Evaluation of the profile and standard of community pharmacy practice in Lesotho

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ABSTRACT

EVALUATION OF THE PROFILE AND STANDARD OF COMMUNITY PHARMACY PRACTICE IN LESOTHO

The profession of pharmacy is growing fast and like in many countries, Lesotho has seen more growth in community pharmacy practice. The increased number of community pharmacies should be matched with necessary regulations, policies and human resources. Lesotho faces the provision of pharmaceutical services being in the hands of mostly non-pharmacy personnel and obsolete statutes regulating the pharmaceutical sector. A lack of up-to-date laws governing the ownership and licensing of community pharmacies, as well as the practice itself endangers Basotho lives as unqualified people might operate community pharmacies. The lack of laws poses questions about the standard of pharmaceutical services provided.

The research project assessed the extent to which community pharmacies in Lesotho comply with the good pharmacy practice (GPP) guidelines of the World Health Organisation (WHO), as well as South Africa as a neighbouring country. The study evaluated the standard of premises, facilities and equipment of community pharmacies in Lesotho and lastly investigated the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

A descriptive, quantitative, cross-sectional study design was utilised, using survey forms and structured questionnaires as data collection tools.

The study consisted of two phases, namely the literature and empirical phase. A comprehensive literature review achieved the literature objectives. The empirical objectives were investigated through the following:

- **Phase I: An assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with GPP guidelines using a structured survey form.**

A structured survey form was used to assess the standard of pharmaceutical services and compliance with GPP guidelines in 36 community pharmacies in Lesotho.

- **Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho through face-to-face interviews according to structured questionnaires with community pharmacists and other stakeholders.**

The face-to-face interviews using structured questionnaires were conducted in the 36 community pharmacies (the same 36 community pharmacies selected for phase 1) with the staff member in charge of the pharmacy and 13 community pharmacy stakeholders.

The results of the study will be made available to decision-makers to be used as a reference regarding the current status of community pharmacy practice and may be used as a tool to improve the practice in general.

The research profiled community pharmacies in Lesotho and evaluated compliance with GPP standards successfully. In conclusion, community pharmacy practice in Lesotho has grown as evidenced by an increase in pharmacy human resources and the number of community pharmacies within the country. Pharmacy personnel increased from 60, including both pharmacists and pharmacy technicians, to 130 pharmacists and 80 pharmacy technicians in 2018 according to the Lesotho Medical, Dental and Pharmacy Council (LMDPC). Community pharmacies increased from 46 in 2010 to 60 in 2016 and 80 by 2019.

Community pharmacies in Lesotho did not comply with standards, as prescribed by the WHO and South Africa. This non-compliance includes registering pharmacy staff with the LMDPC, handling (storage and dispensing) of controlled medicines, community pharmacies' premises, and equipment standards (for example availability of washing area, fire extinguisher and cold chain monitoring).

Community pharmacy practice in Lesotho still faces regulation through outdated laws and therefore; the need for updating of such laws. There is also a need for continued inspections to ensure adherence and maintenance of standards of practice.

Key terms: community pharmacy, dispensing, Good Pharmacy Practice, standard, profile, Lesotho

ACRONYMS

CHAL	Christian Health Association of Lesotho
CHE	Centre of Higher Education
CPD	Continued Professional Development
DEA	Drug Enforcement Administration
DHMT	District Health Management Team(s)
DRA	Drug Regulatory Authority
DSM	Drug Storage Management
EDC	Electronic Drug Capture
EML	Essential Medicines List
EPI	Expanded Program in Immunisation
FIP	Federation of International Pharmacists
FDA	Food & Drug Association
GPP	Good Pharmacy Practice
HIV/AIDS	Human Immune Virus/Acquired Immune Deficiency Syndrome
HR	Human Resources
HREC	Health Research Ethics Committee
HSA	Health System Assessment
LMDPC	Lesotho Medical, Dental and Pharmacy Council
LPC	Lesotho Pharmaceutical Company
LRA	Lesotho Revenue Authority
LRCS	Lesotho Red Cross Society
MDR	MIMS Desk Reference

MDR-TB	Multi-drug resistant tuberculosis
MIMS	Monthly Index of Medical Specialities
MOH	Ministry of Health
MOHSW	Ministry of Health and Social Welfare
MOT	Ministry of Trade
MSH	Management Sciences for Health
MUSA	Medicine Usage in South Africa
NDSO	National Drug Service Organisation
NEML	National Essential Medicines List
NGO	Non-governmental organisation
NHTC	National Health Training College
NMP	National Medicines Policy
NMPC	National Medicines Policy Coordination
NMRC	Namibia Medicines Regulatory Council
NSTGs	National Standard Treatment Guidelines
NUL	National University of Lesotho
OBFC	One-Stop Business Facilitation Centre
PSI	Pharmaceutical Society of Ireland
QE II	Queen Elizabeth II
QMMH	Queen Mamohato Memorial Hospital
SADC	Southern African Development Community
SAMF	South African Medicines Formulary
SAPC	South African Pharmacy Council

SAS®	Statistical Analysis System
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
STGs	Standard Treatment Guidelines
WHO	World Health Organisation

DEFINITIONS

Business entity	an organisation that is opened to buy and sell goods. In this study an organisation is a community pharmacy, and the goods are medicines and medical supplies (Amador-Dumois *et al*., 2013:3).
Community pharmacy	a healthcare facility that specialises in providing pharmaceutical services to the community or people for convenience. Community pharmacy business involves buying medicines from wholesalers and dispensing to the public (Brian *et al*., 2015:33). Community pharmacies can also be referred to as 'chemists' or 'pharmacies' as well as 'retail pharmacy', but for this study, the term 'community pharmacy' is the preferred term.
Chain pharmacies	organisations where two or more pharmacies are operating under the same name and ownership. The business of chain pharmacies used distinctive branding across all outlets (Miller *et al.*, 2018.10).
Dispensing	the process of interpreting, reviewing of a prescription and the preparation as well as the provision of medicines and medical supplies to the named patient according to legal and regulatory requirements. It involves the provision of information by a pharmacist, or under the supervision of a pharmacist, to ensure the safe and effective use by the patient (Wiedenmayer *et al*., 2006:68).
Good Pharmacy Practice (GPP)	the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care to ensure that the patients make the best use of their prescribed medicines (Tiyyagura *et al.,* 2014:27).

Nature of the community pharmacy	refers to the character, type or kind of community pharmacy for example, sole ownership or chain type of community pharmacy.
Ownership	refers to whoever owns the business entity, and the owners have the option to choose which type of business entity they want to start (Amador-Dumois *et al*., 2013:2).
Pharmaceutical care	it is a patient-centred and optimal health outcome-oriented pharmacy care. It relates to the pharmacist's contribution to the care of individual patients to optimise their medicine use and improve health outcomes (Allemann *et al*., 2014: 553).
Pharmaceutical services	in this study, the dispensing of medicines and all other services which may be offered in a community pharmacy.
Premises	in this study, premises refer to the place where community pharmacies operate.
Profile	in this study, profile refers to the description or the outline of the community pharmacy status and practice in Lesotho.
Standard	in this study, standard refers to a guide and measure of the level of quality of the community pharmacy practice in Lesotho

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CHAPTER 1: INTRODUCTION AND RESEARCH METHODOLOGY

1.1 Introduction

This chapter provides an overview of community pharmacy practice in Lesotho as well as a description of the research problem, research aim and objectives, research methodology, statistical analysis and ethical considerations.

1.2 Background

According to the World Health Organisation (WHO) (WHO, 2011a:2), access to essential medicines and health products is critical for reaching universal health coverage, and these items are imperative to address health problems and improve the quality of lives. Essential medicines form an indispensable component of health systems in the prevention, diagnosis and treatment of disease and in alleviating disability and the functional deficiency.

Community pharmacies play a significant role in providing health and pharmaceutical care services in a country. Pharmaceutical care is defined by Hepler and Strand (1990:533-534) as "the responsible provision of drug therapy to achieve definite outcomes that improve a patient's quality of life". Pharmacists are health professionals whose professional responsibilities and accountabilities include seeking to ensure that people derive maximum therapeutic benefit from their medication (WHO, 2011b:313). They have to ensure that a patient's drug therapy is appropriately indicated, is the most effective available, is the safest possible, and is most convenient for the patient. Pharmaceutical care requires pharmacists to keep abreast of pharmaceutical science developments, professional standards and requirements, laws governing pharmacy and medicines, as well as advances in knowledge and technology relating to the use of medicines (WHO, 2011b:313).

The practice of pharmacy encourages safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related medical supplies for the prevention of illness, and the maintenance and management of health (Jesse, 2010: 577).

Community pharmacies in developing countries are one of the most important sources of advice on medicines (Goel *et al*., 1996:1155). Among the reasons that clients or patients indicated are ease of access, availability of medicines, and quality of services (no long waiting time and convenient hours of operation), cheaper products, and an option to buy medicines in small amounts. As stated by Rigby (2010:191), pharmacists play a valuable role in triaging minor conditions in the community and patients will continue to consult pharmacists for minor health problems, as they are trusted and accessible sources of information and advice.

Therefore, community pharmacy practices should be well regulated and monitored. There must be an established national framework of quality standards and guidelines for pharmacy practice in every country (WHO, 2009:9).

Good Pharmacy Practice (GPP) is, thus required to ensure that the practice of pharmacy is appropriately delivered. The WHO (2011b:315) emphasised that GPP is the practice of pharmacy that responds to the needs of the people who use pharmacists' services to provide optimal, evidence-based care. In this study, the GPP guidelines of the WHO (2011b:310-323) were used as a standard and comparisons of the Lesotho situation were made with GPP guidelines of the South African Pharmacy Council (SAPC) (SAPC, 2010:1-230). South Africa, as a neighbouring country, is one of the suppliers of medicines in Lesotho.

The GPP guidelines of the SAPC include the following main elements (SAPC, 2010:4):

- Standards for the premises such as the premises' appearance and control of access.
- Standards for human resources, such as staffing of the pharmacy and registration.
- Standards for the pharmaceutical services, for example, procurement and supply of medicines.
- Standards for pharmacy management such as ethics and professional standards.

The Lesotho Kingdom is a relatively small country of 30.35 km^2, divided into ten administrative districts and further divided into four ecological zones, namely the Lowlands, Foothills, Highlands (mountains) and the Senqu valley (Ministry of Finance (MOF), 2007: 9). The Republic of South Africa surrounds it, with a population of slightly more than 2 million. Approximately 99% of Lesotho's population is ethnic Basotho, with Christianity being the main religion and the national languages; Sesotho and English (Mwase *et al.*, 2010: 5).

In 2010, there were 46 community pharmacies in Lesotho (Mwase *et al.*, 2010:13-45). During the same assessment, it was established that there were 62 pharmacy personnel comprising pharmacists and pharmacy technicians with the latter being the majority. The presence of the National Health Training College (NHTC), which has existed for more than two decades, contribute to available pharmacy personnel. The number of pharmacists in Lesotho has increased since 2003/2004 because pharmacist training commencement at the National University of Lesotho (NUL). The first students graduated in 2007. According to the Registrar of the NUL, In the academic year 2009, there were 191 student pharmacists from year one to

year five, of which 27 graduated in the same year. The increase in the number of pharmacists is showing how much the pharmacy profession in Lesotho has evolved.

Statistics provided by the Lesotho Medical, Dental and Pharmacy Council (LMDPC) indicated that there were 93 licensed pharmacists in 2011, of which 30 worked in the public sector (Lesotho, 2011c:2). There were 59 pharmaceutical technicians and assistants (Lesotho, 2011c:2) in 2011. In 2009, there were approximately twice as many pharmacy technicians as pharmacists.

Registers compiled by the Ministry of Trade (MOT) (2017:1-3) and Ministry of Health (MOH) (2016:1-2) in Lesotho show a growth in the number of community pharmacies from 46 in 2010 to 60 in 2016. This increase shows how the community pharmacy sector has grown in Lesotho during the past few years.

According to Nkomazana *et al.* (2014:6), by 2010, Botswana had 350 pharmacy personnel (pharmacy technicians and pharmacists) which is commendable as it only produces pharmacy technicians locally and no pharmacists, when compared to Lesotho, which produces both cadres locally.

Prescribing, in Lesotho is allowed by doctors, nurses, midwives and at some level by community health workers (Lesotho, 2009:30). According to the Dangerous Medicines Act (21 of 1973), no person shall sell or dispense any habit-forming or potentially harmful medicines as provided by the law unless prescribed and signed by a medical practitioner, a dental surgeon or a veterinary surgeon. Community pharmacists can thus dispense prescriptions from prescribers mentioned. Pharmacists may not prescribe but are allowed to dispense medicine prescribed by doctors, nurses, midwives and at some levels, community health workers. Nurses in Lesotho are allowed to prescribe only from the Essential Medicines List (EML); however, their basic training does not include pharmacotherapy and GPP (Lesotho, 2009:25).

Dispensing, as defined by Wiedenmayer *et al*. (2006:68), is the interpretation and evaluation of a prescription, selection, manipulation or compounding of a pharmaceutical product, labelling and supply of the product in an appropriate container according to legal and regulatory requirements, and the provision of information by a pharmacist, or under supervision of a pharmacist, to ensure safe and effective use by the patient.

Dispensing, in Lesotho, is authorised in terms of the Dangerous Medicines Act (21 of 1973). Only pharmacists may handle dangerous medicines as scheduled by the same law. The Dangerous Medicines Act (21 of 1973) states that, for habit-forming medicines (schedule I),

permission to import, acquire or sell them, should be granted by the MOH. The exception to this law is for medical practitioners, dental surgeons or veterinarians, who also may acquire, purchase and prescribe as well as dispense schedule medicines that fall in the Act for medicinal purpose.

According to the Food, Medicines, Healthcare Administration and Control Authority (FMHACA), controlled medicines are drugs that have a potential for abuse and psychological and physical dependence. These risks may arise from inadequate dispensing of those medicines in case dispensers lack knowledge or professionalism. Regulations on controlled medicines handling vary according to their classification (FMHACA, 2012:20). In Lesotho, these medicines are referred to as controlled/scheduled/dangerous medicines, which are classified according to their risk profile by the Dangerous Medicines Act (21 of 1973).

Drugs are classified or scheduled in the Dangerous Medicines Act (21 of 1973) according to three schedules, which are schedule I (habit-forming medicine or high-risk drugs), schedule II (potentially harmful medicines or risk drugs of abuse) and schedule III (prohibited drugs of abuse).

As mentioned previously, to support GPP, there must be an established national framework of quality standards and guidelines available. There are areas in Lesotho's pharmaceutical policies, laws and regulations that have shown strengths, while, in others, weakness is superior. Strengths are evident when it comes to the presence of a National Medicines Policy, prescribing guidelines and EML. Weak areas include regulatory frameworks for pharmaceutical commodities and pharmaceutical professionals, inadequate supportive supervision for facilities, for example, community pharmacies, irregular updating of guiding documents such as the National Standard Treatment Guidelines (STG) and EML (Mwase *et al.*, 2010:65).

In 1988 and 2003, the WHO published Guidelines for Developing National Drug Policies (Ritz *et al*., 2010:2-6). The objective was to help member countries (Angola, Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Mauritius, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe) to create and improve their national policies and to increase access to medicines. Lesotho as one of the member countries is not well-equipped to apply existing knowledge to develop effective mechanisms for the improvement of the selection and use of essential medicines, ensuring affordable prices, increasing sustainable financing and strengthening reliable supply systems (Ritz *et al*., 2010:2-6).

When it comes to medicine regulation and the improvement of governance in the pharmaceutical sector, Namibia has proven to be healthy, unlike some Southern African Development community (SADC) countries. The National Medicines Policy Coordination (NMPC) and Namibia Medicine Regulatory Council (NMRC), resulted in a streamlined regulatory process for essential medicines and improved availability of multi-source generic antiretroviral medicines and paediatric formulations. Besides, the Therapeutic Information and Pharmacovigilance Centre creates a monitoring system for adverse drug reactions and provides access to drug information (Lynch *et al.,* 2010:10).

In Lesotho, according to the Lesotho Medical, Dental and Pharmacy Order (12 of 1970), an individual wanting to operate a community pharmacy must be a registered pharmacist. In contrast, for a body corporate, the majority of the board members must be individually registered as pharmacists. The South African Pharmacy Act (53 of 1974) initially only allowed for a pharmacy to be owned by an individual licensed and registered as prescribed in the Act. The Act was amended in 1997, and these amendments were ratified in 2003. The statute now allows non-pharmacists to own pharmacies provided that, a registered pharmacist is employed to run the pharmacy at all times. Any person may own a pharmacy subject to South African Government regulations, of which a beneficial interest in a manufacturing pharmacy is one limitation and who is not an authorised prescriber as stated by the South African Pharmacy Act (53 of 1974) (SA, 1974).

There are several African countries, including Ghana, where pharmacy professional registration is regulated. Ghana has legislation relating to pharmacy practice and licensing, sales and medicines prescribing (Ghana, 2012:8-9). Legal provisions restricting dispensing by prescribers exist, though prescribers in the private sector do dispense medicines despite the restrictions (Ghana, 2012:29). Concerning community pharmacy practice in Ghana, it has regulations on ownership, qualification of community pharmacy owners and how many community pharmacies/retail chains are allowed (Lowe & Montagu, 2009:39).

In developed countries such as the United States of America (USA), one of its states, Michigan regulates the distribution of prescription medications through the Michigan Department of Community Health. This department sets requirements for becoming a state-licensed pharmacy, as well as the duties that may be performed by pharmacists, and restrictions placed on them. In the USA, any facility that dispenses prescription drugs must apply for registration with the Drug Enforcement Administration and must renew its registration every three years (Jesse, 2010:577-579).

In a study done by Lowe and Montagu (2009:6) in India, the two main pieces of legislation that pertain to community pharmacy are the Drugs and Cosmetics Act (23 of 1940) (SA, 1940) and the Pharmacy Act (8 of 1948) (SA, 1948). The Pharmacy Act (8 of 1948) regulates the pharmacy councils while the Food and Drug Administration of India, which awards a license only to a qualified pharmacist to operate as such (Lowe & Montagu, 2009:6). However, many pharmacies set up by non-pharmacist businessmen hire a signature pharmacist who works part-time and fulfils the regulatory requirements. These pharmacies are generally staffed by pharmacy assistants or less well-trained staff (Lowe & Montagu, 2009:6).

Pharmacists, as the custodians of medicines, are central to the medicines supply chain. State, territory and commonwealth legislation controls virtually every aspect of pharmacy in Australia, from whom can provide pharmacy services, to where it may be provided and, for the vast majority of prescription medicines, the cost at which they can be sold (Hattingh, 2011:149-150). This means that there is accountability in every pharmacy service provided, and therefore good pharmacy service to the community.

Effective pharmaceutical policy is an essential piece of any country's legislation, particularly given the increasingly widespread availability of inexpensive prescription medicines. In many low-income countries, formulating policies to legislate and regulate the production, approval and sales of medicine remains a challenge (Lowe & Montagu, 2009:40-41).

Differences in legislation between neighbouring countries, inadequate administration and enforcement, and a lack of qualified personnel are challenging for many governments of low-income countries (Lowe & Montagu, 2009:41).

Two laws are governing the pharmaceutical sector in Lesotho. The Dangerous Medicines Act (21 of 1973) governed medicines, for example, imports, exports and dispensing issues and the Medical, Dental and Pharmacy Order (12 of 1970) governed pharmaceutical personnel, for example, registration of pharmacists and pharmacy technicians. These outdated laws governing the pharmaceutical sector, which continues to show very intense growth, have resulted in them being scheduled for reform. This reform involved taking action against a lack of clear drug regulating policies, insufficiencies in drug procurement, management and distribution, drug use, quality control, irrational prescribing, and strengthening human resources in the pharmaceutical sector.

According to Mwase *et al.* (2010:60), to date, the reform of the pharmaceutical sector in Lesotho has involved the following:

- The approval of the National Medicines Policy (NMP) by the Lesotho cabinet in 2005.

- The development of a strategic action plan for the NMP.

- The implementation of capacity building for and further definition of the status of the National Drug Service Organisation (NDSO).

The NDSO is the leading pharmaceutical company responsible for the procurement, supply and distribution of pharmaceutical commodities and medicines in Lesotho. It is the leading supplier for all government and privately-owned health facilities, and some of the suppliers of such items around the country, for example, Tripharm® and Medicare®. These two suppliers are the second and third most used suppliers in Lesotho, especially by the privately-owned health centres (SIAPS, 2013:1-2).

1.2.1 The new laws: proposed and passed laws

Mwase *et al.* (2010:60) reported that the parliament of Lesotho passed the Drugs of Abuse Act (5 of 2008) (SA, 2008), for the control of illicit drugs. The Medicines and Related Substances Amended Bill (SA, 2012), which is in the advanced stages, is waiting for passing by the government Drugs of Abuse Act (5 of 2008) that repeals the Dangerous Medicines Act (21 of 1973) (SA, 1973). The Medicines and Related Substances Amended Bill of 2012 provides the framework for control of pharmaceuticals and seeks to provide price control mechanisms for pharmaceuticals. Once the bill is enacted, which has not happened to date, it will be known as the Medicines Control Act. This Act will establish the Medicines Control Council of Lesotho. This council will be mandated to regulate the quality and use of pharmaceuticals, licensing, inspection and the control of pharmaceutical personnel, manufacturers, distributors, importers, pharmacies (community/retail) and other institutions that handle medicines (Mwase *et al*., 2010:60).

In developing countries, the numbers of trained professional staff are deficient, and a pharmacist/population ratio of less 1:100 000 is standard (Goel *et al*., 1996:1156). In a baseline assessment of the pharmaceutical situation in SADC, the pharmaceutical personnel per 10 000 of the population was 0.3 in Lesotho. Lesotho was shown to have the lowest value compared to other SADC counties: Botswana with 2.3, Swaziland with 0.7, Namibia with 2.0, and South Africa with 4.0 (WHO, 2011a:45). In 2013 a study done in Lesotho on capacity needs assessment for pharmaceutical services for the antiretroviral programme indicated that Lesotho has 0.16 pharmacists and 0.32 pharmaceutical technicians per 10,000 population (Wang *et al.,* 2013:1).

African countries tended to have lower densities of pharmacists, pharmacy technicians and support cadres, and also pharmacies. This shortage has implications for inequalities in access to medicines and medicines expertise (FIP, 2015:15).

In countries such as India, which has a comparatively high number of trained pharmacists, the more significant number of pharmacies could lead to a situation of “officially employed and physically absent” pharmacists, resulting in minimally trained or untrained persons running pharmacies. Staffing by inadequately trained pharmacy staff is seen more in poorly developed urban areas in India (Goel *et al.,* 1996:1156).

1.3 Problem statement

As shown in the introduction, an insufficient amount of qualified human resources and the unavailability of current statutes governing the pharmaceutical sector have plagued pharmaceutical management in Lesotho. A lack of laws governing the owning and issuing of licenses to community pharmacies and the practice itself imply that the profession may be at risk of being in the wrong hands. This lack of governing laws poses questions about the standard of pharmaceutical services provided in Lesotho. This study, therefore, aimed to investigate the profile and standards of community pharmacy practice in Lesotho from the legislation, pharmaceutical care, and human resource perspectives.

This study aimed to fill this gap by providing answers to the following research questions:

- What is the proposed role of community pharmacists in healthcare systems internationally and within the SADC region?
- To conceptualise GPP from available international and national literature.
- Which laws, regulations and policies governing the practice of pharmacy and community pharmacy in Lesotho are still relevant for the current needs of Lesotho?
- What is the current profile, nature and extent of pharmaceutical services provided in community pharmacies in Lesotho?
- Do community pharmacies in Lesotho conform to the GPP guidelines of the WHO and South Africa?
- What is the current standard of premises, facilities and equipment of community pharmacies in Lesotho?

1.4 Research objectives

This research included general and specific objectives.

1.5 General aim

The general aim of the research project was to investigate the profile and standard of community pharmacy practice in Lesotho.

1.6 Specific research objectives

The study was conducted in two phases, namely the literature and empirical phase:

1.6.1 Specific research objectives of the literature review

The specific research objectives of the literature review included the following:

- To investigate the role of community pharmacists in the healthcare system internationally and within the SADC region.
- To conceptualise GPP, from available literature, and its implication for community pharmacy practice in Lesotho.
- To evaluate the relevance of existing laws, regulations and policies governing community pharmacy practice in Lesotho.

1.6.2 Specific empirical research objectives

The specific research objectives of the empirical investigation included the following:

- To assess the extent to which community pharmacies in Lesotho comply with GPP guidelines of the WHO and South Africa.
- To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho.
- To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

1.7 Research methodology

The study was executed in two phases, namely the literature and empirical phase, and the literature objectives were achieved through a comprehensive literature review. After this, the

empirical objectives were achieved using a quantitative cross-sectional study consisting of the following two steps:

- Phase I: An assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with GPP guidelines using a structured survey form.

- Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho employing face-to-face interviews according to structured questionnaires with community pharmacists and other stakeholders.

1.8 Literature review

This literature review was conducted by searching for information in several databases, including PubMed®, Scopus® and Science Direct®. Examples of phrases used are the following:

- "Good Pharmacy Practice guidelines",
- "Southern African Development Community (SADC)",
- "Community pharmacy practice
- "Pharmaceutical services and care",
- "Dispensing guidelines",
- "Pharmaceutical services",
- "Pharmacist",
- "Premises", and
- The literature searches further included published and unpublished articles, and electronically available reports, GPP guidelines and other practice-related documents.

1.9 Empirical study

This section describes the empirical research methodology. It includes a description of different phases, study designs, sample sizes, study populations and sampling strategies, data collection tools, and finally, the statistical methods and ethical considerations.

1.9.1 Phases in the empirical study

The empirical study consisted of the following two phases, as illustrated in Figure 1-1:

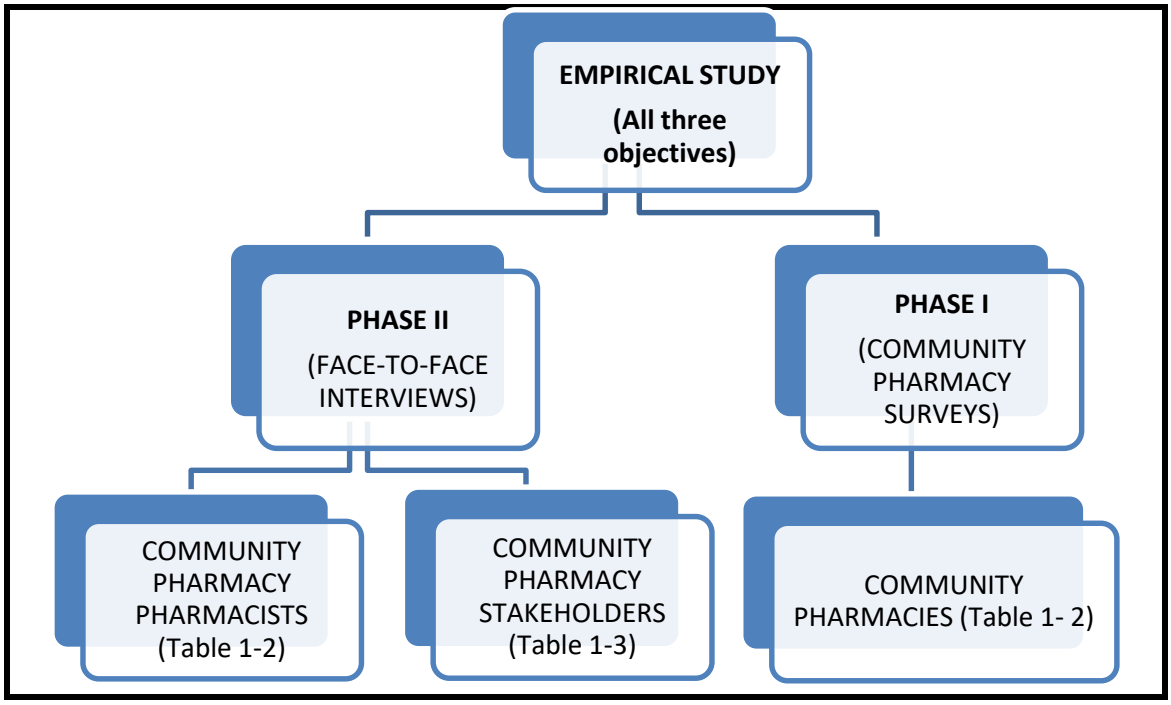


Figure 1-1: Phases of the empirical study and respondents

1.9.1.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with GPP guidelines using a structured survey form

The standard of pharmaceutical services and compliance with GPP guidelines was assessed using a structured survey form completed in 30 community pharmacies in Lesotho (30 community pharmacies of the 36 that were selected from by using a stratified random sampling technique), focusing on the following aspects (Annexure F):

- Human resources (community pharmacy staffing and registration of pharmacist and support personnel),
- Premises and layout,
- Equipment,
- Dispensing of prescriptions and the provision of pharmaceutical care,
- Storage and record-keeping, and
- Availability of medical reference resources.

1.9.1.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho through face-to-face interviews according to structured questionnaires with community pharmacists and other stakeholders

Face-to-face interviews, using structured questionnaires, were conducted in the 30 community pharmacies. Six others declined to participate (the same community pharmacies included in phase I) with the staff member in charge of the pharmacy (refer to Annexure G). The community pharmacies are shown in Table 1-2, and other stakeholders are indicated in Table 1-3 (refer to Annexure H).

The structured questionnaires used during the face-to-face interviews covered, among other things, the following areas of community pharmacy practice in Lesotho:

- The profile, including the number of community pharmacies registered and their geographical location within the country,
- Available human resources (staffing norms, qualifications and registration), and
- Current laws, regulations and policies governing community pharmacy practice in Lesotho.

1.9.2 Research design

This study was a descriptive, quantitative, cross-sectional study utilising a survey form and structured questionnaires as data collection tools. It was descriptive as it involved one-time interaction with groups, in this case, staff in charge of community pharmacies and their stakeholders, without changing the environment (Du Plessis *et al*., 2010). The study was quantitative, as it focused on assessing the measurable characteristics of human behaviour (Brink *et al.,* 2012:10). It was also a cross-sectional study, because it involved the observation of a representative subset, in this case, selected community pharmacies, at one specific point in time (Brink *et al.,* 2012:101). Cross-sectional studies aim to provide data on the entire population under study and generate hypotheses for the future, measure prevalence and are inexpensive (Jehan & Abdul, 2012:409). The study described the current situation of community pharmacy practice in Lesotho.

1.9.3 Study setting

The study was conducted at community pharmacies throughout Lesotho and at the offices of stakeholders of community pharmacy practice, which included the following:

- Ministry of Health (MOH):
    - Director of Pharmaceuticals in Lesotho, and
    - Drug Regulatory Authority (DRA).
- Pharmaceutical suppliers, for example, Directors of NDSO, Tripharm® and Medicare®,
- Registrar of the Lesotho Medical, Dental and Pharmacy Council (LMDPC),
- Ministry of Trade (MOT): One-stop Business Facilitation Centre (OBFC),
- President of the Pharmaceutical Society of Lesotho (PSL), and
- Non-government associations: Directors of Management Sciences for Health (MSH) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS) office has closed. Therefore, the study could not be performed.

1.9.4 Target population

The target populations for the two phases of the empirical study were the following:

1.9.4.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with published GPP guidelines using a structured survey form

All community pharmacies in Lesotho, found on the registers of the MOT and the MOH Department of Pharmaceuticals, were included in both phases I and II. These lists were not publicly available but could be accessed on request at the respective ministries. Verbal permission was obtained to access the necessary information. The two lists were reconciled to avoid duplication, whereby community pharmacies that appear in either will be put together to make a final list. The final list would ensure that community pharmacies included in the study were legally registered at either the MOH or MOT. The total number of community pharmacies in Lesotho are summarised in Table 1-1. These 60 community pharmacies represent the target population for phase I of the empirical study.

Table 1-1: Number of community pharmacies per district in Lesotho

District	Community pharmacies* n
Lowlands	

Maseru	32
Berea	5
Leribe	6
Mafeteng	5
Highlands	
Mokhotlong	2
Thaba-Tseka	1
Qacha's Nek	1
Quthing	1
Foothills/Senqu valley	
Mohale's Hoek	3
Butha-Buthe	4
TOTAL	60

*Obtained from the Registers of the MOH (2017:1) and MOT (2017:1)

1.9.4.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho through face-to-face interviews according to structured questionnaires with community pharmacists and other stakeholders

The target population for phase II included the following:

- A staff member in charge or the owner or manager of community pharmacies as selected for phase I and indicated in Table 1-1;
- All members of the personnel of the following institutions, associations and organisations:
    - Ministry of Health (MOH):
        - Director of Pharmaceuticals in Lesotho, and
        - Drug Regulatory Authority (DRA).
    - Pharmaceutical suppliers, for example, Directors of NDSO, Tripharm® and Medicare®,
    - Registrar of the Lesotho Medical, Dental and Pharmacy Council (LMDPC),
    - Ministry of Trade (MOT): One-stop Business Facilitation Centre (OBFC),

- President of the Pharmaceutical Society of Lesotho (PSL), and
- Non-government associations: Directors of Management Sciences for Health (MSH) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS).

1.9.5 Study population and sampling method

The study populations for the two phases include the following:

1.9.5.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with published GPP guidelines using a structured survey form

During phase I, a stratified random sample according to the district was done, and then a random sample in each district was used to select a total of 36 pharmacies, which represents at least 50% of community pharmacies available per district (refer to Table 1-1). In districts where only one community pharmacy was available, that community pharmacy was selected. Therefore, a total number of 36 community pharmacies, representing ten districts in Lesotho were selected. Informed consent was first obtained from the person in charge of the community pharmacy or the manager or owner. If the person refused, another community pharmacy was randomly selected from the list of non-selected community pharmacies situated in a specific district. If there was no other community pharmacy available in a specific district, then that district was not represented in the study population. The inclusion and exclusion criteria for phase I were as follows:

1.9.5.1.1 Inclusion criteria

- All community pharmacies in Lesotho, on the registers of the MOT and/or the registers of the MOH Department of Pharmaceuticals and whose person in charge of the community pharmacy or the manager or owner, signed the informed consent form.

1.9.5.1.2 Exclusion criteria

- All community pharmacies in Lesotho, which were not found on the registers of the MOT and/or on the registers of the MOH Department of Pharmaceuticals, will be excluded
- The person in charge of the community pharmacy who were absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised

Table 1-2: Number of community pharmacies per district in the study population

District	Community pharmacies*	Study population
Lowlands		
Maseru	32	18
Berea	5	3
Leribe	6	4
Mafeteng	5	3
Highlands		
Mokhotlong	2	1
Thaba-Tseka	1	1
Qacha's Nek	1	1
Quthing	1	1
Foothills/Senqu valley		
Mohale's Hoek	3	2
Butha-Buthe	4	2
TOTAL	60	36

* Obtained from the Registers of the Ministry of Health (MOH, 2017:1) and Ministry of Trade (MOT, 2017:1)

1.9.5.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

1.9.5.2.1 Inclusion criteria

The inclusion criteria for the identification of the study population for phase II include the following:

- Should be a staff member in charge or the owner or manager of one of the 36 community pharmacies identified and recruited during phase II of the empirical study, as indicated in Table 1-2 and who signed the informed consent form.
- Should be one of the 12 respondents from the personnel of the various stakeholders, who signed the informed consent forms, as indicated in Table 1-3.

1.9.5.2.2 Exclusion criteria

- The person in charge of the community pharmacy (as mentioned in above paragraph) who were absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised will be excluded.

- If the 12 respondents from the personnel of the various stakeholders were absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised.

Table 1-3: Number of respondents from various stakeholders representing the study population for step 2

Number	Organisation	Respondent
1	MOHSW	Director of Pharmaceuticals Lesotho
1		Minister of Health
2		Drug Regulatory Authority (DRA)
1	Pharmaceutical suppliers	NDSO; Director
1		Tripharm®; Director
1		Medicare®; Director
1	LMDPC	Registrar
1	MOT	*OBFC officer
1	Pharmaceutical Society of Lesotho	President
1	*MSH/SIAPS Lesotho	MSH Director
1		SIAPS officer

*OBFC: One-stop Business Facilitation Centre

*MSH/SIAPS: Management Sciences for Health/Systems for Improved Access to Pharmaceuticals and Services

1.9.5.3 Recruitment of participants

The recruitment phase consists of the following sections:

- Invitation of participants
- Acquiring of consent

1.9.5.4 Invitation of participants

After obtaining ethical approval to execute the study from the Health Research Ethics Committee (HREC), Faculty of Health Sciences, North-West University, an informed consent form was also obtained from all participants.

Since the researcher could not guarantee whether community pharmacies and stakeholders will partake in the study, participants were recruited telephonically. This was done at least two weeks before the official appointment date by a trained fieldworker (who acted as mediator), explaining the purpose of the research project and requesting their participation. Participants were also informed regarding the possible risks (refer to Table 1-4) and the anonymous nature of the survey.

During the telephonic discussion, the fieldworker asked them for their e-mail address in order to send a letter to get official permission to perform the study. Thus, permission to conduct the study from the community pharmacies and stakeholders were sought in the form of a letter sent by e-mail to the different community pharmacies and stakeholders (Annexures A and C). Respondents were asked to send an e-mail indicating that they were interested in participating in the study.

Two copies of the informed consent form were then sent via e-mail (a week before the official visit or appointment) to those participants (refer to Table 1-2 and 1-3) who preliminarily indicated (by e-mail) that they would participate in the study.

The participants were requested to sign the informed consent form and to get a witness to co-sign before the researcher arrived. The researcher signed the informed consent form on the day of the visit, just before he or she started with the interview. The fieldworker signed the informed consent form on behalf of the researcher. The information and informed consent forms are attached in Annexures D2 and E2.

All participants were informed, at the initial telephonic interview, that participation was voluntary and that they can leave the study at any time before the end of the interview (phase I) or before the end of the survey (phase II).

1.9.5.5 Acquiring of informed consent

An appointment for community pharmacies' survey (phase I) and the face-to-face interview (pharmacist in charge and stakeholders) (phase II) was then made by phone. An appointment was made by phone when the data collection was about to commence. One copy of the signed

informed consent form was collected during the official visit to the community pharmacies and the stakeholders.

1.9.6 Data collection

The following data collection process was followed during phases I and II:

1.9.6.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

The standard of pharmaceutical services provided by community pharmacies and compliance with GPP guidelines were assessed in the 36 selected community pharmacies by using a structured survey form (see Annexure F) completed by the researcher, and two well-trained field workers. The survey form was completed through a one-on-one interview with the pharmacist in charge and/or by observing activities in the pharmacy. The fieldworkers were only involved in those community pharmacies of the easily accessed areas such as the Lowlands (Maseru, Berea, Leribe and Mafeteng).

1.9.6.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

During phase II, structured face-to-face interviews, using a structured questionnaire (see Annexures G & H), was held with the 36 persons in charge of the selected community pharmacies and the respondents representing the different stakeholders. Key correspondents are shown in Table 1-3. The researcher did all interviews with stakeholders, while those for the community pharmacies of the easily accessed areas such as the Lowlands (Maseru, Berea, Leribe, and Mafeteng) were conducted with assistance from two well-trained field workers.

1.9.6.3 Development of data collection tools

Data collection tools refer to the methods used to collect the data. A structured survey form was used in phase I. Various structured questionnaires focusing on the person in charge of the community pharmacy and the various stakeholders were used during the face-to-face interviews in phase II. There are various ways in which a structured questionnaire or survey form can be administered, e.g. mailed, self-administered, online questionnaire, administration in a public place and completed during a face-to-face interview. Researchers or well-trained

field workers completed both the structured survey form and questionnaires during face-to-face interviews with the different participants. Kumar (2011:178) refers to it as a structured interview or an interview schedule, which is a written list of questions, open- and closed questions, thoroughly pre-tested for standardised wording, meaning and interpretation, prepared for use by an interviewer in person-to-person interaction. This may be face-to-face, by telephone or by other electronic media.

The most commonly cited advantages of the administration of structured questionnaires during face-to-face interviews are the following (Neuman, 2014:345; Kumar, 2011:182):

- It has the highest response rate and permits the most extensive and complex questionnaires.
- It allows the interviewers to observe the surroundings and to use nonverbal communication and visual aids.
- It is appropriate for studying complex situations or sensitive issues.
- It is more useful to collect in-depth information and to use more open questions to permit an unlimited number of answers.
- An interviewer can supplement the information obtained from responses on structured questions.
- It is less likely that a question in the questionnaire will be misunderstood, as the interviewer can either repeat a question or explain it.
- It provides uniform information, which assures the comparability of data.
- Structured interviewing requires fewer interviewing skills than does unstructured interviewing.

The disadvantages of the administration of structured questionnaires during face-to-face interviews are the following (Neuman, 2014:345; Kumar, 2014:182):

- It is time-consuming and expensive (travel, supervision and personnel cost for interviews) when potential respondents are scattered over a wide geographical area.
- Interviewer bias is also the greatest in face-to-face interviews.

- The quality of data depends upon the quality of interaction of the interviewer (especially the commitment, experience and skills).
- The quality of the data may vary when multiple interviewers are used.
- Possibility of research bias can happen either in the framing of questions and/or in the interpretation of responses obtained. According to Kumar (2011:183), if a person, paid or voluntary, other than the researcher, conducts the interviews it is also possible that they will exhibit bias in the way they interpret responses, select response categories or choose words to summarise respondents' expressed opinions.

1.9.6.4 Development of the survey form

The survey form used in phase I included the same areas as in phase II as observed by the researcher (Annexure 3). Consultation with the study supervisors at the NWU, an epidemiology consultant in Lesotho, and a literature comparison from South Africa, SADC and WHO were utilised in the development of the questionnaire and survey form. The literature covered different areas of the practice, as indicated in Table 1-4).

Table 1-4: Literature comparison source for the development of the survey.

Country/Entity	Topic covered
WHO (WHO, 2007; WHO, 2011a)	Pharmaceutical situation in Lesotho.
SADC countries (Botsang, 2009; Goel *et al.,* 1996)	Pharmaceutical situation in Botswana comparing it with other SADC countries.
South Africa (SAPC, 2010:1-230)	Regulation of standard and practice of pharmacy in South Africa.

The survey form was developed in English because the official language of the Department of Health in Lesotho is English.

1.9.6.5 Development of structured questionnaires

In this research project, there were two questionnaires, one for the person in charge of the community pharmacies and the other for the stakeholders as described in Table 1-3. Questionnaires were developed in English because the official language of the Department of Health in Lesotho is English.

The questionnaire for the face-to-face interviews, phase II (see Annexure G), covered areas of pharmacy practice. This included GPP; pharmacy legislation in Lesotho (past, present and future), for example, registration of community pharmacies and pharmacists and licensing issues; as well as community pharmacy human resources.

Structured questions were used for individual stakeholders for face-to-face interviews. Close-ended and open-ended questions were used in the questionnaire. This fell under phase II of the research methodology.

- Closed-ended questions: Respondents are provided with possible answers and are asked to select the appropriate answer.
- Open-ended questions: Respondents compose their answers (free responses).

The following basic steps were followed in the construction of the questionnaires:

- A decision about what information would be relevant and required.
- A decision about what type of questionnaires to use.
- Development of an initial draft of the questionnaire, which was submitted to the supervisors for review and approval.
- Repeated re-evaluation and reconsideration of the questionnaire with a view to possible alterations or adaptations.
- Face validity was evaluated in consultation with the statistician to test the questions.
- The questionnaire was again edited.

The questionnaire was used alongside the survey forms in the community pharmacy in phase I. The structured survey form was developed to cover the same areas as those of phase II, including premises, reference sources and general hygiene standards. However, in this case, the researcher or the fieldworkers will complete specific questions during observations in the community pharmacy.

1.9.6.6 Phase II: Face-to-face interviews

Data collection was done in the form of structured questionnaires for different stakeholders indicated in Table 1-3, completed during structured face-to-face interviews (see Annexure H). Furthermore, the face-to-face interviews were conducted at the 36 community pharmacies

mentioned above with the pharmacy personnel in charge (see Annexure G). All interviews were conducted in English because the official language of the Department of Health in Lesotho is English.

Structured interviews are, essentially, verbally administered questionnaires or face-to-face interviews, in which a list of predetermined questions is asked, with little or no variation and with no scope for follow-up questions to responses that warrant further elaboration (Gill *et al*., 2008:292).

Reliability and validity are research techniques used to assess the accuracy of measurement scales. Reliability (or consistency) refers to the stability of a measurement scale, for example, how likely is it to provide similar results on separate occasions (Heale & Twycross, 2015:66). Validity is the degree to which a scale measures what it is intended to measure (Bannigan & Watson, 2009:3238). In addition, Bannigan and Watson (2009: 3238) content validity depends largely on sampling and the careful construction of the instrument and refers to the degree to which the entirety of the phenomenon under investigation is addressed or as the extent to which a concept is accurately measured (Heale & Twycross, 2015:66). Face validity assures only that the instrument and findings appear to be thorough and accurate to reputedly knowledgeable reviewers (Long & Johnson 2000:31).

In this research, reliability was ensured by standardising the interviews by making sure that the researcher and fieldworkers adhere to the same standards of collecting data and fieldworkers are well-trained. Respondents to be interviewed are believed to have the same qualifications or training at the college level, and therefore have the same level of knowledge, which makes the answering of questions in the interviews of the same standard. Furthermore, doing a protocol evaluation to confirm that the questions were clear and understandable would ensure reliability.

1.9.7 Protocol evaluation

As in any research, it is recommended to evaluate first the data collection tools. This allows the research team to establish whether the schedule is clear, understandable and capable of answering the research questions, and if, therefore, any changes to the interview schedule are required (Gill *et al.*, 2008:292). This evaluation will help to prove that the study can be implemented.

The data collection tool evaluation was conducted at two community pharmacies (not included in the empirical study) in Maseru to test the interview schedule and the effectiveness of the survey form (phase I) and the structured questionnaire for the community pharmacist (phase

II), while that of stakeholders was tested on a MOH correspondent from the pharmaceutical directorate.

After completion, participants were asked how understandable the questionnaire was, and suggestions were incorporated into the data collection tools accordingly. This ensured both the reliability and validity of the survey form (phase I) and the structured questionnaire (phase II); therefore, face validity (appropriateness of the questions) and content validity (accuracy of the questionnaire; whether all aspects under investigation are covered).

1.9.7.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

The survey form was tested in four community pharmacies in Maseru. These community pharmacies were not selected during random sampling but qualified for the research.

One of the trained fieldworkers contacted the staff member in charge or the owner or manager of the community pharmacies of two of the community pharmacies telephonically (not included in the empirical study) in Maseru. They were furnished (by e-mail at least a week before the actual visit) with a request letter (see Annexure C) and informed consent form (see Annexure D1) that were signed by the pharmacist in charge upon pharmacy visits by the researcher. A telephone call was made to the community pharmacies to set up the appointment. The researcher, as well as the two fieldworkers, participated in these interviews.

One copy of the signed consent form was gathered on the day of the survey in the specific community pharmacy, and the participant kept a copy of the informed consent form.

After completion, participants were asked how understandable the questionnaire was, and suggestions were incorporated into the data collection tools accordingly.

For the survey form, the researcher ensured that the evaluation of comply/not comply is done consistently by explaining it in the survey form and completing them with the acknowledgement of the pharmacist in charge. This ensured the integrity of the information provided.

1.9.7.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

The structured questionnaire for the community pharmacy was administered to the two community pharmacies mentioned above, whereby a pharmacist in charge was interviewed, and, for the stakeholders' questionnaire, an official from the MOH pharmaceutical department who are not selected for the final study was interviewed.

One of the trained fieldworkers contacted telephonically an official from the MOH pharmaceutical department, which was furnished (by e-mail at least a week before the actual visit) with a request letter (see Annexure C) and informed consent form (see Annexure E1) to be signed by the official from the MOH pharmaceutical department upon the visits by the researcher. A telephone call was made to set up the appointment. The researcher, as well as the two fieldworkers, participated in these interviews.

One copy of the signed consent form was gathered on the day of the survey, and the participant kept one of the copies of the informed consent form. Questionnaires were used (see Annexure H). After completion, participants were asked how understandable the questionnaire was. Suggestions made by these respondents were to be incorporated into the structured questionnaires.

1.9.8 The use and training of fieldworkers

In this research, two fieldworkers were used to collect data in the Lowlands, especially in Maseru, where more community pharmacies were studied. Fieldworkers (former students from the NUL and National Health Training College (NHTC)) were chosen based on their availability when data collection was about to commence, and who stayed around Maseru, which is where the researcher also stayed. The fieldworkers should have completed their studies and have a B. Pharm or Diploma in Pharmacy Technology, respectively.

The researcher trained them during the few weekends following the scheduled data collection time. They were trained on what the study was about, the objectives and research methodology, how to recruit the community pharmacies (specifically for the person who acted as a mediator) and stakeholders, perform the face-to-face interviews with an emphasis on the study's ethical considerations as well as upholding data collection integrity.

It was their responsibility to visit the Lowlands community pharmacies for the survey and face-to-face interviews using the data collection tools mentioned above.

Before data collection, they were trained for action by joining the researcher in the pilot study to test their competence.

1.9.9 Data-gathering process

The researcher was the chief administrator of the structured questionnaires with the help of two fieldworkers who were responsible for administering questionnaires in the Lowlands, especially in Maseru, where many community pharmacies will be studied as per Table 1-1 for both phases I and II.

1.9.9.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

The assessment was done on the 36 randomly selected community pharmacies around Lesotho. Telephonic appointments to conduct the study were made with the staff member in charge or the owner or manager of the community pharmacies. This was furnished with request letters to be signed by the pharmacist in charge upon pharmacy visits by either the researcher or fieldworkers. One copy of the signed consent form was gathered on the day of the survey in the specific community pharmacy. The participants were able to keep one of the copies of the informed consent form. A survey form (see Annexure F) will be used.

Appointments were made by phone and in writing or in person where the need arises for both phases. Gill *et al.* (2008:292) emphasised that before an interview takes place, respondents should be informed about the study details and given assurance about ethical principles, such as anonymity and confidentiality. This gives respondents some idea of what to expect from the interview, increases the likelihood of honesty and is also a fundamental aspect of the informed consent process. The researcher made all appointments.

The researcher implemented the research project in the Foothills and mountains areas for both phases, as access to those areas was a challenge. The researcher furnished the respective areas with the written request to conduct the study and the informed consent forms upon visiting the sites unless requested by the study sites for the prior submission of the written request letters where such were given.

Upon agreement to take part in the study by the community pharmacy, for the Lowlands and Foothills (Maseru, Berea, Leribe, Mafeteng and Mohale's Hoek), the researcher shared the work of data collecting with the fieldworkers, depending on how many community pharmacies are selected for the study. This was done for phase I only where survey forms were used.

It was estimated that the survey was not going to take longer than 45 minutes to complete.

1.9.9.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

In this phase, structured questionnaires were used for the 36 community pharmacies and 12 stakeholders of MOH. All face-to-face interviews for stakeholders were done by the researcher, while those for the community pharmacies were shared, as done in phase I (refer to section 1.1.12.2). The signed informed consent form was gathered on the day of the face-to-face interviews in the specific community pharmacy and for stakeholders.

It was estimated that the face-to-face interview was not to take longer than 30 minutes to complete.

1.9.10 Capturing of data and checking of data

According to Walther *et al.* (2017:7), one of the first steps in analysing data is to look at the data and 'clean' it of any apparent errors due to incorrect data entries. Some software programs allow the user to set defined limits when entering data. He also stated that the major advantage of electronic data capturing (EDC) is that data become available after collection in the field without delay. This enables EDC users to monitor data collection, evaluate the study status and review and analyse data in real-time (Walther, 2017:7).

1.9.10.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

Data collection was done on hard copy survey forms and questionnaires. Data entry was done using an Excel form developed from the survey form after the completion of data collection. The researcher was responsible for data entry on the Excel form. The NWU statistician imported the data into SAS for statistical analysis.

1.9.10.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

Data collection was done using hard copy questionnaires. Data entry was done with Excel forms developed from each questionnaire after the completion of data collection. The researcher will be responsible for data entry on the Excel form. The data were imported into

Statistical Analysis System®, SAS 9.4® (Statistical Analysis System®) (SAS Institute Inc., 2002-2012) for statistical analysis by the NWU statistician.

1.10 Data analysis

1.10.1 Data analysis of open questions

The following method was used to analyse open-ended questions.

- We (researcher and one of the study leaders) independently read through all the responses per questions per questionnaire.
- To get a good sense of the data, we first read through all responses to get a sense of the emerging themes. The researcher, as well as the study leaders, reviewed the responses independently. This helped minimise the influence of the researcher's own biases on the data.
- Next, the researcher, in collaboration with the study leader, developed categories that include the themes that emerged from the initial review of responses.
- Each response was assigned to a category (or categories).
- Having established the categories, we assigned each comment to one or several categories (this is known as "coding").
- Checking and seeing if our categories were appropriate was done.
- Major themes were then reviewed. After we had coded our responses and refined our categories, review to see which of the categories had the most responses were made and, therefore, represented our major themes for the specific question.
- Summary of our findings in the form of descriptive text incorporating some of the comments that exemplified major themes was done.

1.10.2 Statistical analysis of closed questions

The Statistical Analysis System®, SAS 9.4® (SAS Institute Inc., 2002-2012) was used to analyse the data in consultation with a statistician of the Statistical Consultation Services of the NWU. If applicable, statistical significance was determined with a two-sided probability of $p < 0.05$. The practical significance of results was computed when results are statistically significant ($p \leq 0.05$).

Variables were expressed using descriptive statistics such as frequencies (n) and percentages (%) and, if applicable, also means, medians, standard deviations, and 95% confidence intervals (CI). The Chi-square test was used to determine whether an association exists between proportions of two or more categorical variables. Cramer's *V* statistic will be used to test the practical significance of this association (with Cramer's $V \geq 0.5$ defined as practically significant).

1.11 Ethical considerations

Ethical consideration is very important in research. It ensures that participants are protected from harm, and their dignity is respected. Their permission to partake in the study is sought before the study starts.

The protection of human subjects through the application of appropriate ethical principles is essential in any research study, for example, in a qualitative study, ethical considerations have a particular resonance due to the in-depth nature of the study process. Besides, the concern of ethical issues becomes more salient when conducting a face-to-face interview with a vulnerable group of participants (Binti Mohd Arifin, 2018:30).

1.11.1 Permission for the project

Preliminary approval of the project from the Lesotho MOH (Ministry of Health Research and Ethics Committee Lesotho) was followed by provisional ethics approval, which was obtained from the Health Research Ethics Committee (HREC), Faculty of Health Sciences of the North-West University. This provisional ethics approval was used to obtain final approval from the Lesotho Ministry of Health Research and Ethics Committee. Final ethics approval was only given after the final proof of ministerial permission was submitted to the HREC (NWU-00058-15-S1). Data-gathering only started after final ethics approval by the HREC.

Permission to conduct the study from the community pharmacies and stakeholders were sought in the form of a letter (see Annexures A and C). Informed consent was also obtained from those community pharmacists who participated in the protocol evaluation (refer to section 1.8.8). The informed consent form was then sent via e-mail (at least a week before the official date of visit) to those respondents who preliminarily indicated positively to their participation in the study. Respondents were asked to send an e-mail indicating that they are interested in participating in the study. The signed consent forms were collected on the day of the interview or visit to the community pharmacy of stakeholders

1.11.2 Confidentiality

The researcher preserved the privacy of all pharmacists or persons in charge or managers or owners of community pharmacies to be interviewed during phase I and II and for all the stakeholders' face-to-face interviews in phase II.

1.11.2.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

For phase I, the survey form showed no names of the community pharmacies surveyed.

1.11.2.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

All interviews were done in a private room or area, depending on the setup of the specific community pharmacy, for interviews of pharmacists in charge. In addition, respondents from stakeholders were interviewed away from other colleagues and preferably in their own offices to enable confidentiality.

Complete anonymity resulted in confidentiality, as no one working with the data would be able to identify specific participants from the data.

In some districts, only one community pharmacy was available and therefore, was automatically studied as per agreement with the person in charge of the pharmacy upon request. In this case, the survey and interviews were done by the researcher herself and no names were indicated on the survey form.

For the community pharmacies that are the only ones in individual districts, such as Thaba-Tseka, Qacha's Nek and Quthing, the researcher herself did data collection to ensure confidentiality.

For both phases, the data was stored electronically and in the form of hard copies (structured questionnaires and survey form). During the study, all electronic data was protected from unauthorised persons using a password-protected computer, and the survey forms were kept safe in a locked cupboard in a locked office of the researcher in Lesotho.

The only people who worked with the data were the research team and the statisticians. After completion of the study, all hard copies of the data will be kept safe and secure by locking it

up in locked cupboards in the Research Entity's (MUSA's) office, and all electronic data will be stored on an external drive, also locked in a cupboard in the Research Entity's office. The data will be stored for seven years after which it will be permanently removed from the external drive under the direct supervision of the research assistant of MUSA. Furthermore, all hard copies of the data will be shredded under the direct supervision of the leader of MUSA, Prof MS Lubbe.

1.11.3 Anonymity

Anonymity means the participant cannot be tracked. Not revealing their names and identity in the data collection, analysis and reporting of the study findings ensure this. Privacy and confidentiality of the interview environment were managed carefully during telephone communication, interview session, data analysis and dissemination of the findings (Binti Mohd Arifin, 2018:30).

1.11.3.1 Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines using a structured survey form

This study ensured complete anonymity by using letters instead of participants' names. Any information that was required from community pharmacies surveyed was used for the benefit of the study and was not made public.

1.11.3.2 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews with community pharmacists and other stakeholders

Pharmacists in charge of the community pharmacies and stakeholders interviewed in the face-to-face interviews were not identified but coded using letters. For stakeholders, offices'/departments'/ministries' names were used, and not the names of respondents, to avoid individualising them in their respective areas of work.

1.11.4 Respect for recruited participants and study communities

The research project preserved the privacy of all the pharmacists or persons in charge of the pharmacy or managers or owners of the community pharmacies interviewed during phase I and II and for all the stakeholders' face-to-face interviews in phase II.

All interviews with pharmacists in charge were conducted in a private room or area, depending on the setup of the specific community pharmacy. In addition, stakeholder respondents were

interviewed away from other colleagues and preferably in their own offices to enable confidentiality.

Complete anonymity resulted in confidentiality, as no one working with the data was able to identify specific participants from the data.

- All participants were informed, at the initial telephonic interview, that they had the right to know the results of the research.

- All participants were well informed, at the initial telephonic interview, that participation was voluntary and that they could leave the study at any time before the end of the interview (phase I) or before the survey end (phase II).

The researcher's contact details were supplied to participants to address any concerns or questions during the study.

1.11.5 Potential benefits from this study

1.11.5.1 Indirect benefits

- This study will provide information regarding the profession of pharmacy, and consequently, community pharmacy practice in Lesotho.
- It will benefit the stakeholders in knowing where community pharmacy is in terms of GPP, legislation and other aspects of the practice as discussed in the study.
- The study will also assist stakeholders in recognising the importance of, and the role played by community pharmacists in the healthcare system, which is not well documented.
- Pharmacists will benefit from the study by being able to provide an insight into the practice of pharmacy and identify areas where they meet challenges, and consequently indirectly communicating to the responsible bodies in practice, e.g. MOH.
- Making available the research document to all participants and at meetings that will be arranged if participants agree, especially stakeholders will provide feedback on areas that need improvement.
- The MOH will indicate areas where human resources (pharmacists) are lacking, and where some of the shortcomings in terms of legislature place a burden on the profession of pharmacy, and therefore community pharmacy practice.

- Supporting non-government organisations (NGOs), for example MSH, will find out which areas in practice need support and assistance, and could, therefore, offer such support to the MOH, which they are mandated to do.
- Lastly, the statutory body, for example the council, will benefit directly by identifying areas in the practice where they need to regulate or improve regulatory measures. Furthermore, the study will have indirectly profiled the number of registered community pharmacies around Lesotho. This will, in turn, enable LMDPC to follow-up on staff registration needed for practice in terms of percentages of unregistered pharmacists practising without identifying individuals and community pharmacies to ensure confidentiality.

1.11.6 Potential risks to participants

Risk within the context of human subject research refers to the combination of the probability and magnitude of some future harm or injury (physical, psychological, social or economic) occurring as a result of participation in the research study.

In this research, the benefits outweigh the risks, as shown and expanded upon in Table 1-4.

Table 1-4: Classification of the levels of risk

Risk	Level of harm	Description and solution
Phase I		
Psychosocial harm	Minimal	Risk
		The participants' uncertainty that their names or the name of the community pharmacy may be published in the research report, mainly when it is determined that a pharmacy is not adhering to a specific legal requirement.
		Precautions
		For phase I, the survey form will show no names of the community pharmacies or respondents. This will ensure anonymity to avoid victimisation of individual community pharmacies depending on the findings.
		Furthermore, it will be emphasised that anonymity will be ensured; participants will be made to understand that participation is voluntary and confidential and that they may withdraw from the research at any point.

Risk	Level of harm	Description and solution
		Participants will be ensured that this is a research project and not an investigation from any statutory council or the Ministry of Health. Therefore, if it is determined that a pharmacy is not adhering to a specific legal requirement, it will be reported in the dissertation without referring to a specific community pharmacy. Only the research team will have access to the data.
Reluctance to participate	Minimal	The length of the questionnaire may result in reluctance or boredom in participating. This is dealt with by use of yes/no questions and structured questionnaire which will be filled at once
		The researcher and fieldworkers will try to overcome possible boredom during the interview by emphasising that it will only take 30 minutes of their time and that they will try to do it as fast as possible. They will also focus on one aspect on time, for example temperature management or reference books, before going to the next subject.
		The participants are uncertain of what will become of them in the case where they do not adhere to the legal requirements.
		Also, that this may bring their community pharmacy into disrepute hence felt worried to take part. This was dealt with by not using participant's names in the research.
Community harm	Minimal	The survey forms were designed to minimise community harm. The integrity of the community pharmacies will be left uncompromised to the community as the results will not be made public.
Economic	None	There will be no financial implications for any participants if they participate in the research.
Harm to the reputation	Minimal	**Risk**
		Depending on results, surveyed community pharmacies may feel that their reputation may be negatively affected, mainly when it is determined that a pharmacy is not adhering to a specific legal requirement.
		Precautions
		Participants were assured that no names of the community pharmacies or respondents would be indicated on any survey form. This will ensure anonymity to avoid victimisation of individual

Risk	Level of harm	Description and solution
		community pharmacies depending on the findings.
		Furthermore, it was emphasised that anonymity would be ensured; participants will be made to understand that participation is voluntary and confidential and that they may withdraw from the research at any point.
		Participants were assured that they would receive (for those who are interested) copies of the dissertation or any publication of the results. Furthermore, publications would be done with the approval of the tertiary academic institution.
Possible risk of physical harm/car accident	Minimum	The risk involved for actual researchers going to remote areas during wintertime, see comment under section 11 regarding insurance.
Phase II		
	Minimal	**Risk**
		The participants' uncertainty that their names or community pharmacies' names could be published in the research report.
		Precautions
		The questionnaires were anonymous; no names were required to avoid any connection between the participant and his/her responses. This procedure served to preserve the privacy of the participants interviewed. This will be applicable for pharmacists in charge of the community pharmacy and for the stakeholders' face-to-face interviews.
Community harm	Minimal	The questionnaire was designed to minimise community harm. The integrity of the stakeholders will be left uncompromised to the community, as the results will not be made public.
Economic	None	There will be no financial implications for any participants if they participate in the research.
Harm to the reputation	Minimal	**Risk**
		Depending on the results, stakeholders may feel that their reputation may be negatively affected.
		Precautions

Risk	Level of harm	Description and solution
		Stakeholders will be assured that they will receive the copies of the dissertation or any publication of the results. Furthermore, publications will be done with the approval of the tertiary academic institution.

1.11.7 Informed consent

After obtaining consent to execute the study from the Health Research Ethics Committee (HREC), Faculty of Health Sciences, North-West University, informed consent was also obtained from all participants, also during protocol evaluation as described in section 19.7.

Since the researcher could not guarantee whether community pharmacies and stakeholders would partake in the study, participants were recruited telephonically (at least two weeks before the official appointment date) by one of the fieldworkers, explaining the purpose of the research project and requesting their participation. Participants were also informed regarding the possible risks and the anonymous nature of the survey.

During this telephonic discussion, the fieldworker asked them for their e-mail address in order to send a letter to get official permission to perform the study. Thus, permission to conduct the study from the community pharmacies and stakeholders was sought in the form of a letter sent by e-mail to the different community pharmacies and stakeholders (see Annexures A and C). Respondents were asked to send an e-mail indicating that they were interested in participating in the study.

Two copies of the informed consent form were then sent via e-mail (a week before the official visit or appointment) to those participants (refer to Table 1-2 and 1-3) who had preliminarily positively indicated (by e-mail) their participation in the study.

The participants were requested to sign the informed consent form and to get a witness to co-sign before the researcher arrived. The researcher signed the informed consent form on the day of the visit, just before starting with the interview. The field workers signed the informed consent form on behalf of the researcher. The information and informed consent forms were done as per attachments, Annexures D1 and E2.

All participants were well informed, in the initial telephonic interview, that participation was voluntary and that they could leave the study at any time before the end of the interview (phase I) or before the end of the survey (phase II).

An appointment for the community pharmacies' survey (phase I) and the face-to-face interview (pharmacist in charge and stakeholders) (phase II) were then made by phone with all details of dates and times. One copy of the signed informed consent form was collected during the official visit to the community pharmacies and the stakeholders.

1.11.8 Conflict of interest

Conflict of interest might include human aspects where a respondent would be tempted to provide false information to portray a situation that they think is needed for the benefit of their community pharmacy's reputation. In this research, conflict of interest might arise in providing wrong information on both phases, especially during phase II interviews. For all phases where conflict of interest could be identified, the emphasis was placed on the fact that participants should respond truthfully as false information would impact negatively on the research, that the information given would be beneficial to them as it would provide a basis for the government through MOH, MOH stakeholders when making laws, regulations or only improvements.

1.12 Chapter summary

Chapter 1 provided a brief introduction on Lesotho where the study was conducted, an overview of its community pharmacy practice and standards, comparing it with African and international countries as well as some organisations which are stakeholders in the pharmacy practice, for example the WHO and FIP, the research problem and the study objectives. A brief overview of the research methodology, including ethical considerations, was also provided.

CHAPTER 2 LITERATURE REVIEW ON COMMUNITY PHARMACY IN LESOTHO

2.1 Introduction

This chapter will review the profile of Lesotho's demography, socioeconomic, health and its services. This chapter aims to investigate the role of community pharmacists in the healthcare system internationally and within the SADC region in comparison to Lesotho.

According to Unhurian *et al.* (2018:42-43), pharmaceutical practice varies in different countries, including developing countries, transitional and developed countries. In order to support this practice, it is necessary to create a national system of quality standards and guidelines. In light of this, this chapter aims to conceptualise Good Pharmacy Practice (GPP) from available literature and its implication for community pharmacy practice in Lesotho. Lastly, the relevance of existing laws, regulations and policies governing community pharmacy practice in Lesotho were evaluated to give an overview of the progress Lesotho has made in terms of regulating community pharmacy practice.

2.1.1 Geographic and demographic profile of Lesotho

The Lesotho Kingdom is a relatively small country, 30 360 km^2 divided into ten administrative districts and further divided into four ecological zones, namely, the Lowlands, Foothills and Highlands (mountains) and the Senqu valley (MOH, 2016:5). The mountainous terrain makes ground travel very difficult in Lesotho (MOH, 2010:5). The mountainous topography and harsh winters negatively affect access to essential services, including healthcare services (MOH, 2016:9).

The Republic of South Africa surrounds Lesotho, with a population of slightly more than 2 million (MOH, 2016:8). About 99% of Lesotho people are ethnic Basotho, with Christianity being the majority religion. The national languages are Sesotho and English (MOH, 2010:5). Altitudes in Lesotho range from 4,500 to over 13,000 feet (3962.4 meters), and 33% of Lesotho population resides in the urban areas leaving the majority of the population living in the mountain areas. High mountains cover about two-thirds of the country, and snow is expected in the winter months (UNICEF, 2018:5).

Figures 2-1 and 2-2 indicate districts and ecological zones in Lesotho (MOH & ICF International, 2016).

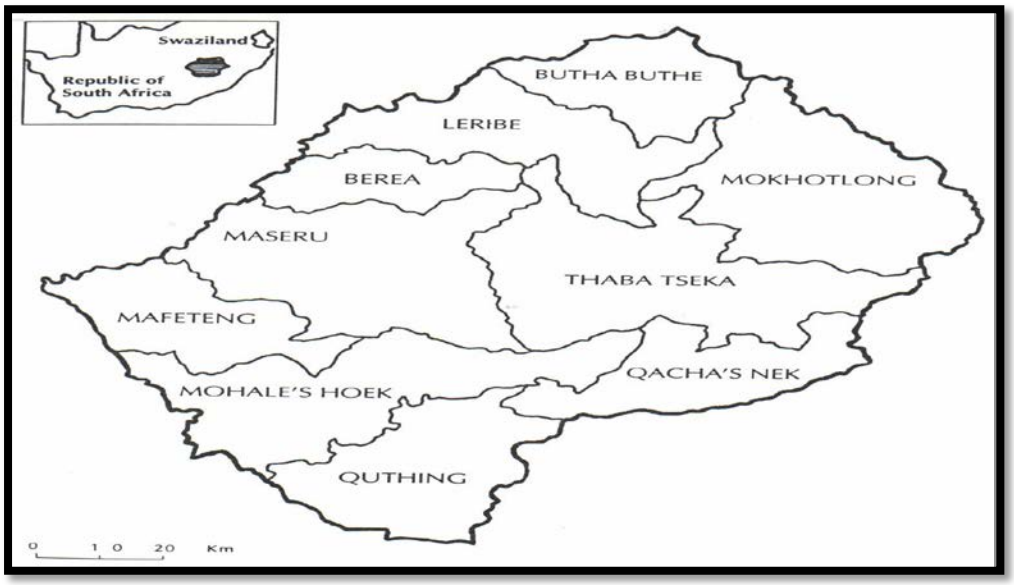


Figure 2-1: Map of Lesotho by districts

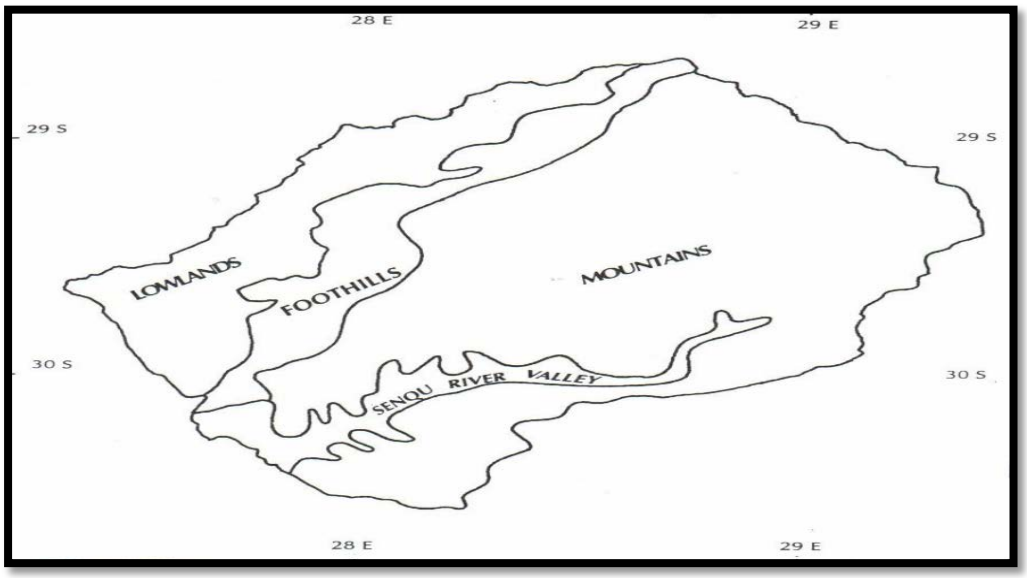


Figure 2-2: Map of Lesotho showing ecological zones

Figure 2-2 indicates that a large percentage of the geographical area of Lesotho consists of mountains. Table 2-1 shows the percentage of the population of Lesotho in the different ecological zones for 2014 (MOH & ICF International: 2016).

Table 2-1: Lesotho population by ecological zone in 2014

Ecological zones	Population	Proportion of total population (%)
Lowlands	1 178 804	57.9
Foothills	262 838	12.9
Mountains	430 965	21.2
Senqu valley	163 694	8.0
TOTAL	2 035 846	100.0

(Adapted from MOH & ICF International: 2016),

Table 2-1 shows that a larger percentage of the Lesotho population lives in the Lowlands than in other zones. Maseru, the capital city of Lesotho (Ministry of Finance and Development, 2007:7), is the most populated district with close to one-quarter of Lesotho's population. The least populated district, on the other hand, is Qacha's Nek with about 4% of the population. Maseru has the largest referral hospital with a capacity of 425 beds and some specialised health services not offered by the other hospitals in Lesotho (Downs *et al.*, 2013:8-9).

2.1.2 Socioeconomic and health status

Lesotho is a small, mountainous and landlocked country where resource deficits, both human and physical, have a debilitating effect on the governance of the country. Lesotho, classified as a lower-middle-income country with a per capita income of US$1879, ranks 161 out of 187 countries on the UN Human Development ranking (Lesotho, 2017:9). National poverty figures indicate that 57.1% of the population lives below the national poverty line (Lesotho, 2017:13). Poverty is particularly acute in the mountainous areas, which are hard to reach (Bertelsmann, 2014:25).

Besides, Lesotho's economy is dependent on clothing and textiles, diamond extraction, exports of water to South Africa and workers' remittances from the Southern African Customs Union (SACU) (Lesotho, 2017:8). The agricultural sector, which accounts for only 8.6% of Gross Domestic Product (GDP), is the primary source of income for the majority of the rural population (Lesotho, 2017:8).

In terms of health status, Lesotho has a high infant mortality rate of 8.3%, and a high human immune virus/acquired immune deficiency syndrome (HIV/AIDS) rate. Additionally, HIV/AIDS prevalence is around 24%, which is one of the highest in the world and approximately half of women aged less than 40 years have HIV/AIDS in urban areas, and the country has a life expectancy of just 42 years (Lesotho, 2017:13). The government provides a high percentage of funding for antiretroviral drugs; however, donors still provide the majority of funding for HIV/AIDS programs, thus making the fight against HIV/AIDS vulnerable to donor withdrawal (Downs *et al.*, 2013:13). The burden of tuberculosis (TB) is very high, putting Lesotho as the fifth highest in estimated TB incidences (MOH, 2016:15). Throughout 2013-2016, HIV/AIDS, TB, pneumonia, anaemia and diabetes were the top five causes of hospital deaths in adults (MOH, 2016:19).

2.2 Health system in Lesotho

The Government of Lesotho adopted primary health care in 1979 as the focal strategy for attaining health for all by the year 2000 (Ministry of Health and Social Welfare (MOHSW), 2008:1), which led to early progress in health service provision. Historically, the health service delivery functioned within the Health Service Areas (HSA). Following decentralisation, health service delivery was assigned to ten administrative districts of the country with the majority of hospitals owned by the government (60%) and CHAL with 40% (MOH, 2016:15).

According to MOHSW (2008:1), the lack of clear policies, changing health environment, improper management and planning practices and the loss of human resources for health have undermined previous accomplishments.

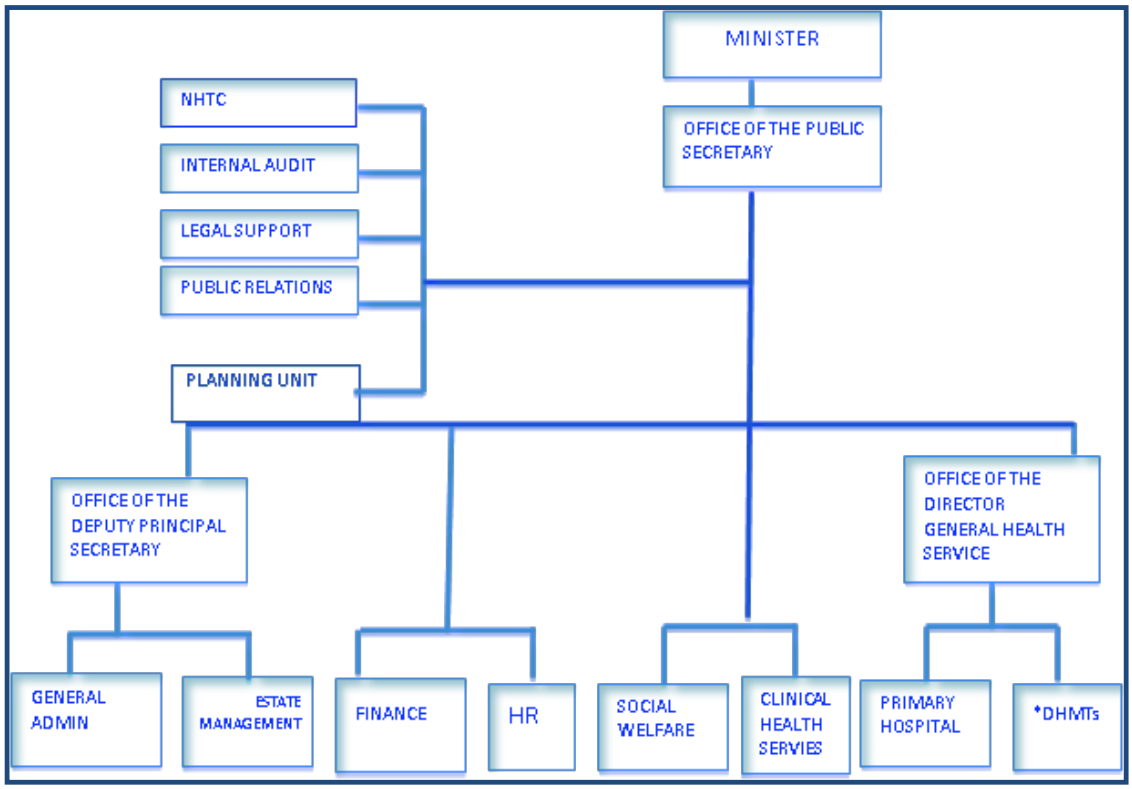
In 2006, the government of Lesotho adopted a public-private partnership (PPP) approach to replace the 100-year-old Queen Elizabeth II (QE II) National Referral Hospital. The hospital is situated in the capital of Maseru. The PPP approach was also followed to upgrade the network of urban clinics, which, together with the hospital, provided publicly funded health care services (Vian *et al.,* 2015:156). According to Vian *et al.* (2015:156), the PPP included the construction of a new 425-bed national referral hospital named Queen Mamohato Memorial Hospital (QMMH), which is currently operational.

2.2.1 Structure and functions of the Ministry of Health (MOH)

The functions of the MOH of Lesotho, subject to the provisions of the Public Health Order (12 of 1970), include the following:

- The promotion of personal and environmental health within Lesotho, preventing and guarding against the introduction of disease from outside;
- Prevention or controlling of infectious diseases, advising and assisting district administrations, and local authorities concerning matters affecting public health;
- Provision of the appointment of advisers, advisory bodies or councils to assist the Minister of Health in all matters concerning public health;
- The promotion or carrying out research and investigations about the prevention and treatment of human diseases;
- The preparation and publishing of reports and statistics or other information concerning public health; reporting to the Minister of Health who may submit such report to the Council of Ministers every year.

Figure 2-3 is the diagrammatic representation of the structure of the MOH (MOH, 2010:123).



(Adapted from MOH, 2010:139) * District Health Management Teams (DHMT)

Figure 2-3: Organogram of the MOH Lesotho

2.2.2 Health service delivery in Lesotho

UNICEF (2013:4) emphasised healthcare delivery in Lesotho is challenging as a result of the fact that the majority of the population lives in remote rural villages, often several hours' walk over rough mountain paths to the nearest clinic. Access to healthcare in Lesotho is also limited by poverty and by lack of healthcare professionals (UNICEF, 2013:4). The provision of healthcare services in Lesotho is organised at three levels: i) primary healthcare at the village health post and health centre level; ii) secondary healthcare at the district level; and iii) tertiary healthcare at the central level or MOH headquarters that is at the capital city, Maseru.

The hospital in each district serves several health centres are staffed with nurses or nurse practitioners and community health workers (Murman & Sullivan, 2008:3). The revised national health strategic plan 2017-2020 also indicated that the delivery of health services in Lesotho is done at three levels namely primary, secondary and tertiary levels and added that in each district, there is a district hospital which is a referral facility for all health centres in the district (MOH, 2016:10).

Figure 2-4 gives a diagrammatic representation of the delivery of health services in Lesotho, showing its different levels.

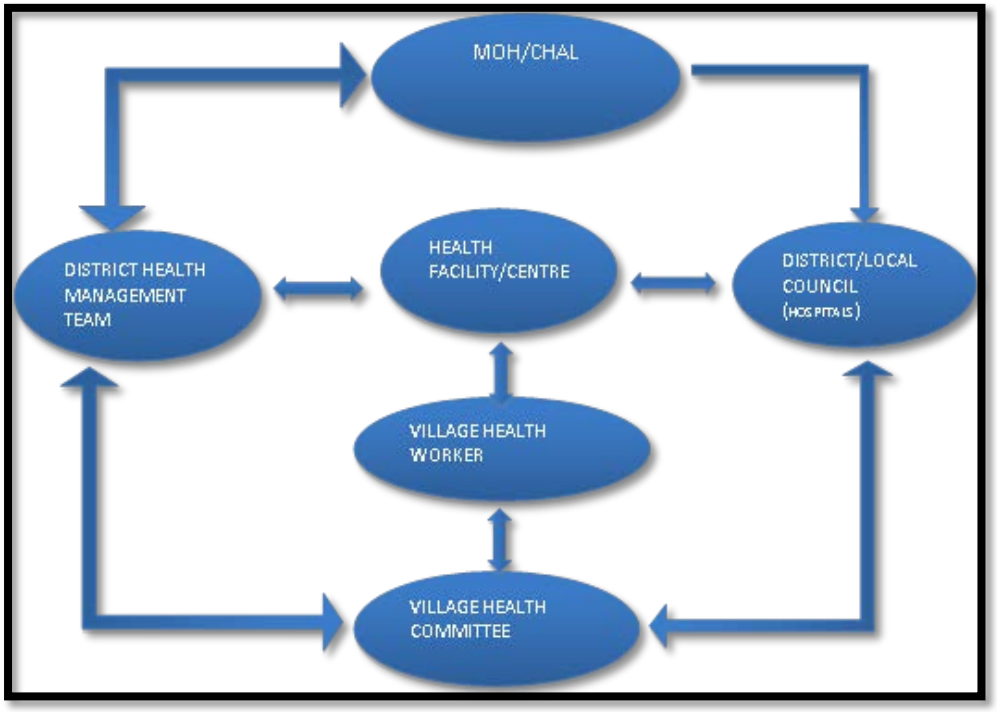


Figure 2-4: Structure of the health service delivery in Lesotho.

(Adapted from MOH, 2010)

There are 372 health facilities in Lesotho: one referral hospital, two speciality hospitals, 18 hospitals, three filter clinics, 188 health centres, 48 private surgeries, 66 nurse clinics and 46 pharmacies (MOH, 2016:10).

The formal system of Lesotho health facilities is divided into the national (tertiary), district (secondary), and community (primary) levels.

2.2.2.1 Health posts

Health posts were established in hard-to-reach areas where the population are very sparse (MOH, 2016:11). Health posts are run by volunteer community health workers (village health workers) and provide outreach type care, such as condom distribution and immunisations (Murman & Sullivan, 2008:6). There is a network of more than 6,000 village health workers (VHWs) working at the health posts. According to Lesotho (2010:10), health posts provide community outreach services and are managed by volunteers. Generally, health posts open at regular intervals (not daily) and provide primitive, preventive, and rehabilitative care in addition to organising health education gatherings and immunisation efforts. One VHW serves about 40 households (MOH, 2016:10).

2.2.2.2 Health centres

Health centres are staffed with nurse clinicians, who provide outpatient primary care. Nurses at health centres supervise and train VHWs. Health centres offer free curative and preventive services, including immunisations, family planning, HIV/AIDS and TB treatment and deliveries (MOH, 2016:10).

2.2.2.3 District and Christian Health Association of Lesotho (CHAL) hospitals

Murman and Sullivan (2008:6-7) explain that large district hospitals provide a variety of outpatient services, including primary care and specialised clinics (such as HIV/AIDS and TB clinics), as well as inpatient services, operating theatres, labour and delivery and emergency rooms. This level offers more complex and sophisticated treatment and diagnostic services as well as primary health care (routine immunisations, antenatal and prenatal care).

Specific services at this level include mental health rehabilitation and management, minor and major operations, ophthalmic, counselling and care of rape victims, radiology, dental, blood transfusions. CHAL facilities are faith-based facilities including Seventh-day Adventist and Catholic. Clients who go to the district hospitals to access services pay user fees (MOH, 2016:10).

2.2.2.4 Tertiary healthcare level

According to Lesotho (2013:10), at tertiary level, there is only one National Referral Hospital (Queen Mamohato Memorial Hospital-QMMH) and two specialised hospitals, namely, Mohlomi Mental Hospital and Bots'abello Leprosy Hospital. If more specialised care is needed, patients are referred to South Africa for quaternary care through the national tertiary referral hospital. There are other specialised health facilities like Senkatana for HIV/AIDS management, Botšabelo for MDR TB and Baylor's Paediatric Centre of Excellence (Lesotho, 2013:10). Table 2-2 shows the distribution of health facilities and ownership in terms of whether public, non-private or private (MOH, 2016:9-10).

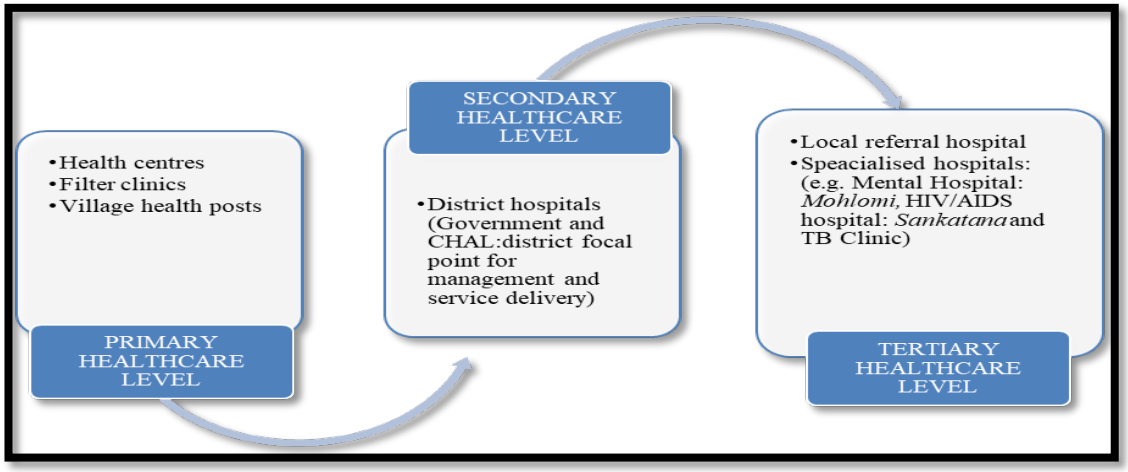
Table 2-2: Health facility distribution, by level and sector

Health facility types	Public		Non-profit*		Private		Total
	No	%	No	%	No	%	No
Referral hospitals	1	100	0		0		1
Special hospitals	2	100	0		0		2
District hospital	9	50	8	44	1	6	18
All hospitals	12	57	8	38	1	5	21
Filter clinics	3	100	0		0		3
Health centres	79	43	80	39	29	18	188
Pharmacies	0		0		46	100	46
Private surgery	0		0		48	100	48
Nurse clinic	0		0		66	100	66
All primary facilities	82	27	80	26	143	47	305
TOTAL FACILITIES	94	29	88	27	190	44	372

(Adapted from MOH, 2016:9-10; 2013:8) * Non-profit includes CHAL and Red Cross facilities.

Health services are undergoing a process of decentralisation to place decision-making authority at the district level. Under this new system, districts will be responsible for budgeting, planning, implementing projects, managing health centres, and tracking resources, while the central level will retain management of hospitals (Lesotho, 2011a:17). Figure 2-4 represents the model of a communication flow for different levels in the public healthcare services in Lesotho.

In addition to CHAL, there are several NGOs and private-for-profit healthcare providers (Lesotho Planned Parenthood Association-LPPA, Red Cross Society, Partners in Health-PIH, Lesotho Flying Doctors, Irish Aid, Mission Aviation Fellowship). They are involved in healthcare service delivery in both urban and rural areas (MOH, 2016:10).



(Adopted from Lesotho, 2011a:17)

Figure 2-5: Communication within the health sector in Lesotho

2.2.3 Healthcare human resource

Human resources for health play a pivotal role in the accessibility of health services to the overall population of any country (MacKinnon & MacLaren, 2012:1).

MacKinnon and MacLaren (2012:2) added that health worker density is the most widely used indicator to determine available human resources. The WHO (2009:5) has set a density indicator of 2.23 healthcare professionals per 1000 population as the minimum threshold for access to public healthcare services. Within that benchmark, significant variance exists between regions regarding the particular skills-mix of doctors, nurses and midwives. The average doctor to nurse/midwife ratios in North America and Europe are relatively balanced, (1:1.2 and 1:2.5 respectively) while in Africa there are on average five nurses/midwives per doctor (Dal Poz *et al.*, 2007:12). Zimbabwe's health worker density at 1.45 per 1000 of the population is higher than those of Sierra Leone and South Sudan but is still less than the

WHO's density benchmark (MacKinnon & MacLaren, 2012:2). In Botswana, according to Nkomazana *et al*. (2014:2), the health worker density is 3.4 doctors and 28.4 nurses per 10 000 of the population. This means that like in Lesotho, shortage of skilled and qualified healthcare workers remains one of the significant barriers towards high-quality healthcare provision (Nkomazana *et al*., 2014:2).

Healthcare human resources include different cadres involved in the provision of healthcare services such as pharmacists, pharmacy technicians, medical doctors and nurses. Pharmacists may further be divided into two groups, those working in the public sector and those in the private sector. The private sector includes community pharmacists responsible for community services and activities in the provision of adequate health (Brian *et al.,* 2015:36-37).

In Lesotho, the MOH faces issues related to technical constraints rooted in the human resource crisis. As a result, clinical service delivery capacity, especially among the higher level cadres, is still dependent on externally sourced health workers (MOH, 2010:43). The NHTC offers training programs at diploma level in areas of nursing, environmental health, medical laboratory technology and pharmacy, all done full time. A certificate-level course in nursing assistance and auxiliary social work is offered, as well as post-basic courses in psychiatric mental health; ophthalmic nursing; anaesthetic nursing; dental therapy and midwifery also nurse clinicians. All four CHAL health training institutions offer nursing courses. The intake of most programmes is about 20 students, but the general nursing program enrols between 40 and 60 students (Lesotho, 2013:18).

The current government's staff establishment list does not take care of health cadres that are needed resulting from the use of modern health technologies, for example equipment, devices and protocols (MOH, 2016:16). Furthermore, there is an acute shortage of expertise within the health sector with many posts on the establishment list of the MOH remaining unfilled. The overall establishment list of the MOH as at the beginning of the year 2015 was 4,610. This represents 50% of the required staff needs. At the end of the 2015 financial year, only 23% of all vacancies were filled. Several factors have been associated with this, such as local circumstances that negatively impacted on training, pay, infrastructure and working conditions (MOH, 2016:16).

To answer the need for medical doctors, the government of Lesotho has established a medical school within the NHTC as part of its strategy to strengthen institutions and improve its human resource base. However, the project faced has been suspended due to its failure to meet the requirements of the Council for Higher Education (CHE) (MOH, 2016:12).

Poor service delivery distorts the referral system whereby patients that should obtain care at lower-level facilities refer themselves to a higher level within the health system, rendering organisation of services chaotic, impairing access to services, and negatively affecting the quality of services offered (MOH, 2010:44).

Table 2-3 shows the human resources in comparison with the Southern Africa Development Community (SADC) within which Lesotho falls (MOH, 2010:46).

Table 2-3: Comparison of Lesotho health human resource per 10 000 population with the SADC region

Category	Lesotho	SADC
Physicians	0.049	0.217
Nurses and midwives	0.623	1.172
Dentists and technicians	0.009	0.035
Pharmacists and technicians	0.034	0.063
Environmental and public health workers	0.031	0.049
Laboratory technicians	0.081	0.057
Other health workers	0.013	0.173
Community health workers	Not available	0.449
Administrative and support staff	0.010	0.411
TOTAL	**0.850**	**2.626**

(Adapted from MOH, 2010:46)

Lesotho fares poorly with other SADC countries in almost all the individual healthcare professional cadres (MOH, 2010:45). The ratio of doctors to population is at 0.5 per 10 000 population, while that of nurses is at 6.2 per 1000 population. Both ratios are far below the WHO Afro region of 2.6 and 12.0, respectively (Lesotho, 2017:3). On average, Lesotho's total health workforce is equivalent to a third of the African average (850/1000 versus 2.626/1000) (Lesotho, 2013:18). The MOH has sent a request to the Ministry of Public Service (MPS) for establishing directorates for quality assurance, supply chain, pharmacy, cancer, laboratory services, blood transfusion and bio-medical engineering as the first step incapacitating the MOH (MOH, 2016:17).

2.2.4 Pharmacy human resources in Lesotho

In Lesotho, staffing at all levels of health delivery does not meet the minimum requirements set by the WHO (Lesotho,2013:17). There are 8 600 personnel working in the health sector: 44 % work in the formal sector comprised of the government of Lesotho, CHAL, NGOs (such

as LRCS); 75% work in government, 22% in CHAL, and 3% in NGOs and the private-for-profit sector. A third of the MOH workforce consists of support staff. Nurses constitute 73.3% of the workforce in MOH, followed by physicians at 6% with other health cadres comprising a low percentage of the workforce (Lesotho, 2013:17). Consequently, this situation has contributed to poor health service delivery at the health centre and hospital level. The poor delivery of health services in the health centres and hospitals has resulted in many people seeking assistance from the community pharmacies for the provision of pharmaceutical services. There is, therefore, a definite need for adequate staffing and services, which will be ensured by proper regulation of the pharmacy profession (MOH, 2010:23).

2.2.4.1 Growth in numbers of pharmacy human resource in Lesotho

The Lesotho Health Systems Assessment done in 2010, established that there were 62 pharmacy personnel comprising of pharmacists and pharmacy technicians with the latter being the majority (MOH, 2010:13-45).

The numbers of pharmacists have increased as a result of the commencement of pharmacy training at the NUL since 2003/2004. The first pharmacy students graduated in 2007. The Registrar of NUL indicated that there were 191 pharmacy students from the 1st year to 5th year during the academic year 2009, of which 27 graduated the same year (NUL, 2010). According to communication with Mothibe (2016) at NUL, 24 pharmacy students graduated in 2014/2015 academic year, and 36 students graduated in 2015/2016. Thus a total of 60 graduates from NUL graduated in two academic years and joined the pharmacy profession in Lesotho. Very few seek employment in Swaziland, Botswana and Namibia. In another communication with the Head of the pharmacy department at NHTC (Letsa, 2016), 22 pharmacy technicians graduated in 2016, and the total students enrolled were 59 from 1st to 3rd year. The total pharmacy graduates in 2016 from both institutions amounted to 82. All of them joined the pharmacy profession through employment at the MOH or other stakeholders of the MOH.

The Head of the pharmacy programme (Namole, 2018) indicated that NUL had 31 and 21 pharmacy students doing final year in the academic years 2017 and 2018, respectively. Table 2-4 presents an enrolment of pharmacy students at NUL (Namole, 2018).

Table 2-4: NUL Pharmacy students in the academic years 2016 – 2018

Year	Enrolled students' numbers per year of study					Total
	Yr. 1	Yr. 2	Yr. 3	Yr. 4	Yr. 5	
2016/17	42	40	26	24	31	163
2017/18	45	45	36	28	21	175

The information in Table 2-4 shows how much the pharmacy profession in Lesotho has evolved, resulting in more pharmacists being injected into the healthcare system.

Consistent with Lesotho (2011b:2), the Lesotho pharmaceutical country profile, the statistics provided by the LMDPC indicated that there were 93 registered pharmacists, of which 30 work in the public sector. Additionally, there were also 59 pharmaceutical technicians and assistants (Lesotho, 2011b:2). There were approximately twice as many pharmacy technicians as pharmacists in 2009 (Lesotho, 2011b:8). Table 2-5 indicates pharmacy human resource according to the MOH

Table 2-5: The status of pharmacy human resources in different health sectors.

Human resource	Number
Licensed pharmacists (all sectors)	93
Pharmacists in the public sector	30
Pharmacy technicians and assistants (all sectors)	59

(Adopted from Lesotho, 2011b:8)

There were 46 community pharmacies in Lesotho by 2010 (MOH, 2010:13-45). As pharmacists' numbers increase, the number of community pharmacies also increased. In accordance with the Registers of MOT (2017:1) and MOH (2017:1), there was an increased number of community pharmacies from 46 in 2010 to 60 in 2017. The two registers were reconciled, and the number of registered community pharmacies per district is indicated in Table 2-6.

Table 2-6: Number of community pharmacies per district in Lesotho

District	Community pharmacies* N
Lowlands	
Maseru	32
Berea	5
Leribe	6
Mafeteng	5
Highlands	
Mokhotlong	2
Thaba-Tseka	1
Qacha's nek	1

District	Community pharmacies* N
Quthing	1
Foothills/Senqu valley	
Mohale's hoek	3
Butha-Buthe	4
Total	60

*Obtained from the Registers of the MOH (2017:1) and MOT (2017:1), compiled in 2017

When comparing India that is more developed with Lesotho and the other SADC countries, according to Othman *et al.* (2010:11-16), community pharmacy practice is not considered a well-established pharmacy sector in India. The same is experienced in Lesotho. In India, community pharmacies are managed by less qualified personnel (diploma trained/pharmacy technicians) compared to many other countries (Othman *et al.,* 2010:11-18). In Lesotho, non-pharmacy personnel or pharmacy technicians sometimes manage community pharmacies. South Africa, however, allows non-pharmacists to own a community pharmacy, unless the group or individual having an interest in opening a pharmacy, such as a prescriber or a pharmaceutical manufacturer (Pharmacy Act, (53 of 1974).

2.2.4.2 Pharmacy human resource qualifications

According to Goel *et al*. (1996:1156) the number of trained pharmacists in developing countries, are very low, and a pharmacist/population ratio of less 1:100 000 are common. In the baseline assessment of the pharmaceutical situation in SADC countries in 2010, the pharmaceutical personnel consisting of pharmacists and pharmacy technicians, per 10 000 of the population was 0.3 in Lesotho, Lesotho showed to be having the lowest value compared to other SADC counties; Botswana with 2.3, Swaziland with 0.7, Namibia having 2.0, and South Africa with 4.0 (WHO, 2011a:45). Staffing by inadequately trained pharmacy staff was more prevalent in poorly developed urban areas than the more developed ones (Goel *et al.,* 1996:1156).

It was stated by Lesotho (2010:59) that the functionality of a pharmaceutical management system of a country could be examined within the many components including pharmaceutical policies, laws, and regulations; procurement; storage and distribution; appropriate use; access to quality products and services; and financing. Findings from the health systems assessment revealed that financing was the weakest performance areas in Lesotho followed by pharmaceutical policies, laws and regulations (MOH, 2010:59).

2.3 Pharmaceutical sector regulatory framework in Lesotho

Effective pharmaceutical policy is an essential piece of any country's legislation, particularly given the increasingly widespread availability of affordable prescription medicines (Lowe & Montagu, 2009:7). The formulating of policies to legislate and regulate the production, approval and sales of medicine in many low-income countries remains challenging. Differences in legislation between neighbouring countries, inadequate administration as well as the enforcement of the legislation and a lack of qualified personnel make this a complicated area for many governments (Lowe & Montagu, 2009:7).

2.3.1 Regulation of medicines in Lesotho

The laws that govern medicines in Lesotho according to Dangerous Medicines Act (21 of 1973) and pharmaceutical personnel as per the Lesotho Medical, Dental and Pharmacy Order (12 of 1970) are still in use though outdated which shows a very intense discrepancy resulting in calls for reform. This involved taking action against lack of clear drug regulating policies, insufficiencies in drug procurement, management and distribution, drug use, quality control, irrational prescribing and also strengthening human resource in the sector (Mwase *et al*., 2010:60).

The LMDPC have the statutory obligation to regulate and maintain professional standards through the registration of professionals and ensuring compliance with professional standards. It is expected that the LMDPC should conduct regular professional and fitness for practice reviews for medical, dental and pharmacy professionals. Strengthening the LMDPC to fulfil the above tasks will go a long way in improving professionalism in the health sector (MOHSW, 2008:19).

MOH enacted the Drugs of Abuse Act (5 of 2008), an Act that repeal the Dangerous Medicines Act (21 of 1973). The aims of the Drugs of Abuse Act (5 of 2008) are to:

- ensure the availability of certain drugs for medical, scientific and related purposes exclusively, while preventing their abuse, being used for illegal trade or manufacturing of illicit drugs aiding drug trafficking,
- determine which certain conduct by drug users are criminal offences,
- stipulate the treatment and rehabilitation of drug-abusing or dependent offenders, and to
- establish the Lesotho Narcotics Bureau.

The Drug of Abuse Bill was discussed by parliament (MOHSW, 2008:78) and was enacted into an Act referred to as Drugs of Abuse Act (8 of 2008), while the National Medicine Act/Bill has not been passed by parliament yet.

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers in Lesotho (Lesotho, 2011a:25).

There must be an established national framework of quality standards, and guidelines that support GPP because there are is essential areas in the Lesotho pharmaceutical policies, laws, and regulations that have shown weaknesses (Lesotho, 2011a:25-26). National lists of essential medicines with or without standard treatment guidelines exist in many developing countries. These lists are based on a consensus of what are the most common diseases and complaints and define the range of medicines that are available for a specific level of care (Wiedenmayer *et al*., 2006:44).

Legal provisions exist to govern the licensing and prescribing practices of prescribers in Lesotho. However, legal provision restricting dispensing by prescribers does not exist. Prescribers in the private sector can dispense medicines (Lesotho, 2011b:26).

Key priority challenges identified through the situational analysis during the policy development process included the following (MOH, 2010:65):

- Obsolete legislation that does not adequately regulate the pharmaceutical sector,
- Absence of a quality assurance system that ensures the quality of medicines within the country,
- Inadequate management systems in the medicines supply chain,
- Absence of national policy guidelines regarding donations,
- Outdated National Standard Treatment Guidelines (NSTGs),
- National Essential Medicines List (NEML). Irregular updating of guiding documents such as the Standard Treatment Guidelines (STG) and Essential Medicines List (EML) of Lesotho,
- Inadequate management and inequitable distribution of available financial resources,

- A small number of pharmaceutical human resources and inequitable distribution of them, and

- Inadequate supportive supervision for facilities, for example community pharmacies.

Individual departments within the MOH developed several policies that include the Occupational Health Quality Assurance Policy, the Adolescent Health Policy, Mental Health Policy, the EPI Policy and the National Medicines Policy; some needs revision, as they have outlived their life spans (Lesotho, 2013:23). The WHO published guidelines for the developing National Drug Policies to help countries create and improve national policies and to increase access to medicines (WHO, 2001:21). Ritz *et al*. (2010:2-6) indicated that some of the areas that needed to be improved on to increase access to medicines included ensuring affordable prices, increasing sustainable financing and strengthening reliable supply systems.

The pharmaceutical sector has some strengths and weaknesses, as indicated by Mwase *et al.* (2010:65) (Table 2-7).

Table 2-7: Pharmaceutical sector strengths and weaknesses in Lesotho

Strengths	Weaknesses
The presence of prescribing guidelines and an essential medicines list, NMP and its strategic action plan. Presence of a medicines supply management system, with a pharmaceutical management information system. Hospital therapeutic committees exist in all hospitals, and individual hospital catalogues have been developed.	Lack of national quantification data for pharmaceutical commodities and procurement systems for medicines. Weak regulatory frameworks for pharmaceutical commodities and professionals. Inadequate supportive supervision for health facilities Lack of pharmaceuticals directorate and drug regulatory unit positions in the establishment list No pharmaceutical staff at the public health centre level Irregular updating of guiding documents such as the National STG and EDL and adherence to STG.

Adapted from Mwase *et al.* (2010:58)

During the implementation of the Health Sector Strategic Plan 2012/13-2016/17, the MOH with support from development partners, for example, Management Sciences for Health (MSH), ensured that there were adequate quantities of safe and affordable essential medicines in the health sector as contained in the EML (Lesotho, 2013:33). The EML has been revised from time to time to ensure that it is in line with the overall disease burden in Lesotho. Besides, the

MOH ensured that guidelines for donations of medicines and national STDs are adhered to (Lesotho, 2013:33).

The formalisation and establishment of a position for a director of the Department of Pharmaceuticals, allocation of funds for the pharmaceuticals program and the deploying of an appropriate number of human resources to the directorate and provision of training and human resource development, as well as mentoring and succession plans were amongst recommendations given to the pharmaceutical department for implementation to strengthen it (MOH, 2010:109).

2.3.2 Control of medicines

The government of Lesotho through the MOH has established national structures to ensure proper control and usage of medicines in the country. Those national structures include essential documentation and guidelines (Lesotho, 2011c:25):

- A National Essential Medicines List (EML)
- The EML was updated in 2006 and has been disseminated to all health facilities through the office of the Director of Pharmaceutical Service. Additional to the medicine identification information (for example strength and dosage form), the EML indicates the levels of care the medicine can be ordered and prescribed. These include:
    - Medicines distributed to hospitals (only prescribed by doctors and specialists)
    - Medicines distributed to health centres and hospitals (prescribed by doctors and nurses)
    - Medicines distributed to health centres and health posts as part of primary health care services (prescribed by doctors, nurses and village health workers)
    - Medicines distributed on demand by specialist doctors.

There are currently 216 medicines on the EML. The National STGs for most common illnesses within which there are specific STGs that cover primary care, secondary care and paediatric conditions are endorsed by the MOH in Lesotho (Lesotho, 2011a:25). Selection of medicines for the EML is not undertaken through a written process. A mechanism aligning the EML with the STGs is in place.

STG and the EML were first released in 2006 and were revised in 2013. The second editions after the revision were released in 2017 (MOH: 2017)

Table 2-8 provides a summary of legislation and regulation of medicines in Lesotho and other SADC countries (Kamwanja *et al.*, 2010:7-9).

Table 2-8 List of legislation and regulations for regulating medicines in SADC member states

Country	Description/Title and year of enactment
Lesotho	Lesotho Drugs of Abuse Act (5 of 2008) Lesotho Dangerous Medicines Act (21 of 1973).
Zambia	Medicines and Related Substances Control Act (13 of 2003) Medicines and Related Substances Control Amendment Act (7 of 2008)
Swaziland	Convention on Psychotropic Substances (1971) Pharmacy Act (38 of 1929) Medicines and Related Substance Bill (2009) WHO Certificate scheme, 1995 UN Convention on Narcotics, 1961 UN Convention on Psychotropic Substances, 1971 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
Tanzania	Tanzania Food, Drugs and Cosmetics Act (1 of 2003)
Botswana	Drug and Related Substances Act (18 of 1992) Drug and Related Substances Act Regulations (1993)
South Africa	Medicines and Related Substances Act (101 of 1965) Pharmacy Act (53 of 1974) as amended. Nursing Act (33 of 2005) (2006) Health Professions Act 56 of 1974)

(Adapted from Kamwanja *et al.,* 2010:7-9)

2.3.3 Scheduling of medicines in Lesotho and comparison with other countries

The scheduling of medicines in Lesotho is done as stipulated by the Lesotho Dangerous Medicines Act (21 of 1973). The scheduling is done in three schedules, I, II and III. The three schedules and the examples of medicines falling within them are:

- Schedule I: habit-forming medicine or high-risk drugs (which includes morphine),
- Schedule II: potentially harmful medicines or risk drugs of use (which includes, e.g. tranquillizers such as diazepam), and
- Schedule III: prohibited drugs of abuse (amongst these is cannabis).

Dispensing in Lesotho is done in terms of the Lesotho Dangerous Medicines Act (21 of 1973) by dispensers who are authorised to perform such duties. These include pharmacists and

pharmacy technicians. Only pharmacists are allowed by the same law to handle dangerous medicines or drugs of abuse as scheduled by the law. According to Drug of Abuse Act (5 of 2008), the drug of abuse means a prohibited drug, a high-risk drug, or a risk drug, and includes a preparation. The Dangerous Medicines Act (21 of 1973) states that for habit-forming medicines (schedule I), permission to import, acquire or sell them should be granted by the MOH. The exception in this law is for medical practitioners, dental surgeons or veterinarians, who also may acquire, purchase and prescribe as well as dispense medicines that fall in the Lesotho Dangerous Medicines Act (21 of 1973) for medicinal purpose.

There was a revision of in the scheduling of the drugs of abuse as per the Drugs of Abuse (5 of 2008) which resulted in 5 schedules instead of three as compared to Lesotho Dangerous Medicines Act (21 of 1973). The revised scheduling according to Drugs of Abuse (5 of 2008) was as follows:

- Schedules 1 - Prohibited Drugs of Abuse: Medicines in this schedule include heroin, fentanyl, cannabis and its resin.
- Schedules 2 - High-Risk Drugs of Abuse: These include morphine, methadone and diphenoxylate.
- Schedules 3 - Risk Drugs of Abuse schedules: Medicines in this include midazolam, diazepam and chlordiazepoxide.
- Schedules 4 - Toxic chemical inhalants and controlled chemicals: Substances in this schedule include ephedrine, ergotamine and hydrochloric acid.
- Schedules 5 - Controlled Materials and Equipment: These include gelatine capsules (for example glucose and lactose base) and tabletting machines.

The currently available laws do not cover day-to-day medicines like flu and chronic medicines, including antibiotics, only schedule/controlled drugs as indicated above. The reason may have been that at the time of the inception of the law, there were no community pharmacies and prescribing was done at the hospitals and clinics.

2.4 Prescribing and dispensing in Lesotho

The basic pharmacy training curriculum includes components on the use of the national EML, STGs, problem-based pharmacotherapy and good practices in prescribing though pharmacists (Lesotho, 2009: 29).

It is estimated that 50% or more of medical expenditure is being wasted through irrational

prescribing, dispensing and patient use of medicine (Berha & Seyoum, 2018:75). Irrational use of medicines may occur at prescriber, dispenser and ultimately, consumer-level which includes:

- medicines are prescribed where none was needed,
- medicines are not prescribed according to STGs,
- ineffective or unsafe medicines are prescribed,
- effective and available medicines are underused; and
- medicines are misused (Arora *et al.*, 2017:14).

Prescribing in Lesotho is allowed for doctors, nurses and midwives according to the Lesotho Dangerous Medicines Act (21 of 1973). This was also mentioned in the Lesotho country profile done by WHO (WHO, 2009:30). Pharmacists are not permitted to prescribe and community pharmacies can only dispense prescriptions from these prescribers. However, doctors, nurses and midwives are allowed to dispense though they all lack basic training in problem-based pharmacotherapy and good dispensing practices. These healthcare professionals' basic training curriculum does not include such components. This may lead to irrational prescribing though other factors may also contribute to it.

Inappropriate prescribing patterns may arise from the demands or misconceptions of patients, although prescribers often exaggerate these demands in order to justify their prescribing habits (Arora *et al.*, 2017:14).

Irrational use of medicines is a global problem (Aki *et al*., 2013:55). Examples of irrational use of medicines such as patient usage of too many medicines (polypharmacy), inadequate dosage of antibiotics, use of antibiotics for non-bacterial infections, over-use of injections when oral medication can be more appropriate, prescribing the medicine that is inappropriate to clinical guidelines and self-medication (Aki *et al*., 2013:55). Antibiotics and some other potent or specialised medicines are usually listed as prescription-only medicines. However, in several countries, antibiotics seem to be sold over-the-counter despite national laws forbidding this practice (WHO, 2011a:31).

The prescribing indicators, as well as the core drug use indicators, are standardised and do not require any country, regional or health facility to modify them. This enables easy comparison (Berha & Seyoum, 2018:53).

Table 2-9 indicates WHO prescribing and patient care indicators and their standards according to in comparison to Lesotho and Ethiopia, as African countries (Berha & Seyoum, 2018:77; Ntšekhe *et al*., 2011:22)

Table 2-9: WHO prescribing indicators and standards in comparison to Lesotho and Ethiopia as African countries

Indicators	Mean values		
	Lesotho	**Ethiopia**	**Standard values (WHO)**
Average number of drugs per encounter	3.8	2.8	1.6 - 1.8
Percentage of encounters with an antibiotic prescribed (%)	37.6	6.6	20.0 - 26.8
Percentage of encounters with an injection prescribed (%)	-	8.4	13.4 - 24.1
Percentage of drugs prescribed by generic name (%)	35.6	97.9	100
Percentage of drugs prescribed from the essential drug list or formulary (%)	79	99.3	100

Adapted from Berha and Seyoum (2018:77); Ntšekhe *et al*. (2011.22); WHO (1997)

Polypharmacy was of concern at six study hospitals in Lesotho (Ntšekhe *et al*., 2011:21). On average, 3.8 medicines were prescribed per encounter within the outpatient setting. Generic prescribing is an area that requires the development of appropriate interventions because only 35.6% of the prescriptions adhered to the National Medicines Policy's (NMP) recommendation for generic prescribing (Ntšekhe *et al*., 2011:22). In the study of Ntšekhe *et al*. (2011:22) all the indicators for prescribing in Lesotho were not adhered to according to WHO standards, as shown in Table 2-9.

In the study done from Berha and Seyoum (2018:77) comparing Lesotho and Ethopia on prescribing indicators, Ethiopia performed well when it came to percentages of drugs prescribed by generic name and that of drugs prescribed from the EML. Lesotho showed low performance and was far from 100% adherence to WHO prescribing standards (Berha & Seyoum, 2018:77).

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities in Lesotho. Sometimes antibiotics are sold over-the-counter without a prescription, and injectable medicines are not sold over-the-counter without a prescription (Lesotho, 2011a:27). There is no provision or regulation for dispensing of antibiotics over-the-

counter available in Lesotho as only drugs of abuse are regulated by the Drugs of Abuse Act (5 of 2008).

In the study done on Lesotho pharmaceutical country profile, some findings were made. It was found out that prescribing by generic name was obligatory in the public sector in Lesotho (Lesotho, 2011c:25). The average number of prescribed medicines per prescription as depicted in Table 2-9, reflected that the average of prescribed medicines is 3.8. Amongst the medicines prescribed in the outpatient public healthcare facilities, 88% were on the national EML. Within patients treated in the outpatient public healthcare facilities, 53% received antibiotics, and 8% received injections. The percentage of prescribed medicines dispensed to patients amounted to 86.5%. In terms of labelling, 31.1% of dispensed medicines were adequately labelled (Lesotho, 2011c:26).

2.5 Pharmacy as a profession and its practice

Pharmacists are healthcare professionals whose professional responsibilities and accountabilities include seeking to ensure that people derive maximum therapeutic benefit from their treatments with medicines (WHO, 2011d:313). They have to ensure that a patient's drug therapy is indicated appropriately, the most effective available, the safest possible, and convenient for the patient, for the disease presented. This requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards and requirements, laws governing pharmacy and medicines and advances in knowledge and technology relating to the use of medicines (WHO, 2011d:313). Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and health care systems (WHO, 2019:4)**.**

Pharmacists ascertain the patient's understanding of medication therapy and provide counselling based on need determined by the pharmacist and/or when requested by the patient; minimally, counselling occurs upon medication initiation, with any change to medication therapy, for high-risk medications, and for high-risk patients (Centre for Pharmacy Practice Accreditation) (CPPA), 2016:18).

A community pharmacy is a healthcare facility that specialises in providing pharmaceutical services to the community. They were called drug stores, but a recent synonym used is a retail pharmacy, since it involves buying drugs from wholesalers and dispensing to the public (Brian *et al*., 2015:33). Community pharmacies are unique hybrids of professionalism, business, and health care. Community pharmacists are responsible for protecting society by providing expert services to help consumers manage risks associated with drug therapies. Historically

pharmacists fulfilled this responsibility by accurately dispensing prescription medications, verifying doses, and allergy checking. There are continuing efforts to transform the basis of community pharmacy practice from product distribution to patient-centred care services (McPherson & Fontane, 2011:2).

It was further expanded to achieve more patient-centred care. Pharmacists should give the person all relevant information in a way they can understand so that they can make informed decisions and choices. In addition, pharmacists should recognise and value diversity, and respect cultural differences of their patients. This will ensure that every person is treated fairly whatever their values and beliefs (General Pharmaceutical Council (GCP), 2017:8).

Community pharmacies in developing countries are one of the most important sources of advice on medicines (Goel *et al*., 1996:1155). Malangu (2014:226) shared the same sentiments that community or retail pharmacies are regarded as one of the most common sources of health services throughout the world. In South Africa, community pharmacies have been providing some primary health care services to clients who could afford to pay for them (Malangu, 2014:226).

Stimulating a professional relationship between a pharmacist and patient begins at the community level because patients must perceive pharmacists as necessary experts within the healthcare system (McPherson & Fontane, 2011:4). People will continue to consult pharmacists for minor health problems as they are trusted and are an accessible source of information and advice (WHO, 2009:9). This, therefore, implies that the community's health is in the hands of the community pharmacists; hence their practice should be well regulated and monitored.

In Nigeria, a study on pharmacy practice pointed out that, patients access health services in pharmacy shops without paying consultation fees. They access counselling, consultations, and varying levels of care without payment of consultation fee. They only part with their resources when there is a product purchased, not largely due to the services rendered (Brian, *et al.,* 2015:33).

Also, McPherson and Fontane (2011:2) stated that pharmacist-provided, patient-centred care services generally include collecting, maintaining, and evaluating patient-specific health information. It also includes direct consultation with patients and their other healthcare providers to implement, monitor, and revise care plans according to patient outcomes**.** People are individuals with their own values, needs and concerns. Person-centred care is delivered when pharmacy professionals understand what is important to the individual and then adapt

the care to meet their needs, making the care of the person their first priority (General Pharmacy Council (GPC), 2017:18).

Pharmaceutical management is among the key areas of health system performance, which combines basic pharmaceutical sciences, marketing and management. The functionality of a pharmaceutical management system can be examined within the following components: budget; pharmaceutical policies, laws, and regulations; procurement; storage and distribution; appropriate use; access to quality products and services; and financing (MOH, 2010: 59).

2.5.1 Role of community pharmacy

As pharmacists increasingly focus their practices on the provision of pharmaceutical care and continue to improve on pharmaceutical care services (Wiedenmayer *et al*., 2006:13), community pharmacy has embraced the following role/activities in pharmacy practice (WHO, 2011d:318-323):

- Ensuring appropriate drug therapy and outcomes,
- Ensuring appropriate pharmacotherapy, patient's understanding/adherence to his or her treatment plan and monitoring and reporting outcomes,
- Dispensing medications and devices,
- Processing the prescription or medicine order, preparing the pharmaceutical product and delivering the medication or devices,
- Health promotion and disease prevention,
- Delivering clinical preventive services, surveillance and reporting of public health issues and promoting safe medication use in society,
- Health systems management, and
- Managing medications throughout the health system, managing the use of medications within the health system, participating in research activities and engaging in interdisciplinary collaboration

To be relevant in the 21st century, community pharmacists must introduce a wide range of additional services relevant to health promotion, diagnosis, and screening in primary healthcare (Brian *et al*., 2015:36).

Some WHO countries like Portugal have continued to add more roles to the community pharmacy as the practice trajectory changes (WHO, 2019:49). Some of the additions include:

- Home support,
- Administering first aid,
- Administration of medicine,
- Use of auxiliary diagnostic and therapeutic methods,
- Nutrition consultation,
- Programs for adherence, medicines reconciliation and unit dose dispensing, as well as educational programs on the appropriate use of medical devices,
- Rapid tests for HIV, and hepatitis B and C screening, including counselling before and after the test, as well as patient referral to the appropriate hospital in the case of positive results, based on procedures adopted by the Ministry of Health, and
- Simple nursing care, including wound care and care to patients with a stoma.

Community pharmacists in Nigeria are one example of African community pharmacists that have embraced the health promotion role. According to Brian *et al*. (2015:36), community pharmacies in Nigeria now engage in varying levels of public health activities, including health education, health screening, family planning, pregnancy, and infant care, immunisation, prevention of smoking/smoking cessation services, weight gain control, health education, and disease prevention services.

The community pharmacist's role in community health promotion has not been incorporated in the primary care structure of Nigeria. Community pharmacies stock health promotion products for new-borns, children, women, geriatric and the general population. They offer harm reduction services, for example smokers. In developed countries like China, Australia and Europe, community pharmacies are centres of opioids substitution, HIV and Hepatitis prevention services (Brian & Henry, 2017:2-3).

Table 2-10 indicates the recommended roles and activities of community pharmacists, according to WHO (2011d:318-323).

Table 2-10: Summary of the roles and functions of community pharmacist

Role	Activities
Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products	Prepare extemporaneous medicine preparations and medical products
	Obtain, store and secure medicine preparations and medical products
	Distribute medicine preparations and medical products
	Dispose of medicine preparations and medical products
Provide effective medication therapy management	Assess patient health status and needs
	Manage patient medication therapy
	Monitor patient progress and outcomes
	Provide information about medicines and health-related issues
Maintain and improve professional performance	Plan and implement continuing professional development strategies to improve current and future performance
Contribute to improving the effectiveness of the health care system and public health	Disseminate evaluated information about medicines and various aspects of self-care
	Engage in preventive care activities and services
	Comply with national professional obligations, guidelines and legislations
	Advocate and support national policies that promote improved health outcomes

Adapted from (FIP/WHO, 2011d:318-323)

A Malaysian study concluded that the majority of respondents 264 (51.97%) felt that pharmaceutical care services provided by the community pharmacies were good. However, improvements could be made concerning understanding patients' comprehension levels. Areas lacking included counselling and spending more time in ensuring that patients have an understanding of their medication hence good health outcomes (Sam *et al.*, 2015:78).

There are a few studies done in countries that focused on the practices of community pharmacies. One is the study done in South Africa by Malangu (2014:226-233) and in Nigeria by Ogbonna *et al.* (2015:33-42). A study conducted in other countries, for example in India by Tiyyagura *et al*. (2014:27-33) provided insight on pharmacy practice. However, the differences

in the healthcare systems make it difficult to extrapolate the results to the Nigerian setting (Brian *et al*., 2015:40). Few studies done for pharmacy practice are elaborated in Table 2-15. In Lesotho, no studies were done in community pharmacies except where statistics regarding the number of community pharmacies have been used (MOH, 2010:13).

2.5.2 Starting a community pharmacy in Lesotho

A community pharmacist is expected to be a capable primary care provider in terms of delivering patient-oriented services, as stated by Schahill (2008:17). In addition to traditional manufacturing and dispensing of medicines, community pharmacy is expected to add value through enhanced services (such as medication review) that stretch the boundaries of what community pharmacy has offered in the past (Scahill, 2008:17).

Policies in Lesotho government through the MOT (Lesotho, 2017:34) made starting a business easier by creating a one-stop-shop for company incorporation and by eliminating the requirements for minimum paid-in capital and notarisation of the articles of association. This is called the One-Stop Business Facilitation Centre (OBFC).

A detailed summary of the legal steps to be followed by entrepreneurs wishing to incorporate and register a business, which includes community pharmacies (chemists) in Lesotho (Companies Act, 18 of 2011) is provided in Table 2-11.

Table 2-11: Steps to follow when opening a new community pharmacy in Lesotho

Steps	Comments
To conduct a company name search and apply for business registration	
To submit a certified proof of address and a certified copy of proof of identity	Certification is done at OBFC
To get a registered legal practitioner to prepare and register company documents	Attorneys do not need to prepare company documents. However, the Registrar of Companies will not allow anyone except a registered attorney to register a company in the Deeds Office or to carry out any statutory requirements in the registrar's records
Receive an inspection by the Public Health Inspector and obtain a health certificate	The Maseru City Council requires a health inspection done by its health officers and will then issue a health certificate after satisfactory results. In the districts, the District Health Management Team (DHMT) is the one that issues health certificates after inspections
To apply for operation license with OBFC at the MOT	It is required to submit the sublease or lease, certified passport copies of all of the directors, and the health certificate
To open a bank account and pay the required initial capital in a bank	
To register with the Lesotho Revenue Authority (LRA) for tax clearance	

Table 2-12 provides a summary of the procedures for the opening of businesses (including community pharmacies) in Lesotho (2017:34).

Table 2-12: Business opening procedure summary in Lesotho

No. of steps to do	Procedure	Time to complete	Agency
1	Conduct a company name search and apply for business registration	7 days	OBFC

No. of steps to do	Procedure	Time to complete	Agency
2	Pay the registration fee, submit the receipt and obtain company registration documents and the Tax Identification Number (TIN)	1 day	OBFC
3	Have land lease stamped and pay the stamp duty	1 day	Deeds Registry and the Land Administration Authority
4	Receive inspection by the Public Health Inspector and obtain a health certificate	14 days	Public Health Inspector
5	Apply for an operational license	7 days	MOT
6	Pay the operational license, submit the receipt and obtain the license	1 day	OBFC
7	File for workman's compensation	1 day	Insurance company

(Adapted from Lesotho, 2017:34)

Contents and conditions for registration, licensing of controlled medicines, chemicals, and equipment according to Drugs of Abuse Act (5 of 2008) include the following:

"A licence issued by the Minister for the above shall specify:
(a) The full name and address of the licensee,
(b) Each activity to which the licence relates,
(c) The drug of abuse, controlled chemical, equipment or material to which the licence relates,
(d) The address of each place and premises at which:
    (i) The licensed activity is to be carried out, and
    (ii) The drugs of abuse, controlled chemical, equipment or materials are to be stored.
(e) Such terms and conditions are necessary and reasonable for ensuring the proper:
    (i) Carrying out and supervision of the licensed activity,
    (ii) Establishment, maintenance and preservation of records relating to that activity, and
    (iii) Reporting to the Minister about the carrying out of that activity."

2.5.3 Community pharmacy ownership and registration

Before 1997, the Pharmacy Act (53 of 1974) of South Africa only allowed for a pharmacy to be owned by an individual licensed and registered as a pharmacist (SA, 1974). The Pharmacy Act (53 of 1974) as amended in 1997 and ratified in 2003 allows non-pharmacists to own pharmacies provided that, a responsible pharmacist is employed to manage the community

pharmacy at all times. In addition, according to the Pharmacy Act (53 of 1974), ownership of a community pharmacy in South Africa is prohibited if the person or a corporate is an authorised prescriber, a manufacturing company or have any direct or indirect interest in the community pharmacy.

Ghana is one African country where pharmacy professional registration is regulated. Ghana also has legislation on pharmacy practice, licensing of pharmacies, medicines prescribing and sales (Lowe & Montagu, 2009:37).

Table 2-13 indicates some of the laws and regulatory bodies governing different aspects of community pharmacy practice for different countries.

Table 2-13: Community pharmacy practice laws and regulatory bodies in different countries

Country	Ownership / practice legislation	Pharmacy registration / licensing	Drug sales/prescription legislation
Ghana	Pharmacy Act (489 of 1994)	Pharmacy council (Registration)	Pharmacy Act (489 of 1994)
South Africa	Pharmacy Act (53 of 1974). Amended 1997, enacted 2003	Director General of Health, Department of Health (Licensing of pharmacies) South African Pharmacy Council (Registration of pharmacists)	Medicines and Related Substances Act (101 of 1965) (amended 1997)
India	Pharmacy Act (8 of 1948)	India Food and drug administration India (FDA) (licensing). State Pharmacy Councils (registration) reporting to the National Pharmacy Council	Pharmacy Act (8 of 1948), Drugs and Cosmetics Act (23 of 1940)

Examples of countries where there are clear regulatory standards regarding different aspects of community pharmacy practice are shown in Tables 2-13 and 2-14.

Ghana has regulations on ownership of community pharmacies as well as stipulated restrictions, and qualification of community pharmacy owners. It also shows how many

community pharmacies chains are allowed, for example 3-5 chains are allowed owned by either pharmacist or non-pharmacist. In the case of ownership by a non-pharmacist, a supervising pharmacist should be available either full-time or part-time (Lowe & Montagu, 2009:39).

Table 2.14 below indicates different types of community pharmacy ownership and their restrictions as a representation of how pharmacy ownership differs in Africa, with Ghana and SA as examples, as well as internationally with India as an example.

Table 2-14: Ownership of community pharmacies.

Country	Who can own	Ownership restrictions	Qualifications	Retail chains
Ghana	Sole proprietors or corporate entities	Pharmacists and non-pharmacists permitted to own. Must be a supervising pharmacist but can be part-time	BPharm, 1500 hours internship (480 hours in a recognised community pharmacy), pass in professional exams	3-5
South Africa	Individuals and body corporates	There must be a registered pharmacist in all stores. Must satisfy a need for a new pharmacy in that area	BPharm (4-year degree), 12 months practical training period, pre-registration evaluation, 12 months public sector community service	>7
India	Individuals, partnerships or body corporates	Individuals must be pharmacists. Partnership and body corporate-owned stores must have a supervising pharmacist, often a *"signature pharmacist*	BPharm (4-year degree) or DPharm (2-year diploma course from an approved institution followed by 500 hours of practical training over 3 months)	>10

In Australia, current state and territory regulatory structures mainly restrict ownership to pharmacists or corporate entities controlled by pharmacists (Hattingh, 2011:147).

In the United States of America (USA), the State of Michigan regulates the distribution of prescription medications through the Michigan Department of Community Health. This department sets requirements for becoming a state-licensed pharmacist including the

responsibilities that must be performed by pharmacists as well as restrictions (Jesse, 2010:578).

In India, the Drugs and Cosmetics Act (23 of 1940) and the Pharmacy Act (8 of 1948) requires individual states to create Pharmacy Councils whose responsibility will be keeping a register of pharmacists and information relating to their qualifications and place of practice.

2.5.4 Community pharmacies inspection

In Lesotho, legal provisions exist, allowing for the appointment of government pharmaceutical inspectors to inspect premises where pharmaceutical activities are performed (Lesotho, 2011a:14). Such inspections are not required by law but are a prerequisite for the licensing of private facilities. Where inspections are legal requirements, these are not the same for public and private facilities. These include community pharmacies (Lesotho, 2011a:14). These inspections are carried out on several entities as outlined in Table 2.15 but are not carried out on a routine basis

Table 2-15: Pharmaceutical entities and their inspection in Lesotho

Local entities inspected	Inspection
Private wholesalers (for medicines and medical supplies)	Yes
Retail distributors (for medicines)	Yes
Public pharmacies and stores	Yes
Pharmacies and dispensing points	Yes

(Adapted from Lesotho, 2011b:14)

A study on Lesotho country profile, revealed that the most reliable performance area in the pharmaceutical management system is the proper storage and distribution of medicines and medical products (Lesotho, 2011c:23). This is due to the availability of the central medicine store named the NDSO, which is responsible for procurement, supply and delivery of medicines and medical supplies around Lesotho for hospitals, clinics and community pharmacies. The distribution of medicines and medical supplies through NDSO is currently in place in the pharmaceutical sector, including community pharmacies.

Although much effort has been put into the reform of the pharmaceutical sector in Lesotho, not much can be done on enforcement if laws are not passed. Therefore, community pharmacy would still be in the wrong hands for a few more years to come, which poses a concern for patient care and safety.

2.5.5 Role players or stakeholders in community pharmacy practice in Lesotho

Stakeholders in the community pharmacy practice are the individual organisations, ministries and departments that are responsible for the progression, regulation and support of community pharmacy practice. These include:

- Ministry of Health (MOH): The MOH is a Member of Parliament and responsible for all health issues in Lesotho including i) the development of health policies; ii) development of standards and guidelines, mobilisation of health resources and monitoring and evaluation of health sector interventions. It is also responsible for providing a legal framework within which health services are delivered. The MOH through the office of the Director Pharmaceutical Services ensures adherence to a good standard of practice, for example GPP; human resource (employment and training) and other resources needed for the development of the Ministry, for example STGs and EMLs. MOH also ensures coordination with non-governmental organisations for support of the ministry, for example WHO, Management Science for Health (MSH) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS) (Lesotho, 2013:33). The MOH also collaborates with other public sectors as well as health stakeholders on health matters (Lesotho, 2011b:18). The following are the MOH collaborations:

- The structure of the MOHSW; after decentralisation, has defined roles and functions of the MOH as the central administration and the district's management teams. The MOH will concentrate on policy, strategic planning, supervision as well as monitoring and evaluation, while districts should implement the plans for the districts, resource mobilisation, advocacy for health and partners coordination as well as provision of a regulatory framework for all health care providers (Lesotho, 2011b:25).

- Ministry of Trade (MOT): The MOT co-ordinates commercial activities within the country to maintain an appropriately regulated and harmonious domestic trading environment. Its main objectives include establishing guidelines and procedures for issuing trading licenses and coordinating the issuing of trading licenses by a local licensing board, including those of community pharmacies as businesses. It achieves its mandate through the established OBFC (Lesotho, 2017:34).

- Lesotho Medical, Dental and Pharmacy Council (LMDPC): It is the statutory body that ensures that health personnel (medical, dental and pharmacy personnel) practice according to the law; registration of personnel and handling of schedule drugs according to LMDPC Order (13 of 1970).

- Pharmaceutical suppliers: These are companies that are responsible for the procurement of medicines and medical supplies (consumables), their sale and distribution within the country. Some suppliers are local, and others are from outside Lesotho.

- All public government facilities of Lesotho and private non-profit (CHAL and Red Cross) facilities procure pharmaceuticals from the NDSO; however, CHAL facilities also regularly procure their pharmaceuticals from Tripharm®, a private wholesaler. The facilities use the NDSO product catalogue for placement of orders, and, hence, international non-proprietary names are used during procurement (MOH, 2010:62). The NDSO is responsible for the procurement, storage, and distribution of medicines and other health and medical supplies for CHAL and government facilities but also serves private health facilities and pharmacies (Lesotho, 2013:16).

STGs summarise recommended treatments for commonly occurring conditions. They should represent a consensus on what is regarded as the most appropriate treatment for each condition. The aim of providing such information is for treatment protocols to become standardised throughout a health system and that prescribing for the conditions covered is rationalized (Lesotho, 2011b:279).

2.6 Pharmaceutical supply and management system in Lesotho

Patients, members of the public and other healthcare professionals are entitled to expect that medicines sold or supplied within the course of professional pharmacy practice are obtained from a reputable source, that appropriate distribution processes are followed and that the medicines are fit for the intended purpose (Pharmaceutical Society of Northern Ireland, 2016:5)

Medicines constitute a significant burden on people as well as government budgets. As a result, community pharmacies play a significant role in providing health services to the people and pharmaceutical care as per need.

Drug supply management (DSM) is monitored, and tools are developed for government and CHAL hospitals. The tools used include the Drugs Supply Management Manual that was developed in 2008 and reviewed in 2016 (MOHSW, 2016:6). Besides, the MOHSW (2016:6) showed that in 2016 the Supply Chain Coordinating Unit was established to support the implementation of, amongst others, the supply chain management of pharmaceuticals for all health facilities including laboratory, dental, family health and nutrition commodities. The implementation procedure would be ensured through the Lesotho Standard Operating

Procedures (LeSOPs). The LeSOPs are intended to guide and standardise pharmaceutical supply chain operations in the government and CHAL hospital pharmacies (MOH, 2016:2)

2.7 Pharmaceutical procurement in Lesotho

Medicines play an integral part of healthcare delivery. However, they are expensive commodities and account for a significant proportion of overall health expenditure in most countries (Ofori-Asenso & Agyeman, 2016:1).

Effective and efficient procurement and supply chain management systems are essential towards the achievement of millennium development goals and the promotion of sustainable development (WHO, 2011c:2) and will, among others, ensure availability of essential medicines at every point of need (MSH, 2012:12).

Pharmaceutical procurement is a significant determinant of drug availability and total health costs. It is indicated that medicine expenditure represents the single largest expenditure after salaries, and accounts for approximately 20 to 40% of the total healthcare budget and up to 90% of the household budget in the sub-Saharan region (MSH, 2012:1).

Procurement of medicines is relatively expensive as Lesotho relies on importation from other countries. This challenge is compounded by the limited capacity to timely quantify the requirements/needs leading to speculations and increase in medicine prices (Lesotho, 2011b:31).

In Lesotho, medicine procurement takes place through a semi-autonomous national procurement agency, named the National Drug Service Organisation (NDSO). The NDSO was established as the trading account (financed through a mark-up system) for the Ministry of Finance and is mandated to procure, store and distribute medicines, as well as medical, laboratory and X-ray supplies to all public health facilities in the country (Lesotho, 2011c:22). The NDSO provides commercial (trade) stock of pharmaceutical products and medical and laboratory supplies to government hospitals and health centres, CHAL facilities, and private clinics and pharmacies (SIAPS, 2013:1).

Medicine procurement is, directly and indirectly, dependent on the availability of updated policies and procedures and a functional Hospital Pharmaco-Therapeutic Committee (HPTC). Consequently, the proper drug selection, forecasting and quantification of medicines will be possible (MSH, 2012:1).

The country introduced universal primary healthcare in 2008, only to result in a massive shortage of drugs and poor delivery of essential health services, worsened by the fact that the CHAL, which gets a 70% subsidy, were forced to provide healthcare services free of charge without making provision to increase subsidies to 100% (Bertelsmann, 2014:22).

In the case of any licence to import, export or bring to Lesotho in transit a drug of abuse, controlled chemical, equipment or material, the condition that a separate import, export or transit permit is first obtained about any such transaction before it takes place (Drugs of Abuse Act 5 of 2008).

Financing arrangements for pharmaceuticals and medical supplies comprise of a public and a private domain; information on the private domain is lacking. The government is currently fully responsible for meeting the public facilities' requirements. Drugs and vaccines are entirely the responsibility of the government in collaboration with some development partners and global funding (MOH, 2010:55). The collaboration is not for all health commodities but with a complement of donors whose support is in the areas of HIV/AIDS, TB, family planning, nutrition and the Expanded Programme on Immunisation (EPI) (MOH, 2010:65).

2.8 Good Pharmacy Practice (GPP)

Pharmacy practice as defined by Wiedenmayer *et al*. (2006:70) is the provision of medications and other healthcare products and services to help people and society in making the best use of them. It encourages safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related products for the prevention of illness, and maintenance and management of health (Jesse, 2010: 577). Jesse (2010:577) continued to show that the professional functions associated with the practice of pharmacy include: the interpretation and evaluation of the prescription: drug product selection; the compounding, dispensing, safe storage and distribution of drugs and devices; the maintenance of legally required records; advising the prescriber and the patient as required about the contents; therapeutic action, utilisation, and possible adverse reactions or interactions of drugs.

Just as pharmacy practice will vary among nations, it will also vary among practice locations. At the national or appropriate (for example state or provincial) level, it is necessary to establish the following (WHO, 2011b:316):

- A legal framework that:
    - Defines who can practice pharmacy defines the scope of pharmacy practice and ensures the integrity of the supply chain and the quality of medicines.

- A workforce framework that:

    - Ensures the competence of pharmacy staff through Continuing Professional Development (CPD) or Continuing Education (C.E.) programmes and defines the personnel resources needed to provide GPP.

GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care (WHO, 2011b:315).

According to WHO (1996:6), leading elements of GPP are:

- Health promotion and ill-health prevention: health education and specific campaign on quality of equipment used in diagnosis,

- Supply and use of prescribed medicines and other health care products,

- Self-care; this involves identifying who is sick, possible reason, and when should a referral to medical practitioner be done, and

- Influencing prescribing and medicine use; includes national standards and regulations, for example standard treatment guidelines and essential medicines list.

Table 2-16 indicates some of the studies done in community pharmacy covering different aspects and its role as well as the standard of practice.

Table 2-16: Community pharmacy practice studies done in different countries

Country	Description of Study (Topics Covered)	Details of Studies Done (Examples)
South Africa	Community practice and standards	Malangu, N. 2014. The future of community pharmacy practice in South Africa in the light of the proposed new qualification for pharmacists: implications and challenges. *Global Journal for Health Science*, 6(6):226-233. Results: The new authorised pharmacist prescriber qualification will definitely expand the responsibilities of pharmacists and diversify their income streams from examining, diagnosing and monitoring treatment outcomes of their clients or patients

Country	Description of Study (Topics Covered)	Details of Studies Done (Examples)
Nigeria	Community practice, standards and its challenges Community pharmacists in public health	Ogbonna, B., Ejim, C.E., Ikebudu, C.C., Uzodinma, S.U. & Orji C.E. 2015. Pharmaceutical care and community pharmacy practice in Nigeria; grappling with the frontier. *European Journal of Pharmaceutical and Medical Research*, 2(7):33-42. Ogbonna, B.O. & Ndukwe, H.C. 2017. Community pharmacists and health promotion activities in the 21st century; maximizing the expanded roles for universal health coverage and population health optimisation. *MedCrave Online Journal of Public Health,* 6(3):354-358. Results: Nigeria has not evolved in terms of community pharmacy practice, still behind on pharmaceutical care and non-pharmacy professionals are involved in the practice
India	Good Pharmacy Practice	Tiyyagura, S.R., Purnanand A. & Rathinavelu M.R. 2014. Assessment of Good Pharmacy Practice (GPP) in pharmacies of community settings in India. *International journal of scientific reports journal of pharmacy,* 4(12):27-33. Results: Non-pharmacy personnel and underqualified sometimes even uneducated personnel are involved in community pharmacy practice
Ethiopia	Pharmaceutical Services	Teshale C., Hussein J. & Mussa R. 2014. Assessment of pharmaceutical services in Jimma Zone, Oromia Regional State, South-West Ethiopia. *International journal of teaching & practice,* 2(5):960-966. Results: The average number of drugs per prescription was 2.3. 72.8% prescriptions were found to be legible, 12.8% and 34.8% respectively contained injections and antibiotics, while only 5.6% of the patient knew the potential side effects of their medications
Lesotho	N.A.	No study was done on either a pharmacy practice or community pharmacy practice and its standards

2.9 Requirements of Good Pharmacy Practice

Pharmacy practice does not take place in a vacuum but in the healthcare environment. It aims to improve health.

Requirements of GPP, according to WHO (2011b:314), includes the following:

- A pharmacist's first concern in all settings is the welfare of patients.

- The core of the pharmacy practice is to help patients make the best use of medicines. Fundamental functions include the supply of medication and other health care products of assured quality, the provision of appropriate information and advice to the patient, administration of medication, when required, and the monitoring of the effects of medication use.

- An integral part of the pharmacist's contribution is the promotion of rational and economical prescribing, as well as dispensing.

- The objective of each element of pharmacy provision is relevant to the patient, is clearly defined and is effectively communicated to all those involved. Multidisciplinary collaboration among health care professionals is the key factor for successfully improving patient safety.

Good Pharmacy Practice (GPP) is, therefore required to ensure that the practice of pharmacy is appropriately delivered. The WHO (2011b:315) emphasised that GPP is the practice of pharmacy that responds to the needs of the people who use pharmacists' services to provide optimal, evidence-based care (WHO, 2011b:315). The GPP guidelines of the SAPC include the following main elements (SAPC, 2010:4):

- Standards for premises, for example premises' appearance and control of access;
- Standards for human resources, for example staffing of the pharmacy and registration;
- Standards for pharmaceutical services, for example procurement and supply of medicines; and
- Standards for pharmacy management, for example ethics and professional standards.

The GPP guidelines that will be used in this study as a standard will be those of Lesotho (2010:310-323), and some comparisons will be made with those of the SAPC (2010:1-230) as a neighbouring country and one of the suppliers of medicines in Lesotho. Some reference to international standards will also be made for emphasis.

According to Ogbonna *et al*. (2015:35), there are factors that have limited the growth of pharmaceutical care practice in Nigeria, especially at the community pharmacy level. These factors include limited consulting time, lack of private counselling areas at the community pharmacies, the perception that patients are not willing to pay for specialised care, and unfriendly inter-professional dispositions. Also, Ogbonna *et al*. (2015:35) stated that lack of enforcement of standards for pharmacists in their daily practice had been identified as a

limitation to widespread implementation of pharmaceutical care.

2.10 Different professional standards of good pharmacy practice

Professional standards describe how best pharmacists and their teams can provide optimal, honest and high quality services to their patients by providing a broad framework to support their professional practice development whilst ensuring that pharmacists and their teams are equipped and geared towards future services and more expanded roles (RPS, 2017:5).

According to Royal Pharmaceutical Society (RPS) (2017:5), the professional standards help to build trust between pharmacy personnel and patients that ensures patients are put first and that professionalism is ensured. These standards will help patients experience a consistent quality of service within and across healthcare providers that will protect them from incidents of avoidable harm and help them to get the best outcomes from their medicines (RPS, 2017:5).

A properly functioning community pharmacy should be operating under some set standards, including professional standards that must be adhered to. The standards are a statement of what people expect from pharmacy professionals and also reflect what pharmacy professionals have told us they expect of themselves and their colleagues to deliver safe and effective care (GPC), 2017:4)**.** These standards include the following:

2.10.1.1 Professional standards for premises

Premises are places or areas allocated for provision of community pharmacy services and should be registered. A premise should also be easily identifiable e.g. its name displayed at the premises (PSI, 2012:4-5)

There is a need to include national standards that will ensure that facilities for a confidential conversation with patients to ensure privacy is available, that the premises do not allow direct sunlight to the medicines, guarantee their quality and safety and the quality of equipment used is assured (WHO, 1996:7-8).

2.10.1.1.1 Layout of pharmacies

The physical layout of the community pharmacy should be designed to provide maximum privacy for professional interaction (MOH, 2010:9).

In Ireland, the community pharmacies' sales area is maintained in a way, which enhances the image. The layout of the pharmacy must facilitate the pharmacist to supervise the sale and supply of medicines (PSI, 2012:7).

The community pharmacy layout and fittings should allow for proper storage of medicinal products. It should also have a suitable waiting area with seating option and a separate, designated, conveniently located patient consultation area should be provided (PSI, 2012:7-8)

Pharmacy practice should have adequate space to conduct its operations. The workflow designs should provide for safe dispensing practices and delivery of patient care services. The working environment should be created to minimise interruptions and allow staff to concentrate on their assigned duties (Centre for Pharmacy Practice Accreditation (CPPA), 2016:7).

In South Africa, it was also stated the design and layout of the community pharmacy must reflect a logical flow of work, effective communication allowing for easy supervision by the pharmacist. A pharmacist should be able to see everywhere in the dispensary area (SAPC, 2018:35).

2.10.1.1.2 Dispensing area

A dispensing area should be conducive enough to allow for easy access and communication by pharmacists and their patients while still maintaining privacy and confidentiality (SAPC, 2018:35). The following are some of the standards to be maintained in the dispensing area as stipulated by SAPC:

- the dispensing area should maintain an ambient environment with temperature maintained between 15^0C and 25^0C.
- air-conditioner must be installed.
- dispensing area should be furnished with equipment and fittings that are suitable for dispensing purposes.
- a refrigerator maintained at 2^0C and 8^0C.
- suitable and clean weighing and counting equipment.

Some community pharmacies offer the concession of segregating a continuous counter space with vertical partitions in an attempt to create the illusion of privacy for patients. While these structures are a small step in the right direction of adhering to acceptable standards of premises, patients may still feel reluctant to share personal information in such an environment (PSI, 2012:7).

The dispensing area should be located within the professional service area, is appropriately constructed and maintained and facilitates quality dispensing and compounding activities (PSI, 2012:8- 10).

Dispensing site/area is neat, clean, and organised to maintain and project a professional appearance (CPPA, 2016:7).

2.10.1.2 Professional standards for pharmacy human resource

In Britain, according to the GPC (General Pharmaceutical Council) (2017:6), all pharmacy professionals (pharmacists and pharmacy technicians) contribute to delivering and improving the health, safety and wellbeing of patients and the public. It was highlight that being professional, ensuring safety and effective service to patients are central and vital for community pharmacy professionals' roles. Furthermore, it was affirmed that it is the attitudes and behaviours of pharmacy professionals in their day-to-day work, which make the most significant contributions to the quality of care, of which safety is a vital part (GPC, 2017:4).

2.10.1.2.1 Pharmacy professionals' responsibilities

There is a need to have standards to determine who should provide community pharmacy services to patients, e.g., whether by a pharmacist or a pharmacy technician and what their roles should be. It is not a prerequisite for employment to register with the pharmacy council in Lesotho, especially when the government consumes newly qualified pharmacy personnel. This is evident from the list compiled by the council that shows only the privately employed registered pharmacists and pharmacy technicians (LMDPC, 2014:1-3).

The ability of a country to meet its health goals depends mainly on the knowledge, skills, motivation and deployment of people responsible for organising and delivering health services (MOH, 2010:24).

Patients receive safe and effective care when pharmacy professionals observe some standards and have responsibilities to ensure those standards are met. In the Great Britain, standards for pharmacy should be met by both pharmacists and pharmacy technicians (GCP, 2017:8-16). Some of those standards include:

- provision of patient cantered care to ensure wellbeing of patients.
- co-operating with other health professionals to provide best possible health outcome for the patient.
- behaving in a professional manner to keep abreast the honour and dignity of pharmacy.
- being able to communicate effectively with patients ensuring confidentiality at all times.
- maintaining and developing their professional knowledge and skills. This benefits patients in that pharmacy personnel will stay up-to-date with new developments and

health technologies hence make better decision and provide relevant information at patient counselling.

- ensuring professional independence; knowing their professional limits and conflict of interests as well practising with the legal and professional boundaries.

Pharmacy professionals in South Africa are also guided by the same professional standards (SAPC, 2018:16-29).

Pharmacy professionals in Britain must provide person-centred care, work in partnership with others, communicate effectively, maintain, develop and use their professional knowledge and skills, use professional judgement, behave professionally, respect and support the person's confidentiality and privacy, and speak up when they have concerns or when things go wrong always demonstrating leadership (GPC, 2017:6).

In Lesotho, available information on the public health services providers mainly show the numbers of doctors and nurses. There is silence about those who are dedicated to the delivery of medicines in both public and private sectors (WHO, 2011a:2).

According to the WHO (2011a:2), to ensure that only quality and authorised products are made available to the population, it requires a functional and well-resourced pharmaceutical supply and regulatory system, with adequate numbers of trained staff.

Requirements for registration are original or certified copies of certificates, letter of employment in Lesotho (for foreign doctors), a completed application form, certificate of good standing from the most recent registration jurisdiction, photographs, curriculum vitae, and an application fee (MOH, 2010:55). In addition, once registered, health professionals' requirements are not monitored, and the council does not have the capacity to require recertification.

2.10.1.3 Professional standards for pharmaceutical services

The professional standards describe quality pharmacy services and provide an outline to support pharmacists and their teams to develop their professional practice, continually improve services, shape future services and roles, and deliver high-quality patient care across all settings (RPS, 2017:5).

Pharmaceutical services form an integral part of health services to optimise therapies with good health outcomes for patients. These pharmaceutical services include patient counselling and the availability of medicines to mention a few. Patient counselling services are a vital part

of pharmaceutical care services that include assessing the patients' comprehension concerning their medication (SAPC, 2010:43).

Availability of medicines and reliability of service play an integral part in the provision of pharmaceutical care. The SAPC (2010:43) states that patients need to be certain of the fact that the professional activities provided are those that will ensure confidentiality of their health information; that the medicines they receive are of good quality and efficacy for their ailments. Pharmacy personnel responsible have a task of procuring medicines from reputable suppliers hence the need for standards for the pharmaceutical services.

As new models of care develop and pharmacy services evolve, the professional standards will continue to apply (RSP, 2017:5). Table 1-17 illustrates some of the updated standards of pharmacy services.

Table 2-17: Updated standards of pharmacy services

Standards	Benefits in the provision of pharmaceutical care
Putting patients first	Pharmacy services enable patients to be fully involved in their own care and to make shared decisions about their treatment and their medicines
Episode of care	Patients' medicines requirements are regularly assessed and responded to in order to keep them safe and to optimise outcomes from medicines.
Integrated transfer of care	Health and social care practitioners receive and share relevant information about the patient and their medicines when a patient transfers from one care setting to another
Medicine governance	Pharmacy expertise is available seven days a week to support the safe and effective use of medicines. The pharmacy team leads a multidisciplinary approach to safe medication practices
Efficient supply of medicines	Medicines supply is safe, efficient and timely seven days a week whether provided in house or outsourced
Leadership	Pharmacy has strong professional leadership, a clear strategic vision and the governance and controls assurance necessary to ensure patients are safe and get the best from their medicines
Systems governance and financial management	Safe systems of work are established and pharmacy services have sound financial management
Workforce	The pharmacy team has the right skill mix, capability and capacity to provide safe, quality services to patients

2.10.1.4 Professional standards for community pharmacy management

Professional standards for community pharmacy management should be observed to ensure effective provision of pharmaceutical care and the pharmacy is well organised as well as establish accountability by managers (SAPC, 2018:173).

Community pharmacists must always uphold the standards of the profession, practice with ethical consideration as they are entrusted with the first-line treatment before patients seek further management, most of the time, they are the referral system. They also should abide by the statutes governing the profession. For example, in Lesotho, according to the LMDP Order (13 of 1970), both pharmacists and pharmacy technicians should be registered with the LMDPC before they can practice.

Only qualified personnel should be able to work as a pharmacist and should continue with their continuing professional development. Pharmacists should be licensed and regulated and

be a part of the healthcare system and be accountable for all the activities in the community pharmacy as well as supervising subordinates (FIP, 2020:23).

Just as pharmacy practice will vary among nations, it will also vary among practice locations. Therefore, standards should recognise the uniqueness of different pharmacy practice settings (for example community and hospital pharmacy) (PSI, 2012:7). Besides, as medicines and needs change, the standards should acknowledge evolving practice settings and provide these developing services with guidance without negatively affecting the evolutionary nature of practice.

In order for smooth running of the community pharmacies in the UK, they are advised to practice regular audits. The audits are a way of assessing and offer evidence confirming that the pharmacy continues to provide good care to the patients and adheres to al set regulations. Good management also includes staff training; patients' risk assessment hence does follow ups. This will require keeping records of patients for monitoring (GPC, 2015:10).

The professional standards for community pharmacy management are aimed at giving guideline to the administrative side of the community pharmacy practice. These are inclusive of pharmacy management that seeks to ensure proper planning of human resource as well as the financial aspects of the practice. The other is quality management, which encompasses quality of care, quality of standard of the practice and its effectiveness of the services systems assessing patients' satisfaction as a monitoring one of the tools. Lastly the pharmacy management should be on ethics and professional standards whereby the focus should be on inter-personal relationships and standard operating procedures (SAPC, 2018:177).

2.10.1.5 Professional standards for dispensing

Professional standards for dispensing are the standards that will ensure the dispensing practice is done to benefit the patient and adhere to the set standards by individual country. Pharmacy professionals should make sure that medicines they dispense are clinically appropriate, are prepared with utmost care and dispensed when needed (RPS, 2017:20).

2.10.1.5.1 Dispensing

The pharmacist is responsible for ensuring that prescription medications are dispensed accurately and in a timely manner (McPherson & Fontane, 2011:1).

In terms of the Medicines and Related Substances Control Act (101 of 1965) of South Africa, the dispensing of medicines should be regulated. A medical practitioner, dentist, nurse or other

person registered in terms of this Act may compound or dispense medicines only on the authority and subject to the conditions of a licence granted by the relevant council and any applicable legislation; and shall not be entitled to keep an open shop or pharmacy. Pharmacists are prevented from supplying most common medicines from Schedule 3 of the Medicines and Related Substances Control Act (101 of 1965)

Like in a number of cases in Lesotho, in Nigeria, the dispensers working at community pharmacies have minimal formal education, with little or no professional training. They rely on information gathered from the medical representatives of pharmaceutical companies and experiences on the job over the years (Ogbonna *et al.,* 2015:40). With this state of qualification and training, it, therefore, means that these dispensers (in Lesotho, they are termed loosely as pharmacist assistants) carry out the functions of a dispenser, storekeeper, inventory manager, accountant, prescriber, procurement officer, and patient counsellor (Ogbonna *et al.,* 2015:40).

In Lesotho, only pharmacy personnel (pharmacist and pharmacy technicians) can dispense but the law gives a provision for prescribers (doctor, dentist but not a nurse) to dispense medicines Lesotho Medical, Dental & Pharmacy Order (12 of 1970).

2.10.1.5.2 Counselling of patients

It is the responsibility of the community pharmacy personnel to offer counselling for their patients. This is important especially when patient-centred care is encouraged. Counselling of patients encourages that the right information and support with effective medicines are done as well as prioritising patients' needs and monitoring patients' outcomes (RPS, 2018:8). This was re-affirmed by Algae and Norah (2015:2) who expressed that pharmacists led counselling improves clinical outcomes, quality of life, drug and disease knowledge. In addition, it achieves patients' satisfaction with service provided.

A study carried out in Nigeria to determine the extent of patient counselling in community pharmacies revealed that 25% of pharmacists never talked to their patients. In comparison, 47% of all patients never received any verbal drug information from pharmacy staff (Ogbonna *et al.,* 2015:35).

A study done in Saudi Arabia on patient counselling where the pharmacists dispensing claimed that they always provide information on dose, duration of use, and how to use the medication, however, this was not evidenced at the actual dispensing practices observed. The majority of patients were informed only when they started to be inquisitive and probed for information (Algae & Norah, 2015:6).

2.10.1.5.3 Dispensing equipment

In South Africa, there must be adequate, suitable dispensing equipment in the dispensary. Each item must be clean, in good repair and of suitable material. These include suitable means of counting tablets and capsules; counting trays and spatulas, dispensing balance, mortars and pestles (especially if compounding is done in the community pharmacy) and refrigerator maintained at 2°C-8°C (SAPC, 2010.17).

Lebanon also maintains the standard of dispensing equipment. It was stated that pharmacies should have an air-condition/heating system to keep the ambient temperature between 15 and 25°C. In addition to the air-condition/heating system, the refrigerator should be equipped with a suitable thermometer that is capable of storing products at temperatures between 2°C and 8°C used solely for medicinal products (Hallit *et al.*, 2018:8).

Due to the expanding demands on the community pharmacy, the services offered may need some equipment added. These may include but are not limited to the following equipment namely: a stethoscope, otoscope, blood glucose machine, first aid equipment, oxygen with flow meter and clinical thermometer (SAPC, 2018:45).

A high standard of equipment maintenance and cleanliness must be consistently applied. Equipment should be maintained, serviced and calibrated following the manufacturer's instructions and records of such service and calibration should be kept.

In Ireland, the community pharmacy should be equipped with a range of suitable containers for packaging when dispensing, plastic spoons and measuring cups for measuring liquid medicines. In addition, suitable weighing scales, mortars & pestles sets and protective clothing for extemporaneous preparations (PSI, 2012:18-19).

2.10.1.6 Professional standards for documentation and record-keeping

2.10.1.6.1 Provision of pharmaceutical services records

It is stipulated in the GPP guidelines of SAPC (2010:115) that the pharmacist must retain a written record of the result of the test done for patients, together with the following information for at least three years:

- The type of test done to the patient, for example cholesterol;
- Batch number of the test material; and advice or referral is given to the patient.

Such records must be stored safely to preserve confidentiality. The pharmacist must keep all information provided by the patient and the result of the test, confidential and only disclose information with the consent of the patient (SAPC, 2010:115).

Jesse (2010:578) emphasises that pharmacies must compile inventory records every two years, keep complete and detailed records, of their inventories and the dispensing of controlled substances. In the US, schedule drugs' records must be kept in a separate location from other records, and all records must be kept in a location that is readily available when the information is needed (Jesse, 2010:577-579).

2.10.1.6.2 Records on dispensing

In Lesotho record-keeping of dispensing of scheduled drugs, registers and prescriptions are a requirement according to Drugs of Abuse Act (5 of 2008). Additionally, the records should be kept under lock and key. According to the SAPC (2010:74-76), patient medication records must be kept in the pharmacy, except in institutional pharmacies where the pharmacist has access to the necessary information in the patient's medical/clinical records.

Historically, in Malaysia, where records were kept on paper (manual records), there was need for a table of contents. This was the only measure put in place to ensure that the record stayed associated with the correct patient and was stored in the same folder as their other records. However, in Malaysia, now that is no longer necessary with electronic records systems (Neame, 2014:85). Lesotho has a hybrid Health Information System, with a mix of integrated and stand-alone data systems as a step to move away from paper-based records (Lesotho, 2013:8-9). Table 2-18 gives a summary of the electronic system for record-keeping and monitoring and their functions.

Table 2-18: MOH electronic systems for record-keeping and their function

MOH records electronic system	Functions
An Open Medical Record System (OpenMRS)	Partners in Health have implemented it in selected sites in Lesotho in the nine hard-to-reach health centres. The system is not an electronic medical record system but rather an electronic register
BookWise HIV and Aids Clinic Management System	Integrated Clinic Management System designed to assist with the management of the ART antiretroviral treatment program
RxSolution	Integrated computerised pharmaceutical management system specifically designed to

MOH records electronic system	Functions
	manage pharmaceuticals and medical supplies, from procurement to dispensing to patients

(Adapted from Lesotho, 2013:8-9)

Routine health activity data are recorded daily in all GOL, CHAL and private health facilities using standardised registers and record forms. There are currently no legal provisions requiring private facilities to report on any diseases (Lesotho, 2013:9).

Neame (2014:85) alerted that community pharmacy owners do not even have the right to share the records, while they remain identifiable, with third parties except with the consent of the patient.

2.10.1.7 Professional standards for the storage of medicines

Storage of medicine is very critical, according to SAPC (2010:14). Some of the storage standards included the following:

- Adequate space in the reception area for the store to allow for stock checking before warehousing,
- All medicinal products should be stored at temperatures below 25 degrees Celsius in the main storeroom. Only appropriate building design to maintain acceptable air temperatures is acceptable with natural lighting where possible,
- The cold storage for vaccines and other thermo-labile products can be provided by space adequate for two large fridges with glass doors,
- The flammable store should have an external entrance and must comply with building regulations and safety standards, and
- Air extraction facilities should be provided at appropriate areas.

It was emphasised that all medicinal products requiring cold chain/refrigeration should be maintained at 2-8^{0}C (SAPC, 2010:15).

According to the SAPC (2010:15), goods should be unpacked in an appropriately designated area and stored securely, safely and hygienically.

2.10.1.8 Professional standards for reference sources

To be real pharmacotherapy experts, pharmacists need a solid therapeutic knowledge base and critical thinking skills. Since pharmacists also frequently provide drug information to other

health care professionals and patients, staying current can be a daunting task as the entirety of medical knowledge regularly doubles (Clauson *et al*., 2008:569).

The pharmacy has an appropriate range of reference materials to promote the informed use of prescription and non-prescription medicines. In Ireland, reference sources provided or kept in the community pharmacy must be appropriate, up-to-date and sufficient to meet the practice-specific requirements of the individual pharmacy and promote the informed and rational use of both prescription and non-prescription medicines (PSI, 2012:22).

References should always be available in the community pharmacies as indicated in the GPP document of the SAPC (2010:18-19). Table 2.18 shows some of the reference material that must be available for consultation in all pharmacies per individual country.

Table 2-18: Different countries' pharmacy reference work requirements

South Africa	Ireland	Malaysia	Ethiopia
One of the latest three editions of Martindale	A complete drug reference source, current edition or access to up-to-date online edition (such as Martindale)	Martindale the Extra Pharmacopoeia	Drug package inserts
MIMS	MIMS (current edition)	References available at the practice site	National standard treatment guidelines
MDR/SAMF	Current British National Formulary (BNF), access to the most recent edition must be available	British National Formulary	Textbooks
Comprehensive textbook on Pharmacology	Drug interaction reference	British Pharmaceutical Codex	National formularies
Medical dictionary	Access to current pharmacy legislation, including like the Irish statute book	Malaysian medical resource	Internet, for example, drug.com Databases, for example Medscape
Daily Drug Use (Tincture Press Publications) or other drug interactions reference source	Access to Summary of Product Characteristics (SmPCs) for medicinal products authorised in Ireland,	Online resources used e-book	Colleagues Medical journals or peer-review journals

South Africa	Ireland	Malaysia	Ethiopia
The latest copy of the Pharmacy Act 53 of 1974, as amended, and the Medicines and Related Substances Act 101 of 1965, as amended	Access to PSI guidelines, guidance documents, alerts and publications, such as monthly PSI pharmacist eNewsletter	Non-manufacturer websites	Drug information centre
Good Pharmacy Practice Manual	The Irish Medicines Formulary (IMF) and/or IPHA Medicines Compendium	Manufacturer's websites	
The latest copy of the Standard Treatment Guidelines and Essential Drug List for the appropriate level of care	A medical dictionary and an up-to-date reference for non-prescription medicines are also recommended	Online journals	
Paediatric Dosing Reference Guide (where applicable)	Paediatrics reference, current edition or access to up-to-date online edition (such as the BNF for Children) (BNFC), Paediatric Formulary, Neonatal Formulary	Internet connection at the workplace	
Comprehensive textbook on complementary medicine (where applicable)	Appropriate reference sources are made available where relevant, such as for Psychiatric care services, Alternative/Herbal Medicinal Products, Palliative Care, Pregnancy and/or Lactation, A veterinary medicines reference, Contraception and Immunisation services	Leaflets provided by company representatives	

South Africa	Ireland	Malaysia	Ethiopia
Pharmacopoeia (BP, USP, EP) (where applicable)	Comprehensive and up-to-date reference material and support documentation must be made available relating to the implementation, practice and standard requirements for the provision of pharmacy services and pharmaceutical care offered by the specific pharmacy		
Electronic access to the required references is also acceptable			

2.11 Chapter summary

In order to understand pharmacy practice, hence, community pharmacy practice in Lesotho, reviewing the profile of Lesotho's demography, socioeconomic, health and its services including pharmacy services, is of crucial importance. Profiling community pharmacies in terms of their numbers and distribution around Lesotho will assist in determining the practice growth. These factors were reviewed and discussed in this chapter. Also reviewed was, the role of community pharmacists in the healthcare system internationally and within the SADC region, especially SA, in comparison with Lesotho. Standards from international organisations that regulate pharmacy practice worldwide like the WHO and FIP were used as references in evaluating and assessing where Lesotho is in terms of adhering to the prescribed standards.

CHAPTER 3 RESULTS AND DISCUSSION

3.1 Introduction

Chapter 3 provides the results of the empirical investigation of the study. The results will be presented and discussed according to the two phases. Phase I: Assessment of the standard of pharmaceutical services provided by community pharmacies and compliance with good pharmacy practice guidelines

3.2 Response

The response from community pharmacies and stakeholders who participated in the study is analysed and discussed.

The protocol evaluation took about a two weeks to complete because the participating community pharmacies were selected from the capital town, Maseru. This included getting consent and the actual data collection. The response was very good. With the surveys, a lot of challenges were met due to the hard to reach areas of Lesotho and change in weather, the winters made it hard to travel. To the community pharmacies who could give consent via email, the response was good. This therefore meant telephonic calls and signing of consent during the data collection. Data gathering happened over a 2-year period, from Jan 2017 to December 2018.

Fincham (2008:1) stated that for survey research intended to represent all schools and colleges of pharmacy, a response rate of ≥ 80% was expected. A study done in Australia indicated that there had been a decline in the response rate for survey studies but demonstrated that there is no direct correlation between response and validity (Morton *et al.,* 2012:107). This finding by Morton *et al.* (2012:10) was confirmed in the USA, where it was shown that there was an overall response rate of 66% to 83% varying between surveys depending on different topics and programs that was acceptable (Brtnikova *et al*., 2018:5).

There were 60 community pharmacies according to the list compiled from MOH and MOT registers in Lesotho (MOH,2017:1, MOT, 2017:1). The sample, however, for this phase of the study was 36 community pharmacies which represented 60% of the total number of community pharmacies in Lesotho that participated in both phases I and II of the study. From the 36 community pharmacies, 30 gave consent to participate in the study, which indicates and represents 83% response.

Table 3-1 shows the registered community pharmacies in Lesotho and the ones sampled for the study as well as those that responded.

Table 3-1: Number of community pharmacies per district engaged in this study in Lesotho

District	Community pharmacies*	Study population	Response
Lowlands			
Maseru	32	18	16
Berea	5	3	3
Leribe	6	4	4
Mafeteng	5	3	2
Subtotal	*48*	*28*	*25*
Highlands			
Mokhotlong	2	1	0
Thaba-Tseka	1	1	1
Qacha's Nek	1	1	1
Quthing	1	1	0
Subtotal	*5*	*4*	*2*
Foothills/Senqu valley			
Mohale's Hoek	3	2	2
Butha-Buthe	4	2	1
Subtotal	*7*	*4*	*3*
TOTAL	**60**	**36**	**30**

*Obtained from the Registers of the Ministry of Health (MOH, 2017:1) and Ministry of Trade (MOT, 2017:1)

3.2.1 Community pharmacy details

In this section, the geographical location of community pharmacies, in terms of ecological zones and districts within Lesotho will be given. In addition, the nature of community pharmacies' existence as a sole owner, or in partnership, will be discussed. The legal requirements regarding the registration of community pharmacies in Lesotho will also be addressed.

Legislation and regulations may set several requirements, especially in terms of workforce, premises, equipment, processes and practices such as opening hours (WHO, 2019:31), which will guarantee the proper functioning of a community pharmacy.

3.2.1.1 Area where the community pharmacies are situated

A study done in South Africa revealed that the differences in community pharmacy density between the most and least rural provinces decreased from 1.3 per 10 000 residents to 0.72 per 10 000 residents between 1994 and 2012 (Ward *et al.*, 2014:484). In the same study, the findings showed that there are 3.5 pharmacies per 10 000 citizens, concentrated mostly in the cities (72.3%), with unbalanced access to medicinal products for the patients living in suburban (7.83%) and rural areas (3.02%) (Ward *et al.*, 2014:484).

The same trends are experienced in Lesotho. The results, as depicted in Figure 3-1, shows that the majority 83% (n=25) of the participating community pharmacies in Lesotho were situated in the Lowlands which are mostly urban. Of the participating community pharmacies in the Lowlands, 64% (n=16) were located in Maseru. Community pharmacies at the Foothills constituted 10% (n=3) followed by Highlands with 7% (n=2) of all participating community pharmacies. These community pharmacies are situated in the districts towns though the foothills and mountains are considered rural areas.

Based on the population, the highest percentage (57.9%) of the population of Lesotho lives in the lowlands, followed by the mountains and highlands, the foothills, and the Senqu valley, which account for 21.2%, 12.9% and 8.0% of the total population, respectively (MOH, 2016:22). The Lowlands in Lesotho is thus the most populated of all ecological zones. Table 3-1 shows that 80% (n=48) of the population of community pharmacies in Lesotho are situated in the Lowlands.

Table 3-2: Distribution of community pharmacies in comparison with population per ecological zone

District	**Community pharmacies***	**Population**	**% of community pharmacy distribution per ecological zone**
Lowlands			
Maseru	32	519 186	
Berea	5	262 616	
Leribe	6	337 521	
Mafeteng	5	178 222	
Subtotal	*48*	1 297 545	**0.004**

Mountains (Highlands)			
Mokhotlong	2	135 347	
Thaba-Tseka	1	135 347	
Qacha's Nek	1	74 566	
Quthing	1	115 469	
Subtotal	*5*	460 729	**0.001**
Foothills/Senqu valley			
Mohale's Hoek	3	165 590	
Butha-Buthe	4	118 242	
Subtotal	*7*	283 832	**0.003**
TOTAL	**60**		**0.008**

Table 3-2 shows that the distribution of community pharmacies is extremely low in comparison to South Africa. In Lesotho, for the Lowlands, 1,297,545 population shares 0.004% (n=48), in terms of 10 000 population the density is around 0.003 which is low in comparison to South Africa 3.5 pharmacies per 10 000 citizens. The distribution percentage lowers as we get to the less accessible zones in Lesotho (Table 3-2).

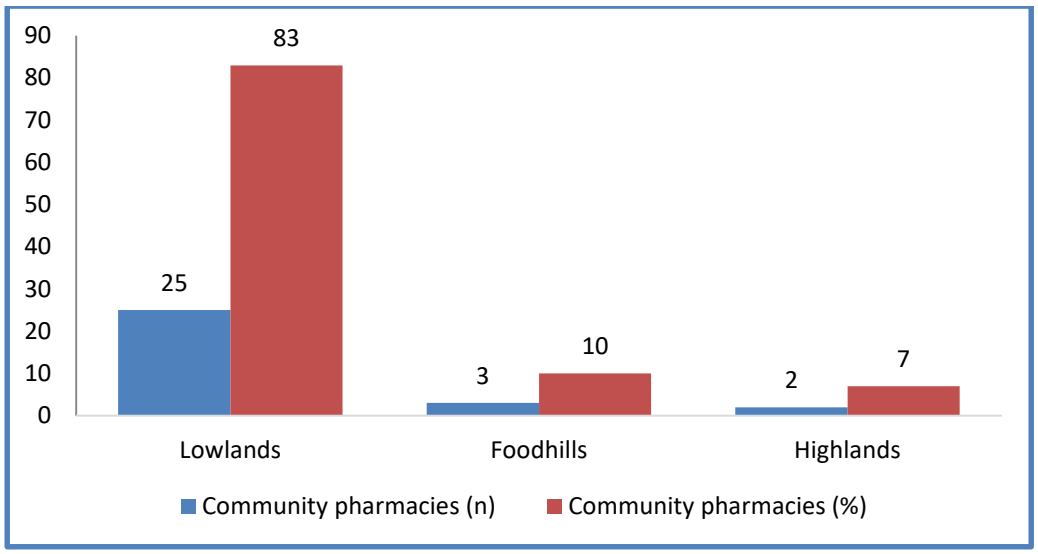


Figure 3-1: Distribution of community pharmacies according to the ecological zones within Lesotho

3.2.1.2 District where the pharmacy is situated

The most recent census by the Bureau of Statistics (BOS) in 2016, as shown in Table 3-2, indicated the population of Lesotho was estimated at 2 007 201. The majority of the Basotho (66%, n=1 321 263) reside in rural areas and 34% (n=685 938) in urban areas. The population density is lower in the Highlands than in the Lowlands. There are ten districts in Lesotho. The four districts with the largest populations are Maseru, Leribe, Berea and Mafeteng, constituting 62.2% of Lesotho's population (BOS, 2016:2).

It was stated that, in South Africa, community pharmacies should be located taking into account the healthcare needs, income groups, size of the population and what is required to make a pharmacy viable, for example based on population, the ratio applied is one pharmacy per 5000 of the population (South Africa, 2014:8). Ward *et al*. (2014:486) indicated that despite the set standards for situating pharmacies, South Africa continues to have pharmacies concentrated in urban areas.

Table 3-3: Population per district in Lesotho

District	Population
Lowlands	
Maseru	519 186
Berea	262 616
Leribe	337 521
Mafeteng	178 222
Foothills	
Butha-Buthe	118 242
Mohale's Hoek	165 590
Mountains	
Qacha's nek	74 566
Thaba-Tseka	135 347
Quthing	115 469
Mokhotlong	135 347

*Adapted from Lesotho 2016 census (BOS, 2016:2)

The general distribution of all community pharmacies (n=60) in Lesotho, as illustrated in Table 3-1 and Figure 3-2 shows that 53% (n=32) of community pharmacies are located in Maseru district which is also the capital city of Lesotho. Leribe as the second-largest (10%, n =6) district followed by Berea and Mafeteng with 8% (n=5) each.

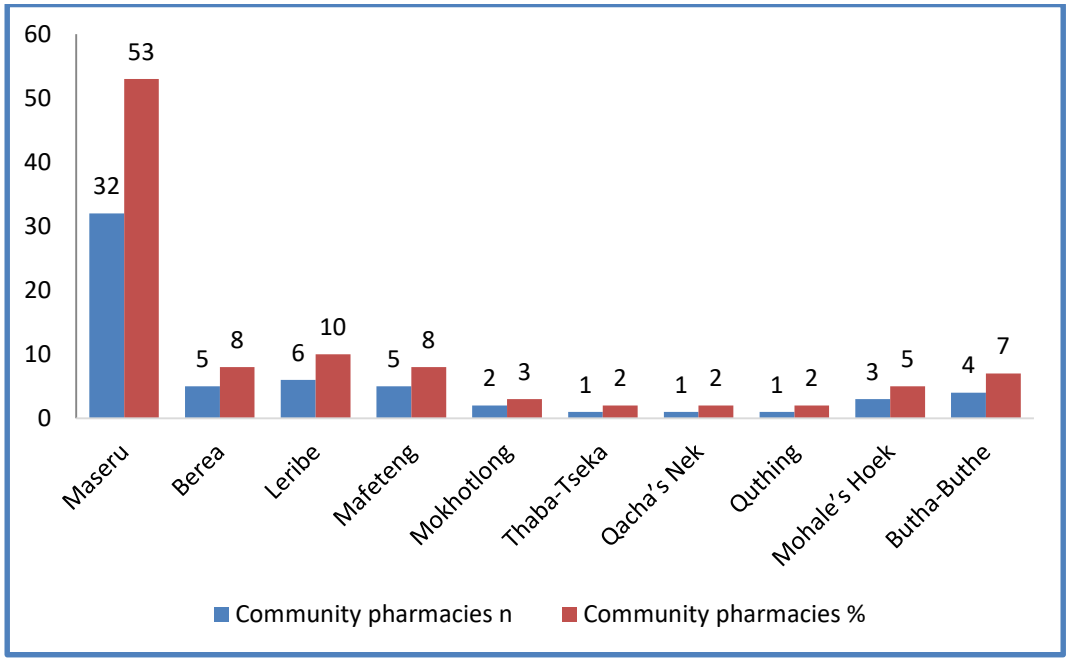


Figure 3-2: Distribution of community pharmacies per district in Lesotho.

Countries in the WHO European Region, for example the Republic of Moldova and Croatia use geographical criteria to determine whether a new pharmacy license can be issued to open a community pharmacy. (WHO, 2019:20). These criteria aim to prevent the concentration of community pharmacies in the same geographical area. A very commonly used approach is the distance between the planned new pharmacies and existing ones, for example in North Macedonia, 100 m distance is allowed while Belgium allows 5 km (WHO, 2019:20). This distance can refer to other pharmacies within the limits of a city or village, but it may also refer to pharmacies in neighbouring towns or villages.

The Ministry of Health of Malaysia (2015:11) in Malaysia, a new pharmacy should be located at least a 300-meter radius from an existing pharmacy outlet. For a pharmacy within a facility/shopping complex/business centre/multi-storey building, there should be one outlet for every 200,000 square feet rentable space and below. The new pharmacy should be located at least 150 meters in a linear measurement distance (shortest legal travelling route) to the main entrance of the facility from the nearest pharmacy (Ministry of Health Malaysia, 2015:11)

In South Africa, newly opening community pharmacies should provide the proposed location of their pharmacy including the accurate location on the street map, the Global Positioning System (GPS) as well as the district and sub-district where the pharmacy will be located before issuing a license for pharmacy premises (South Africa, 2014:5).

Some countries have no restrictions on the location of a new pharmacy, provided it complies with other legal requirements (WHO, 2019:22). According to the results of the study (refer to section 3.4.1), this is the case in Lesotho. Community pharmacies that are registered and comply with MOT and MOH requirements may be opened anywhere. The Lesotho Medical, Dental and Pharmacy Order (13 of 1970) and Drugs of Abuse Act (5 of 2008) are not prescriptive regarding the location or placement of community pharmacies in Lesotho.

3.2.1.3 Nature of community pharmacies in Lesotho

Starting a business involves deciding on what form of business entity to establish. The most common nature or form of businesses is the sole proprietorship, partnership, and corporation. In this study, the nature of community pharmacies in Lesotho was assessed.

The results as illustrated in Figure 3-3 showed that 50% (n=15) of community pharmacies in Lesotho that participated were independently owned pharmacies, while the remaining half were chain community pharmacies (more than one community pharmacy existing owned by the same owners). Individuals owned the community pharmacies that participated in the study, not a corporate (company or business groups).

The community pharmacy sector in Nigeria consists of different forms of business entities ranging from corporately owned chain pharmacy shops to pharmacy departments in supermarkets or independently owned pharmaceutical shops that provide prescription services plus lines of health-related products (Brian *et al.,* 2015:33-34).

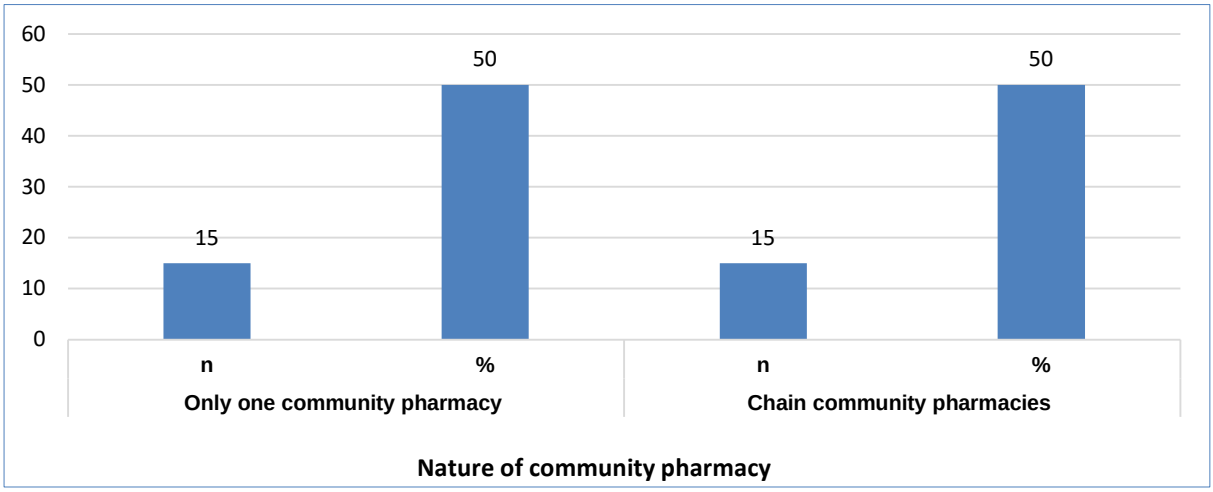


Figure 3-3: Nature of community pharmacies based on the type of business entity in Lesotho

3.2.1.4 Type of community pharmacies business entities in Lesotho

According to Amador-Dumois *et al*. (2013:3), business entity refers to an organisation that is opened to trade. The four primary business entities are sole proprietorship, partnership, corporation, and limited liability company as stated by Amador-Dumois *et al*. (2013:3). Ownership refers to whoever owns the business entity, and the owners have the option to choose which type of business entity they want to start (Amador-Dumois *et al*., 2013:2).

The types of business entities for community pharmacies in Lesotho were sole ownership (one owner; a pharmacist alone) and partnership (more than one owner; a pharmacist with other partner or partners). Most community pharmacies fell within the partnership type with 57% (n=17), whereas sole ownership accounted for 43% (n=13) of community pharmacies (Figure 3-4).

In Lesotho, regulation of community pharmacies is made by the medical, Dental and Pharmacy Order (13 of 1970) that stipulate that “for this subsection the use of the description ‘pharmacy’ in connexion with a business carried on in any premises shall be deemed to be reasonably calculated to suggest that the owner of the business and the person having control of the business on those premises are pharmacists”.

In the case of a body corporate, the law states that body corporate must be incorporated under the laws of Lesotho and the majority of the members of the board must be individuals registered as pharmacists. Lastly, in the case of a partnership, the majority of the partners must be individuals registered as pharmacists (Medical, Dental and Pharmacy Order, 13 of 1970).

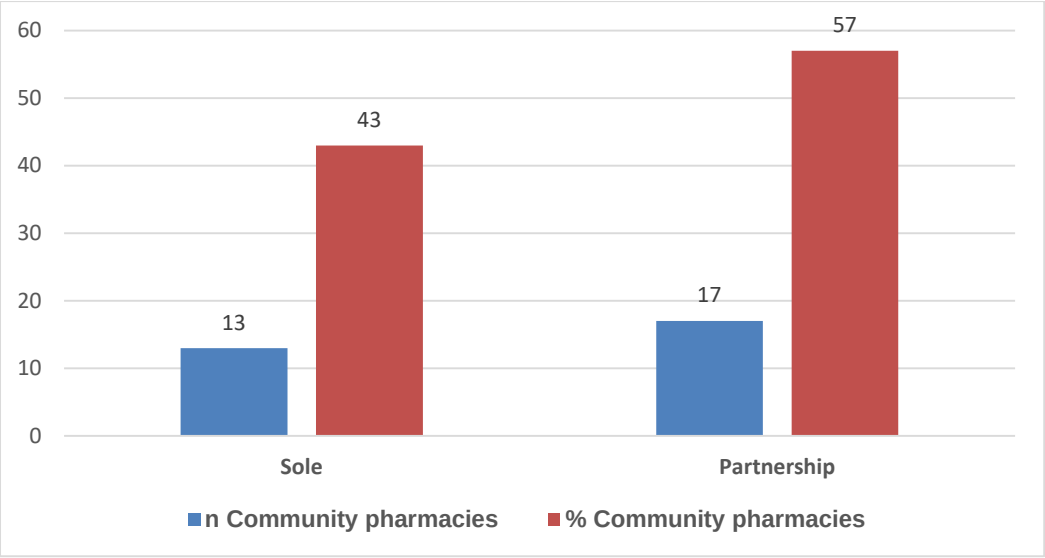


Figure 3-4: Types of ownership of community pharmacies in Lesotho

3.2.1.5 Is the community pharmacy registered according to the law of Lesotho?

In South Africa a community pharmacy must be registered with the SAPC and comply with GPP standards to operate in South Africa (SAPC, 2010:2).

The results indicated that in Lesotho, community pharmacies register with MOH and MOT according to the study findings. Almost all community pharmacies; 83% (n=25) were registered with the MOT only, while 17% (n=5) were registered with both the MOT and MOH (Figure 3-5). No law compels community pharmacies to register with the LMDPC.

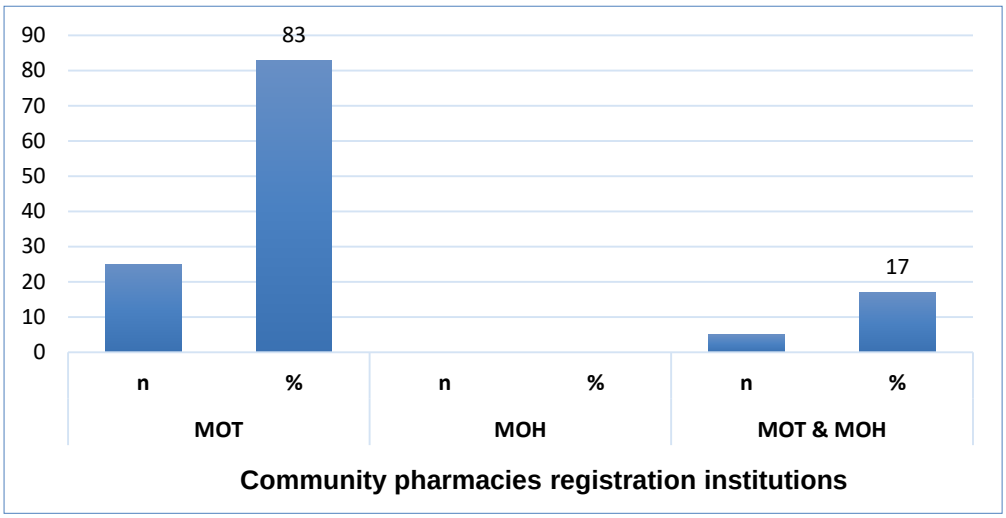


Figure 3-5: Registration of community pharmacies with the MOH and/or with the MOT of Lesotho

3.2.1.6 Pharmacy staffing and staff registration

The availability of healthcare workers, for example pharmacy personnel is not sufficient to ensure equitable healthcare service provision. Those healthcare workers need to be equitably distributed and accessible by the population. They also should possess the required competency, be motivated and empowered to deliver quality healthcare services. These factors together can, in turn, translate into adequate service coverage (WHO, 2016:10).

In Lesotho, community pharmacy staffing includes pharmacists, pharmacy technicians and other assistants (non-health personnel) but ownership is reserved for pharmacists only or pharmacists in partnership according to the Medical, Dental and Pharmacy Order (13 of 1970). Lesotho has 0.16 pharmacists and 0.32 pharmacy technicians per 10 000 of the population (Wang *et al.*, 2013:1).

The global median number of pharmacists per 10 000 of the population stands at 1.67 per 10 000 of the population (FIP, 2017:7). In the African region, the median number stands at 0.61 pharmacists per 10 000 of the population while that of the European region at 8.28 pharmacists per 10 000 of the population, according to FIP (2017:7). These numbers reveal the imbalances in global community pharmacy human resources and imply that the African region does not meet standards for community pharmacy human resources. This shortage of human resources in the community pharmacy sector relates to the situation in Lesotho with 0.16 pharmacists per 10 000 of the population, as stated before.

3.2.1.7 Is the owner of the community pharmacy a pharmacist?

Pharmacists owned 83% (n=25) of community pharmacies, as shown in Figure 3-6 while non-pharmacists owned only 17% (n=5). The latter was mainly in the Lowlands area, especially Maseru. Further investigations indicated that the 17% (n=5) of community pharmacies owned by non-pharmacists were owned by nurses (n=3), other non-pharmacy non-health professional who owned a community pharmacy was a paramedic (n=1). This is not in accordance with the laws of Lesotho regarding community pharmacies. The Lesotho Medical, Dental and Pharmacy Order (13 of 1970) clearly states that ownership of a community pharmacy should be by a pharmacist, alone or in partnership, wherein that partnership, a pharmacist should be a majority shareholder. This should be the future of ownership of community pharmacies in Lesotho whereby only pharmacists own the profession and pharmacy as a business.

In South Africa, the Pharmacy Act (53 of 1974) stipulates that anyone can own a community pharmacy as long as they can prove that they do not affiliate with any manufacturers, is not prohibited by any legislation from owning, is not a prescriber and proof that such person can comply with standards of GPP as determined by the SAPC.

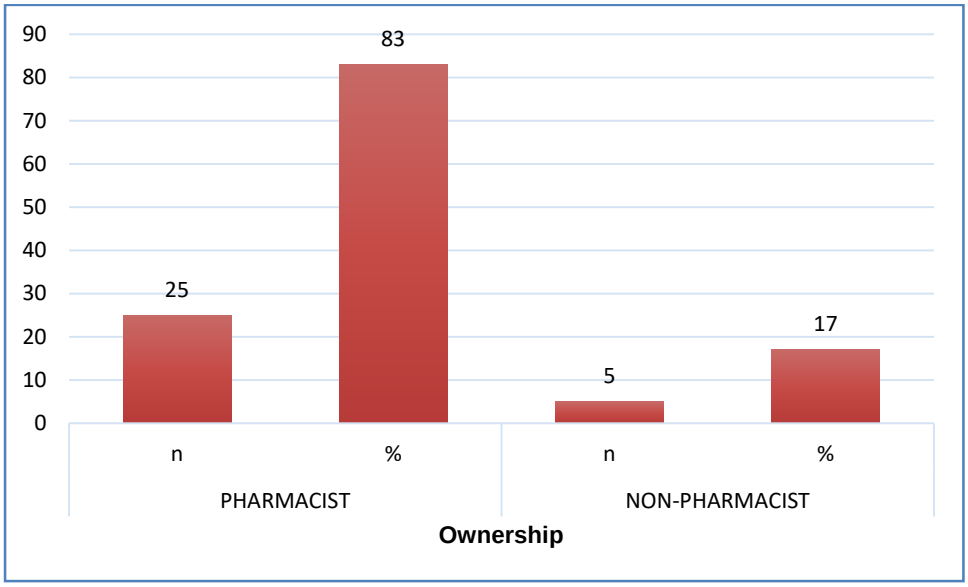


Figure 3-6: Ownership of community pharmacies by personnel

3.2.1.8 Is there a full-time pharmacist in charge of this community pharmacy?

The results in Figure 3-7 indicate that full-time pharmacists are in charge of 57% (n=17) of community pharmacies and 37% (n=11) of community pharmacies operated with a part-time

pharmacist. This includes owners of community pharmacies who work in their free time, usually during weekends. The last group of community pharmacies amounting to 6% (n=2) had neither full-time nor part-time pharmacists.

According to the Medical, Dental and Pharmacy Order (13 of 1970) in Lesotho, a community pharmacy should have a pharmacist operating the community pharmacy all the time.

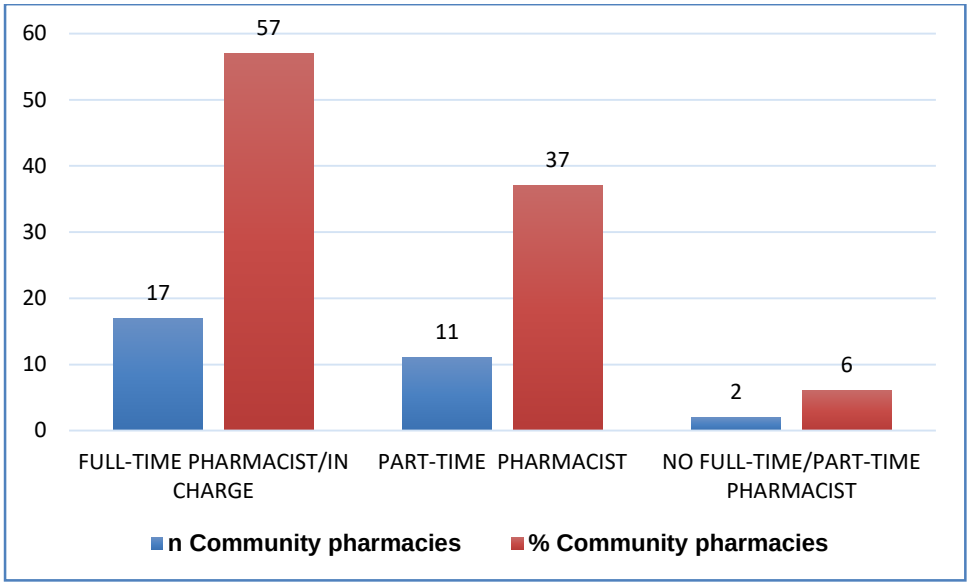


Figure 3-7: Availability of a full-time pharmacist in the community pharmacies

3.2.1.9 Is there any pharmacy technician working in the community pharmacy?

Pharmacy technicians and other pharmacy support personnel are used to ensure essential services if the pharmacist is unavailable in many environments. This is due to the lack of sufficient human resources to provide pharmaceutical services (Koehler & Brown, 2017:271).

The results indicate that in Lesotho community pharmacies do not deploy pharmacy technicians as much as pharmacists, 93% (n=28) of the community pharmacies did not have pharmacy technicians, and 7% (n=2) were staffed with pharmacy technicians (Figure 3-8). Globally, Koehler and Brown (2017:277) reported that it was established that there are countries where there are neither pharmacy technicians nor pharmacy support workforce cadres, only pharmacists are employed in the community pharmacies, e.g. Japan.

The Rwandan MOH guidelines on medicines dispensing have stated that their professional or statutory councils must register all people who are involved in dispensing of medicine and their working licenses have to be renewed annually (Rugamba, 2016:35). In Lesotho, both

pharmacists and pharmacy technicians should register with the LMDPC as stipulated by the Lesotho Medical, Dental and Pharmacy Order (13 of 1970).

With regards to pharmacist registration with LMDPC, 93% (n=28) of community pharmacies complied, meaning the majority of operating pharmacists are registered. Only 7% (n=2) of community pharmacies were found to be operating with unregistered pharmacists, as shown in Figure 3-9.

In the study done on a global picture of pharmacy technicians and other pharmacy support workforce, findings on their practice were arrived at. Those finding showed that global pharmacy respondents who participated amounting to 58% (n=198) indicated that pharmacy technicians work independently with minimal supervision (Koehler & Brown, 2017:272). The supervision and involvement of the pharmacist are essential to giving support and legitimacy to the actions of pharmacy technicians. Even when technicians perform some pharmacy activities, the technical and legal responsibility of the service and interventions conducted fall on the pharmacist (Melo *et al.,* 2017:267).

Figure 3-8 shows the registration with LMDPC status of pharmacy technicians. Almost all participating community pharmacies; 93% (n=28), did not have pharmacy technicians employed. The results, therefore, showed 'not applicable' regarding the registration of pharmacy technicians. The results indicated that the other 7% (n=2) of community pharmacies complied by having employed registered pharmacy technicians.

A study done in Rwanda confirmed that 97.3 % of pharmacists and pharmacy technicians who work in community pharmacies in Rwanda, were registered with their statutory council (Rugamba, 2016:35). In Lesotho, the majority of the pharmacists have shown to comply with LMDPC registration guidelines.

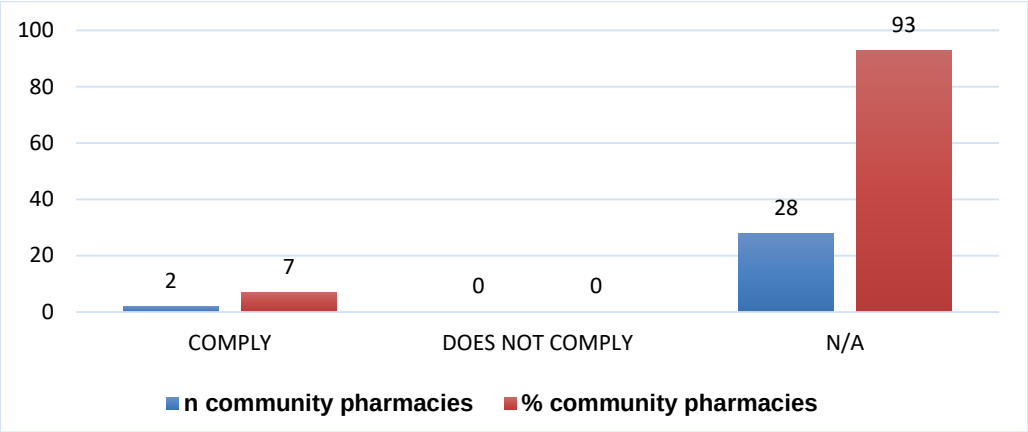


Figure 3-8: Availability of registration of Pharmacy Technicians with LMDPC

3.2.1.10 Are there any other personnel working in the pharmacy?

Ofori-Asenso and Agyeman (2016:6), stated that in Ghana, dispensing should be carried out by a trained pharmacist or dispensing technicians. It was added that dispensing of medicine by anyone not qualified is considered as non-ideal and that this practice poses a problem of medicine errors as it does not adhere to GPP standards.

The majority of the participating community pharmacies in Lesotho, 70% (n=21), as illustrated in Table 3-3, were staffed with personnel with COSC (Cambridge Overseas School Certificate), high school level qualifications. The second highest cadre staffing as per Table 3.3 was nursing with 47% (n=14) of the community pharmacies. Other health professionals constituting of paramedic and counselling accounted for staffing by 7% (n=2) of community pharmacies.

Non-health personnel were deployed in 37% (n=11) of community pharmacies. Few community pharmacies employed non-health staff with lower-level high school Junior Certificate (JC) qualifications. This last group made 7% (n=2) of the staff of community pharmacies in Lesotho.

Table 3-4: Other personnel employed in community pharmacies

Community pharmacies per district	Nurses	Other health professionals	Non- health professionals	COSC	JC
Maseru	4	0	8	11	1
Berea	1	0	1	1	0
Leribe	2	0	1	3	1

Mafeteng	1	0	0	2	0
Butha-bothe	2	1	1	0	0
Mohale's hoek	2	0	0	2	0
Qacha's nek	1	1	0	1	0
Thaba-Tseka	1	0	0	1	0
Total community pharmacies (n)	14	2	11	21	2
% Community pharmacies	47	7	37	70	7

3.2.1.11 If (Yes) to the above, what are their qualifications?

Qualifications of other community pharmacies' staff included Cambridge Overseas School Certificate (COSC) which is high school, non-health diplomas or degrees, a Certificate in Nursing assistance, Diploma in Nursing and JC as reflected in Figure 3-9. The majority of other staff in community pharmacies have the qualification employed COSC by 70% (n=21). The non-health personnel who worked in community pharmacies comprised of different professions including teaching and business and these worked in 37% (n=11) of the community pharmacies.

From a global perspective, there is a significant variation in pharmacy support workforce education ranging from the certificate (1-2 years) and diploma (3-4 years) as the more common, spanning the vocational and academic education pathways (Koehler & Brown, 2017:275).

This global perspective, therefore, implies that Lesotho is not the only country that is crippling with the deployment of non-pharmacy staff carrying out community pharmacies services.

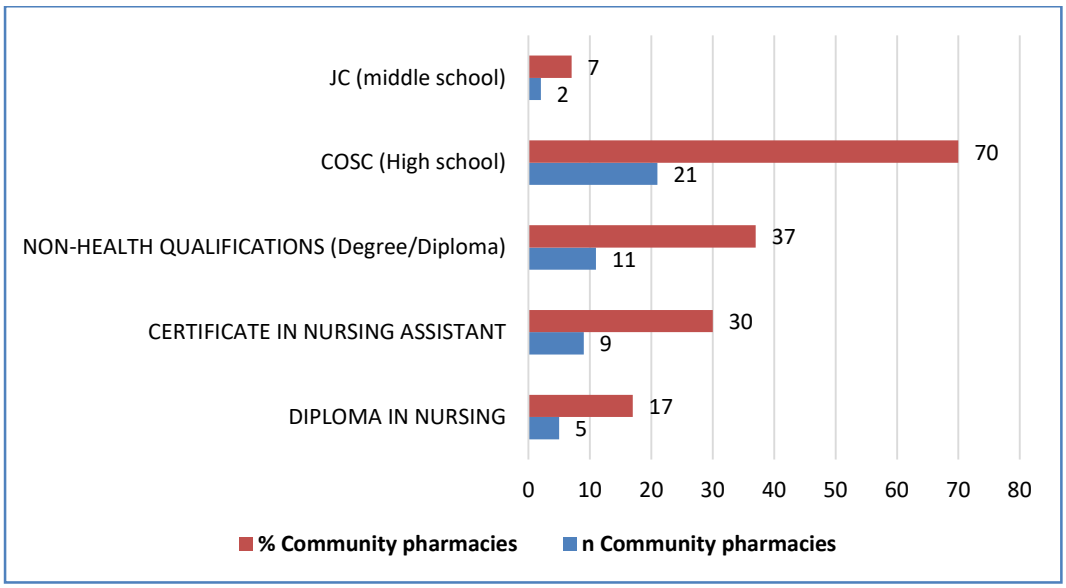


Figure 3-9: Other community pharmacy staff qualification in Lesotho

3.2.2 Premises and layout

In Rwanda, the Food, Medicine, Healthcare Administration and Control Authority (FMHACA) (2012:3) stated that the quality of premises plays a significant role in the reflection of the quality of services to be offered in a given pharmacy. The quality of premises also inspires confidence in patients regarding the nature of pharmaceutical service delivered.

In a study done in Lesotho assessing pharmaceutical services for health facilities' ART programs, it was stated that a well-organised dispensary is one of the measures to prevent or reduce dispensing errors (Wang *et al.*, 2013:13). The challenges regarding infrastructure and space that affected the healthcare workers' productivity included insufficiencies of space shelves and pallets, lighting, and cold room; lack of privacy in the counselling area (Wang *et al.*, 2013:23).

In countries like Finland and Denmark, the requirements for pharmacy premises state that facilities should be appropriate for dispensing and storing of medicines, as well as for compounding, or that the premises must be designed and equipped so that they are suitable for their activities, including being protected from burglary (WHO, 2019:36).

Figures 3-10, 3-11, 3-12 and 3-13 give a diagrammatic breakdown of compliance of premises and layouts from the study findings.

Figure 3-10 reflects cleanliness and orderly/tidiness as premises and layout criteria to which community pharmacies should comply. The majority of community pharmacies comply with cleanliness (87%; n = 26) and all 30 community pharmacies adhered to tidiness.

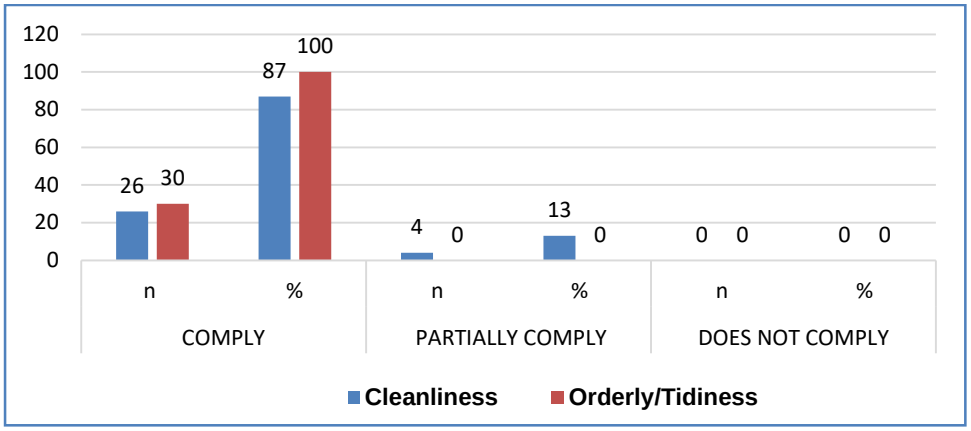


Figure 3-10: Cleanliness and tidiness criteria for premises and layout

Only ten community pharmacies had windows (33%, n=10). The same percentage of community pharmacies (33%, n=10) partially complied with the availability of windows and those that partially meet the criteria, do not maintain the windows to allow sunlight.

All participating community pharmacies (n=30) adhered to the criteria regarding the availability of suitable light, for example fluorescent light (Figure 3-11).

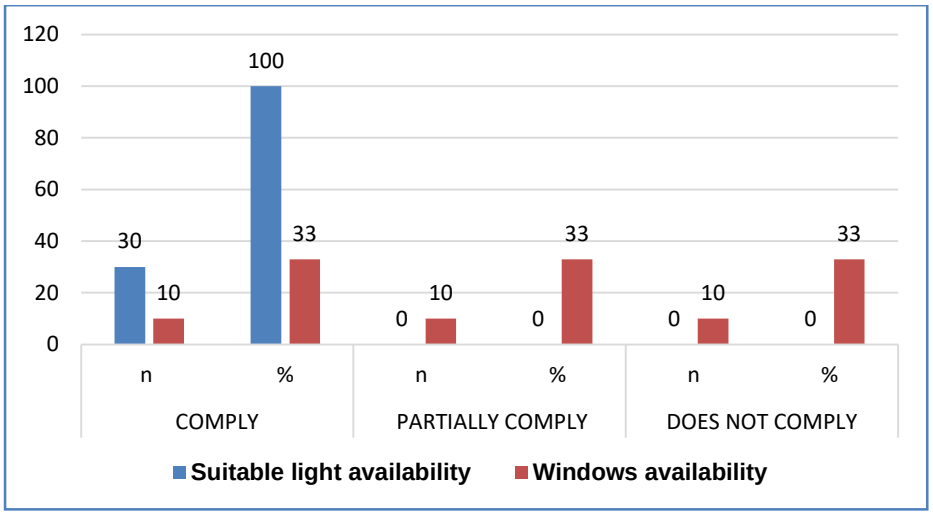


Figure 3-11: Suitable light and windows availability in the community pharmacies

The survey for community pharmacies, as illustrated in Figure 3-10 revealed that most community pharmacies (83%, n=25) adhered to floor maintenance and washable walls (80%, n=24). Floor maintenance and washable walls were some of the criteria used for evaluating standards for premises of community pharmacies in Lesotho.

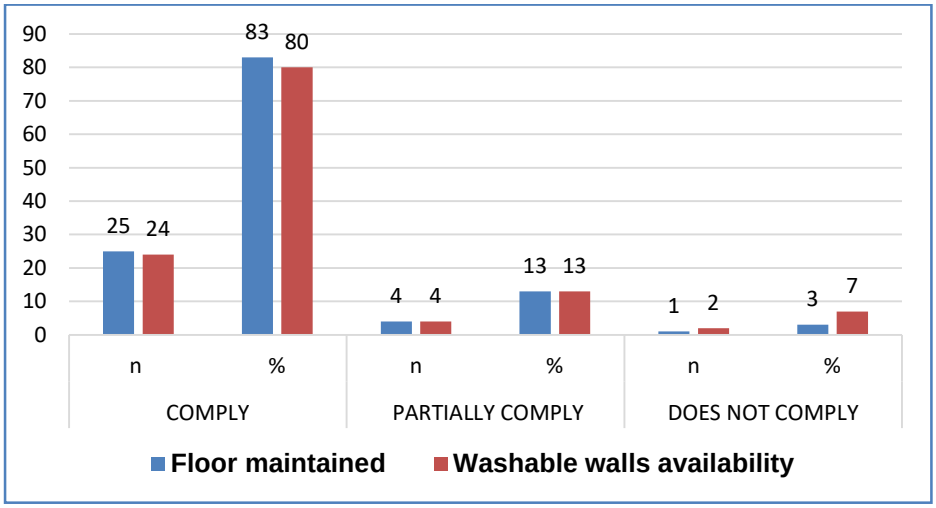


Figure 3-12: Floor maintenance and washable wall

The study revealed that 63% (n=19) of community pharmacies had screening areas (Figure 3-11). Non-compliance to availability of hand wash area was seen with 40% (n=12) of community pharmacies, and 43% (n=13) fell short on the availability of an extemporaneous preparation area (Figure 3-13). The screening areas were used for consultation of patients where privacy was needed. These areas were equipped with furniture (chairs and a table) as well as diagnostic tools (for example, blood pressure, urine and blood sugar machines).

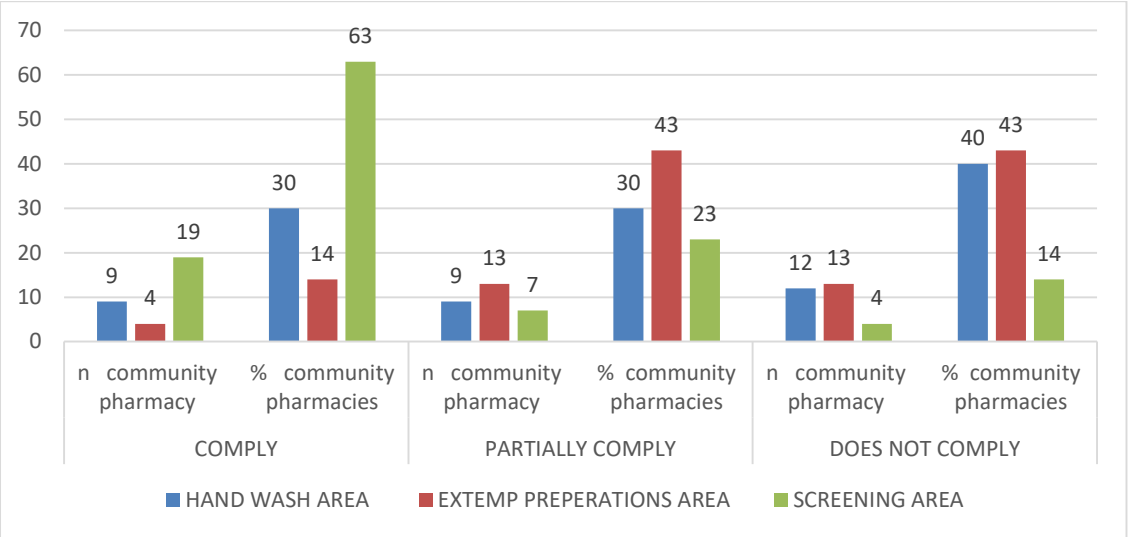


Figure 3-13: Availability of hand wash, extemporaneous and screening facilities in the community pharmacy

Figure 3-14 is a graphical representation of the layout standards of community pharmacies in Lesotho. It, however, portrayed a different scenario with most community pharmacies showing non-compliance to most of the criteria. The criteria used for layout standards included the availability of an air conditioner, temperature monitoring (room and refrigerator thermometer) and fire extinguishing equipment. The results showed the highest percentages of non-compliance by community pharmacies. Seventy-three per cent (n=22) of community pharmacies did not comply with having an air conditioner, while 77% (n=23) showed non-compliance regarding the availability of fire extinguishing equipment.

The worst performance for almost all community pharmacies was with temperature monitoring of the fridge and room temperatures whereby only 3% (n=1) of community pharmacies comply. Non-compliance of temperature monitoring was seen with 87% (n=26) of the community pharmacies. Partial compliance with this indicator was due to community pharmacies monitoring only room temperature not that of the refrigerator, which constituted 10% (n=3) of the community pharmacies.

General storage of medicines must be in dry, well-ventilated premises at temperatures of 15 to 25°C or, depending on climatic conditions, up to 30°C. Extraneous odours, other indications of contamination, and intense light must be excluded. Medicine products that must be stored under defined conditions require appropriate storage instructions, for example a refrigerator (FMHACA, 2012:9). The heat will also affect many products. It melts ointments and creams and affects other products. It is essential to have thermometers, hygrometer, and other equipment to regulate the temperature and humidity of storage areas (FMHACA, 2012:10).

Cold storage conditions should be maintained by using refrigerators and freezers for products that may be rapidly degraded when kept at room temperature or even at cool places, for example, insulin (FMHACA, 2012:11).

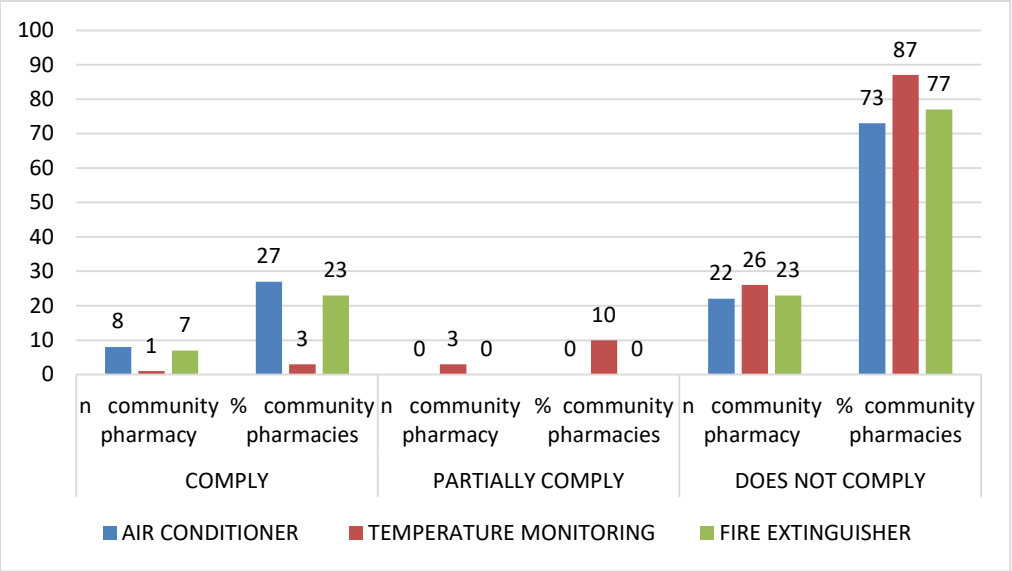


Figure 3-14: Availability of an air conditioner, temperature monitoring and a fire extinguisher in the community pharmacies

Equipment

The owner or pharmacist in charge of the community pharmacy should make sure that the equipment on the premises is adequate and suitable for all the operations that have to be carried out. Dispensing equipment used for measuring liquids or counting tablets or capsules should be kept clean at all times to avoid cross-contamination (FMHACA, 2012:4)

The results from the study on the indicator equipment are presented in Figure 3-15 and 3-16. The results are grouped into two criteria, namely: compounding and measuring equipment for dispensing (Figure 3-15) and dispensing supporting equipment (Figure 3-16).

The study revealed that most community pharmacies, 73% (n=22), were not equipped with weighing balance and volume measures with 66% (n=20) not having a mortar and pestle for using in dispensing. Compliance with the availability of a weighing balance, volume measure and mortar and pestle were achieved by 27% (n=8), 20% (n=6) and 17 (n=5) of community pharmacies respectively. Although some community pharmacies kept mortars and pestles,

17% (n=5) were partially compliant because it was broken or incomplete only 7% (n=2) of community pharmacies was partially compliant with the availability of volume measures and this was due to breakage.

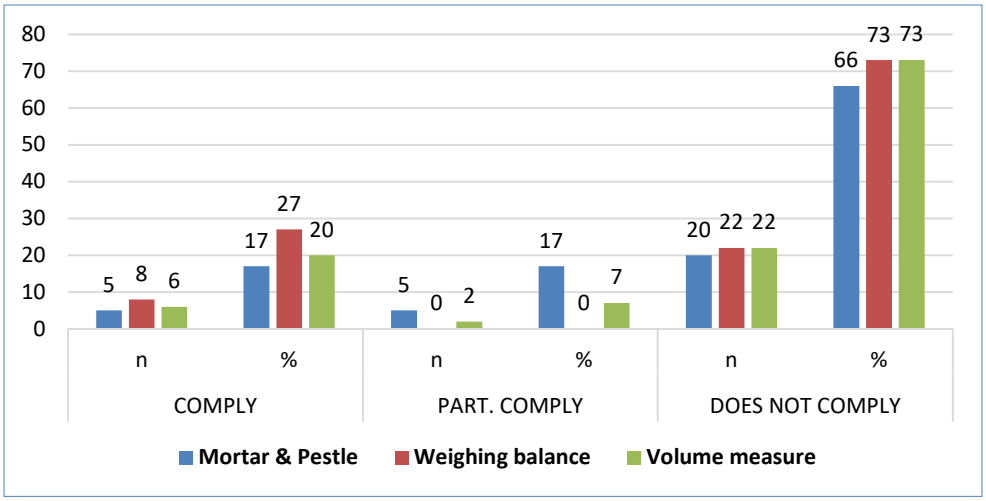


Figure 3-15: Compounding and measuring for dispensing equipment

According to MSH (2012:12-13), equipment for dispensing is essential as their use aid in efficient dispensing management. This equipment includes but not limited to the apparatus used for measuring, weighing and counting. Besides, they can be used when repackaging. Therefore, it should always be kept clean (MSH, 2012:13). Most of the community pharmacies in Lesotho did not have equipment for measuring, weighing and compounding, non-compliance being 73% (n=22) for measuring and weighing, and 67% (n=20) for the latter.

In a study done in Nigeria, the results showed that dispensing data in most community pharmacies were kept manually while a few premises used computers and software packages for dispensing. Paper or manual documentation is obsolete in developed countries today but still very common in Nigeria (Brian *et al.*, 2015:35).

Because technology is continually advancing, electronic resources are often substituted for print references, especially since they often offer timely and easily accessible information compared to print references (Clauson *et al.*, 2008:576). It is therefore important for community pharmacies in Lesotho to use computers for dispensing, record keeping as well as for instant reference checking.

The results presented in Figure 3-16, show that 97% (n=29) of the community pharmacies were equipped with counting apparatus but not compliant to the availability of other equipment.

Only 10% (n=10) did not comply with having a counting apparatus. The highest non-compliance was with the use of a dispensing computer with 33% (n=10) of community pharmacies fulfilling. Community pharmacies that showed partial compliance to having a dispensing computer amounted to 40% (n=12). These community pharmacies had computers but no dispensing system nor Internet to be able to use it. The last group, 27% (n=8) of community pharmacies, did not have any computer for dispensing.

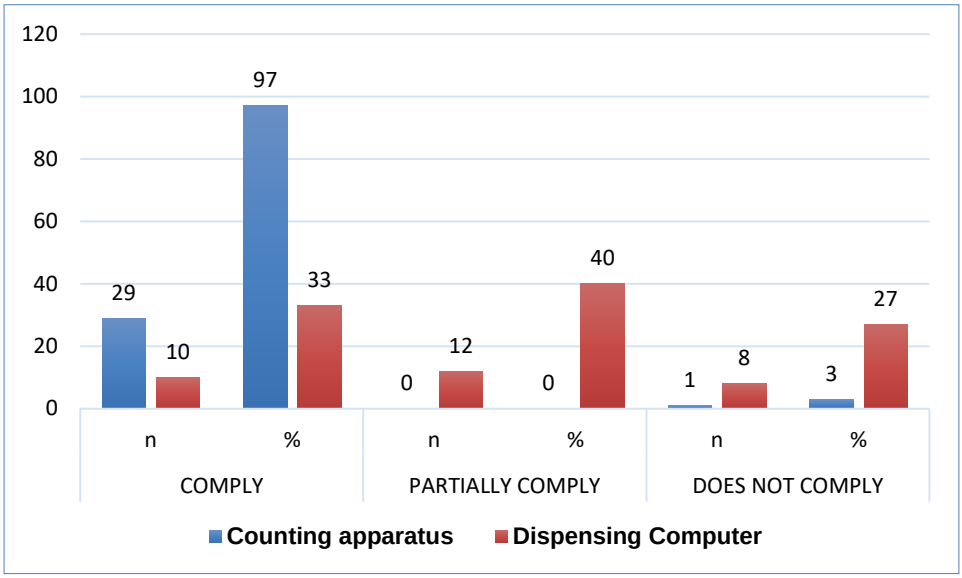


Figure 3-16: Equipment for dispensing

3.2.3 Dispensing of prescriptions and provision of pharmaceutical care

FIP (2012:319) guidelines state that pharmacists should assess and evaluate all paper or electronic prescriptions received, considering the therapeutic, social, economic and legal aspects of the prescribed indication(s) before supplying medical products to the patient. Where possible, generic substitution is recommended. The pharmacist and/or their assistants must explain to patients how to take their medication correctly and assessing the patients' comprehension concerning their medication is another mandatory role of the community pharmacist (Sam *et al.*, 2015:78).

Figures 3-17, 3-18 and 3-19 give an illustration of compliance of community pharmacies regarding dispensing. The criteria include prescription handling, patient-based criteria and pharmaceutical care and lastly handling of controlled medicines in Lesotho.

In the study done in Malaysia, the majority of the respondents 264 (51.97%) felt that the pharmaceutical care services provided overall by the community pharmacists were good, though improvements could be made about understanding the patients' comprehension levels (Sam *et al*., 2015:78).

Figure 3-17 illustrates the criteria for handling prescriptions in the participating community pharmacies. The majority of community pharmacies, 90% (n=27) complied to generic substitution whereas 73% (n=22) complied well with prescription scrutinising. Only 27% (n=8) of community pharmacies partially complied. This partial compliance was due to inconsistency with the scrutinising prescription, it was not done to all patients during the time of data collection and when patients were many. Partial compliance on medicine labelling was experienced by 57% (n=17) of the community pharmacies, and the reason was incomplete labelling, especially on pre-packs to be dispensed, for example no batch number labelled.

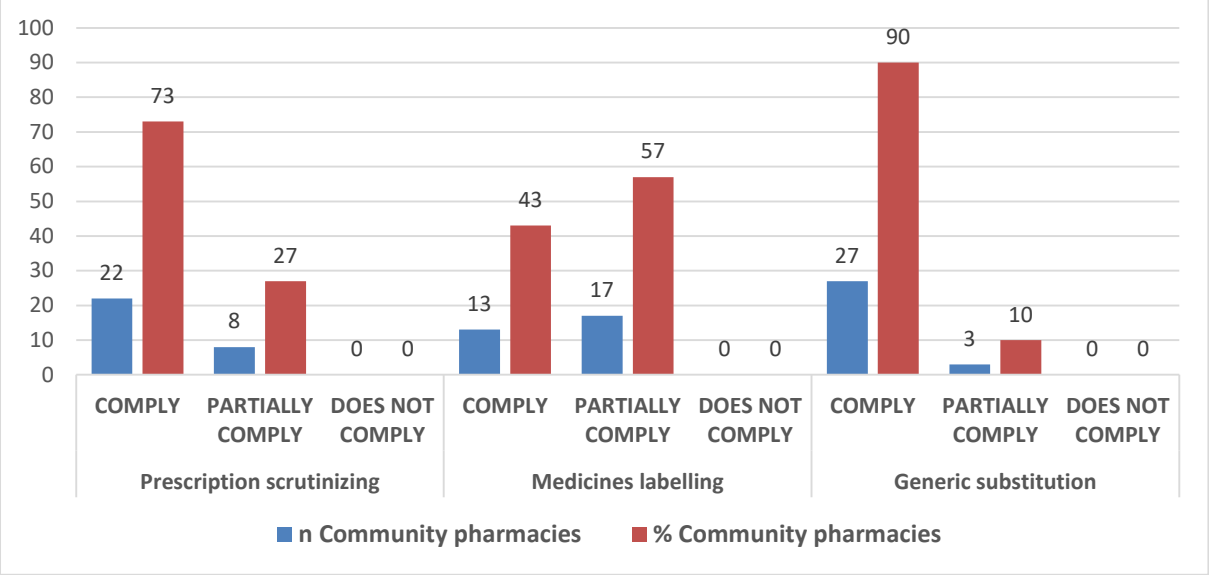


Figure 3-17: Prescription handling in the community pharmacy

Performance by community pharmacies on dispensing and pharmaceutical care for dispensing associated with patients represented diagrammatically in Figure 3-18. These include patients' counselling, availability of counselling area and information leaflets for patients, and progress monitoring for patients.

Of the community pharmacies participating in the study, 70% (n=17) complied with the availability of patient counselling area, those without any counselling area amounted to 13%

(n=4). Some community pharmacies, 17% (n=5) had counselling areas but were not conducive for counselling in terms of privacy and also were not equipped, for example no furniture.

Most community pharmacies, 70% (n=21) did not adhere to having patient's information leaflets while 23% (n=7) did not have them consistently hence partially complied. Only 7% (n=2) complied in having the patient's information leaflets.

Monitoring of patient's non-compliance was done by 80% (n=24) of community pharmacies, with only 17% (n=5) monitoring their patients' progress. The smallest percentage of community pharmacies 3% (n=1) monitored the progress of some of their patients. Counselling of patients was done by 67% (n=20) with 23% (n=7) partially complying due to non-conducive counselling areas. Community pharmacies that did not comply amounted to 10% (n=3).

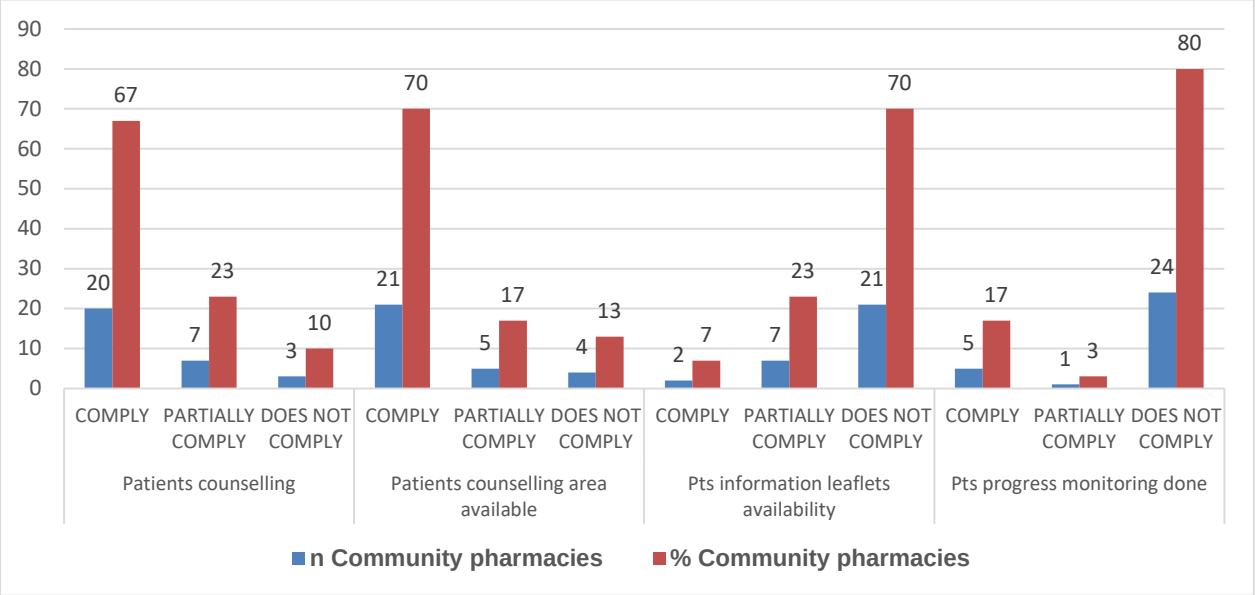


Figure 3-18: Patients based indicators for dispensing and pharmaceutical care

As much as 80% (n=24) of community pharmacies had controlled medicines on the shelves, when it came to those controlled medicines being dispensing by a pharmacist, most community pharmacies, 70% (n=21) did not comply (Figure 3-19). This implies that controlled medicines in Lesotho are not dispensed according to the Lesotho Medical, Dental and Pharmacy Order (13 of 1970). This law restricts the dispensing of controlled medicines to pharmacists only.

In Rwanda, a study conducted on the quality dispensing of controlled medicines, found that 147 community pharmacies were representing 98% of those visited, were handling controlled medicines while only 2% did not. All community pharmacies that were registered in Rwanda were allowed to handle and dispense controlled medicines even though all of them did not have them (Rugamba, 2017:26).

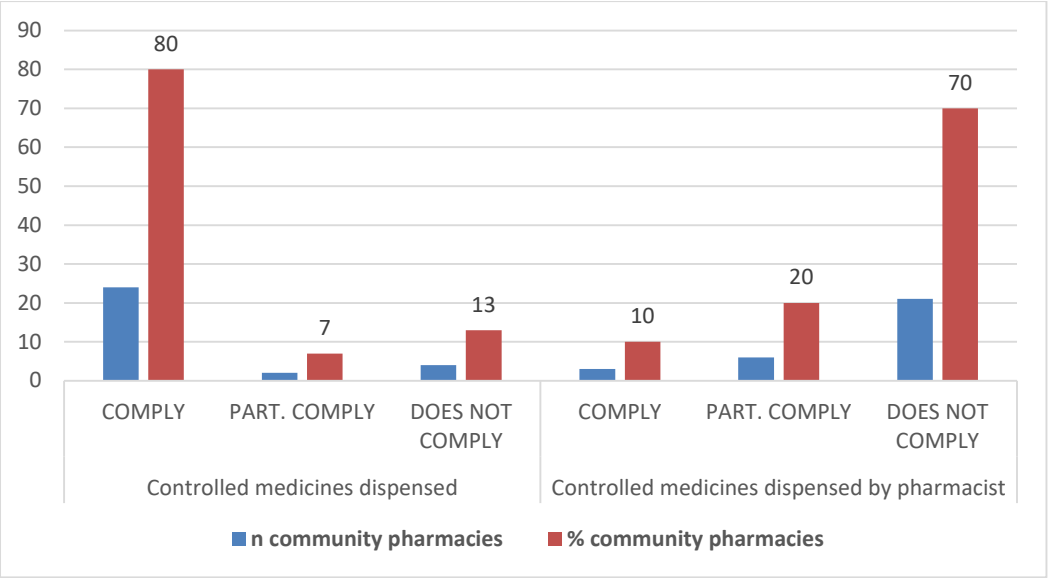


Figure 3-19: Handling of controlled medicines

3.2.4 Storage and record-keeping

Storage and record-keeping standards were assessed, and the results were presented as follows: the storage infrastructure maintenance; general medicines storage management and storage and record keeping of controlled medicines.

Amongst other storage and record-keeping indicators, storage management was the most adhered to by community pharmacies. Twenty-seven community pharmacies (90%) had no expired medicines on their shelves, and they practised prepacking of medicines for dispensing. Community pharmacies, 87% (n=26) were compliant to, was systemic medicine arrangement of medicines and medicals supplies on the shelves (Figure 3-20).

Health institutions and retail medicine outlets can use one or a combination of the following commonly used methods of medicine arrangement: pharmacotherapeutic category, alphabetical order, generic order or by dosage forms (FMHACA, 2012:8)

In this study, as shown in Figure 3-20, 83% (n=25) and 70% (n=21) of pharmacists of community pharmacies showed compliance to separating storage of unusable stock (for

example expired or damaged) and stock off the floors respectively. Non-compliance to stock off the floor was seen in only 17% (n=5) of community pharmacies, and the reasons included unavailability of pallets.

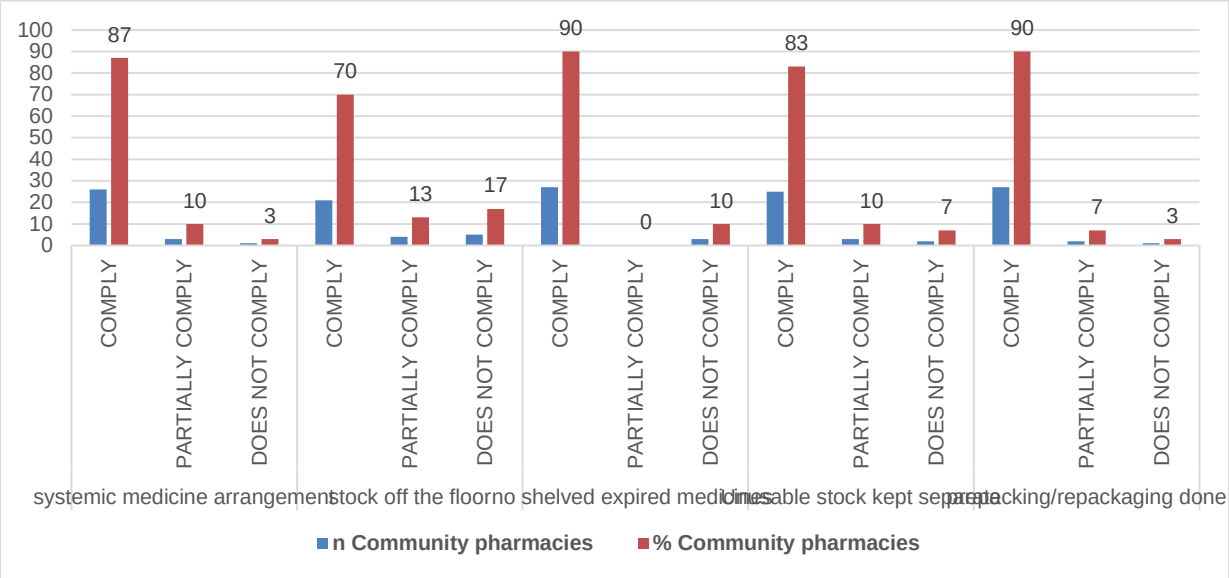


Figure 3-20: Stock (medicines & medical supplies) management indicators in the community pharmacies

A high standard for equipment maintenance and cleanliness must be consistently applied. Equipment should be maintained, serviced and calibrated following the manufacturer's instructions (PSI, 2012:17).

Findings, as shown in Figure 3-21, indicate that storage infrastructure indicator was adhered to by community pharmacies even though some areas needed improvement. Most of the community pharmacies amounting to 77% (n=23), complied with maintaining good hygiene in the store. The next indicator adhered to was the availability of storage lighting by 70% (n=21) of community pharmacies. The good storage practice, i.e. pharmacologic or alphabetic arrangement of medicines was maintained by 67% (n=20) of community pharmacies while 57% (n=17) of community pharmacies adhered to good maintenance of storage equipment. Partial compliance with storage equipment by community pharmacies was with well-equipped storage, storage hygiene and storage lighting with 37% (n=11), 23% (n=7) and 20% (n=6) respectively. Figure 3-23 continues to show that some community pharmacies, 17% (n=5) did

not comply with storage maintenance, meaning that they did not even meet any criteria of that indicator.

As controlled medicines might be associated with a risk of abuse, they have to be stored in a safe environment that limits their accessibility to the public.

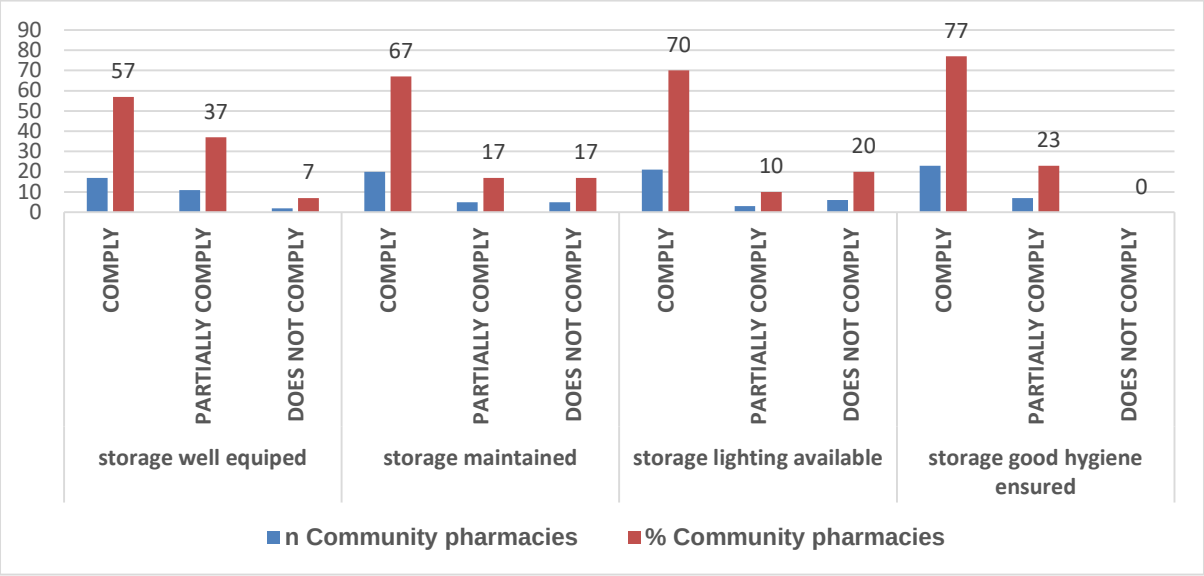


Figure 3-21: Storage infrastructure maintenance in the community pharmacies

In most countries, regulations and legislation require that community pharmacies maintain records of medicines dispensed from a prescription and/or compounded from a prescription. The dispensing records must be reviewed at least once a year and be kept for ten years (WHO, 2019:41).

In Lesotho, from the results and available literature, records keeping were not adhered to by community pharmacies. Ramathebane *et al*. (2012:32) reported the dispensing records found available at the health facilities studied were tally sheets, notebooks and computers. Most health facilities used tally sheets followed by notebooks, whereas a few used a computer. There were those health facilities that did not keep any dispensing records at all.

All community pharmacies that participated in the study, 100% (n=30) did not comply with proper storage and record keeping of controlled medicines as evident in Figure 3-22. Figure 3-23 indicated that 80% (n=24) of community pharmacies dispensed controlled medicines, but as seen in Figure 3-22, compliance with storage and record keeping remained a challenge. This, therefore, implies that the controlled medicines available in the community pharmacies

were not kept/stored according to proper storage that ensured limited access, for example in controlled medicines cabinets/cupboards.

In Rwanda, community pharmacies that handle controlled medicines are supposed to have unique cupboards for controlled medicines. Only 96.6% of all visited pharmacies had appropriate cupboards (Rugamba, 2016:29),

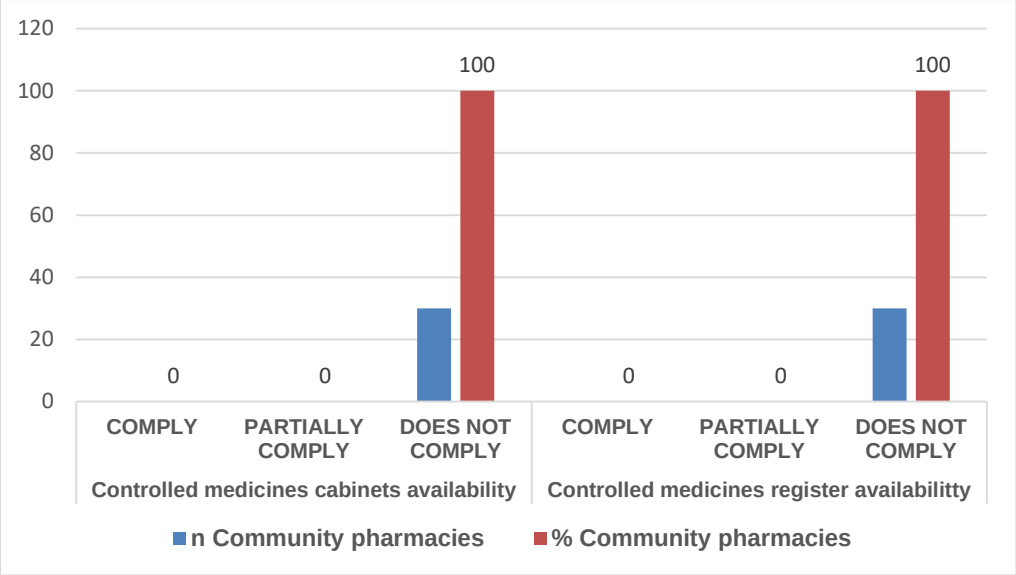


Figure 3-22: Storage and record keeping of controlled medicines in the community pharmacies – storage and record-keeping indicator

References

In this section, references kept in community pharmacies in Lesotho were divided into two categories: Lesotho references (local) and other references and textbooks (non-local).

The results in Figure 3-23 show that most community pharmacies; 57% (n=17) kept Lesotho Medical Formulary (LMF) followed by 43% (n=13) community pharmacies who adhered to keeping the Lesotho Standard Treatment Guidelines (LSTG). The majority of community pharmacies (77%; n=23) did not keep a copy of the Lesotho pharmacy laws; 73% (n=22) had no Lesotho Essential Medicines List (LEML) and LSTG was not available in 57% (n=17) of the community pharmacies which were studied.

In the USA, the states are mandated to keep drug information references. Also, a majority of the states require that pharmacies maintain a copy of the current laws and regulations (Clauson *et al.,* 2008:576).

A study done in Lesotho that was explicitly for health facilities/centres/clinics and on antiretroviral treatment (ART), indicated that ART treatment guidelines were available in almost all, 94% the health facilities/centres/clinics, of which 91% had manuals as references (Wang et al.,2013:25).

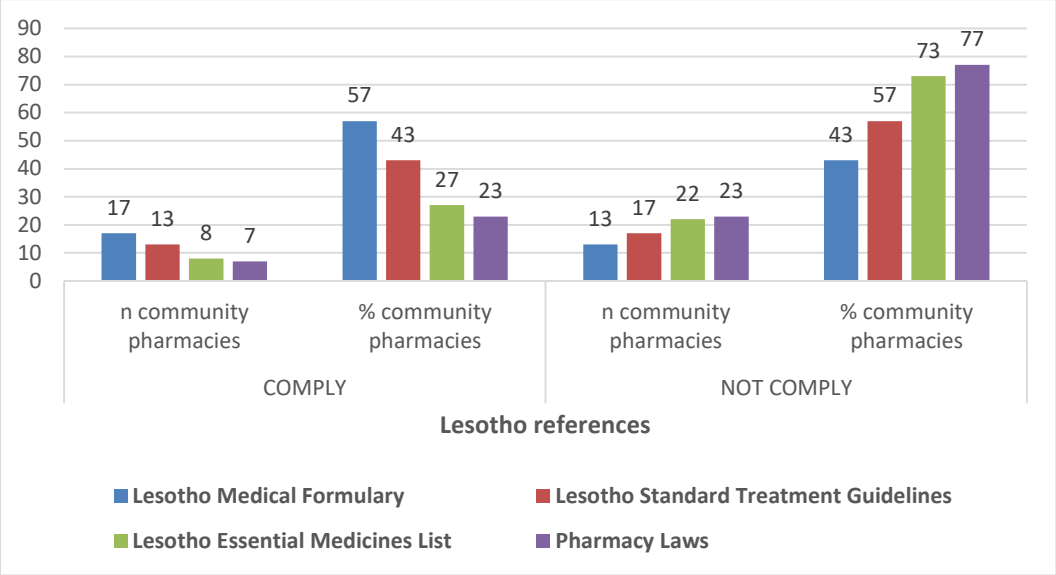


Figure 3-23: Availability of Lesotho references in the community pharmacies

All community pharmacies who participated in the study; 100% (n=30) kept South African Medicines Formulary (SAMF), 67% (n=20) had online reference, and 53% (n=16) kept symptoms in the pharmacy textbook for reference (Figure 3-26).

By recognising the need for timely, easily accessible, and searchable dispensing information, the majority of states in the USA expressly permit electronic resources to satisfy the board of pharmacy requirements (Clauson *et al*., 2008:576). Although printed references still exist in Tennessee, USA, electronic resources, in the form of databases or Internet resources, have been the mainstay of medical information for healthcare providers (Borja-Hart & Leachman, 2016:185).

Good Pharmacy Practice (GPP) and Pharmacology textbooks were the references that were mostly not kept by community pharmacies, 80% (n=24) each as depicted in Figure3-24.

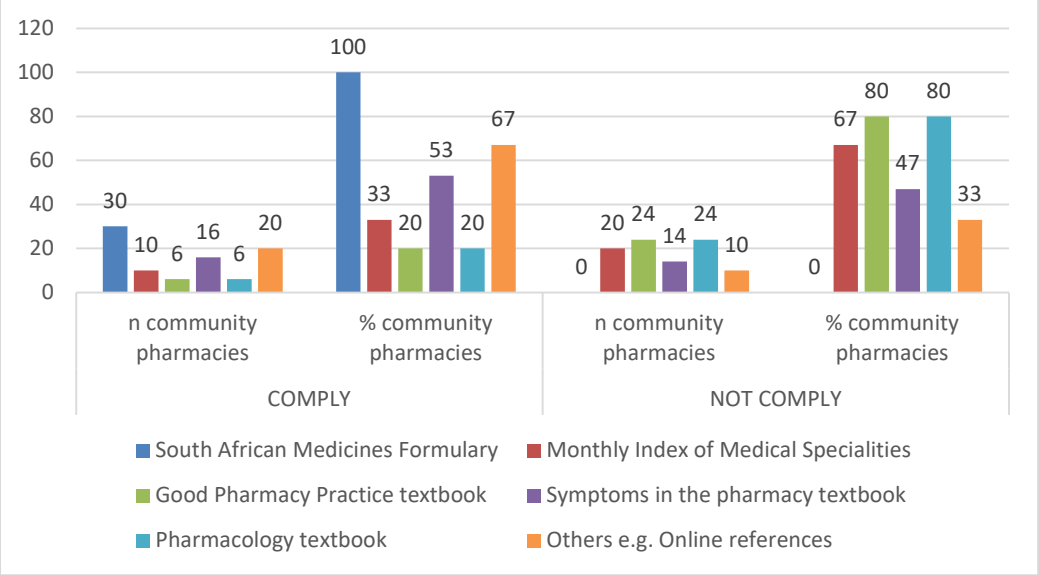


Figure 3-24: Other references kept and used in the community pharmacies

3.3 Phase II: Explore the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho using face-to-face interviews according to structured questionnaires with community pharmacists and other stakeholders.

3.3.1 Community pharmacist's perspective

Community pharmacists' perspective on community pharmacy practice was gathered through face-to-face interviews with owners or pharmacists in charge of the community pharmacy participating in the study. It constituted phase II of the study.

3.3.2 Business entity types of community pharmacies

In Lesotho, the Medical, Dental and Pharmacy Order (13 of 1970) allows both sole and partnership ownership of community pharmacies under the following conditions:

- In the case of an individual who wants to own a community pharmacy, must be registered as a pharmacist.

- In the case of a body corporate, that body must comply and be incorporated under Lesotho Medical, Dental and Pharmacy Order (13 of 1970).
- Also, the majority of the members of the board of that body corporate must be individually registered as pharmacists.
- In the case of a partnership, the majority of the partners must individually be registered as pharmacists.

Figure 3-25 shows that pharmacists owned 83 % (n=25) of community pharmacies, while non-pharmacists owned only 17% (n=5).

Ownership of a community pharmacy is restricted to a pharmacist (or group of pharmacists) in many countries in the WHO European Region (WHO, 2019:26). The main reason is that it is considered by some to enable a high level of professional judgement by mitigating the risks of corporate ownership, which might give directives to favour profit over individual and population health (WHO, 2019:26).

In countries where non-pharmacists can own a pharmacy, the legislation and regulations require a pharmacist to be in charge of the community pharmacy (WHO, 2019:32).

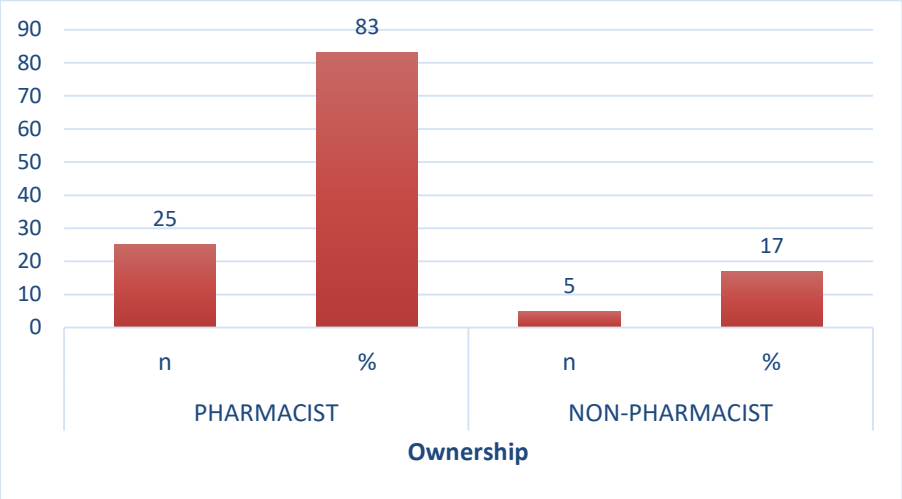


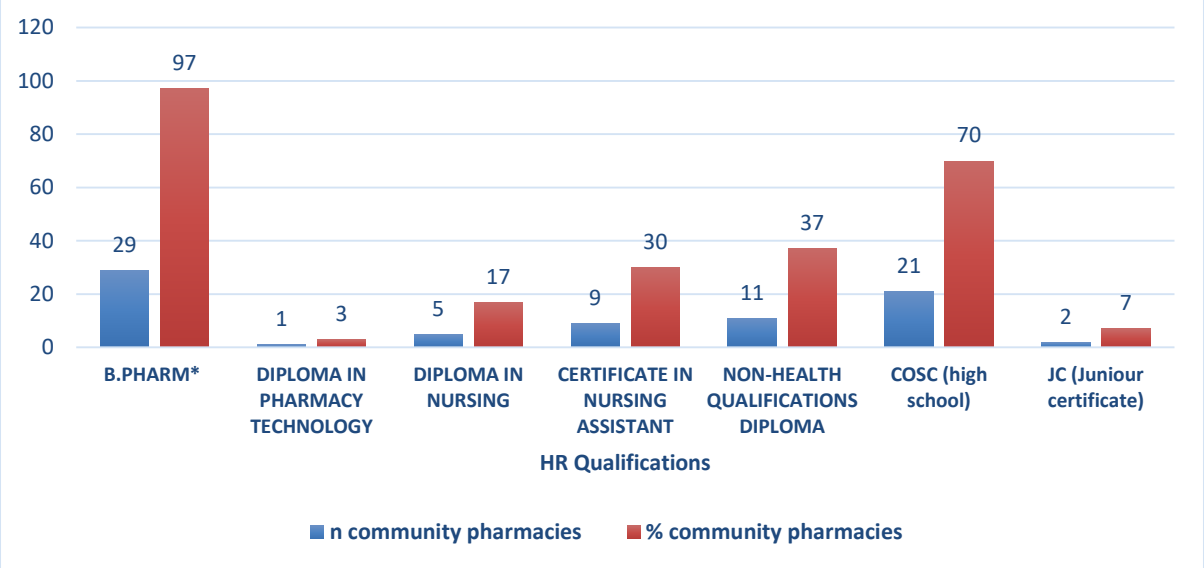
Figure 3-25: Ownership of community pharmacies by pharmacists in Lesotho

3.3.3 Human resources available in community pharmacies and their qualifications

Figure 3-26 shows the available human resource for the community pharmacy and their qualifications. Most community pharmacies, 97% (n=29) were compliant with having a pharmacist; Bachelor of Pharmacy (BPharm) holders. The percentage included pharmacists

in charge, the owner of community pharmacies, full-time pharmacists and part-time pharmacists.

Second, to BPharm were the COSC (high school) qualified personnel who formed staffing for 70% (n=21) of studied community pharmacies. Community pharmacies were also staffed with non-health, non-pharmacy staff that had formal education in other fields, such as education. These formed staffing for 37% (n=11) of the community pharmacies. The other human resource for community pharmacies as shown in Figure 3-26, comprised of nursing assistants by 30% (n=11), diploma holding nurses by 17% (n=5), JC (secondary school) holders by 7% (n=2) and lastly, pharmacy technology diploma holders being employed by 3% (n=1) of community pharmacies.



B.Pharm* (Bachelor of Pharmacy) includes all pharmacists, community pharmacy owners and part-time pharmacists

Figure 3-26: Human resource for community pharmacies in Lesotho based on educational qualifications

3.3.4 Number of years a community pharmacy has been in operation

Community pharmacies involved in this study (53%, n=16) were operational between 1 to 5 years, followed by 27% (n=8) of community pharmacies in operation between 5 to 10 years. Only 10% (n=3) of community pharmacies had been open for less than a year. Lastly, the

other 10% of community pharmacies have been in existence for over 10 years. In this group, the longest in operation was for 11 years (Figure 3-27).

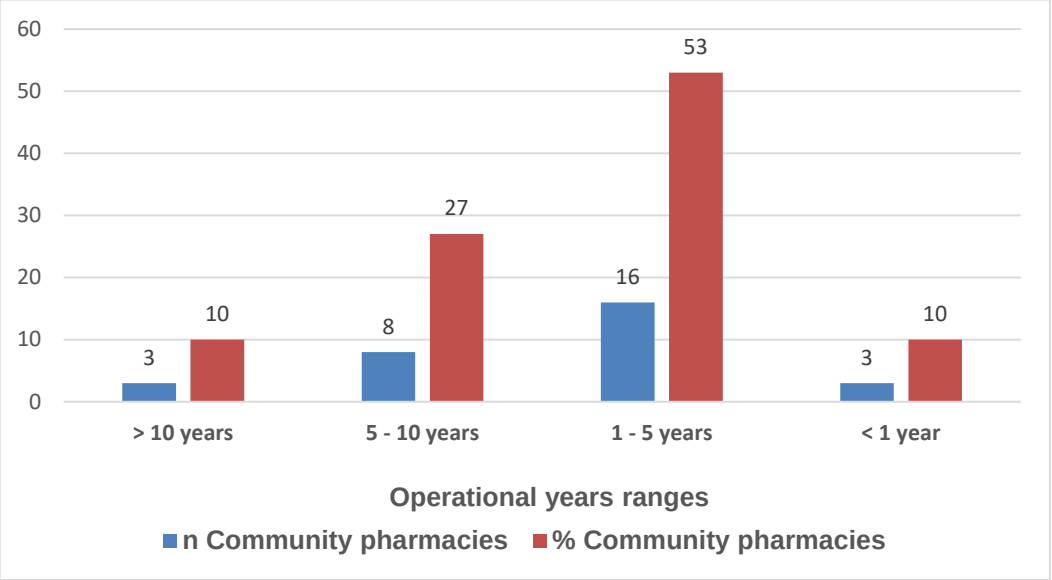


Figure 3-27: Operational years within which community pharmacies have been providing community services in Lesotho

3.3.5 Inspections of pharmacies

Routine community pharmacy inspections by the MOH are done, as illustrated in Figure 3-28. The majority of community pharmacies (67%, n=20) confirmed that MOH did routine inspections while 33% (n=10) stated that inspections have never been conducted at their community pharmacies.

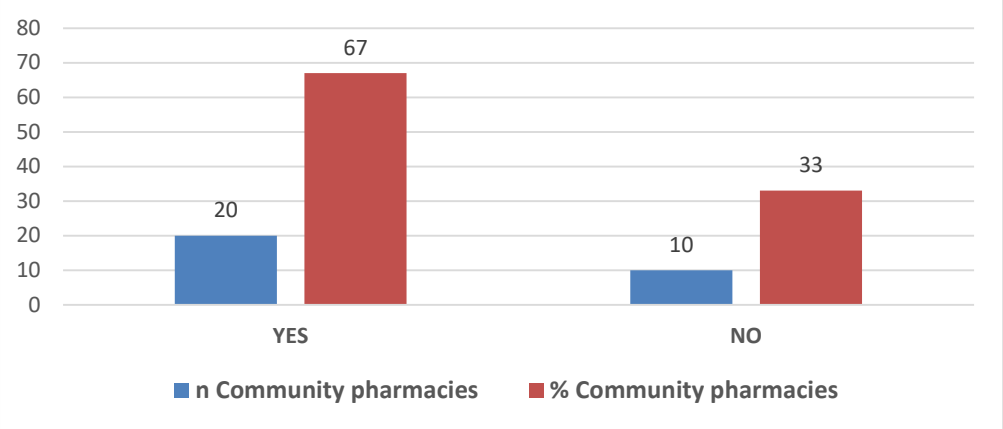


Figure 3-28: Community pharmacies inspection in Lesotho

Community pharmacies, 53% (n=16) indicated that MOH conducted routine inspection annually while 27% (n=8) had never been inspected since the opening of the community pharmacy and were not aware that inspections were done (Figure 3-29).

Community pharmacies to which routine inspections were conducted constituted 10% (n=3) whereas 7% (n=2) were never inspected even though those community pharmacies had been operational for more than a year. No quarterly or monthly routine inspections were conducted in community pharmacies, as shown in Figure 3-29.

Findings from the study done in Lesotho for health facilities, attributed poor service delivery even where resources are in abundance to lack of supervision and the fact that health professionals are generally not appraised to determine whether they perform effectively or not (MOH, 2014:67).

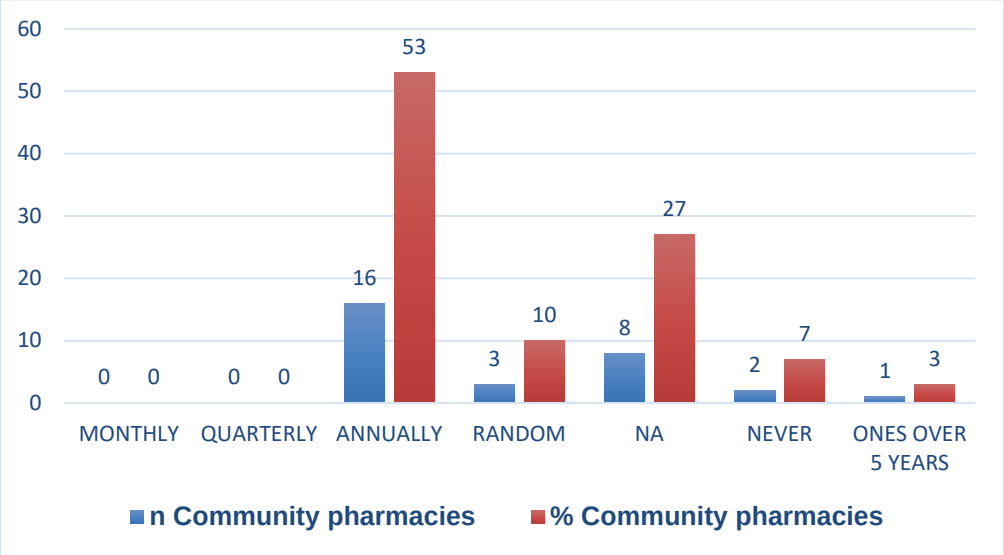


Figure 3-29: Community pharmacies' routine inspection intervals by the MOH

Table 3-4 shows the criteria from which MOH inspections are done. Community pharmacy legal issues were inspected on 53% (n=16) of community pharmacies followed by 37% (n=11) and 33% (n=10) community pharmacies inspected on Good Pharmacy Practice and human resource respectively.

Premises and layout were not inspected in 57% (n=17) community pharmacies while 33% (n=10), 37% (n=11) and 30% (n=9) of community pharmacy indicated that it is not applicable

for their specific pharmacies, because their community pharmacy has been open less than a year ago and the MOH has not visited them yet.

Table 3-5: Community pharmacies MOH inspection criteria

MOH inspection criteria	Compliance to MOH inspection criteria					
	YES	**%**	**NO**	**%**	**NA**	**%**
Community pharmacy legal issues	16	53	4	13	10	33
Good Pharmacy Practice (GPP)	11	37	9	30	10	33
Premises and layout	2	7	17	57	11	37
Human resource (HR); if pharmacist available	10	33	11	37	9	30

3.3.6 Procurement of medicine

Developing countries are frequently exposed to products that may be inefficacious or toxic, which may threaten to erode confidence in the healthcare system (Tiyyagura *et al.*, 2014:28). It is, therefore, important to source pharmaceuticals from reputable suppliers.

In Lesotho, the NDSO is mandated to procure and manage the distribution of medicines and other health commodities on behalf of the MOH to public healthcare facilities. The NDSO also sells medicines to private outlets to generate an income for operational and/or running costs (MOH, 2010:62). These private outlets include local suppliers and community pharmacies.

Table 3-5 shows pharmaceutical suppliers from which Lesotho community pharmacies procure their stock (medicines and medical supplies). Most community pharmacies; 93% (n=28) procured their stock from Medicare® followed by NDSO with 80% (n=24) then Tripharm® with 77% (n=23). Supralatex® Maseru pharmacy and Lifeline® as other local suppliers, only supplied medicines and medical supplies to 3% (n=1) of community pharmacies each.

Few community pharmacies procured supplies from non-local suppliers. Upon face-to-face interviews with community pharmacies that procured medicines from non-local suppliers, they

indicated that they only sought non-local suppliers for products that NDSO did not keep or were out of stock for an extended period. The non-local registered suppliers were United Pharmaceutical Distributors (UPD)®, Adcock Ingram®, PD Pharmaceuticals® and Impulse Pharma®, which are South African based and are registered in their country. The results indicate that 20% (n=6) of community pharmacies procured their supplies from UPD®, 13% (n-4) from Adcock® and PD pharmaceuticals® each, while only 7% (n=2) of them procured from Impulse as tabulated in Table 3-5.

Table 3-6: Procurement of medicines and medical supplies should be done from reputable suppliers.

DISTRICT	LOCAL SUPPLIERS						NON-LOCAL SUPPLIERS			
	NDSO	TRIPHARM®	MEDICARE®	SUPRALATEX®	MASERU PHARMACY	LIFELINE®	ADCOCK®	UPD®	PD®	IMPULSE®
Maseru	13	14	15	1	1	1	3	0	0	1
Berea	2	2	3	0	0	0	0	0	0	0
Leribe	3	1	4	0	0	0	1	0	0	0
Butha-Buthe	1	1	1	0	0	0	0	0	0	1
Mafeteng	2	1	2	0	0	0	0	0	0	0
Mohale's Hoek	2	2	1	0	0	0	0	0	0	0
Qacha's Nek	1	1	1	0	0	0	0	0	0	0
Thaba-Tseka	0	1	1	0	0	0	0	0	0	0
TOTAL n Community Pharmacy	**24**	**23**	**28**	**1**	**1**	**1**	**4**	**6**	**4**	**2**
% Community pharmacies	**80**	**77**	**93**	**3**	**3**	**3**	**13**	**20**	**13**	**7**

3.3.7 Dispensing of schedule I, II and III drugs (controlled medicines) in community pharmacies in Lesotho

Dispensing of scheduled drugs should be done by a registered pharmacist according to the Drugs of Abuse Act (21 of 2008). Figure 3-28 shows that 90% (n=27) of community pharmacies dispensed controlled medicines in their community pharmacies while only 10% (n=3) did not dispense them (Figure 3-30).

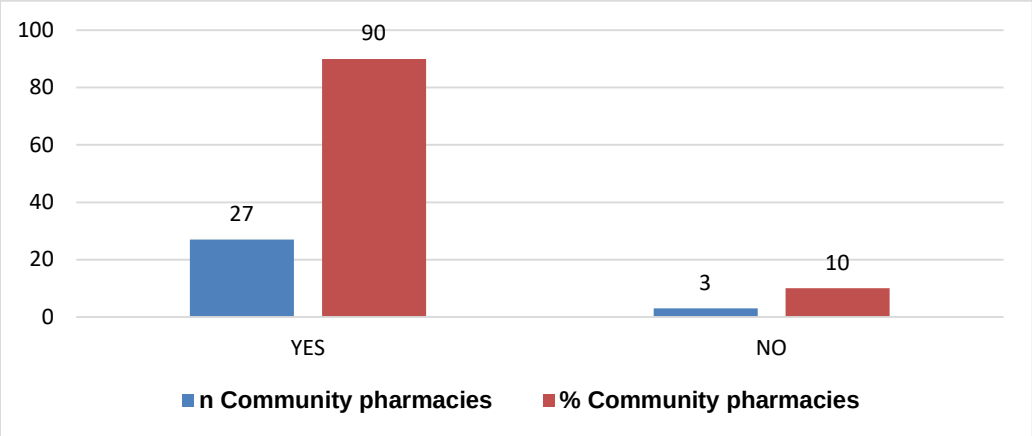


Figure 3-30: Dispensing of controlled medication in the community pharmacies

Figure 3-31 demonstrated that 36% of community pharmacies handle controlled medicines the same as any over-the-counter medicines while 57% handle them like prescription-only medicines and in both cases, any personnel dispensing at the time dispense them. This is contrary to good dispensing practices. Therefore, the majority of community pharmacies, 93% do not adhere to good dispensing procedures of scheduled medicines.

As reflected in Figure 3-31, controlled medication is dispensed in 90% (n=27) of community pharmacies. Of those, only 11% (n=3) followed the guidelines according to the Drugs of Abuse Act (13 of 2008) of Lesotho. Some community pharmacies, 30% (n=8) handled controlled medicines like prescription-only medicines while most, 59% (n=16) community pharmacies dealt with them as prescription-only and over-the-counter (OTC) medicines. This is contrary to the Drugs of Abuse Act (21 of 2008).

In Rwanda, 98% of all community pharmacies visited, handled controlled medicines, and only 2% did not (Rugamba, 2012:29).

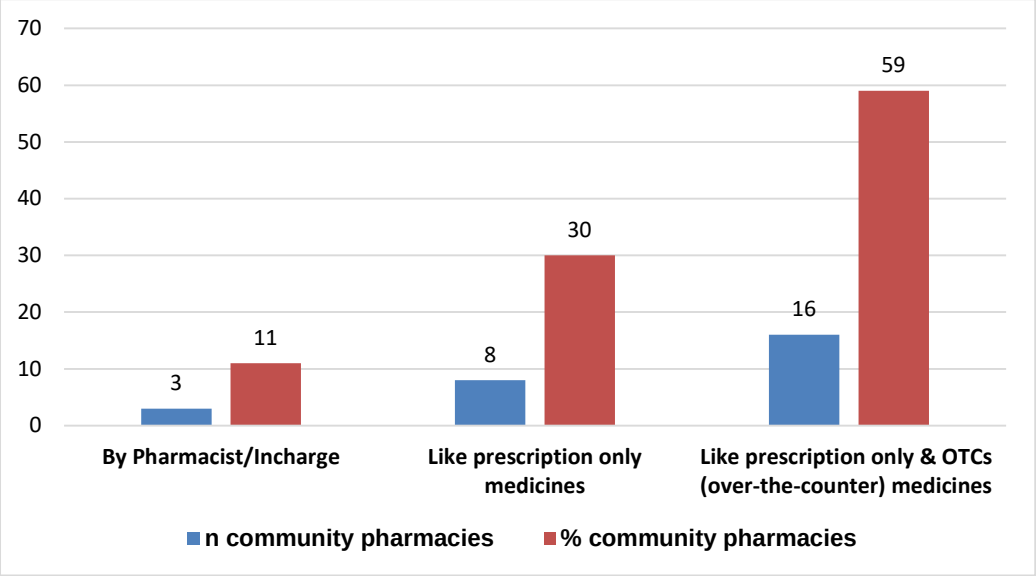


Figure 3-31: Handling and dispensing of controlled medicines

3.3.7.1 Future of community pharmacy in Lesotho

In a study done in South Africa, the results indicated that the total number of community pharmacies registered with the SAPC increased with 13% between 1994 and 2012 in the country as a whole. However, the growth in community pharmacies did not keep pace with the 25% increase in population over the same period (Ward *et al.,* 2014:482).

A study done in Lesotho in 2016 showed that there were 46 community pharmacies (MOH, 2016:10). In this study, see Table 3-1, the assessment revealed an increase in the number of community pharmacies, from 46 in 2010 to 60 in 2017. However, it was the general feeling amongst pharmacists from community pharmacies who participated in this study; 87% (n=26) that there is a need to increase the number of community pharmacies (Figure 3-32).

Community pharmacists from 17% (n=5) of the community pharmacies saw the increase in services provided as a factor to be improved on going forward. Three community pharmacies (10%) indicated that they observed an increase in patients seeking help from community pharmacies. In addition, interviewed staff mentioned that with the anticipated growth, there is a need for an increase in the employment of pharmacists by community pharmacies. The main reason for the addition of new products on procurement lists is that a growing number of patients requested current treatments. The last two way-forward issues were the views from 3% (n=1) of community pharmacies.

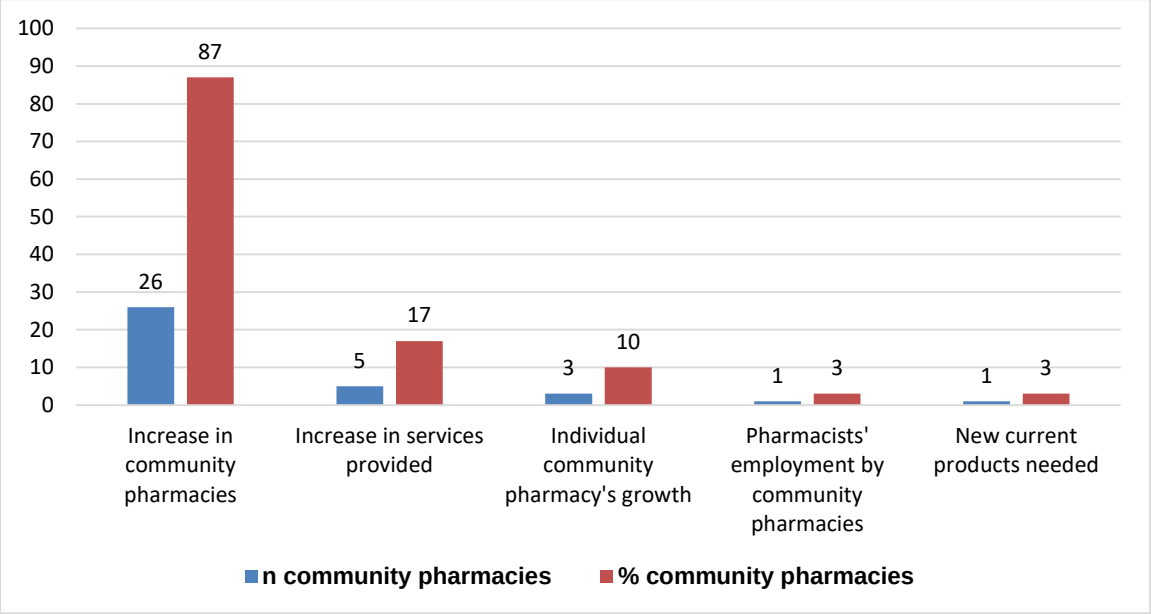


Figure 3-32: Future of community pharmacy in Lesotho community pharmacists' perspective

These are different departments or entities that are involved with MOH activities and for this study have a role to play in the community pharmacy sector in Lesotho.

3.3.8 Ministry of Trade (MOT)

The MOT is responsible for licensing community pharmacies in Lesotho for trading because it is a business. However, it is also expected that community pharmacies should register with MOH additionally though it is not a prerequisite.

In several countries, in the WHO European Region, a licence to open a new pharmacy can only be issued if specific demographic criteria are met. The most common criterion is the number of inhabitants (population) within a given city, county or administrative region (WHO, 2019:19). This was not the case with most of the communities in Lesotho as pharmacies were situated close to each other. For example, pharmacies were located across the road in the same street). The observation from this study was that the availability of a working space seems to be a decision-maker of where the community pharmacy will be trading despite the presence of already existing community pharmacies in the vicinity.

In the USA, the Drug Enforcement Administration (DEA, 2010:10) states that the certificate of registration must be maintained at the registered location and kept available for official

inspection. If a person owns and operates more than one pharmacy, each business location must be registered.

Table 3-6 shows the documents needed by the MOT for submission for approving registration of a community pharmacy. All of them are to be required and failure to produce either delay or hinder the registration of the community pharmacy with the MOT's OBFC) office. In Lesotho, the OBFC office gives guidance and support to complete the steps of obtaining a manufacturing or trading license, registering as an importer, import and export permits and securing work, and residency permits and registration of companies started in 2011 (Companies Act, 18 of 2011).

Table 3-7: MOT required documents for submission for community pharmacies' registration

Documents for submission for community pharmacy registration with MOT	Required
Pharmacist's academic qualifications	√
Partners' credentials, such as an ID	√
Community pharmacy lease	√
Company Extracts: Certificate of incorporation	√
Sublease for rentals	√
Financial Statements copy for re-registration	√
Tax clearance for re-registration	√
MOH registration certificate	√

3.3.8.1 Community pharmacy registration

According to the Drug of Abuse Act (5 of 2008), there are stipulated requirements for the application of a license to operate controlled medicines but none for generic medication. Such application shall specify private and business addresses of the operator; the activity of which registration is sought; if the operator is a company, the full name and residential address of each director and the company secretary; if the operator will engage in the activity under a business name, that name (Figure 3-33).

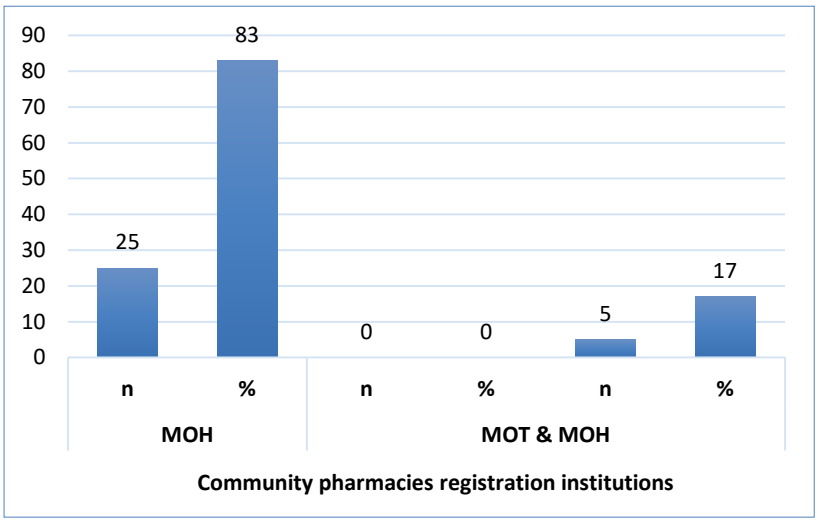


Figure 3-33: Registration institutions for community pharmacies in Lesotho

3.3.9 Lesotho Medical, Dental and Pharmacy Council (LMDPC)

The LMDPC is the council that regulate three professions, namely, medical doctors, dentists and pharmacy personnel (pharmacists and pharmacy technicians).

3.3.9.1 Human resources and registration

According to Lesotho Medical, Dental and Pharmacy Order (13 of 1970) if the registrar is satisfied that the degree, diploma or certificate and the facts or documents submitted in support of the application are following the requirements of this Order, he shall, upon payment by the applicant and issue to him a certificate that he is registered in the registry applicable to him.

The registrar showed that there were 130 registered pharmacists and 80 pharmacy technicians (Mohapeloa, 2017), that appear in the register of LMDPC and do annual re-registering though no measures are taken to ensure their adherence.

Registration with LMDPC is done at the discretion of an individual person, or depending on where they work. A pharmacists working in the community pharmacies or owning one, for example, needs the LMDPC certificate to practice. No law forces pharmacists to register with the LMDPC. The council also stated that there were no inspections or visits nor any training for its members. The failure to conduct an inspection by the council was attributed to financial constraints (Mohapeloa, 2017).

Table 3-7 shows the required documents for registration for Lesotho and foreign pharmacists. Qualification certificates and identity documents were the commonly needed documents for both Lesotho and foreign nationals.

Extra documents for foreign nationals were needed and those included original school transcripts, letter of good standing and two passport size photos. Lesotho nationals are requested to bring certified copies in case of school transcripts.

Table 3-8: Documents required for submission for registration with LMDPC by pharmacists

	LMDPC	
Requirements	**Local pharmacists**	**Foreign pharmacists**
Qualification certificates (original)	√	√
Institution transcripts (certified copies)	√	
Institution transcripts (original)		√
Pharmacist' document (certified copies)	√	√
Letter of good standing		√

3.3.10 Suppliers

These are community pharmacies' medicines and medical supplies wholesalers, whether government-owned or private.

In Lesotho, procurement is done from reputable local and foreign suppliers. These suppliers require different documents as a way of authenticating the community pharmacies to which they supply stock to (medicines and medical supplies) as depicted in Table 3-8.

The study has identified that community pharmacies in Lesotho procure from ten suppliers. Only 40% (n=4) procured their supplies from foreign suppliers, while 60% (n=6) exclusively procured from local suppliers.

The documentation required for registration to do procurement for foreign suppliers according to pharmacists' interviews includes trader's license, tax clearance, business profile, banking details and pharmacist's registration. For local suppliers, the requirements are as shown in Table 3-8.

3.3.10.1 National Drug Service Organisation (NDSO)

NDSO requested all documents excluding the lease and banking information. Both NDSO and Medicare® emphasised that without the mentioned documents, approval for procurement cannot be granted.

3.3.10.2 Medicare®

Medicare® is one of the third largest suppliers in Lesotho. It supplies community pharmacies and some of the CHAL health facilities. Unlike NDSO, it is not government-owned and does not supply any government health facilities (Ibrahim: 2017).

Table 3-8 displays the documents required by local suppliers in Lesotho for the procurement of medicines and pharmaceutical supplies. Pharmacist's credentials and registration, community pharmacies registration and proof of residency (lease), compliance with tax regulations (tax clearance) and banking details are the needed requirements for procurement authorisation by the suppliers. As indicated in Table 3-8, all documents were requested by Medicare© for allowing them to procure medicines and medical supplies.

Table 3-9: Document requirements for procurement by local supplies

Requirements	Local supplier	
	NDSO	**MEDICARE®**
Pharmacist's Qualification Certificate	√	√
Pharmacist LMDPC Reg. Certificate	√	√
MOH Registration Certificate	√	√
MOT Registration Certificate	√	√
Tax clearance	√	√
Certificate of incorporation	√	√
Lease/sublease form		√
Community pharmacy banking information		√

3.3.11 Pharmaceutical Society of Lesotho (PSL)

In every country, the relevant associations of pharmacists should be available. This is done to produce a Code of Ethics for pharmacists, setting out their professional obligations and taking steps to ensure that pharmacists comply with the provisions of that Code (FIP, 2012:18).

LMDPC and PSL are the bodies directly involved with community pharmacy practice. Table 3-9 mentions the organisation and its responsibilities in the practice of pharmacy in Lesotho. The differences between the two lie in their mandates. LMDPC is the regulatory council responsible for the registration of health personnel (Doctors, Dentists and Pharmacy personnel) while the major role of PSL is advocacy in the practice of pharmacy. Findings from both regulatory bodies revealed that none gets any assistance in terms of the capacity building or financial from the government

The Medical, Dental and Pharmacy Council generally lack appropriate staffing levels for them to carry out their work of ensuring that professional health workers carry out their work professionally (Lesotho, 2013:17). Mohapeloa (2017) reiterated that because of lack of finances and human resource, the council does not conduct supervisory visit or training necessary to capacitate its members.

The WHO emphasised that governments, professional councils and associations should work together to develop appropriate task-sharing models and inter-professional collaboration. In addition, governments should ensure that all cadres with a clinical role, beyond their professions, also benefit systematically from accreditation and regulation processes (WHO, 2016:21).

Table 3-10: Regulatory bodies in the pharmacy profession and their roles

Role of the LMDPC (Lesotho Medical, Dental and Pharmacy Council) and PSL (Pharmaceutical Society of Lesotho) on Pharmacy Practice and regulation	
BODY	**ROLE**
LMDPC	Registration of practitioners (medical doctors, dentists and pharmacy)
	Regulatory body
PSL	Advocacy for community pharmacists' role in the practice
	Advocating for updated pharmaceutical law
	Continuous training through seminars
	PSL involved in pharmaceutical laws review

3.4 Chapter summary

In this chapter, the study results were presented and discussed based on empirical investigations. Community pharmacy practice and profiling in Lesotho were evaluated with

reference to the WHO, FIP and SA as a neighbouring country. Reference to SADC and other countries were also made on the same standards. Some comparisons with the results of other studies on the standards of GPP were done.

CHAPTER 4 CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

4.1 Introduction

In this chapter, conclusions are drawn based on the objectives of the study. Limitations of the study are discussed, and recommendations are made from the results of the empirical research results

4.2 Conclusions

4.2.1 The general aim of the research

The general aim of the study was to investigate the profile and standard of community pharmacy practice in Lesotho.

It can be concluded that community pharmacy practice in Lesotho has grown and therefore, an increase in pharmaceutical services to patients. This is evidenced by community pharmacies increase in number as well as an increase in the numbers of pharmacists. The standard of practice, in most cases, did not adhere to the WHO (2011b: 310-323) and SA standards (SAPC, 2010:14-115; Pharmacy Act (53 of 1974)). Sections 4.2.2 and 4.2.3 provides more details on the conclusions drawn.

4.2.2 Conclusions based on the findings from the literature review objectives

In this section, conclusions are drawn from the literature review objectives.

4.2.2.1 To investigate the role of community pharmacists in the healthcare system internationally and within the SADC region.

The main roles of community pharmacists in the healthcare system as developed by WHO and FIP were given as follows (WHO, 2011b:15)

Role 1: To prepare orders, obtain orders, maintain storage, ensuring security, distribute, administer, dispense and dispose of medical products as a way of ensuring the availability of appropriate medicinal products.

Role 2: To provide effective medication therapy management by tracking and keeping records of patients' outcomes of therapy to enable follow-ups.

Role 3: To maintain and improve professional performance by ensuring continues professional development through, for example training.

Role 4: To contribute to improving the effectiveness of the health care system and public health by collaborating with other health professionals and partaking in health promotion activities.

These main roles were shown to differ depending on the area/country of practice of a community pharmacist but should be used as a guide for standardising of practice. (WHO, 2011b:16).

Pharmacists have to play an important role in collaborating with other health care providers. This should be done to ensure that an effective process for medication reconciliation is in place and adhered to, to reduce medication errors and some related medication challenges. To fulfil this role, a more patient-centred approach to designing and managing care is paramount (American Pharmacists Association (APhA) & American Society of Health System Pharmacists (ASHP), 2012:3)

In response to the need to improve vaccine uptake, in the UK, a pharmacy-based vaccination service was commissioned for the 2014/15-flu season by the National Health Services of England (Rai & Wood, 2017:359).

Lesotho community pharmacies are not yet equipped to embrace the new roles e.g., offering flu vaccines. This is revealed by the results, which showed only 3% of the participating community pharmacies equipped with refrigerators. It can be concluded that cold chain is not maintained (refer to section 3.2.3).

In Uganda, the country is facing maternal mortality, and as a way of combating it, community pharmacies provided injectable contraception to patients generally who were already on the injections but not initiate those contraceptives. Patients prefer community pharmacies over government providers due to reduced waiting times, convenience, and respect patients received from community pharmacies, and this reflects good services by community pharmacies (Akol *et al*., 2014:474).

The primary role that seemed to be adhered to by community pharmacists in Lesotho was Role 1 (WHO, 2011b:15) of the main roles even though some aspects of storage were not

met. The other roles, 2 to 4 were not fulfilled, for example record-keeping and patients' monitoring, continued professional development and health promotion activities (refer to sections 2.7.1 and 3.2.5).

4.2.2.2 To conceptualise GPP from available literature and its implication for community pharmacy practice in Lesotho.

The GPP standards explored in the literature review included standards for community pharmacy premises, human resources, pharmaceutical services, management, dispensing, documentation and record-keeping, storage of medicines and reference sources (refer to section 2.7.2).

In community pharmacy practice, GPP is required to ensure that authorised staff appropriately delivers the practice of pharmacy, through its many elements. In Thailand, Wuttipanich and Kitisopee (2015:110) stated that GPP is a standard for pharmacy services and failure to implement the practice would have financial implications. From the human resource aspect of GPP, it was added that the absence of pharmacists on duty has increased the risk of inappropriate dispensing of medication and directly affected patients' health.

In Lesotho, failure to implement GPP, especially with the availability of appropriate staffing has resulted in community pharmacies using unqualified personnel for dispensing to the patients. Premises standards that are not adhered to may result in operations of community pharmacy practice in an unsafe environment (no fire extinguisher) and storing of medicines without maintaining proper cold chain (no refrigerators).

4.2.2.3 To evaluate the relevance of existing laws, regulations and policies governing community pharmacy practice in Lesotho.

In Lesotho, four laws govern the pharmacy, pharmacy professionals and controlled medicines. The other two laws have been in the process of been enacted into laws for a long time and are just bills.

Table 4-1 shows the existing laws governing community pharmacy practice in Lesotho and the functions of those laws.

Table 4-1: Laws governing community practice in Lesotho

Existing laws governing community pharmacy practice in Lesotho	Functions
LMDP Order (12 of 1970)	Regulates the registration of Doctors, Dentists and pharmacist
Dangerous Medicines Act (21 of 1973)	Regulates scheduled medicines manufacturing, dispensing and use (old law)
Drug of Abuse (5 of 2008)	Regulates scheduled medicines manufacturing, dispensing and use (new law)
The Companies Act (15 of 2011)	Regulates registering of businesses
Medicines Bill (2012)	Once enacted into law, will regulate all medicines use
Health Professional Bill	Once enacted into law, will regulate all health professions and professionals

The investigations revealed that all of the laws governing the practice were outdated with the most recently updated done in 2008. It was also found that there were no laws or regulations that govern community pharmacy practice specifically.

4.2.3 Conclusion based on the findings of the empirical research objectives

In this section, conclusions are drawn from investigations done to answer the empirical research objectives.

4.2.3.1 Objective one: To assess the extent to which community pharmacies in Lesotho complied with the GPP guidelines of the WHO as well as South Africa as a neighbouring country

Some GPP guidelines and standards for community pharmacy practice in Lesotho assessed included:

- Pharmacy staffing and staff registration
- Dispensing of prescription and pharmaceutical care
- Storage and record-keeping
- Availability of references
- Procurement of medicines

According to the WHO (2003:128), at each storage site (for example community or hospital pharmacy), there should be an adequate number of qualified personnel to achieve

pharmaceutical quality assurance objectives. The WHO (2003:131) indicated that information, written or electronic, should exist for each stored material or product indicating recommended storage conditions, any precautions to be observed and retest dates. Comprehensive records should be maintained, showing all receipts and issues of materials and pharmaceutical products procured.

The results from this study revealed that 57% of the community pharmacies in Lesotho had full-time pharmacists with the rest being run by high school graduates with or without the supervision of a pharmacist. Majority of community pharmacies that kept controlled medicines treated them like OTC medicines (51%) or dispensed them as prescription-only medicines (Refer to section 3.3.7). Dispensing was done manually without the use of computers for either dispensing or record keeping.

It can be concluded that community pharmacies in Lesotho did not adhere to WHO guidelines regarding staffing, storage and record keeping. Results, however, indicate that procurement was done from reputable local suppliers, which is in accordance to the WHO/FIP guidelines (WHO, 2011b: 312-323).

4.2.3.2 Objective two: To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho

Standard of premises for community pharmacies in Lesotho was studied on the basis of the following criteria:

- Cleanliness and tidiness
- Availability of suitable light and windows
- Floor maintenance and washable walls
- Availability of hand wash, extemporaneous and screening areas
- Availability of an air conditioner, temperature monitoring and fire extinguisher

Storage areas should be of sufficient capacity to allow the orderly storage they should be clean and dry and maintained within acceptable temperature limits. Medicines and medical supplies should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be maintained in a good state of cleanliness and repair. Supplies that need special storage, for example cold chain and storage away from fires should be stored as such. Refrigeration and fire extinguishing should be ensured (WHO, 2003:128-129).

It can be concluded that community pharmacies in Lesotho complied with cleanliness and tidiness/orderliness, suitable light availability, floor maintenance, availability of washable walls,

availability of screening area of patients. Community pharmacies showed partial compliance or non-compliance for the rest of the listed criteria for premises and layout like availability of a screening area for patients and extemporaneous preparation area as well as the availability of fire extinguishers (refer to section 3.2.3) as stipulated by WHO (2003:129).

Equipment standard was categorised by assessment of the following:

- Compounding and measuring equipment for dispensing
- Dispensing supporting equipment

Compounding and measuring equipment for dispensing (for example counting trays) was found available in under 30% of community pharmacies in Lesotho. Community pharmacies complied with the availability of dispensing supporting equipment (counting apparatus) with poor performance with the availability of dispensing computers, meaning that dispensing was done manually in almost all community pharmacies. These, therefore, mean that dispensing procedures were not followed as per GPP standards (refer to section 3.2.4).

4.2.3.3 Objective three: To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho

Lesotho has weak pharmaceutical legislation and policies in place since the Medicines Bill (2012) (MOH, 2010:57) has not yet been enacted into law. To a greater extent, this weakness critically affects almost all basic functions of a community pharmacy situated in Lesotho.

Ownership of a community pharmacy is restricted to a pharmacist (or group of pharmacists) in many countries in the WHO European Region (WHO, 2019:26). The main reason is that restricted ownership is considered by some to enable a high level of professional judgement by mitigating the risks of corporate ownership with non-pharmacists, which might give directives to favour profit over individual and population health (WHO,2019:26). For Lesotho, ownership rules stipulate that community pharmacies should be owned by pharmacists or in the case of non-pharmacist in a partnership with pharmacists, majority shareholders should be pharmacists (Medical, Dental and Pharmacy Order, No. 13 of 1970). This, therefore, means that in terms of community pharmacies ownership, Lesotho has restrictions on ownership to protect pharmacy practice which is the same as the WHO European Region (WHO, 2019:26).

4.2.3.3.1 The profile and nature of community pharmacies in Lesotho

There were 60 community pharmacies in Lesotho in total according to the results of the study. Majority of these community pharmacies in were situated in the Lowlands; 83% according to the findings with few in the Foothills and Highlands (refer to Table 3.1 and section 3.2.2).

Half of the studied community pharmacies were chains (more than one existing) (refer to section 3.2.2.3). Additionally, in terms of ownership types, most community pharmacies were partnerships (57%) while the rest were sole ownerships. Pharmacists (87%) owned most of the community pharmacies. It can be concluded that community pharmacies have increased in number in Lesotho, and as much as there were shortcomings in terms of ownership standards, adherence was good.

4.2.3.3.2 The extent of pharmaceutical services provided in Lesotho

The pharmaceutical services provided by the community pharmacies included prescription scrutinising, dispensing and provision of counselling on medicines and their use as well as generic substitution. Besides, the services include medicine procurement and storage management. The services, however, fell short on public health activities and other diagnostic tests. Mostly the tests done were blood sugar levels and Blood pressure.

The results showed that the MOH did not fulfil its mandate in terms of inspection of community pharmacies.

4.3 The limitations of the study

The limitations of this research included geographical information and participation aspects. When considering geographical aspects, Lesotho is a mountainous country, and it is difficult to reach some of the areas in the districts. Data collection during the winter was delayed due to the harsh winter season in Lesotho, which is usually snowy, resulted in postponement and rescheduling.

In terms of information, there was little information or literature available in Lesotho that deals with community pharmacy practice and pharmacy practice in general; the limited literature available deals with hospital pharmacy. This means that the review of community pharmacy practice was based on limited information, which was the one motivator for the researcher executing the research study. This would provide information on community pharmacy practice in Lesotho, the first since the few available literatures that concentrated on hospital pharmacy practice.

Some participants decided not to take part in the research project, as participation was voluntary, thereby reducing the sample size. Six community pharmacies abstained from participating bringing the sample size to 30 instead of the anticipated 36 (2: Maseru, 4: Mafeteng, Butha-Buthe, Quthing & Mokhotlong).

About the stakeholders, MSH/SIAPS closed office before data collection hence reduced the number of participants for phase II of the study. MOH (Minister or delegation), Tripharm© (supplier), DRA and Director Pharmaceuticals did not respond hence excluded from the study.

4.4 Recommendations

The following recommendations can be made. The recommendations derived from the study include focus on pharmacy human resources, good pharmacy practice and role of the MOH in community pharmacy practice in Lesotho.

The specific research projects that can be done on community pharmacy practice and services in Lesotho include:

Assessment study on community pharmacies' distribution in Lesotho

Perceptions of the patients on community pharmacy practice in Lesotho

4.4.1 Pharmacy human resources

Lesotho has an urgent need to establish a comprehensive human resource information system, especially for community pharmacy that will be resourced adequately to keep it up-to-date in real-time and accessible to all stakeholders.

Governing of the practising pharmacists in the community pharmacy practice is scarce if there at all. The little supervision and training are done for only hospital pharmacists. Supervisions and training would help pharmacists improve their service, as they are the first contacts with patients seeking healthcare.

4.4.2 Good Pharmacy Practice standards

With the increased emergence of community pharmacies, there is a need to update the list of available community pharmacies by the MOH of Lesotho. The laws and regulations that govern the practice also need to be updated to be in line with the ever-changing profession and training as well as international standards. There is a need to review the available regulations/standards/statutes every 4-5 years, as recommended by the WHO (2012:52). The

review will help the pharmacy profession to hold abreast GPP standards and have guidance in their practice.

The strict control of the ownership of community pharmacies and access to medicines from suppliers should be put in place to ensure that unauthorised personnel do not provide medicines.

4.4.3 Role of MOH in community pharmacy practice in Lesotho

The MOH should be hands-on in terms of supervising, issuing and monitoring of community pharmacy practice and standards. This would include ensuring that all practising personnel is registered according to the law wherever they practice in the country; this should be prerequisite for employment.

4.5 Chapter summary

This chapter included conclusion drawn from both the literature review and the empirical research objectives hence answering the general aim of the research. In addition, the limitations experienced and recommendations made were also included in this chapter.

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ANNEXURE A: APPLICATION FOR PERMISSION FROM MOH TO CONDUCT THE RESEARCH

Good Health Pharmacy

Box 591

Teyateyaneng 200

27 July 2014

Ministry of Health

Research and Ethics Committee

PO Box 514

Maseru 100

Lesotho

Dear Sir/Madam

RE: APPLICATION TO CARRY OUT RESEARCH IN LESOTHO

I wish to request permission to research community pharmacies in Lesotho and some of the Ministry of Health's stakeholders, for example MSH/SIAPS, LMDPC and NDSO, as elaborated upon in the research protocol. The research is a requirement for the completion of my MPharm (Pharmacy Practice) at the North-West University.

TITLE OF THE RESEARCH PROJECT: Evaluation of the profile and standard of community pharmacy practice in Lesotho

This study is aimed at investigating the profile and standards of community pharmacy practice in Lesotho from the legislation, pharmaceutical care, and human resource perspective. This will be achieved by:

- Assessing the current standard of practice of your community pharmacy by completing a survey form;

- Conducting, using a structured questionnaire, face-to-face interviews with selected correspondents (pharmacists and stakeholders' representatives).

I am a Mosotho woman doing her master's degree in Pharmacy (Pharmacy Practice). I am a pharmacist currently working at Queen Mamohato Memorial Hospital with a B.Pharm (Hons) from NUL.

Please find attached the research proposal according to NWU prescriptions. For further information, you are welcome to contact my supervisor, Prof Martie S Lubbe at martie.lubbe@nwu.ac.za or call +27-18 299 22895 and researcher Retsepile Tlali at tsepz80@yahoo.co.uk or call +266 58726959.

Hoping my application will be highly considered.

Kind regards

Retsepile Tlali

ANNEXURE B1: APPROVAL LETTER TO CONDUCT THE RESEARCH FROM NWU (HREC)

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

Private Bag X6001, Potchefstroom
South Africa 2520

Tel: 018 299-1111/2222
Web: http://www.nwu.ac.za

Health Research Ethics Committee (HREC)
Faculty of Health Sciences
Private Bag X6001
Potchefstroom
South Africa 2520

Dear Prof Greeff

CONFIRMATION OF APPROVAL OF RESEACH PROTOCOL BY MUSA QUALITY ASSURANCE COMMITTEE

I hereby confirm that the following research project was approved by the Quality Assurance Committee of MUSA on the 20 February 2015.

Post-graduate student	Supervisors	Title of research project
RL Tlali 23905255	Prof MS Lubbe Prof JJ Gerber Mrs Adelé Naudé	Evaluation of the profile and standard of community pharmacy practice in Lesotho

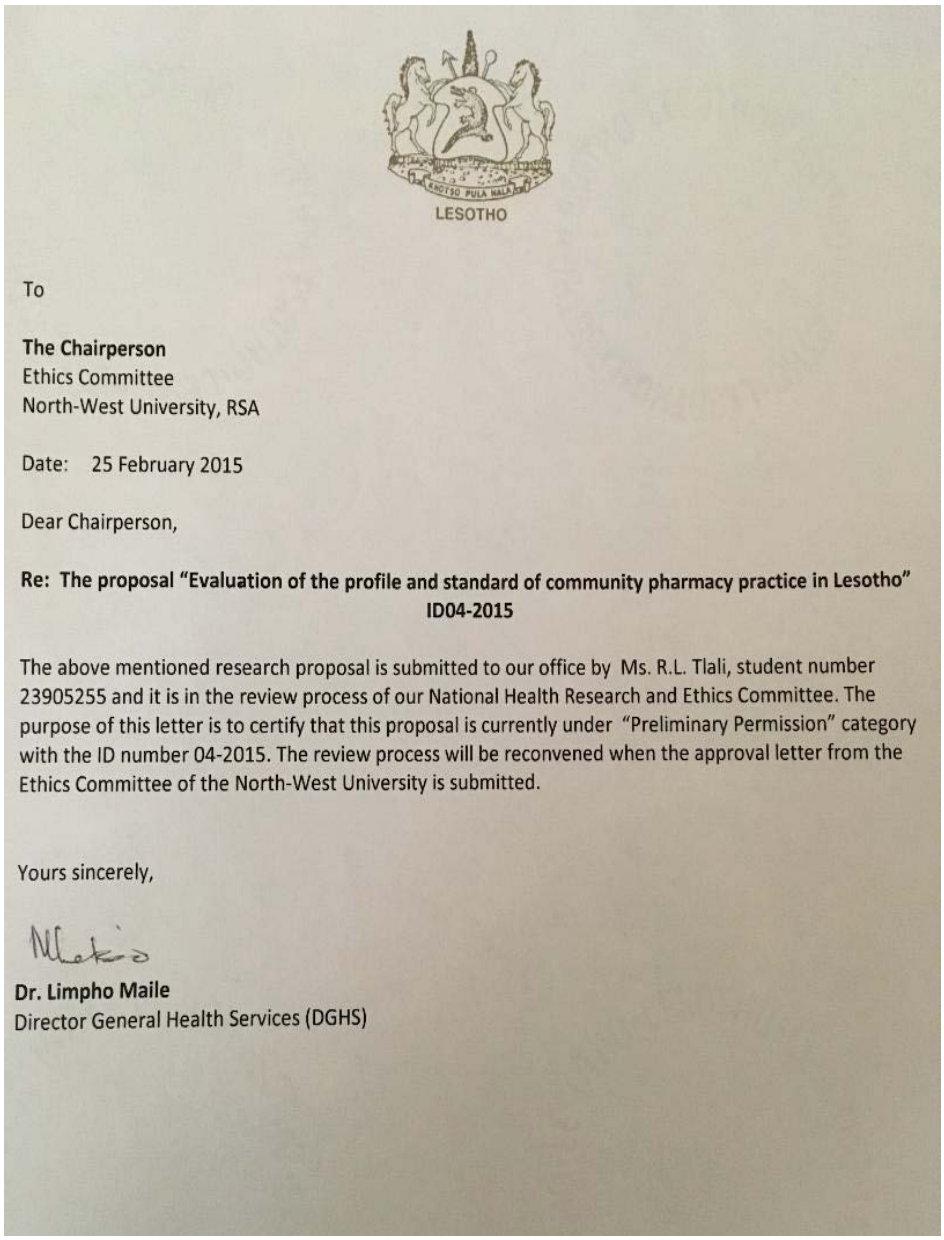
The Quality Assurance Committee members were:

Dr JR Burger
Mrs M Cockeran
Dr JM du Plessis
Mrs I Kotze

Kind regards

Prof Martie S Lubbe
Leader: Medicine Usage in South Africa

ANNEXURE B2: APPROVAL LETTER TO CONDUCT THE RESEARCH FROM MOH



LESOTHO

To

The Chairperson
Ethics Committee
North-West University, RSA

Date: 25 February 2015

Dear Chairperson,

Re: The proposal "Evaluation of the profile and standard of community pharmacy practice in Lesotho" ID04-2015

The above mentioned research proposal is submitted to our office by Ms. R.L. Tlali, student number 23905255 and it is in the review process of our National Health Research and Ethics Committee. The purpose of this letter is to certify that this proposal is currently under "Preliminary Permission" category with the ID number 04-2015. The review process will be reconvened when the approval letter from the Ethics Committee of the North-West University is submitted.

Yours sincerely,

Dr. Limpho Maile
Director General Health Services (DGHS)

ANNEXURE B3 LANGUAGE EDITING LETTER

Dynamic Language & Translation Specialists

Antoinette Bisschoff
71 Esselen Street,
Potchefstroom
Tel: 018 293 3046
Cell: 082 878 5183
Language@dlfs.co.za
CC No: 1995/017794/23

Tuesday, 15 December 2020

To whom it may concern

Re: Confirmation of language edit, typography and technical precision

The MBA dissertation by **RL Tlali**, "**Evaluation of the profile and standard of community practice in Lesotho**" was edited for language, typography and technical precision. The referencing and sources were checked and comply with the Harvard guidelines specified by the 2020 NWU Reference guide.

Final, last-minute corrections remain the responsibility of the author.



Antoinette Bisschoff

BA Languages (UPE – now NMU); MBA (PU for CHE – now NWU); Translation and Linguistic Studies (NWU)

Officially approved language editor of the NWU since 1998
Member of SA Translators Institute (no. 100181)

Precision ... to the last letter

ANNEXURE C: REQUEST FOR PERMISSION TO CONDUCT RESEARCH ON COMMUNITY PHARMACIES





Dear Colleague

COMMUNITY PHARMACY PRACTICE PROJECT

The profession of pharmacy is growing in Lesotho. This is evident by the number of graduating pharmacists and pharmacy technicians every year, as well as by the increasing number of community pharmacies in Lesotho during the past 10 years. Though growth is evident, the laws governing the profession are outdated and have not been amended to fit the practice in modern times. This raises the suspicion that the practice of pharmacy – including community pharmacy – may not be compatible with the set international and SADC standards, and therefore should be reviewed. The research findings will be useful in improving the practice or maintaining the areas where the practice is strong in Lesotho. The research topic is the investigation of the demographic profile and standard of community practice in Lesotho. It aims to profile community pharmacies in Lesotho demographically and to investigate the nature and extent of community pharmacy practice.

You have been selected to participate in this important research project, which cannot be completed without your much-needed participation and assistance. It would be highly appreciated if you could spare some time to participate in the completion of survey forms for your community pharmacy as well as a face-to-face interview with a questionnaire to be conducted by either a researcher or well-trained fieldworker. Anonymity will be ensured. The results of the research will be made available to all participants and to the Ministry of Health of Lesotho; therefore, it will allow you to contribute directly to the improvement of the pharmacy profession in Lesotho.

An appointment will be made by phone when the data collection is about to commence with all details of dates and times. Before the data collection process commencing, a consent form of agreement to participate in the research will be completed.

The research is a requirement to complete my MPharm (Pharmacy Practice) at the North-West University.

Kind regards

Retsepile Tlali

Researcher/pharmacist

ANNEXURE D1: COMMUNITY PHARMACIES' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

HREC Stamp

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR COMMUNITY PHARMACIES' PARTICIPANTS involved in the protocol evaluation

TITLE OF THE RESEARCH PROJECT: Evaluation of the profile and standard of community pharmacy practice in Lesotho

REFERENCE NUMBER: NWU-00058-15-S1

PROJECT LEADER:

Prof Martie S Lubbe

ADDRESS:

North-West University

Private Bag X6001

Potchefstroom

2522

CONTACT NUMBER:

018 299 2285

PRINCIPAL RESEARCHER:

Retsepile Tlali

ADDRESS:

Good Health Pharmacy

Box 591

Teyateyaneng 200

Lesotho

CONTACT NUMBER:

63493499

You are being invited to take part in a research project. You are specifically requested to help us to evaluate the research process and data collection tools that we are going to use in this project. None of the data documented will be used in the final research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher any questions about any part of this project, including the questionnaire that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Furthermore, your participation is **entirely voluntary,** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from this process at any point, even if you do agree to take part. The research project is a requirement for the completion of the researcher's MPharm (Pharmacy Practice) degree at the North-West University

This study has been approved by the Health Research Ethics Committees at the North-West University (NWU-00058-15-S1). It will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. It

might be necessary for the research ethics committee members to inspect the research records.

What is this research study all about?

This study is aimed at investigating the profile and standards of community pharmacy practice in Lesotho from the legislative, pharmaceutical care, and human resource perspective. The study will include an assessment of the current standard of practice of community pharmacy practice. The researcher or a well-trained fieldworker will complete a survey form and perform a face-to-face interview with you, according to a structured questionnaire.

A total of 36 community pharmacies were selected throughout Lesotho to participate in this study; therefore, 36 face-to-face interviews will be performed with the staff member in charge or the owners or managers of the community pharmacies. A further 12 interviews will be performed with different pharmacy stakeholders.

The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could perform, according to a structured questionnaire and survey form, a face-to-face interview with you in order to evaluate the content of the structured questionnaire and survey form. This is necessary to evaluate the interview schedule and the effectiveness of the survey form and a structured questionnaire. None of the data documented during this interview will be used in the final research project.

The specific research objectives of the empirical investigation include the following:

- To assess the extent to which community pharmacies in Lesotho comply with the GPP guidelines of the WHO as well as South Africa as a neighbouring country.
- To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho.
- To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

Why have you been invited to participate?

You have been invited to participate because you are the person in charge of a community pharmacy or the manager or owner of a community pharmacy in Lesotho, but your pharmacy is not included in the final study.

You have also complied with the following inclusion criteria:

- Your community pharmacy is situated in Maseru in Lesotho;

- Your community pharmacy is found on the registers of the Ministry of Trade (MOT) and/or on the registers of the Ministry of Health (MOH) Department of Pharmaceuticals. You should also sign the informed consent form.

You will be excluded if you are absent from work when we visited you, and where follow-up visits within the protocol evaluation period could not be realised

What will your responsibilities be?

You are selected to participate in this study to help us to evaluate our research process. The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could visit your pharmacy to:

- assess the current standard of practice of your community pharmacy by completing a survey form; and

- perform, according to a structured questionnaire, a face-to-face interview with you.

It is estimated that the completion of the survey will not take longer than 45 minutes, and the face-to-face interview will only take 30 minutes to complete.

Your participation is entirely voluntary, and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point.

What are the researchers' responsibilities?

After completion of the survey form and structured questionnaire, we will ask you for any recommendations regarding the processes followed as well as the questions. These recommendations will be considered by the researcher and the necessary changes will be made on the survey form and questionnaire.

The researchers are also responsible for ensuring that the research is carried out in accordance with the research protocol, that your data remains anonymous and confidential, and finally to give you feedback on the results of the study should you ask for it.

Will you benefit from taking part in this research?

The indirect benefits will be the following:

- You, as a participant, will have the opportunity to share your opinions and experiences and to help us to improve the standard of our research processes and data collection tools.

- Your involvement will also help you in assessing the extent of your community pharmacy's conformation to the good pharmacy practice standards and which areas still have room for improvement. This will enhance your understanding of the practice that you are part of and, therefore, can improve performance and staff morale.

- This study will help in providing more knowledge on the profession of pharmacy, and consequently, community pharmacy practice in Lesotho.

- It will benefit the stakeholders in knowing where community pharmacy is in terms of GPP, legislation and other aspects of the practice as discussed in the study.

- The study will also help to recognise the importance of and the role played by community pharmacists in the healthcare system, which is not well placed and documented.

- The study will also help to profile the registered community pharmacies in Lesotho in terms of numbers as an indication of the growth of the profession.

Are there risks involved in your taking part in this research?

The risk to you as a participant is minimal in this study. The answering of questions during the face-to-face interview could cause you some emotional distress; however, you may rest assured that your answers are completely confidential. None of the data documented during this visit will be used in the final research project.

- Furthermore, should you be uncomfortable with the assessment of your community pharmacy or with answering any question, you may choose to skip it. Otherwise, you may also withdraw from the survey altogether.

- The benefits outweigh the risks.

What will happen in the unlikely event of some form of discomfort occurring as a direct result of your taking part in this research study?

If a specific question makes you uncomfortable, you may skip it and proceed to the next question. Alternatively, you may also withdraw from the study without any penalties.

Participation in this research project is absolutely voluntary. You are free to decline to participate in this study or to decline at any point even after the consent is signed. Should you be willing to participate, you are requested to sign below.

Who will have access to the data?

All data will be handled with strict confidentiality. No data gathered during the visit will be electronically captured. It will only be used to evaluate and process data collection tools. The only people who will work with the data are the research team and consultants from the Statistical Consultation Services, North-West University. As a result, participation is completely anonymous and you or your pharmacy will not be identified in any publication of the results.

On request, the Ministry of Health of Lesotho, as well as the Health Research Ethics Committee (HREC) of the North-West University, may also have access to the data.

What will happen with the data?

All data will be in the form of hard copies (structured questionnaires and survey forms). During the study, the survey forms and questionnaires will be kept safe in a locked cupboard in a locked office of the researcher in Lesotho.

After completion of the study, all hard copies of the data will be kept safe and secure by locking it up in a locked cupboard in the Research Entity's (MUSA) offices. The data will be stored for seven years, after which all hardcopies of the data will be shredded under the direct supervision of the leader of MUSA, Prof MS Lubbe.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to participate in this study, and there will be no cost to you as a result of participation in this study. Findings will be made available to all participants if you are interested and will be made available to the Ministry of Health of Lesotho.

Who are the members of the research team and what are their qualifications?

- Project leader, Prof Martie S Lubbe (PhD Pharmacy practice) at martie.lubbe@nwu.ac.za or +27-18 299 22895
- Researcher/post-graduate student: Researcher, Ms Retsepile Tlali at 63493499
- Co-supervisor: Prof JJ Gerber (PhD Pharmaceutical Chemistry)

- Co-supervisor: Mrs A Naude (BPharm)

Is there anything else that you should know or do?

- If you encounter any problems or have any questions regarding your consent or the survey, you are welcome to contact the:

- Researcher: Ms Retsepile Tlali at 63493499

- Project leader: Prof Martie S Lubbe at martie.lubbe@nwu.ac.za or +27-18 299 22895.

- You can contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 2089; carolien.vanzyl@nwu.ac.za, if you have any concerns or complaints that have not been adequately addressed by the researcher.

- You will receive a copy of this information and consent form for your own records.

- The findings of the research will be shared with you if you are interested.

This research proposal has been reviewed and approved by the Ministry of Health Research and Ethics Committee Lesotho, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the institution, the following contact details can be used:

Ministry of Health

Research and Ethics Committee

PO Box 514

Maseru 100

Tel: (+266) 223 144 04

How will you know about the findings?

- This research will be concluded with a dissemination session on the national level during which time the results will be presented to the MOH and all pharmacy-related stakeholders.

- A hard copy of the research report will also be made available to the MOH.

- The findings of the research will also be shared with all community pharmacists if they are interested. You are welcome to contact Prof Martie S Lubbe regarding this matter at martie.lubbe@nwu.ac.za or +27-18 299 22895.

- The result will **also** be presented at both national (in Lesotho) and international conferences (in South Africa) and in the form of published articles.

INFORMED CONSENT FORM

Declaration by participant

By signing below, I …….. agree to take part in a research study titled: *Evaluation of the profile and standard of community pharmacy practice in Lesotho*

I declare that:

- I have read this information and consent form and they are written in a language with which I am fluent and comfortable.

- I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary,** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

- I may be asked to leave the study before it has finished if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*)..... on (*date*) …….. 20....

Signature of participant Signature of witness

Declaration by the person obtaining consent

I *(name)* …….. declare that:

- I explained the information in this document to ……..

- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*)..... on (*date*) …….. 20....

Signature of the person obtaining consent Signature of witness

Declaration by researcher

I *(name)* …….. declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*)..... on (*date*) …….. 20....

Signature of researcher Signature of witness

ANNEXURE D2: COMMUNITY PHARMACIES' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM



HREC Stamp

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM FOR COMMUNITY PHARMACIES' PARTICIPANTS

TITLE OF THE RESEARCH PROJECT: Evaluation of the profile and standard of community pharmacy practice in Lesotho

REFERENCE NUMBER: NWU-00058-15-S1

PROJECT LEADER:

Prof Martie S Lubbe

ADDRESS:

North-West University

Private Bag X6001

Potchefstroom

2522

CONTACT NUMBER:

018 299 2285

PRINCIPAL RESEARCHER:

Retsepile Tlali

ADDRESS:

Good Health Pharmacy

Box 591

Teyateyaneng 200

Lesotho

CONTACT NUMBER:

63493499

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Furthermore, your participation is **entirely voluntary,** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point before submitting the questionnaire, even if you do agree to take part. The research project is a requirement for the completion of the researcher's MPharm (Pharmacy Practice) degree at the North-West University

This study has been approved by the Health Research Ethics Committees at the North-West University (NWU-00058-15-S1). It will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. It might be necessary for the research ethics committee members to inspect the research records.

What is this research study all about?

This study is aimed at investigating the profile and standards of community pharmacy practice in Lesotho from the legislative, pharmaceutical care, and human resource perspective. The study will include an assessment of the current standard of practice of community pharmacy practice. The researcher or a well-trained fieldworker will complete a survey form and perform a face-to-face interview with you, according to a structured questionnaire.

A total of 36 community pharmacies were selected throughout Lesotho to participate in this study; therefore, 36 face-to-face interviews will be performed with the staff member in charge of the owners or managers of the community pharmacies. A further 12 interviews will be performed with different pharmacy stakeholders.

The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could perform, according to a structured questionnaire and survey form, a face-to-face interview with you.

The specific research objectives of the empirical investigation include the following:

- To assess the extent to which community pharmacies in Lesotho comply with the GPP guidelines of the WHO as well as South Africa as a neighbouring country.
- To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho.
- To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

Why have you been invited to participate?

You have been invited to participate because you are the person in charge of a community pharmacy or the manager or owner of a community pharmacy in Lesotho.

You have also complied with the following inclusion criteria:

- Your community pharmacy is in Lesotho and is found on the registers of the Ministry of Trade (MOT) and/or on the registers of the Ministry of Health (MOH) Department of Pharmaceuticals.
- You should also sign the informed consent form.

You will be excluded if you are absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised

What will your responsibilities be?

You are one of the stakeholders selected to participate in this study. The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could:

- assess the current standard of practice of your community pharmacy by completing a survey form; and
- perform, according to a structured questionnaire, a face-to-face interview with you.

It is estimated that the completion of the survey will not take longer than 45 minutes, and the face-to-face interview will only take 30 minutes to complete.

Your participation is entirely voluntary, and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point.

What are the researchers' responsibilities?

The researchers are responsible for ensuring that the research is carried out in accordance with the research protocol, that your data remains anonymous and confidential, and finally, to give you feedback on the results of the study should you ask for it.

Will you benefit from taking part in this research?

The indirect benefits will be the following:

- You as a participant, will be given the opportunity to share your opinions and experiences. Your involvement in the study will help you in assessing the extent of your community pharmacy's conformation to the good pharmacy practice standards and which areas still have room for improvement. This will enhance your understanding of the practice that you are part of and, therefore, can improve performance and staff morale.
- This study will help in providing more knowledge on the profession of pharmacy, and consequently, community pharmacy practice in Lesotho.
- It will benefit the stakeholders in knowing where community pharmacy is in terms of GPP, legislation and other aspects of the practice as discussed in the study.

- The study will also help recognise the importance of and the role played by community pharmacists in the healthcare system, which is not well placed and documented.

- The study will also help to profile the registered community pharmacies in Lesotho in terms of numbers as an indication of the growth of the profession.

Are there risks involved in your taking part in this research?

- The risk to you as a participant is minimal in this study. The answering of questions during the face-to-face interview could cause you some emotional distress; however, you may rest assured that your answers are completely confidential. By no means will answers be traced back to you. Furthermore, should you be uncomfortable with the assessment of your community pharmacy or with answering any question, you may choose to skip it. Otherwise, you may also withdraw from the survey altogether.

- The benefits outweigh the risks.

What will happen in the unlikely event of some form of discomfort occurring as a direct result of your taking part in this research study?

If a specific question makes you to uncomfortable, you may skip it and proceed to the next question. Alternatively, you may also withdraw from the study without any penalties. Participation in this research project is absolutely voluntary. You are free to decline to participate in this study or to decline at any point even after the consent is signed. Should you be willing to participate, you are requested to sign below.

Who will have access to the data?

All data will be handled with strict confidentiality and will be stored on a password-protected computer in a locked office. The only people who will work with the data are the research team and consultants from the Statistical Consultation Services, North-West University. No individual participants will be identified from the data he/she gave. As a result, participation is completely anonymous, and no participant can be identified in any publication of the results.

On request, the Ministry of Health of Lesotho, as well as the Health Research Ethics Committee of the North-West University, may also have access to the data.

What will happen with the data?

All data will be stored electronically and in the form of hard copies (structured questionnaires and survey forms). During the study, all electronic data will be protected from unauthorised

persons by means of a password-protected computer and the survey forms will be kept safe in a locked cupboard in a locked office of the researcher in Lesotho.

After completion of the study, all hard copies of the data will be kept safe and secure by locking it up in a locked cupboard in the Research Entity's (MUSAs) office, and all electronic data will be stored on an external drive, also locked in a cupboard in the Research Entity's office. The data will be stored for seven years, after which it will be permanently removed from the external drive under the direct supervision of Mrs A Bekker, the research assistant of MUSA. Furthermore, all hardcopies of the data will be shredded under the direct supervision of the leader of MUSA, Prof MS Lubbe.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to participate in this study, and there will be no cost to you as a result of participation in this study. Findings will be made available to all participants if you are interested and will be made available to the Ministry of Health of Lesotho.

Who are the members of the research team and what are their qualifications?

- Project leader, Prof Martie S Lubbe (PhD Pharmacy practice) at martie.lubbe@nwu.ac.za or +27-18 299 22895
- Researcher/post-graduate student: Researcher, Ms Retsepile Tlali at 63493499
- Co-supervisor: Prof JJ Gerber (PhD Pharmaceutical Chemistry)
- Co-supervisor: Mrs A Naude (BPharm)

Is there anything else that you should know or do?

If you encounter any problems or have any questions regarding your consent or the survey, you are welcome to contact the:

- Researcher: Ms Retsepile Tlali at 63493499
- Project leader: Prof Martie S Lubbe at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- You can contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 2089; carolien.vanzyl@nwu.ac.za, if you have any concerns or complaints that have not been adequately addressed by the researcher.
- You will receive a copy of this information and consent form for your own records.

The findings of the research will be shared with you if you are interested.

This research proposal has been reviewed and approved by the Ministry of Health Research and Ethics Committee Lesotho, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the institution, the following contact details can be used:

Ministry of Health

Research and Ethics Committee

PO Box 514

Maseru 100

Tel: (+266) 223 144 04

How will you know about the findings?

- This research will be concluded with a dissemination session on a national level during which time the results will be presented to the MOH and all pharmacy-related stakeholders.
- A hard copy of the research report will also be made available to the MOH.
- The findings of the research will also be shared with all community pharmacists if they are interested. You are welcome to contact Prof Martie S Lubbe regarding this matter at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- The result will **also** be presented at both national (in Lesotho) and international conferences (in South Africa) and in the form of published articles.

INFORMED CONSENT FORM

Declaration by participant

By signing below, I …….. agree to take part in a research study titled: *Evaluation of the profile and standard of community pharmacy practice in Lesotho*

I declare that:

- I have read this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary,** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*).....…….. on (*date*) ……...…….. 20....

Signature of participant Signature of witness

Declaration by person obtaining consent

I *(name)* ……..……. declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*).....…….. on (*date*) ……...…….. 20....

Signature of person obtaining consent Signature of witness

Declaration by researcher

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*).....…..…….. on (*date*) ……...…….. 20....

Signature of researcher Signature of witness

ANNEXURE E1: STAKEHOLDERS' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM – FOR PROROCOL EVALUATION

HREC STAMP

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

STAKEHOLDERS' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: Evaluation of the profile and standard of community pharmacy practice in Lesotho

REFERENCE NUMBER: NWU-00058-15-S1

PROJECT LEADER:
Prof Martie S Lubbe
ADDRESS:
North-West University
Private Bag X6001
Potchefstroom
2522
CONTACT NUMBER:
018 299 2285

PRINCIPAL RESEARCHER:
Retsepile Tlali
ADDRESS:
Good Health Pharmacy
Box 591
Teyateyaneng 200
Lesotho
CONTACT NUMBER:
63493499

You are being invited to take part in a research project. You are specifically requested to help us to evaluate the research process and data collection tools that we are going to use in this project. None of the data documented will be used in the final research project. Please take some time to read the information presented here, which will explain the details of this project.

Please ask the researcher any questions about any part of this project, including the questionnaire that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Furthermore, your participation is **entirely voluntary,** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from this process at any point, even if you do agree to take part. The research project is a requirement for the completion of the researcher's MPharm (Pharmacy Practice) degree at the North-West University

This study has been approved by the Health Research Ethics Committees at the North-West University (NWU-00058-15-S1). It will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. It might be necessary for the research ethics committee members to inspect the research records.

What is this research study all about?

This study is aimed at investigating the profile and standards of community pharmacy practice in Lesotho from the legislative, pharmaceutical care, and human resource perspective. The study will include an assessment of the current standard of practice of community pharmacy practice.

A total of 36 community pharmacies were selected throughout Lesotho to participate in this study; therefore, 36 face-to-face interviews will be performed with the staff member in charge or the owners or managers of the community pharmacies. A further 12 interviews will be performed with different pharmacy stakeholders.

The specific research objectives of the empirical investigation include the following:

- To assess the extent to which community pharmacies in Lesotho comply with the GPP guidelines of the WHO as well as South Africa as a neighbouring country.
- To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho.
- To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could perform, according to a structured questionnaire, a face-to-face interview with you to evaluate the content of the structured questionnaire. This is necessary to evaluate the interview schedule and the effectiveness of the structured questionnaire. None of the data documented during this interview will be used in the final research project.

Why have you been invited to participate?

You have been invited to participate because you are an official from the MOH pharmaceutical department who has not selected for the final study. You will be excluded if you are absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised

What will your responsibilities be?

You are selected to participate in this study by helping us to evaluate our research process. On agreement to participate in the study, you will be expected to do the following:

- Share your opinions and insight on community pharmacy practice in Lesotho during a face-to-face interview.

- It is estimated that the face-to-face interview will only take 30 minutes to complete.

Your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point.

What are the researchers' responsibilities?

The researchers are responsible for ensuring that the research is carried out in accordance with the research protocol, that your data remains anonymous and confidential, and finally to give you feedback on the results of the study should you ask for it.

Will you benefit from taking part in this research?

The indirect benefits will be the following:

- You, as a participant, will have the opportunity to share your opinions and experiences.
- This study will help in providing more knowledge on the profession of pharmacy, and consequently, community pharmacy practice in Lesotho.
- It will benefit you as a stakeholder in knowing where community pharmacy is in terms of GPP, legislation and other aspects of the practice as discussed in the study.
- The study will also help you as a stakeholder to recognise the importance of and the role played by community pharmacists in the healthcare system, which is not well placed and documented.
- The study will also help to profile the registered community pharmacies in Lesotho in terms of numbers as an indication of the growth of the profession.

Are there risks involved in your taking part in this research?

- The risk to you as a participant is minimal in this study. The answering of questions during the face-to-face interview could cause you some emotional distress; however, you may rest assured that your answers are completely confidential. By no means will answers be traced back to you. Furthermore, should you be uncomfortable with the assessment of your community pharmacy or with answering any question, you may choose to skip it. Otherwise, you may also withdraw from the survey altogether.
- The benefits outweigh the risks.

What will happen in the unlikely event of some form of discomfort occurring as a direct result of your taking part in this research study?

If a specific question makes you uncomfortable, you may skip it and proceed to the next question. Alternatively, you may also withdraw from the study without any penalties. Participation in this research project is absolutely voluntary. You are free to decline to participate in this study or to decline at any point even after the consent is signed. Should you be willing to participate, you are requested to sign below:

Who will have access to the data?

All data will be handled with strict confidentiality and will be stored on a password-protected computer in a locked office. The only people who will work with the data are the research team and consultants from the Statistical Consultation Services, North-West University. No individual participants will be identified from the data he/she gave. As a result, participation is completely anonymous and no participant can be identified in any publication of the results.

On request, the Ministry of Health of Lesotho, as well as the Health Research Ethics Committee of the North-West University, may also have access to the data.

What will happen with the data?

All data will be in the form of hard copies (structured questionnaires and survey forms). During the study, the survey forms and questionnaires will be kept safe in a locked cupboard in a locked office of the researcher in Lesotho.

After completion of the study, all hard copies of the data will be kept safe and secure by locking it up in a locked cupboard in the Research Entity's (MUSAs) offices. The data will be stored for seven years, after which all hardcopies of the data will be shredded under the direct supervision of the leader of MUSA, Prof MS Lubbe.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to participate in this study, and there will be no cost to you as a result of participation in this study. Findings will be made available to all participants if you are interested and will be made available to the Ministry of Health of Lesotho.

Who are the members of the research team and what are their qualifications?

- Project leader, Prof Martie S Lubbe (PhD Pharmacy practice) at martie.lubbe@nwu.ac.za or +27-18 299 22895
- Researcher/post-graduate student: Researcher, Ms Retsepile Tlali at 63493499
- Co-supervisor: Prof JJ Gerber (PhD Pharmaceutical Chemistry)
- Co-supervisor: Mrs A Naude (BPharm)

Is there anything else that you should know or do?

If you encounter any problems or have any questions regarding your consent or the survey, you are welcome to contact the:

- Researcher: Ms Retsepile Tlali at 63493499
- Project leader: Prof Martie S Lubbe at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- You can contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 2089; carolien.vanzyl@nwu.ac.za, if you have any concerns or complaints that have not been adequately addressed by the researcher.
- You will receive a copy of this information and consent form for your own records.

The findings of the research will be shared with you if you are interested.

This research proposal has been reviewed and approved by the Ministry of Health Research and Ethics Committee Lesotho, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the institution, the following contact details can be used:

Ministry of Health

Research and Ethics Committee

PO Box 514

Maseru 100

Tel: (+266) 223 144 04

How will you know about the findings?

- This research will be concluded with a dissemination session on the national level during which time the results will be presented to the MOH and all pharmacy-related stakeholders.
- A hard copy of the research report will also be made available to the MOH.

- The findings of the research will also be shared with all community pharmacists if they are interested. You are welcome to contact Prof Martie S Lubbe regarding this matter at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- The result will **also** be presented at both national (in Lesotho) and international conferences (in South Africa) and in the form of published articles.

INFORMED CONSENT FORM

Declaration by participant

By signing below, I …….. agree to take part in a research study titled: *Evaluation of the profile and standard of community pharmacy practice in Lesotho*

I declare that:

- I have read this information and consent form, and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*)..... on (*date*) …….. 20....

..... **.....**

Signature of participant Signature of witness

Declaration by the person obtaining consent

I *(name)* …….. declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understand all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*)..... on (*date*) …….. 20....

..... **.....**

Signature of the person obtaining consent Signature of witness

Declaration by researcher

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*).....…..…….. on (*date*) ……...…….. 20....

..... **.....**

Signature of researcher Signature of witness

ANNEXURE E2: STAKEHOLDERS' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

HREC STAMP

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

STAKEHOLDERS' PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: Evaluation of the profile and standard of community pharmacy practice in Lesotho

REFERENCE NUMBER: NWU-00058-15-S1

PROJECT LEADER:
Prof Martie S Lubbe
ADDRESS:
North-West University
Private Bag X6001
Potchefstroom
2522
CONTACT NUMBER:
018 299 2285

PRINCIPAL RESEARCHER:
Retsepile Tlali

ADDRESS:
Good Health Pharmacy
Box 591
Teyateyaneng 200
Lesotho

CONTACT NUMBER:
63493499

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the

researcher any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Furthermore, your participation is **entirely voluntary,** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point before submitting the questionnaire, even if you do agree to take part. The research project is a requirement for the completion of the researcher's MPharm (Pharmacy Practice) degree at the North-West University

This study has been approved by the Health Research Ethics Committees at the North-West University (NWU-00058-15-S1) and will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. It might be necessary for the research ethics committee members to inspect the research records.

What is this research study all about?

This study is aimed at investigating the profile and standards of community pharmacy practice in Lesotho from the legislative, pharmaceutical care, and human resource perspective. The study will include an assessment of the current standard of practice of community pharmacy practice.

A total of 36 community pharmacies were selected throughout Lesotho to participate in this study; therefore, 36 face-to-face interviews will be performed with the staff member in charge or the owners or managers of the community pharmacies. A further 12 interviews will be performed with different pharmacy stakeholders.

The researcher would therefore appreciate it if you can give consent that either the researcher or a well-trained fieldworker could perform, according to a structured questionnaire, a face-to-face interview with you.

The specific research objectives of the empirical investigation include the following:

- To assess the extent to which community pharmacies in Lesotho comply with the GPP guidelines of the WHO as well as South Africa as a neighbouring country.
- To evaluate the standard of premises, facilities and equipment of community pharmacies in Lesotho.
- To investigate the profile, nature and extent of pharmaceutical services provided by community pharmacies in Lesotho.

Why have you been invited to participate?

You have been invited to participate because you are one of the following stakeholders of the community pharmacy sector in Lesotho:

- All members of staff of the following institutions, associations and organisations:
    - Ministry of Health (MOH):
        - Director of Pharmaceutical in Lesotho
        - Drug Regulatory Authority (DRA)
        - Minister of Health
    - Pharmaceutical suppliers, for example directors of NDSO, Tripharm and Medicare
    - Registrar of the Lesotho Medical, Dental and Pharmacy Council (LMDPC)

- Ministry of Trade (MOT): One-stop Business Facilitation Centre (OBFC)
- President of the Pharmaceutical Society of Lesotho (PSL)
- Non-government associations: Directors of Management Science for Health (MSH) and Systems for Improved Access to Pharmaceuticals and Services (SIAPS).

You will be excluded if you are absent from work during the data-gathering period, and where follow-up visits within the data collection period could not be realised.

What will your responsibilities be?

You are one of the stakeholders selected to participate in this study. On agreement to participate in the study, you will be expected to do the following:

- Share your opinions and insight on community pharmacy practice in Lesotho during a face-to-face interview.
- It is estimated that the face-to-face interview will only take 30 minutes to complete.

Your participation is entirely voluntary, and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point.

What are the researchers' responsibilities?

The researchers are responsible for ensuring that the research is carried out in accordance with the research protocol, that your data remains anonymous and confidential, and finally, to give you feedback on the results of the study should you ask for it.

Will you benefit from taking part in this research?

The indirect benefits will be the following:

- You, as a participant, will have the opportunity to share your opinions and experiences.
- This study will help in providing more knowledge on the profession of pharmacy, and consequently community pharmacy practice in Lesotho.
- It will benefit you as a stakeholder in knowing where community pharmacy is in terms of GPP, legislation and other aspects of the practice as discussed in the study.
- The study will also help you as a stakeholder to recognise the importance of and the role played by community pharmacists in the healthcare system, which is not well placed and documented.
- The study will also help to profile the registered community pharmacies in Lesotho in terms of numbers as an indication of the growth of the profession.

Are there risks involved in your taking part in this research?

- The risk to you as a participant is minimal in this study. The answering of questions during the face-to-face interview could cause you some emotional distress; however, you may rest assured that your answers are completely confidential. By no means will answers be traced back to you. Furthermore, should you be uncomfortable with the assessment of your community pharmacy or with answering any question, you may choose to skip it. Otherwise, you may also withdraw from the survey altogether.
- The benefits outweigh the risks.

What will happen in the unlikely event of some form of discomfort occurring as a direct result of your taking part in this research study?

If a specific question makes you to uncomfortable, you may skip it and proceed to the next question. Alternatively, you may also withdraw from the study without any penalties. Participation in this research project is absolutely voluntary. You are free to decline to

participate in this study or to decline at any point even after the consent is signed. Should you be willing to participate, you are requested to sign below:

Who will have access to the data?

All data will be handled with strict confidentiality and will be stored on a password-protected computer in a locked office. The only people who will work with the data are the research team and consultants from the Statistical Consultation Services, North-West University. No individual participants will be identified from the data he/she gave. As a result, participation is completely anonymous and no participant can be identified in any publication of the results.

On request, the Ministry of Health of Lesotho, as well as the Health Research Ethics Committee of the North-West University, may also have access to the data.

What will happen with the data?

All data will be stored electronically and in the form of hard copies (structured questionnaires and survey forms). During the study, all electronic data will be protected from unauthorised persons by means of a password-protected computer and the survey forms will be kept safe in a locked cupboard in a locked office of the researcher in Lesotho.

After completion of the study, all hard copies of the data will be kept safe and secure by locking it up in a locked cupboard in the Research Entity's (MUSA) office and all electronic data will be stored on an external drive, also locked in a cupboard in the Research Entity's office. The data will be stored for seven years, after which it will be permanently removed from the external drive under the direct supervision of Mrs A Bekker, the research assistant of MUSA. Furthermore, all hardcopies of the data will be shredded under the direct supervision of the leader of MUSA, Prof MS Lubbe.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to participate in this study, and there will be no cost to you as a result of participation in this study. Findings will be made available to all participants if you are interested and will be made available to the Ministry of Health of Lesotho.

Who are the members of the research team, and what are their qualifications?

- Project leader, Prof Martie S Lubbe (PhD Pharmacy practice) at martie.lubbe@nwu.ac.za or +27-18 299 22895
- Researcher/post-graduate student: Researcher, Ms Retsepile Tlali at 63493499
- Co-supervisor: Prof JJ Gerber (PhD Pharmaceutical Chemistry)
- Co-supervisor: Mrs A Naude (BPharm)

Is there anything else that you should know or do?

If you encounter any problems or have any questions regarding your consent or the survey, you are welcome to contact the:

- Researcher: Ms Retsepile Tlali at 63493499
- Project leader: Prof Martie S Lubbe at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- You can contact the Health Research Ethics Committee via Mrs Carolien van Zyl at 018 299 2089; carolien.vanzyl@nwu.ac.za if you have any concerns or complaints that have not been adequately addressed by the researcher.
- You will receive a copy of this information and consent form for your own records.

The findings of the research will be shared with you if you are interested.

This research proposal has been reviewed and approved by the Ministry of Health Research and Ethics Committee Lesotho, which is a committee whose task it is to make sure that

research participants are protected from harm. If you wish to find out more about the institution, the following contact details can be used:

Ministry of Health

Research and Ethics Committee

PO Box 514

Maseru 100

Tel: (+266) 223 144 04

How will you know about the findings?

- This research will be concluded with a dissemination session on the national level during which time the results will be presented to the MOH and all pharmacy-related stakeholders.
- A hard copy of the research report will also be made available to the MOH.
- The findings of the research will also be shared with all community pharmacists if they are interested. You are welcome to contact Prof Martie S Lubbe regarding this matter at martie.lubbe@nwu.ac.za or +27-18 299 22895.
- The result will **also** be presented at both national (in Lesotho) and international conferences (in South Africa) and in the form of published articles.

INFORMED CONSENT FORM

Declaration by participant

By signing below, I …….…… agree to take part in a research study titled: *Evaluation of the profile and standard of community pharmacy practice in Lesotho*

I declare that:

- I have read this information and consent form, and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions to both the person obtaining consent, as well as the researcher and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary,** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*).....…..…….. on (*date*) ……..…….. 20....

..... **.....**

Signature of participant Signature of witness

Declaration by person obtaining consent

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understand all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*).....…….....…….. on (*date*) ……...…….. 20....

..... **.....**

Signature of person obtaining consent Signature of witness

Declaration by researcher

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*).....…….....…….. on (*date*) ……...…….. 20....

..... **.....**

Signature of researcher Signature of witness

ANNEXURE F: SURVEY FORM FOR COMMUNITY PHARMACIES

In the spaces provided, mark an X or fill out in writing, where applicable. The choices *complies*, *partially complies* and *do not comply* provided in the tables, and an X should be made where applicable. The scoring of 1, 2, 3 will be used where 3 implies comply, 2, partially complies, and 1 is does not comply. Where partially complies is marked with asterisks, the criterion will be shown below each table and if the criterion is not indicated, only *complies* and *does not comply* are applicable, partially complies should not be marked.

(a) COMMUNITY PHARMACY DETAILS

Community pharmacy number (name given for researcher's benefit and a number given for analysis and publication)			_____ _____ _____ _____		
1. Area where the pharmacy is situated		**Lowlands** _____	**Foothills** _____	**Mountains** _____	**City (capital town)** _____
2.District where the pharmacy is situated	**Maseru** _____	**Berea** _____	**Leribe** _____	**Butha-Buthe** _____	**Mokhotlong** _____
	Thaba-Tseka _____	**Qacha's Nek** _____	**Quthing** _____	**Mohale's Hoek** _____	**Mafeteng** _____
3. What is the nature of the pharmacy?				**The only one**	**Chain (more than one)**

	_____		_____	
4. What type of ownership is the pharmacy?	**Sole proprietary** _____		**Partnership** _____	**Other** _____
5. Is the pharmacy registered according to the law of Lesotho?	**(Y)** _____		**(N)** _____	
6. If (Y), is there any proof of registration?	**MOH** **(Ministry of Health)**	**MOT** **(Ministry of Trade)**	**Both** **(MOH & MOT)**	

(b) PHARMACY STAFFING AND STAFF REGISTRATION

	Yes	**No**
7. Is the owner of the community pharmacy a pharmacist?	1	2
8. Is there a full-time pharmacist in charge of this community pharmacy?	1	2
9. Is there any pharmacy technician working in the community pharmacy?	1	2
10. If (Yes) to either question 7 or 8, are they registered with the council (LMDPC)?	1	2
11. If (Yes) to question 9, is the pharmacy technician registered with the council?	1	2
12. Are there any other personnel working in the pharmacy?	1	2
13. If (Yes) to the above, what are their qualifications?		

LMDPC: Lesotho Medical, Dental and Pharmacy Council

CRITERIA FOR A and B

For questions 1-12, a (Yes) and a (No) are the options of choice to mark with an X. Unlike in the questions to follow, where options (comply), (partially comply) and (does not comply) are options of choice, in the above form scores to allow for uniformity of answers as with the questions to follow which will bear the 3 options as shown below.

Scores:

3- If (Yes) meaning the community pharmacy fully complies.

2- If (Yes) but partially complies as described in the criteria below.

If (No) meaning the community pharmacy does not comply at all.

***partially complies 1-9 & 12; if such personnel are contracted to work with the community pharmacy but come in arranged times only.**

10 & 11; refers to the availability of registrations by personnel with the LMDPC that are not up-to-date (available but not renewed annually as per LMDPC regulations).

(c) PREMISES AND LAYOUT

	Complies	Partially	Does not comply
14. The premises are clean.	1	2	3
15. The premises are orderly and tidy.	1	2	3
16. The lighting is suitable and effective to allow for enough visibility in the pharmacy.	1	2	3
17. There is air conditioning in the pharmacy.	1	2	3
18. The room temperature is maintained below 25˚C and fridge temperature below 8˚C (thermometer available).	1	2	3
19. There is at least one fire extinguisher that is well serviced.	1	2	3
20. The floor is well maintained.	1	2	3
21. The walls are well finished with a washable material.	1	2	3
22. There is a separate place to wash hands.	1	2	3
23. There is a separate place for extemporaneous compounding.	1	2	3
24. Windows are high enough not to allow direct sunlight onto medication.	1	2	3
25.There is a suitable private consultation area for screening, for example blood pressure (BP) and blood sugar level (BSL) checks.	1	2	3

CRITERIA FOR C

For questions 14-25, the choices, *complies*, *partially complies* and *does not comply* are provided in the tables and an X should be made where applicable.

***Partially complies: 14. If the premises are well mopped but dusty.**

15. If the premises is either tidy or orderly (arranged according to some order) without the other.

16. If light is available but not enough hence the place looks dark.

17 & 18. If air conditioner/thermometer is available but not working or if either room or fridge temperature (not both) is maintained.

19. If a fire extinguisher is available but not serviced

20 & 21. If floor/ wall is tiled or painted but has cracks and areas where tiles are, are broken or unavailable.

23. If there is a place, but not equipped or conducive for extemporaneous compounding.

24. Windows available, but still allow sunlight in.

25. Area available, but not conducive to function, for example no table or chair.

(d) EQUIPMENT

In the table below, mark X where applicable.

	Complies	Partially complies	Does not comply
26. The pharmacy is equipped with the following:			
26.1. At least one mortar and pestle available;	1	2	3

	Complies	Partially complies	Does not comply
26.2 A suitable calibrated mass meter for dispensing, for example weighing balance;	1	2	3
26.3 A suitable calibrated volume measures, for example measuring cylinders;	1	2	3
26.4 Enough counting apparatus, for example counting trays;	1	2	3
27. All equipment is clean to avoid contamination;	1	2	3
28. A computer is used for dispensing.	1	2	3

CRITERIA FOR D

For questions 26-28, the choices *comply*, *partially complies* and *do not comply* are provided in the tables, and an X should be made where applicable.

***Partially complies:**

26.1 If either a mortar or a pestle is missing or broken.

26.2 If weighing balance is available but broken.

26.3 If the volume measures are available but broken or calibration not visible enough.

26.4 If counting apparatus is broken.

27. Not all equipment is clean

28. A computer is not used for dispensing at all times

(e) DISPENSING OF PRESCRIPTIONS AND GOOD PHARMACEUTICAL CARE

	Complies	Partially	Does not comply
29. Prescriptions are well scrutinised before dispensing by the pharmacist.	1	2	3
30. The dispensed medication is labelled properly according to good dispensing practices (GDP).	1	2	3
31. Generic substitutions are done.	1	2	3
32. Pharmacist gives advice to patients receiving pharmacist-initiated therapy.	1	2	3
33. There is a suitable place to give advice from the pharmacist or technician.	1	2	3
34. Patient information leaflets or pamphlets are available at the dispensary.	1	2	3
35. Procedure to monitor patient progress is in place.	1	2	3
36. Controlled medicines are dispensed in the pharmacy.	1	2	3
37. Controlled medicines are handled by a pharmacist only.	1	2	3

38. The pharmacy is operational (specific time)	**From**	**To**	**Total hrs/day**	**N/A**	**Scores**
Monday to Friday					
Saturdays					
Sundays					

Public holidays					

CRITERIA FOR E

For questions 26-27, the choices *comply*, *partially complies* and *do not comply* are provided in the tables, and an X mark should be made where applicable. For question 28, like in Criteria B, to allow for uniformity, scores are allocated. This is done because the question requires times and not the usual compliance or not. The scoring for question 38 is shown below

***partially complies**

29-30: If the mentioned activities are not done all the time.

33: If room for counselling is available but not conducive; no chair or table.

34: If pamphlets are not always available

35: If progress is kept for few patients, not all.

36: If controlled medicines are dispensed but not recoded according to the law; in the schedules register book.

37: If controlled medicines are handled by a pharmacist and other pharmacy personnel.

Scores for 38

3: If a community pharmacy opens from Mondays through Sundays and on most public holidays or on all of them.

2: If it opens from Mondays to Sundays only

1: If it opens Mondays to Saturdays

STORAGE AND RECORD-KEEPING

	Comply	Partially comply	Does not comply
39. Medicines are stored according to the system (such as an alphabetically or pharmacologically).	1	2	3
40. Storage is large and with shelves or pellets to allow for orderly arrangement of stock and movement.	1	2	3
41. There are no cracks, holes or signs of water damage or pests.	1	2	3
42. There is light in the storage (electrical light).	1	2	3
43. Good hygiene is ensured; floors and walls are clean and window(s) are available for ventilation.	1	2	3
44. All stock is stored off the floor, for example on pallets or shelves.	1	2	3
45. There are no expired medicines on the shelves.	1	2	3
46. Damaged and contaminated stock is kept away from normal trading stock.	1	2	3
47. Prepacking of medicines is done where necessary.	1	2	3
48. Medicines that require refrigeration are kept in the fridge.	1	2	3
49. Controlled medicines are kept locked in a cupboard as required by the law.	1	2	3
50. Record or register of all schedule medicines is kept.	1	2	3
51. Medicines are purchased only through legally authorised suppliers	1	2	3

CRITERIA FOR F

For questions 39-51, the choices *comply*, *partially complies* and *do not comply* are provided in the tables, and an X should be made where applicable.

***partially complies 39 If medicines are not stored in a particular order.**

41 If either cracks, holes, pests exist.

42 The light in the store is not adequate, hence darker.

43 If floors or walls are dusty and windows are too small or cannot be opened.

44 If some items are on the floor and shelves or pallets are broken but available

45 If expired items are on the shelves not kept away or disposed of as required.

48 If the fridge is available but not used or is broken.

49 If some controlled medicines are kept accordingly but some are still accessible (on the shelf).

50 & 51 If records are available but incomplete.

51 If not all medicines are purchased from legal suppliers.

(f) AVAILABILITY OF REFERENCES

	Yes	No
52. The community pharmacy has copies of the following (all copies should not be older than 10 years except for the laws):		
52.1 Lesotho medical formulary (LMF)	1	2
52.2 Lesotho standard treatment guideline (LSTG)	1	2
52.3 Lesotho essential medicines list (LEML)	1	2
52.4 South African medical formulary (SAMF)	1	2
52.5 MIMS	1	2
52.6 Good pharmaceutical practice book, including GDP (good dispensing procedures)	1	2
52.7 Symptoms in the pharmacy book	1	2
52.8 Pharmacy laws: Dangerous Medicine Act 21 of 1973 & Lesotho Medical, Dental and Pharmacy Order 13 of 1970	1	2
52.9 Pharmacology textbook	1	2
53. List any other available references in the spaces provided below		

CRITERIA FOR G

For question 52, a (Yes) and a (No) are the options of choice to mark with an X. For sub-question 53, a listing of the books available is needed, and on the basis of how many they are, scoring is done. Unlike in some of the questions above where options (comply), (partially comply) and (does not comply) are options of choice, the above form scores to allow for uniformity of answers as with the questions to follow which will bear the three options as shown below.

Scores: 3- If the community pharmacy gets a clear (Yes).

2- If a community pharmacy gets a Yes, but partially complies as shown below.

Partially complies if the reference is missing some pages, torn or year of edition older than 10 years.

1- If the community pharmacy gets No.

For question 53:

Scores:

3- If the community pharmacy lists two or more reference books

2- If it lists only one reference book.

1- If there are no extra references.

ANNEXURE G: COMMUNITY PHARMACIES QUESTIONNARE



Questionnaire will be given to the responsible member of staff in charge of the different community pharmacies in which the face-to-face interview will be conducted.

COMMUNITY PHARMACY

Respondent number: _____

Qualification: _____

Position: _____

If a pharmacist, registration with the Council **(Y) (N)**

Please tick (X) the correct answer where options are provided;

1.1 Who owns this community pharmacy?

A **Pharmacist**

B **Pharmacist in partnership with someone**

C **Pharmacy technician**

D **A none pharmacy personnel**

1.2 **If the person interviewed is not a pharmacist,**

Is there any schedule for the pharmacist to visit? **(Y) (N)**

If (Y)

How often does the pharmacist come for routine visits?

A Weekly

B Monthly

C Quarterly

D Other _____

_____

_____

1.3 How many members of staff work in this community pharmacy?

A Registered pharmacist _____

B Unregistered pharmacist _____

C Pharmacy technician _____

D Others, specify _____

_____

1.4 Fill in Table 2 below with the details required about the staff working in the community pharmacy.

Table 2

TYPE OF PERSONNEL, for example pharmacist, pharmacy tech, nurse, doctor or non-health personnel	**QUALIFICATION**	**JOB DESCRIPTION**

1.5 How long has this community pharmacy been operational?

_____
__

(i) If more than a year, do you do annual re-registration or licence renewal? (Y) (N)

(ii) If Yes (Y), what documents or information do you submit for license renewal?

_____
_____
_____
_____
_____

Where is the re-registration or renewal done?

_____
_____
_____
_____
_____

1.6 Are routine inspections by the Ministry of Health performed? (Y) (N)

(i) If (Y), How often are the inspections performed?

A Monthly

B Quarterly

C Annually

D Other
_____

_____
___

(ii) What are the inspections on?

INSPECTION AREAS	TICK (x)
Community pharmacy legal status (registration profile of the pharmacy and pharmacy personnel & tax certificates)	
Good Pharmacy Practice	
Premises and layout maintenance monitoring	
Others specify _____ _____ _____ _____ _____	

1.7 Where does the pharmacy purchase the medicines and medical supplies (stock)?

i) Local suppliers:

A NDSO

B Tripharm

C Medicare

D Dodapharm

ii) Outside Lesotho suppliers:

A Alpha Pharm

B Adcock Ingram

C Others:

_____

_____

_____

1.8 What are the requirements for purchasing supplies from the different suppliers; prerequisites before buying medicines and medical supplies?

(i) Local suppliers:

_____

_____

_____

(ii) Outside Lesotho supplies:

_____

_____

1.9 Do you dispense schedule I, II and III drugs according to the law (Dangerous Medicines Act of 1973)? (Y) (N)

(i) If yes, how are they handled in your pharmacy?

_____

_____

_____

_____

_____

1.10 Do you think community pharmacies as health service providers and business are growing in Lesotho? (Y) (N)

(i) If yes, motivate your answer.

_____

_____

_____

_____

ANNEXURE H: STAKEHOLDERS' QUESTIONNAIRE





NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
POTCHEFSTROOM CAMPUS

Different stakeholders will be given a questionnaire during face-to-face interviews to be filled after signing a consent form (Annexure 1A).

A DIRECTOR OF PHARMACEUTICALS LESOTHO

Face-to-face interview and respondent information will be completed as follows:

Date of interview:

_____

Respondent number (not a name for confidentiality purposes):

_____

Respondent's work position:

_____

(g) 1. What role does the Director of Pharmaceuticals Lesotho play in the regulation of community pharmacy practice?

Tick (Y) or (N) for the roles listed below

(i) Issuing of licences to open and run community pharmacies (Y) (N)

(ii) Inspections of community pharmacies (Y) (N)

(iii) Registering of community pharmacies around Lesotho (Y) (N)

(iv) Monitoring of ownership of community pharmacies (Y) (N)

(v) Standards of community pharmacy practice (SOPs) (Y) (N)

(vi) Others

_____

_____
_____
_____
_____

(h) 2. How many community pharmacies have to date registered with the pharmaceutical department or the directorate office in Lesotho?

_____

(i) 3. Are there any laws pertaining to community pharmacy practice in Lesotho? (Y) (N)

(i) If (Y), Provide examples of such laws

_____
_____
_____
_____

(ii) If (N), what measures are put in place to control community pharmacy practice in Lesotho?

Ownership:

_____
_____
_____

Licensing:

_____
_____
_____

Pharmacist registration:

_____
_____
_____

Community pharmacy registration:

_____

_____

_____

(iii) How are those measures implemented?

_____

_____

_____

_____

(j) (4) By law, do community pharmacies have to register with the pharmaceutical department of the Ministry of Health?

(k) _____

_____

(l) (5) When last were the laws governing the pharmaceutical sector reviewed?

_____

(m) (6) What is the current status of the following pharmacy legislature in Lesotho?

Medicines Bill:

_____

_____

_____

Medicines Control Act:

_____

_____

_____

Health Professional Bill:

_____

_____

_____

_____

B MINISTRY OF TRADE

Face-to-face interview and respondent information will be completed as follows after consent is obtained:

Date of interview:

_____

Respondent number (not a name for confidentiality purposes):

_____

Respondent's work position:

_____

_____

1. Which of the following documents are required for the application of a license to open a community pharmacy;

(i) Qualification certificate of a pharmacist (Y) (N)

(ii) Credentials of other partners if a community pharmacy is owned in partnership (Y) (N)

(iii) Lease of the community pharmacy; lease of where it is found (Y) (N)

(iv) Certificate from MOH for inspection of the building and requirement for infrastructure. This gives the Ministry of Trade permission to proceed with the issuing of the trader's license (Y) (N)

(v) Other documents needed for registration:

_____

_____

C LESOTHO MEDICAL, DENTAL AND PHARMACY COUNCIL





Face-to-face interview and respondent information will be completed as follows:

Date of interview:

_____

Respondent number (not a name for confidentiality purposes):-

_____

Respondent's work position:

_____

_____

1. What are the requirements for pharmacists and pharmacy technicians to register with the Council?

_____

_____

_____

_____

2. Are there any measures put in place to ensure that all pharmacists and pharmacy technicians register with the council?

(i) If (Y) what those measures are?

_____

_____

_____

_____

(ii) If those measures are not adhered to, what steps does the Council take to ensure that all pharmacy professionals are registered?

_____

_____

(iii) Does the council ever conduct inspection visits to community pharmacies to ensure that practising pharmacy professionals are those who are registered members? (Y) (N)

(iv) Does the council (LMDPC) liaise with the Ministry of Health, pharmaceutical directorate on pharmacy professional practising in Lesotho? (Y) (N)

(v) What is the number of registered pharmacy professionals in Lesotho?

Pharmacists: _____

Pharmacy technicians: _____

D SUPPLIERS





The following suppliers will be interviewed using the table below on registration requirements:

(a) NDSO (Mafeteng; supplies all government health facilities and privately-owned health facilities)

(b) Tripharm agencies (Maseru; supplies most privately-owned and government facilities and it is also supplied by NDSO)

(c) Medicare (Leribe; supplies most privately-owned healthcare facilities and is also supplied by NDSO)

To qualify to purchase medicines and medical supplies (consumables) from the suppliers, community pharmacies need to submit the following documents to the suppliers:

- **Pharmacist's qualification certificate**
- **Pharmacist's current council registration certificate**
- **Ministry of Health (MOH) pharmacy registration certificate**
- **Trader's license**
- **Tax clearance**

In Table 1 below, the supplier will be asked to indicate which of the documents listed above are required to qualify to be supplied. Upon ticking as per directions below, scoring will be done to determine compliance (complies, partial compliance, poor compliance and no compliance) by pharmacies, 1 document to 5 documents ticked.

Face-to-face interview and respondent information will be completed as follows:

Date of interview:
_____

Supplier:
_____

Respondent number (not a name for confidentiality purposes):
_____

Respondent's work position:
_____

_____

Table 1

Mark with an X in the applicable documents below and score accordingly as shown in Table 1.

SUPPLIER	DOCUMENTS					*SCORE
	Pharmacist Certificate	Pharmacist Council Registration Certificate	MOH Registration Certificate	Trader's License	Tax Clearance Certificate	
NDSO						
Tripharm						
Medicare						

NB **If all 5 documents are marked, the supplier scores 3, and therefore complies.**

If 3-4 documents are available, the supplier scores 2, and therefore partially complies.

If only 1-2 documents are available, the supplier scores 1, and therefore does not comply.

E MINISTER OF HEALTH OR THE MINISTER'S OFFICE



Face-to-face interview and respondent information will be completed as follows:

Date of interview:

_____

Respondent number (not a name for confidentiality purposes):

_____

Respondent's work position:

_____

_____

(d) 1. What role does the MOH play in the community pharmacy practice?

Tick (Y) or (N) for the roles listed below

(i) Making of laws (Y) (N)

Repealing of laws (Y) (N)

Setting up of offices governing the profession (Y) (N)

Updating policies and regulations governing the practice (Y) (N)

Others _____

_____

_____

(e) 2. Are there any laws pertaining to community pharmacy practice in Lesotho? (Y) (N)

(i) If (Y), provide examples of such laws

_____

_____
__

_____
__

(ii) If (N), what measures are put in place to control community pharmacy practice in Lesotho?

_____

_____

_____

3. How are those measures implemented?

_____

_____

(f) 4. When last were the laws governing the pharmaceutical sector mentioned above reviewed? Indicate a law and the year it was reviewed/enacted.

_____

_____

(g) 5. What is the current status of the pharmacy legislature in Lesotho?

(i) Medicines Bill

_____

_____

_____

(ii) Health Professional Bill

_____

_____

_____

(iii) Medicines Control Act_____

_____

F. MSH/SIAPS





Face-to-face interview and respondent information will be completed as follows:

Date of interview:

_____

Respondent number (not a name for confidentiality purposes):

_____

Respondent's work position:

_____ _____

(h) 1. What role does the MSH/SIAPS play in community pharmacy practice in terms of support to the MOH?

Tick (Y) or (N) for the roles listed below

(i) Making of laws (Y) (N)

Repealing of laws (Y) (N)

Setting up of offices governing the profession (Y) (N)

Updating policies and regulations governing the practice (Y) (N)

Others

_____

_____

(i) 2. Are there any laws pertaining to community pharmacy practice in Lesotho? (Y) (N)

(i) If (Y), provide examples of such laws

_____

(ii) If (N), what measures are put in place to control community pharmacy practice in Lesotho?

_____

_____

(iii) How are those measures implemented?

_____

_____

3. When last were the laws governing the pharmaceutical sector mentioned above reviewed? Indicate a law and the year it was reviewed/enacted.

_____

_____

_____

4. What is the current status of the pharmacy legislature in Lesotho?

(i) Medicines Bill

_____

_____

(ii) Health Professional Bill

_____

_____

(iii) Medicines Control Act

_____

_____

G. PSL

1. What is the role of PSL in community practice in Lesotho?

_____

_____

_____

_____

2. Are there any laws pertaining to community pharmacy practice in Lesotho?
(Y) (N)

(i) If (Y), provide examples of such laws

_____

_____

_____

(j) 3. Are the above mentioned laws reviewed?
(Y) (N)

(i) If (N), why not?

_____

_____

(ii) If (Y), how long ago were they reviewed and what role does PSL play in the reviews?

_____

_____

_____

_____