THE INFLUENCE OF PHARMACEUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

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By

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"A Dissertation Submitted in Fulfilment of the Requirements for the Degree of Master of Pharmacy in Industrial Pharmacy of

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled; **"The influence of pharmaceutical regulatory framework in promotion of pharmaceutical industrialization in Tanzania"** fulfillment in the requirements for the degree of Master of Pharmacy in Industrial Pharmacy of Muhimbili University of Health and Allied Sciences.

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Date ……

……

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(Co-supervisor)

Date …….

DECLARATION AND COPYRIGHT®

I, Rana Ahmed Saada, hereby declare that this dissertation is my original work, and it has not been presented nor will it be presented to any other University for similar or any other degree award.

Signature: _____ Date: _____

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Last but not least is to my beloved family. Thank you so much for your prayers, love and continued support. This study somehow made me unavailable for you and you really share a great piece of its success.

DEDICATION

This dissertation is dedicated to my family and friends. Thank you for your love, prayers and tireless support and understanding.

ABSTRACT

Background: Tanzania, has low pharmaceutical manufacturing capacity which causes high imports of pharmaceutical products to meet the local demands. Pharmaceutical regulatory framework is in place to guide local manufacturers. However, it's not well known how pharmaceutical regulatory framework influence the growth of local pharmaceutical industrial in Tanzania.

Objective: To explore the influence of pharmaceutical regulatory framework in promoting of pharmaceutical industrialization in Tanzania.

Methodology: Exploratory qualitative study design that involved interviews with key informant responsible for policy making, manufacturers, drug GMP, registration, product, taxation and product quality. The key informants were from the Ministry of Health Community Development, Gender, Elderly and children (MoHCDGEC), Ministry of industry and Trade Tanzania, Medical Store Department (MSD), Tanzania Revenue Authority (TRA), (Tanzania Medical device and drugs Authority (TMDA) and Pharmaceutical industries. Data was collected using semi-structured interview guide. Prior to thematic analysis verbatim transcription was conducted for the audio recorded data which were enriched by notes taken during interviews. The sub-themes and themes were produced deductively from the codes generated.

Results: The total of ten key informants were interviewed. We found that, lack of awareness on policy, poor government support as well as pharmaceutical regulatory bureaucracy deterred promotion of pharmaceutical industrialization in Tanzania. In addition, low production capacity of existing pharmaceutical industries is contributed by the use of outdated machinery, poor infrastructural support, lack of capital and lack of skilled personnel. These factors also affected the compliance to GMP standards and medicine registration.

Conclusions and Recommendations: The selected components of pharmaceutical regulatory framework are not well implemented, which adversely affect the promotion of pharmaceutical industrialization in Tanzania. The key players of pharmaceutical industries are TMDA, MSD, MoHCDGEC, TRA, DRA, TIC and local industries should jointly resolve the challenges that hinder pharmaceutical industrialization in Tanzania.

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LIST OF ACRONYMS AND ABBREVIATIONS

API	Active pharmaceutical ingredient
CAGR	Compound Annual Growth Rate
DSM	Dar es Salaam
EAC	East African Community
EU	The European Union's
EU-GMP	The European Union's GMP
GDP	Gross Domestic Product
GMP	Good Manufacture Practice
GRevPs	Good Review Practices
MITI	Ministry of Industry, Trade, and Investment
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MOHSW	Ministry of Health and Social Well fare
MRH	Medicines Regulation Harmonization
MSD	Medical Store Department
MUHAS	Muhimbili University of Health and Allied Sciences
NCE	New chemical entities
NIMR	National Institute of Medical Research
NMRAs	The National Medicines Regulatory Authority
R&D	Research and Development
TFDA	Tanzania Food and Drugs Authority
TMDA	Tanzania Medicines and Medical Devices Authority
TRA	Tanzania Revenue Authority
VAT	Value Added Tax
WHO	World Health Organization

DEFINITION OF TERMS

Industrialization: The process of converting to a socioeconomic order in which industry is dominant [1].

Pharmaceutical Industrialization: The discovery, development, and manufacture of drugs and medications (pharmaceuticals) by public and private organizations [1].

Regulatory Affair: Also called government affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, agrochemicals (plant protection products and fertilizers), energy, banking, telecom etc. Regulatory affairs also have a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods) [2].

Medicines Regulatory Authority: Means any governmental authority or instrumentality with responsibility for granting any licenses, approvals, authorizations or granting pricing and approvals necessary for the marketing and sale of pharmaceutical products in any regulatory authority [3].

National Health Policy: Refers to decisions, plans, and actions that are undertaken to achieve specific health care goals within a society [4].

Generic Drugs: A pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents [5].

Innovators Drugs: Is the first drugs created containing its specific active ingredient to receive approval for use. It is usually the product for which efficacy, safety and quality have been fully established [6].

Pharmaceutical Manufactures: Means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs [7].

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Pharmaceutical industry in Tanzania like in the rest of the world is experiencing the same phenomenon that many other industries have faced in the past. Many companies have been forced to try and reinvent themselves in the face of challenges in their business environment which had effect on their development [8]. A regulatory authority is a public governmental body authorized by law independently exercise regulatory powers concerning the development, production, marketing and surveillance of medical products, the term implies that a single organization is responsible for all regulatory functions, indeed these functions may be undertaken by one or more institutions reporting to the same or different senior official. The regulatory authority plays a critical role in ensuring the quality, safety, efficacy and performance of medical products as well as the relevance and accuracy of product information [9].

Three main components seen as the main contributors to regulatory functions (a) regulatory framework composed of legal framework along with guidelines and guidance documents (b) regulatory institutions which may be represented by one or more entities including the national regulatory authority (NRA), the national control laboratory, pharmacovigilance centre, research ethics committee and other (c) resources including human and financial resources, infrastructure and equipment and information management systems [9].

In Tanzania, laws governing regulation of medicines and food products began in 1978. In 2003, legislations were merged to form Tanzania Food, Drugs and Cosmetics Act which established Tanzania Food and Drugs Authority (TFDA). TFDA was mandated to regulate, medicines, food, cosmetics and medical devices. In 2019, the Tanzania Food, Drugs and Cosmetics Act was again amended and renamed to Tanzania Medicines and Medical Devices Act which also established Tanzania Medicine and Medical Device Authority (TMDA) to regulate medicines, medical devices and diagnostics only.

The amendments were made to streamline processes, reducing duplication of efforts and minimizing the number of permits issued by different regulators in Tanzania to promote pharmaceutical manufacturing [10].

The registration of medicines was made under Section 51 (1) of the Tanzania Food, Drugs and Cosmetics Act, 2003. The act provides conditions under which a medicinal product may be registered in Tanzania that include the availability of medicine to be of the public interest, safe, efficacious and of acceptable quality, the premises and manufacturing operations should comply with the current good manufacturing practices (GMP) requirements or any other requirements as may be prescribed by the authority [11].

Medicine registration is an official authorization or registration of a product by TMDA for the purpose of marketing or free distribution in the country after evaluation for safety, efficacy and quality [12].

A medicinal product application dossier is a set of documents that consists of data on administrative, pharmaceutical, clinical and labelling of the product. The administrative part gives preliminary information of that medicine, applicant and its manufacturer. The quality part contains detailed information of the active pharmaceutical ingredient(s) (APIs) used and finished pharmaceutical product whereas in ensuring medicines safety and efficacy, these data are provided in the clinical part of the dossier [12].

In Tanzania, the regulatory framework is in place to ensure that the regulatory authorities fulfil their mandatory roles of ensuring medical products are of acceptable quality, safety and efficacy. It is mainly composed of legal components along with guidelines that stipulates the medicine registration and GMP procedures and guidance. The regulatory authorities focus on components which are GMP and medicine registration as core contributors for strong pharmaceutical industries. Other contributors that are likely to affect the pharmaceutical industries are enabling environment factors such as policy, taxation, infrastructural support, cost of raw materials and government support. Similarly, environmental factors like infrastructure, tax consideration, government support, pharmaceutical policy and government incentives. Many countries with successful pharmaceutical sector have such framework in place.

The imported medicines either by vertical program through public health programs (under MoHCDGEC) and MSD or by market authorization holders who should be registered by TMDA. It is worth noting that, both MSD and TMDA are public institutions under MoHCDGEC. In addition, the local pharmaceutical industries are registered by Ministry of

Industry and Ministry of Trade. They import raw material which are subjected to taxation (by TRA), the manufactured medicines must be registered by TMDA. The policy that governs access to medicines are developed by MoHCDGEC and determines which medicine category are national priority. However, GMP compliant industry, medicine registration process and enabling environmental factors may determine availability of medicines in Tanzania.

The study will explore the influence of GMP, medicine registration and environmental factors on local pharmaceutical industries in Tanzania. Regulatory framework includes provision of services such as licensing of premises for manufacturing, ensuring industry comply to principles of good manufacturing practices (GMP). Such principles include appropriate premises, having quality management system, appropriate and adequate number of qualified personnel, proper documentation and adhering to good production practices [13].

1.2 Problem Statement

The government of Tanzania has emphasized on industrialization as a country policy. Nevertheless, the growth of pharmaceutical industry is limited. To date only two local pharmaceutical manufacturing are GMP standard. Pharmaceutical regulatory framework is obliged to make and implement policies and regulations regarding the establishment and growth of local pharmaceutical industries. Furthermore, local manufacturers in Tanzania are faced by number of challenges including low technology, financial hardship and limited market share [14].

In addition, they depend on importation of raw and packaging materials which are associated with import duty and value-added tax (VAT) that may increase production cost and impose them to low market competition. These may be the reasons for the stagnant growth of local Pharmaceutical industry. The slow rate of growth of the pharmaceutical sector in Tanzania has several effects to the economy and health sector of the country. Since local manufactures contribute about 30% of the national medicines needs, the country has to import the remaining 70% from abroad.

This also has negative impact on the health of the public especially when government is unable to procure all medicines needed due to financial constraints. In fact, the Pharmaceutical regulatory framework could address some of these challenges through policy incentives in order to promote the growth of local manufacturing.

Nevertheless, there is limited data regarding the influence of pharmaceutical regulatory framework on growth of sustainable local pharmaceutical industries in Tanzania. Therefore, this study intended to explore the influence of pharmaceutical regulatory framework on local pharmaceutical production in Tanzania. Such information might evoke dialogue between stakeholders, assist policy makers and potentiate the growth of pharmaceutical industries in Tanzania.

1. 3 Conceptual framework

Pharmaceutical regulatory framework function involves GMP and registration of medicine in relation with local pharmaceutical production. Good manufacture practice may ensure products are consistently produced and controlled according to quality standards and to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product [15].

The components of GMP includes availability of skilled personnel, inspection, premises and equipment as well as proper documentation of procedures and processes. Easy availability of these aspects facilitates local pharmaceutical production. The drug registration process affects the local production i.e. the cost and time taken for dossier evaluation have direct impact on the operation cost for instance, the longer the time and high cost of drug registration delays marketing of produced medicines which affects the locally produced medicines and also the quality and safety of drugs which has to be registered and approved by pharmaceutical regulatory authorities before placed in market.

Similarly, environmental factors influence the local production of pharmaceuticals such as availability of power and water supply, infrastructural support, taxation and government support as well as availability of policy for easing establishment of local pharmaceutical industries and low taxes for importation of raw materials.

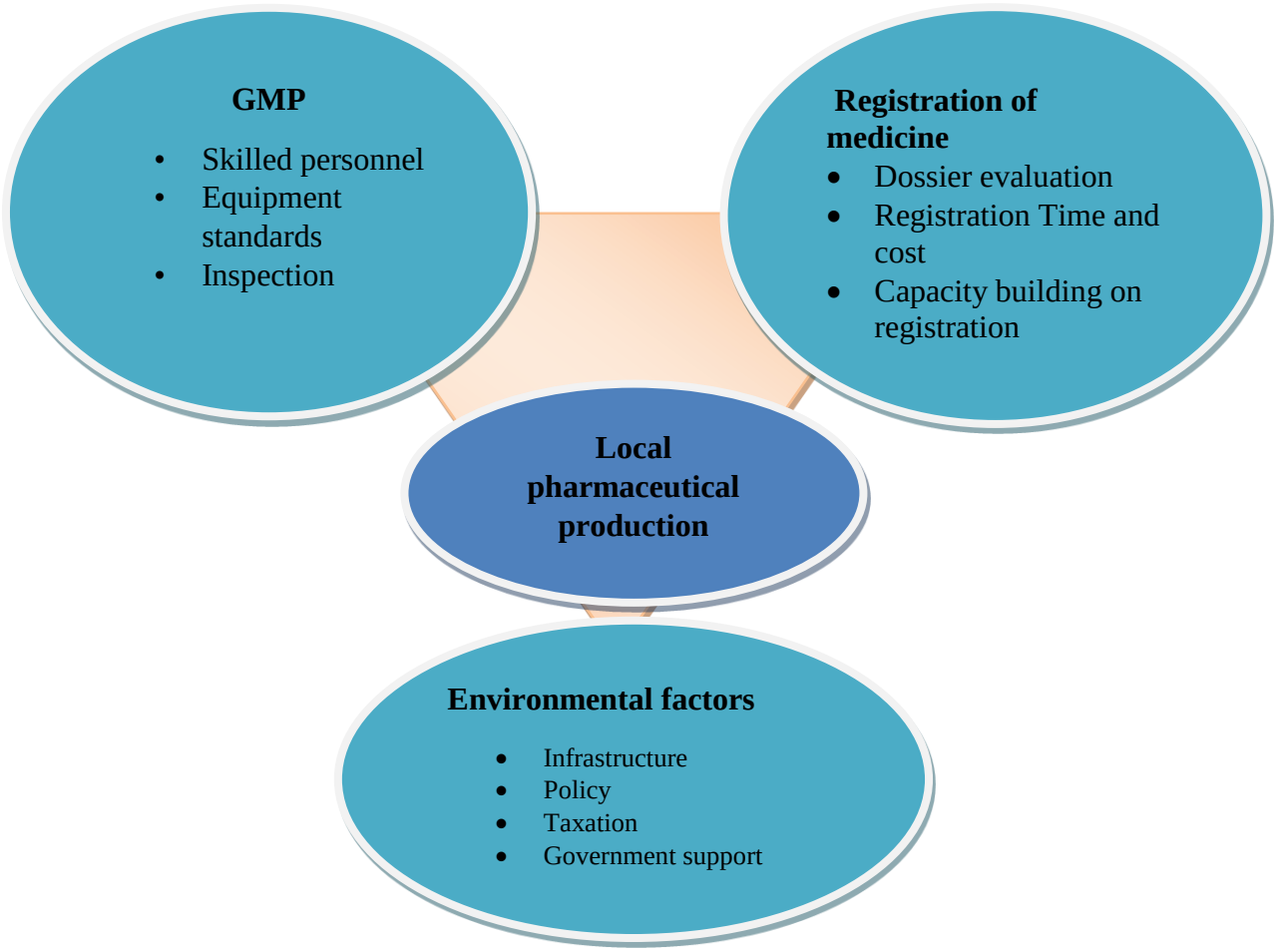

Figure 1: Conceptual Framework of the study

1. 4 Rationale of the study

Finding of study will increase the pool of knowledge by providing information **related** to influence of pharmaceutical regulatory framework in promotion of local pharmaceutical **industries** in Tanzania.

Government and pharmaceutical regulatory framework makers may gain understanding of the factors that influence **promotion** of local pharmaceutical industries.

It will assist the management of local pharmaceutical manufacturers to adhere to pharmaceutical regulatory framework.

1. 5 Main research question

The main research question of the study was what are the influence of pharmaceutical regulatory framework in promotion of pharmaceutical industries?

1. 5.1 Specific research questions

1. What is the influence of GMP implementation on local production in Tanzania?
2. What is the influence of medicine registration process on local production in Tanzania?
3. What are the environmental factors and challenges affecting pharmaceutical regulatory framework in local production of pharmaceuticals?

1. 6 Main research objective

1. 6.1 Broad Objective

The main objective of this study was "Exploration of the influence of the pharmaceutical regulatory framework on promotion of pharmaceutical industrialization in Tanzania" and the following were specific objectives: -

1. 6.2 Specific Objectives

i. To explore the influence of GMP implementation on local production in Tanzania.
ii. To explore the influence of medicine registration process on local production in Tanzania.
iii. To determine environmental factors and challenges affecting pharmaceutical regulatory framework in local production of pharmaceuticals.

CHAPTER TWO

2.0 **LITERATURE REVIEW**

2.1 Local Pharmaceutical Industrialization

Locally owned, small scale manufacturers serving a portion of the domestic market, the discovery, development, and manufacture of drugs and pharmaceuticals is done by both public and private organizations. The pharmaceutical industry develops, manufactures, and sells drugs [16].

In Africa, pharmaceutical industry varies, with some countries producing highly sophisticated products that they sell across the region and other countries with very little production and relying completely on imports. African pharmaceutical production falls within a highly integrated global market in which developing economies and firms are struggling to compete. Ten countries represent 70 percent of Africa's pharma market; Algeria, Egypt, Kenya, Ivory Coast, Libya, Morocco, Nigeria, South Africa, Sudan, and Tunisia Increasingly [17].

In Tanzania, pharmaceutical industry began in 1962. Between 1962 and 2009 seven (7) firms were in existence [18]. From 2018 to 2020, there were twelve registered pharmaceutical manufacturing factories in Tanzania. As of May 2020, nine (9) pharmaceutical manufacturing facilities in the country were in operation, of which two (2) were for veterinary medicines and seven (7) were for human medicines. The dosage forms manufactured by these facilities included Oral Solid Dosage forms in form of tablets and capsules and oral liquid dosage forms (Dry powder for suspension and liquid orals) and products for topical applications such as creams and ointments. The seven (7) registered pharmaceutical manufacturing industries were Zenufa Laboratories Limited, Shelys Pharmaceuticals Limited, Mansoor Daya Chemical Industries Limited, Keko Pharmaceuticals Limited, Prince Pharmaceuticals Limited, A.A Pharmaceuticals Limited and Sri Balaj Pharmaceuticals Limited, These few Pharmaceutical manufacturing facilities contributes about 30% percent of the national medicines needs and the rest is imported from abroad [19] .

Furthermore, twelve facilities were under construction of which nine (9) are for human medicine and three are for veterinary medicine. The dosage forms expected to be manufactured by these facilities include large volume parenteral (LVP), oral liquids, powders, tablets, vaccines, topical formulations, creams, ointments and ophthalmic preparations. The list of the facilities that are under construction are Kairuki Pharmaceuticals Industry Limited (KPIL), Biotec Laboratories Limited, Vista Pharma Limited, Africana Pharmaceuticals Limited, Alfa Pharmaceuticals Limited, Cure Afya Pharmaceuticals Limited, Emedics Pharmaceuticals Limited, Vine Vision Infusion Limited and National Institute of Medical Research (NIMR) [19].

The pharmaceutical supply in Tanzania is managed by the private and public distributor Medical stores department (MSD), which is an autonomous body under the Ministry of Health, Community Development, Elderly and Children is the single largest distributor of drugs in Tanzania. About 71% of MSD purchases are sourced from foreign countries, the remaining 29% are from local manufacturers [20].

2. 2 Good Manufacture Practice (GMP)

Production standards known as good manufacturing practices (GMPs) are quality requirements that have been adopted as guidelines by the industry and the world health organization (WHO). The GMP system ensures that products are consistently produced according to quality standards appropriate to their intended use. GMP comprises of a set of safeguards and procedures in production of pharmaceutical products to ensure products are effective and safe. This required skilled qualified industrial pharmacist and workers who are trained and educated on procedures related to GMP. The pharmaceutical industry has the most precise requirements and manufacturing guidelines in terms of quality. As a result, it is critical that pharmaceutical manufacturing equipment comply with good manufacturing practice (GMP), Layout and design, cleaning equipment should be cleaned using validated procedures and Equipment for cleaning, equipment for washing, cleaning and drying should be suitable for use and not contaminate products [21].

Globally, in developed countries the World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry, enforce similar requirement to attain compliance and ensure effective and safe drugs and pharmaceutical manufacturing equipment comply with good manufacturing practice (GMP) [22].

In Africa, Medicines must be manufactured under close technical supervision and by technically qualified people to ensure the safety, efficacy and quality of the products. This requires skilled technicians to set up and run good manufacturing practice (GMP), skills in developing pharmaceutical products are often missing [23].

In Tanzania, among the registered plants, only five (5) were categorized as TMDA (by then TFDA) good manufacturing practices (GMP) compliant pharmaceutical manufacturing factories. They are namely, Shelys Pharmaceuticals Limited, Zenufa Laboratories Limited, Pharma Centre, Prince Pharmaceuticals Limited and Tanzania Pharmaceutical Industries Limited. Shelys Pharmaceuticals Limited holds a 70% share of locally manufactured pharmaceuticals in the country, In the year 2000, after an inspection by Tanzanian Food and Drugs Authority (TFDA), three registered manufacturing facilities were ordered to stop production, since then, production facilities have been upgraded, with substantial investments in several pharmaceutical companies. Tanzania Pharmaceutical Industries began to establish a GMP-compliant manufacturing facility for antiretroviral medicines. Shelys was the first company in Tanzania to comply with World Health Organization (WHO) GMP requirements. Currently, only Zenufa Laboratories satisfies WHO GMP requirements in Tanzania and is about to be certified by TMDA [24].

2. 3 Registration of Medicine

Globally, many countries have evolved systems of drug registration to ensure that products approved for sale meet the criteria of efficacy, safety, and quality. Medicine registration, also referred to as licensing or marketing authorization, is often a major element in pharmaceutical regulatory framework. In its fully developed form, however, it is costly and labour intensive having a complete register of drugs in market.

This allows pharmaceutical Regulatory authorities to evaluate information from other countries or from WHO about problems with a particular medicine (for example, toxicity, contamination, evidence of inactivity), to determine whether the product is on sale in their country, and what actions might be taken [25].

In Africa, developing countries Pharmaceutical regulators are often under resourced and lack access to the high levels of scientific expertise needed for the effective assessment of registration dossiers for new chemical entities (NCE) compared to developed countries which rely on the assessments of major medicines regulatory authorities, such as those in the US and Europe, when faced with an application for registration of an NCE [26].

In Tanzania, TMDA is a regulatory body responsible for controlling the quality, safety and effectiveness of medicine and medical devices [27]. The Authority has been ensuring safety, efficacy and quality of medicines by quality control tests; in addition to other quality assessment mechanisms. Currently, the market is highly dependent on imports, which account for around 75% of the total pharmaceutical market. The procedures and approval requirements of new drugs, variations, import, export and disposal have been set up by the TMDA, which help in maintaining quality of the drug products that are imported as well being produced locally [27].Tanzania Food, Drugs and Cosmetics Act, 2003 prescribes that a medicinal product shall be registered only if; (a)The availability of the medicine is in the public interest. (b) The medicine is proved to be safe, efficacious and of acceptable quality. (c) The premises and manufacturing operations comply with the current Good Manufacturing Practices (GMP) requirements. (d) The medicine complies with any other requirements as may be prescribed by the Authority [28].

2. 4 Environmental Factors

Africa faces a range of economic, social, health, and environmental challenges that many of these challenges are reflected in the Sustainable Development Goals (SDGs). Supporting the development of a more competitive and sustainable pharmaceutical industry in sub-Saharan Africa is a powerful contribution to the achievement of the SDGs.

Environmental factors, like government support, infrastructure, assistance from pharmaceutical regulatory authority, taxation on packaging material, outdated machinery, dependency on importation, lack of capital, and lack of local expertise all are factors which effect growth of local industries and may hinder inclusive sustainable industrialization [29].

Over the years, local pharmaceutical manufacturers in Africa have learned to do business and grow in difficult market conditions. The market share of local production is low and declining in some African countries. Existing supply systems often favor imports as taxes and tariffs are often charged on inputs to pharmaceutical production and not on the importation of finished products. African manufacturers suffer from several cost disadvantages including higher unit costs associated with manufacturing, materials and machinery, finance and utility services. Foreign firms with large manufacturing plants serving bigger markets can economies on costs with larger production batch sizes and can 'afford' dedicated facilities for particular formulations, which saves costs of change over between products. A firm with a larger plant producing larger volumes can also buy materials at lower prices. Unit labor costs in Africa are generally higher due to lower productivity and higher cost for hiring technically qualified people and experts from abroad.

African manufacturers rely on imported sources for most of their requirements of excipients, primary packaging materials, machinery and equipment. Import duties and value added tax (VAT) on these materials and equipment increase the cost in many countries while imported medicines are often exempt from duties and taxes [30].

Infrastructure, the unreliable, insufficient supply and high cost of electricity and water not only substantially increase operating costs, but also act as barriers against effective use of installed production capacity. The poor conditions of roads are also a major challenge, often causing long delays in clearing the imports of raw materials and delivery to manufacturers. There is often limited availability of land that is connected to utilities and suitable for pharmaceutical production.

The pharmaceutical industry is a technologically intensive industry. Medicines must be manufactured under close technical supervision and by technically qualified people to ensure the safety, efficacy and quality of the products. This requires not only qualified industrial pharmacists, but workers who are educated and trained in chemistry, biochemistry, engineering, and related sciences [31].

Investigations by the Ministry of Health and Social Welfare and a survey by Mwilongo identified the following major problems for local production of pharmaceuticals in Tanzania. Access to working capital Insufficient supply and high cost of electricity and water, poor infrastructure, delays in clearing the imports of raw materials, lacks local skills in pharmaceutical manufacturing and higher costs of imported materials and pharmaceutical machinery [32]

CHAPTER THREE

3.0 METHODOLOGY

3.1 Introduction

This chapter describes the methodology that was employed to undertake this study. It presents the study area, study design, study participants and study context, sample size and sample selection procedures, data management and analysis, data collection tools, data collection procedures, ethical consideration, confidentiality, trustworthiness of the study and study limitation and mitigation.

3. 2 Study Area

The study was conducted during December 2020 to June 2021 in Tanzania i.e. Dar es Salaam and Dodoma where five government institutions and two pharmaceutical industries in Dar es salaam, and one government institution in Dodoma.

3. 3 Study Design

The exploratory qualitative study design was implemented in this study. Qualitative design was preferred because it provides a wide range of information in responding to study objectives [32]. Data collection employed semi-structured interviews and thematic analysis as the method of data analysis [34]. A phenomenological approach was used to explore the experience of participant on the influence of pharmaceutical regulatory framework in promotion of pharmaceutical industrialization in Tanzania.

The use of exploratory qualitative approach for data collection and analysis was potential to provide a rich descriptions and comprehensive picture of the influence of pharmaceutical regulatory framework on local pharmaceutical production [35].

3. 4 Study Participants and Study Context

The study population included key personnel working in pharmaceutical regulatory authorities in Tanzania as well as directors from private pharmaceutical industries included Mansoor Daya Chemicals Ltd and Zenufa Pharmaceuticals Ltd in Tanzania. Pharmaceutical regulatory authority included key informants from the Ministry of Health Community Development, Gender, Elderly and children (MoHCDGEC), pharmaceutical policy department, Tanzania Revenue Authority (TRA),

Domestic Revenue Department (DRD), Tanzania investment centre (TIC), Medical store Department (MSD), Tanzania Medicines and Medical Devices (TMDA).

3. 5 Sample Size and Sample Selection Procedures

The study included ten (10) personnel who are experienced, heading the department or section, director of the organization or institute who are responsible for supervising implementation of pharmaceutical regulatory framework in local pharmaceutical industry in Tanzania. They are considered to be knowledgeable on the area to be studied. The following key informants were recruited conveniently for interview; one chief pharmacist from MoHCDGEC from pharmaceutical policy department, two principle investment promotion officer involved in pharmaceutical industrialization from Tanzania investment centre, two pharmacists from TMDA; one from medicine registration department and one from GMP department, one pharmacists from MSD from procurement department, one officer from TRA from industrial taxation department, one officer from Domestic revenue department and two CEO from two different pharmaceutical industries in Tanzania. Appointments were asked from each key informant to schedule the interview date and time at their convenience. The total number of key informants were determined by saturation point. Also, it included documentary review to supplement information from key informants. Documents that were reviewed included pharmaceutical sector action plan 2020 and the national health policy 2017 (Medicines and Health Commodities) which pointed on private pharmaceutical sector strategies spearheaded by the MOHSW, e.g. An assessment of ways to address MSD's debt, working capital and financial sustainability challenge, Facilitation of disposal of expired pharmaceuticals at health facilities (includes development of new guidelines).

3. 6 Data Collection Tools

Data was collected using key informant in-depth interview using semi-structure guide consisting of questions for government officials from MoHCDGEC (pharmaceutical policy), TMDA, MSD, TRA, DRD, TIC and pharmaceutical industries in Tanzania.

The interview guide was developed by the principal researcher to explore the influence of pharmaceutical regulatory framework in promotion of pharmaceutical industrialization in Tanzania. The questions focused on GMP in pharmaceutical industries, registration of medicine process, taxation system, investment promotion, government support, policy of drugs on availability of medicines, procurement of drugs and importation procedures, extent to which their effect on the promotion of pharmaceutical industries (table 1). Interviewees were asked to share with the research team any relevant documents and were asked to suggest opinions on how to develop pharmaceutical industrialization and challenges faced. The main components of the interview guide are reflected in table 1.

Table 1: Components of interview

Predetermined themes	Predetermined sub-themes
GMP	Existence of GMP system Regular GMP Inspection High cost of GMP implementation Lack of skilled personnel to implement GMP Availability of GMP training program Provision of technical support on GMP Compliance to GMP Perception on GMP standards
Medicine registration	Medicine registration procedures Registration time Cost of registration Challenges in dossier evaluation Capacity building on registration procedures
Environmental factors	Lack of government support Political will Taxation on packaging material Regulatory challenges Incentives/promotion Infrastructural Outdated machines Low production capacity Unavailability of local expertise Dependence of cheap imported pharmaceuticals Dependence on imported product Lack of capital

3. 7 Data Collection Procedures

Data was collected using key informant interviews. Before interviews was done, the researcher approached each key informant and agreed on time and place for interviews.

Importantly, consent forms were read before the interview and distributed to them for signing before the start of interview. Also, an explanation of study objectives and benefits of participation were given to key informants. The interviews were conducted by researchers in a comfortable, private room with no distractions at the participant`s convenience time and to ensure confidentially.

A list of questions to key informants guided collection [35].The audio recorder was used to ensure that the information provided by the participants is captured which helped the researcher to use direct quotes from participants during data analysis. Additional notes on verbal and non-verbal aspects of the interview was taken to compliment with the audio recorded data in consistent with qualitative studies.

3. 8 Confidentiality

All the information obtained from this study was used for the research purpose only and was not shared to anyone without participants ‘consent. No names were recorded during the interview and numbers were used for identification purposes. The recorded voices will be deleted three months after final submission of the dissertation.

3. 9 Trustworthiness of the Study

In qualitative research, trustworthiness is described by four aspects; credibility, dependability, conformability and transferability[37]. Purposive sampling of the participants and the use of key informant interviews in data collection allow triangulation of data which will increase credibility. Also, the use of Kiswahili language, the building of trust with participants and the quality of the researcher will limit the risk of misinformation. To ensure dependability, the data collection guides were used and the researchers reviewed and examined the research process and the data analysis in order to ensure that the findings are consistent. The detailed procedures on how this study will be conducted and triangulation of settings and researchers was enhanced conformability of the study findings.

A detailed description of the study setting, selection of participants, data collection methods employed was provided to facilitate the transferability to the other contexts.

3. 10 Data Management and Analysis

Data analysis was conducted parallel to data collection to ensure availability of data that respond to study questions. The researcher then ensured the analysis focuses on the data being collected. therefore, thematic data analysis method was employed to provide a wide range of analytic options from key informants [38].

The collected information on demographic characteristics of study participants and was summarized in Microsoft excel and coded. All the interview was audio recorded, transcribed verbatim using F4 program and saved into a computer program based on text file. F4 is a computer program that allow user to easily transfer audio file to verbatim. Which was protected by password. Only the researcher will have access to the collected information. The recorded voice was deleted from the voice recorder to prevent access by un-authorized person.

Thematic analysis approach described by Braun and Clarke`s guided the analysis of data which involves six main steps [39]. The audio recorded interviews was transcribed verbatim, read and re-read by the researchers to become familiarized with the data before the coding process. The transcribed information was properly stored and that, only researcher will have access to the storage cabinet.

Transcripts were then imported to NVIVO 11 to be coded and sorted. NVIVIO 11 is a computer software used to organize qualitative data. Transcripts were initially examined to identify primary coding categories as well as the range of themes present within each category. Codes and sub-codes that were derived directly from the transcripts were used as guidelines when coding. Developed codebook contained identified coding categories and themes, new emerged themes were attached in appropriate code as coding proceeding. The purpose of this process is to systematically group text data into fewer content-related themes that share the same meaning.

The coding process helped the researchers to identify features of the data that was interesting and got the meaningful data. The sub-themes and themes were produced deductively from the codes generated. The final themes were reviewed and discussed by the team and then finalized.

Repeatedly reading of all the transcripts from the time the data is collected, transcribed, codes development and data analysis enable the researcher to understand data intensely, identify important areas that need changes/suggestion when moving to new field area for data collection and the completion of analysis and report writing for both sites.

Repeatedly reading allowed the researcher to identify emerging themes, easily analysis of data and interpretation.

Table 2: Coding process and theme generation

Transcript	Codes	Sub- theme	Main theme
"Ooooh! A lot of challenges. When one inspector comes he says this little crack there, it must be rectified. All right, we'll do it. We did the crack colouring. The other says the colour is different… one inspector says, you must have it this way. The other inspector comes says no, according to that one, it should be this way. So there is no consistent of GMP inspection…."	• Lack of consistent GMP inspection • GMP as a prerequisite requirement of market	• GMP Inspection	GMP

3. 11 Ethical Considerations

Ethical clearance was requested from the research and publication committee of Muhimbili University of Health and Allied Sciences (MUHAS) prior to the study. Permission for data collection was obtained from the administrators of each pharmaceutical industry and respective ministry as well as government authority in Tanzania, involved in the study. Informed consent was sought and obtained from the participants. Participants were informed about the objectives of the study and that their participation is voluntary in data collection. Participants were informed that they will be free to decline and that it would not interfere or affect their duties. Participants were assured that the information provided will be treated with utmost confidentiality and will be disclosed only for study purpose.

3. 12 Study limitations and Mitigation

Response bias happened due to the reluctance. This may compromise the quality and richness of data. The mitigation measure was to avoid leading questions and to use questions which are clear and simple.

Slow response from key informants on interviews appointments happened this was mitigated by physically daily attendance and follow up with key informants.

CHAPTER FOUR

4.0 PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction

The information collected from key informants generated overarching themes along with sub-themes describing the influence of pharmaceutical regulatory framework in p of pharmaceutical industrialization in Tanzania. The three main themes were local production challenges; GMP (good manufacture practice); Medicine Registration; and Environmental factors.

4. 2 Description of study participants

Ten key informants were involved in the study whereby majority (8/10) were male with age ranging 35-96 years old with working experience of more than five years. Most of the key informants were pharmacists (6) working in either private industries or public institutions. Of the interviewed industries, two were private whereas one was a partnership between private and the public (the public held large share). The institutions involved in the study were TMDA, TRA, MSD, TIC, MoHCDGEC and Pharmaceutical industries.

Pharmacist N=6	
Sex	Male 4, female 2
Age	28 -96 years
Period of experience	5- 56years
Promotion officer N= 2	
sex	Male 2
Age	35-45years
Period of experience	5-10years
Customs officer N=2	
sex	Male 2
Age	34-45years
Period of experience	7-10years

Table 3: Demographic characteristics of study participants

4. 3 Good Manufacturing Practice (GMP) Implementation

i. Existence of GMP system

The participants stated that, there exists GMP system in the country. The system includes availability of guidelines, law, regulation, documents and capacity. The regulatory authority uses East African compendium and local guideline to guide local pharmaceutical industries.

> *"We have the systems in place and the capacity…. we have a GMP system, where we inspect pharmaceutical manufacturers, be it locally or from abroad and ensure they comply to GMP standards before their products are registered and supplied to the market."* (P3, Male aged 53 years of age, working experience of >10 years).

To ensure that the authority's GMP implementation activities comply to international standards, there exists audit system that evaluate its performance.

> *"We do have the audit system to evaluate the way we perform our GMP inspection and this one can be done from within and outside the country. For example, the authority is ISO-certified whereby those who certify us come to verify if we are doing as per procedures. So we have a system in place for GMP."* (P3, Male aged 53 years of age, working experience of >10 years).

ii.Regular GMP inspection

The authority conduct inspection to pharmaceutical industry to ensure GMP compliance. The authority has competent inspectors who inspect local and foreign pharmaceutical industries at least once a year to ensure safe and efficacious medicines are supplied to the market.

> *"We do inspect annually for local manufacturers, that's the routine one, but in between we can schedule inspection, for proper verification. So when the inspector rises some queries, they respond, we evaluate and we can go for inspection. So we can go for a couple of verification within that year. We can do investigative inspection, but whenever you go for an inspection, you should check on the implementation of the previous nonconformance which were advised."* (P3, Male aged 53 years of age, working experience of >10 years).

It was insisted that, GMP inspection is conducted as a prerequisite for international market. It was noted, neighboring countries inspect the Tanzania pharmaceutical industries before allowing them to export.

> *"…. because, if neighboring countries want to procure medicines from our country, they come to inspect the industries for GMP compliance. Therefore, if there is no GMP compliance they cannot buy our medicines nor allowed to export."* (P7, male aged 37 years old, working experience of 7 years).

Despite the GMP implementation by the regulatory authority, the participants from pharmaceutical industries complained on the inspection process; lack of consistence on the observations during inspection. This caused hardship in addressing queries raised, hence limiting GMP certification of local industries.

> *"Ooooh! A lot of challenges. When one inspector comes he says this little crack there must be rectified. All right, we'll do it. We did the crack coloring. The other says the color is different… one inspector says, you must have it this way. The other inspector comes says no, according to that one, it should be this way. So there is no consistent of GMP inspection…." (*P1, Male aged 96 years old, working experience of 56 years).

iii. High cost of GMP implementation

GMP implementation was found to be costly. It requires setting up of high standard facility and dedicated equipment for production of quality products. Most of local pharmaceutical industries could not afford.

> *"You need to have a dedicated equipment for manufacturing activities which meet standards for producing quality products. So you need fund to buy that equipment. Now, since the GMP requires qualified equipment, calibrated equipment and to those activities needs outsourcing, for example, in our aspect, we incur cost."* (P4, Male, aged 35 years of age, working experience of 3.5years).

> *"…there is a challenge with the capital, GMP is costly, so it affects the operation of the manufacturers."* (P3, Male aged 53 years of age, working experience of >10 years).

iv.Lack of skilled personnel to implement GMP

Majority of participants who were interviewed reported lack of awareness among the technical personnel on GMP activities. Indeed, they reported lack of skilled technical personnel to implement GMP in the local pharmaceutical industries.

> *"Mainly they have a challenge on the technical part for the personnel, majority of the personnel are not aware of the GMP aspects, even if they know it, but not that much good. As a country, we don't have industrial pharmacists. So that's the main challenge…."* (P3, Male aged 53 years of age, working experience of >10 years).

v.Availability of GMP training program

Regulatory authority confirmed on the training programs for GMP inspectors. This helped in building the capacity of inspectors. The support is received from international organizations such as World Health Organization. The authority collaborates with high education institutions in training GMP for regulatory and technical personnel. Also, there exists on job training for GMP inspectors. This enables availability of competent inspectors.

> *"We have a mechanism across region…. Firstly, for personnel to be a GMP inspector or GMP audit, you have to go through training, specific training regarding GMP apart from the general training for all personnel, for example, pharmacist and other personnel. But we have specific courses on GMP internally and externally before being qualified to be a GMP inspector."* (P3, Male aged 53 years of age, working experience of >10 years).

vi. Provision of technical support on GMP

Technical support is provided to local pharmaceutical industries by the regulatory authority, and the key personnel are trained on GMP. Free consultative meetings are held with local industries. Similarly, supportive supervision is delivered to aid local industries upgrade to GMP certification.

> *"…we guide local manufacturers to build or construct the plant according to the GMP guidelines, we hold regular face to face meetings with these people. But also we provide training to key technical personnel so that they can produce product according to the guidelines because at the end we want product which is safe and of*

good quality…. we also connect them to the proper channel such as WHO to access guidelines on technical issues… also when they are importing we advise them on what machine and equipment is fit to the facility…." (P10, Male aged 54 years old, working experience of 15 years).

vii.Compliance to GMP

Non-compliance to GMP was noted to affect market of local products, also lead to closure of pharmaceutical industries. This affects the growth of local pharmaceutical industry. Only two pharmaceutical industries were noted to be GMP certified. Other industries comply to local GMP guidelines.

"Now we comply with the GMP principles largely from our own local regulatory authorities…. which are largely adopted from East Africa Community harmonization GMP practices, and also adopted from WHO…. We don't have valid GMP certificate, but we are under regular regulatory inspection." (P4, Male, aged 35 years of age, working experience of 3.5years).

viii.Perception on GMP standards

On contrary to the pharmaceutical industries, participants from regulatory authority perceived the implementation of GMP as not costly. They insisted that, GMP is all about documentation and depend on the type of product manufactured.

"GMP is not costly, is how you implement it, the knowledge you have to implement it because these are guidelines, are principles on how to manufacture the medicines. Also, GMP depends on the type of product, you are producing…." (P10, Male aged 54 years old, working experience of 15 years).

Participants from regulatory authority reported poor perception on GMP standard among the key players of local manufacturers. The manufacturers do not see the significance of investing a lot amount of money to meet GMP standards. Instead, they should be allowed to produce medicines which will facilitate the growth of the local pharmaceutical industries since they do not have enough capital.

> *"It's the poor perception of the players within the manufacturing facilities with regards to GMP standards. So they think, why should we invest a lot on GMP while we can manufacture and sell without following GMP standards. So that's a main challenge I can say."* (P3, Male aged 53 years of age, working experience of >10 years).

It was perceived that, the implementation of GMP have advantage as it increases product utilization and market due to quality and safe product. They perceived that, without GMP you cannot compete in the market and that affects local pharmaceutical industries which are not GMP certified. They stated, GMP increase public trust and enhance market reliability.

> *"GMP Compliance will give an indication of the quality of the product, which is going into the market, therefore, from there people will have the confidence on the product and actually utilization will improve because the large consumers of products give an indication of increase in demand of the product."* (P4, Male, aged 35 years of age, working experience of 3.5years).

The participants claimed that, GMP increase confidence of users due to consistence of manufactured products. Thus, products that are not consistent affects the market of the product hence local pharmaceutical industries. Poor quality and products that are not consistent are likely to lose customers.

> "*Yeah it is required in order to survive, in order to acquire confidence from users, the public, the product has to comply with the best of highest standard…. the product has to be consistent. You can't keep on changing the quality or the taste or the appearance which loses the interest of the customer. So you have to be consistent of what you are doing….. That's the policy of my company."* (P1, Male aged 96 years old, working experience of 56 years).

> *"...so the users like yourself, would say uh! It doesn't taste like before, something is wrong then you stop buying, this is gone substandard or is not standard."* (P1, Male aged 96 years old, working experience of 56 years).

4.4 Medicine Registration

i. Medicine registration procedure

The current medicine registration system is electronic by which the application can be done via online without submission of hardcopies. The local pharmaceutical industries have option of submitting their application either online or physically (hardcopies). The participants from regulatory authority stated that, the registration process have been improved compared to previous process that the applicant had to submit both online and hardcopy. It was noted that, the registration process follows various updated guidelines such as WHO documentation procedures, SADC joint assessment and the national assessment. Similarly, medicine registration is guided by national law and locally established standard operating procedures (SOPs). Comprehensive evaluation is conducted to ensure safe and efficacious medicines are registered. The provided registration certificate is renewed after every five years and the list of registered products are reflected in the institution website. The registration process is stepwise and takes up to one year to issue certificate of safety of the local product.

> *"First the product has to be registered, so you get initial registration certificate, from there, each year you have to retain the registration of the product so there is retention every year, and then certificate of registration is valid for five years, so you have to renew after every five years…and in between the five years if there is any variation in the registered medicine…then there is variation that will be happening in between the five years…"* (P2, Female aged 28 years old, working experience of 3 years).

There exists a technical committee to advice the director general on medicine registration. The committee is composed of various cadres to represent the medicinal products used such as medical doctors, veterinary doctors, herbalists and pharmacists. This ensures representativeness.

> *"…the technical committee is composed to different cadres just to mention few are medical doctors, pharmacists, veterinary doctors and herbalists, so all personnel representing the product we are regulating…"* (P2, Female aged 28 years old, working experience of 3 years).

Participants from regulatory authority reported the procedures are synchronized and streamlined such that the online system saves time. It was noted from regulators that the submission software is user friendly.

> *"Ah! Right now my opinion is that, we are in the right track, there is a lot more that have been done and we are doing it more efficiently, there is no delay in registration of product as long as the application have been submitted with all the supporting documents."* (P2, Female aged 28 years old, working experience of 3 years).

Despite the existence of updated guidelines and online system. Participants from pharmaceutical industries stated that the online system is not user friendly and is frustrating.

> *"So now that when they've gone everything online. And sometimes the online work sometimes doesn't work and it's very frustrating."* (P1, Male aged 96 years old, working experience of 56 years).

ii. Registration time

All participants from pharmaceutical industries claimed slow and long registration time which affected the local pharmaceutical production. It was noted that, it took up to six months of more for registering medicinal product.

> *"Takes too long…., six months sometimes. I have one product which is for Corona, immunity booster, we have made the whole thing, we submitted everything…. we are fighting 6months."* (P1, Male aged 96 years old, working experience of 56 years).

Contrary to pharmaceutical industries, regulatory author reported short registration time and that, the locally produced medicines are registered within short time than products from foreign manufacturers which was in line with the signed client service charter.

> *"We do align the client service charter which identifies for each procedure we are taking… the time I can't say it is long, but it is reasonable to ensure that assessment is done and responses are given to the applicant."* (P2, Female aged 28 years old, working experience of 3 years).

It was noted that, the essential medicines are registered within short time than generic products and products that are approved by other agencies such as United States Food and Drug Administration and European agencies.

> *"…there is a separate guideline for registration of essential drugs which is more compressed to shorten registration time, however the registration of generic and multisource drugs is a long procedure since we have to refer to the innovator documents…."* (P2, Female aged 28 years old, working experience of 3 years).

iii.Cost of registration

All participants confirmed that, the cost of registration of local products is low compared for foreign products. This was found to positively influence local production.

> *"…… the registration fee is low for all local manufactured products. This is to fasten and facilitate industrialization in our country…. the registration procedures are the same to imported products but time to give response is shortened."* (P2, Female aged 28 years old, working experience of 3 years).

iv.Challenges in dossier evaluation

The key informants from regulatory authority stated poor arrangement of documents from applicants as the main challenge they face during dossier evaluation. They further reported that, manufacturers do not know how to compile dossiers. Most of the applications received by regulatory authority from local industries are incomplete.

> *"The challenge is the arrangement of the documents……the submission system is composed of five modules, that's where the complication happens the arrangement is uses more time…most dossiers are incomplete."* (P2, Female aged 28 years old, working experience of 3 years).

> *"The challenges they are facing is how to compile the dossier, following the required format, that's the only challenge I am seeing."* (P2, Female aged 28 years old, working experience of 3 years).

The dossier evaluation undertakes a series of processes. It takes two to three weeks to complete a single dossier evaluation process.

> *"To evaluate one dossier takes two to three weeks to be completed, this is because the evaluation has stages, it starts with the first evaluation, second evaluation and then quality auditing so it has stages each stage can take two to three weeks."* (P2, Female aged 28 years old, working experience of 3 years).

v. Capacity building on registration process

The participants from regulatory authority confirmed that, since the system is new, they are providing training to key personnel both in the regulatory authority and pharmaceutical industries. There has been regular training on the current online registration system to build the capacity of technical personnel involved submission of the application. The training module is blended with other contents depending on the needs. Emphasis is provided to attend such training.

> *"The process of registration of medicinal product after being turned into online application…we are undergoing several training. So trainings are not much, but from the emphasis you have to attend."* (P4, Male, aged 35 years of age, working experience of 3.5years).

> *"I attended such training, GMP training. Part of the training was dossier medicinal product registration. So yeah, I can say gained training for registration process."* (P4, Male, aged 35 years of age, working experience of 3.5years).

Similarly, the regulators are receiving training in order to build their capacity on the new system of registration. In house and external training is provided to regulatory staff.

> *"We do get training every now and then according to the demand and what area to be improved."* (P2, Female aged 28 years old, working experience of 3 years).

4. 5 Environmental Factors

i. Lack of government support

Local manufacturers are complaining on the lack of support from the government and politicians. They have many challenges communicated to the government. However, there is no feedback.

> *"I have big fight with the government because it doesn't help us, there are too many problems." (*P1 Male, aged 96 years old, working experience of 56 years).

> *"... these are the issues, so we went to Dodoma and presented the paper to the Member of Parliament committee. All said yes, yes, you're right…. But that's full stop, no more action. So I'm trying to see what we can do. But these are the key problems." (*P1 Male, aged 96 years old, working experience of 56 years).

ii. Political will

Participants reported lack of political will on pharmaceutical industry. It was stated that, investors are afraid of establishing pharmaceutical industries in Tanzania due to lack of policy predictability. These affect promotion industrialization of pharmaceuticals.

> *"Some investors are complaining; For example, if today we talked like this, tomorrow after parliament session you find something have emerged, so I cannot predict of what will happen tomorrow…in such aspects some investors are saying no, if I cannot predict my tomorrow is not possible for me, my survival will be in danger… I cannot inject my money in such environment..."* (P9, Male aged 49 years old, working experience >10 years).

The informant from the Ministry responsible for Health reported on the existence of policy on pharmaceutical industry. It was acknowledged that, the previous policy was weak and it has been updated after receiving complaints from local manufacturers. Similarly, the National pharmaceutical plan is underdevelopment which aims to promote the growth of local pharmaceutical industries. It was reported that, due to the attractive conditions set forth in the current policy, new pharmaceutical industries are being established.

"We have pharmaceutical policy……one big area in pharmaceutical policy, is pharmaceutical industry…the role is to promote local pharmaceutical industry, and we are doing it very well…. some new pharmaceutical industries have been established…" (P8, Female, aged 50 years old, working experience >10 years).

iii. Taxation of packaging material

All the participants reported existence of high cost of packaging materials. This stated to increase the cost of production hence high cost of local products which consequently affect local industrialization.

"On the packaging materials still there are some debates… there are some packaging material on the medical products which are exempted, but some are not…." (P5, Male, aged 42 years old, working experience of 7 years).

Also, strict condition has been set by law to print name of the brand and manufacturers which is difficult for some packaging materials such as PVC. The printed packaging materials are exempted while failure to print the names and address are taxed.

"Packaging material is taxable, however now there is requirement that according to the amended law, that if the packaging materials are bearing the name of the main brands and name of the manufacturers there is exemption, but if you just import they are taxable." (P9, Male aged 49 years old, working experience >10 years).

However, local manufacturers are complaining on the condition of printing name and address on the package material, since it is difficult and expensive to print on materials such as PVC foils.

*"… [crackling sound, opening a package] …this is aluminum foil…. government says print the name and address of your companies here. The government says this is called the PVC foil, you must have your name on the foil. It's impossible! impossible! The whole world, nobody has a name printed on the PVC so they charge us more VAT…" (*P1 Male, aged 96 years old, working experience of 56 years).

iv. Regulatory challenges

The interviewed local manufacturers complained on the challenges they encounter from regulatory authorities. One of the main challenges they face is bureaucracy and less assistance from regulators.

> *"The [] has got guidelines for us to follow… but the guideline has some complicated issues in a sense that is easily written guideline to follow it, we get less assistance, we write…. they reject and tell us to read the guidelines and to look up the standard…. We asked for registration, they said no, finish and resubmit again, instead of telling us that we will send somebody to teach you how to do it, then we do it." (*P1 Male, aged 96 years old, working experience of 56 years).

> *"……so I said shame. You don't trust the pharmaceutical industry; they know what they're doing when they give a word… So I told them, if you don't help us, then I'll go to DG. Then I'll go to minister of health. Because I have every right as industry director to see that you help us. So they don't like me. They don't want me to go there. They refuse. But there is a little bit of bureaucracy. The bureaucracy is no good. Any industry if you have a bureaucracy, you ask people trouble…" (*P1 Male, aged 96 years old, working experience of 56 years).

The interviewed manufacturers also complained of delay in credit refund. It was reported that, there is no specific time for VAT refund. This affects the investment capital.

> *"There is no specific time because the payment of refund in the process is depends on the level of compliance, the verification process. So, it depends on the compliance of the tax payer does so, but there is no specific time."* (P6, Male, aged 40 years old, working experience of 5 years).

> "*Another challenge that they are complaining is on the credit refund, because they are told to pay the VAT and then apply for refund, so the refund takes a lot of time."* (P8, Female, aged 50 years old, working experience >10 years).

v. Incentives/promotions

Most of the participants acknowledged on the incentives and promotions from the government. They stated that, the active pharmaceutical ingredients, raw materials and finished products are not taxed. They stated that, currently the import duty has been reduced. Also, free export permit is issued and no tax or duties on export of local pharmaceuticals. The specialized machinery for production are tax free.

> *"Well! specialized equipment for the pharmaceutical industry, are also recognized under the value added tax schedule of exemption whereby once they are recognized and authorized by the [] authority they get the permission on importation. Also they enjoy exemption of zero rated."* (P5, Male, aged 42 years old, working experience of 7 years).
>
> *"We are in the industrialization drive and the pharmaceutical is one of the sector which has made us get a lot of attention from the government. They are enjoying exemptions, whereby on the development stage, they enjoy the 75% imported duty exemption on all the material they are using for the development stages."* (P5, Male, aged 42 years old, working experience of 7 years).

vi. Infrastructural support

a. Unreliable and expensive power supply

The interviewed manufacturers stated the source of electricity as one of the factor that hinder growth of pharmaceutical industries. They reported unreliable availability of power supply which necessitates use of fuel which is expensive. One of the reasons they provided was the monopoly of the power supplying company which is not held accountable. They insisted that the cost of power supply is high and is one of the big problems they are facing in daily operations- increase cost of production.

> *"If we talk of power supply [laughing] is a big problem. It is because of monopoly, there are no competitors of electricity supply. Only one company, you see! They are not held accountable even if electricity goes off. If you ask them, they just say, it is a normal thing, and life goes on. In short, poor electric supply highly contribute to poor industry development. Because if electricity is not available in a day, we opt for generator. Cost of fuel for a generator in a day is very high. So it affects us a lot…."* (P7, Male aged 38 years old, working experience of 7 years).

b. Unreliable and expensive water supply

Most of the participants reported unreliable source of water from the government agency. This necessitates them drain wells as source of water. Some, have underground tanks to keep water to ensure constant water flow. They reiterated to incur high cost in draining and keeping water underground. Similarly, the cost of water from the government agency is high which ultimately increase cost of production.

> *"We drain the water, we get the water from [] and store to the underground tanks for reuse. The [] source sometimes is not reliable. So we store in the underground 15 tanks and the other one goes into the direct loop of production…. Now the cost of running is very high …. but you have to undergo such process…"* (P4, Male, aged 35 years of age, working experience of 3.5years).

c. Existence of poor roads

Some of the participants stated existence of poor roads which makes the industry not accessible during the rainy season. They incur high cost of transportation of raw materials and products. increases cost of production and product price.

> *"I remember, one pharmaceutical company in ….is complaining about the road that cars can hardly pass during the rainy season… this can compromise production."* (P8, Female, aged 50 years old, working experience >10 years).

d. Expensive waste disposal process

Manufacturers reported to incur high cost in disposing wastes, either expired raw materials or products. They stated, waste disposal is a big problem and the system is not well established. They complained that, the process takes a lot of time and very high cost.

> *"Now waste disposition of drugs also I can say that it is costly because we have to undergo the whole regulatory activities of disposing the expired or unfit products or waste products. Now the whole process requires meeting people for inspection and people for site visiting. You see! So, all of these, the one who is disposing incurs the cost. It is costly, it is costly…"* (P4, Male, aged 35 years of age, working experience of 3.5years).

vii. The use of outdated machinery

All of the participants from pharmaceutical industries acknowledged the use of outdated technology in medicine production activities. They use semi-manual or semi-automated activities which prolonged the time required to complete one batch of products.

> *"We do use semi-manual…. not fully automated machines.... we produce only four batches of medicines in a whole day……the fully automated machines can produce one batch in one hour. You see! [laughing]."* (P7, male aged 37 years old, working experience of 7 year).

viii. Low production capacity

The participants argued that, the local pharmaceutical industry's' production capacity is low. This was due to the use of outdated technology which affected the production capacity. They insisted that, produced medicines cannot satisfy the local market demand causing limited exportation.

> *"…we can't produce enough to export." (*P1 male, aged 96 years old, working experience of 56 years).

ix. Unavailability of local expertise personnel

There is lack of skilled personnel. It was noted that, limited number of local technical personnel to work in pharmaceutical industries is available. They contended a notable gap in practical training despite the availability of graduate pharmacists. It was insisted that, the available pharmacists are knowledgeable in various aspects of pharmaceutical industry, however they lack exposure to industries during their undergraduate programs. Other participants alleged that, only few pharmacists are devoted to pharmaceutical industry thus, the undergraduate degree is not sufficient, has insufficient practical training. The few industrial pharmacists who are employed in industrial do not engage directly in production activities.

> *"There is an increase in emphasis of investment in pharmaceutical industries, but one challenge, which is still a very big challenge is to get the right technical personnel to be involved in the production activities."* (P4, Male, aged 35 years of age, working experience of 3.5years).

*"The foundation of the qualified persons is sufficient, but they need experience… we had to teach and train them… we employed one pharmacist who was very qualified and knowledgeable but did not have exposure to industries…" (*P1 male, aged 96 years old, working experience of 56 years).

"Currently we have to get the master graduate of industrial pharmacy which is very challenging, there are just few of them …those are posted in senior positions such as production managers or quality assurance manager and so forth, but in a low level production, most of them are casual workers. They're not very much technical personnel. They gain experience through train, on job training." (P4, Male, aged 35 years of age, working experience of 3.5years).

The private pharmaceutical industries are profit oriented and are not ready to sponsor their employee to undertake masters in industrial pharmacy and acquire advanced practical skills.

"Most of the investors are private and they don't want to sponsor their employee as it is expensive, what they are looking for is profit making…." (P8, Female, aged 50 years old, working experience > 10 years).

x. Availability of cheap imported pharmaceutical products

One of the challenges that was stated by all participants was the availability of cheap imported medicines. The imported products are widely available and cheap which is normally preferred by customers. Participants reiterated that, local manufacturers cannot compete with the imported products; the imported products satisfy the market needs, are safe and efficacious. Thus the locally manufactured medicines do not have the market competitive advantage.

"The main challenge facing local pharmaceutical industry is availability of imported medicines… For example, when you manufacture paracetamol at the cost of Tsh.1100…. many wholesalers are available, can import at cost up to Tsh. 900…. You see! The difference of Tsh.200." (P7, Male aged 38 years old, working experience of 7 years).

*"…. but the worst scenario is that imported products affect the local production because they don't pay duty, they don't pay VAT where they buy, they pay nothing. It all comes at a price with these people cannot meet. So these are the problem." (*P1 Male, aged 96 years old, working experience of 56 years).

"Local manufacturers cannot compete with imported products, because the imported pharmaceuticals are not taxable and the reason is, when we started there were only few industries. Charging duties and taxes on the imported pharmaceuticals implied that, the cost of this pharmaceuticals could have been very high for anyone to afford…." (P9, Male aged 55 years old, working experience >10 years).

ix. Dependence on imported products

It was found that, there is conflict of interest among the local manufacturers. The local manufacturers are at the same time distributors of imported products which may limit their commitment to expand local production. Therefore, they enjoy importation. This practice affects local production.

"First thing first, most of the raw materials are imported, very few are available locally. You can find, out of 100 commodities, 95 are found abroad. Even if you will procure locally, they are sourced from abroad. Therefore, their price is high." (P7, Male aged 38 years old, working experience of 7 years).

x. Lack of capital

Most of the participants from industries stated lack of capital as one of the challenges that affect local production. Most stated to fund the facility from private servings and bank loan with high interest rates. They revealed lack of soft loans from the government, which affected the extent to which they invest in pharmaceutical industry.

*".... I spent my whole money, I borrowed from the bank…. the bank knows me very well….and I pay interest on it, 14%...no incentives from the government…... I pay the interest, everything I get, I have to pay the bank, this restricts from expanding." (*P1, Male aged 96 years old, working experience of 56 years).

CHAPTER FIVE

5.0 DISCUSSION

The chapter provides a discussion of the study findings based on established themes and sub-themes relevant to study questions and objectives. The study examined the influence of pharmaceutical regulatory framework on promoting of pharmaceutical industries in Tanzania. The implementation of GMP guidelines, registration system and environmental enabling factors such as taxation, government involvement and infrastructural support were examined. We found inadequate implementation of pharmaceutical regulatory framework by which led to low turnover rate of investors and commitment to invest in pharmaceutical industry. This has led to low production capacity and continue dependence on importation of raw materials as well as finished pharmaceutical products.

On the other hand, the production capacity of the existing local pharmaceutical industries was low to meet the national medicines demand. This exacerbated the dependence on importation. This is in agreement with previous study conducted by Anyakora to evaluates benefits against the cost of investing in GMP, using a Nigerian pharmaceutical company, Chi Pharmaceuticals Limited, as a case study. This paper also discusses how to drive more local manufacturers to invest in quality to attain GMP compliance; and proffers practical recommendations for local manufacturers who would want to invest in quality to meet ethical and regulatory obligations, which found more than 70% of pharmaceuticals in sub-Saharan Africa, including Tanzania, were imported [39].

This was explained to be due to weak local industries partly contributed by use of outdated machinery which have limited production capacity. It was also found that, local manufacturers depended at large on importation of raw materials and packaging materials which increase the cost of production, hence, market disadvantaged compared to the imported medicines which were available at cheap prices. This was similar to a study which was conducted by Warren on; local production industrial policy and Access to medicines which reported 40-50% of the cost of medicines sold is dedicated to raw materials [40].

Utility supply is another factor that was identified to humper local pharmaceutical industrialization in Tanzania. Manufacturers complained of high cost of electricity and water which, on the contrary, was also not reliable. A study made by world health organization (WHO) on; Improving access to medicines in developing countries through technology transfer and local production which showed growth of industry requires availability of cheap and reliable power and water sources. These decrease the production cost, hence, the increase in production capacity of cheap and equally safe and quality products [41].

It was also observed that the production cost was further increased by the cost of waste disposal which was found to be high. Waste disposal is managed by National Environment Management Council (NEMC) and supervised by TMDA which charges TZS fourteen million for single disposal of industrial waste. The cost was found to be entirely covered by the manufacturers. This practice is common in low or middle income countries by which the cost of waste disposal has been found to be high compared to developed countries where the cost of waste disposal is shared among manufactures and contributed by either Local Authorities, Pharmaceutical Industry Groups or Government a study which was conducted by Bunagua on; Aspects regarding the pharmaceutical waste management in Romania [42]. The developed countries have been the main exporter of cheap medicines in the country which is contributed partly by the incentives given by their mother countries.

Lack of adequate number of skilled technical personnel in industrial pharmacy was among the challenges that was sited to affect development of pharmaceutical industries in Tanzania. Among the reasons for this were lack of committed pharmacists to work in pharmaceutical industries as well as inadequate practical training at collage level. It was found that pharmacists were theoretically knowledgeable on industrial issues, however they did not have adequate exposure in industries. This was in line with the study by Manaka who studied bachelor of pharmacy industrial training: performance and preceptor perception, in which they described the importance of including industrial practical training as it provides the hands-on experience [43]. Also, it was revealed that, investors are not ready to sponsor technical personnel for further studies in order to improve their skills. Lack of technical personnel not only affected local production capacity but also GMP compliance. Compliance to GMP standards requires well trained and skilled technical personnel.

GMP system exists in Tanzania and the local regulatory authority has the capacity to reinforce GMP guidelines. All participants acknowledged on the presence of local, EAC harmonized and WHO GMP guidelines. These guidelines are implemented in Tanzania as part of the regulatory action to ensure that manufactured products are safe and of acceptable standards. Local pharmaceutical manufacturers in Tanzania struggles well to implement requirements of GMP using the regulatory guidelines already in place; and they receive regular inspections from the TMDA. A study conducted by Tauqeer identified that manufacturing facilities operated under different GMP standards and interpretations, pointing towards an absence of harmonization in quality standards across the industry [44].

In order to raise levels and number of facilities with GMP compliance status in Tanzania, interviewed regulators acknowledged the need for providing more training, technical assistance and guidance to local industries. It was, however, found that, compliance by most of pharmaceutical industries was a challenge; out of all pharmaceutical industries registered in Tanzania, only two complied to WHO GMP standards and the other two which were interviewed are still undergoing corrective and preventive action (CAPA) review process. These limit market competitiveness and exportation thereby contributing towards affecting the country's economy as shown by a study conducted by Kaplan [40].

The manufacturers and most of regulators stated that, compliance to GMP standards is costly undertaking. The required equipment's and setting up of the factory is expensive. This was made worse by the lack of capital as noted by the interviewed manufacturers. This is similar to the study conducted in Nigeria to evaluate Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer [39]. It was found in the study that although GMP is expensive, it ensures availability in the market of safe and quality products and has high cost-benefit [39]. Also, as noted in our study shortage of technical personnel which is similar to a study done in Nigeria which observed same challenges as shortage of technical personnel, inadequate training and inconsistence inspection observations by inspectors, as well as poor perception on GMP by manufacturers.

Similar challenges have also been reported elsewhere where lack of commitment of manufacturers to invest in GMP, poor regulatory control has as well been reported [44,45]. It has been documented that most developing countries are faced with lack of regulatory capacity, lack of expertise and capital to enforce GMP [39,41,44]. This jeopardizes the implementation of implementation of regulatory framework in low-middle income countries.

Manufacturers complained on the medicine registration process including, submission system being complicated as well as time (takes long time to register). These were contrary with the views from regulators who claimed that the system is easy to use and takes short time to register locally manufactured medicines. In Tanzania, there has been notable changes from analogy system to electronic or online system. This is similar to the changes on the submission system which is currently electronic and no hardcopy submission of the dossier is required. These changes have been thought to facilitate timely processing of the applications, hence, registration. Most participants confirmed that, registration takes up to six (6) months. However, one participant from industry claimed that, his product has taken almost five years since initial submission. Long registration time has been noted in other African countries including Kenya and Ghana, whereby the median review time takes up to 25 and nine (9) months respectively. The time ranges are consistent with previous WHO report which reported review period ranged from three (3) months to five (5) years [46]. Long registration reviews and registration periods may hinder the effectiveness of regulatory framework in local pharmaceutical industrialization. It was further found that, delay in product registration was due to incomplete submission of documents by manufacturers. This situation of incomplete submission was also found in a study conducted by Kaplan to facilitate growth of local industries which highlighted that some manufacturers of API do not furnish full documents which are necessary in product registration, hence, delay in registration. The cost of registration for local products was said to be reasonable, which is in line with the suggestions given by Kaplan to facilitate growth of local industries [40].

Similar findings have been reported by Petra who studied access to high quality essential medicines is critical to sustainable development. However low- and middle-income countries struggle to ensure access to all medicines on their national essential medicines lists and concluded that the cost of registration is not a barrier to registration of locally manufactured medicines [47].

There are incentives that are given to the local manufacturers such as tax exemptions on raw materials and specialized equipment's for production. These facilitates rapid growth of local pharmaceutical industries and promote the competitiveness in the market by assuring availability of locally manufactured cheap medicines. However, there were complains on high tax rate on the packaging materials. Taxation of packaging materials increases the cost of production which is reflected on the high prices of locally made medicines compared to the imported ones. This lead to poor marketing of local medicines to customers, thereby customers may end up affording the imported medicines as study conducted by Kaplan [40].

Manufacturers complained lack of government support and bureaucracy from regulatory authorities. These deterred implementations of Health policy which is very essential to ensure conducive environment for establishing pharmaceutical industries. Since there was no support from the government, lack of awareness on policy, hence, resulted in fear of investment among investors. These dissuade development of pharmaceutical industries in Tanzania. Similar observations have been documented and were regarded to be the cause of poor economic development in low- or middle-income countries. A study done by Sarvajayakesavalu, on Sustainable Development Goals (SDGs), to develop a global vision for sustainable development, balancing economic growth, social development, and environmental protection over the next fifteen years [48].

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6. 1 Conclusion

It was revealed there exists a pharmaceutical regulatory framework in Tanzania which involved products registration, GMP, facility inspections and environmental factors.

However, this study observed that, the growth of pharmaceutical industries in Tanzania is slow and only few new industries have been established. There is poor implementation of the core components of pharmaceutical regulatory framework by the manufacturers including complying to GMP and registration system requirements. The study found that, the medicine registration system is available and easy to use but manufacturers find it hard to practice. Also, the study found that, the slow pace of industrialization is contributed by unreliable utilities supply, support, lack of technical personnel, high cost of production, poor government support, lack of awareness on policies, dependence on importation of raw material as well as taxation of packaging materials.

All these leads to poor production capacities that results in country's continued dependency on importation of pharmaceutical products. Local pharmaceutical industries ultimately end up contributing less to the economy.

6. 2 Recommendations

Four levels of recommendations were obtained from the study:

I. REGULATORY AUTHORITY

- Regulatory authority should continue providing assistance and technical support to local pharmaceutical industries.
- The regulation should set minimum criteria for skilled personnel to every newly established local pharmaceutical industries. This will ensure competent and skilled personnel are available in the industries.
- The regulatory authority should raise awareness on GMP among key players of local pharmaceutical industries and other government agencies which are involved in pharmaceutical industry.

- The regulatory authority should improve the waste disposal system. Should establish a central system/incinerator for disposal of expired raw materials and finished products such that, local industries will submit the unfit products and pay prescribed fee for the regulator to dispose instead of the current disposal system which is expensive.

II. High education pharmacy training institution

- Improvement to the pharmacy degree curriculum to include practical training on industrial pharmacy in bachelor degree of pharmacy

III. Local pharmaceutical industry

- The local pharmaceutical manufacturers should follow the proper communication channel to the Government to register challenges they are encountering.
- The manufacturers should comply with the registration process as required in the appropriate guidelines and the online system.
- The local pharmaceutical industries should invest in GMP compliance.
- The local pharmaceutical industries should sponsor their technical personnel for continued education training in order to improve their skills.

IV Policy makers

- The government to improve incentives for local pharmaceutical industries.
- Health Policy should restrict importation of medicines that are widely produced local

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APPENDICES

Appendix I: Assessment Guide for pharmacist in Pharmaceutical Industries in Tanzania

THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No ……

Name of interviewer ……

PART A: Administrative Information

Name of Industry……

Year started…….....

Location…….

Title of the Interviewee …….

Age …….

Level of Education……

Working Experience……

PART B:

1. What is the type of industry?

   a. Private only

   b. Government owned

   c. Both

2. What was the source of capital?

   a. Bank Loan

   b. Government support

   c. Saving

3. What type of products are you manufacturing?

4. Tell me about your products which are registered by TMDA?

5. Tell me about your products which used domestically only? Export only? Or both?

6. What about implementing principles of Good manufacturing practices (GMP)? How about other quality system?

7. GMP, which standard do you comply with? (Local/international? Mention)

8. Tell me about your valid GMP certificate?

9. In your opinion if well implemented GMP, will it reduce our high dependency on imported pharmaceutical?

10. A well implemented GMP can motive local industrialization?

11. What is the role of pharmaceutical regulatory framework in supporting your industry?

12. What are the challenges you are facing in implementing GMP?

13. What other factors within Government, supports your industry?

14. Good Manufacturing Practices and enforcement of standards affect your industry?

15. How does the availability and cost of utilities affect production of essential medicines? Probe on:

- Power
- Water
- Waste disposal

16. How many dossiers have you submitted at TMDA for registration? (in numbers) and among them how many have been registered?

17. Tell me about time allocated for medicine registration process convenient?

18. Tell me about your professional training, how adequately prepared you to review dossiers for registration purpose?

19. How about any training on dossier preparation and compilation for registration purpose? explain where and for how long?

20. What information that are required to be submitted before dossier can be evaluated? explain

21. Tell me about medicine registration process is? please explain

22. What information are required to be submitted in the dossier for generic products?

23. What challenges do you encounter during medicines registration process?

24. In your opinion what should the TMDA management do in order to efficiently and effectively improve the process?

25. Tell me about, technical and production staffs available locally?

26. How about import duties on pharmaceutical ingredients packaging materials and equipment?

27. Give your opinion on how to increase the production of essential medicines in to meet the need.

28. In your opinion, what factors played a vital role in promotion or decline of pharmaceutical Industry?

29. How about educational system that can supply trained workers?

30. What suggestions can develop pharmaceutical industries?

31. What challenges are you facing?

32. What type of government support due you have to motivate local production?

33. What's your opinion on taxation system here?

34. Why do we think we are very highly dependent on importation of pharmaceuticals?

35. Give your opinion, how does the current pharmaceutical regulatory framework effect pharmaceutical industrialization?

Appendix II: Assessment Guide for qualified Pharmacist in Tanzania in TMDA
THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No……

Name of the interviewer ……

PART A: Administrative Information

Name of Ministry/ Authority……

Title of Interviewee…….

Location ……

Age …….

Level of Education……

Working Experience……

PART B

1. What medicines registration process is all about?

Probe on;

- The history when it started,
- Current situation and
- Future plans
- His experience on medicines registration

2. What are challenges of medicines registration?

Probe on;

•time taken for assessment of dossier

•comply with regard to registration guidelines

•composition of committee members

•update of registration guidelines

•update list of registered medicines

3. What is the status of laws on pharmaceutical registration?

4. Tell me about system for medicine registration? A basic authorization procedure? A full registration procedure? Is periodic renewal required?

5. In your opinion what should the TMDA management do in order to efficiently and effectively improve the process?

6. What challenges do you encounter during medicines registration process?

7. How about medicine registration based on an assessment of a medicine's efficacy, safety, quality and truth of packaging information?

8. Tell me about different registration procedures for essential medicines, generic products, multisource drugs, or imported products from selected countries?

9. Time take to complete process of registration of new medicine produced locally? And its fees?

10. What are your process in dossier in section dealing with stability and bioequivalence studies?

Probe; if they enforce local manufactures to perform these studies

11. How is dossier submission manually or Ectd?

12. What type of software used to upload dossier? And if name?

13. Tell me about manufactures submission bioequivalence and stability studies documents?

14. Tell me about manufactures facing any overlapping of mandates during dossier submission?

15. How long does it take to grant approval on safety and quality of drugs?

16. What challenges are TMDA facing in Dossier?

17. What challenges are the manufactures facing in Dossier?

18. How do you describe the support you get from the management?

19. How much are you satisfied with your dossier evaluation payment?

20. How often do you encounter dossiers that are insufficiently submitted resulting in Rejection or queries being raised?

21. Was the registration guideline reviewed/updated recently within last 12 months? If yes, explain if newly updated version comply with the current situation of medicines registration criteria of the WHO and other regional harmonization policy?

22. During medicines evaluation, how are the SOPs?

23. How long do you normally take to evaluate one dossier?

24. Have you received any training on medicines evaluation/assessment? If yes, explain where and for how long?

25. Tell me about the importance of using standard operating procedure (SOP) during Medicine evaluation? Please explain when it was last reviewed

26. Which are the important information required to be submitted in the dossier for generic Products?

27. In your opinion do registration has influence on promotion of pharmaceutical industrialization?

28. In your opinion what would be the first action that you would take to improve medicine registration process in Tanzania

29. According to your experience how can we developed pharmaceutical industrialization in Tanzania

30. Why do you think we are highly dependent on imported pharmaceutical products?

GMP

1. How TMDA systems and capacity to assure product quality through GMP and enforcement of standards?

2. Tell me about mechanisms exist for control of pharmaceutical personnel and for manufacturing?

3. How many inspections are done on manufactures for GMP?

4. Tell me about audit system to evaluate the inspection system?

5. What measures exist for enforcement of pharmaceutical laws and regulations for GMP? Are they enforceable administratively or through court actions?

6. How many pharmaceutical industries implemented GMP?

7. What challenges are local pharmaceutical industry facing in implementing GMP?

8. To what extent GMP effects the production of medicine in Tanzania?

9. How poor GMP implementation has effect on growth of pharmaceutical industries?

10. Poor GMP implementation, can this make Tanzania more dependent on importation?

11. In your opinion if all industries are well GMP implemented will it reduce our high dependency on pharmaceutical importation?

12. What type of GMP standard do we follow in Tanzania?

13. What challenges is TMDA facing in regard with GMP?

14. In your opinion GMP plays role in availability of safe, and high efficacy medicine in TZ?

15. Some pharmaceutical faces high cost of GMP, in your opinion is it the cause of less promoting of local industries?

16. Tell me about skilled worker who can comply with GMP procedures?

17. How about pharmaceutical industries premises comply with GMP Standard?

18. What training programs for personnel?

19. Pharmaceutical machines /equipment comply with GMP standards?

20. What are the Documentation of procedures and Documentation of process of GMP?

21. Local pharmaceutical industry how they handle finished and primary product in term of GMP compliance?

22. In your opinion, GMP implementation influence the promotion of local pharmaceutical industrialization?

23. From your experience how can Tanzania motivate local pharmaceutical industrialization?

24. In your opinion, poor GMP implementation makes Tanzania dependent on importation?

Appendix III: Assessment Guide for government Qualified Pharmacist in Tanzania in Medical Store Department (MSD)

THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No…… Name of the interviewer ……

PART A: Administrative Information

Name of Ministry/ Authority……

Title of Interviewee…….

Location ……

Age …….

Level of Education……

Working Experience……

PART B

1. What are the policy regarding medicines policy, medicines pricing and procurement? Probed on;

- Presence of National Medicines Policy
- Presence of policy for medicines pricing control
- Presence of guidelines for medicines procurement process

2. What are challenges your facility face during the procurement of medicines.

3. What do you think? Probed on

- Cost of procurement
- Price of medicines
- Delivery time
- Quality of the products

4. What types of procurements which you have?

5. Which agency is responsible for awarding tenders?

6. How is your tendering process?

7. How many tenders do you have annually and types of tenders?

8. Tell me about tenders only for local manufactures?

9. What are the total procurement of medicine annually?

10. Probe; increasing or decreasing from past years to up to date?

If decreasing or increase probe;

•on reasons and why happening?

11. There were studies made showed very high dependency on importation? Why?

12. Tell me any future plan to deal with situation of increasing of pharmaceutical imports?

13. from your total procured medicine, what's the % of locally procured and % of imported procured?

14. Tell me about procured medicines importation which have been locally produced?

15. Tell me about procured medicine comply with TMDA guidelines? Suppose local manufacture medicine production does not comply TMDA guidelines do you import the product?

16. How do you support local pharmaceutical industrialization?

17. How about procurement process have easy procedures? Probe

•Taxation procedures and its cost

18. What are Tax exemptions on procured products? Probe on %

19. What's the % of tax on imported pharmaceuticals?

20. What about time taken during port clearance process?

21. Why do you think we are highly dependent on importation of pharmaceutical product?

22. How do you ensure the procured product are safe for public use?

23. How do you motivate local pharmaceutical industries?

24. What are the government incentive given for local industries?

25. What challenges do you think the local manufactures are facing?

26. How procurement of medicines effects local production?

27. In your opinion why do you think we don't have growth in pharmaceutical industries?

28. Tell me about the influence of pharmaceutical regulatory framework on the promotion of local industrialization?

Appendix IV: assessment guide for government officials in MOHCDGEC (drug policy department)

THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No…… Name of the interviewer ……

PART A: Administrative Information

Name of Ministry/ Authority……

Title of Interviewee…….

Location ……

Age …….

Level of Education……

Working Experience……

PART B: MOHCDGEC (DRUG POLICY DEPARTMENT)

1. What are the main issue addressed by pharmaceutical policies in recent past a current policy?

2. What are the polices in place, Probe on;

- Since when are they in place
- Practicability
- Hinder pharmaceutical production?
- Any suggestions regarding the laws and policies

3. What efforts have made to encourage more production of medicines in Tz?

4. What about financial resources available to retain skilled workers?

5. To what extent has the government drug policy affected the growth of pharmaceutical firms in Tanzania?

6. How can government drug policy enhance the growth of pharmaceutical manufacturing industry in Tanzania?

7. In your opinion, what drug policy should the government put in place to enhance the promotion of local pharmaceutical manufacturing in Tanzania?

8. What about national medicine policy approved by the government? Is the policy suitable to regulate the market? When it was last updated?

9. Tell me about any legislation by the government for the growth of the pharmaceutical manufacturing in Tanzania?

10. Tell me about the government offer encouragements to local pharmaceutical manufacturing firms aimed at enhancing their growth?

11. in your opinion, what legislation should the government put in place to enhance the

Growth of pharmaceutical manufacturing in Tanzania?

12. Why do you think local industries in the country do not produce to meet the needs of essential medicine in the country?

13. Probe on;

- Capital
- Government tax on imported ingredients
- Lack of skilled personnel
- Poor government support

Appendix V: Assessment Guide for Government Officials in Tanzania Revenue Authority (TRA)

THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No…… Name of the interviewer ……

PART A: Administrative Information

Name of Ministry/ Authority……

Title of Interviewee…….

Location …….

Age ……..

Level of Education……

Working Experience……

PART B

1. Tell me about duties or import controls on? And percentage?

    a. Active pharmaceutical ingredients (API)?

    b. Inactive pharmaceutical ingredients and other raw materials?

    c. Packaging materials?

    d. Specialized pharmaceutical equipment/ machinery?

    e. Finished Pharmaceutical imported products?

2. What efforts have made to encourage more local production of medicines?
3. What promotion/incentives is given for local pharmaceutical manufacturing investors?
4. What are the exemptions on imported pharmaceutical products? Probe; on percentage
5. What financial incentives are given to pharmaceutical industrial investors? Are industrial promoting funds available (access to start-up capital)?
6. How about export incentives for pharmaceuticals local produced? Tax exemption?

i. Probe; on percentage?

7. What provisional tax applied on investors before running the industry? how do you motivate it? because this can cause investor to increase his capital.

8. How long does it take for VAT return period for manufacturers (product)?

9. Capital gain tax(CGT), are there any instalments payments? Any Exemptions particularly on Pharmaceutical investors? And how is it evaluated (any procedures for evaluation)?

10. What's the percentage city services levy on product? Any exemption on it? is it applied on pharmaceutical industries?

11. How about free zones in Tanzania? What are the services providing and exemptions?

12. Worker compensation fund (WCF) tax is it positive addition/ helpful for pharmaceutical manufacturing?

13. Skills development levy (SDL) tax is it imposed on pharmaceutical industry? Exemptions on it?

14. PAYE tax is this not overload on investor/ local manufacturers?

15. What exemptions or Grace period for overall tax payment on employee/workers/staff?

16. How about Stamp duty on local manufacture/investor? Any exemptions and motivations.

17. Tax on margin? Percentage %?

i. Probe; if its high or low percentage?

18. What plans on how to motivate local manufactures / investors?

19. How do you think local pharmaceutical manufacturing can be developed?

Appendix VI: Assesment Guide For Government Officials In Tanzania Investment Center(TIC)

THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

Code No…… Name of the interviewer ……

PART A: Administrative Information

Name of Ministry/ Authority……

Title of Interviewee…….

Location ……

Age …….

Level of Education……

Working Experience……

PART B

1. Tell be about duties or import controls on? And percentage?
    - Active pharmaceutical ingredients (API)?
    - Inactive pharmaceutical ingredients and other raw materials?
    - Packaging materials?
    - Specialized pharmaceutical equipment/ machinery?
    - Finished Pharmaceutical imported products?

2. What efforts have made to encourage more local production of medicines?

3. What promotion/incentives is given for local pharmaceutical manufacturing?

4. What are the duty exemptions on imported pharmaceutical products? If yes probe on percentage?

5. What financial incentives are given to pharmaceutical industry? Are industrial promoting funds available (access to start-up capital)?

6. Tell me about export incentives for pharmaceuticals locally produced? Is there Tax exemption?

Probe; on percentage?

7. What provisional tax applied on investors before running the industry? how do you motivate it? Because this can cause investor to increase his capital.

8. Tell me about free zones in Tanzania? What are the services providing and exemptions?

9. What are the government support on local pharmaceutical manufactures?

10. How about infrastructure and power supply? What's the situation on local manufacture's?

11. What tax exemptions on pharmaceutical equipment's?

12. What are the funding resources?

13. What are the training programs for skilled workers?

14. Tell me about the availability of local experts?

15. In your opinion why we are not very developed in pharmaceutical industrialization?

16. What plans on how to motivate local manufactures / investors?

17. How do you think local pharmaceutical manufacturing can be developed?

Appendix VII: Consent form (English version)

STUDY PARTICIPANTS INFORMED CONSENT FORM

TITLE: THE INFLUENCE OF PHARMACUTICAL REGULATORY FRAMEWORK IN PROMOTION OF PHARMACEUTICAL INDUSTRALIZATION IN TANZANIA

NAME OF INVESTIGATOR: RANA AHMED SAADA

ADDRESS: MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

P.O BOX 65001, DAR ES SALAAM

Identification number……

Introduction:

Hello! This consent form contains information about the research named above. In order to be sure that you are informed about being in this research, we are asking you to read or have read to you this consent form. You will also be asked to sign it or make a mark in front of the witness. You will be given a copy of this form. This consent form might contain some words that are unfamiliar to you. Please ask us to explain anything you might not understand.

Reason for the Research:

You are being asked to take part in this research that aims influence of regulatory framework in promotion of pharmaceutical industrialization in Tanzania.

General information and your part in Research:

If you agree to be in this research you will be required to participate in data collection. The Data collection will be conducted at the required site, therefore there will be no additional costs for traveling.

Risks:

We do not expect any harm to happen to you because of joining this study.

Benefits:

The information you give will contribute on improving the production of medicines locally in our country and therefore reduce dependency on importation.

Right to withdraw and Alternatives:

Taking part in this study is completely your choice. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty.

Confidentiality:

All the information and data collection obtained from this study will be used for the research purpose only, and will not be shared to anyone without participant cons

Who to Contact:

If you have any questions about your rights as a participant, you may call;

Principal Investigator,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65001, Dar es Salaam.
Rana Ahmed Saada.
Mobile Phone: 067-5523456
Email: rana.saada79@gmail.com

And

Main Supervisor of this Study,

Director of laboratory service at TMDA

Dar es Salaam.

Dr. Danstan Hipolite Shewiyo

Mobile Phone: 022-2450512/2450751

Email:dahishe76@yahoo.com

Declaration:

I, (ID number) have read the information available in this form.

All my questions have been answered. I agree to participate in this study.

Participant's signature: ……..

Signature of the researcher: ……

Date of signed consent: …….

Appendix VIII: Consent Form (Kiswahili Version)
FOMU YA RIDHAA KWA WASHIRIKI WA UTAFITI

MADA: KAZI YA MFUMO WA UDHIBITI KATIKA MAENDELEO YA VIWANDA VYA DAWA TANZANIA.

JINA LA MTAFITI: RANA AHMED SAADA

ANUANI:

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

S.L.P 65001,

DAR ES SALAAM

Namba ya utambulisho: _____

Utangulizi:

Habari! Fomu hii ya ridhaa ina taarifa juu ya utafiti kama ilivyotajwa hapo juu. Kwa ajili ya kua na uhakika juu ya kuhusishwa katika utafiti huu, tunaomba usome fomu hii ya ridhaa. Pia utaombwa kuweka sahihi au kuapishwa mbele ya shahidi. Utapewa nakala ya fomu hii. Formu hii ya ridhaa yaweza kua na baadhi ya maneno yasiyojulikana kwako, tafadhali tuulize tutakueleza chochote amabacho utakua hujakielewa.

Sababu ya kufanya utafiti:

Tunakuomba ushiriki katika utafiti huu wenye lengo la kuangazia juu kazi za mfumo wa udhibiti katika maemdeleo ya viwanda Tanzania.

Maelezo ya ujumla na ushiriki wako katika utafiti huu:
Ikiwa utakubali kua katika utafiti huu utahitajika kushiriki katika ukusanyaji wa data. Ukusanyaji wa data utafanyika katika eneo husika, kwa hivyo hakutakuwa na gharama za ziada za kusafiri.

Hatari kwa washiriki

Hatutarajii hatari yoyote kukutokea kwa ikiwa utajiunga na utafiti huu.

Faida

Taarifa utakazotupa zitachangia katika kuboresha uzalishaji wa dawa ndani ya nchi yetu na hivyo kupunguza kutegemea kutoka nchi za nje.

Haki ya kujiondoa na njia mbadala

Kushiriki katika utafiti huu ni chaguo lako. Unaweza kuacha kuashiki katika utafiti huu wakati wowote, hata ikiwa tayari umeshatoa idhini yako. Kukataa au kujiondoa kushiriki katika utafiti huu hakutahusisha adhabu.

Usiri

Taarifa zote zinazokusanywa katika utafiti huu zitatumika kwa dhumuni ya utafiti pekee, hazita tumika sehemu nyingine yoyote bila idhini ya mshirkiki.

Nani wa kuwasiliana

Ikiwa una maswali yoyote kuhusus haki zako kama mshiriki, unaweza kuwasiana na;

Mtafiti mkuu,

Chuo kikuu cha afya na sayansi shirikishi Muhimbili,

S.L. P65001,
Dar es salaam.
Rana Ahmed Saada
Namba:067-5523456
Barua pepe: rana.saada79@gmail.com
Na
Msimamizi Mkuu wa utafiti huu,

Mkurugenzi Huduma za Maabara TMDA

Dar es Salaam

Dr. Danstan Hipolite Shewiyo

Namba ya Simu: 022-2450512/2450751

Barua pepe: dahishe76@yahoo.com

Tamko

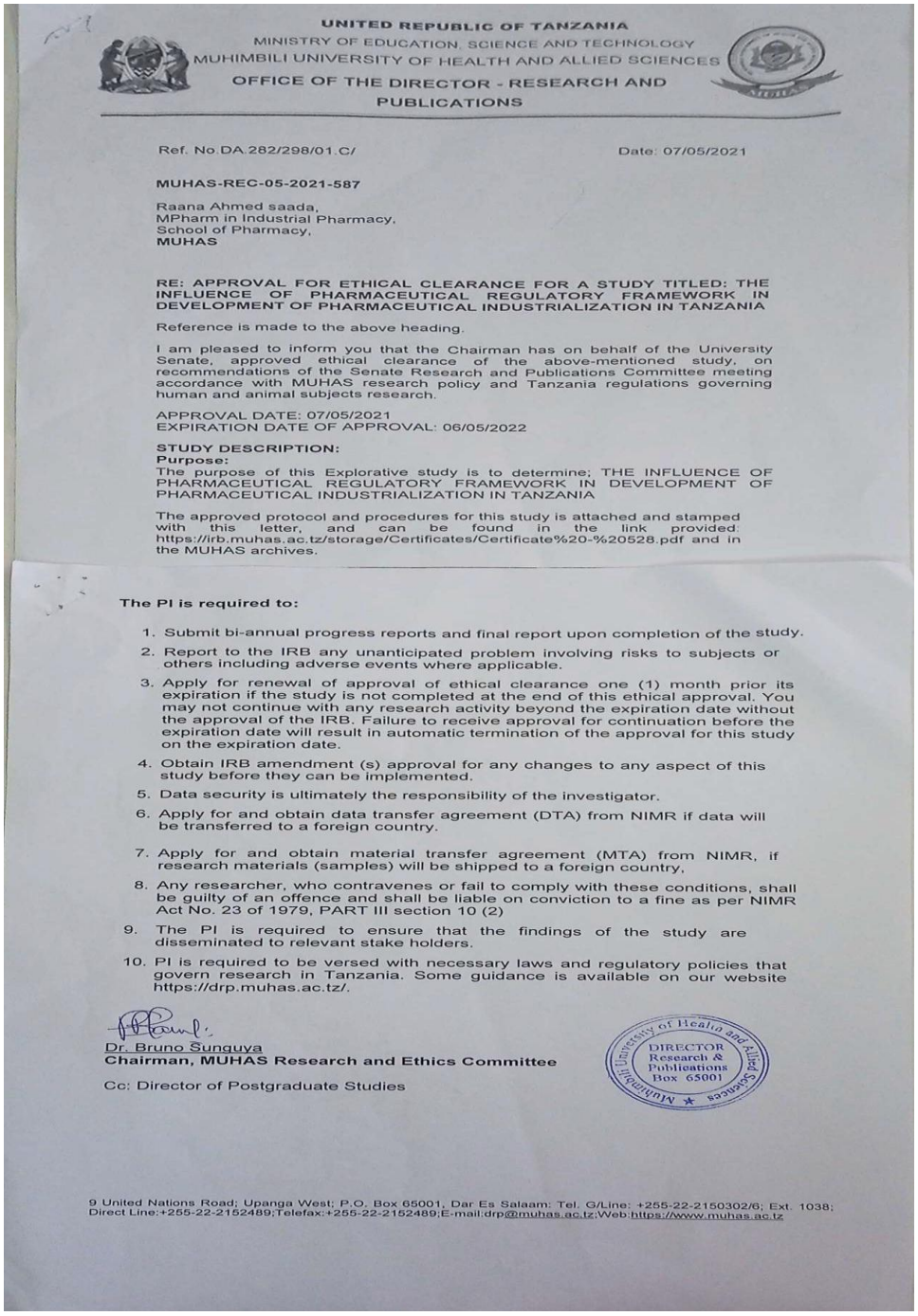
Mimi, (namba ya utambulisho) ……. nimesoma taarifa zote katika fomu hii. Maswali yangu yote yamejibiwa. Ninakubali kushiriki katika utafiti huu.

Jina la mshiriki…….

Sahihi ya Mtafiti…….

Tarehe iliyosainiwa…….

Appendix Ix: Ethical Clearance



UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

Ref. No.DA.282/298/01.C/ Date: 07/05/2021

MUHAS-REC-05-2021-587

Raana Ahmed saada,
MPharm in Industrial Pharmacy,
School of Pharmacy,
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: THE INFLUENCE OF PHARMACEUTICAL REGULATORY FRAMEWORK IN DEVELOPMENT OF PHARMACEUTICAL INDUSTRIALIZATION IN TANZANIA

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: 07/05/2021
EXPIRATION DATE OF APPROVAL: 06/05/2022

STUDY DESCRIPTION:
Purpose:
The purpose of this Explorative study is to determine; THE INFLUENCE OF PHARMACEUTICAL REGULATORY FRAMEWORK IN DEVELOPMENT OF PHARMACEUTICAL INDUSTRIALIZATION IN TANZANIA

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20528.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Cc: Director of Postgraduate Studies

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix X: Introduction Letter of Medical Stores department

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

Ref. No. HD/MUH/T.456/2019 — 7th May, 2021

DIRECTOR GENERAL,
MEDICAL STORES DEPARTMENT,
P.O BOX 9081,
DAR ES SALAAM-TANZANIA.

Re: INTRODUCTION LETTER

The bearer of this letter is Raana Ahmed Saada (HD/MUH/T.456/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Mpharm. Industrial Pharmacy.

As part of her studies she intends to do a study titled: **"The Influence Of Pharmaceutical Regulatory Framework In Development Of Pharmaceutical Industrialization In Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School Pharmacy, **MUHAS**
cc: Raana Ahmed Saada

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix Xi: Introduction Letter of ministry of industry and trade

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

Ref. No. HD/MUH/T.456/2019

7th May, 2021

PERMANENT SECRETARY,
MINISTRY OF INDUSTRY AND TRADE,
P.O BOX 2996,
DODOMA-TANZANIA.

Re: INTRODUCTION LETTER

The bearer of this letter is Raana Ahmed Saada (HD/MUH/T.456/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Mpharm. Industrial Pharmacy.

As part of her studies she intends to do a study titled: **"The Influence Of Pharmaceutical Regulatory Framework In Development Of Pharmaceutical Industrialization In Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School Pharmacy, **MUHAS**
cc: Raana Ahmed Saada

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix Xii: Introduction Letter of Development, Gender, Elderly and Children

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

Ref. No. HD/MUH/T.456/2019

7th May, 2021

PERMANENT SECRETARY,
MINISTRY OF HEALTH, COMMUNITY
DEVELOPMENT, GENDER, ELDERLY AND
CHILDREN (MoHCDGEC),
P.O BOX 743,
DODOMA-TANZANIA.

Re: INTRODUCTION LETTER

The bearer of this letter is Raana Ahmed Saada (HD/MUH/T.456/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Mpharm. Industrial Pharmacy.

As part of her studies she intends to do a study titled: **"The Influence Of Pharmaceutical Regulatory Framework In Development Of Pharmaceutical Industrialization In Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School Pharmacy, **MUHAS**
cc: Raana Ahmed Saada

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix Xiii: Introduction Letter of Tanzania Revenue Authority

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

Ref. No. HD/MUH/T.456/2019 — 7th May, 2021

DIRECTOR GENERAL,
TANZANIA REVENUE AUTHORITY,
P.O BOX 11491,
DAR ES SALAAM-TANZANIA.

Re: INTRODUCTION LETTER

The bearer of this letter is Raana Ahmed Saada (HD/MUH/T.456/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Mpharm. Industrial Pharmacy.

As part of her studies she intends to do a study titled: **"The Influence Of Pharmaceutical Regulatory Framework In Development Of Pharmaceutical Industrialization In Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School Pharmacy, **MUHAS**
cc: Raana Ahmed Saada

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix Xiv: Introduction Letter of TMDA

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

Ref. No. HD/MUH/T.456/2019

7th May, 2021

DIRECTOR GENERAL,
TMDA,
P.O BOX 31356,
DAR ES SALAAM-TANZANIA.

Re: INTRODUCTION LETTER

The bearer of this letter is Raana Ahmed Saada (HD/MUH/T.456/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Mpharm. Industrial Pharmacy.

As part of her studies she intends to do a study titled: **"The Influence Of Pharmaceutical Regulatory Framework In Development Of Pharmaceutical Industrialization In Tanzania".**

The research has been approved by the Chairman of University Senate.

Kindly provide her with the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School Pharmacy, **MUHAS**
cc: Raana Ahmed Saada

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz