ACCEPTABILITY OF LAWS AND REGULATIONS RESTRICTING OVER-THE-COUNTER SELLING OF ANTIBIOTICS AMONG COMMUNITY PHARMACISTS IN KINONDONI MUNICIPAL, DAR ES SALAAM

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By

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A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Public Health Implementation Science of the Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **Acceptability of laws and regulations restricting over-the-counter selling of antibiotics among community pharmacists in Kinondoni municipal, Dar es salaam.,** in (partial) fulfillment of the requirements for the degree of Master of Public Health – Implementation Science of the Muhimbili University of Health and Allied Sciences.

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Date

DECLARATION AND COPYRIGHT

I, **Babuali Ahmed Ally**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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I acknowledge the effort of my supervisors, classmates, and the Department of Epidemiology and Biostatistics staff at Muhimbili University of Health and Allied Sciences who in one way or another gave constructive recommendations that guided me through the development of this work.

DEDICATION

I dedicate this work to my father, Ahmed Ally Mohamed, for his unconditional support and guidance. To my family, my wife Rehema Ramadhani Mbalamwezi and children, Evan Godfrey Matiko and Amani Babuali Ahmed for their unconditional love patience and support through this academic journey.

To my late Mother, Ruth Samson Mtinda, from whom I still see the impact of her prayers over my life journey.

To friends and relatives, I dedicate this work as a token of gratitude.

ABSTRACT

Introduction: The world is faced with a major problem of antimicrobial resistance. Over-the-counter (OTC) selling of antibiotics is one of the factors fueling the irrational use of antibiotics due to easy access. Despite present laws and regulations restricts, over-the-counter selling of antibiotics is still common in community pharmacies. There were no comprehensive information on the acceptability of implementation of these laws and regulations from community pharmacist perspectives in Tanzania.

Objective: This study aimed to comprehensively explore the acceptability of laws and regulations restricting over-the-counter selling of antibiotics from the perspectives of community pharmacists in Dar es Salaam.

Materials and method: An explorative case study design focusing on community pharmacists was conducted in Kinondoni municipality. A total of 15 in depth interviews with community pharmacists and 5 key informant interviews with inspectors from the Pharmacy council of Tanzania were conducted. Carefully prepared and pre-tested interview guides were used to collect data on affective attitudes, perception of burden and self-efficacy of community pharmacists on laws and regulations restricting OTC selling of antibiotics. A thematic analysis approach was used to analyze data.

Findings: Attitudes and perception towards laws, professional and moral values, perception of burden, professional confidence and autonomy in dispensing were identified as key areas associated with decision to comply and acceptance of laws and regulations. Findings revealed that community pharmacists understand the importance of these regulations in preventing misuse and professional misconduct. Despite this, deliberate non-compliance occurred, driven by factors such as customer demand, business pressures, and moral dilemmas. Community pharmacists reported a positive attitude towards compliance, appreciating the professional safeguards the laws provide. However, the acceptance of these regulations was mixed, with most pharmacists noting negative business impacts. Conflicts arose between adherence to regulations

and personal morals, especially when customers were in urgent need or unable to afford prescriptions.

Conclusion: Overall, the study highlights the need for increased awareness efforts, to balancing professional values, business viability, and public health. This study highlights requirements of collaborative efforts in addressing economic pressure, burden viewed by community pharmacists and therefore enhancing adherence to restriction and promoting responsible antibiotic use.

Recommendations: There is a need for regulators to consider economic realities associated with adherence which will ensure professional conduct and business sustainability of community pharmacies while protecting public health. Furthermore, deliberate efforts by the Pharmacy Council of Tanzania along with other regulators, should be made to increase awareness on rational use of antibiotics at community level combined with improving accessibility and quality of health services to reduce customer demand in community pharmacies.

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ABBREVIATIONS

AMR	-	Antimicrobial Resistance
IDI	-	In-depth Interview
IRB	-	Institutional Review Board
LCMIS	-	Low- and Middle-income countries
MUHAS	-	Muhimbili University of Health and Allied Sciences
OTC	-	Over-the-Counter
TFA	-	Theoretical Framework on Acceptability
TMDA	-	Tanzania Medicines and Medical Devices Authority.

DEFINITIONS

Antibiotics: A chemical substance of small molecular weight and microbial origin which in small concentration can inhibit or kill other microorganisms with minimal toxicity to the host and therefore used as medicines to treat infectious diseases (1).

Antimicrobial Resistance: is defined as the capacity of microorganisms (viruses, bacteria, fungi, and protozoa) to withstand the effects of drugs that were once successful in curing illness and treating the diseases they cause (2).

Cognitive perception: This is the way through which the human mind deals with the information obtained from the surrounding environment. The mental capacity of an individual to group and classify information in classes and groups through their characteristics whether they are related to one another or not, and to use the classes to influence decisions or actions (3).

Community pharmacy: Publicly accessible and privately owned, registered healthcare premises, recognized by the law and licensed to provide pharmaceutical services and sell pharmaceutical products in a retail business model (4)

Community pharmacist: Licensed drug dispenser within a community pharmacy. A registered pharmacist by law practicing in a community pharmacy in providing pharmaceutical services, dispensing pharmaceutical products, and selling medicinal and other related products in a retail business model (5) and pharmaceutical technicians of diploma level, legally registered and recognized to provide pharmaceutical services in the same manner as registered pharmacists.

Law: Is defined as a set of justiciable rules that regulate conduct (6).

Over-the-counter selling of antibiotics: This is defined as the selling of prescription-only antibiotics without a valid prescription from a licensed and recognized prescriber (7).

Prescription-only medicines: defined as any medicinal product required to be dispensed only upon a prescription by a medical surgeon, veterinary surgeon, or any other person recognized, licensed, and authorized by law (8).

Regulation: Rule or directive maintained by a body in relation to legislation created by the state (9).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background information

By the early 21st century, the world realized that it faced a problem of microbial resistance against major antibiotics used (10,11). Higher consumption of antibiotics has been reported to be associated with antimicrobial resistance (7,12). Elements of irrational use such as improper prescription, self-medication practices, and misuse of antibiotics contribute to the emergence of resistant microorganisms (13–16). Selling antibiotics over the counter (OTC) and without a valid prescription is one of the activities that raises great concern in fueling the irrational use of antibiotics (17,18). Globally, evidence from publications suggests that the extent to which antibiotics are sold without prescription ranges from 8% to 100% with the best estimate being 60% (19). In Africa, the estimated pooled proportion is 69% with countries such as Eritrea, Ethiopia, Zambia, and Uganda reporting 87.6%, 87.6, 71%, and 94% of antibiotics sold without prescription (20–23). Tanzania employs two types of pharmaceutical retail businesses: community pharmacies and Accredited drug dispensing outlets. Even though the full extent of antibiotics sold over the counter in the country is unknown. There have been several studies conducted in Moshi, Mbeya, Dar es Salaam, and Morogoro regions reporting a range from 53% to 92% (18,24–28). Weak regulatory enforcement, a limited number of professionally qualified pharmacists, low knowledge, and awareness of AMR from both patient and pharmacist, failure to obtain a prescription by patients, and desires to make profits, are among the factors attributed to OTC sale of antibiotics (27–30).

In response to the growing concern of the OTC selling of antibiotics without prescription, many countries including Tanzania enacted laws and enforced regulations to prevent the act (7,31). Such interventions have been having varying success in different parts of the world. A review conducted by Jacobs *et al.* 2019 which included 15 studies from 10 countries reported OTC sales of antibiotics were reduced by the multifaceted implementation of laws and regulations (7). An interrupted time series study conducted in Brazil reported a 19% decrease in the OTC

selling of antibiotics after enforcement of prescription retention and inspections (32). The success of the implementation of laws and regulations was greatly associated with effective engagement, education and awareness, effective enforcement, and political willingness to implement (7,31).

Tanzania's regulatory framework against the OTC selling of antibiotics involves the Pharmacy Act, Tanzania Medicines and Medical Devices Act, the regulation schedule of medicines, and the recent prescription handling and control regulations under the Pharmacy Act (5,8,33,34). Section 55(f) of the Pharmacy act governs the Prescription Handling and Control Regulation of 2019, that provides a comprehensive approach to the management and control of prescription pharmaceuticals, including antibiotics. According to this regulation, a current prescription is required (8). Regulatory interventions restrict community pharmacies and dispensing outlets from selling antibiotics over the counter without a valid prescription. However, research studies conducted in various methodologies including simulated customer approach continue to report high percentages of OTC sales of antibiotics (18,35). Reported factors associated with this misconduct include a lack of stringent enforcement and a desire to maximize (27).

Acceptability of these interventions can be defined as how community pharmacists perceive the laws and regulations to be appropriate based on their anticipated or experimental cognitive and emotional responses (36). The way to which laws and regulations are satisfactory, agreeable, and palatable is based on the perceptions and experiences of community pharmacists (37). The degree to which laws and regulations restricting OTC sales of antibiotics are acceptable has only been indirectly linked to dimensions of awareness, knowledge, and perception of pharmacists on the activity. In a study conducted in Tanzania targeting community pharmacists reported adequate knowledge and positive attitudes towards restrictions on OTC sale of antibiotics (27). Similar studies in middle east reported knowledge on the legal restrictions and that selling antibiotics over the counter could lead to irrational use, and yet it was reported to be a common among community pharmacists (38). From these studies, desires for profit, common perceptions, and knowledge were greatly associated with community pharmacists selling antibiotics without a prescription. Such findings suggest that the acceptability of laws and

regulations is critical for successful adherence. Thus, we can deduce that; the impact and effectiveness of laws and regulations on the OTC sale of antibiotics by community pharmacists can be associated with evidence from other countries with similar contexts and data for knowledge, awareness, and attitude towards the practice exist but are insufficient (27). However, there is also no comprehensive information on the acceptability of implementation of these laws and regulations from community pharmacist perspectives in Tanzania. This study comprehensively explored the acceptability of such regulatory interventions on the OTC sale of antibiotics utilizing the theoretical framework for acceptability of health interventions developed by Sekhon, Cartwright, and Francis in 2017. The study captured the cognitive and emotional responses of community pharmacists towards the implementation of laws and regulations using the constructs of the theoretical framework. Therefore, gaining an in-depth and comprehensive understanding of their acceptability for the aim of informing enforcement strategies, antimicrobial stewardship programs, and behavior change interventions to effectively combat AMR.

1.2 Problem statement

In 2019 it was estimated that 4.95 million deaths globally, were related to AMR out of which – 1.27 million deaths were attributed to AMR (39). A systematic review conducted with 85 studies estimates that 60% of antibiotics globally were sold without prescription (19). In sub-Saharan Africa, the pooled proportion of antibiotics sold over the counter is slightly higher at 69% (20). In Tanzania it is estimated that total of 54,000 deaths are associated with AMR and 12,500 deaths attributed to AMR (40). Mystery customer studies conducted in Kilimanjaro and Morogoro in Tanzania found that 92% of antibiotics and 79% of drugs including antibiotics respectively, were sold without a proper prescription (18,24). Tanzania has enacted laws and regulations against OTC sales of antibiotics. These include the Pharmacy Act, the Tanzania Medicines and Medical Devices Act, the Schedule of Medicines regulations, and the prescription handling regulations (5,8,33,34). Enforcement of such laws and regulations is faced with challenges of human and financial resources (41). Poyongo and Sangeda, 2020 reported that 77.7% and 79.2% of community pharmacists had adequate knowledge and positive attitudes toward implemented

regulatory restrictions (27). A similar study was conducted in Saudi Arabia and reported only a quarter of community pharmacists are aware of laws and regulations while 55% believe OTC selling of antibiotics is a common practice (38). Inadequate regulatory capacity was reported to influence and shape the practices, perceptions, and attitudes of community pharmacists toward the laws and regulations (27).

Based on the available studies, there is limited information on the actual acceptability of the laws and regulations on OTC selling of antibiotics. Previous studies on over-the-counter selling of antibiotics have been limited to awareness, knowledge, attitudes, and perceptions towards the act, but there are no studies conducted focusing on the acceptability of enacted laws and regulations restricting OTC by the public or community pharmacists. This study, therefore, aimed to fill this information gap by providing a comprehensive exploration of the implementation acceptability of laws and regulations restricting OTC selling of antibiotics from the perspectives of community pharmacists. Furthermore, this study will inform antimicrobial stewardship programs and behavior change interventions targeted to combat AMR in Tanzania.

1.3 Conceptual framework

The study utilized the theoretical framework on acceptability (TFA) formed by Sekhon, Cartwright & Francis in 2017 on assessing the acceptability of healthcare interventions. This theoretical framework has seven constructs which are affective attitude which centers on the feeling of an individual while participating in the intervention. The second is burden which focuses on the amount of effort that is required in implementation of the intervention. Third is ethicality which assesses the fitness of the intervention with an individual value system. Fourth is intervention coherence which focuses on the understanding of the intervention. Fifth is opportunity costs which assess the benefits and profits that must be sacrificed to implement the intervention. Sixth is perceived effectiveness which assesses the perceived likelihood of the intervention to achieve its intended objective. Lastly is self-efficacy which assesses the confidence of the participants in performing behaviors required to implement the intervention. For this study and given limited time and resources, only three constructs from the theory which

are the affective attitude, burden, and self-efficacy were utilized. These were modified to meet the objectives without altering the core meaning and associated concepts. The study sought to capture the cognitive responses of community pharmacists towards the implemented laws and regulations on the OTC selling of antibiotics which are critical in demonstrating willingness leading to acceptability.

Under the construct of affective attitude, this study explored how community pharmacists feel about complying with laws and regulations restricting OTC selling of antibiotics. The exploration focused on compliance experience and influence personal and professional values.

Construct of burden referred to the perception of efforts by community pharmacists that are required to comply with laws and regulations restricting OTC selling of antibiotics. Under this construct of burden, the exploration focused on the perceived workload, perceived time requirement, and cognitive effort which translates to efforts necessary to practice under the environment of adherence to laws and regulations restricting OTC selling of antibiotics. The regulation intervention requires community pharmacists to check and scrutinize prescriptions, therefore pharmacists use time. During dispensing community pharmacies can be overwhelmed with customers hence adherence to requirements of laws and regulations may be translated to too much workload. Scrutiny of prescription may require extra cognitive and mental effort which influence the action of whether to dispense or not and therefore this mental effort/burden may influence how community pharmacists view the regulatory interventions as acceptable or not.

Under the construct of self-efficacy, this study explored community pharmacists' confidence in their capacity of behavior necessary to perform, implement, and comply with the regulations. The exploration in this study was centered on concurrent acceptability whilst laws and regulations are being enforced.

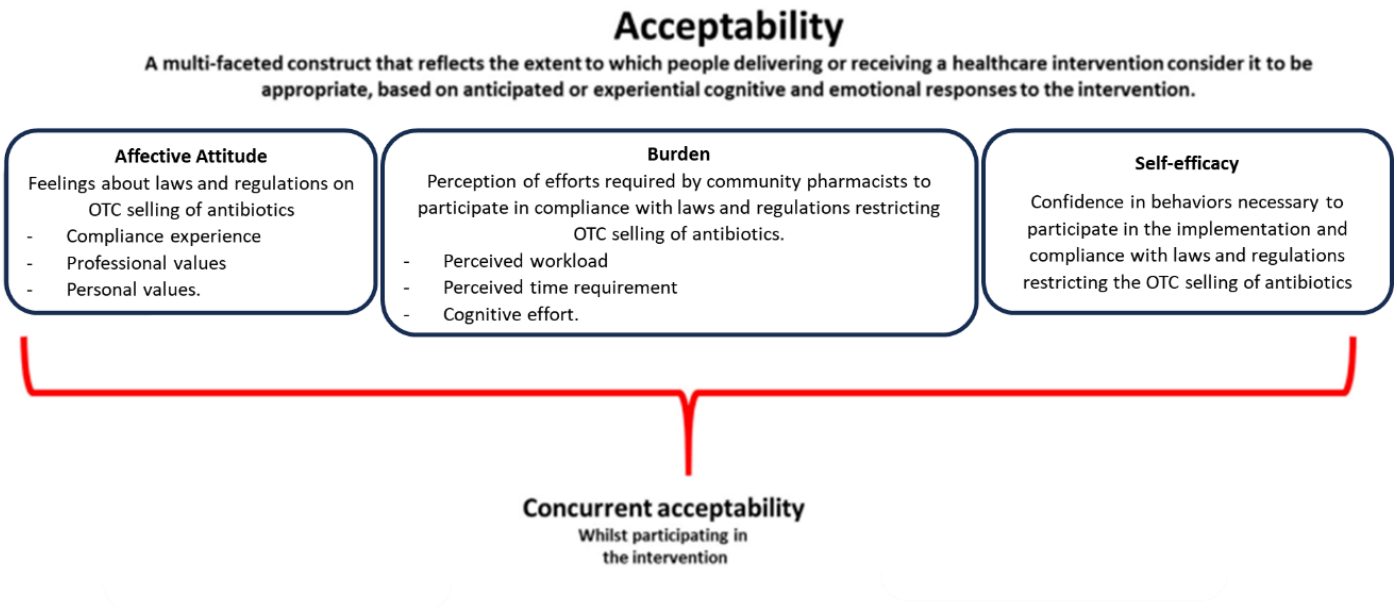


Figure 1. A conceptual framework for exploring the acceptability of laws and regulations on OTC selling of antibiotics adopted from TFA by Sekhon, Cartwright & Francis in 2017 (36). 0744675677

1.4 Rationale

In Tanzania, there are laws and regulations which restrict antibiotics to be sold only with a valid prescription. However, there are several reports where community pharmacists sell antibiotics over the counter. This is concerning because it fuels the irrational use of antibiotics which increases the risk of propagation of antimicrobial resistance. Understanding challenges in adherence to and compliance with laws and regulations on the OTC selling of antibiotics is imperative in designing enforcement interventions. Depth insights into community pharmacists' perspectives will provide comprehensive information on the implementation acceptability of laws and regulations restricting the OTC selling of antibiotics. Knowledge and information from this study will assist in shaping enforcement strategies. Furthermore, insights from this study will reshape antimicrobial stewardship programs and behavior change interventions at the level of community pharmacists to effectively solve the challenge of irrational use of antibiotics and hence contribute efforts to combating AMR.

1.5 Research questions.

Main Research Question

How do community pharmacists perceive the acceptability of laws and regulations restricting over-the-counter (OTC) selling of antibiotics in Dar es Salaam?

Specific Research Questions

i. What is the affective attitude of community pharmacists towards laws and regulations restricting over-the-counter (OTC) selling of antibiotics?
ii. What is the perceived burden experienced by community pharmacists in compliance with laws and regulations restricting the OTC selling of antibiotics?
iii. What is the self-efficacy regarding the community pharmacists' compliance with laws and regulations on the over-the-counter (OTC) selling of antibiotics?

1.6 Research Objectives

General objective

To explore the acceptability of laws and regulations on the over-the-counter (OTC) selling of antibiotics by community pharmacists in Dar es Salaam.

Specific objectives

i. To explore the affective attitudes of community pharmacists towards laws and regulations restricting the over-the-counter (OTC) selling of antibiotics.
ii. To find out the perceived burden experienced by community pharmacists while complying with laws and regulations restricting the OTC selling of antibiotics.
iii. To explore the self-efficacy of community pharmacists in compliance with laws and regulations on the over-the-counter (OTC) selling of antibiotics.

CHAPTER TWO

2.0 LITERATURE REVIEWS

2.1 Perceptions and attitudes of community pharmacists towards over-the-counter selling of antibiotics.

Perception refers to the process through which individuals organize and interpret sensory information about the environment to make sense of it. It is a complex process that involves past experiences, expectations, and beliefs (42). This can be referred to as the cognitive process in which meaning is created based on information leading to commands that control appropriate actions and expressions (43). Attitudes are based on the individual subjective evaluation that governs behavioral responses and actions (44). Affective attitudes are considered one of the strongest predictors of intentions to act (36).

Community pharmacists are considered the terminal point of communication and access to medication (45). Their role is critical in ensuring controlled access and rational use of medications critical for health such as antibiotics (45). Selling antibiotics without a prescription has been linked with leading to irrational use in several studies (13,18,19,30). This is concerning because it exacerbates the problem of antimicrobial resistance (19,20,30,46). Understanding the perceptions and attitudes of community pharmacists on the drivers of the OTC selling antibiotics is of high importance in designing strategies to combat the problem (27,38). Several studies conducted have been focused on the community pharmacists' perspectives targeting their perceptions on the OTC selling of antibiotics. In these studies, desires for profit, failure to obtain a prescription, customer-pharmacists' relationships, and inadequate regulatory capacity were reported to influence and shape the practices of selling antibiotics without a proper prescription (28–30). Few studies have focused on the perceptions regarding laws and restrictions on the OTC sale of antibiotics. These few studies particularly focused on the knowledge, attitudes, and practices towards such regulatory interventions and reported a considerable level of awareness among community pharmacists (31,38). Yet, the exact feelings of participating in adherence to the laws and regulations have yet to be studied. Many studies have found that community

pharmacists share a common agreement and a professional value in that OTC selling antibiotics is unethical and increases the risk of AMR (13,18,19,29,47,48). Some of these studies went over to conclude that interventions designed to promote adherence to, and enforcement of laws and regulations should be initiated (20,27,47,48). However, it is imperative to understand the affective attitudes of community pharmacists regarding laws, regulations, and interventions restricting the selling of medicines without a prescription to guarantee success in implementation. Information is scarce on the perceptions and attitudes of community pharmacists towards restrictions on OTC selling of antibiotics. Hence, this study intends to provide insight into the affective attitude of community pharmacists which leads to acceptability of implementation of laws and guidelines restricting the OTC selling of antibiotics.

2.2 Perceived burden associated with compliance with laws and regulations restricting over-the-counter selling of antibiotics.

In research conducted by the World Health Organization, it was found that regulations were key and an important tool to facilitate efforts of implementation of standards on antimicrobial use (49). In most LMICs, a top-down approach is used to enforce regulations with drafting of regulations done centrally with minimal involvement of the participants with whom the laws are enforced (50). This same observation is made on laws restricting OTC selling of antibiotics without a valid prescription. The laws are designed to empower inspectors to ensure compliance through monitoring and issuing fines and punishment in case of breach of conduct (7).

Tanzania among other LMICs has placed laws and regulations that ensure that prescription-only medicines are sold only with a valid prescription from licensed and recognized health practitioners. For Tanzania these include the Pharmacy Act, Tanzania Medicines and Medical Devices Act, the regulation schedule of medicines, and the recent prescription handling regulations under the Pharmacy Act identify antibiotics groups of medicines to be among prescription-only medicines with restrictions for OTC selling (5,8,33,34). Among statements of the acts and regulations, section 55(f) of the Pharmacy (Prescription Handling and Control) Regulation of 2019, created under the Pharmacy Act of 2011, offers a detailed comprehensive

manner of management and control of prescription drugs including antibiotics. In this regulation, a valid prescription is mandatory. The regulation recognizes both manually and electronically generated prescriptions and regardless, all are required to have a serial number, patients' information, disease code, details of the prescribing facility, prescribing officer information, dispensing instructions, generic name of the medication, and the validity period together with the period of use. The regulation strictly forces prescribers to adhere to treatment guidelines. All this above information is required to be validated for correctness and retained by community pharmacists as dispensers of medicines. This is combined with restrictions on editing and alteration of prescriptions. Apart from the directives above, the regulatory body responsible for the act and respective regulations is tasked to conduct regular inspections to ensure that good dispensing and pharmacy practices are maintained.

Despite having a comprehensive regulatory framework in place to ensure that antibiotics are sold only with a valid prescription, there is still no reported documentation of the burden and nature of effort required by community pharmacists to effectively practice under the environment of compliance. Thus, to better understand acceptability in implementation of laws and regulations restricting OTC selling of antibiotics it is imperative to explore the perceived burden and cognitive effort stifling community pharmacists whilst practicing under a regulated environment restricting the OTC selling of antibiotics. Hence this study aims to explore and document the perceived burden experienced by community pharmacists while operating in a regulated environment which influences their perception of acceptability of the laws and regulations restricting OTC selling of antibiotics.

2.3 Self-efficacy of community pharmacists in implementation of laws and regulations restricting over-the-counter selling of antibiotics.

Several interventions to promote adherence to prescription-only dispensing of antibiotics have been executed under antimicrobial stewardship programs and campaigns (51–53). Despite these efforts, the prevalence of OTC selling of antibiotics is still high (18,24,35). Studies conducted among dispensers revealed that customer demand for antibiotics while not having a prescription

is among the major drivers of OTC selling (29). In some other studies, community pharmacists have declared an ethical dilemma on whether to send the patient back to obtain a prescription or simply help in treating the patient without a prescription and breaking the law (18). However, in these studies, the ethical dilemma of increasing the challenge of AMR was reserved. The desire to maximize profit came out as one of the important drivers resulting in challenges of adherence to laws and regulations by community pharmacists (18,27,35). A systematic review conducted by Belachew et al, 2021 which included 23 articles reported such drivers create a conflict between commercialism and professionalism (48). This is particularly fueled by the lack of adequate regulatory enforcement that exists in low- and middle-income countries including Tanzania (20,28,29,48). Despite OTC selling of antibiotics being regarded as a common thing to do, community pharmacists have reserved confidence in their capacity to participate in effective compliance to laws and professional conduct which goes hand in hand with effective means of dealing with the identified potential barriers of adherence (48). However, only a few studies have documented this confidence, and no studies have linked it with the perception of acceptability towards the laws and regulations on OTC selling of antibiotics by community pharmacists. Therefore, this study aimed to fill the information gap by exploring the self-efficacy of community pharmacists in the conduct of behavior necessary to implement laws and regulations on the OTC selling of antibiotics concerning perceptions of acceptability towards such regulatory interventions.

Although there are reports on the knowledge, attitudes, and practices of community pharmacists regarding the sale of antibiotics without a prescription, limited attention has been given to the emotional and psychological factors such as affective attitudes, perceived burden, and self-efficacy which contribute to shaping their compliance with regulatory requirements. While many studies highlight the ethical and legal challenges involved, few have explored how pharmacists' views on regulations influence their willingness to comply and their confidence in doing so without external enforcement. This study sought to address this gap by examining pharmacists' emotional attitudes, perceived challenges, and sense of self-efficacy in relation to regulations restricting OTC antibiotic sales. The findings will offer insights that could inform

future policies and strengthen antimicrobial stewardship by identifying key factors that affect pharmacists' acceptance and implementation of these regulations. Findings in this study will also contribute to the body of knowledge in science by highlighting key factors associated with perceived acceptability of laws and regulations on OTC selling of antibiotics.

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study Design

This study employed an exploratory case study design that focused on exploring, understanding the experiences of community pharmacists in Kinondoni Municipality. The design suited the study as it provided the opportunity for the participants in the municipality to give in-depth information using semi structured interview guide to obtain data on the true experiences of community pharmacists in operating under the environment regulated by laws and regulations restricting OTC selling of antibiotics.

3.2 Study Area

This study was conducted in Kinondoni municipal, and the Pharmacy council offices located at the TMDA eastern Zone Compound off Mandela Road in Dar es Salaam. The population of the municipality is 982,328 residents of all ages (54). The selected study area had the largest number of registered community pharmacies compared to other municipals in the region with the total being 429 (55). Kinondoni Municipal hosted an estimated 740 registered pharmacists and pharmaceutical technicians (56). These numbers made the selected study area appropriate and representative of other regions in this study.

3.3 Study Population

This study targeted community pharmacists and pharmaceutical technicians with a minimum of 2 years of experience in the retail business of selling pharmaceuticals. Also, the study included inspectors from the Pharmacy Council of Tanzania as key informants. These inspectors were charged with the mandate to enforce regulations against OTC selling of antibiotics hence, they provided insight on the views of how the laws and regulations were accepted by community pharmacists.

3.4 Sample and Sampling Process

This study included 15 pharmacies from Kinondoni municipality of Dar es Salaam and 5 inspectors from the Pharmacy Council of Tanzania, Dar es Salaam office. Non-probability purposive sampling was used to select participants. The criteria adhered in sample selection was number of years of practice as a community pharmacist. As population size is linked to antibiotic use (57), 10 pharmacies were selected from most densely populated areas with pharmacists having a minimum of two years of practice and 5 other pharmacies were selected from least populated areas where the pharmacist had a minimum of four years of practice as a community pharmacist. Densely populated wards of the municipal each contributed one pharmacy in the selection. The five least populated wards contributed one pharmacy in the selection. Criteria for a pharmacy being selected was having operated for a minimum of five years. Population statistics were obtained from the most recent census data from the Tanzania Bureau of Statistics and was used to rank wards in descending order. Selection of specific pharmacies in a ward was based on accessibility and relevance to the set criteria to be included in the study as stipulated above.

Purposive sampling was also used to select inspectors from the regulatory authority with the criteria having the mandate and responsibility of conducting inspection activities. Convenient sampling was used to approach inspectors having time to for fixing an appointment to conduct in depth interviews. A total of 5 inspectors were selected and interviewed in this study.

3.5 Data collection method

Data was collected using in-depth interviews with participants and key informants. This method enabled obtaining in-depth and detailed information about the study topic. Furthermore, the selected method facilitated rapport and increase the depth and quality of data. Two in depth interview guides were used in this study to capture experience of community pharmacists and inspectors from the pharmacy council of Tanzania. Open ended questions were carefully structured to enable participants to express their in-depth experiences. Questions in the guide for community pharmacists explored their attitudes towards compliance of laws and regulations,

challenges in compliance, the perceived burden of operating in environment regulated by laws and regulations as well as their confidence in their ability to adhere to the set regulatory interventions without enforcement. For the Inspectors questions explored the perspective of inspectors on the community pharmacists' perception of acceptability of laws and regulations restricting OTC selling of antibiotics and challenges faced in adherence attempts.

Appointments with the participants were scheduled in a time that allowed participants to fully express their views and participate in the study. A total of 15 interviews were conducted with community pharmacists at their respective business premises while 5 interview sessions were conducted with inspectors at the pharmacy council of Tanzania Dar es salaam offices. Interviews were conducted by the principal investigator and lasted between 35 minutes to one hour while a trained and employed research assistant took notes of the sessions. A tape recorder was used for audio recording after being consented with the interviewee.

3.5.1 Data collection procedure

To increase efficiency, this study recruited one research assistant who was trained on the objectives of the study, the broad and specific research questions, data collection protocols, handling, and storage of data as well as research ethics associated with this type of the study. Permission to undertake this research was obtained from the Pharmacy Council of Tanzania (Appendix VII and VIII). During data collection, researchers gave the participants a chance to express what they feel and their experiences regarding the laws and regulations restricting OTC selling of antibiotics (53). Due to the sensitive nature of the topic, the researcher took extra care and sought to effectively build rapport with the participants to create a comfortable environment that encouraged the sharing of in-depth insights (58). Individual consents were requested from each participant before the interview session. Upon receiving consent to participate in the study a scheduled appointment was set for the interview session at the time which allowed the participant to express fully and freely. Interview sessions with community pharmacists were conducted at the respective business premises at the appropriate appointed time. Interviews with key informants from the Pharmacy Council were conducted at the respective inspectors' offices

at an appropriately appointed time. A single interview session lasted for a maximum of 50 minutes. Despite reaching saturation by the 12th interview data collection continued to a total of 20 interviews as planned. This decision was made in order to ensure comprehensive coverage and to honor the design of the study which aimed to capture a wide range of potential perspectives of community pharmacists. Thus, it enabled to validate the emerged themes across the full sample.

3.5.2 Pre-testing of IDI guide

IDI guide was tested before collecting data within the study. The pretesting was done under a similar context in Ilala district which is the second in having a larger number of registered pharmacies. This was done in three interviews to check the effectiveness and appropriateness of the IDI guide to collect data necessary to answer the research questions. Through pretesting, the interview questions were refined where necessary.

3.6 Data management and analysis

Thematic analysis approach by Guest et al., 2012 was used to analyze data collected in this study (59)**.** The analysis steps involved familiarization and organizing data using key words, coding data into subthemes which were later joined and grouped to generate themes associated with the acceptability of laws and regulations restricting OTC selling of antibiotics. This approach utilized inductive reasoning in the generation of codes and themes from obtained field data combined utilizing the concepts highlighted from the TFA.

Transcription, translation and familiarization: Data was collected verbatim, transcribed using Microsoft Word and analyzed using Dedoose version 9.0.46. Transcriptions and audio recordings were stored on an encrypted hard drive to ensure security and confidentiality. The data was translated from Kiswahili to English. In ensuring that loss of original meaning is avoided, back translation was done for a few transcripts. Researchers kept a separate journal which was used to write field notes which were arranged in chronological order to maintain a good audit trail. To avoid confusion, each interview session was given a unique code identifier.

Transcribed and translated verbatim carried the same unique code identifier to the interview session to facilitate the traceability of information. All data was backed up on two separate encrypted hard drives to avoid loss of information.

Researchers engaged in continual familiarization with the transcripts and field notes to gain a deeper understanding of the content within transcripts. Utilizing key words in phrases within the data the researcher was able to group data according to the construct as per the specific research questions.

Open coding: The following stew was to generate codes inductively from the data which involved putting labels on segments of data. The principal researcher passed through the transcripts and assigned labels to specific portions of the data and therefore condensing the information into understandable concepts and ideas. This resulted in organized ideas and concepts arising from transcribed data. A total of 75 open codes were identified. In condensing data into meaningful segments similar codes were grouped into major codes that encapsulated similar information and this process resulted into 34 major codes which served as the final codes to be used in the analysis. To enhance the validity of the codes, experts in qualitative studies were consulted for opinions and discussions. Consensus and agreed codes were used in analyzing and reviewing other transcripts while the study progresses. This process assisted in focusing the analysis on important ideas and aspects of data while maintaining the grounded nature of the data. Major codes were defined and described in a codebook.

Theme identification and evaluation: After coding all collected data from translated transcripts, similarities and difference were compared between codes. Similar codes were then grouped to generate sub-themes that were further compared and those with similar meaning were further grouped to generate themes which were reviewed for clarity of information. Lastly, themes were defined and assessed for alignment with the study objectives.

Table 1. Thematic analysis and code inclusion

Domain as per objectives	Subcodes	Code	Subtheme	Theme
Affective attitude	• Understanding law requirements	Understanding law requirements	Adherence and understanding of law requirements	Attitudes and Perceptions towards laws and regulations restricting OTC selling of antibiotics
	• Adherence to the law, • Prevent professional misconducts • Know the rules and deliberate violating	Adherence to the law		
	• Sensitization of pharmacist to follow laws and regulations	Sensitization of pharmacist to follow laws and regulations		
	• Feeling good on adherence • Laws remind us and protects us; we need to follow them	Positive attitude towards compliance	Attitude towards compliance	
	• Laws accepted but not appropriate • Laws appropriate for users but impacts business,	Appropriateness of the law	Acceptance and Appropriateness of Laws	
	• Accepted and adhered to, • Challenge is with customer demand. • No acceptance of the law. • Laws should be adjusted to give pharmacist mandate to treat	Acceptance of law		
	• Laws align with professional values because we have studied in class, • Conflict with professional privileges, believe they have right to sell	Clash and alignment with professional values	Clash and alignment of laws and regulations with the professional ethics and moral values	Ethics, morals and prescription practices of community pharmacists

	• Clash with personal values	Clash with personal values		
	• Perception of unfairness to the disadvantaged patients • Conflicts with natural sense of help to the needy	Perception of unfairness to customers	Conflict and dilemma between adherence and moral values	
	• Sense of help to poor customers • Bending rules to help the needy	Help to poor and customers in need		
	• Moral values impact on confidence	values effect on adherence confidence		
	• Perception on necessity of prescription	Prescription necessity in practice	Perception of Prescription Necessity	
	• Positive attitude towards prescription • Prescriptions ensures accuracy in treatment	Positive perception on prescription		
Perception of burden	• Burden when person comes without prescription • Analyze medical history and instruct medicine usage • Use of mental resources with no prescription • Fatigue when most customers come without prescription	Cognitive burden: No Prescription	Workload and Cognitive Impact Across Prescription Status	Workload, cognitive effort and economic burden
	• More time spent on unprescribed patients	Time requirement in attending patients/customers		
	• Requirement to explain the prescription • Verifying prescription against illness	Perception of workload burden with prescription		

	• Challenges associated with quality of prescriptions			
	• Adherence affecting business • Business competition • Struggles in selling medicines	Adherence impact on business	Business challenges in adherence to the law	
	• Losing customers due to prescription • Reducing income on sales • Reduction of sales impacting confidence in adherence	losing customers and reduction in sales		
	• Owners influence on adherence • Owners who are not pharmacists influencing professionalism	Businessmen owning pharmacies impact on adherence	Owners' business attitude and influence on adherence (Pharmacist vs non-pharmacist)	
	• Pharmacies should be owned by pharmacists • Even if owned by pharmacists, still impacts adherence	Ownership of pharmacy business by pharmacists		
	• Risking business collapse • Bending rules to retain customers • Desires to make and maximize profit	Desires for a profitable business	Profit and compliance tensions	
	• Reduce cost of medical services,	Cost reduction in medical services		
Self-efficacy	• Not fully confident to comply • Feeling professionally safe on adherence, • Adherence confidence based on education and experience	Confidence in compliance	Confidence in compliance and sources of confidence	Professional Confidence and Autonomy in dispensing practices

	• Confidence influenced by customer understanding			
	• Lacking confidence due to symptoms knowledge • Knowing condition requiring antibiotics	Confidence in knowing condition; impacting adherence		
	• Autonomy in decision to dispense antibiotics • Pharmacists' autonomy in dispensing can reduce misuse	Professional autonomy in dispensing antibiotics	Professional autonomy in dispensing antibiotics	

3.7 Trustworthiness of the research

To ensure the trustworthiness of this study elements of scientific rigor were adhered. The researcher strived to ensure credibility, dependability, and transferability within the study (60,61).

3.7.1 Credibility

Credibility was enhanced through careful selection of participants to be included in the study. Only participants with a depth of experience as community pharmacists were included in this study. Enough information about the study and objectives was provided to participants. The researcher made an extra effort to build rapport at the beginning of the interview sessions. Information collected from community pharmacists was triangulated with the data collected from regulating and enforcement staff from the Pharmacy Council of Tanzania – Dar es Salaam office. Furthermore, peer consultation was utilized to compare and evaluate codes to be used in data analysis.

3.7.2 Dependability

Dependability was ensured through documentation of methodology that described how the findings in the study were reached. Dependability along with credibility were further enhanced through the inclusion of interviews from key informants.

3.7.3 Transferability

In achieving transferability, the researchers provided sufficient contextual information associated with this study. This information included a clear description of the study participants as well as observed limitations associated with the methodology and findings. This will help consumers and readers understand the contextual characteristics underlying this study and apply the findings to the same and similar contexts.

3.8 Researcher reflexivity

As a researcher with experience in pharmaceutical regulations, I was aware that my knowledge of drug policies and pharmacy practice could influence my interpretation of the data collected in this study. Throughout this study I ensured that I remained subjective to minimize the impact of my preconceptions on the research findings. To maintain reflexivity, I engaged in regular discussion with peers and research assistant which broadened my perspectives of the subject matter. Given my role as a researcher and the nature of the study, I was mindful of potential power imbalances during the interviews. Pharmacists may have been hesitant to express certain views on antibiotic regulation, especially if they perceived me as aligned with regulatory authorities. I made conscious effort not to disclose any information of affiliation with regulatory any regulatory authority. I recognize that my own beliefs about the importance of antibiotic regulation could have influenced the way I interpreted pharmacists' attitudes. To address this, I continually cross-checked emerging themes with the raw data and sought feedback from my research peers to mitigate personal biases. Through engaging in reflexivity, I became more aware on the assumptions regarding impact of antibiotic restrictions that might affect the data.

This awareness allowed me to approach the analysis with caution to ensure that participants voices are accurately reported in this research.

3.9 Ethical considerations

Ethical principles associated with conducting qualitative research were observed in conducting all activities associated with this research study. The proposal for this study was reviewed by the Institutional Review Board (IRB) of the Muhimbili University of Health and Allied Sciences (MUHAS) and provided with an Ethical clearance certificate number MUHAS – REC – 02 – 2024 – 2052 (see appendix VI). Permission to collect data in this study was obtained from the registrar of the Pharmacy Council of Tanzania and the respective owners of selected community pharmacies (see appendix VII and VIII).

Written informed consent to participate in the study were obtained from all participants before the interview sessions. Information was given on the meaning and aim of the study through the consent form. To maintain trust ethical principles of confidentiality, consenting, and anonymity were adhered. Data and information collected will be used for research purposes only and not otherwise.

CHAPTER FOUR

4.0 FINDINGS

4.1 Introduction

This research study was designed under three main objectives which were centered on exploring the affective attitudes of community pharmacists towards laws and regulations restricting the over-the-counter (OTC) selling of antibiotics, finding out the perceived burden experienced by community pharmacists while complying with laws and regulations restricting the OTC selling of antibiotics and lastly exploring the self-efficacy of community pharmacists in compliance with laws and regulations on the over-the-counter (OTC) selling of antibiotics. The analysis of the data to answer this set of objectives revealed a wide range of perceptions and challenges in adherence which can be classified into four main themes.

First theme explained on the Attitudes and perceptions towards laws and regulations restricting OTC selling of antibiotics that influence decision and action to comply with laws and regulation. The first theme was closely related to the second theme which explained interplay and dilemma between professional values morals and prescription practices that influenced perception of acceptability of laws and regulations. Third emerging theme was associated with the of perception of burden in the circumstances of presence and absence of prescription. Lastly, professional confidence and autonomy in prescription practices emerged as a theme which linked with other themes and influenced perception of self-efficacy towards adherence and appropriateness of laws and regulations restricting OTC selling of antibiotics.

4.2 Characteristics of Participants

A total of 20 participants were interviewed in this study, with 15 individuals purposively selected from community pharmacies within 15 selected wards of Kinondoni municipality and 5 individuals selected from the pharmacy council team of inspectors. As indicated in table 2, selected community pharmacists had working experience ranging from four to eight years in the retail business of selling and dispensing medicine with varying professional qualifications where 3 had a bachelor's degree in pharmacy and 12 had a diploma in pharmaceutical sciences.

Participants from the pharmacy council had extensive working experience in inspections and enforcement. Regarding their education qualification, 3 had a master's degree and 2 had a bachelor's degree in pharmaceutical sciences and had been inspectors for a period ranging from 5 to 15 years with the most experienced inspector having worked for 15 years. The age distribution of all participants was that 13 respondents were between 24 and 31 years and 7 respondents were between 32 and 40 years old.

Table 2. Demographic characteristics of participants

Characteristics	**Number (n=x)**	**%**
Sex		
Male	9	45.0%
Female	11	55.0%
Marital status		
Married	7	35.0%
Single	13	65.0%
Age (years)		
24-31	13	65.0%
32-Above	7	35.0%
Level of education		
Diploma	12	60.0%
Bachelor Degree	5	25.0%
Masters Degree	3	15.0%
Occupation		
Pharmaceutical Technician	12	60.0%
Pharmacist	8	40.0%
Working experience		
4 - 5 years	13	65.0%
6 – 9 years	3	15.0%
10 years and above	2	10.0%

4.3 Attitudes and perceptions towards laws and regulations restricting OTC selling of antibiotics

During analysis the theme of attitudes and perceptions of community pharmacists towards laws and regulation restricting OTC selling of antibiotics was identified. This theme was characterized by three subthemes namely, adherence and understanding of laws and regulations, attitudes towards compliance and acceptance and appropriateness of laws restricting OTC selling of antibiotics. Combination of subthemes reported on the affective attitudes of community pharmacist associated with acceptability of laws and regulations. Findings on the sub themes are elaborated below.

4.3.1 Adherence and understanding of law requirements

This study found that community pharmacist had a substantial understanding of the requirements of laws and regulations concerning selling antibiotics. With that fact, respondents reported an understanding of their position and requirement to adhere to such laws in their daily practices. This went further to acknowledge that such regulations existed to ensure the rational use of medication and prevented professional misconduct aimed at profit gains through selling without prescription.

> *"Adherence to laws and regulations prevents me from using my power to dispense medicine for personal gain. Although it's a big thing that limits pharmacists or community pharmacies from dispensing antibiotics, actually, what I see is, maybe there are other reasons, but the main reason that makes sense to me is that it limits me from profiting or not profiting because of my decision not to dispense medication."(Community pharmacist 14)*

Despite having this knowledge, interviews with community pharmacists revealed that there was a deliberate violation of these laws. Participants commented the need for them to actually practice adherence to the laws and regulations and not just read and leave them in class. They went further to highlight a need for strict laws and enforcement to actually be able to adhere.

".:.And we pharmacists also need to follow our professional ethics; the laws, we should practice them, not just study them in class and leave them there. But we should put them into practice. I think that will help us more. So, sometimes we need to be encouraged, maybe even stricter laws could help us....."(Community pharmacist 01)

4.3.2 Attitudes towards compliance

Community pharmacists interviewed in this study reserved their positive attitudes and perceptions towards compliance through indication of positive and good feelings while practicing in a regulated environment. This was combined with the acknowledgment that they needed to provide antibiotics only to patients who have been diagnosed with diseases caused by bacteria.

I" feel good to have that law to work with that law that requires us as pharmacists or pharmacists to follow that law, we need to provide these antibiotics to someone with a prescription that they have been diagnosed with a certain disease caused by these bacteria and given antibiotics..."(Community pharmacist 01)

4.3.3 Acceptance and Appropriateness of Laws

Looking at how such attitudes and perceptions impacted the acceptance and appropriateness of laws and regulations it was revealed that there was half-half acceptance for most community pharmacist. Participants reported laws to be appropriate for community health but the challenge was on reduction of sales.

".... I can say that pharmacists accept these regulations about fifty-fifty. The laws are good because they help with community health, but they also restrict sales. So, pharmacists are kind of in the middle, fifty-fifty. We want to advise people and do it, but sometimes, people lose hope and just give in. But it's good to continue the effort."(Community pharmacist 07)

Even though laws were accepted, it was noted that demands from customers to obtain antibiotics were a critical factor in causing a professional dilemma that shifted the balance between

adherence to business impact. In the perception of obtaining such a balance community pharmacists recommended adjustments to the regulations to give a mandate to treat using medicine for clinical conditions that did not require a doctor's intervention and hospitalization. One of the community pharmacists responded:

"..to treat using medicine, not the other because there are known symptoms. If I see something that's beyond me, I have to refer the person to a doctor. You see, I must tell them to go to the doctor to do this and this, but I know this is within my capabilities. I'm sure I can do it." (Community pharmacist 17)

4.4 Professional Values, Morals, and Prescription Practices

Professional values, morals and prescription practices of community pharmacists had four subthemes namely, Clash and alignment of laws and regulations with professional ethics and moral values; Conflict and dilemma between adherence and moral values; and Perception of Prescription Necessity. This emerging theme was vital in understanding acceptability as it was directly linked with attitudes which influence compliance action.

4.4.1 Clash and alignment of laws and regulations with professional ethics

Study findings revealed mixed responses on the alignment of laws and regulations with professional ethics. Community pharmacists perceived the alignment of laws and regulations with professional values and ethics since they had studied the applications of such laws in professional studies. Participants reported that they could not be prevented to sell antibiotics while they had been professionally trained and they know drugs. They explained that even if a person went to the hospital they would likely be given the same medication.

"I see a conflict because we have something called professionalism, right? For us in the pharmaceutical profession, I know drugs. So, you cannot tell me not to sell antibiotics, which are drugs, and I know them well. I understand their side effects, how they work, pharmacodynamics, everything. So, it means I know exactly that if a patient goes to a doctor, they will be given this drug.,....."(Community pharmacist 06)

4.4.2 Conflict and dilemma between adherence and moral values

Moreover, respondents interviewed in this study reported a conflict and dilemma between adherence and personal moral values of humanity centered on the sense and desire to help poor customers and those in urgent need of medication. Findings indicated that community pharmacists perceived laws and regulations to be unjust and unfair in circumstances where customers were in urgent need of drugs. In another circumstance where a customer could not afford the costs of obtaining a prescription community pharmacists were more inclined to bend the rules and compromise to help the client.

> *'Someone might say they don't even have the fare to reach the hospital, so they ask for your help. For example, someone might tell you they've had diarrhea since morning. If you tell them about going to the hospital, they might line up from morning. Honestly, in such cases, what needs to be done is sometimes looking at the person and deciding whether to help them." (Community pharmacist 09)*

Respondents revealed that alignment and conflict with moral values had a significant impact on the decision of a community pharmacist to adhere to laws and regulations restricting the selling of antibiotics without a prescription. Respondents shared that combining the pressure of the customer with personal compassion to help those in need significantly lowered their confidence in adherence. Most of the time found themselves dispensing without a prescription. One of the respondents said:

> *'".....there are times when confidence drops, like when a customer comes and you see them crying, pleading, saying, 'Please, I need this."So, the confidence you had drops. You feel compelled to lower it, and you end up reducing your confidence."(Community pharmacist 05)*

4.4.3 Perceptions of community pharmacists on prescription

Respondents interviewed in this study reported positive perception towards the necessity of prescription. Respondents claimed that the presence of prescriptions in their daily practices

helped in ensuring the treatment they provided through medication is accurate and is going to be effective in curing the patient. They further reported that it gave them assurance that patients had consulted a doctor and had been properly diagnosed. This gave participants confidence in the services they provided.

> *"When a person has a prescription, it gives you confidence because you know they have seen a doctor who understands the symptoms…. As a pharmacist, I also know the symptoms and can provide care, but having a prescription ensures that the diagnosis and treatment plan is accurate. It makes you feel more confident in the service you provide" (Community pharmacist 06)*

4.5 Perception of burden related to compliance

In the analysis of findings in this study a theme associated with perception of burden related to compliance emerged. This theme was characterized with four subthemes namely, Workload and Cognitive impact across prescription status; Business challenges in adherence to the law; Ownership pressure influencing adherence (Pharmacist vs non-pharmacist); and Profit and compliance tensions. These subthemes highlighted community pharmacists' perceptions of burden associated with decisions and compliance action. Findings on each subtheme are discussed below.

4.5.1 Workload and cognitive impact across prescription status

While comparing circumstances in their daily activities when a client had a prescription and when they did not have a prescription, respondents reported more burden experienced on the side when the customer presented with no prescription. Respondents revealed this burden to be associated with the extensive use of mental resources and cognitive efforts to analyze patients' medical history which involved understanding the presented symptoms so that they could give out proper medication and proper instructions on usage and the importance of completing the dose. One of the respondents declared that this results in fatigue particularly when you consider that most customers came without prescriptions:

"The impact is fatigue because if ten people come without prescriptions and they're sick, you have to listen to them and explain a bit, it takes time and it is exhausting." (Community pharmacist 10)

In conjunction with the cognitive and mental efforts, respondents reported more time was required and used in attending to patients who presented themselves without a prescription. This time was utilized in cross-examining the patient to understand how they felt and advising on the proper and rational use of medication.

On the angle of patients who had a prescription, respondents perceived the workload to be associated with the requirement to understand the prescription and verify it against the ailment. Respondents revealed a major challenge lied within the quality of prescriptions in that most of them were unreadable and unclear. This resulted into patients leaving without medication because a pharmacist could not understand the information written.

"The biggest challenge regarding prescriptions might be the prescription itself. Sometimes you find the writing is unclear.… the prescription doesn't have the doctor's number or whatever. The doctor has scribbled something. … In the end, the patient left without being served because I couldn't understand what medication they were prescribed …. This is a challenge too. I think prescriptions should have a section to fill out the hospital name, and the doctor's name, but they don't do that… "(Community pharmacist 03)

4.5.2 Business challenges in adherence to the law

Business dynamics was one of the major reported challenges that influenced the decision to adhere to laws and regulations restricting OTC selling of antibiotics. Interviewed inspectors revealed that, presence of illegitimate pharmacy outlets selling medication without compliance with laws and regulations fueled business competition with community pharmacies impacting adherence efforts.

"...they have a significant influence. It's like any other business; there's competition. Rogue pharmacies exist, and they compete with legitimate ones, which affects compliance." (Inspector 02)

Interviewed respondents revealed that requirements of dispensing with a valid prescription meant that they must send customers back to get a prescription. Respondents reported that this significantly reduced sales volumes and income from sales. Respondents revealed that reduction in sales influenced the perception of no success in business goes together with strict adherence to laws and regulations of operations. Several respondents reported this reduction in sales impacted the confidence of community pharmacists to adhere to laws and regulations restricting the OTC selling of antibiotics. One of the respondents commented that:

"When sales decline or fluctuate, and you are someone who strictly follows the laws, it can affect your confidence. People say that to succeed, you can't strictly follow the laws. This has some truth, although it's not good. When sales are down, even if the boss wants to follow the laws, it will hurt. For example, if five people come wanting medicine without a prescription, saying they have general body pain or back pain, and you turn them away, your sales will be zero. This reduces your confidence."(Community pharmacist 09)

4.5.3 Profit and compliance tensions

In line with the reduction in sales, respondents reported a greater risk of collapse of pharmacy businesses if laws and regulations were to be adhered completely. In their perspective, respondents have reported a big challenge to be associated with the desire to create and maximize profit in the business. Even though the primary requirement was to deliver health services by ensuring the availability of medicine at the community level, respondents and key informants have declared that business intent and profit were the core objectives of opening any community pharmacy business. One respondent declared that:

"But profit, my brother, depends on your investment; it depends on your money, how it's going to produce and come back. You see, when it comes to profit, it becomes the first priority.

Don't think because a pharmacist owns a pharmacy, their store will be just for treatment; then they should open a hospital. If that's the case, why open a pharmacy? But the reason why they open a pharmacy is for business." (Community pharmacist 12)

Combining the two aspects of profit and the fact that most customers did not have a prescription respondents revealed that community pharmacists have had to ignore the rules to serve and retain customers. This was in the belief of respondents that if they sent customers away to get a prescription, they would not return to them instead they would go to another pharmacy to buy antibiotics.

4.5.4 Owners' pressure influencing adherence (Pharmacist vs non-pharmacist)

Findings from this study showed that businessmen owning pharmacies had a significant impact on professionalism and adherence to laws and regulations restricting OTC selling of antibiotics. Key informants revealed that businessmen with no pharmacy background exerted more pressure to yield profit that made it difficult for community pharmacist to comply with laws and regulations. Respondents went further to reveal that it would be more convenient and practical for pharmacy businesses to be owned by pharmacists as they had significant knowledge of medication and the context in which certain restrictions were put in place. Inspectors shared a common perception of the easiness of enforcing laws and regulations if the pharmacy business were to be owned by pharmacists rather than businessmen with no pharmacy background:

Businessman expects the business to yield; you see, they expect sales to be there. So, it contributes because they rely on sales. Even if the pharmacist was following the rules, you find they also revert to not following the law …. I would prefer it to be solely a pharmacist's business because then, when you set regulations, they understand why, unlike someone who hasn't studied…. With pharmacists, it's easier to enforce the law because they understand the implications, including on their careers. So, it's a good thing, considering our circumstances. (Inspector 02)

However, one respondent shared that no significant differences would be achieved in adherence through ownership modalities. The respondent declared that when a pharmacist owned a community pharmacy sats in the position of a businessperson and the main target shifted from providing services towards generating income and profit.

"... if the owner is a pharmacist, it means they are already a businessperson. They no longer stand as a pharmacist but as a businessperson.... That's the main reason they opened the business. Yes, we are here to help the community, but they look at the profit first."(Community pharmacist 13)

4.6 Professional Confidence and Autonomy in dispensing practices

This theme reported on the self-efficacy centered on the confidence of respondents to adhere to laws and regulations restricting the OTC selling of antibiotics together with sources that derived that confidence. Analysis of findings in this study revealed two subthemes associated with this theme namely, Confidence in compliance and sources of confidence; and Professional autonomy in dispensing practices. Subthemes are discussed here under.

4.6.1 Confidence in compliance and sources of confidence

This study revealed that most community pharmacists felt professionally safe when operating in a regulated environment that restricted OTC selling of antibiotics. Respondents declared feeling confident and safe when providing antibiotics while adhering to the regulatory requirements of receiving prescriptions. Respondents had commented that in cases where treatment possessed challenges to the patient, they can always shift the responsibility to the prescriber.

"That prescription guides you more, and it's also more safety for you. If something goes wrong, when you're asked, you can say why you gave that medicine; it was written by a doctor; you have safety."(Community pharmacist 14)

Respondents claimed that feelings of confidence in adherence were derived from the fact that they had been trained on the law and had knowledge of the impact and consequences of lack of compliance. Respondents also revealed that customer understanding when advised to look for a prescription had a significant impact on their decision to comply. Furthermore, participants reported a build in trust with customers when proper information and awareness is conveyed.

I can just say I am confident enough. When you explain it to someone, when you follow the law and regulations properly, especially for those of us who provide services, you build trust in them. When someone comes, you explain something well to them, they understand it, and maybe the next time they come, they'll ask for someone else, saying they explain well." ((Community pharmacist 01)

4.6.2 Professional autonomy in dispensing practices

In line with all sources of confidence and influence on adherence, this study found that community pharmacists perceived a requirement to have professional autonomy in making decisions to dispense antibiotics. Respondents believed it would be wise for community pharmacists to have a mandate to dispense certain specific types of antibiotics. Respondents went further to comment that the idea of prescription only medicine should start to consider prescription from pharmacists.

"……. it wouldn't be bad if there were a certain line of antibiotics—not all antibiotics, because they say "prescription only" means the doctor, the transcriber, but we can talk about "prescription only" at the same time whether it is a prescription of a pharmacist... (Inspector 01)

Respondents went further to explain that autonomy in dispensing antibiotics will assist in the reduction of burden in hospitals. Respondents and key informants reported that pharmacists at the community level sit in a better position to advise and help clients and identify symptom and provide antibiotics for minor ailments. However, respondents reserved that referrals to hospitals would still be required on more complicated conditions which demand close attention in

treatment. Respondents went further to comment that granting autonomy in dispensing could help to reduce the problem of irrational use of antibiotics.

"..... antibiotics are delicate because we coexist with bacteria. If pharmacists were given more authority to dispense antibiotics, it could reduce the load on hospitals. Pharmacists can identify symptoms and provide antibiotics for straightforward cases. However, for more complex cases, referrals to physicians would still be necessary. Granting pharmacists more authority could help ensure proper use and reduce misuse."(Community pharmacist 06)

CHAPTER FIVE

5.0 DISCUSSION

5.1 Introduction

This study explored the acceptability of laws and regulations restricting the over-the-counter (OTC) sale of antibiotics among community pharmacists in Kinondoni Municipal, Dar es Salaam. The research aimed to understand pharmacists' attitudes, perceived burdens, and self-efficacy regarding compliance with these regulations. Through thematic analysis of in-depth interviews with community pharmacists, pharmaceutical technicians, and inspectors from the Pharmacy Council of Tanzania, four key themes were revealed: attitudes towards laws and regulations, ethics and morals in prescription practices, workload and cognitive effort, economic impact, customer challenges, and professional confidence. These findings highlight the complex interplay of factors that influence pharmacists' compliance with regulations restricting OTC antibiotic sales.

5.2 Attitudes and Perceptions influencing action.

Community pharmacists in Kinondoni Municipal are aware of the regulations restricting OTC sales of antibiotics and understand their importance in combating AMR. Despite this awareness, many pharmacists continue to dispense antibiotics without prescriptions which questions their views on the appropriateness of laws and regulations. This behavior is influenced by several factors, including the desire to meet customer demands and maintain business profitability. The disparity between knowledge, awareness, and practice observed in this study is consistent with findings from other low- and middle-income countries (30,47). For instance, studies in different parts of the world within similar contexts have indicated that economic pressures and customer demand significantly influence pharmacists' decisions to dispense antibiotics without prescriptions (7). Similar findings are observed in studies in other parts of Tanzania where pharmacists are generally knowledgeable about antibiotic regulations, but practical challenges such as customer demand and maintaining profit often led to non-compliance (27). These

findings underscore the need for multifaceted strategies that address compliance's cognitive and economic aspects.

5.3 Professional Values, Morals, and Prescription Practices

Pharmacists frequently face dilemmas when regulations conflict with their professional judgment or personal morals. Many pharmacists' resort to dispensing antibiotics without prescriptions in cases where they believe it is necessary to help patients, particularly those in urgent need or with financial constraints (62). This study identifies that those values and moral conflict are significant barriers to regulatory compliance decisions. Pharmacists' duty to assist patients and improve their quality of life (63) often outweighs their adherence to regulations, highlighting the complex interplay between professional ethics, morality, and legal obligations (62,64). These findings align with studies from other regions, where pharmacists similarly prioritize patient care over strict regulatory adherence (38). Waful *et al.,* (2022) while exploring prescription practices in countries within Sub-Saharan Africa reported that often dispense antibiotics without prescriptions due to patient's immediate health needs (65) which are directly associated with moral consideration and obligation to meet them. This moral conflict highlights the need for regulatory frameworks that consider the realities of practice and support pharmacists facing these dilemmas.

5.4 Workload, Cognitive Effort, and Economic Impact

Compliance with regulations restricting OTC antibiotic sales imposes significant cognitive and time burdens on pharmacists. Verifying prescriptions, educating customers about the necessity of prescriptions, and managing non-compliant requests can be time-consuming and exhausting. Furthermore, missing or incomplete prescription information and unreadable prescriptions greatly hinder the decision of community pharmacists to follow and retain prescription copies as mandated by the law (66,67). This study argues that the quality of prescriptions is the only factor that will influence compliance action associated with the burden of verifying correctness. However, more burden is experienced when on patients without a prescription. Requirements to examine the patient, understand symptoms, provide appropriate antibiotics, and explain dosage

to the customer require more cognitive effort and consume more time. This finding is in line with a study by Belachew et al., 2021 where community pharmacists sought to use more time to engage with customers and understand symptoms before issuing antibiotics (20). Many pharmacists reported feeling overwhelmed by these tasks, which not only affect their professional well-being but also impact the overall efficiency of their operations. Nevertheless, this burden has little influence on compliance decisions. Pharmacists are more aligned with the satisfaction of having the opportunity and privilege to administer direct treatment through directly handing out antibiotics based on their understanding of explained symptoms (48).

In addition to cognitive and time burdens, the economic impact of regulatory compliance is a major concern for pharmacists. Adhering to regulations is often perceived to result in lost sales and reduced income, creating a strong incentive to dispense antibiotics without prescriptions (24,47,48). Many pharmacists expressed frustration with the financial pressures they face, noting that their businesses struggle to remain profitable while complying with the regulations. More pressure is exerted on circumstances where pharmacy business owners do not have pharmaceutical knowledge and background. Such finding echoes other studies such as that by Torres et al., 2020 which reported great pressure exerted from owners who are not pharmacists whose primary goal is to generate income and profit rather than adhere to good prescription practices and regulatory requirements (68). This economic challenge is a significant barrier to compliance and highlights the need for regulatory frameworks that support the financial viability of community pharmacies.

5.5 Professional Confidence and autonomy

This study's findings underscore the critical role of professional confidence and autonomy in promoting adherence to regulations that restrict OTC sales of antibiotics. The data suggest that pharmacists' confidence is closely linked to their comprehensive training and understanding of both legal requirements and the clinical implications of antibiotic misuse (27). This professional confidence enables pharmacists to navigate regulatory landscapes effectively, ensuring that their dispensing practices align with public health objectives.

Pharmacists' sense of professional autonomy, derived from their medical expertise, is pivotal in making informed decisions about antibiotic dispensing and compliance with laws and regulations. This autonomy is not only beneficial for managing straightforward cases effectively but also plays a significant role in reducing the irrational use of antibiotics (69). The study indicates that when pharmacists are empowered to use their judgment in dispensing antibiotics, they can alleviate some of the burdens on healthcare facilities, allowing for more efficient use of healthcare resources. This is in line with the survey conducted in Nigeria which identified that pharmacist autonomy in dispensing will play an important role in improving access to healthcare (70). Such finding partly conforms with regulation directives that requires pharmacist and pharmaceutical personnel to promote rational use of medicines and manage minor ailments (8,63,71). However, there is a need to define straightforward cases and minor ailments and increase awareness among community pharmacists as perceptions observed in this study contradicts with the existing directives in that ailments requiring antibiotics are not under the mandate to be managed within community pharmacies (71).

Moreover, the study highlights the importance of continuous education and effective communication in enhancing pharmacists' confidence and adherence to regulations. By fostering an environment where pharmacists feel both knowledgeable and empowered, it is possible to improve acceptability and compliance with regulations and promote responsible antibiotic use (69). This approach aligns with the broader public health goal of combating antimicrobial resistance, ensuring that antibiotics remain effective for future generations. Aligning support to pharmacists through ongoing professional development and granting them appropriate dispensing autonomy can significantly enhance regulatory adherence and contribute to better health outcomes. Henceforth, addressing the objectives of improving compliance and reducing antibiotic misuse.

5.6 Strengths and Limitations of this study

The biggest strength of this study is that it was grounded on the perceptions and feelings of pharmacists and pharmaceutical technicians who are at the immediate selling point of

antibiotics. The information collected from pharmacists and technician was triangulated with the information obtained from inspectors which helped to validate the findings. However, this study did not include perspectives of other key stakeholders such as community pharmacy owners, superintendents and customers which could also be important in finding out the acceptability of laws and regulations on OTC selling of antibiotics.

Furthermore, as the study is concerned with an illegal misconduct of selling antibiotics over the counter, it was more prone to receive socially desirable responses from participants. To mitigate this the principal researcher used measures to build an effective rapport through making the respondent more comfortable to speak and elaborate. Humor and respect to the role of pharmacists in the community was used to create a comfortable ground for discussion. The researcher ensured that interviews are conducted in areas where participants are more confident and freer to speak and share their feelings. Concise details of the study were provided to the participants, together with details of use of collected information and confidentiality.

During collection of data, the researcher ensured that sensitive questions were asked indirectly and assured participants that they can share their experience freely and the aim is only to discuss their perspectives of the restriction on OTC selling of antibiotics. Furthermore, probing was used together with personal experience to provide context to the questions.

Use of thematic analysis, interpretivism reasoning, inductive coding during analysis of data ensured that data analysis is subjective grounded on the experiences of participants. However, the inductive nature of the process warrants the risk of personal bias in the analysis. To mitigate, the researcher employed an assistant who took part in transcribing and translating the data. Also, the researcher utilized peer consultation with expert, consensus coding utilization and member check to ensure findings are not contaminated with bias.

This study covers only a snapshot of the perspectives of community pharmacists on acceptability of laws and regulations utilizing an explorative approach. Even though findings in this study have their own scientific merit in supplementing proceeding quantitative studies of acceptability utilizing frameworks such as TFA, such finding are not generalizable as they are qualitative in

nature and have only focused on one district of Dar es salaam region. It would be feasible to expand the exploration to cover larger area utilizing deeper qualitative research method such as ethnography to better understand affective attitudes, perceptions and practices of community pharmacists in relation to antibiotics and prescription regulations. It would also be more feasible to conduct a quantitative study utilizing probabilistic functions so as to establish association between factors and the perceptions and attitudes of community pharmacists leading to generalizable results

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study provides valuable insights into the challenges faced by community pharmacists in Kinondoni Municipal in adhering to regulations restricting OTC sales of antibiotics. The study reveals the key findings which influence the perception of acceptability of laws and regulations restricting OTC selling of antibiotics. This study went further to reveal factors that might influence community pharmacist affective attitudes and decision to comply. This is through an observation of the interplay between realities of community pharmacy business, customer behaviors and actions, knowledge and awareness all together linked to the perception of appropriateness and acceptability of such regulatory interventions.

The findings highlight the need for ongoing education, stricter enforcement mechanisms, and public health campaigns to improve compliance. Addressing the economic pressures and cognitive burdens faced by pharmacists is crucial for enhancing regulatory adherence and combating antibiotic resistance. By implementing these strategies, policymakers and healthcare professionals can work together to promote better health outcomes and ensure the responsible use of antibiotics. Policymakers can develop more effective strategies for improving compliance with antibiotic regulations. This includes not only enhancing enforcement mechanisms but also addressing the economic and moral considerations that influence pharmacists' decision-making. Through a comprehensive and supportive approach, it is possible to improve regulatory adherence, reduce the misuse of antibiotics, and ultimately combat the growing threat of antimicrobial resistance.

6.2 Recommendations

1. Pharmacy council of Tanzania working together with Tanzania Medicine and Medical Devices Authority need to consider the economic realities faced by community pharmacies. This is through issuing essential policies and regulations that balance patient care with business sustainability are essential. This could include a collaborative approach that will

support pharmacies in adhering to regulations. The Pharmacy council of Tanzania as a regulatory body should also consider implementing regular audits and stricter enforcement mechanisms to ensure higher compliance rates.

2. The Pharmacy Council of Tanzania working together with the Ministry of Health and other Regulatory authorities should exert more effort in public health campaigns aimed at increasing awareness about the crucial importance of prescriptions for antibiotics. Educating the public about the dangers of antibiotic resistance and the necessity of proper prescription practices can reduce the pressure on pharmacists

3. The Local government Authority should strive to ensure that rogue and unlicensed pharmacies do not exist in their areas such that to eliminate business pressure which may influence attitudes of community pharmacies leading to professional misconducts of selling medicine without prescription. Furthermore, Local governments should exert more enforcement to the drug dispensing outlets to ensure that they abide by the requirements of the law and practice at such outlets.

4. Further exploration by the scientific community needs to be conducted to obtain perceptions and attitudes of community pharmacists over a larger area beyond the study population included in this study to obtain a deeper understanding of the acceptability of the laws and regulation. Furthermore, quantitative research needs to be conducted to cover for the limitations of this study and making findings more generalizable to similar and different contexts.

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APPENDICES

Appendix I: Consent Forms - English

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

CONSENT FORM

ID NO ……

Consent to participate in the study.

Greetings! My name is BABUALI AHMED. I am a student pursuing a Masters in Public Health Implementation Science at Muhimbili University of Health and Allied Sciences. On behalf of the University, I am exploring the Acceptability of laws and regulations restricting over-the-counter selling of antibiotics among community pharmacists in Kinondoni Municipal, Dar es Salaam.

Purpose of the study: This study aims to explore and collect information on the perceptions and experiences of community pharmacists on the acceptability of laws and regulations restricting OTC selling of antibiotics. You are humbly requested to participate in this study because we believe that you have vital information to meet the prime objectives of conducting this study.

Confidentiality: We assure you that any information you provide shall be kept highly confidential and will not be shared with anyone except those directly involved in the fulfillment of this study. Only people who are involved in this study will have access to the information of this study. Your name and other forms of identification will not be disclosed to anyone.

The requirement for participation: If you consent to participate in this study, you will be required to answer a series of questions prepared for the study through interviewing and allowing me to observe to obtain the intended information regarding the acceptability of laws and regulations restricting over the counter selling of antibiotics among community pharmacists.

Benefits: The information provided will help to understand the current perceptions and feelings of community pharmacists towards the laws and regulations restricting the over-the-counter selling of antibiotics. This will help to inform behavior change strategies and initiatives targeted towards rational use of antibiotics which is pivotal in fighting against antimicrobial resistance. The interview will take not more than 40 minutes. Please speak freely as there are no right or wrong answers.

Right to withdraw and alternatives: Your participation in this study is entirely your choice. If you choose not to participate in this study or if you decide to stop participating in this study, you will not receive any harm or punishment. You can stop participating anytime, even if you have already signed the consent form. If you receive to participate or withdraw from the study, there will be neither a penalty nor losses.

Risks: We do not anticipate any harm to you due to your participation in this study.

In case of injury: We do not expect any harm to you or your family from participating in this study.

Whom to Contact: In case of any questions or queries concerning this study, do not hesitate to get in touch with the principal investigator, Babuali Ahmed (MPH-IS), from MUHAS, P.O, Box 65001, Dar es Salaam, mobile number 0753899583. If you have any questions about your rights as a participant, please contact Dr. Nahya Masoud, Chairperson of the Research and Publications Committee, MUHAS, P.O Box 65001, Dar es Salaam – Tanzania, Tel. +25521503026

Signature

Do you agree?

Participant Agree, Not Agree.

I …… have read the content in this form. My questions have been answered, and I agree to participate in this study.

Signature of the participant. ……

Signature of the research assistant …….

Date of signed consent …….

Appendix II: Consent Form – Swahili

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA UTAFITI NA MACHAPISHO

FOMU YA RIZAA

Namba ya utambulisho ……

Ridhaa ya kushiriki kwenye utafiti.

Utambulisho; Habari, naitwa Babuali Ahmed, ni mwanafunzi wa shahada ya uzamili ya Afya ya Jamii na sayansi ya utekelezaji katika chuo kikuu cha afya na Sayansi shirikishi Muhimbili. Kwa niaba ya Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili, naomba ridhaa yako ili kufanya utafiti kuhusu kukubalika kwa sheria na kanuni zinazozuia mauzo ya antibiotiki bila kuwa na cheti cha hospitali kati ya wauzaji katika maduka ya dawa ya jumuiya katika halmashauri ya Wilaya ya Kinondoni, Dar es salaam.

Madhumuni ya utafiti: Lengo la utafiti ni kuchunguza na kukusanya taarifa juu ya mtazamo wa wafamasia wa kijamii kuhusu kukubalika kwa sheria na kanuni zinazozuia mauzo ya dawa za antibiotiki bila kuwa na cheti. Unaombwa sana kushiriki katika utafiti huu kwa sababu mchango wako ni muhimu sana na tunaamini kuwa una taarifa muhimu itakayowezesha kufikia malengo ya utafiti huu.

Usiri: Tunakuhakikishia kuwa taarifa zote utakazozitoa, zitakuwa ni siri na hakuna mtu mwingine ambaye hahusiki kwenye utafiti huu ataziona. Utafiti huu hautatumia majina halisi wala namna yeyote ya utambulisho wako.

Mahitaji katika ushiriki: Ukiridhia kushiriki katika utafiti huu, utatakiwa kujibu maswali kadhaa yaliyoandwaliwa katika muongozo maalumu wa mahojiano na yatakayoruhusu watafiti kupata taarifa sahihi kuhusiana na kukubalik kwa sheria na kanuni zinazouia wafasia wa kijamii kuuza dawa za antibiotiki bila cheti.

Faida: Taarifa za utafiti huu zitasaidia kuelewa hali ya mtazamo na ufahamu wa wafamasia wa jamii kuhusu sheria na kanuni zinazouia mauzo ya dawa za antibiotiki bila kuwa na cheti. Taarifa hizi zitasaidia harakati za mabadiliko ya tabia zizolenga kuhamasisha matumizi sahihi ya dawa ambalo ni suala muhimu sana katika mambano dhidi ya changamoto za usugu wa vimelea vinavotibiwa na dawa za antibiotiki. Mahojiano hayatachukua Zaidi ya dakika 40. Tafadhali kuwa huru na ongea kwa uhuru kwa kuwa hakuna jibu sahihi au lisilo sahihi katika mahojiano haya.

Haki ya kujitoa au vinginevo: Kushiriki katika utafiti huu ni hiari na sio lazima. Hivyo unaweza kuamua kutoendelea kwenye utafiti huu wakati wowote na hakutakuwa na adhabu wala hutopoteza haki yako yeyote.

Madhara: Maswali yataulizwa kuhusiana na mtazamo wako juu ya kukubalika kwa sheria na kanuni zinazoia uuzwaji wa dawa za antibiotiki bila cheti. Hatutarajii madhara yeyote kujitokeza kwako kutokana na kushiriki katika utafiti huu. Pia, hatutarajii madhara yeyote kwa familia yako kutokana na kushiriki kwako katika utafiti huu.

Wajibu wa mtafiti kwa mfamasia wa jamii aliyeridhia kushiriki katika utafiti huu: Mtafiti atawajibika kumuelekeza au kumpatia maelezo yakinifu mtu yeyote atakayehitaji kujua kuhusu dhumuni la utafiti huu.

Mawasiliano: Kama kuna uhitaji wa ufafanuzi zaidi juu ya utafiti huu, usisite kuwasiliana na Mtafiti Mkuu Babuali Ahmed, mwanafunzi wa shahada ya uzamili ya afya ya jamii na sayansi ya utekelezaji katika chuo kikuu cha Afya na Sayansi Shirikishi, Muhimbili. S.L.P 65001, Dar es salaam, Namba ya simu ya kiganjani 0753 899583. Kama una swali juu ya stahili zako unaweza kuwasiliana na Dr. Nahya Masoud, Mwenyekiti wa Kamati ya Utafiti na Machapisho,

S.L.P 65001, chuo kikuu cha Afya na Sayansi Shirikishi, Muhimbili, Dar es salaam, Namba ya simu ya kiganjani +255 21 50302-6

Je, umekubali?

Mshiriki amekubali ( ), Mshiriki hajakubali ( ).

Mimi …… Nimesoma/nimeelezewa na kuridhia maelezo yote yaliyotolewa katika fomu hii, hivyo kwa ridhaa yangu mwenyewe nakubali kushiriki katika utafiti huu.

Saini ya Mshiriki ……..

Saini ya mtafiti msaidizi …….

Tarehe ……..

Appendix III: In-depth interview guide for Community pharmacists

INSTRUCTIONS TO THE INTERVIEWER

1. The interview is to be conducted in confidence.
2. Introduce yourself and assign an ID number to the interviewee.
3. Explain the purpose of the study and informed consent.
4. The interview will take approximately 45 to 60 minutes.
5. The interview should be tape-recorded and field notes should be taken to complement the recorded interview.

Basic participants information			
Interview Session number		Age	
Date of the interview		Sex	
Duration at workplace		Marital status	
Years of practice as a community pharmacist		Education Level	
Interview Start time		Interview finish time	

INTERVIEW QUESTIONS

I. AFFECTIVE ATTITUDE

1. How do you feel about complying with the laws and regulations that restrict the OTC selling of antibiotics?

Probes:

i. Can you share specific experiences related to your compliance with these regulations?

ii. How do these regulations align with your personal and professional values?

2. In what ways has your compliance experience influenced your personal and professional values?

Probes:

i. Can you provide examples of situations where your values were impacted by compliance?
ii. How do you navigate situations where compliance may conflict with your values?

II. PERCEIVED BURDEN

1. What efforts are required to comply with the laws and regulations on OTC selling of antibiotics?

Probes:

i. Can you describe the perceived workload, time requirements, and cognitive effort associated with adhering to these regulations?
ii. Are there instances where the burden of compliance affected your daily practice?

2. Can you share specific challenges or positive aspects you've encountered in complying with the laws and regulations?

Probes:

i. How have these challenges or positive aspects influenced your perception of the regulations?
ii. In what ways have you adapted your practice to address these challenges?

III. SELF EFFICACY

1. How confident do you feel in your capacity to comply with the regulations on OTC selling of antibiotics?

Probes:

i. What behaviors do you believe are necessary to implement and adhere to these regulations effectively?
ii. Can you share experiences where you felt confident in your ability to comply, and conversely, situations where confidence was a challenge?

2. In your view, how does your confidence in compliance impact the overall acceptability of these regulations?

Probes:

i. In what ways does your confidence contribute to the overall acceptability of the regulations?
ii. Are there factors that influence your confidence in compliance that you believe could enhance acceptability?

CONCLUSION

1. Thank the participants for their time and insights.
2. Provide an opportunity for the participant to ask questions or add any additional comments.

Appendix IV: In-depth Interview Guide for Pharmacy Council Regulators/Inspectors

INSTRUCTIONS TO THE INTERVIEWER

1. The interview is to be conducted in confidence.
2. Introduce yourself and assign an ID number to the interviewee.
3. Explain the purpose of the study and informed consent.
4. The interview will take approximately 45 to 60 minutes.
5. The interview should be tape-recorded and field notes should be taken to complement the recorded interview.

Basic participants information			
Interview session ID no.		Age	
Date of the interview		Sex	
Duration at workplace		Marital status	
Years in the current position		Education Level	
Interview Start time		Interview finish time	

INTERVIEW QUESTIONS

I. AFFECTIVE ATTITUDE

1. How do you perceive the compliance of community pharmacists with the laws and regulations that restrict the OTC selling of antibiotics?

Probes:

i. Can you share specific instances or challenges related to community pharmacists' compliance?

ii. How do you perceive the affective attitudes of community pharmacists towards these regulations?

iii. In what ways do these attitudes influence compliance levels?

2. In what specific scenarios have you observed affective attitudes positively influencing compliance?

Probes:

i. Can you provide examples where positive attitudes resulted in better compliance outcomes?
ii. How can positive attitudes be further encouraged to enhance compliance?

II. PERCEIVED BURDEN

1. From your perspective, what efforts are required by community pharmacists to comply with the laws and regulations on OTC selling of antibiotics?

Probes:

i. How would you describe the perceived workload, time requirements, and cognitive effort for community pharmacists in adhering to these regulations?
ii. Are there specific challenges faced by community pharmacists that you've observed?
iii. Can you provide examples of situations where the perceived burden impacted compliance positively or negatively?

2. Can you share instances where variability in perceived burden among community pharmacists led to distinct compliance outcomes?

Probes:

i. How does understanding and addressing variability contribute to more effective regulation enforcement?
ii. Are there strategies that could be employed to standardize the burden and improve overall compliance?

III. SELF EFFICACY

1. How confident are you in the capacity of community pharmacists to comply with the regulations on OTC selling of antibiotics?

Probes:

i. What behaviors do you believe are necessary for community pharmacists to effectively implement and adhere to these regulations?
ii. How does your confidence in their compliance impact your role in enforcing these regulations?
iii. Can you share experiences where confidence positively influenced compliance?

2. In your experience, how does the self-efficacy of community pharmacists influence the overall acceptability of regulations?

Probes:

i. Can you provide examples where self-efficacy has positively or negatively affected compliance?
ii. What strategies can be employed to enhance self-efficacy and, consequently, the acceptability of regulations?

CONCLUSION

1. Thank the participant for their time and insights.
2. Provide an opportunity for the participant to ask questions or add any additional comments.

Appendix V: Muongozo wa mahojiano ya kina kwa Wafamasia wa Kijamii.

MAELEKEZO KWA ANAYEHOJI

1. Mahojiano yatazingatia mazingira ya usiri.
2. Jitambulishe na mpe mhojiwa nambari ya utambulisho.
3. Elezea madhumuni ya utafiti na kibali cha ridhaa.
4. Mahojiano yatachukua takriban dakika 45 hadi 60..
5. Mahojiano yanapaswa kurekodiwa na kumbukumbu ya maandishi itachukuliwa pia kuweka ukamilifu wa mahojiano.

Taarifa za muhimu za washiriki			
Namba ya utambulisho wa mahojiano		Umri	
Tarehe ya mahojiano		Jinsia	
Muda; mahali pa kazi		Hali ya Ndoa	
Miaka ya kufanya kazi kama mfamasia wa jamii		Kiwango cha elimu	
Muda wa kuanza mahojiano		Muda wa kumaliza mahojiano	

MASWALI YA MAHOJIANO

I. MTAZAMO WENYE KUATHIRI MATENDO

1. Unajisikiaje kuhusu kutii sheria na kanuni zinazozuia kuuza dawa za viuavijasumu kupitia kaunta bila kuwa na cheti?

Chunguza zaidi:

i. Unaweza kunipa uzoefu wako mahususi unaohusiana na utii wako wa kaununi hizi?

ii. Je kanuni hizi zinaendana vipi na maadili yako binafsi na ya kitaaluma?

1. Ni kwa njia gani uzoefu wako wa kufuata sheria na kanuni umeathiri maadili yako ya kibinafsi na kitaaluma?

Chunguza zaidi:

i. Je, unaweza kutoa mifano ya nyakati ambazo maadili yako yaliathiriwa na utiifu wa sheria na kanuni na kanuni husika?

ii. Je, huwa unafanyaje unapokumbwa na hali ambapo kufuata sheria na kanuni kunakinzana na maadili yako?

II. MTAZAMO WA MZIGO

1. Je, ni jitihada/juhudi gani zinahitajika ili kufuata na kutii sheria na kanuni zinazozuia uuzwaji wa viuavijasumu kupitia kaunta bila kuwa na cheti?

Chunguza zaidi:

i. Je, unaweza kuelezea mzigo wa kazi uliopo, mahitaji ya muda, na juhudi za utambuzi zinazohusiana na utii/uzingatiaji wa kanuni hizi?

ii. Je, kuna matukio ama namna yeyote ambapo mzigo wa kufuata kanuni uliathiri utendaji wako wa kila siku?

2. Unaweza kutuambia ni changamoto gani mahususi hasi na chanya ambavo umekuwa ukiumbana navo katia kutii sheria na kanuni?

Chunguza zaidi:

i. Je, changamoto hizi hasi na chanya zimeathiri vipu mtazamo wako wa sheria na kanuni husika?

ii. Ni kwa njia gani umeweza kubadilisha mwenendo wako wa utendaji ili kukabiliana na hizi changamoto?

III. UFANISI BINAFSI

1. Je, unahisi kujiamini kiasi gani katika uwezo wako wa kutii sheria na kanuni za uuzaji wa viuavijasumu kupitia kaunta bila cheti?

Chunguza zaidi:

i. Je, ni tabia gani unaamini ni za muhimu katika kutekeleza na kuzingatia kanuni na sheria kwa ufanisi?

ii. Je, unaweza kutushirikisha uzoefu wako kwa kutuambia ni wakati gani ulihisi kujiamini sana katika kutii, na ni wakati gani ambapo kujiamini katika kutii kulikuwa ni changamoto?

2. Kwa maoni yako, ni kwa namna gani Imani yako/kujiamini kwako katika kutii kunaathiri vipi kukubalika kwa jumla kwa sheria na kanuni hizi?

Chunguza zaidi:

i. Ni kwa njia gani imani yako/kujiamini kwako kunachangia kukubalika kwa jumla kwa sheria na kanuni?

ii. Je, kuna mambo yanayoathiri Imani yako/kujiamini kwako katia kutii ambayo unaamini yanaweza kuongeza kukubalika?

HITIMISHO

1. Mshukuru mshiriki kwa muda na Mawazo yake.
2. Toa fursa kwa mshiriki kuuliza maswali au kuongeza maoni yeyote ya ziada.

Appendix VI: Muongozo wa mahojiano ya kina kwa Wadhibiti/Wakaguzi kutoka Baraza la Famasi.

MAELEKEZO KWA ANAYEHOJI

1. Mahojiano yatazingatia mazingira ya usiri.
2. Jitambulishe na mpe mhojiwa nambari ya utambulisho.
3. Elezea madhumuni ya utafiti na kibali cha ridhaa.
4. Mahojiano yatachukua takriban dakika 45 hadi 60.
5. Mahojiano yanapaswa kurekodiwa na kumbukumbu ya maandishi itachukuliwa pia kuweka ukamilifu wa mahojiano.

Maelezo ya msingi ya washiriki			
Namba ya utambulisho wa mahojiano		Umri	
Tarehe ya mahojiano		Jinsia	
Muda mahali pa kazi		Hali ya Ndoa	
Muda katika nafasi ya sasa		Kiwango cha Elimu	
Muda wa Kuanza Mahojiano		Muda wa kumaliza mahojiano	

MASWALI YA MAHOJIANO

I. MTAZAMO WENYE KUATHIRI MATENDO

1. Nini mtazamo wako juu ya wafamasia wa jamii kufuata sheria na kanuni zinazozuia kuuza kwa dawa viuavijasumu kupitia kaunta bila cheti?

Chunguza zaidi:

i. Je, unaweza kutushirikisha matukio maalumu ama changamoto zinazohusiana na utii wa wafamasia wa jamii?
ii. Je, unaionaje mitazamo inayoathiri matendo ya wafamasia wa jamii kuhusu sheria na kanuni hizi?
iii. Ni kwa njia gani mitazamo hii inaathiri viwango vya utiifu wa sheria na kanuni?

2. Ni katika mazingira gani mahusisi umewahi kushuhudia mitazamo ikiwa na athari chanya katika kushawishi utiifu wa sheria na kanuni?

Chunguza zaidi:

i. Je, unaweza kutoa mifano ambapo mitazamo chanya ilisababisha hali bora ya matokeo ya utiifu wa sheria na kanuni?
ii. Je, mitazamo chanya inawezaje kuhimizwa zaidi ili kuimarisha utiifu?

II. MTAZAMO WA MZIGO WA KAZI

1. Kwa mtazamo wako, wafamasia wa jamii wanahitaji kuweka juhudi/jitihada kiasi gani ili kutii sheria na kanuni zinazozuia mauzo ya viuavijasumu kupitia kaunta bila cheti?

Chunguza zaidi:

i. Je, unaweza kuelezea vipi mtazamo wa kiwango cha mzigo wa kazi, mahitaji ya muda, hitaji la juhudi za utambuzi vinavowakumba wafamasia wa jamii katika utii wa sheria na kanuni?
ii. Je, kuna changamoto mahususi zinazowakabili wafamasia wa jamii ambazo umezishuhudia?
iii. Je, unaweza kutoa mifano ya mazingira ambapo mtazamo wa mzigo wa kazi umeleta athari hasi ama chanya?

2. Je, unaweza kutushirikisha matukio ambayo utofauti wa mtazamo wa mzigo wa kazi kwati ya wamafamsia wa kijamii ulisababisha utofauti katika matokeo ya utiifu?

Chunguza zaidi:

iii. Je, kuelewa na kufanyia kazi utofauti huu wa mtazamo wa mzigo wa kazi kunachangia vipi ufanisi katika utekelezaji wa sheria na kanuni?

iv. Je, kuna mikakati ambayo inaweza kutumika kuleta usawa katika mtazamo wa mzigo wa kazi na kuboresha utiifu kwa jumla?

III. UFANISI BINAFSI

1. Je, una Imani kiasi gani juu ya uwezo wa wafamasia wa jamii kuzingatia na kutii sheria na kanuni zinazozuia uuzaji wa viuavijasumu kupitia kaunta bila cheti?

Chunguza zaidi:

i. Je, unaamini ni tabia gani ni za muhimu kwa wafamasia wa jamii kuwa nazo ili kutekeleza, kuzingatia na kutii sheria na kanuni kwa ufanisi?

ii. Je, imani yako katika utiifu wao inaathirije jukumu lako katika kutekeleza sheria na kanuni hizi?

iii. Je, unaweza kutushirikisha tajriba na uzoefu wako mahali ambapo imani/kujiamini kulileta athari chanya katika utiifu?

2. Katika tajriba yako, ufanisi wa kibinafsi wa wafamasia wa jamii unaathiri vipi kukubalika kwa ujumla kwa sheria na kanuni?

Chunguza zaidi:

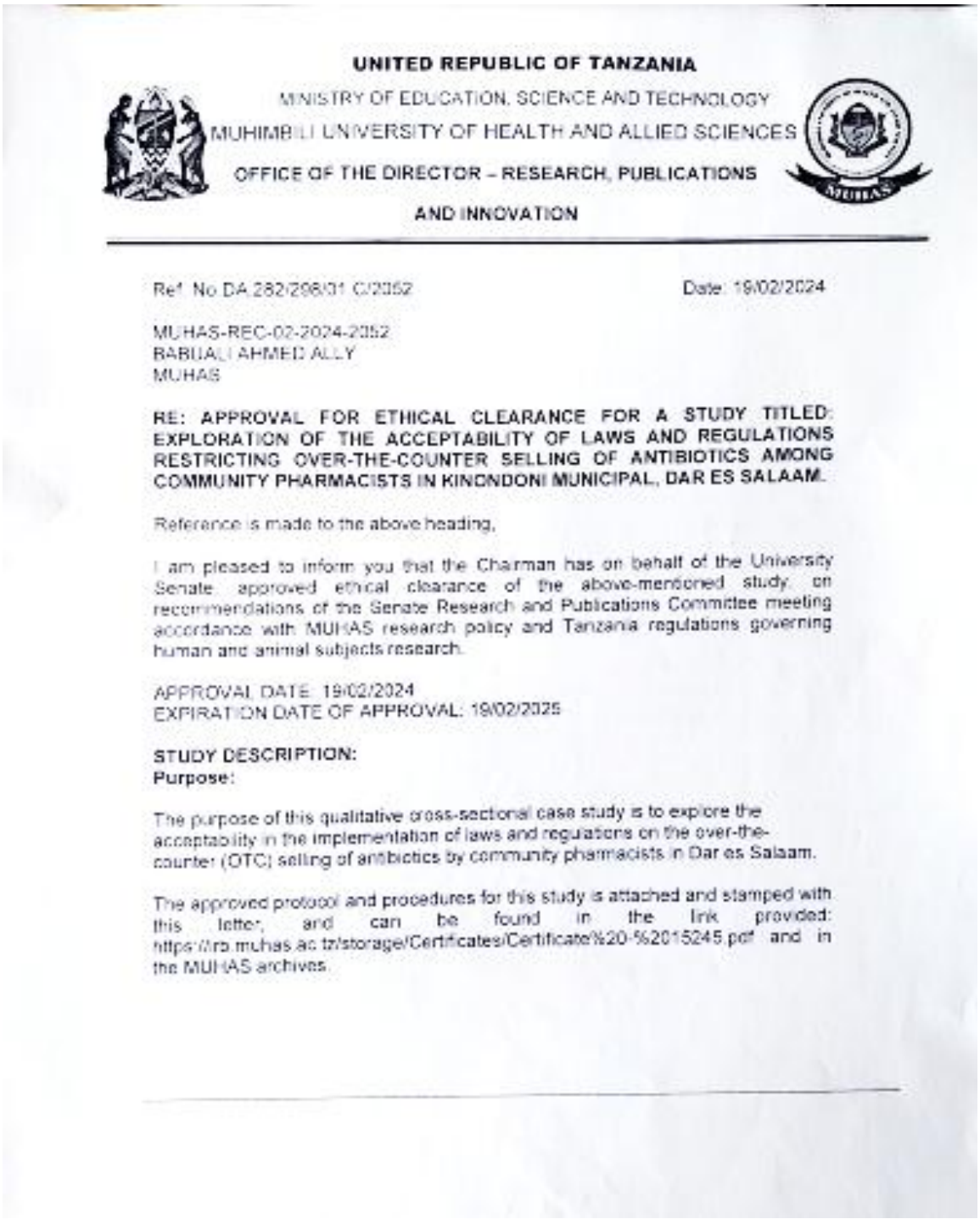
i. Je, unaweza kutoa mifano ambapo ufanisi wa kibinafsi umeathiri vyema au vibaya utiifu?

ii. Ni mikakati gani inaweza kutumika ili kuongeza ufanisi wa kibinafsi na matokeo yake kukubalika kwa sheria na kanuni?

HITIMISHO

1. Mshukuru mshiriki kwa muda na Mawazo yake.
2. Toa fursa kwa mshiriki kuuliza maswali au kuongeza maoni yeyote ya ziada.

Appendix VI: Ethical clearance certificate



UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No DA.282/298/01 C/2052 Date: 19/02/2024

MUHAS-REC-02-2024-2052
RABIJALI AHMED ALLY
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: EXPLORATION OF THE ACCEPTABILITY OF LAWS AND REGULATIONS RESTRICTING OVER-THE-COUNTER SELLING OF ANTIBIOTICS AMONG COMMUNITY PHARMACISTS IN KINONDONI MUNICIPAL, DAR ES SALAAM.

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate approved ethical clearance of the above-mentioned study on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 19/02/2024
EXPIRATION DATE OF APPROVAL: 19/02/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this qualitative cross-sectional case study is to explore the acceptability in the implementation of laws and regulations on the over-the-counter (OTC) selling of antibiotics by community pharmacists in Dar es Salaam.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://rb.muhas.ac.tz/storage/Certificates/Certificate%20-%2015245.pdf and in the MUHAS archives.

Appendix VII: Pharmacy council permission to collect data in community pharmacies.



JAMHURI YA MUUNGANO WA TANZANIA

WIZARA YA AFYA

BARAZA LA FAMASI

Unapojibu tafadhali taja:

Kumb.Na.AC.313/381/01/9 **26 Machi, 2024**

KWA YEYOTE ATAYEHUSIKA

Yah: KUMTAMBULISHA MWANAFUNZI BABUALI AHMED ALLY KATIKA FAMASI JAMII JIJINI DAR ES SALAAM

Tafadhali rejea kichwa cha habari hapo juu.

2. Ofisi ya Msajili inamtambulisha mwanafunzi Babuali Ahmed Ally kutoka chuo cha Afya na Sayansi Shirikishi Muhimbili (MUHAS) mwenye usajili **HD/MUH/T.776/2022** anayefanya utafiti kwenye famasi zilizosajiliwa jijini Dar es Salaam kama kigezo cha kukamilisha masomo yake ya shahada ya uzamili ya afya ya jamii.

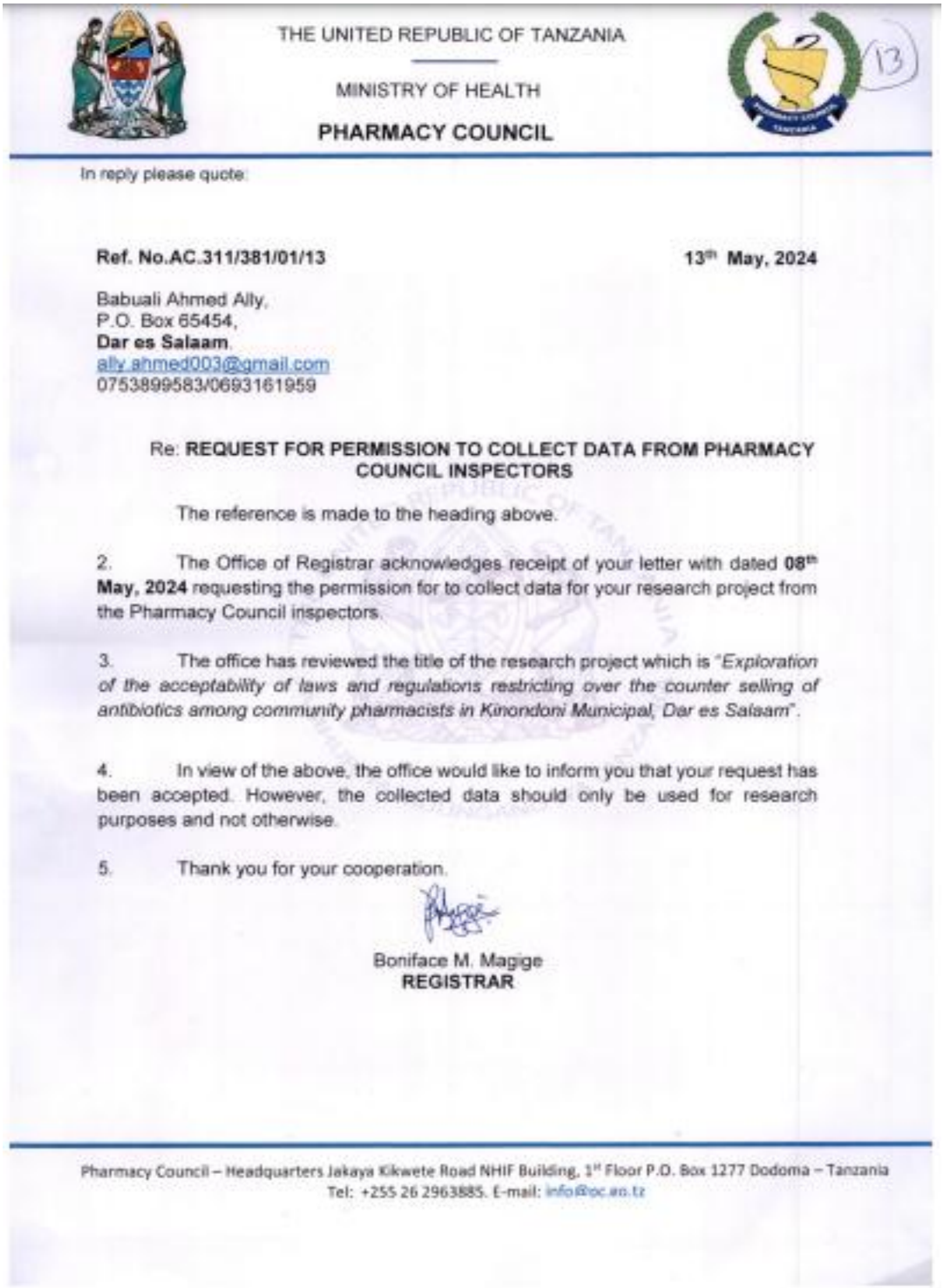
3. Hivyo basi, unaombwa kumpatia ushirikiano mwanafunzi Babuali Ahmed Ally pindi afikapo katika famasi yako.

4. Wako katika ujenzi wa Taifa.

Godfrey Ngonela
MSAJILI MSAIDIZI

Baraza la Famasi-Makao Makuu, Barabara ya Jakaya Kikwete Jengo la Bima ya Afya – Ghorofa ya Kwanza S.L.P.1277 Dodoma-Tanzania
Simu: +255 26 2963885, Barua Pepe: info@pc.go.tz

Appendix VIII: Pharmacy council permission to collect data from inspectors



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

PHARMACY COUNCIL

13

In reply please quote:

Ref. No.AC.311/381/01/13 **13th May, 2024**

Babuali Ahmed Ally,
P.O. Box 65454,
Dar es Salaam.
ally.ahmed003@gmail.com
0753899583/0693161959

Re: **REQUEST FOR PERMISSION TO COLLECT DATA FROM PHARMACY COUNCIL INSPECTORS**

The reference is made to the heading above.

2. The Office of Registrar acknowledges receipt of your letter with dated **08th May, 2024** requesting the permission for to collect data for your research project from the Pharmacy Council inspectors.

3. The office has reviewed the title of the research project which is *"Exploration of the acceptability of laws and regulations restricting over the counter selling of antibiotics among community pharmacists in Kinondoni Municipal, Dar es Salaam"*.

4. In view of the above, the office would like to inform you that your request has been accepted. However, the collected data should only be used for research purposes and not otherwise.

5. Thank you for your cooperation.

Boniface M. Magige
REGISTRAR

Pharmacy Council – Headquarters Jakaya Kikwete Road NHIF Building, 1st Floor P.O. Box 1277 Dodoma – Tanzania
Tel: +255 26 2963885. E-mail: info@pc.go.tz