3).
>
> *... when I take it, I feel dizzy. I complained to the man (dispensary assistant) about it but he gave it to me. ... I went and bought different medicines* (FHS1).

On the contrary, some health seekers did not see the need to engage in self-medication because what was given to them at the health facilities was enough for them. Others regarded self-medication as an improper thing to do. These are what they had to say:

> *…what was given to me was even too much; I could not take all* (MHS3).

> *I think it is not proper for one to be going around buying medicines whilst having the prescribed ones from the hospital* (MHS1).

Examining medicine dispensing practices and the influence they may have on the rational use of medicines, there are indications that some of the dispensing practices have influenced the rational use of medicines among health seekers. The dispensary staff at the tertiary hospital and some Municipal hospitals were trained to be very effective and efficient in dispensing medicines. There were posters at the tertiary hospital to guide medicine dispensing. In some health facilities and community pharmacies, much attention was not given to equipping the dispensary staff to serve patients well. The data point to the fact that there were problems with the organisation of some of the health facilities and pharmacies, some health seekers had problems with how they were communicated to, and there were also problems with how information on medicine dosage and expected side effects was given out. The waiting time and attitude of some dispensary staff were all complained about. These were reflected in the use of medicines. Some refused to complete their medication because of side effects, some also took their medicines at the wrong times because of the communication gap between health seekers and the dispensary staff and others engaged in self-medication for several reasons which all emanated from the experiences they might have had at the dispensary. These imply that the medicine dispensing practices had influenced the irrational use of medicines among health seekers.

6.3 Medicine Pricing Policy and Availability of Medicines

The third specific objective of this study was to find out how medicine pricing in Ghana affects the availability of medicines to the subscribers of the National Health Insurance Scheme at the health facilities. To address this objective from the qualitative point of view, interviews were

conducted among key informants and secondary data was also gathered. The data collected based on this objective generated several themes and sub-themes.

6.3.1 Medicine Pricing Policies in Ghana

The procedure used by the NHIA to price medicine for use by the NHIS is that; a national survey of medicine prices was conducted across the 16 regions of Ghana. Data was gathered on prices from all categories of health facilities, pharmaceutical wholesale distributors and private pharmacies. After capturing the prices of the selected medicines, the prices of generic versions were used for each formulation for the price analysis. However, if the medicines were still under patent protection the innovator prices were used for the analysis. This was the formula, in addition to the Framework Contract Agreement pricing, used to arrive at the medicine prices for reimbursement by the NHIS in 2022. In 2023, there was a 20 per cent increase from the 2022 prices across board, except for medicines on the Framework Contract Agreement and infusions on the NHIS medicine list which had previously experienced an increase in 30 per cent contract prices and 30 per cent operational prices respectively (NHIA, 2023).

However, some pharmacists indicated that the NHIA was not utilising the data being gathered and analysed in their survey. They said that upon all the stakeholder consultations the NHIA would settle on the prices of their choice. They put it this way:

> *They consult the hospital pharmacists, the suppliers, and all the stakeholders. In the end, the prices being proposed during the consultation will not be the prices the NHIA will put out. Their prices will be lower than what has been agreed upon* (PGMH).
>
> *If consultation takes place before the pricing, do they implement the suggestions of the stakeholders?* (PHARM1).

Another pharmacist complained that the consultation being done was not broad enough to enable the NHIA to arrive at good decisions that would meet the needs of the people. He complained that

the data gathering was not getting to the rural areas. The focus was just on the urban areas and pharmacists at the teaching hospitals who did not know what was happening to people in the rural areas. He narrated it as follows:

> *When they are going to do these things (enter into such agreements) they don't involve those of us in the districts who work with the chunk of the poor people, who see the reality. They will go and call the professors at Korle-Bu and TTH who do not know Ngani [a village in Yendi Municipality]. They don't know how Ngani people live* (PYMH).

There was a procurement strategy that the government adopted to ensure lower medicine prices, especially, for the NHIS subscribers. That strategy was called the Framework Contracting Agreement. With this strategy, medicines were bought at the national level and sent to Central Medical Stores to be distributed to the Regional Medical Stores and the Teaching Hospitals. Since the government was buying the medicine in large quantities, it used that power to bargain for lower prices. That means the supply of medicines to the government hospitals had to be done through the Framework Contracting Agreement. This is how a pharmacist explained the strategy:

> *... the Minister [of Health] came up with what is called Framework Contracting. With this contracting, drugs are bought at the national level and the idea is that if the drugs are bought in huge volume, and economies of scale, the suppliers will beat down the prices from 50 to 80 per cent lower* **(**PTTH).

According to Koduah et al (2023), the Framework Contracting was in phases, Phase 1 was in 2018, Phase 2 in 2019 and Phase 3 in 2021. The pricing model used in Phase 1 was the Least Price Model. The price model for Phase 2 was the Least and Average Price Model and the price model for Phase 3 was the Least and Median Price Model. The procurement procedure under the pricing models is presented below:

> *"Least price model: Medicines priced highly negotiated to the least tender price. Required quantities are shared equally among selected vendors.*

> *Least and average price model: Prices negotiated and 4 responsive vendors selected. 1st least priced vendor allocated 40% of the total quantity. 2nd least priced vendor allocated 30%. 3rd & 4th least priced vendors allocated 15% each.*
>
> *Least and median price model: Prices negotiated and 4 responsive vendors selected. Vendor with the least price allocated 40% of the total quantity. Three other vendors supplied at the negotiated median price"* (Koduah et al, 2023 : 7).

The pharmacies at the hospitals and the managers of community pharmacies complained about how the prices of medicines were fixed by the NHIA. They bemoaned that the prices of medicines changed regularly throughout the year but medicine prices were fixed to cover the whole year. This, they believed militated against the pharmacy outlets which were accredited by the NHIA. Below are extracts of their responses during the interview.

> *The National Health Insurance is not also responsive to market price changes. They do it [adjust the prices] yearly. The prices of medicines do not remain the same throughout the year. As of now [December 2023], they have not yet reviewed the 2023 price list* (PTTH).
>
> *They give us their price list but within a month the prices of medicines increase* (PPHARM1).
>
> *They have fixed prices for an entire year but the prices increase several times within a year* (PPHARM3).
>
> *When the NHIS gives us the price list, there are some medicines whose prices will escalate within two to three months* (PPHARM3).
>
> *Their prices are for a whole year but prices may even change within days* (PPHARM2).

The hospital pharmacies and the managers of community pharmacies unanimously lamented so much about the price fixtures. They complained that the NHIA always fix prices of medicines lower than the prevailing prices in the market. They said that, when the NHIA was about to come up with a price review, the new prices were leaked to suppliers and they increased the wholesale prices either equal to or higher than the new prices that were about to be introduced by the NHIA. The narrations of the participants in this study are shown below:

> *National Health Insurance comes to say that, we are going to buy paracetamol at Gh¢1.30. If you look at the common paracetamol in town, you find it difficult to get one meeting that price. Their (NHIS) prices are sometimes even dead on arrival, they don't meet the prices of the drugs [in the market]* (PTTH).
>
> *You know, the National Health Insurance, the prices that they pay or they reimburse, 60 per cent are not up to the prices you buy them* (PYMH**)**.
>
> *Can you believe the price they sell drips to us at the Regional Medical Stores is higher than the price given by the NHIS?* (PGMH).
>
> *The ideal thing is that the prices of the NHIS are supposed to be the retail prices at the medicine outlet. But whenever the NHIS is about to come out with new pricing, the suppliers will adjust their prices higher or equal to the new prices that are not even made available to the medicine outlets. So, when hospitals go for the medicines and sell them at the prices of NHIS, the hospitals will have negative balances* (PGMH).

The NHIA and the private pharmaceutical outlets were said to have different motives in their pricing of pharmaceutical products. Whilst the NHIA priced medicines to meet the health needs of the population, the private pharmacies priced their medicines to make a profit. This created a problem in medicine availability for the subscribers of the NHIS. This is how the participants in this study presented their views:

> *That [pricing of NHIS medicines] affects a lot because the National Health Insurance Scheme is designed to deal with population problems but there are individualised problems that cannot be addressed by National Health Insurance* (PTTH).
>
> *The NHIS medicine pricing is different from ours because we have different motives for pricing our medicine. NHIS prices their medicines to enable them to manage their resources to sustain the Scheme. We also price our medicines based on the market forces to remain in business* (PPHARM3).

The claims by the NHIA authority about the stakeholder involvement, and evidence-based pricing of the NHIS medicine are very refreshing. However, the contrary statement being made by the hospital pharmacists and managers of private pharmacies is an indication that there is information gap between the pharmacists and pharmacy managers and the NHIA. However, the pharmacist at

the tertiary hospital who is one of the stakeholders was not pleased with how the NHIA priced their medicines.

6.3.2 Medicine Availability for National Health Insurance Subscribers

According to the regulations set by the government, hospitals that required medication were expected to request replenishment from the Regional Medical Stores, except for teaching hospitals, which were allowed to obtain their medications directly from the Central Medical Stores. If a particular medication was not available at the medical stores, pharmacists were permitted to obtain it from the open market. However, if the medication was not declared unavailable but had not been supplied by the Regional Medical Stores, pharmacists might request permission from their Regional Director of Health to obtain it from the open market.

It's essential to note that medications covered by the NHIS were still supposed to be provided to subscribers of the Scheme and could not be sold out-of-pocket. This means that hospitals and pharmacists were to ensure that NHIS subscribers received their prescribed medications without any additional charges. It was the responsibility of healthcare providers to ensure that they adhered to these regulations to ensure that patients received the care they needed without any financial burden.

During the interviews, it was revealed that when the hospitals were out of stock of medicines and requested medicines from the Regional Medical Stores, they would be given those that were available, if some were not available, the Regional Medical Stores would not declare them unavailable, they would tell the hospital pharmacists to wait, that the medicines unavailable would be supplied soon. Consequently, as they kept waiting, the hospitals would run short of those medicines.

> *When we run short of medicines, we are required to buy them from the Regional Medical Stores (RMS). If they do not have the medicine, they have to declare the medicine unavailable before we can procure it outside. Sometimes, when the medicine is not available, the RMS will not declare it unavailable, they will tell you to wait until the medicine is in. They will be waiting for the suppliers, whom the government has contracted, to supply the Medical Stores before they supply the hospitals* (PGMH).

The interviews revealed that the lower prices being offered by the government for the medicines under the Framework Contracting Agreement led to medicine stockouts at various levels of the medicine supply chain. It led to the failure to supply medicines by the suppliers who were given the contract under the Framework Contracting Agreement. Below is the narration by the participants of the study:

> *… some companies did the bidding, and we gave them the award, Dollar said, wait and see. Even though they are manufactured locally, the raw materials are not produced locally, the cost of the raw materials determines the cost of the drugs. The dollar has an effect, so they were given the contract but they failed to supply. Every year, the contract is signed. In January (2024), we will go to Accra to do the tender of the Framework Contracting, we will give them the award but some of them will decline to supply. It is going to be on credit and if the manufacturer is going to be at a loss, he will refuse to supply* (PTTH).

> *… some of them will fail to supply because the price they gave to the government may emerge as unrealistic in the market. Sometimes adverse global economic events will shoot up the prices. As those suppliers do not supply the government will not give others the contract to supply. As a result, there will always be stockouts* (PGMH).

However, in another view, the failure to supply the medicine by the suppliers under the Framework Contracting was due to defaulting to pay them by the government. This is what a pharmacist in a Municipal hospital said:

> *As part of the MoU signed, the government has to pay the suppliers within a period. The government fails to pay as a result the suppliers try to adjust the prices of what has been supplied already* (PYMH).

In consonance with this testimony, Koduah et al (2023) indicated that, some facilities defaulted to pay the vendors. The vendors withheld the supplies and gave a condition that those facilities should pay the prevailing medicine prices (not the previously agreed prices) before they could supply the medicines. This implies that, the facilities failed to pay the medical stores for the medicines collected. Consequently, the medical stores also defaulted to pay the suppliers. This led to the refusal to supply the medicines.

The failure to supply the medicines to the medical stores was reflected in the public healthcare facilities. There were medicine stockouts there too. If those facilities even got approval and procured the medicines from the open market, they would be required to give out those medicines to the subscribers of the NHIS so that they would be reimbursed later. However, when the hospitals got to the market and the prices of the medicines were higher than the price list of the NHIS, they also returned and only wrote prescriptions for patients to look for the medicines and buy. This is how it was presented by a pharmacist:

> *It can take up to one month and medicines will not be at the hospital and the people will come and insult us that if you go to Yendi hospital common paracetamol, you cannot get. Because of that, you have to go to the regional director and explain the situation, as a result you request that you want to buy a small quantity of some drugs. If you even get the authority and go and buy at the open market you still have to sell it under insurance. So, when you go and the price is much higher than the insurance you come and sit down* (PYMH).

It was further discovered that, if the medicines were even available at the Regional Medical Stores, some of the hospital pharmacists would avoid them because of the differences in prices. There were complaints about the prices of some medicines at the Regional Medical Stores being higher than the NHIS prices. In order to avoid collapsing of the medicine funds in their hospitals, the pharmacists avoided buying the medicines at the Regional Medical Stores whose prices were

higher than the NHIS prices. Some of the pharmacists would even look for certain medicines that were not covered by NHIS. Below are extracts from the interviews:

> *… you can't use the drug money for anything apart from the drugs. Because of the prices of the insurance being lower when insurance reimburses as against what you go and pick at the medical stores, the one pesewa, two pesewas [losses], the drugs are in volumes. It becomes very huge money then you lose all. You are there too you don't want people to say the working capital is depleting under you. So, you don't want to go for drugs that will cause you to incur losses. When the Dr or physician assistant prescribe the drugs you write it for them (patients) to go and buy the drugs* (PYMH).

> *There are a lot of medicines we cannot stock. Common paracetamol tablets, we tell patients to go out and buy. We do that because any patient who comes must have a minimum of 18 tablets and the NHIS price for a tablet of paracetamol is 13 pesewas. However, the price outside is higher. So, if we have to give all these patients 18 paracetamol you can imagine the loss we will incur. What we do is stock paracetamol injection which is not covered by the NHIS and administer that one to our in-patients and tell the OPD patients to go and buy the tablets* (PGMH).

As a result of the difficult situation regarding medicine availability that was created by medicine pricing, the tertiary hospital sidestepped the directive from the government to purchase most of their medicines under the Framework Contracting Agreement. According to the director of pharmacy at the tertiary hospital, the only medicines being sought at the Central Medical Stores by the tertiary hospital were the program medicines. Besides that, the hospital went for competitive tender for the supply of the rest of the medicines needed. The director of pharmacy presented his narration as this:

> *Central Medical Stores don't always have what we want. It is only the program drugs we get from the Central Medical Stores. That is those that are sponsored by NGOs, UNICEF and others, for the routine medicines we do national competitive tender* (PTTH).

When the tertiary hospital procured its medicines from the open market, the prices of the medicines would be higher than the NHIS medicines prices. As a result, those medicines were not given to the patients with NHIS subscriptions. The director of pharmacy had this to say:

> *... sometimes you want to buy and (they say) that this is a framework drug we shouldn't buy, teaching hospital we refuse. But when you buy you cannot give it to insurance because the prices of the Framework Medicines are what fit into insurance* (PTTH).

Some of the municipal hospitals also found a way of dealing with the medicine stockouts and the lower price being paid for the medicine by the NHIA. Even though the Regional Medical Stores did not easily allow hospitals to purchase medicines in the open market, when those medicines were not available at the Regional Medical Stores, some hospitals found a way of purchasing outside. This is how they did it:

> *When you request medicines that are not available, the Regional Medical Stores will indicate nil at those places, some hospitals regard the nil as a declaration of unavailability and go ahead to buy their medicines at different sources* (PGMH).

As a result of the lower prices of medicines being paid by the NHIA, some hospitals decided to introduce co-payment as a way of not running losses in the sale of medicines to the NHIS subscribers. They believed that it was better to take a token from the patients than allow them to go and buy the medicines at higher prices outside. They knew it was illegal to do that but they regarded that illegality as a way of helping patients. The participants narrated the issues as shown below:

> *When we bring in the medicines with the NHIS pricing, to help the patients and protect the hospital financially, we may ask patients to top up on the price of the NHIS to obtain the medicine but that is illegal. However, it is better than telling the patient to go out and buy which price will be higher and which quality we cannot be sure of* (PGMH).

> *We have our pharmacy which we stock always. So, when our doctors prescribe a medicine for an NHIS subscriber whose price is lower than the market price we let the patient pay the difference. We will not let the patient go out and suffer in looking for the medicine* (PHF1).

The quality of the medicine supplied under the Framework Contracting Agreement was even doubted. A pharmacist complained about how the cost of a quality medicine would be reduced to

the level the suppliers were selling. It was indicated that there were conditions that could be managed for a while with the medicine from the Framework Contract and there would not be a change. However, if another medicine was introduced, the condition changed immediately. This is how the view was expressed:

> *You know Ernest Chemist, most of their drugs are considered to be good but we are not able to put their drugs on NHIS. It is similar to the drugs of Kinapharma and M&G. We would rather be buying from Indian firms. These Indians, only God knows how they can do [manufacture] their drugs. Even a drug which is sold at Gh¢15 by other manufacturers will be sold at Gh¢5 cedis by the Indians. Only God knows the content of that drug. We cannot say that they are producing on a large scale, so economies of scale, no. We have a drug, paracetamol injection from the Indians, they will administer it to a patient and the temperature is still there. But you will give another drug and the temperature will go fast* (PTTH).

The difficulties related to the medicine procurement and the consequent perineal medicine stockouts at the health facilities created a black market of medicines in some of the municipal hospitals. It was confirmed by the pharmacists of one of the municipal hospitals that no private pharmacy shop was found on the hospital premises. Nonetheless, patients were directed to a cubicle in that hospital to buy medicines when they could not obtain the same medicines at the dispensary of the hospital. The situation was narrated by a patient as this:

> *When they told me the medicine was not available, I was about to leave and another person asked me if I did not get the medicine, when I said yes, he directed me to another cubicle to go and show the prescription to the man sitting there. He checked it and told me the cost of it if I wanted to buy it. I said I would buy so he sold it to me* (MHS1).

Some patients bought the medicines at an alternative dispensary of the same hospital they attended. They were told the medicine was not available when they went to one of the dispensaries of the hospital. When they changed to another dispensary of the same hospital and offered to buy the medicine, it was sold to them. One of the health seekers who had this encounter narrated it as this:

> *When they told me the medicine was not available, I went to another counter and told them that I wanted to buy that medicine. They took the prescription, checked it and told me the cost, so I should pay the cashier and come back. I did that and collected a receipt and gave it to the dispensary guys and they gave the medicine to me* (FHS3).

Some of the community pharmacies also refused to give out medicines to some patients who went to them with NHIS prescriptions. When the patients sent others to go to the same pharmacies to buy the medicines out-of-pocket, the medicines were sold to them. Below is a narration by one of the participants of this study:

> *When they told me it was not there, I came home and my husband took it back to the same pharmacy and told them he wanted to buy it and they sold it to him* (FHS2).

Some health seekers had to switch pharmacies and offered to buy the medicines prescribed for them out-of-pocket before they were given attention. They initially sent the prescriptions to NHIA-accredited pharmacies, but they were told the medicines were not available, they switched to another accredited pharmacy and offered to buy before the medicines were sold to them. This experience was narrated as this:

> *I went to the ABS [NHIA accredited] pharmacy with the prescription and they told me it was not there. I took it to CYB [also NHIA accredited] and told them I wanted to buy and they sold it to me* (MHS3)**.**

The managers of the community pharmacies corroborated the experience of the health seekers. They complained of the difficult situation they found themselves in given the lower prices of medicines in the NHIA medicines list and the delay in reimbursement of their money when they gave out medicines to the subscribers of the scheme. Some of the managers complained of buying the medicines on credit at prices which are higher than the prices of the NHIA. Below are extracts from the interviews:

> *… If we are supplied with medicine on credit and the payment period is short, we will not be able to give it out to NHIS subscribers. Because we have problems with the pricing and the time of reimbursement* (PPHARM1).
>
> *I have to be frank with you my brother, it does. When we realise that we have given out a lot of medicines to NHIS subscribers in a particular month, we stop and only sell to those who buy directly. That is what will help us remain in business because of the prices and the timing the Scheme reimburses us. If we don't do that our capital will be depleted* (PPHARM3).

Despite all the difficulties regarding medicine stockouts and hidden activities taking place within the hospitals' premises, some health seekers successfully obtained medicines prescribed for them as subscribers of the NHIS. Some of the participants said they encountered no difficulty and had all the medicines prescribed for them. Others complained of a delay at a community pharmacy but ultimately obtained the medicines at those pharmacies as subscribers of the NHIS. The following are extracts of their responses to the interview:

> *I did not face any challenge, when I went to the dispensary, they gave me all the medicine* (FHS4).
>
> *They delayed me at the pharmacy but they gave me all the medicine* (MHS3).

The NHIA authority gathered data on medicines prices across the country and consulted stakeholders in the pharmaceutical supply chain to come up with realistic prices for medicines in the NHIA medicines list. However, this study found that the consultation being done by the authority was not broad. Also, the data gathered and the information obtained from the stakeholders were not factored into the pricing of medicines in the NHIA medicines list. It was also discovered that the government introduced a procurement strategy which enables it to negotiate for lower prices because of the volume of medicines being bought.

The pricing of the medicines and the procurement strategy turned round to be a blight on access to quality medicines at the hospitals besides the teaching hospital. There had been consistent stockouts as a result of the failure to supply medicines in the new procurement strategy because of

the lower prices. Hospitals refuse to stock medicines because of the lower prices being paid by the NHIA. Pharmacies refused to give medicines to NHIS subscribers because of the lower prices being paid by the NHIA and delays in reimbursement. This brought about secret sales of medicines on hospital premises. Succinctly, the pricing of medicines in Ghana led to the unavailability of medicines to the subscribers of the NHIS at the hospitals and the community pharmacies.

6.4 The Medicine Regulation Authority and Quality of Medicines

The fourth specific objective of this study was to examine how the medicine regulation authority ensures the safety of medicines in Ghana. Both primary and secondary data were gathered to answer the research question that germinated from this specific objective. The data gathered was coded and the codes were used to generate themes and sub-themes.

Food and Drugs Authority (FDA) embodies the Medicine Regulation Authority in Ghana. The enabling legislation of the FDA is the Public Health Act, of 2012 (Act 851). Parts six. seven and eight of the Act 851 point out the functions of the FDA. Those functions designated in the Act reflect the categorisation of the FDA into various technical divisions and departments. Each function of the FDA has guidelines which direct how the functions are performed. However, since this study is on pharmaceutical governance, it focuses on aspects of the functions of the FDA which are to ensure the quality of medicines. The key functions of the FDA in ensuring the quality of medicines in Ghana are medicine registration and inspections. The FDA collaborates with other agencies in the performance of those functions.

6.4.1 Medicines Registration

Section 118 of the Public Health Act, 2012 (Act 851) avers that drugs and herbal medicinal products have to be registered in Ghana before they can be manufactured, imported, advertised and distributed. This excludes medicines that are imported for personal use or a sample of medicine imported for the purpose of registration. Based on this provision, the FDA developed a guideline for the registration of allopathic and herbal medicines.

Before allopathic medicine can be registered by the FDA, every relevant information regarding the quality of the medicine has to be submitted to the FDA including the quality control procedures. Any medicine to be imported into Ghana will require six months from the day of application for registration of the medicine. However, locally manufactured medicines and program medicines need three months for registration in Ghana. Besides the information on the quality of medicines, registration of herbal medicines requires a toxicology report and evidence of claim about the efficacy of the medicines.

Regarding the donation of medicines, any medicine that is not registered in Ghana shall not be donated to any entity in Ghana. This implies that, before anyone wants to donate a medicine which is not registered to the country, the person has to go through the registration procedures. The registration will take three months if the medicine is a public health program medicine. That is if it is a medicine for malaria, tuberculosis, antiretroviral medicine or maternal and child health medicine. If the medicine does not fall within this category, then the registration procedure will take six months. Besides the registration, the quality of the medicine to be donated must be acceptable in the country of origin before it can be accepted in Ghana. This guideline is to prevent the dumping of rejected medicines from other countries in Ghana. Also, medicine with a shelf life of more than 24 months should have a minimum of 60 per cent of its shelf life remaining but those

with a shelf life of 24 months and less should have a minimum of 80 per cent of its shelf life remaining before it can be donated to Ghana. This implies that people should not donate medicines to Ghana because they are about to expire.

Ghana imports most of its medicines, as a result, FDA has a hefty task to ensure that the medicines imported are of good quality. Consequently, guidelines for importation of medicines have been developed pursuant to section 148 of Act 851. As expected, only registered medicines in Ghana are allowed to be imported into the country. However, patients with prescriptions for special drugs who are importing the medicine for personal use are not required to register those medicines. This implies that the quantity of medicines to be imported for personal use will be determined by the treatment regimen shown in the prescription. The FDA also allows the importation of medicines into the country for registration, promotion and clinical trials without prior registration.

FDA also licenses manufacturing facilities for pharmaceutical and herbal medicines to ensure the quality of the medicines. Before the license can be issued for those facilities, the manufacturers have to present a quality manual to FDA for inspection. The manual is required to contain policies for storage, distribution and procedures in the manufacturing process that may affect the quality of the medicines. There is also supposed to be a site Master File which is composed of a document prepared by the wholesale distributor which contains information on the condition of storage being carried out at the site and during distribution. The File is also supposed to be inspected by the FDA to ensure standards of storage and distribution.

6.4.2 Inspections

Another key function of the FDA is to conduct inspections of the pharmaceutical products that are granted marketing authorisation. This function emanates from section 125 (3) of the Public Health Act, 2012 (Act 851) which states that:

> *"The Authority shall continually monitor the safety of the products regulated under this Act by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary".*

This provision empowers the FDA to engage in pharmacovigilance activities which may lead to a recall of medicines. FDA developed guidelines that aid in their pharmacovigilance activities and recall of medicines. This implies the guidelines spell out the functions of the FDA. The essence of pharmacovigilance inspection is to ensure that "local representatives and Marketing Authorisation Holders adhere to the regulations" (FDA, 2016). There are two kinds of pharmacovigilance inspections. They are routine and targeted inspections. The risk analysis criteria of pharmaceutical products determine the frequency of routine pharmacovigilance inspection. The routine inspection is done to verify the systems and facilities in place for pharmacovigilance as specified in Act 851. The targeted inspection is unannounced, it is triggered when there is a suspicion of failure to monitor the safety of products by Local representatives or Marketing Authorisation Holders.

Targeted inspections may come up after reports of Adverse Drugs Effects (ADE). FDA has a form for ADE reporting. Therefore, individuals can report ADE using the form at the FDA website. All medicine outlets are required to gather ADE reports of the medicines they distribute and forward them to the FDA for action. Pharmacists at a tertiary hospital explain these regarding the ADE report in their hospital:

> *We report adverse drug reactions to them [FDA]. FS is the head of that unit [pharmacovigilance]. Others report (ADE) to her and she also reports to the FDA* (PTTH).

However, a manager of a community pharmacy indicated that they were not recording any ADE reports. They only sold medicines to those who reported mild ADEs to douse the effect. If the ADE was serious, they advised the person to go to the hospital. Below is the narration by the manager of a community pharmacy:

> *Some people do come and complain of some illnesses after taking the medicines they bought from us. If that medicine was prescribed at a health facility, we tell the person to go back to the health facility but if the person bought the medicine directly from us, we check if the person took the right dosage, and after that, we sell another medicine to the person to calm the effect of the medicine they took. If the effect is serious, we tell the person to go to the hospital* (PPHARM1).

When deficiencies in products are found after ADE reports and inspection, those deficiencies are classified into critical, major and minor depending upon the extent of damage the product can cause to the populace. A manufacturer or Local representative will be informed of the deficiency and how to remedy it. If the deficiency is consistently not addressed, sanctions will then be applied which includes product recall.

There are three types of recalls: Types A, B and C. In type A, the recall is done at the consumer level. The recall message is sent to reach all medicine suppliers and consumers through the media. The manufacturer or importer is also informed to retrieve the medicine from all their distributors. Type B recall; the message is distributed to the suppliers, that is wholesalers, all categories of hospitals, pharmacies and retailers. The recall letter is also sent to manufacturers or importers and healthcare professionals. In type C recall, the message is sent to the wholesalers and other distribution points. A firm whose product has been recalled is responsible for informing all its outlets that distribute the products being recalled. The format of the information is that the product being recalled has to be specifically mentioned, instruction has to be given to stop the distribution and what to do with the product has to be specified to all the outlets.

FDA also work with health facilities to dispose of unwholesome medicines. When medicines in stock at the health facilities become unwholesome, they write to the FDA. The Authority will then go and examine the unwholesome medicines and take records of them. After that, the facility writes to the District/Municipal/Metropolitan Assembly where the facility is located. They also write to the waste management agency in the district. A date will then be fixed for these three agencies to come together with the facility to dispose of the unwholesome medicines. This is done at the cost of the health facility. These were the explanations given by pharmacists at the tertiary hospital and a municipal hospital:

> *When medicines expire, we separate them and keep them under lock and key. After a certain period, we write to the FDA, then we pay a certain fee. We involve waste disposal entities like the Assembly, Zoom Lion and Co. We then come together and dispose of it at a land field site which is operated by the Assembly. We pay a certain fee to the assembly too because we use their personnel and their trucks to convey the medicine to the land field site. FDA will then give us a certificate* (PTTH).

> *When drugs expire, we list the medicine and write to the FDA. They will come and assess them at the cost of the hospital. You also write to the sanitation department of the Municipal Assembly, notifying the Municipal Chief Executive of the need to dispose of some unwholesome drugs. You also write to the regional director (GHS). The municipal assembly will then give you the site to go and dispose of the medicine. These days burial of the medicine is advised. So, the municipal assembly then sent their excavator to dig for the burial of the medicine* (PYMH).

However, at the community pharmacies, no specific unwholesome medicine disposal was explained during the interviews. Some of their managers only mentioned that some people were going to those pharmacies for the unwholesome medicines but they did not know how it was disposed of. Others said they mixed them in their rubbish and disposed of them. These are what they said:

> *Some people come for it. They are supposed to destroy them but we don't follow up to see how they do it* (PPHARM3).

> *We mix them with our rubbish and dispose of them* (PPHARM2).

There are indications that the unwholesome medicines can return to the medicine outlets to be sold out to consumers. Giving out unwholesome medicines to some people without knowing how it is disposed of and mixing them in rubbish are dangerous things. The complex process and the cost involved in the disposal of unwholesome medicine can ignite illegal activities that may expose health seekers to unsafe medicines.

FDA works in collaboration with some agencies to ensure the quality of medicines in the country. Among the collaborators are the Customs Division of Ghana Revenue Authority and the Ghana Police Service. Whilst the Customs manage the borders to prevent the smuggling of medicines, the Police Service mounts checkpoints to find illegal activity within the country. To examine the effectiveness of the collaboration between the FDA and these two state agencies, the study found out from the private pharmacies and itinerant medicine sellers their sources of medicine supply. Some of the community pharmacies indicated that they only buy medicines from local manufacturing companies. Others said they buy from both importers and local manufacturers. These are extracts of the interviews:

> *The local pharmaceutical companies supply us with different kinds of medicines* (PPHARM3).
>
> *There are different manufacturers and distributors of medicines in Ghana. So, we receive supplies from the distributors based on some factors. The price and how fast our requests are responded to when you call for any medicine are key in determining our choice of suppliers* (PPHARM1).
>
> *Different companies manufacture and distribute them. People also come here for different kinds of medicines. So, we call for supplies from different companies depending on what we need* (PHARM1).
>
> *If demand for certain medicines is high and they are not produced locally, we contact some importers to supply us* (PHARM2).
>
> *We have foreigners who supply us. Some of them, especially, the Nigerians come as individuals and introduce themselves to us with a sample of the medicines they*

> *can supply. If they have medicines that are in high demand, we take the supplies and keep doing business with them. PPHARM3*
>
> *Some companies and individuals approach us, telling us that they bring medicines into the country so they want us to be their distributors. If they have a good deal we accept and start contacting them when we need supplies* (PHARM1).

During a recent interaction with a group of itinerant medicine sellers, it was revealed that their source of medicines was through smuggling. According to their account, the suppliers of these medicines were based in Togo. These suppliers would then transport the medicines to Ghana via motorbikes, often travelling through remote and difficult-to-access areas to avoid detection. It is concerning to note that such illegal trade of medicines not only poses a significant risk to public health but also undermines the integrity of the pharmaceutical industry as a whole. This is a narration from a participant:

> *… he is at Lome; he uses his motor to supply me. He knows how he bypasses the security. That is why I don't go there to buy; the security can easily get me* (IMS1).

The study went further to find out if there was a way the community pharmacies verified the quality of medicines before purchasing them. Some of the participants of the study intimated that they verified from the suppliers if they were licensed by the FDA, others rather verify if the medicine to be supplied was registered with the FDA. However, some participants rather relied on their previous knowledge of the medicines to verify the quality before buying them. The following are some of the statements made by the participants:

> *… we verify from the supplier if their medicines are registered with the Ghana FDA. We get evidence of that before accepting to do business with anyone* (PPHARM3)
>
> *… if the supplier is licensed by the FDA, we assume the medicine of that supplier is genuine* (PPHARM1).
>
> *Most of the drugs those Nigerians bring are those we are already familiar with. They are not fake medicines* (PPHARM3).

> *It does not matter where they import the medicine from, as far as the medicines they are selling to us are registered with the FDA, the medicine is demanded and the price is reasonable, we take the supplies from them* (PPHARM2).
>
> *FDA has a list of registered medicines on their website, so if we are to get supplies, we first all take a sample and check at the FDA site if that medicine is registered* (PPHARM3)
>
> *We do that [verify the quality] when the medicine is new to us but if it is what we have been selling, already we don't doubt the quality* (PPHARM1).

6.4.3 Safety of Medicines

Concerning the safety of medicines, when drugs are wrongly administered, they produce negative effects. That is called an adverse drug reaction (Alomar, 2014). However, when medicines have not gotten the required scrutiny and get into the market, or are not properly handled in the distribution process, they become unsafe to the consumer (Tauqeer, 2019). In such a situation, unsafe medicine may be toxic and produce an adverse effect (Aronson & Ferner, 2005). This makes it logical to measure the prevalence of unsafe medicine by using the adverse effects of the medicine among those who consumed it. Therefore, the Adverse Drug Effect (ADE) among health seekers was used to measure the safety of medicines.

The study revealed that some of the participants experienced ADE after taking certain medicines. Some of them believed the medicines they took were expired. Their belief came from the texture of the medicines. They indicated that the medicine was unusually soft which they could crush with their fingers. One of the respondents narrated her experience below:

> *That paracetamol was very soft. When I removed it from the seal, it got broken. I could grind it with my thumb and index finger. I took 2 as I have been taking paracetamol, and started feeling dizzy. I believe it expired* (FHS1).

Some of the participants rather believed the medicines they took were fake. Some of them detected fake names on the medicines they took that resulted in the ADE, some based on the price others

used strange language written on the medicine. The following are extracts from the response on the ADE:

> *That medicine was advertised on Facebook, I contacted them and bought it because I could not get it from the drugstore I had been buying it. When I took it, I started getting palpitations and headache. That was my first time having that experience after taking that medicine. I have been buying it from the drug stores. This particular one is a counterfeit medicine* (MHS3).
>
> *I went to the pharmacy and asked for 'Flucoday' which is orange in colour. That is what I take whenever I have a cold. The pharmacy assistant brought another medicine with the name 'Flukoday' which had a yellow colour. I said it was not the one I wanted. He said it was the same as the one I wanted. He explained the dosage to me. When I went home and took it as he told me to do, it became difficult for me to even lift my hand. My tongue became heavy. My brother had to intervene by giving me a tin of milk to take before I was able to sit up in about 2 hours* (MHS3)
>
> *I was always taking that medicine to keep my house in order (sex enhancement). I bought it from Mr M that day and took it immediately after my supper, as I usually do. I then started shivering. My hydraulic (manhood) could not even lift (could not get an erection). I then believed the rumours that go around about that man that he sells fake medicines* (MHS3)
>
> *I was having abdominal pains and went and explained to the pharmacy assistant. He told me the same medicine had different prices. I bought the less costly one. When I took it, I got a headache in addition and my temperature started rising. I then realised the low-cost medicine he sold to me was not a genuine one* (FHS2)
>
> *When he sold it to me, I already suspected I was buying fake medicine. He buys his medicine from Togo. The text on it was not in English. There was no expiry date on it. There was no manufacturer name on it. However, the guy convinced me that it was one of the most effective malaria medicines. When I took it, my sickness intensified* (MHS3).

All those who experienced the ADE bought the medicines from a pharmacy, a nurse managing an over-the-counter medicine store, online or an itinerant medicine seller and some were advised by nurses to buy those medicines. None of them obtained the medicines from a hospital.

The data indicates that the functions of the FDA were engraved in legislation. Besides, a lot of guidelines were developed by the Authority to enhance effective functioning for good medicine quality. The Authority works in collaboration with other agencies. Among the agencies were

Ghana Police and Customs Division of Ghana Revenue Authority. A loop hole has been identified by some medicine distributors. This category of distributors successfully smuggled medicines to Ghana. The lack of capacity to regularly check private pharmacies for expired medicines may lead to the existence of unsafe medicines in the market. Consequently, some patients reported an incidence of ADE.

6.5 Summary of the Chapter

This chapter aims to provide a detailed analysis of the qualitative aspect of the data collected during this study. The specific objectives of the study were to: firstly, examine the medicine prescription behaviour of health professionals and how it influences the affordability of medicine in Ghana, secondly, examine medicine dispensing practices and how they influence the rational use of medicines, thirdly find out how medicine pricing in Ghana affects the availability of medicines to the subscribers of the National Health Insurance Scheme at the health facilities and fourthly, examine how the medicine regulation authority ensures the safety of medicines in Ghana. The data collected based on the above objectives were organised into themes. Therefore, the data analysis was based on the themes identified from the data.

The study found that there were a lot of guidelines on medicine prescription in Ghana. These guidelines are the Standard Treatment Guidelines (STG), Essential Medicines List (EML) and the National Health Insurance Authority (NHIA) prescription and dispensing guidelines. The study indicates that the STG and the EML guided prescription at the Municipal hospital. However, those guidelines were regarded as useless at the tertiary level of healthcare. Also, there were prescription audits at all levels of healthcare delivery. The prescription audits were based on the guidelines stated by the NHIA. The study found that only a few patients were involved in the prescription process. A lot of other patients were not involved. It was also discovered that some prescribers

directly sold medicines to patients and some directed patients to specific health facilities to buy their prescribed medicines. It was confirmed by managers of the community pharmacies that, some prescribers kept medicines at those pharmacies and directed patients with prescriptions to buy those medicines. The failure to involve patients in the prescription process contradicted a section of Act 851. Also, involvement in medicine sales by medicine prescribers did not conform with STG, EML and the prescription and dispensing guidelines outlined by the NHIA. These behaviours that violated the policies were found to influence the affordability of medicines by some of the health seekers.

Also, one of the important points in the pharmaceutical life cycle is medicine dispensing. The study found that some dispensary personnel in government hospitals were trained and were given guidelines on medicine dispensing to facilitate their performance to serve patients well. However, the community pharmacies did not give much attention to training the pharmacy staff. In terms of communication at the dispensary, it was found that none of the health facilities had a specialist to interpret messages to the hearing and visually impaired. Only one hospital also had people who could interpret medication information at the dispensary in different languages for health seekers. In addition, whilst some health seekers were satisfied with how the dispensary staff communicated to them, others complained of lower voices and refusal to talk at all at the time of dispensing medicines to them. Some health seekers also complained of negative attitude, and failure to give clear dosage and side effect information by the dispensary staff. There were also complaints of poor organisation and longer waiting times at the dispensary. All these appeared to have a negative influence on the rational use of medicines.

Furthermore, a lot of consultation and surveys took place before medicine was priced in Ghana. However, the pharmacists being interviewed indicated that the information gathered during the

consultation and the surveys were not utilised in pricing medicines for the NHIS. Prices of the NHIS medicines were said to be lower than the prices of medicines in the market. Besides that, the Government adopted a procurement strategy which was supposed to bring down the prices of medicines in the system, this rather created shortages of medicines because of the lower prices the government offered. These shortages extended to the health facilities. Community pharmacies were also hesitant to give out medicines to health seekers under the NHIS because of the lower prices the NHIA would pay for the medicines given to their clients. These left subscribers of the NHIS buying medicines out-of-pocket after visiting hospitals. Therefore, the pricing of medicine by the NHIA led to the unavailability of medicines to the subscribers of the NHIS at the health facilities.

Lastly, the Food and Drugs Authority (FDA) embodies the Medicine Regulation Authority in Ghana. It performs a lot of functions to ensure the quality of medicines in Ghana. The functions of the FDA are defined in the Public Health Act, 2012 (Act 851). The FDA registers all kinds of medicines before they can be manufactured, imported, donated or distributed in Ghana. A registered medicine has market authorisation to be distributed in the Ghanaian medicine market. The authority also licenses both herbal and allopathic medicine manufacturing and distribution facilities to enhance the quality of medicines production and distribution in Ghana. After the medicines get to the market, the FDA inspects the medicines. If any medicine is found to be defective a recall of that medicine is done to eliminate the medicine from the market. The Authority also works with health facilities to dispose of unwholesome medicine. The FDA works in collaboration with several government agencies. Some lapses appear to emerge from that collaboration which leads to the proliferation of unsafe medicines in the Ghanaian market. As a result, many people reported an experience of adverse drug effect (ADE).

CHAPTER SEVEN

PRESENTATION AND ANALYSIS OF QUANTITATIVE FINDINGS

7.0 Introduction

This chapter aims to present and analyse the quantitative data gathered for this study. Firstly, it outlines the socio-demographic characteristics of the selected health seekers for this study. Secondly, it presents and analyses the quantitative data in alignment with the study's objectives and addresses the research questions it was designed to answer. The chapter encompasses the prescription behaviour of health professionals and its impact on medicine affordability, as well as information on health personnel's dispensing practices and their influence on the rational use of medicine. Additionally, the chapter provides data on the prices of medicines in the NHIS medicine list, the availability of medicines to NHIS subscribers, and the functions of the FDA and medicine safety. The data is presented in raw figures, accompanied by corresponding percentages, and cross-tabulations are used where necessary to demonstrate relationships between variables.

7.1 Socio-Demographic Characteristics of Respondents

The socio-demographic characteristics of respondents in this study are sex, age, religious beliefs, marital status, level of education, occupation, income and health insurance subscription status. The data indicates that out of the 500 respondents, the majority were males; they constituted 55 per cent of the respondents. In terms of the age distribution of the respondents, those who were between the ages of 30 – 34 were high at 25 per cent and the lower number of respondents were those who were from 55-59 years, over 60 years and those between the ages of 35 – 39 and 45 – 49. Each of those age groups constituted five per cent of the respondents. Also, 70 per cent of the

respondents said they belonged to the Islamic religious faith. Regarding marital status, 70 per cent said they were married, 20 per cent said they were divorced and the rest said they were single.

Table 11: Demographic Characteristics of Respondents

Sex	**Frequency**	**Per cent**
Males	275	55
Females	225	45
Age (Years)		
20-24	75	15
25-29	75	15
30-34	125	25
35-39	25	5
40-44	50	10
45-49	25	5
50-54	75	15
55-59	25	5
60+	25	5
Religious Affiliation		
Islam	350	70
Christianity	150	30
Marital Status		
Married	350	70
Divorced	100	20
Single	50	10
Level of Education		
Post Graduate Education	25	5
First Degree	125	25
Diploma	25	5
Secondary Education	100	20
Basic Education	50	20
No Formal Education	175	35
Occupation		
Farmer	100	20
Trader	150	30
Teacher	87	17.4
Civil Servant	63	12.6
Other Public Sector Worker	25	5
Unemployed	75	15
Monthly Income (GH₵)		
Below 500	125	25
500 –1000	200	40
1001-2000	100	20
2001-3000	75	15

Source: Compiled by the author from the field data, 2023

In addition, as much as 35 per cent of the respondents said they had no formal education and only five per cent had post-graduate education. Besides, 30 per cent of the respondents were traders, 20 per cent were farmers and only five per cent were other public sector workers besides teaching and civil service. Of the 500 respondents, 40 per cent said their monthly income was in the range of GH₵500 - GH₵1000. Those with the lowest income bracket said their monthly income was below GH₵500. Those with a higher monthly income said they were earning GH₵2001- GH₵3000. They constituted 15 per cent of the respondents. The data indicates that all the respondents subscribed to the NHIS. The demographic characteristics of the respondents are shown in Table 6.

7.2 Prescription Behaviour of Health Professionals and Affordability of Medicines

The first objective of this study was to examine the medicine prescription behaviour of health professionals and how it influences the affordability of medicine in Ghana. In this section, we delve into the quantitative findings that pertain to the first objective of the study. In the context of this chapter, prescription behaviour encompasses the degree of involvement of patients in the prescription process as well as the level of involvement of medicine prescribers in the sale of medicines to patients. Patient's affordability, on the other hand, is determined by their ability to purchase the prescribed medicine without resorting to borrowing, seeking financial assistance, selling property, or sacrificing other financial obligations. A comprehensive analysis of the data provides a more detailed understanding of the impact of prescription behaviour on patient affordability of medications.

The survey conducted on the 500 individual health seekers revealed that all of them were active subscribers of the NHIS and had received prescriptions during their most recent visit to a healthcare facility. However, the survey findings indicate that the healthcare professionals who provided the prescriptions engaged in discussing alternative medication options with some of their

patients. Interestingly, 35 per cent of the respondents claimed that they were informed about alternative medications that could be available to them. Moreover, 40 per cent of the respondents stated that they were made aware of the cost of the prescribed medication, which could have impacted their decision to accept that medication if there was an option. Additionally, approximately 20 per cent of the respondents reported that the prescriber asked them if they could afford the medication prescribed. In all, some of the health seekers were involved in some or all the indicators of involvement in the medicine prescription process. This then follows that about 50 per cent of the respondents were involved in the prescription process in a way, which could have allowed them to raise concerns about preferences related to the prescribed medication.

The survey revealed that almost 49 per cent of the respondents purchased all of the medications prescribed for them. Also, about 29 per cent of the respondents stated that they had to pay for some of their prescribed medications. On the other hand, almost 15 per cent of the respondents confirmed receiving all of their prescribed medications as NHIS subscribers. To gain a better understanding of the role of medicine prescribers in medication sales, the respondents were asked if their prescriber had directed them to purchase the medicine from a specific location. As per the survey results, about 35 per cent of the respondents responded positively. As a result of the directive to patients to buy their medications at particular places, about 7 per cent of the respondents discontinued their treatment from the health facility. Almost 21 per cent of the respondents said they purchased the medication from where the prescriber directed them to buy it which included the prescriber self. Therefore, 5 per cent bought their medication directly from the prescriber and 16 per cent bought them from the pharmacies they were directed to buy their medications

Generally, among the 500 respondents surveyed, 77.8 per cent reported that they purchased some or all of the prescribed medicines, while the remaining health seekers either received the medicine

as subscribers of the NHIS (15 per cent) or decided to stop the treatment from the health facility (7 per cent). Surprisingly, Among the 77.8 per cent of those who bought some or all of the medicine out-of-pocket, 7 per cent borrowed money to buy the medicines, about 13 per cent had to sell an asset to buy the prescribed medicines, about 13 per cent had to forgo other basic needs to buy the medicines and about 9 per cent sought financial support to buy the medicines. However, 36 per cent of the respondents were able to purchase the medicines without any difficulty. This then follows that almost 42 per cent of the respondents indicated that the medicine was not affordable. Table 12 below displays the responses regarding the medicine prescription behaviour of health professionals and how that behaviour influenced medicines' affordability.

Table 12: Prescription Behaviour and Medicine Affordability

Was medicine prescribed for you when you went to the hospital?	**Frequency**	**Per cent**
Yes	500	100
Did the prescriber tell you anything about alternative medicine that could be prescribed?		
Yes	175	35
No	325	65
Did the prescriber tell you anything about the cost of the medicine prescribed?		
Yes	200	40
No	300	60
Did the prescriber ask you if you could afford the medicine?		
Yes	99	19.8
No	401	80.2
Is there any way the prescriber involved you in the prescription process?		
Yes	249	49.8
No	251	50.2
How did you get the medicine prescribed?		
I bought all	244	48.8
I was given all as an NHIS subscriber	74	14.8
I was given some and I bought the rest	146	29.2
I did not obtain the medicine	36	7.2

Did the prescriber instruct you to buy the medicine at a specific place?		
Yes	174	34.8
No	326	65.2
Did you buy the medicine from where the prescriber instructed you to buy it?		
Yes	107	21.4
No	31	6.2
Where did you buy the medicine?		
From the Prescriber	26	5.2
From the Hospital	204	40.8
From a Pharmacy	160	32
How did you afford the medicine?		
I borrowed money to buy it	35	7.0
I sold an asset to buy it	63	12.6
I had to forgo other basic needs to buy it	64	12.8
I sought support from others to buy it	47	9.4
I bought it without any challenge	180	36
I discontinued the treatment	36	7.2
Afforded the medicine?		
Yes	180	36
No	209	41.8

Source: Compiled by author from the field data, 2023

A cross-tabulation of the involvement of patients in the medicine prescription process and affordability of medicine indicates that among those who bought some or all the prescribed medicines out-of-pocket, about 26 per cent of them who were not involved in the prescription process were not able to afford the prescribed medication but about 12 per cent of those who were not involved in the prescription process were able to afford the medicines. On the other hand, almost 16 per cent of those who were involved in the prescription process were not able to afford the medicines but about 24 per cent of those who involved in the prescription process were able to afford the medicines. The crosstabulation analysis is based on the 77.8 per cent of the respondents who purchased some or all the medicines. The crosstabulation is shown in Table 13 below.

Table 13: Crosstabulations of Prescription Behaviour and Affordability of Medicines

Prescription Behaviour		Affordability of Medicines					
		No	Percent	Yes	Percent	**Total**	**Percent**
InvP	No	129	25.8	59	11.8	**188**	**37.6**
	Yes	80	16	121	24.2	**204**	**40.2**
	Total	**209**	**41.8**	**180**	**36**	**389**	**77.8**
InvMS	No	0	0	31	6.2	**31**	**6.2**
	Yes	81	16.2	26	5.2	**107**	**21.4**
	Total	**81**	**16.2**	**57**	**11.4**	**138**	**27.6**

Source: Computed by the author from the field data, 2023

A correlation analysis shown in Table 14 below was conducted to measure the relationship between patients' involvement in the medicine prescription process and the affordability of medicines to those patients. The results show a significant but moderately positive correlation between involvement of patients in the prescription process and affordability of medicines to those patients.

Table 14: Correlation Coefficients for Prescription Behaviour and Affordability of Medicines

	Aff	*InvP*	*InvMS*
Aff	1		
InvP	0.26* (0.00)	1	
InvMS	-0.13* (0.00)	0.06 (0.21)	1

Source: Computed by the Author from the field data, 2023

Note: P-values are shown in parenthesis

Also, a Probit Regression analysis conducted to examine the influence of prescription behaviour of medicine prescribers on the affordability of medicine shows that, involvement of patients in the prescription process increases the likelihood of the patients' ability to afford their medication. Specifically, the is a about 25 per cent likelihood that patients will be able to afford their medications if they are involved in the prescription process than if they are not involved. The results are shown in Table 15 below.

Table 15: Probit Regression Coefficients for Coefficients for Prescription Behaviour and Affordability of Medicines

Prescription Behaviour	*Coeficients*	*P > [z]*
InvP	0.7083481 (0.2463821)	0.000 (0.000)
InvMS	-0.4662855 (-0.1621863)	0.002 (0.001)
Constant	-0.6369688	0.000
n	500	
Pseudo R^2	0.0686	
$\chi 2$	44.83	
Prob > $\chi 2$	0.0000	

Source: Computed by the Author from the field data, 2023

Note: The margins are in parenthesis

Regarding the involvement of medicine prescribers in medicine sales and affordability of medicines, a cross-tabulation of responses of those who bought their medications from where the prescriber instructed them to buy them and the affordability of those medicines was conducted. The results show that all those who did not buy the medicines from where the prescriber directed them to buy them regarded the medicine as being affordable. About 5 per cent of the respondents

who bought the medicine according to the prescribers' directives also said the medicine was affordable. Conversely, 16 per cent of the respondents who bought the medicines per the prescribers' directive complained that the medicine was not affordable. The results of the crosstabulation are shown in Table 13 above.

A correlation analysis of prescribers' involvement in medicine sales and affordability of medicines has a positive significant but weak correlation between prescribers' involvement in medicine sales and affordability of medicines. The correlation figures are shown in Table 14 above. Also, the probit regression analysis to find out the likely influence of prescribers' involvement in medicine sales and medicine affordability indicates that involvement in medicine sales by a prescriber is likely to reduce the affordability of medicines than when the prescriber is not involved in medicine sales. Specifically, the affordability of medicine is likely to decrease by about 16 percent if a prescriber is involved in medicine sales than if he/she is not involved. The figures for the probit regression are shown in Table 15 above.

The data shows a significant influence on the medicine prescription behaviour of health professionals and the affordability of the medicines. In all, the marginals of the probit regression give the magnitude of the influence of prescription behaviour by medicine prescribers on the affordability of medicines. There is an indication that, when prescribers discuss the prescription process with health seekers and seek their opinion, the is a likelihood that the medicines the patient can afford is what will be prescribed. On the flip side, if medicine prescribers involve in medicine sales, the supply chain may be prolonged which will reduce the likelihood of the medicine being affordable to the health seekers.

7.3 Medicine Dispensing Practices

The second specific objective of the study is an examination of the dispensing practices at health facilities and how they may influence the rational use of medicines. The specific variables that guided the data collection to address this objective and answer the research question are the following: waiting time at the dispensary/pharmacy, organisation of the dispensary/pharmacy, explanation of the dosage of medications, information about possible side effects of the medications, the attitude of the personnel at the dispensary/pharmacy towards the health seekers and how the dispensary personnel communicate to the health seekers. These specific variables collectively served as a measure of dispensary practices which is the independent variable. The dependent variable; rational use of medicine was measured by absence of self-medication, adherence to medication regimen (completion of medication regimen) and adherence to the time for the medication (taking medication at the specific times given). Involvement by the health seeker in any of them is regarded as irrational use of medicine.

Generally, the data shows that only 87.6 per cent of the respondents went through the dispensary or pharmacy for their medications. The rest either truncated the treatment process with the health facility after consultation or bought the medicines directly from the prescriber. However, medicine dispensing had taken place between the prescribers and those they sold medicines to. Therefore, the data on waiting time by health seekers at the dispensary and their satisfaction with the organisation of the dispensary/pharmacy excluded those who truncated the health-seeking process after consultation and those who bought medicines directly from the prescriber. Nonetheless, the rest of the data on the other specific variables only excluded those who truncated the treatment process.

Regarding waiting time at the dispensary/pharmacy, the study found that 21 per cent of the respondents waited for less than five minutes before being attended to. However, about 10 per cent of the respondents waited for 40 – 44 minutes before the dispensary/pharmacy personnel attended to them. The rest of the respondents waited a minimum of five minutes and a maximum of 39 minutes before getting to the counter of the dispensary/pharmacy to receive their medication. An interaction of the variables revealed that all those who waited for 40 – 44 minutes had that experience of waiting for a long time at the private pharmacies. Nonetheless, all of them either obtained some or all the medicines as subscribers of the NHIS. It is possible that the health seekers were patient enough to wait that long because the private pharmacies remained their only source of hope to obtain the medication as subscribers of the Scheme. None of those who waited for less than five minutes obtained all the medication as subscribers of the NHIS. All of them either bought some or all their medications out-of-pocket from private pharmaceutical outlets. This shows how prompt attention is given to those who are buying medicine out-of-pocket. Generally, about 65 per cent of the respondents were satisfied with the time they waited at the dispensary. However, the rest of the respondents were not satisfied.

Table 16: Dispensing Practices and Rational Use of Medicines

	Frequency	**Per cent**
Can you estimate the time you spent waiting before going to the counter to receive the medicine?		
> 5 minutes	105	21.0
5 – 9 minutes	94	18.8
10 – 14 minutes	19	3.8
15 – 19 minutes	12	2.4
20 – 24 minutes	24	5.5
25 – 29 minutes	24	4.8
30 – 34 minutes	49	4.8
35 – 39 minutes	62	12.4
40 – 44 minutes	49	9.8

Were you satisfied with how long you waited at the point of medicine collection?		
Yes	327	65.4
No	111	22.2
Were you satisfied with how the dispensary/pharmacy was organised?		
Yes	242	48.4
No	196	39.2
Did the person who gave you the medicine explain the dosage of the medicine to you?		
Yes	452	90.4
No	12	2.4
If yes, were you satisfied with the information given to you about the medicine dosage?		
Yes	284	56.8
No	180	36.0
Were you given any information about the possible side effects of the medicine?		
Yes	177	35.4
No	287	57.4
Did you feel disrespected when the medicine was to be given to you?		
Yes	144	28.8
No	320	64.0
Were you satisfied with the attitude of the personnel who gave you the medicine?		
Yes	184	36.8
No	280	56.0
What language did the personnel who were to give you the medicine speak to you?		
English	184	36.8
Dagbani	280	56.0
Did you understand the language?		
Yes	464	92.8
Were their voices loud enough to let you hear and understand them?		
Yes	268	53.6
No	196	39.2
Generally, were you satisfied with how the personnel who gave out the medicine to you communicated with you?		
Yes	244	48.8
No	220	44.0
Did you go to buy any other medicine besides what was prescribed for you?		
Yes	377	75.4

No	87	17.4
Did you take all the medicine obtained from the prescription list?		
Yes	306	51.2
No	158	31.6
Did you take the medicine at the times you were told to take it?		
Yes	384	76.8
No	80	16.0
Medicine was rationally used		
Yes	25	5.0
No	439	87.8

Source: Compiled by the author from the field data, 2023

Also, 48 per cent of the respondents were satisfied with the organisation of the dispensary/pharmacy but 32 per cent were not satisfied. The data shows that all those who obtained the medicines as subscribers of the NHIS at the hospitals they attended were not satisfied with the organisation of the dispensaries of those hospitals. However, all the NHIS subscribers who obtained all the medications at the private pharmacies were satisfied with the organisations of those pharmacies. Concerning the explanation of the medicine dosages to health seekers, an overwhelming majority of the respondents (90 per cent) said the dosage of the medication they received was explained. Conversely, 36 per cent of those who said the dosage was explained to them said they were not satisfied with the explanation given to them about the dosage of their medication. It is interesting to note that, all those who bought their medication from the prescriber were satisfied with the explanation given to them on the dosage of their medication. Besides, most of those who were satisfied with the explanation of their medication dosage were the health-seekers who went for the medicine at private pharmacies including those who obtained the medication as NHIS subscribers at those pharmacies.

Regarding information about minor side effects of medications which may be normal with respect to some medications, respondents were asked if they were given information about such side effects during their last visits to the health facilities. The majority of the respondents (57 per cent) responded negatively indicating that they were not given such information. The consequence of the absence of such information could be a discontinuity of medication when such expected side effects come up in the course of taking the medication. It is, therefore, not surprising that about 20 per cent of the respondents in this study who were not given any information about minor side effects of their medications discontinued the medications.

With regard to the attitude of the dispensary/pharmacy personnel towards health seekers, almost 29 per cent of the respondents felt that they were not respected at the time they went for their medicines. It is worth noting that as much as 56 per cent of the respondents were not satisfied with the attitude of the dispensary/pharmacy personnel. It is not surprising that the number of those who said the language spoken to them was the local language (Dagbani) was the same number that felt dissatisfied with the attitude of the health personnel. The culture might have played a role here. The expectations of people in the locality about how they should be dealt with might not have been met which triggered the feeling of dissatisfaction with the dispensary/pharmacy personnel.

Given that some dispensaries/pharmacies have closed counters with small openings through which communication between the dispensary/pharmacy personnel takes place, 39 per cent of the respondents complained that the voices of the personnel at the dispensary/pharmacy were not audible to enable them to hear what was said to them. In general, about 49 per cent of the respondents were not satisfied with how the dispensary/pharmacy personnel communicated with them. This may have dire consequences on adhering to a medication treatment regimen. The data for the dispensing practices is shown in Table 16 above.

7.3.1 Rational Use of Medicines

The essence of examining the dispensing practices was to find out their influence on the rational use of medicines. The data indicates that 75 per cent of the respondents bought other medicines besides what was prescribed for them. This is an indication of possibly, a high level of self-medication among the respondents. Besides, 51 per cent of the respondents did not take all the medicines given to them in the prescription list and 16 per cent were inconsistent with the times given to them to take their medications. The high level of self-medication and incompletion of medication dosage are indications of irrational use of medicines. The figures for prescription practices and rational use of medicines constitute Table 16 above.

The interaction of responses of the respondents' satisfaction with the waiting time and rational use of medicines indicates that all those who were not satisfied with the waiting time did not use their medication rationally. However, 60 per cent of the respondents who were satisfied with the waiting time also engaged in irrational use of medicines.

Also, a cross-tabulation of the responses on satisfaction with the organisation of the dispensary/pharmacy indicates that, about 34 per cent of the respondents who were not satisfied with the organisation of the facility involved in irrational use of medications. However, 48 per cent of the respondents were satisfied with the organisation of the dispensary/pharmacy but also engaged in irrational use of medicines.

Furthermore, the data shows that all those who were not satisfied with the dosage information given to them had possibly engaged in irrational use of medications. However, 52 per cent of the respondents who were satisfied with the dosage information might have also used medications irrationally. This implies that other factors might influenced the irrational use of medicines by that

category of respondents or the respondents might have misunderstood the dispensary staff but rather thought they understood them.

In addition, a cross-tabulation of the data about the information given to patients on minor side effects of the medications and rational use of medicines indicates that all those who were not given information about the side effects of their medications did not use their medicines rationally. Conversely, 30 per cent of those who were given information about the side effects of their medications might have equally engaged in the irrational use of medicines. In examining an association between satisfaction with the attitude of workers at the dispensary/pharmacy and rational use of medicines, the data shows that 34 per cent of the respondents who were not satisfied with the attitude of the dispensary/pharmacy were involved in the irrational use of medications.

Regarding the association between satisfaction with how the dispensary/pharmacy staff communicated with health seekers and the tendency to use medicines rationally by the health seekers, results of a cross-tabulation of the data indicate that, 39 percent of the respondents who were not satisfied with how the dispensary/pharmacy personnel communicated with them involved in irrational use of medicines. However, 49 percent of the respondents were satisfied with how they were communicated to but were also involved in the irrational use of medicines. Contrary to this, about 5 per cent of the respondents use medicines rationally but were not satisfied with how they were communicated to. The figures for the crosstabulations are shown in Table 17 below.

Table 17: Crosstabulations of Dispensing Practices and Rational Use of Medicines

Dispensing Practices		Rational Use of Medicines					
		No	Percent	Yes	Percent	**Total**	**Percent**
	No	11	2.2	0	0	**111**	**22.2**
SatiWt	Yes	302	60.4	25	5	**327**	**56.4**
	Total	**413**	**82.6**	**25**	**5**	**438**	**87.6**
	No	196	39.2	24	4.8	**220**	44
Comm	Yes	243	48.6	1	0.2	**244**	48.8
	Total	**439**	**87.8**	**25**	**5**	**464**	**92.8**
	No	180	36	0	36	**180**	**36**
InfD	Yes	259	51.8	25	5	**284**	**56.8**
	Total	**439**	**87.8**	**25**	**5**	**464**	**92.8**
	No	287	57.4	0	0	**287**	**57.4**
InfSE	Yes	152	30.4	25	5	**177**	**35.4**
	Total	**439**	**87.8**	**25**	**5**	**464**	**92.8**
Attitude	No	171	34.2	13	2.6	**184**	**36.8**
	Yes	268	**53.6**	12	2.4	**280**	**56**
	Total	**439**	**87.8**	**25**	**5**	**464**	**92.8**
Organisation	No	172	34.4	24	4.8	**196**	**39.2**
	Yes	241	48.2	1	0.2	**242**	**48.4**
	Total	**413**	**82.6**	**25**	**5**	**438**	**87.6**

Source: Computed by the author from the field data, 2023

The correlation analysis to show the relationship between medicine dispensing practices and rational use of medicines indicates a positive and significant but weak correlation between satisfaction with waiting time at the dispensary/pharmacy, satisfaction with dosage information, information given on possible side effects of medications, as dispensing practices and rational use of medicines. However, there is a multicollinearity between satisfaction with the organisation of

the dispensary/pharmacy and communications between the dispensary personnel and health seekers. Attitude of dispensary staff toward health seekers was found not to be significantly correlated with rational use of medicines. The correlation matrix is shown in Table 18 below.

Table 18: Correlation Coefficients for Prescription Practices and Rational Use of Medicines

	RU	*SatiWt*	*Org*	*InfD*	*InfSE*	*Attitude*	*Comm*
RU	1.00						
SatiWt	0.13* (0.00)	1.00					
Org	-0.20* (0.00)	0.70* (0.00)	1.00				
InfD	0.17* (0.00)	0.40* (0.00)	0.48* (0.00)	1.00			
InfSE	0.28* (0.00)	0.31* (0.00)	0.35* (0.00)	0.65* (0.00)	1.00		
Attitude	-0.05 (0.23)	0.30* (0.00)	0.37* (0.00)	0.32* (0.00)	0.03 (0.47)	1.00	
Comm	-0.21* (0.00)	0.39* (0.00)	0.70* (0.00)	0.48* (0.00)	0.35* (0.00)	0.57* (0.00)	1.00

Source: Computed by the Author from the field data, 2023

Probit regression analysis was conducted to examine the effect of the dispensing practices on rational use of medicines. The correlation coefficients revealed a multicollinearity between the organisation of the dispensary and communications between the dispensary personnel and health seekers as medicine dispensing practices. To avoid the effect of the multicollinearity, organisation of the dispensary was removed from the estimators of rational use based on anecdotal information that, a well-organised dispensary may have a satisfactory waiting time and well-trained personnel

to communicate satisfactorily to the health seekers. Also, attitude of dispensary staff was removed from the estimators of rational use because the correlation coefficient between attitude of dispensary staff and rational use of medicine was not significant.

The coefficients of the probit regression indicate that satisfaction with waiting time by health seekers at the dispensary/pharmacy is likely to increase their rational use of medicines. Specifically, the marginals indicate that it may increase rational use of medicines by about 8 per cent. Also, when health seekers are not satisfied with the communications at the dispensary, it can possibly decrease rational use of medicines by 9 per cent. In addition, when health seekers are not satisfied with the dosage information given to them at the dispensary/pharmacy, there will be a likelihood of a decrease in rational use of medicine by 11 percent. Finally, if information on possible side effects of medication is given to health seekers at the dispensary, it may increase rational use of medicines by 20 percent. Table 19 below shows the regression coefficients, their margins, and their levels of significance.

Table 19: Probit Regression Coefficients for Prescription Practices and Rational Use of Medicines

Dispensing Practices	*Coef.*	*P > [z]*
SatiWt	2.570273 (0.0761194)	0.000 (0.000)
Comm	-3.191682 (-0.0945226)	0.002 (0.000)
InfD	-3.955891 (-0.117148)	0.006 (0.000)
InfSE	7.052545 (0.2088632)	0.009 (0.001)
Constant	-4.197283	0.000

n	500
Pseudo R^2	0.7666
χ^2	156.66
Prob > $\chi 2$	0.0000

Source: Computed by the Author from the field data, 2023

Note: The margins are shown in parentheses

In general, there are indications of a significant influence of prescription practices on the rational use of medicine. Among the practices listed earlier, satisfaction with waiting time at the dispensary, communications at the dispensary, satisfaction with the dosage information given at the dispensary, and information given about the potential side effects of medication were found to have more influence on rational use of medicines.

7.4 Medicine Pricing

This section presents and analyses the quantitative data of the third objective of this study. The objective was to find out how the medicine pricing policy by the National Health Insurance Authority (NHIA) affects the availability of medicines to the subscribers of the NHIS at health facilities. The study found that the NHIA, through consultation with the stakeholders came up with a list of generic medicines, their prices and level of prescription every year. The list serves as a guideline for reimbursement of health facilities. An extract of the medicine list and their prices with changes in the pricing from 2020 to 2023 is shown in Table 20 below.

Table 20: NHIS Medicine Pricing

Prices (GH₵) and Price Changes, 2020 - 2023

Medicine Name & Pricing Unit	2020	2021	2022	Difference (2021/2022)	(%)	2023	Difference (2022/2023)	(%)
Acetazolamide Injection, 500 mg (Ampoule)	28.0	28.0	13.00	-15	(-53.6)	15.60	2.60	(16.7)

Acetazolamide Tablet, 250 mg (Tablet)	0.25	0.25	0.46	0.21	(45.7)	0.55	0.09	(16.4)
Acyclovir Suspension, 200 mg/5 mL (20 mL)	47.60	47.60	68.90	21.3	(31.3)	82.68	13.78	(16.7)
Amodiaquine + Artesunate Tablet, 135 mg + 50 mg (12 tabs) (1 Course)	2.59	2.59	3.84	1.25	(32.6)	4.61	0.77	(16.7)
Amoxicillin + Clavulanic Acid Suspension, 250 mg + 62 mg (70 mL)	7.52	9.03*	10.66	1.63	(15.29)	8.20	-2.46	(-29.27)
Artemether + Lumefantrine Tablet, 20 mg + 120 mg (12's) (1 Course)	1.25	1.25	1.25	0		1.50	0.25	(16.7)
Calciferol Tablet, 10,000 units (Tablet)	23.0	23.0	1.99	-21.01	(-1,055.78)	2.39	0.4	(16.7)
Cetrimide Solution (200 mL)	1.85	1.85	2.41	0.56	(23.2)	2.89	0.48	(16.6)
Chloramphenicol Injection, 1 g (1G)	3.90	3.90	5.20	1.3	(25)	6.24	1.04	(16.7)

* increased by GH₵1.51 (20%)

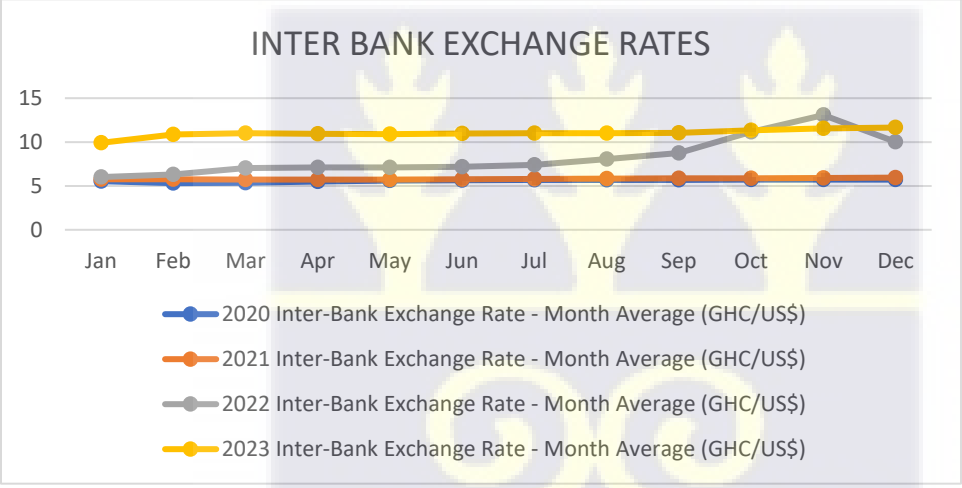
Source: Extracted from 2020 to 2023 NHIS Medicines List

The data in Table 19 shows that the NHIA virtually did not change the prices of medicine from 2020 to 2021. An exception is 'Amoxicillin + Clavulanic Acid Suspension, 250 mg + 62 mg' whose price was increased by 20 per cent per 70 mL. From 2021 to 2022, the Authority increased medicines prices from a range of 15 per cent to 46 per cent. However, the prices of some medicines were decreased by over 1,055 per cent and 54 per cent. Such decreases might have emanated from the availability of generic versions of those medicines which previously might not be in existence

and compel the NHIA to include a patented medicine in the list. In 2023, the prices of medicines were increased by around 16.7 per cent across board.

One of the possible determinants of pharmaceutical prices, just like other commodities, in Ghana is the exchange rate; especially, as Ghana imports 70 per cent of medicines. As the value of Ghana Cedis fluctuated regularly against foreign currencies, the NHIA had a fixed price throughout the year. Figure 3 shows the interbank monthly averages of the Ghana Cedis to Dollar exchange rate from 2020 to October 2023.

Figure 3: Ghana Cedi to Dollar Interbank Exchange Rate Fluctuations, 2020 to 2023



Source: Constructed by the Author using Bank of Ghana Figures, 2023

The figure above indicates the fluctuation of the Ghana Cedi against the US dollar. The worst performance of the Cedi against the Dollar between 2020 and 2023 was in 2022. The monthly average in January 2022 was about GH¢6 to US$1 the Cedi then depreciated to about GH¢10 to US$1. This led to an upsurge in the prices of all items in the country but the prices of medicines in the medicines list of NHIA remain the same.

7.4.1 Availability of Medicines

Regarding the availability of medicines to the subscribers of the NHIS at the health facilities, the data indicates that all the respondents had active subscriptions to the NHIS during their last visits to the health facilities. Out of the 500 health seekers surveyed, it was only about 10 per cent who obtained all the medicines prescribed for them as subscribers of the Scheme at the hospital they visited. Among those who were not given the medicine at the facility they attended, 24 per cent were told by the dispensary personnel to look for the medicines at the NHIS accredited pharmacies. As a result, about 5 per cent of them were given the medicines at those pharmacies. However, 34 per cent were told at the dispensary that the medicine was not available. Interestingly, some of the respondents were told by the prescriber that the medication prescribed for them was either not covered by the NHIS (22 per cent) or it was not in town (3 per cent).

Ultimately, all the respondents who could not get the medicines as subscribers of the NHIS got the same medicines to buy. It is important to highlight that a significant number of individuals who were unable to obtain their prescribed medication from hospitals they attended as NHIS subscribers were still able to purchase the same medication out-of-pocket from the same hospitals. Specifically, 41 per cent of respondents fell into this category. Similarly, 12 per cent of NHIS subscribers who were informed at the NHIS-accredited private pharmacies that their prescribed medication was not available were able to purchase the same medicine out-of-pocket from the same pharmacies. Interestingly, 20 per cent of respondents purchased their medicines from other accredited pharmacies, rather than the ones they initially sought the prescribed medications from as subscribers of NHIS. Lastly, as previously mentioned, 5 per cent of the respondents purchased their medicines directly from the prescriber. These are indications that the medicine retailers might be hesitant to give out their medicines to the subscribers of the NHIS. The data on the availability of medicines to NHIS subscribers is shown in Table 21

Table 21: Availability of Medicines to the NHIS subscribers

	Frequency	Per cent
Was your health insurance active at the time you attended the hospital?		
Yes	500	100
Were you given all the medicine prescribed at the hospital you attended?		
Yes	50	10
No	414	82.8
If you were not given all or some of the medicines, what did they tell you?		
I was told the Medicine was not available	171	34.2
I was told to check NHIS accredited pharmacies	118	23.6
I was told the medicine is not covered by the NHIS	112	22.4
I was told the medicine could not be found in town	13	2.6
If the medicine was not given to you at the hospital you attended was it given to you at any of the NHIS accredited pharmacies?		
Yes	24	4.8
No	390	78
If no, did you get the medicine to buy?		
Yes	390	78
If yes, where did you get it?		
From the same hospital, I attended	204	40.8
From the pharmacy, I could not get it as an NHIS subscriber	60	12
From different pharmacy	100	20
From the Prescriber	26	5.2
If from different pharmacies, were those pharmacies NHIS accredited?		
Yes	100	20

Source: Compiled by the author from the field data, 2023

Looking at the fluctuation of the value of Cedis against the Dollar which has an impact on the pricing of commodities. It is reasonable to deduce that the prices fixed for the NHIS approved medications throughout the year, may not be the same prices the medicine outlets sell their medicines to consumers who buy the medicines out-of-pocket throughout the year. Certainly, the

price of the medication to the out-of-pocket consumers will be higher. This may explain why the medicine outlets may prefer to sell their medicines to those with ready cash. Based on this, it can be stated that one of the reasons the availability of medicines to the subscribers of the NHIS erratic is the pricing of the medication by NHIA. The specific information on why the hospitals and pharmacies sold medicines out-of-pocket to the subscribers of the NHIS is in the previous chapter which presents the qualitative responses on this subject matter from the hospitals and pharmacies.

7.5 Functions of Pharmaceutical Regulatory Authority

The fourth objective of the study was to examine how the medicine regulatory authorities function to ensure the safety of medicines in Ghana. The focus of this objective is the Food and Drugs Authority (FDA). The general functions of the FDA are product registrations, licensing of facilities, market surveillance and product quality testing. Table 22 below shows the functions of the FDA between 2018 and 2022 in figures.

In 2018, 7,268 products being regulated by the FDA were registered by the FDA. This number increased to 17,045 in 2022. In the year 2022, among the products registered, pharmaceutical products were; allopathic medicines, which accounted for 20 per cent of the total registered products, herbal medicine, 7 per cent, and medical devices, 4 per cent.

Table 22: Functions of FDA

Functions	2022	2021	2020	2019	2018
Registration	17,045	17,909	15,824	11,549	7,268
Licensing of Facilities	3,351	3,399	2,541	2,544	2,603
Market Surveillances	1,330	1,324	765	649	778
Outlets Visited	15,215	15,135	8,218	11,146	9,062
Non-Compliant Products Identified in Trade	95,093	22,135	26,660	124,905	40,767

Product Quality Tested	4,220	5,409	6,419	2,390	2,759

Source: ***2018 to 2022 FDA Annual Reports***

Also, 2,603 facilities were licensed for the production and distribution of the FDA regulated products. This number increased to 3, 351 in 2022. In addition, the market surveillance team did 778 surveillances in 2018 but the number of surveillances increased to 1,330 times in 2022. Outlets visited during the market surveillance were 9,062 but this number went up to 15,215 in 2022. Non-compliant products identified in trade during the surveillance were 40,767 in 2018 which went up to 95,093. These are indications that the number of non-compliant products keeps increasing. The more surveys conducted the more non-compliant product will be discovered. The FDA conducted market surveillance operations under the Take Back Unwanted Medicines (TBUM) project in 2022. The initiative proved successful in collecting a total of 1,099 unwanted medicines from 32 pharmaceutical shops in Greater Accra, 30 in Ashanti, and 36 in the Western Region.

Besides the market surveillance, the FDA receive reports on adverse drug reactions (ADR) which gives them a lead to conduct further investigations to ensure the quality of medicines in the country. Table 23 below is the spontaneous report of ADR from the regions to the FDA. The report is presented as the number of ADR experiences received by every 100,000 people per year in a region. The reports indicate that Upper West and Eastern regions lead in ADR reporting to the FDA. From 2019 to 2022, Northern, North East, Savannah and Western North regions did not do well in their ADR reportage to the FDA. In general, they had poor reporting of ADR to the FDA IN 2020. The best year of ADR reporting was in 2019.

Table 23: Spontaneous ADR Regional Reports Per 100,000 People in a Year

Region	Number of ADR Reports Per 100,000 in a Year			
	2022	**2021**	**2020**	**2019**
Eastern	11	9	0.82	11
Greater Accra	5	5	0.63	5
Ashanti	3	2	0.15	3
Northern	0	0	0.16	5
North East	0	0	-	0
Savannah	0	0	0.01	1
Volta	8	5	0.50	5
Oti	8	1	0.22	1
Bono	0	3	0.92	9
Bono East	0	1	0.98	7
Ahafo	0	0	0.38	9
Upper East	1	5	0.43	7
Upper West	9	18	1.13	9
Western North	0	0	0.03	1
Central	0	3	0.27	11
Western	1	2	0.11	4
Total	**46**	**54**	**6.74**	**84**

Source: From FDA's 2023, 2022, 2021 and 2020 Drug Lens.

As a result of the pharmacovigilance measures which include ADR reporting, there have been regular recalls of medicines from the market whenever the quality of any medicine emerges to be compromised. From 2018 to 2022, 36 medicines were recalled from the market from five local and three foreign pharmaceutical manufacturers by the FDA due to quality deficiencies. The pharmaceutical manufacturing companies, the number of medicines recalled from each company and the market authorisation holders of the medicines recalled are shown in Table 24. Most of the medicines recalled were analgesics, antimalarials and antihypertensive medicines.

Table 24: Medicine Recalls by FDA from 2018 to 2022

Manufacturer	Number of Recalls	Market Authorisation Holder
Kinapharma Limited, Accra	12	Kinapharma Limited, Accra
Phyto-Riker (Ghana) Pharmaceuticals Ltd. Accra	8	Phyto-Riker (Ghana) Pharmaceuticals Ltd. Accra
Pharmanova Ltd, Accra	10	Pharmanova Ltd, Accra
New Global Pharmaceuticals Limited.	1	New Global Pharmaceuticals Limited.
Roxin Ghana Limited	1	Roxin Ghana Limited
Actavis Limited, UK	2	Actavis Limited
Denk Pharma GmbH & Co. KG, Germany	1	Denk Pharma GmbH & Co. KG, Germany
Torrent Pharmaceuticals Limited, Gujarat, India	1	Aspen Pharmacare Holdings
Total	**36**	

Source: 2018 to 2022 Food and Drugs Authority Data on Medicines Recalls

The FDA appears to be doing well with respect to revenue generation and usage. This was demonstrated in the annual reports of the FDA from 2018 to 2022. Through their functions FDA generates revenue and a portion of the revenue is retained to enhance their functions. In certain

years like 2019 and 2022, the expenditure of the FDA was less than the IGF retained. The financial performance of the FDA is shown in Table 25 below.

Table 25: Financial Performance of FDA

Year	Revenue Generation (GH¢)	IGF Retained (GH¢)	Expenditure (GH¢)
2018	60,721,187.66	38,721,186.66	36,760,625.09
2019	61,835,392.87	49,835,392.87	54,245,793.80
2020	85,287,479.49	56,424,463.03	56,835,717.48
2021	108,667,195.69	76,067,036.98	52,758,521.86
2022	141,078,363.64	104,755,886.35	147,501,493.91

Source: ***From the FDA 2018 to 2022 Annual Reports***

7.5.1 Safety of Medicines

This study wanted to cross-check the safety of medicine in the Ghanaian pharmaceutical market. Therefore, primary data was gathered to find out the prevalence of adverse drug effect (ADE). A high incidence of ADE suggests the existence of substandard and falsified (SF) medicines, which could pose a significant threat to public health. The study went further to find out the medicine outlets that were involved in the distribution of SF medicines. Participants in the study were asked if they had ever fallen ill or experienced negative effects after taking any medication. The results were that 71 per cent of those surveyed responded in the affirmative, indicating that they had experienced ADE. When asked where they had obtained the medication that caused the ADE, 30 per cent of the respondents said they had gotten it from over-the-counter (OTC) stores, while 26 per cent had purchased it from itinerant medicine sellers. Nearly 10 per cent of the respondents

had purchased the medicine from a pharmacy, while the rest had acquired it online. This suggests that there is a significant problem with the sale of substandard and counterfeit drugs in the market.

The purposes of taking the medication which was believed to cause ADE were for the treatment of illnesses or for enhancing sexual performance. All of the participants who had experienced ADE stated that they had received advice from a pharmacy assistant, an OTC attendant, an itinerant medicine seller, or a nurse, or had learned about the medication from the media. The respondents also claimed to have followed the advice of those who recommended the medication to them. They believed that the illness or adverse condition they experienced was due to the medicine they consumed, which was either fake (40 per cent) or expired (31 per cent), as they had taken the same medicines before without experiencing any such effects. None of the participants admitted to having overdosed on the medication. The findings on the quality of medicines are summarised in Table 26 below.

Table 26: Safety of Medicines

	Frequency	**Per cent**
Have you ever experienced any illness or worse condition after taking medicine?		
Yes	356	71.2
No	144	28.8
Where did you get the medicine?		
Pharmacy	49	9.8
OTC	151	30.2
Iterant Seller	130	26
Online	26	5.2
Why was the medicine taken?		
To Cure Illness	180	36
For Sex Enhancement	176	35.2
Did you get advice from anyone/Somewhere before taking the medicine?		
Yes	**356**	**100**
Who/Where?		

Pharmacy Assistant	49	9.8
OTC Seller	126	25.2
Itinerant Medicine Seller	79	15.8
Media	25	5.0
A Nurse	77	15.4
Did you follow the advice given to you?		
Yes	**356**	**71.2**
Have you previously taken the medicine that gave you a problem this time?		
Yes	**356**	**71.2**
No	**356**	**71.2**
What do you think is responsible for the problem you encountered this time after taking the medicine?		
This one is fake	**200**	**40.0**
This one is expired	**156**	**31.2**

Source: Compiled by the Author from the field Data, 2023

It is clear from the reports of the FDA that a lot is being done by the Authority to eliminate the menace of unsafe medicines in Ghana. There has always been improvement in the functions of the FDA. However, unsafe medicines also keep proliferating. This may be attributed to several factors, which include a lack of capacity to operate actively outside the urban areas.

7.6 Summary of the Chapter

This chapter aims to present and analyse the quantitative data gathered for this study. Firstly, it outlines the socio-demographic characteristics of the selected health seekers for this study. Secondly, it presents and analyses the quantitative data in alignment with the study's objectives and addresses the research questions it was designed to answer. The chapter encompasses the prescription behaviour of health professionals and its impact on medicine affordability, as well as information on health personnel's dispensing practices and their influence on the rational use of medicine. Additionally, the chapter provides data on the prices of medicines in the NHIS medicine

list, the availability of medicines to NHIS subscribers, and the functions of the FDA and medicine safety. The data is presented in raw figures, accompanied by corresponding percentages, and cross-tabulations are used where necessary to demonstrate relationships between variables.

The survey indicated that a lot of the patients were involved in the prescription process by the health professional. That is, there were discussions between the medicine prescribers and the patients on the alternative medicines that could be prescribed, the cost of the medicines and whether the patients could afford the prescribed medications. The majority of the respondents either bought all or some of the medicines prescribed for them. The medicine prescribers were found to be involved in medicine sales as a result some of the respondents truncated their pursuit of health care at the health facilities they attended. The statistical test conducted revealed that failure to involve patients in the prescription process was not significant in influencing the affordability of medicine by patients. However, the involvement of medicine prescribers in medicine sales was found to be significant in influencing patients' affordability of the prescribed medicines.

Dispensing practices examined in the study were patients' satisfaction with; waiting time at the dispensary, organisation of the dispensary, information given on medicine dosage and expected side effects of the prescribed medicine, attitude of the dispensary staff and communications at the dispensary. The specific variables examined to determine the rational use of medicine were completion of prescribed medication, taking medication at the prescribed time and avoidance of self-medication. The study found that there was a significant association between patients' satisfaction with waiting time at the dispensary and rational use of medicines. There was also an indication of a significant association between patients' satisfaction with the organisation of the dispensary and rational use of medicines. Again, there was a significant association between

patients' satisfaction with dosage information and rational use of medicines. In addition, there was an indication of a significant association between giving information on the side effects of medications and the rational use of medicines. A similar association was identified between satisfaction with communication at the dispensary and rational of medicines. However, no significant association was found between patients' satisfaction with the attitude of dispensary staff and the rational use of medicines. In all, there was an indication that dispensing practices influence the rational use of medicines.

Regarding the pricing of medicines in Ghana, there were indications of pricing and adjustment of medicine prices for the medicines in the NHIS medicine list which might have not reflected the real prices of medicines in the market. This might have resulted in the refusal to give out medicine to the subscribers of the NHIS subscribers at the health facilities. Finally, the general functions of the FDA are product registrations, licensing of facilities, market surveillance and product quality testing. Through the surveillance, the FDA has been able to identify medicines with problems and recall them. The FDA also successfully identified and removed non-compliant products on sale from the pharmacies of four regions in Ghana. Despite all the efforts of the FDA, the pharmaceutical market is inundated with unsafe medicines. This may be attributed to a lack of capacity to expand their rigorous activities to the nook and cranny of Ghana.

CHAPTER EIGHT

DISCUSSION OF FINDINGS

8.0 Introduction

This chapter follows from chapters six and seven. It discusses both the qualitative and the quantitative findings of this study. The study was designed to achieve specific objectives which emanated from the literature review and answer the research questions of the study. The discussion of the findings is done in line with the objectives of the study. Also, the findings of the study are discussed in the context of the conceptual framework which is in chapter four of this study. The discussion of the findings goes further to juxtapose the findings of this study with other previous studies. The objectives of the study and a summary of the major findings are presented in Table 25 below.

Table 27: The Study Objectives and a Summary of the Major Findings of the Study

Objectives	Major Finding
1. The study examined the medicine prescription behaviour of health professionals in the context of prescription regulations and how it affects the affordability of medicine in Ghana.	The study found the existence of prescription regulations in all hospitals. However, there was no evidence of the use of those regulations. The prescription behaviour did not conform to the regulations. Therefore, the affordability of medicines was problematic.
2. The study examined medicine dispensing practices in the context of responsiveness and how they affect the rational use of medicines.	There was a problem of responsiveness to the expectations of health seekers. This led to a high level of dissatisfaction with the prescription practices. As a result, rational use of medicines among those patients was negatively affected
3. The study found out how medicine pricing in Ghana is participatory and the influence of the pricing on the availability of medicines to the subscribers of the National Health Insurance Scheme at the health facilities.	The study found that there was no broader consultation of stakeholders in the pricing of medicine for the National Insurance Scheme. This led to unrealistic reimbursable prices of the Insurance medicines. Consequently, there was a problem with the availability of medicines to the subscribers of the National Health Insurance Scheme.

4. The study examined how the medicine regulation authority ensures the safety of medicines in Ghana.	The regulatory framework of Ghana was found to be very strong. The Food and Drugs Authority works within the regulation to ensure the safety of medicines. However, the Authority is challenged in regulating herbal medicines and its collaboration with other entities to control drug smuggling. This resulted in the prevalence of unsafe medicines in Ghanaian pharmaceutical outlets.

Source: Compiled by the author, 2023

8.1 The Medicine Prescription Behaviour and Affordability of Medicines in Ghana.

As previously stated, the prescription behaviour of health professionals is regulated by the Standard Treatment Guidelines (STG), Essential Medicine List (EML), and the prescription guidelines set out in the National Health Insurance Medicines List. However, the STG was found to be detached from reality because it was not regularly updated. Therefore, the treatment options existing in the guidelines might have been archaic. If treatments were based on the STG, there would be the potential of giving prescriptions that might not yield the desired result. There were indications that the EML was irrelevant at the tertiary level of health care. It was said to be composed of generic medicines that were not as effective as the original or branded medicines. However, the EML has medicines for various levels of care which include the tertiary and specialist levels. Side-stepping the EML as a result of a level of autonomy by the tertiary hospitals defeats the purpose of making health care affordable to all at every level of healthcare delivery.

The study found that about 50 percent of the respondents were either involved in the discussion of alternative medicines that could be prescribed, the cost of the medicines to be prescribed and or the affordability of the medicine to be prescribed. This finding can be described as moderate participation in the prescription process by patients. This is different from a study in Malaysia

(Ambigapathy et al, 2016) where all the patients in the study had either active, shared or passive participation in decision-making at the time of consultation. This implies that whilst the was about 50 percent participation in the treatment process in Ghana, there was 100 percent participation in Malaysia. The finding is also different from the findings of other studies in Uganda (Nuwagaba et al, 2021) and Tanzania (Vedasto et al, 2021) where participation of patients in decision-making was found to be low. Generally, whilst the other studies examined participation in decision-making in either every process of healthcare delivery or only at the time of consultation, this study focused on the involvement of patients in the medicine prescription process. Even though, there is an indication of moderate involvement in the prescription process, about 50 percent of the respondents who were not involved in the prescription process had a negative reaction from the prescribers. Some patients made an effort to give out information to aid the prescription but the prescriber's response to the patient was unwelcoming; there was a display of anger by the prescriber in response to the effort of some patients.

The study found that even though patients were moderately involved in the prescription process, their participation had a significant impact on their ability to afford medicines. This suggests that while involving patients in the prescription process may have other benefits, such as improving adherence and patient satisfaction, it may also lead to better affordability of medicines. The findings highlight the need for more involvement of patients in the prescription process to improve the affordability of medicines, especially for patients who may already be struggling with financial constraints.

Also, the study found that some prescribers were involved in selling medicines. They either sold the medications directly to the patient or kept them with a pharmacy and directed patients to purchase them there. These were corroborated by the pharmacists in the hospital and the managers

of the community pharmacies. Some of the prescribers even sold herbal medicines to patients at the time of consultation despite that the hospitals in which they were working were not offering herbal medical services. The act of involvement of prescribers in medicine sales was described as unacceptable by some of the hospital pharmacists.

The finding of direct sales of medicines to patients by medicine prescribers is different from the finding of another study in Lebanon where sexual advances were made by female pharmaceutical representatives to male physicians, payments for strip clubs and prostitutes, sponsorship of marriages or honeymoons, and financing of family vacations, boat trips, and local retreats to influence the prescription of some medicines (Hajjar, et al. 2017). This finding is also different from the findings of other studies (DeJong et al, 2016 and Brax et al, 2017) where a simple single meal every day and other incentives were used by pharmaceutical companies to influence an upsurge in the prescription of their products. In the case of Ghana, monetary gain was a driving force that influenced the prescription decision of health professionals. In the other studies pleasure and an ordinary kind gesture were the drivers that influenced the prescription decision of the health professionals. The practice of prescribers providing patients with prescriptions and directing them to purchase their medications from specific community pharmacies (which may be kept there by the prescribers) is problematic. This can lead to a prolonged supply chain, which may increase the cost of the medicines due to the markup that the pharmacy may add to the price. This practice can also create conflicts of interest, as the prescribers have financial incentives to steer patients towards certain pharmacies or medications. Furthermore, it can be difficult for patients to compare prices and make informed decisions about their healthcare when they are directed to a particular pharmacy. This finding is again different from other studies (Perlis & Perlis, 2016; Burkhard et al. 2019 and Goldcare, 2019) which found that in the health systems where the regulations permitted

prescribers to dispense medicines, the prescribers opted to prescribe expensive medicines for monetary benefits. Those studies did not indicate if the patients were able to afford the medicines. In addition, this finding is different from that of Hammer & Zilic (2017) who did not find any monetary inducement for the prescription decision of medical professionals.

Irrational prescription was also detected in a particular case where the prescriber prescribed up to 6 medicines for a patient and directed him to buy the medicine from a particular pharmacy. The patient suspected something wrong and rather went to another pharmacist for advice. This finding conforms to the findings of other studies in the Tamale metropolis and India where there were prescriptions of an average of 3.89 and 5.6 medicines respectively higher than the WHO standard of 3 (Mohammed & Tiah, 2019 and Akhtar et al., 2012). However, this finding contradicts another finding in Nigeria where the prevalence of polypharmacy was rather among patients with health insurance coverage than those who were on out-of-pocket expenses (Onah, & Idoko, 2022). This study found a significant correlation between involvement in medicine sales by prescribers and the affordability of medicines. There is an indication that when prescribers are involved in medicine sales, affordability becomes problematic.

From the perspective of the institutional theory, the system has not been coercive enough or the regulative component of the institutional theory is not equipped to ensure the isomorphism. In the context of good governance, there is an indication of a problem of policy capacity concerning the policies and guidelines that regulate medicine prescription. The STG is found not to have the capacity to be relied on because it appears outdated. Also, defiance to rely on the EML at the tertiary level of health care signifies the absence of binding policies to compel all healthcare workers to work with the EML to make healthcare affordable to health seekers.

Also, in the view of Institutional theory, the Patient Charter served as the regulative pillar that coerced the health professionals to moderately involve the patients in the prescription process. This reflects a step towards isomorphism of standard practices in the health sector. Examining the involvement of patients in the prescription process in the light of the principles of good governance at the level of medicines prescription, there is a moderate display of policy capacity in that respect. The Patient Charter encourages the involvement of patients in the healthcare delivery process.

Again, from the context of Institutional theory, the act of involvement in medicine sales by prescribers defied the principles of the regulative component of the institutional theory. The guidelines were not coercive enough to compel prescribers to act selflessly to achieve the isomorphism of access to medicines by all. Viewing the involvement of prescribers in medicine sales through the lens of good governance, there was no show of policy capacity in the healthcare facilities. The act violated the prescription procedure outlined by the NHIA. It did not also conform to the convention of hospitals which recommends prescription audits. The requirement for the use of expert knowledge to have the policy capacity was snubbed by the prescribers. Even though the act was described as unacceptable, no action was taken to stop it.

Generally, the hospitals did not have the capacity to implement the regulations. Consequently, the regulative component of the health institutions was not coercive to achieve the isomorphism of access to medicines because there was no policy capacity. This led to the unaffordability of medicines which resulted in poor access to quality medicines.

8.2 Dispensing Practices and Rational Use

The ability of dispensary staff to work to meet the needs of patients may be influenced by the knowledge and the attitude they have to dispense medicines. In the realm of public healthcare

facilities, continuous training and guidelines were considered highly important. To ensure that the dispensary staff were aware of the standard practices in medicine dispensing, hospitals regularly organised refresher training. This was supposed to help to keep the staff up-to-date with the latest information and procedures. On the other hand, community pharmacies believed that on-the-job training is more effective than certificates. They preferred to train their staff in the actual work environment where they could learn from hands-on experience. However, community pharmacies might sometimes resort to employing workers who lack prior training in medicine dispensing. This could be because they want to save costs by relying on a cheap labour force. This approach can put the health and safety of patients at risk and highlights the need for continuous training and guidelines in the field of medicine dispensing. However, the training and the guidelines given to the dispensary staff at the public healthcare facilities did not reflect in the practices of some of the dispensary staff.

This study examined how satisfaction with waiting time at the dispensary may influence the rational use of medicines. A significant correlation was found between satisfaction with waiting time and rational use of medicines. This implies that the more people are satisfied with how long they wait at the dispensary, the more the possibility of their rational use of medicines. In addition, the organisation of the dispensary was found to have a significant association with the rational use of medicines. Some patients had problems with where to sit to wait for their medicines and others had problems with the appointment system at the dispensary. These might have caused the patients to lose confidence in the health facilities and refuse to take their medications seriously. However, satisfaction with the attitude of the dispensary staff was found not to be significantly correlated with the rational use of medicines. Another key medicine dispensing practice is communication. This study found that satisfaction with communication at the dispensary was significantly

correlated with the rational use of medicines. These findings are different from other studies (Siele et al, 2022; Priyadarshani, 2021; Akl, 2014; Silva et al., 2018; Gidebo, 2016 and El Mahalli, 2012) which concentrated on the time spent at the medicine counter. Those studies assumed that the more time spent at the dispensing counter, the more information about the medicine would be given to the patient about the medicines. Those studies did not include the content of what was being discussed at the dispensing counter which is covered by this study.

Information given to patients about the medicine dosage and the possible side effects of the medicines were also found to be significantly correlated with the rational use of medicine. This study is again different from other previous studies (Wendie, 2021; Siele et al. 2022; Sisay, 2017 and Chandelkar & Rataboli, 2014) which examined the extent to which medicines are labelled at the dispensary and the knowledge of patients about the medicine's dosage. The essence of every action at the dispensary is to ensure adherence to the medication being given for better treatment outcomes. All the previous studies did not find out the consequences of the practices at the dispensary. That is another shortfall that makes the previous studies different from this one which examined the dispensary practices and the rational use of medicines.

In the view of Institutional theory, normative isomorphism did not show up in the practices of the dispensary staff. The expectations of the people which was a reflection of their social institutions were not met. The standards set by the pharmacies to serve patients to ensure medication adherence were not followed. Therefore, the isomorphism of ensuring rational use of medicines through dispensary practices fell short. Examining the dispensing practices and the rational use of medicines in the view of responsiveness as a principle of good governance, the workers at the dispensary were, to an extent, not responsive to the needs of the health seekers. There were complaints from the health seekers of mockery of patients' names, disrespect to patients, poor

communication, failure to give dosage information to the health seekers, and poor appointment systems at the dispensary. All that were complained about were the expectations of the patients which some of the dispensary staff did not respond to. The poor responsiveness displayed by the dispensary staff led to the irrational (unacceptable) use of medications. This implies poor access to quality medicines.

8. 3 Medicine Pricing and availability of medicines

The procedure the NHIA indicates it follows to arrive at the medicine prices for the NHIS medicine can be classified as an Internal Reference Pricing (IRP) policy. An incremental procedure was then used to adjust the medicine prices in 2023. The IRP policy might be the basis for the supplier prices of medicine negotiated under the Framework Contracting Agreement. This contracting resonates with the procurement strategy used in Indonesia and South Africa (Anggriani et al. 2020 and Woutersa et al. 2019) where prices of medicines were lowered as a result of the procurement strategy.

Two reasons emerge from the data explaining the failure of the suppliers under the Framework Contracting. First, is the lower prices being offered by the government which incapacitates the suppliers to fulfil their contracting agreement when the economic indicators swing against the plans. The second is a failure on the part of facilities to pay for the medicine being supplied at the agreed time which compels the suppliers to withhold supplies and demand payment of prevailing prices before another supply can be made. The failure to pay by the health facilities may be due to delayed reimbursement by the NHIA for the medicine being given to the subscribers of the Scheme. In such a situation, the NHIA whose clients are the beneficiaries of the supplies happens to be the obstacle to the availability of medicines to their clients.

The Framework Contracting Agreement which has become the main procurement strategy for the supply of most medicines used by the NHIS appears to be problematic. The negotiated pricing seems not to consider economic projections. Also breaching of contracts seems normal in the Framework contracting. The suppliers refuse to supply if they encounter any adversary. The government side too fails to pay in the situation of any inconvenience. However, the NHIA placed its hope on the negotiated prices and came up with the price list of the medicine being used by the NHIS. Therefore, as the suppliers fail to supply the medicines, access to medicines by the subscribers of the NHIS becomes erratic.

Besides, the private sector, which is a key player in healthcare delivery might not have been considered when prices were negotiated under the Framework Contracting. All medicines were supposed to be supplied to the Central Medical Stores (CMS) which would then be distributed to the Regional Medical Stores (RMS) and the Teaching Hospitals. The RMS will also distribute the medicines to public healthcare facilities. This means that public healthcare facilities have to be stocked with medicines before private healthcare facilities can get medicines from the RMS. That further implies that if all the medicines are supplied to the public healthcare facilities, the private healthcare facilities will rely on the open market to procure their medicines. The prices in the open market will certainly be higher than the price list of the NHIS. This has three implications on the availability of medicines to the subscribers of NHIS at healthcare facilities: 1) Out-of-pocket sales of medicines to the subscribers of the NHIS. That is, health facilities stocked medicines that were not covered by the scheme and sold them on cash and carry; 2) Writing prescriptions to the patients to go and buy from private pharmacies or 3) Introduction of co-payment which is illegal. Interestingly some of the health facilities, both public and private, resorted to co-payment to run their facilities. But when this was detected by the NHIA, the Chief executive wrote to all the

stakeholders on 5th February 2024. The letter notified the stakeholders of the illegal activity and the steps taken to deduct the funds being paid to those facilities through co-payment from the money to be reimbursed to those facilities by NHIA.

The idea of a Framework Contracting Agreement could be the best idea to bring down the prices of medicines and increase the availability of medicines in the health system which would ultimately lead to robust NHIS. If realistic prices were agreed on and all corruption and corrupt-related activities were eliminated in the contract. The suppliers would supply medicines at prices which would be reasonably low. This would have forced the other private sector suppliers to decrease their prices. Medicine would then be cheap and available in the system.

In general, the medicine pricing policy has affected the availability of medicines to NHIS subscribers in several steps. First of all, the government gives the contract for medicine supplies to the contractors whose prices may be lower. Secondly, the NHIA came up with a medicine list based on the prices agreed on by the contractors to supply the medicines. Thirdly, the contractors got back and analysed the economic situation and realised the prices being agreed on were not realistic or the government failed to pay for the previous supplies. Therefore, the suppliers fail to supply the medicines which leads to stockouts at the CMS. Fourthly, the RMS and the CMS keep waiting for the suppliers and do not allow health facilities to buy medicines from the open market. Fifthly, when the health facilities finally get the approval and get to the open market to buy the medicines, the prices will be higher than the reimbursable prices by the NHIA. Sixthly, some of the health facilities will also leave the procurement from the open market and wait for RMS to get supplies to restock their pharmacies. Lastly, the private healthcare facilities and the teaching hospitals will buy from the open market but will sell the medicines out-of-pocket to the subscribers of the NHIS, telling them to go and buy or initiate co-payment. These explain why the subscribers

of the NHIS were denied medicines at the medicines outlet and they had to move from pharmacy to pharmacy without getting medicines. However, immediately they offered to buy the medicines, they were made available to them.

Whilst this study explains how the pricing of medicine affects the availability of medicines to the subscribers of the NHIS, many other studies (Maniadakis et al. 2017; Panteli et al. 2016; Bangalee & Suleman, 2016; Bangalee & Suleman, 2019; Cassar & Suleman, 2019; Fink, et al. 2014 and Tran et al. 2020) focused on how the pricing of medicines affects the affordability of medicines. A particular study that appears similar to this one was the study conducted by Mordi et al, (2015). It also examined how medicine pricing by the NHIA affects the availability of medicines. However, it was not able to point to the specific point in the health system where the medicine availability was affected by the pricing of the NHIA.

In the context of Institutional theory, the stakeholders in the pharmaceutical sector constitute a community of its own with a subculture of knowledge and skills regarding pharmaceutical governance. These stakeholders have a cognition where mimicking best practices takes place. This leads to mimetic isomorphism that makes medicines accessible to all health seekers equally. However, there was an absence of broader stakeholder consultation that led to the failure to supply medicines further leading to regular medicine stockouts at the health facilities. In the context of good governance, participation requires that those who are to be affected by decisions must get access to decision-making and have the power to obtain a meaningful stake in the work of the institutions (Woods 1999). However, the final decision-making on the prices of medicines in the NHIA medicine list was solely made by the authority without considering the inputs of the stakeholders. The data collected shows that, there were no mimetic isomorphic steps taken in the medicine pricing process due to poor participation which led to defective pricing. This

consequently affected the availability of medicines at the health facilities. In effect, there was no access to quality medicine to the subscribers of the NHIS.

8.4 Medicine Regulation and Safety of Medicines

This study found that the FDA has a very strong regulatory framework to perform its functions. This is reflected in the Public Health Act, 2012 (Act 851) and the guidelines designed by the Authority. This finding does not agree with that of Ndagije et al. (2023) and Ampadu, et al. (2018) which regarded the absence of a regulatory framework as one of the obstacles to medicine's regulatory authorities in some African countries in discharging their functions. The functions of the FDA concerning the safety of medicine can be broadly classified into two. They are registrations and inspections. They register all kinds of medicines before they are distributed into the market for consumption. The registration implies Market Authorisation of the medicines. Before a medicine is registered, the applicant is required to present key information regarding the quality of the medicine to be registered. The FDA has a laboratory which tests medicines before registration. The essence of the testing is to ensure that the quality management of the product being presented for registration meets the international standard of ISO/IEC 17025:2017. The dangerous thing the FDA can do is to only cross-check the quality of information given to them by the applicant for registration without conducting further tests to verify the authenticity of the information given.

Among medicines that can be imported into Ghana are medicines for donations and prescribed restricted medicines for personal use. The FDA has given guidelines concerning medicines that can be donated to Ghana. The FDA has been able to forecast the possibility of others dumping medicines whose shelf life is about to end just to avoid the hassle of disposing of the medicines as unwholesome medicines. Since the medicine that can be imported into Ghana for personal use may

not be registered, the quantity of medicines that can be imported for that has to be determined by the prescription. That is the treatment regimen will determine the quantity that can be imported for personal use. This will avoid the collusion to import unregistered medicines for small-scale sales in the name of personal use. The cumbersome task of the FDA is controlling the importation of unregistered medicines. This task falls within the ambit of the security forces. Unfortunately, there are unapproved routes which ease the smuggling of medicines into the country. This was confessed by an itinerant medicine seller. This leads to the flooding of unregistered medicines in Ghana, some of which may be unsafe. This reflects the findings of Bekoe et al. (2020) in Ghana which indicates that over 66 per cent of sampled antibiotics were substandard.

Herbal medicine is equally supposed to be registered in Ghana. However, this seems impossible because of what can be regarded as herbal medicine. Most herbal medicines in developing countries are regarded as traditional medicines. The Traditional medicine sector is made up of herbalists, divine healers/spiritualists, bone setters and traditional birth attendants (McCracken & Phillips, 2017a; Twumasi, 1988 and Sato, 2012). The healing practices of herbalists are regarded as a social responsibility which reflects the values of the society. As a result, trying to regulate the herbs used to ensure safety becomes an attempt to alter the values of society. This makes it almost impossible to regulate herbal medicine by the FDA.

One of the critical points to ensure the quality of medicines is the point of storage and distribution. Some medicines may require a particular temperature during storage. Some may have a limit of exposure to open air during storage and transportation. Consequently, the FDA licences facilities for wholesale storage and distribution. The major problem is how medicines are stored and distributed in the rural areas. Itinerant medicine sellers move from house to house and shop to shop in the markets to sell medicines. Their operation is illegal but society accepts them and patronises

their services. This reduces the efforts of the FDA to control medicine distribution at the micro level to null.

The FDA also conducts inspections to ensure that the medicines in the market are those that passed through their regulated activities. Through these inspections, tests are conducted on the quality of suspected adulterated medicines to ensure that medicines in the market are of the right quality. The inspections lead to medicines recalls. In some situations, information about unregistered and adulterated medicines in the market is circulated to the medicine outlets and the general public through the media. The information on substandard and falsified (SF) medicines in the market is directly sent to the teaching hospitals and through the right channels to the hospitals under the Ghana Health Service. The same information is also sent to the manufacturers or the marketing authorisation holders to withdraw those medicines through their distribution channels. However, if detected SF medicines are intentionally introduced into the country, the withdrawal becomes problematic because they may largely be circulated in the informal sector.

Another challenge to the FDA in the performance of its regulatory functions is the distribution of medicines through emerging markets. That is the social media. This study found that some of those who experienced adverse drug effects (ADE) obtained their medicine through social media. How the FDA clumps down or regulates that channel of distribution is not shown in any of the FDA reports. This finding is similar to the finding of a study conducted by Mackintosha et al. (2018) and Ahiabu et al. (2018) who regarded the proliferation of online pharmacies as one of the causes of the prevalence of substandard and falsified medicines.

The FDA also works with medicines outlets to outlets to dispose of unwholesome medicines. Clear explanations were given by the public hospitals regarding how unwholesome medicine is disposed of. A similar clear explanation was not given by the private medicine outlets. This created an

impression that unwholesome medicines could be distributed in one way or another for consumption by health seekers. In connection with the disposal of medicines, this study found that some of those who experience ADE obtained the medicines from itinerant medicine distributors, over-the-counter medicine shops managed by nurses and pharmacies. This resonates with the findings of Bekoe et al. (2020) that the sampled falsified medicines found in Ghana were distributed by both authorised and unauthorised medicine outlets. Those who said they experienced ADE in this study associated the ADE they experienced with either counterfeit or expired medicines. These participants were able to describe the features of counterfeit or expired medicines This also agrees with an earlier finding in Ghana in which features of falsified and expired medicines like the absence of expiry date, soft texture of tablets or wired colour and scent of syrups identified by participants of the study (Hamill et al. 2019).

In the context of the Institutional theory, there is a strong regulative component or there is a coercive isomorphism in the medicine regulation sector. The legal framework and the guidelines for regulatory measures to ensure the safety of medicines in Ghana are very strong. In the context of good governance, there are very strong policies that outline the functions of the FDA to ensure the safety of medicines in Ghana. The problem is the capacity to implement those policies in every part of Ghana. This explains the reasons for the prevalence of unsafe medicines in the country.

8.5 Summary of the Chapter

This chapter follows from chapters six and seven. It discusses both the qualitative and the quantitative findings of this study. The study was designed to achieve specific objectives which emanated from the literature review and answer the research questions of the study. The discussion of the findings is done in line with the objectives of the study. Also, the findings of the study are discussed in the context of the conceptual framework which is in chapter four of this study. The

discussion of the findings goes further to juxtapose the findings of this study with other previous studies.

The medicine prescription in Ghana is guided by the Standard Treatment Guidelines, Essential Medicines List and the guidelines put together by the National Health Insurance Authority. Whilst the municipal hospitals worked with the prescription policies, the tertiary hospital had problems with them and resorted to other guidelines and their own established practices due to their semi-autonomous nature. Concerning the involvement of patients in medicine prescription, there was a very high level of involvement of patients. However, no significant association was found between the involvement of patients in the prescription process and the affordability of medicines. Medicine prescribers were found to be involved in medicine sales where some prescribers even sold medicines directly to patients. The was also a detection of polypharmacy in the medicine prescription by some medicine prescribers. Ultimately, the involvement in medicine sales by medicine prescribers was found to be significantly associated with the affordability of medicine. The more the patient was involved in the medicine sales, the more the medicine became unaffordable to the patient. These findings, except the involvement of patients in the prescription process, contradict the regulative component or the coercive isomorphism of the Institutional theory and also demonstrate that there is no policy capacity in relation to medicine prescription behaviour.

Regarding dispensing practices and rational use of medicines, public sector hospitals regarded training and equipping their dispensary staff with updated information concerning their work very paramount. However, the community pharmacies rather regarded on-the-job training as more relevant. However, the training and the guidelines given to the dispensary staff did not reflect the practices of some of the dispensary staff. This study found a significant association between

satisfaction with waiting time and rational use of medicines. This implies that the more people are satisfied with how long they wait at the dispensary, the more the possibility of their rational use of medicines. In addition, the organisation of the dispensary was found to have a significant association with the rational use of medicines. Some patients had problems with where to sit to wait for their medicines and others had problems with the appointment system at the dispensary. These might have let the patients lose confidence in the health facilities and refuse to take their medications seriously. Other dispensing practices that were found to have a significant association with the rational use of medicines were communication at the dispensary, information on dosage and information on side effects. In effect, there was no normative isomorphism of ensuring rational use of medicines through dispensary practices due to the absence of responsiveness to the expectations of patients.

When it comes to the medicine pricing policies and availability of medicines to the subscribers of the NHIS, the study found two pricing policies: Internal Reference Pricing (IRP) and Framework Contracting pricing. Even though the IRP may be the premise of the Framework Contracting pricing. These prices were found to be lower than the market prices of medicines which led to breaches of contracts in terms of supplies. Therefore, stockouts ensued which led to the unavailability of medicines to the subscribers of the NHIS. Given Institutional theory, there was no cognitive isomorphism due to poor participation in the medicine pricing procedure.

Lastly, looking at the functions of the regulatory authority and the safety of medicines, the study found that the FDA is legally equipped with the Public Health Act, 2012 (Act 851). The Authority registers and inspects pharmaceutical products. The FDA registers all medicines before their distribution in the country except those imported for personal use and for registration and promotion. Through inspections, the FDA make recalls of medicines to which manufacturers or

market authorisation holders fail to comply with the regulation. However, there are a lot of challenges faced by the FDA with regard to logistics and personnel. Besides, the FDA collaborates with other state agencies to ensure the quality of medicines. The failure of those agencies affects the performance of the FDA. These lead to the abundance of substandard and falsified medicines in the Ghanaian market. In the context of Institutional theory, there is a strong regulative component in the regulative institution which leads to coercive isomorphism in the angle of medical regulations. However, there is no policy capacity to implement all the regulations.

CHAPTER NINE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

9.1 SUMMARY

Medicine is one of the important aspects of health technology that enhances the functioning of a health system. WHO has always been functioning to achieve UHC with access to medicine as a bedrock to that goal. The discovery of penicillin for the treatment of sepsis, chloroquine for the treatment of malaria and antiretroviral drugs for boosting the immune system of HIV/AIDS patients exemplifies the relevance of medicines in prolonging life and enhancing well-being of the humans. There are studies indicating that the absence of medicines in health facilities leads to medical errors and even creates distrust in healthcare professionals by patients which adversely affects patients' care. However, access to medicines appears to be a mirage, especially to the vulnerable and the socially excluded who need the medicine most. The prevailing scarcity of medicines can be attributed to problems of governance in the pharmaceutical sector. There is evidence pointing out that, what is been touted regarding the need for ATM leading to UHC at the global level is not reflected in countries' policy formulations and implementations. This calls for a need for studies at various country levels to inform policy formulations that synchronise what is being advocated for at the global level and what is implemented in various countries.

Ghana seems to have made a lot of advances towards the achievement of UHC before it even became a Sustainable Development Goal (SDG) at the global level. A social health insurance scheme was introduced to extend healthcare to every segment of Ghanaian society. Food and Drugs Authority also made a lot of advancements and gained global recognition. These advancements are expected to be reflected in access to quality medicines in Ghana. Unexpectedly,

there are problems related to access to medicines under the health insurance scheme and there is a proliferation of SF medicines in Ghana. There are a lot of studies that give so much knowledge on pharmaceutical governance, however, there are gaps in those studies that will not permit policy formulations to be based on them to deal with the problem of access to medicines. This calls for a study to find out how pharmaceutical governance affects access to medicines in Ghana.

Looking at the health systems and the medical system of Ghana, there are six components of a health system that must functionally link together to ensure an effective and efficient healthcare delivery. The objectives for health systems: health improvement of the population within its jurisdiction; being responsive to the people's needs; and provision of the means to absorb the financial shocks of the sick. The situation under which the industrialised countries constructed their health institutions was not the same in the developing countries. The inability of LMICs to expand healthcare coverage to their wider population led to the emergence of other health service providers to meet the healthcare needs of the populace. This brought plurality in health services provision, the kind that nearly blur the distinction between private and public sectors in the LMICs. WHO came up with essential medicines. Those medicines must be available, affordable, effective and safe to enhance healthcare delivery. To increase access to medicines, the WHO also advocates for the integration of traditional and complementary medicine in the health systems of all the member countries.

Regarding the medical system of Ghana, the Ministry of Health had solely been on the frontline of healthcare provision. Ghana Health Services was then created to take on the healthcare delivery role but still worked as an agency of the Ministry of Health. Therefore, the structure of Ghana's healthcare delivery system has the Ministry of Health at the apex overseeing the other agencies in the performance of their functions assigned to them by the laws that created them. Healthcare

delivery is in a hierarchy; teaching and specialist hospitals are on top followed by regional hospitals, district hospitals, health centres, clinics and CHPS compounds. Medicines in Ghana are largely imported. They are stored in a privately-owned store and a publicly owned temporary store. There are regional stores that take medicines from the central stores for onward distribution to the districts.

There have been a lot of studies on regulations governing advertising in various countries. Also, the effects of promotions of pharmaceutical products on prescription decisions of medical professionals have been widely studied. In addition, how medical professionals who prescribe and dispense medicines at the same time to certain patients take advantage of that to increase their revenue has been studied. Rational prescription in line with the standards established by WHO has been widely explored in many countries.

Medicine dispensing is a key determinant of the rational use of medicine. The WHO designed guidelines for the prescription and dispensing of medicines to ensure the rational use of medicines. Among the indicators, those that are supposed to guard dispensing are found in the patient-care indicators. The metrics specify that the average dispensing time should not be less than 90 seconds. Also, all medicines must be adequately labelled and all patients should have knowledge of the dosage of the medicines dispensed. As a sequel to these guidelines, a lot of studies have been conducted to verify the conformity of prescriptions to those guidelines. Most of the empirical studies on medicine dispensing measure how the dispensing practices fit into the guidelines developed by the WHO.

The pharmaceutical pricing policies that are enforced in different countries vary widely based on various factors, such as the patent status of the product, whether it is on or off patent, or a generic version. One of the pharmaceutical pricing policies is free pricing. This allows manufacturers to

fix their prices after marketing authorisation. Due to the negative effect, it may have on access to medicines, other measures are used by the state to control the pricing of pharmaceuticals. Another pricing policy is Internal Reference Pricing. Pricing of medicine under this policy calls for a comparison of the active ingredients of pre-existing medicine. The pricing is then done based on the price of similar medicines. In external reference pricing, prices of medicines produced in a particular country are determined by the prices of other selected countries. The selection of a country for comparison is based on whether they are located in the same region and the similarity of their health systems. Value-based pricing is another pricing policy that prices medicines based on their benefits. The question regarding this policy is the definition of a value, especially, in the case of multinational pharmaceutical companies. Additionally, cost plus pricing is another pricing policy that determines the price of medicines using the cost of the production process and that of the product plus a markup. Besides, state control is the control of pharmaceutical prices by the state without necessarily negotiating with the manufacturers. This can manifest itself from an extreme to a flexible state control. Other policies that can be used to achieve lower medicine prices are lower VAT rates, the use of single exit price, the use of a Revolving Fund and encouragement of the use of generic medicines. Due to the extreme importance of access to medicine in healthcare delivery, no country uses a single pharmaceutical policy to determine the prices of pharmaceutical products. The policies being used are adopted to strike a balance between making medicines accessible to society and keeping pharmaceutical companies in business.

Falsification of medicines is not new in the history of medicine production. However, globalisation, coupled with problems of access to medicines and poor pharmaceutical governance enhances the spur of pharmaceutical counterfeiting across the world. Legislations have been promulgated at the international and national levels to curb the proliferation of SF medicines.

Those legislations led to the establishment of various regulatory bodies to ensure the elimination of the menace of SF medicines. However, the economic challenges of developing countries are reflected in their ability to effectively protect their society from the vagaries of SF medicines. Several studies show evidence of the proliferation of SF medicines in Low- and middle-income countries, the prevalence of prescription of antibiotics wrongly and the consequences of the wrong use of antibiotics.

Generally, among the studies reviewed on medicine pricing policies, there are no recent studies that point out how the medicine pricing policies facilitated the availability of medicines. This means there is scanty literature that links medicine pricing policy to the availability of medicines especially, under a third-party payer scheme. Also, the studies on the prescription behaviour of medical professionals for revenue generation focus much on situations where there are third-party payers. There have not been studies on how the prescription behaviour of medical professionals is geared towards raising money from out-of-pocket financing health seekers. Besides, all the reviewed studies on medical professionals' prescription behaviour for revenue generation were conducted in the developed world which has health systems different from those of developing countries. In addition, many studies have been conducted on the time used at the counter of dispensaries, the proportion of medicines labelled and the knowledge of patients about medication dosage. However, there are scanty studies on the waiting time at the dispensary, the pattern of communications by the dispensary staff, the organisation of the dispensary and how the attitude of the dispensary staff affect the rational use of medicines. Lastly, there are scanty studies, if some exist at all, that explain the policy capacity of the regulatory bodies in Ghana to control the prevalence of SF medicines. The gaps identified in the literature are the motivations for this study.

This study was conducted within the context of Institutional theory and the principles of good governance. The institutional theory emphasises adaptation and flexibility of organisations in their environment to achieve the set target. This study is on how pharmaceutical governance affects access to medicines in Ghana. The dimensions of good governance that are used to measure the elements of the pharmaceutical life cycle share the same features as the pillars of institutional theory. The regulative, cognitive and normative pillars (Scott, 2008) and coercive isomorphism, mimetic isomorphism and normative isomorphism (DiMggio & Powel, 2008) of institutional theory correspond to the policy capacity, participation and responsiveness respectively which are the dimensions of good governance in this study.

The research methodology started with the research philosophies. Researchers have their worldviews which are reflected in the way they conduct their studies and interpret their findings. These worldviews are research paradigms. There are two extreme postures regarding research paradigms. There is positivism which is vehemently opposed by interpretivism. Between the two are middle-range paradigms that lit their torch the two paradigms that are opposed to each other. One of those paradigms in the middle is pragmatism. This shares the features of both positivism and interpretivism. This study was conducted within the context of pragmatism. A mixed method was used for the study. The study was conducted in the Northern region because it is found in the Savanna ecological zone which has a very high incidence of poverty. Northern regions also experienced a decline in health insurance coverage and OPD attendance. A cluster sampling procedure was used to select individual respondents and purposive sampling was used to select health facilities for the study. A survey was used to gather the quantitative data and in-depth interviews were used to gather the qualitative data. Pharmaceutical policies and administrative

guidelines were also reviewed. Descriptive statistics was used to analyse the quantitative data and thematic analysis was used to analyse the qualitative data.

In terms of the qualitative results, the study found that there were a lot of guidelines on medicine prescription in Ghana. These guidelines are the Standard Treatment Guidelines (STG), Essential Medicines List (EML) and the National Health Insurance Authority (NHIA) prescription and dispensing guidelines. The study indicates that the STG and the EML guided prescription at the Municipal hospital. However, those guidelines were regarded as useless at the tertiary level of healthcare. Also, there were prescription audits at all levels of healthcare delivery. The prescription audits were based on the guidelines stated by the NHIA. The study found that only a few patients were involved in the prescription process. A lot of other patients were not involved. It was also discovered that some prescribers directly sold medicines to patients and some directed patients to specific health facilities to buy their prescribed medicines. It was confirmed by managers of the community pharmacies that, some prescribers kept medicines at those pharmacies and directed patients with prescriptions to buy those medicines. The failure to involve patients in the prescription process contradicted a section of Act 851. Also, involvement in medicine sales by medicine prescribers did not conform with STG, EML and the prescription and dispensing guidelines outlined by the NHIA. These behaviours that violated the policies were found to influence the affordability of medicines by some of the health seekers.

Also, one of the important points in the pharmaceutical life cycle is medicine dispensing. The study found that some dispensary personnel in government hospitals were trained and were given guidelines on medicine dispensing to facilitate their performance to serve patients well. However, the community pharmacies did not give much attention to training the pharmacy staff. In terms of communication at the dispensary, it was found that none of the health facilities had a specialist to

interpret messages to the hearing and visually impaired. Only one hospital also had people who could interpret medication information at the dispensary in different languages for health seekers. In addition, whilst some health seekers were satisfied with how the dispensary staff communicated to them, others complained of lower voices and refusal to talk at all at the time of dispensing medicines to them. Some health seekers also complained of negative attitude, and failure to give clear dosage and side effect information by the dispensary staff. There were also complaints of poor organisation and longer waiting times at the dispensary. All these appeared to have a negative influence on the rational use of medicines.

Furthermore, a lot of consultation and surveys took place before medicine was priced in Ghana. However, the pharmacists being interviewed indicated that the information gathered during the consultation and the surveys were not utilised in pricing medicines for the NHIS. Prices of the NHIS medicines were said to be lower than the prices of medicines in the market. Besides that, the Government adopted a procurement strategy which was supposed to bring down the prices of medicines in the system, this rather created shortages of medicines because of the lower prices the government offered. These shortages extended to the health facilities. Community pharmacies were also hesitant to give out medicines to health seekers under the NHIS because of the lower prices the NHIA would pay for the medicines given to their clients. These left subscribers of the NHIS buying medicines out-of-pocket after visiting hospitals. Therefore, the pricing of medicine by the NHIA led to the unavailability of medicines to the subscribers of the NHIS at the health facilities.

Lastly, the Food and Drugs Authority (FDA) embodies the Medicine Regulation Authority in Ghana. It performs a lot of functions to ensure the quality of medicines in Ghana. The functions of the FDA are defined in the Public Health Act, 2012 (Act 851). The FDA registers all kinds of

medicines before they can be manufactured, imported, donated or distributed in Ghana. A registered medicine has market authorisation to be distributed in the Ghanaian medicine market. The authority also licenses both herbal and allopathic medicine manufacturing and distribution facilities to enhance the quality of medicines production and distribution in Ghana. After the medicines get to the market, the FDA inspects the medicines. If any medicine is found to be defective a recall of that medicine is done to eliminate the medicine from the market. The Authority also works with health facilities to dispose of unwholesome medicine. The FDA works in collaboration with several government agencies. Some lapses appear to emerge from that collaboration which leads to the proliferation of unsafe medicines in the Ghanaian market. As a result, several people reported experiencing adverse drug effects (ADE).

Concerning the quantitative results, the survey indicated that a lot of the patients were involved in the prescription process by the health professional. That is, there were discussions between the medicine prescribers and the patients on the alternative medicines that could be prescribed, the cost of the medicines and whether the patients could afford the prescribed medications. The majority of the respondents either bought all or some of the medicines prescribed for them. The medicine prescribers were found to be involved in medicine sales as a result some of the respondents truncated their pursuit of health care at the health facilities they attended. The statistical test conducted revealed that failure to involve patients in the prescription process was not significant in influencing the affordability of medicine by patients. However, the involvement of medicine prescribers in medicine sales was found to be significant in influencing patients' affordability of the prescribed medicines.

Dispensing practices examined in the study were patients' satisfaction with; waiting time at the dispensary, organisation of the dispensary, information given on medicine dosage and expected

side effects of the prescribed medicine, attitude of the dispensary staff and communications at the dispensary. The specific variables examined to determine the rational use of medicine were completion of prescribed medication, taking medication at the prescribed time and avoidance of self-medication. The study found that there was a significant association between patients' satisfaction with waiting time at the dispensary and rational use of medicines. There was also an indication of a significant association between patients' satisfaction with the organisation of the dispensary and rational use of medicines. Again, there was a significant association between patients' satisfaction with dosage information and rational use of medicines. In addition, there was an indication of a significant association between giving information on the side effects of medications and the rational use of medicines. A similar association was identified between satisfaction with communication at the dispensary and rational of medicines. However, no significant association was found between patients' satisfaction with the attitude of dispensary staff and the rational use of medicines. In all, there was an indication that dispensing practices have an influence on the rational use of medicines.

Regarding the pricing of medicines in Ghana, there were indications of pricing and adjustment of medicine prices for the medicines in the NHIS medicine list which might have not reflected the real prices of medicines in the market. This might have resulted in the refusal to give out medicine to the subscribers of the NHIS subscribers at the health facilities. Finally, the general functions of the FDA are product registrations, licensing of facilities, market surveillance and product quality testing. Through the surveillance, the FDA has been able to identify medicines with problems and recall them. The FDA also successfully identified and removed non-compliant products on sale from the pharmacies of four regions in Ghana. Despite all the efforts of the FDA, the

pharmaceutical market is inundated with unsafe medicines. This may be attributed to a lack of capacity to expand their rigorous activities to the nook and cranny of Ghana.

9.2 Limitations of the Study

This study was conducted within the context of Institutional theory and three dimensions or principles of good governance. The specific principles of good governance used in this study were participation, policy capacity and responsiveness. The governance principles were found to be similar to the pillars or the processes of isomorphism of the Institutional theory. These dimensions and the theory were used to examine how the pricing, distribution, prescription and dispensing of medicines can affect access to quality medicines. However, other principles of governance like accountability, transparency, efficiency, effectiveness and many others could be combined with other befitting theories to explain access to medicines. This implies that the information found in this study that explains the problems of access to quality medicines is not exhaustive. Other approaches can add more information to this study.

Secondly, pharmaceutical governance issues are very sensitive. It was tough to convince hospital pharmacists, managers of community pharmacies and itinerant medicine sellers to grant the researcher interviews. One of the hospital pharmacists even refused to be recorded. He said politicians might not spare him when his voice was heard explaining the issues on the pharmaceutical to the researcher. However, these limitations have not affected the quality of the study.

9. 3 Conclusion

Firstly, in line with the first objective, the study concludes that some of the medicine's prescribers were involved in the medicine's sales. That involvement inflated the cost of the medicines. This

created difficulty for patients to afford their medications. Therefore, the prescription behaviour of health professionals influences the affordability of medicines by patients.

Secondly, in correspondence with the second objective, the study concludes that some patients were not satisfied with the waiting time and organisation of the dispensary. Also, some dispensary staff did not communicate well with patients, some did not give dosage information to the patients and some did not give information about minor effects of medicine that had them. These pushed some of the health seekers to self-medication, non-adherence to the times for medication and incompletion of medication. Consequently, the dispensing practices of the dispensary staff influence the rational of medicines.

Thirdly, in conformity with the third objective, this study concludes that the Framework Contracting and pricing leads to stockouts at the medical stores. This further leads to stockouts at the public secondary and lower hospitals. The hospitals find it difficult to buy from the open market because the prices of medicines in the open market are higher than the prices of medicines in the NHIA medicine list. So, when patients go to public hospitals medicines are either sold to them, co-payment is introduced or prescriptions are written for them to obtain the medicines outside. When patients go to private medicine outlets, they experience the same situation. Therefore, the medicine pricing policy does not make medicines available to the subscribers of the NHIS.

Lastly, the FDA has the legal framework and the guidelines to ensure the safety of medicines in Ghana. It does registrations and licensing to regulate manufacturing, importation and distribution of medicines in Ghana. It also conducts inspections to clean the market of substandard and falsified (SF) medicines. It collaborates with other agencies to regulate the medicine market. However, it lacks the logistics and personnel to extend its effective services to every part of the country. Besides that, when their collaborators fail to honour their part of the collaboration it affects the

functions of the FDA. So, the FDA functions effectively but its logistical challenges lead to the prevalence of unsafe medicines in the market.

In general, the study concludes that there are serious challenges to pharmaceutical governance in Ghana which do not allow access to quality medicines.

9.3.1 Contribution of the Study to Theory

This study combined institutional theory with principles of good governance to explain how pharmaceutical governance leads to access to quality medicines. The study used the principles of good governance to examine how various behaviours, practices, policies and functions within the pharmaceutical life cycle led to access to quality medicine. This study has added to the Institutional theory of how the principles of good governance can stir the institutional processes to reach the level of isomorphism. The following is how the study has done that:

The study has been able to explain that, the fragile or null policy capacity of institutions will not permit the regulative component of the institutions to enhance the isomorphic state by coercive means. Also, lack of or insufficient stakeholder participation in the institutional process will not permit the sharing of ideas, skills, opinions and perceptions to achieve common institutional goals. This berates the cognitive pillar of the Institutional theory and will sabotage the achievement of mimetic isomorphism. Lastly, if there is no responsiveness to the expectations of the people which certainly emanates from the institutions. Then normative pillar of the Institutional theory is damaged which will not permit normative isomorphism. In general, the absence of good governance will not permit isomorphism which will further affect the realisation of organisational goals.

9. 3.2 Contribution of the Study to Empirical Literature

This study has added to the recent existing empirical literature (Ambigapathy et al, 2016; Nuwagaba et al, 2021and Vedasto et al, 2021) on patient participation in decision-making in the healthcare process. However, whilst the other studies examined participation in decision-making in either every process of healthcare delivery or only at the time of consultation, this study focused on the involvement of patients in the medicine prescription process. Also, other studies found that the involvement of medicine prescribers in medicine sales were either influenced by the representatives of pharmaceutical companies (Hajjar, et al. 2017; DeJong et al, 2016 and Brax et al, 2017) or was permitted by the health system (Perlis & Perlis, 2016; Burkhard et al. 2019 and Goldcare, 2019). However, the findings of this study revealed that the involvement in medicines sales by medicine prescribers was done against the health system regulations. In addition, this study has been able to link the influence of the prescribers' involvement in medicine sales to patients' ability to afford the medication which is not in the previous studies.

Furthermore, most studies on medicine dispensing measure the metrics set by WHO on rational dispensing which are time spent with the dispensing staff at the counter, the number of medicines labelled and the knowledge of dosage by the patients (Siele et al., 2022; Priyadarshani, 2021; Silva et al., 2018; Gidebo, 2016; Chirwa, 2014; Prasad, 2015; Wendie, 2021; Sisay, 2017; Akl et al. 2014; Chandelkar & Rataboli, 2014). However, the dispensing practices examined in this study included waiting time at the dispensary, organisation of the dispensary, information given to patients on medicine dosage and the information on expected side effects. Additionally, the previous studies only examined rational dispensing practices, they did not examine how the rational prescriptions influenced rational use of medicines. That is another gap this steady has filled.

Also, most recent studies on medicine pricing policies only linked the pricing policies to the affordability of medicines (Alefan et al, 2018; Maniadakis et al. 2017; Panteli et al. 2016; Bangalee & Suleman, 2016; Bangalee & Suleman, 2019; Cassar & Suleman, 2019; Fink, et al. 2014 and Tran et al. 2020). This study went further to fill the literature gap by explaining how the pricing policies affect availability of medicines to patients under third party payers at the health facilities.

Lastly, most of the recent studies focused on the prevalence of off-label, unlicensed and SF medicines in developing countries (Gore et al. 2017; Pratico, et al. 2018 and Saiyed et al. 2015 Hamill et al. 2019, Bekoe et al., 2020). Some studies also explain the presence of antibiotics at unauthorised places which were prescribed by unapproved persons (Yevutsey et al., 2017; Ahiabu et al., 2018 and Afari-Asiedu et al. 2018) and other studies attributed the presence of SF medicines in developing countries to poor regulations, reliance on the private sector, poverty and proliferation of online pharmacies (Mackintosha et al., 2018 and Ahiabu et al., 2018). This study has added to the existing literature by explaining the functions of medicine regulatory authorities which are found within stronger regulatory frameworks and the reasons for the presence of SF medicines in such domain.

9.3.3 Contribution of the Study to Health Policy and Management

There are various forms of governance of the healthcare systems that are studied in Health Policy and Management. This study adds to the literature on Pharmaceutical Governance. The essence of studying Pharmaceutical Governance should be on how access to quality medicines can be achieved. The study explains the application of the principles of good governance within the context of Institutional theory to explain and predict access to quality medicines. Therefore, this study can be one of the resource materials for the Pharmaceutical Governance aspect of Health Policy and Management.

9.3.4 Recommendation for Further Studies

This study combined participation, policy capacity and responsiveness with Institutional theory to examine how the pricing, distribution, prescription and dispensing of medicines can affect access to quality medicines. Therefore, another study can use other principles of governance like accountability, transparency, efficiency, effectiveness and many others with other befitting theories to examine access to quality medicines.

9.3 Policy Recommendations

1. There is a need for the Standard Treatment Guidelines to be regularly updated to reflect prevailing medical evidence. Very categorical and strong regulations should be made to compel all hospitals to rely on the Essential Medicine List for their medicine procurement. A robust link should also be established between consulting rooms and pharmacies at the hospitals so that the decision to recommend medicine for patients to buy from an external medicines outlet will be a collective decision between the pharmacists and the prescriber. Many patients realise it when moves are made to sell medicines to them wrongly. However, some of them submit themselves to such moves and remain quiet because they do not know whom to complain to or they believe complaining to anyone will never yield any results. It is therefore recommended that the Ministry of Health introduces and publicises an SMS short code to let patients send complaints of wrongdoing at the health facilities to the Ministry. Management of the hospital in question and the district directorates of Ghana Health Services should be tasked to deal with the complaints. Evidence of the number of complaints resolved satisfactorily should be demanded and added to the health statistics annually. This should be part of the indices used to rate the performance of health facilities.

2. The Ministry of Health should task every Regional Directorate of Health Services and every teaching hospital to develop a manual for dispensing medicines. The manual should cover the regular scientific medicine dispensing practices as well as the norms, values, customs and beliefs of the people in the regions. That manual should be used to train medicine dispensing staff periodically. Some dispensary staff may still fail to relate well with health seekers, if they are not well supervised, because they may believe the health seekers are powerless. Therefore, every dispensary staff should be given a code in the form of mini stickers. Any dispensary staff who dispenses medicine should attach his/her wrappers or boxes of medicines dispensed to health seekers. This can be used to track individual dispensary staff. Periodic exit interviews should be conducted with the health seekers to appraise the dispensary staff who attended to them. The appraisal results should be added to the key requirements for the promotion of the dispensary staff. Specialists are also needed at the dispensaries to enhance communication with the disabled.
3. The Ministry of Health may be negotiating for very low medicine prices in the Framework Contracting Agreement to cater for the needs of the poor. However, the poor end up buying medicines, whose quality cannot be guaranteed, at higher prices. Therefore, the Framework Contracting Agreement should be streamlined. More consultation is needed to determine the reality of the tender pricing when the contracts are to be signed. An upward adjustment should be made to the premium paid by the subscribers of the National Health Insurance Scheme. The National Health Insurance Law should also be streamlined to let the Health Insurance Fund focus only on the delivery of preventive and curative healthcare. These will allow the National Health Insurance Authority to come up with realistic reimbursable prices to curb the unavailability of medicines to the subscribers of the Scheme.

4. The revenue being generated by the FDA should be wholly retained by the Authority to perform its regulatory functions. More grants should be sought for the Authority to establish and operate offices in every district. The personnel of the FDA who are already trained on investigations should be in every district and they should have informer allowances to enhance investigations.

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APPENDIX I

QUESTIONNAIRE TO HEALTH SEEKERS

A. Socio-Demographic Background of the Health Seeker

1. Place of residence of respondent …….

2. Sex (1) Male [ ] (2) Female [ ]

3. What is your Age (in years)? (1)15 – 19 [ ] (2) 20 – 24 [ ] (3) 25 – 29 [ ] (4) 30 – 34 [ ] (5) 35 – 39 [ ] (6) 40 – 44 [ ] (7) 45 – 49 [ ] (8) 50 – 54 [ ] (9) 55 – 60 [ ] (10) 60+ [ ]

4. What is your religion? (1) Islam [ ] (2) Christianity [ ] (3) Traditional Religion [ ] (4) No Rel. [ ]

5. Marital status. (1) Married [ ] (2) Single [ ] 3. Divorced

6. What is your level of education? (1) No formal education [ ] (2) Basic Education [ ] (3) Secondary Education [ ] (4) Diploma [ ] (5) Degree [ ] (6) Postgraduate [ ] (7) Religious education [ ] (8) Other, specify .....

7. What is your occupation? (1) Farmer [ ] (2) Trader [ ] (3) Teacher [ ] (4) Civil servant [ ] (5) Banker [ ] (6) NGO worker [ ] (7) Other public sector worker [ ] (8) Artisan [ ] (9) Religious cleric [ ] (10) Unemployed [ ] (11) Other, specify ……

8. Can you estimate your monthly income (health seeker) or the caretaker?

(1) Below Gh¢500 [ ] (2) Gh¢500 - Gh¢1000 [ ] (3) Gh¢1001 - Gh¢2000 [ ]

(4) Gh¢2001 - Gh¢3000 [ ] (5) Gh¢3001 - Gh¢4000 [ ] (6) Gh¢4001 - Gh¢5000 [ ]

(7) Over Gh¢5000 [ ]

9. Health facility attended ……

10. Category of the health facility attended (1) Public [ ] (2) Mission [ ] (3) Private [ ]

11. Location of health facility attended. (1) Urban [ ] (2) Rural [ ]

12. Have you subscribed to the NHIS (1) Yes [ ] (2) No [ ]

B. Prescription Behaviour and Affordability of Medicine

13. Was medicine prescribed for you when you went to the hospital? (1) Yes [ ] (2) No[ ]

14. If yes, did the prescriber tell you anything about alternative medicine that could be prescribed?
(1) Yes [ ] (2) No [ ]
15. Did the prescriber tell you anything about the cost of the medicine prescribed? (1) Yes [ ] (2) No [ ]

16. Did the prescriber ask you if you could afford the medicine? (1) Yes [ ] (2) No[ ]

17. Is there any way the prescriber involved you in the prescription process? 1. Yes [ ] 2. No [ ]

18. How did you get the medicine prescribed? (1) I bought all [ ] (2) I obtained it as NHIS subscriber[ ]

(3) I was given some and I bought the rest [ ]

19. Did the prescriber instruct you to buy the medicine at a specific place? (1) Yes [ ] (2) No [ ]

20. Did you buy the medicine at where the prescriber instructed you to buy it from? (1) Yes [ ] (2) No [ ]

21. Where did you buy it from? ……

23. How did you afford the medicine?

(1) I borrowed money to buy it [ ]. (2) I sold an asset to buy it [ ]. (3) I had to forgo other basic needs to buy it [ ]. (4) I sought support from others to buy it [ ]. (5) I bought it without any challenge [ ]. (6) I discontinued the treatment [ ]

C. Medicine Dispensing and Rational Use of Medicines

24. Can you estimate the time you spent before going to the counter to receive the medicine?

……

25. Were you satisfied with how long you stayed at the point of medicine reception? (1) Yes [ ]

(2) No [ ]

26. Were you satisfied with how the dispensary/pharmacy was organised? (1) Yes [ ] (2) No [ ]

27. Did the person who gave you the medicine explain the dosage of the medicine to you? (1) Yes [ ](2) No[]

28. If yes, were you satisfied with the information given to you about the medicine dosage?
(1) Yes [ ] (2) No [ ]

29. Were you given any information about the possible side effects of the medicine? (1) Yes [ ] (2) No [ ]

30. Did you feel disrespected when the medicine was to be given to you? (1) Yes [ ] (2) No

31. Were you satisfied with the attitude of the personnel gave you the medicine? (1) Yes [ ] (2) No [ ]

32. What language did the personnel who were to give you the medicine speak to you? ……

33. Did you understand what they told you? (1) Yes [ ] (2) [ ]

34. Were their voices loud enough to let you hear and understand them? (1) Yes [ ] (2) No [ ]

35. Generally, were you satisfied with how the personnel who gave out the medicine to you communicated with you? (1) Yes [ ] (2) No[ ]

36. Did you go to buy any other medicine besides what was prescribed for you? (1) Yes [ ] (2) No [ ]

37. Did you take all the medicine obtained from the prescription list? (1)Yes [ ] (2)No [ ]

38. Did you take the medicine at the time you were told to take it? (1)Yes[ ] (2)No[ ]

C. Availability of Medicine

39. Was your health insurance active at the time you attended hospital? (1) Yes [ ] (2) No [ ]

40. If yes, were you given all the medicine prescribed at the hospital you attended? (1) Yes [ ] (2) No [ ]

41. If no, was the medicine given to you at any of the NHIS accredited pharmacies (1) Yes [ ] (2) No [ ]

42. If no, did you get the medicine to buy? (1) Yes [ ] (2) No [ ]

43. If yes, where did you get it? (1) at the same hospital attended [ ] (2) At the same pharmacy we could not get it as NHIS subscribers [ ] (3) At different pharmacy [ ]

44. If at different pharmacy, does that pharmacy accept health insurance (1) Yes [ ] (2) No [ ]

D. Medicine Distribution Regulations and Medicine Safety

45. Have you ever experienced any illness after taking medicine? (1) Yes [ ] (2) No [ ]

46. If yes, where did you get the medicine from? …….

47. Why was the medicine taken? ……

48. Was advice sought from anyone before taking the medicine? (1) Yes [ ] (2) No [ ]

49. If yes, who? ……

50. Did you follow the advice? 1. Yes [ ] 2. No [ ]

51. If you took it for treatment, did you suspect that your problem was worsened by the medicine you took?

(1) Yes [ ] (2) No [ ]

Thank You

APPENDIX II

INTERVIEW GUIDE FOR HEALTH SEEKERS

1. What health problem did you send to the hospital?
2. What discussion went on between you and the prescriber before medicine was prescribed for you?
3. What expectations did you have when the medicine was to be prescribed for you?
4. Were there some difficulties you encountered in obtaining the prescribed medicines?
5. Did you have any problem with how the dispensary/pharmacy was organised?
6. What did the person who dispensed the medicine to you tell you about the medicine dosage?
7. What were you told about the side effects of the medicine given to you?
8. Did you have any problem about the attitude of the workers at the dispensary?
9. Did you see the need to go and obtain any other medicine besides what was prescribed for you?
10. Did you see the need to stop taking the medicine you obtained from the prescription list?
11. When you went to buy medicine what did they tell you before the medicine was sold to you?
12. Have you ever experienced any illness after taking medicine?
13. Why did you take that person?

APPENDIX III

INTERVIEW GUIDE FOR COMMUNITY PHARMACIES

1. Can you please tell me where you get your supplies from?
2. Do you import medicines?
3. How do you dispose of expired medicines?
4. Do the doctors/medical assistants leave some medicines here for you to sell?
5. Do you sometimes contact the health workers to inform them about new medicine in stock at your shop?
6. Do the health workers help you in any way to sell your medicine?
7. What is the relationship between the pricing of your medicine and that of the NHIS?
8. Does medicine pricing by the NHIS affect how you give medicines to the NHIS subscribers?
9. Is there any difficulty you face in giving medicines to NHIS subscribers?
10. Is there a qualification you require to employ your workers here?
11. Are the guidelines on dispensing medicines kept in this pharmacy?
12. Do you have a person who understands sign language?
13. How do you label medicine for the visually impaired?
14. How do you communicate with those who are speech and hearing impaired?

APPENDIX IV

INTERVIEW GUIDE FOR HOSPITALS/HEALTH CENTRES

1. Name of Hospital/health centre
2. Position of Respondent
3. Please do you have the Essential Medicine List?
4. Do you have the Standard Treatment Guide?
5. Do you have any administrative guidelines for medicine prescription in this facility?
6. Is the information about the medicine in stock in the dispensary available to the medicine prescribers?
7. Is there any manual for dispensing medicine that guide the personnel at the dispensary?
8. Are there translators at the dispensary?
9. How often to you stock medicines in this facility?
10. Besides the CMS, do you get medical supplies from somewhere?
11. Is there any disparity in the prices of medicines from your suppliers and that of the NHIS?
12. Does the pricing of medicine by the NHIS affect the stocking of medicines in your facility?
13. How do you dispose expired medicines?

UNIVERSITY OF GHANA
ETHICS COMMITTEE FOR THE HUMANITIES (ECH)
P. O. Box LG 74, Legon, Accra, Ghana

My Ref. No: ECH 072/ 23-24.

November 30, 2023

Abdul-Rahaman Abdul Salam
Dept. of Public Administration and Health Services Management
University of Ghana
Legon

ETHICAL CLEARANCE
(ECH 072/ 23-24)

The Ethics Committee for the Humanities (ECH) conducted a full board review and approved your protocol titled:

PHARMACEUTICAL GOVERNANCE AND ACCESS TO QUALITY MEDICINES IN GHANA

PRINCIPAL INVESTIGATOR: **ABDUL-RAHAMAN ABDUL SALAM**

Please note that the final review report must be submitted to the Committee at the completion of the study. Your research records may be audited at any time during or after the implementation. Any modification of this research project must be submitted to ECH for review and approval prior to implementation.

Please report all serious adverse events related to this study to ECH within seven (7) days verbally and in writing within fourteen (14) days.

This certificate is valid until November 29, 2024. You are required to submit annual reports for continuing review.

Please accept my congratulations.

Yours Sincerely,

Professor C. Charles Mate-Kole
ECH Chair

Cc: Professor Gordon Abekah-Nkrumah, Department of Health Services Management, UG
Professor Patience Aseweh Abor, Department of Health Services Management, UG

Tel: +233 30 393 3866 Email: ech@ug.edu.gh

DEPARTMENT OF RESEARCH &DEVELOPMENT
TAMALE TEACHING HOSPITAL

In case of reply the number and date of this letter should be quoted

Box TL 16, Tamale
West Africa-Ghana
GPS: NT-0101-5331

Tel: 03720-00180
Our Ref: TTH/R&D/SR/335/23
Your Ref:

21st December, 2023.

To whom it may concern

CERTIFICATE OF AUTHORIZATION TO CONDUCT RESEARCH IN TAMALE TEACHING HOSPITAL

I hereby introduce to you **Mr. Abdul-Rahama Abdul Salam** a PhD (Candidate) in Health Policy and Management at the University of Ghana Business School,Legon.

Having shown evidence of ethical approval, from the Ethics Committee for the Humanities (ECH) of the University of Ghana, with the ID (ECH 072/23-24), Mr. Abdul Salam has been duly authorized to conduct a study titled **"Pharmaceutical Governance and Access to Quality Medicine in Ghana".**

Please accord him the necessary assistance to enable him complete the study. If in doubt, kindly contact the Research Unit on the second floor of the administration block or on Telephone 0209281020. In addition, kindly report any misconduct of the Researcher(s) to the Research Unit for necessary action.

Upon completion, you are required to submit a copy of the final study to the Hospital.
Please note that this approval is given for a period of six months, beginning from 21st December,2023 to 20th June, 2024.

Thank You.

ALHASSAN MOHAMMED SHAMUDEEN,
(DEPUTY DIRECTOR, RESEARCH & DEVELOPMENT)

OUR CORE VALUES:
1. People-centered
2. Professionalism
3. Teamwork
4. Innovation
5. Discipline
6. Integrity

My Ref No: GHS/NR/RHD/18-01/770
Your Ref No: .....

Regional Health Directorate
Ghana Health Service
P.O. Box 99
Tamale, Northern Region
Tel: +233 (03720)22912/22710/22146
GPS Address: NT-0001-7027
Email: rdhs.nr@ghs.gov.gh

Monday, December 11, 2023

THE MEDICAL SUPERINTENDENTS
- **YENDI MUNICIPAL HOSPITAL**
- **GUSHEGU MUNICIPAL HOSPITAL**

LETTER OF INTRODUCTION

Mr. Abdul-Rahaman Abdul Salam is a PhD candidate in Health Policy and Management at the University of Ghana Business School Legon.

He has selected your facilities to conduct a research on the topic, "Pharmaceutical Governance and Access to Quality Medicine in Ghana" as part of the requirement of his programme.

You are by this letter informed that, Mr. Abdul-Rahaman Abdul Salam is permitted to conduct his research in your facilities.

Kindly accord him the necessary support during the data collection process.

Thank you.

DR. ABDULAI ABUKARI
REGIONAL DIRECTOR OF HEALTH SERVICE
NORTHERN REGION

CC: CHIEF PHARMACIST, NORTHERN REGION

THE DEPUTY DIRECTOR, CLINICAL CARE, NORTHERN REGION

FILE