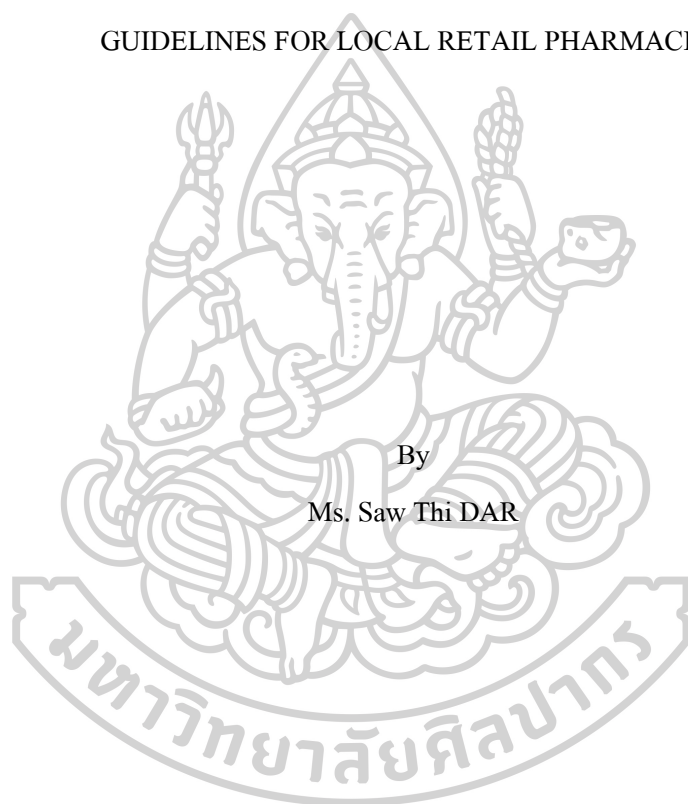




PROPOSING THE OPTIMUM MYANMAR GOOD PHARMACY PRACTICE (GPP)  
GUIDELINES FOR LOCAL RETAIL PHARMACIES



A Thesis Submitted in Partial Fulfillment of the Requirements  
for Doctor of Philosophy SOCIAL AND ADMINISTRATIVE PHARMACY

Silpakorn University

Academic Year 2022

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Proposing the optimum Myanmar Good Pharmacy Practice (GPP) guidelines for local  
retail pharmacies



วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรเภสัชศาสตรดุษฎีบัณฑิต  
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Title                    Proposing the optimum Myanmar Good Pharmacy Practice (GPP) guidelines  
                                 for local retail pharmacies

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Field of Study         SOCIAL AND ADMINISTRATIVE PHARMACY

Advisor                 Assistant Professor Panoopat Poompruek, Ph.D.

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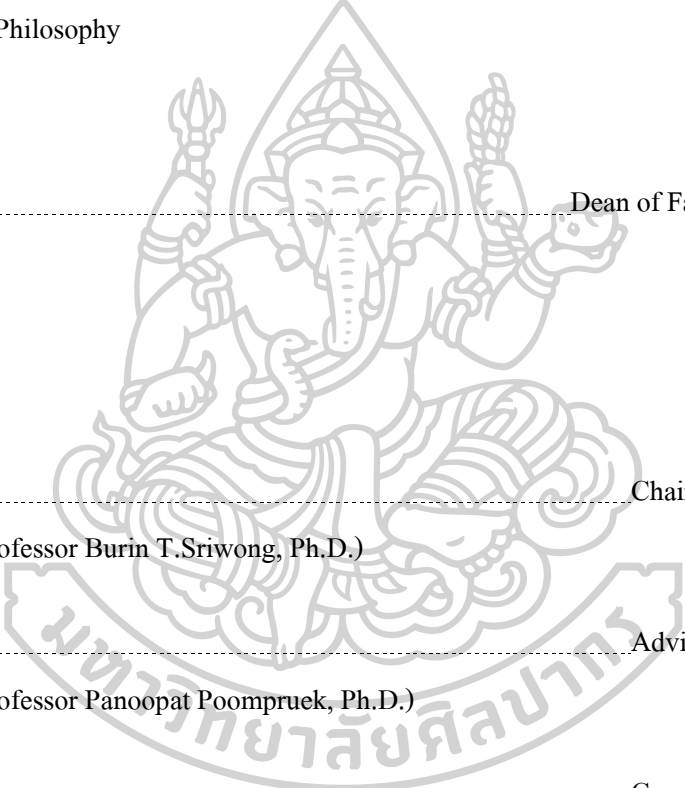
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Ms. Saw Thi DAR : Proposing the optimum Myanmar Good Pharmacy Practice (GPP) guidelines for local retail pharmacies Thesis advisor : Assistant Professor Panoopat Poompruek, Ph.D.

The present study was aimed to develop optimum Good Pharmacy Practice (GPP) guidelines for local retail pharmacies by inclusion of multiple-stakeholders in designing the implementation cycle and then propose these optimum guidelines to policy-makers to support the process of policy implementation. Therefore, a cross-sectional descriptive study using quantitative and qualitative methods was employed to investigate the situations of current pharmacy services and find out the contents for implementation of GPP guidelines in Myanmar context through participation of stakeholders. The pharmacy business is significantly increased number in recent decade to respond customers' demands and they are found to be shared values among customers, patients and their partners like pharmaceutical companies. However, from the professional point of view, their pharmacy practices are acceptable for pharmaceutical services and far acceptable for pharmaceutical care. Regarding the GPP principles and its scope, the vast majority of stakeholders have neither heard nor familiar with the terms and it was found to be beyond their interest and knowledge. Therefore, this study found that the GPP implementation might be a bit challenge in practical ways with diverse understanding on principles of GPP and limited abilities of pharmacy staffs to follow it. Moreover, it was realized that pharmacies are barely profit business rather than a channel for care giving. As a result, stakeholders' collaboration is fragmented and disconnected in new regulations of pharmacy practice. The government should bring all multiple-stakeholders together before seeding the principles of GPP and evaluate the process with a system thinking lens and promote dynamic networks of diverse stakeholders. Therefore, this study finds out the pragmatic agenda for policy to implement GPP guidelines for retail pharmacies in Myanmar. 7 main strategies composing 33 strategic plans are proposed to approach the seeding of GPP principles and implementing the GPP guidelines. They are; 1. Education and training on understanding the meanings of GPP and risks of safety, 2. Management for Human Resource, 3. Effective communication and collaboration to implement GPP standards, 4. Persuasion, support and encouragement to follow GPP standards, 5.

Governance and regulations, 6. Sustainable processes for GPP implementation and 7. Changing Mindsets.



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## CHAPTER 1

### INTRODUCTION

#### 1.1. BACKGROUND INFORMATION AND PROBLEM STATEMENT

The Union of Myanmar, a member of the Association of Southeast Asian Nations (ASEAN), with the population of 51,486,253 million people, is in transition from a long-established authoritarian system to democratic system gradually within a decade (Department of Population & Ministry of Labour, Immigration and Population, 2014). During 2005-2012 period, the government attempted at health reform and recovery sectors, linked to emerging trends in national political reform and international policy. With the aim of achieving the universal health coverage (UHC), the government resolved to improve accessibility and affordability of medicines for its millions of people (Ministry of Health, 2014). Therefore at the end of 2015, one of the members of ASEAN - Myanmar approached a new milestone. The ASEAN Economic Community (AEC) is intended to implement regional economic integration in year 2020. The initiation of AEC is intended to create easy access to trade facilitation condition and to promote services across boundaries within ASEAN (Association of Southeast Asian Nations, 2009). As the healthcare is one of the priority sectors for AEC, it is important for Myanmar to make sure current attempts of preparation for the transition to the AEC include healthcare development. As a result, one of the tasks in harmonizing with ASEAN standards and collaborating with other countries in the region is to improve compliance to best practices as much as it can, for examples, Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Regulatory Practice (GRP), Good Pharmacy Practice (GPP) etc. During the most recent period, the central state has set one of the standard guidelines, named Good Pharmacy Practice (GPP) regarding the practices of retail pharmacies and planned it to implement in near future, beyond 2020.

Good Pharmacy Practice (GPP) is a guideline distributed by International Pharmaceutical Federation (FIP) and encouraged by World Health Organization (WHO) for people who provide pharmacy service. This guideline describes how to promote the services and practices in best

ways to benefit the people they served. With the purposes of minimizing the risks of unsafe practice, WHO recommended pharmacists for taking the roles of ensuring the rational use of medicines and providing the necessary care along the patients' medication duration which is technologically termed pharmaceutical cares. The Good Pharmacy Practice (GPP) with these aims, merging the philosophy of pharmaceutical care into community pharmacy practice, has been developed as a reference for national standards to improve the pharmacy services, drug distribution and usage and education to the community. The practice of pharmacy thus is intended to respond to well-beings of the population and needs of people by providing optimal, evidence-based care (FIP/ WHO, 2011, Annex 8).

In Myanmar, three pluralistic sectors of provider are taking a share of health service provision: public institutions, private organizations and nongovernmental organizations (NGOs) such as Myanmar Maternal and Child Welfare Association and the Myanmar Red Cross Society. The Ministry of Health and Sports takes the roles of major provider of comprehensive healthcare covering activities for promoting health, preventing diseases, providing effective treatment and rehabilitation. The profit-oriented private sectors regarding the pharmaceutical distribution have been regulated by Food and Drug Administrative Department under the Ministry of Health and Sports, and also been enforced through the National Drug Law (NDL) (1992). It is the major law concerning the regulation of pharmaceuticals from manufacturing to distribution and selling of medicines to the customers (Thida and James, 2000) with the aim of ensuring safe, efficacious and assured quality of medicines in the local pharmaceutical markets. The Law describes that the retail pharmacies are product-oriented pharmaceutical activities such as custody of premises and medicines, storage, quality control of medicines and overlooks such activities as professional practice and scope of pharmacists'. At the time of promulgation of NDL around 1992, the pharmacy professional was still in a very early stage of establishment in Myanmar, as the pharmacy profession entered pretty late into Myanmar. The main sources are the official website page of University of Pharmacy Yangon and Mandalay, Myanmar (<http://www.uopygn.gov.mm>) and (<http://www.uopmdy.gov.mm>) respectively. As a consequence, pharmacists have not yet been playing a mandatory professional role in pharmacy business. According to the descriptions in the NDL, any graduate, who holds a Bachelor of Science degree whether it is a pharmacy's or not, is allowed to run or own pharmacy business in the country. By law, a pharmacist is only required to

be present in a retail pharmacy if the controlled drugs are sold there. This widespread liberalized condition has led pharmacies to be increasingly seen as part of the commercial sector rather than private health care services and to be less valued at professionalism. Actually, the private retail pharmacies are a part of private health services. They are officially recognized and considered to take part in the national health care system as an integral part in accordance with the national health policy. However, to fulfill this role, the area of pharmacy practice needs to be standardized and extended to patient-care practice related to the delivery of pharmaceutical care by the pharmacists. In order to ensure the implementation of GPP principles in current situations, there might be many challenges to face in Myanmar. There are constraints of resources. The requirements suggested for GPP implementation way by FIP and WHO are quite far and also mismatched for conditions in Myanmar. Therefore, the present study aims to develop the optimum conditions of Good Pharmacy Practice (GPP) guidelines for Myanmar that match with local context, and to find out a certain condition that could adapt and confront all the above stated barriers.

## 1.2. RESEARCH QUESTIONS

Therefore, the main question that arises for this study is – *What kind of good pharmacy practice (GPP) guidelines does the Myanmar match for retail pharmacies if there is no or little contribution of pharmacists?*

In order to develop the GPP guidelines, we should know about – *What are the current situations of pharmacy practices in Myanmar? What the advantages and disadvantages of pharmacy practice and services in current situations? How can we develop good pharmacy practice (GPP) guidelines for retail pharmacies in Myanmar with deficient resource of pharmacists? If there is a Government's plan or policy to implement the GPP guidelines in Myanmar, what will be the barriers and facilitators for pharmacies and for the regulators?*

### **1.3. OBJECTIVE OF THE STUDY**

#### **General Objective**

To propose the optimum Myanmar Good Pharmacy Practice (GPP) guidelines for local retail pharmacies

#### **Specific Objectives**

To investigate and analyze the current situations of pharmacy practice among local retail pharmacies by using the standards GPP guidelines, adopted from FIP/WHO framework and formulated by other developing countries,

To develop optimum Good Pharmacy Practice guidelines for local retail pharmacies by collaborative contribution of stakeholders, and

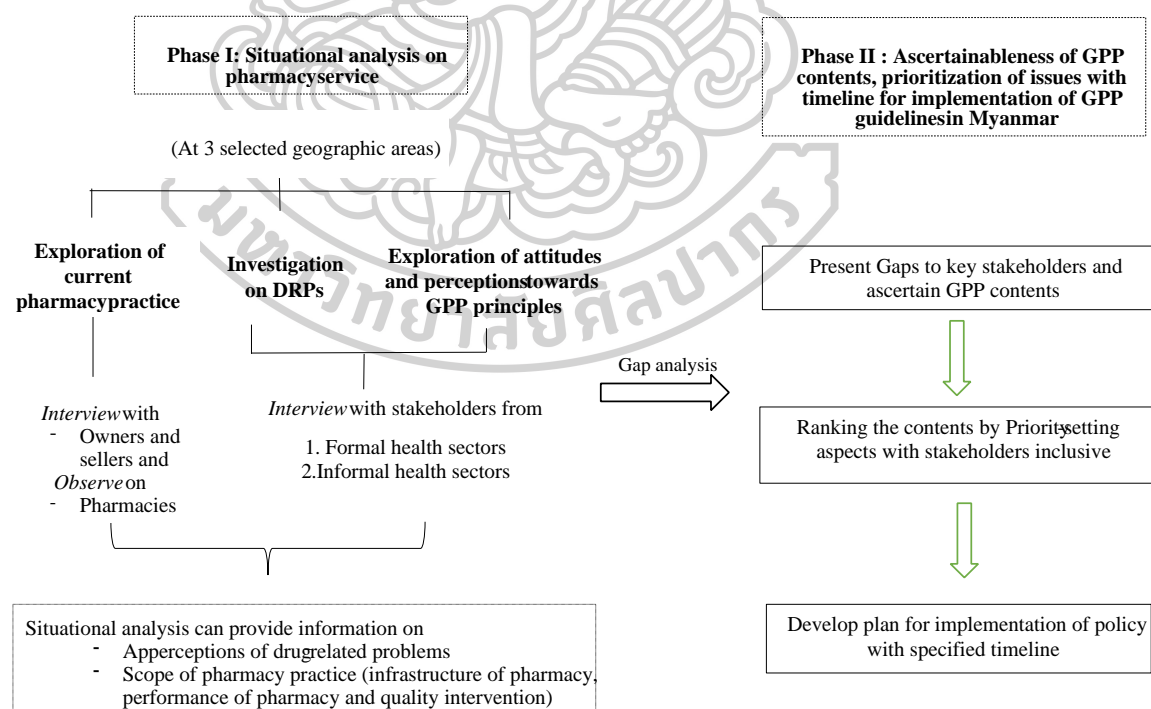
To develop a plan for implementation of Myanmar Good Pharmacy Practice guidelines by prioritizing the issues responding to national health priorities.

### **1.4. SCOPE OF THE STUDY**

The situations in Myanmar have to be aligned with the AEC integration blue print and so preparatory attempts have to be made for the transition to the AEC through establishment of ASEAN standards of the best practices for pharmaceutical sector. Since the standards of GPP often exceed those provided by national legislation and the country nature, limited resources and the contexts of Myanmar, the policy-makers in Myanmar have concentrated on those aspects perceived to be most applicable and relevant to country's situation. A set of guidelines has been developed in 2017 for local registered retail pharmacies and a plan is set up to implement it in 2020 and onwards. However, the legal approval for the entire nation is still on-processing and this is why it has not been enforced to launch till now. The contents of guideline, also, have not been evaluated regarding the real benefit or in practicality. Therefore, the government needs to set up a strategic plan in accordance with available current resources and to use it in most efficient way for the future. Therefore, the present study aims to find out the optimum conditions for GPP guidelines implementation which are suitable for Myanmar local context and are beneficial to the Myanmar citizens. In order to do so, situational analysis on pharmacy contexts must be carried out firstly to see their strength and weakness, thereby we can find out the contents of Good

Pharmacy Practice (GPP) that are applicable in Myanmar context. Since many factors could have involved before, during and after implementation process, we need to find out those different key factors and generate related information. The possible key factors might be socio-demographic factors, economic factors, regulatory factors, health system factors, pharmaceutical industry and innovation factors, pharmacy profession factors, cultural factors and collaboration factors. Therefore, it is important to take a broad view from the individual who is concerned about the health service and pharmacy practices. This study was conducted through participation and inclusion of different groups of stakeholders with different attitudes, perspectives and experiences. From their different aspects and suggestions, the data were constructed and identified with key participants. Finally, a priority-setting approach was applied to develop the initiations of GPP guidelines implementation. In this research, all the different levels of stakeholders actively collaborated and participated to support the process of policy implementation.

Figure 1 Scope of the study (Flow Diagram)



## 1.5. OPERATIONAL TERMS

Community pharmacy – is the registered retail outlet designated primarily for selling medicines and other related products directly to the public. Sometimes the term is interchanged the word with “drug stores”. Pharmacy practice – the pharmacy practice in this study refers to the processes encompassing procure, store and maintain of medicines and their necessary documentaries, maintain the pharmacy’s environment, selling OTC medicines and refilling the POM.

Optimized condition/Optimization - refers to the condition where the necessary statements in GPP guidelines are practicality and could follow convenient way by using it for drug owners and drug sellers.

Good Pharmacy Practice Guidelines of Myanmar – the guidelines developed for local drug stores that are crucial for improvement in practices of drug sellers as well as owners to benefit the patients and customers. In addition, these guidelines should be complementary to the National Drug Law of Myanmar.

## 1.6. CONCEPTUAL FRAMEWORK

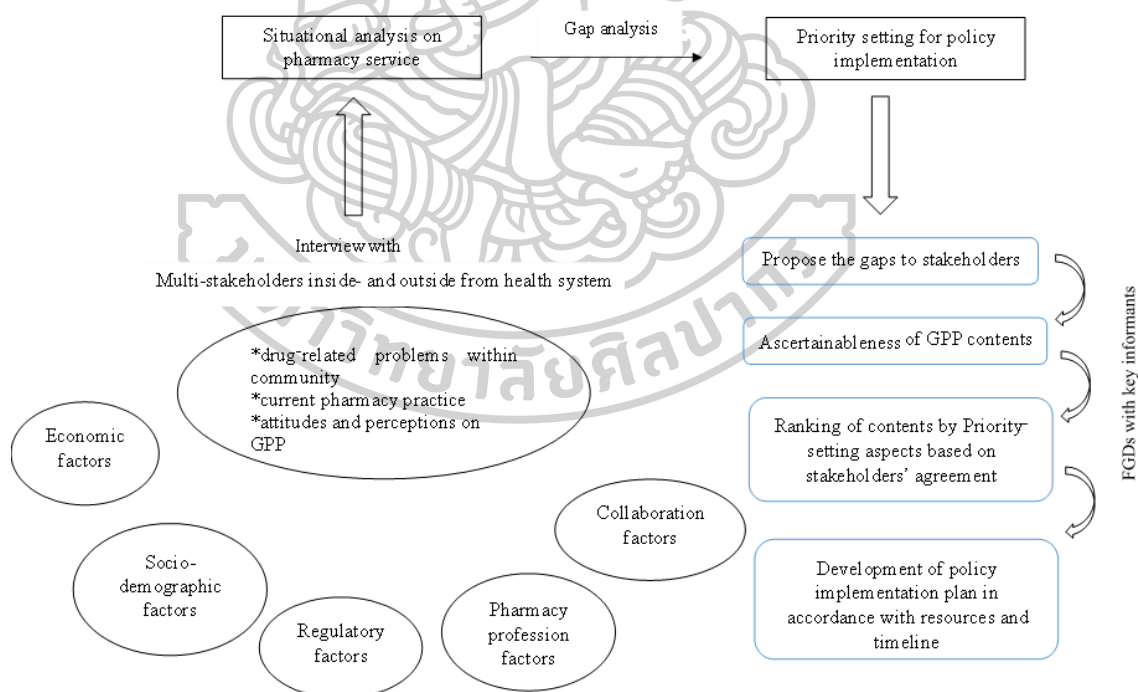
The conceptual framework of this study comprises 2 components and their relationships are as shown in following figure 2. It assumes that the phase I study is analysis of current situations of pharmacy services regarding the pharmacy practice in retail pharmacies, how to manage the pharmacy business in professional way, and apperception of drug-related problems within community due to medication errors or dispensing errors from retail pharmacies and/or groceries. Moreover, the attitudes and perceptions of stakeholders are interviewed for investigation of perceptions towards pharmacy and its practice, principles of good pharmacy practice and the establishment of these principles to retail pharmacies in Myanmar. This study covers the areas in

(i) current structures of pharmacies (how to operate the pharmacy in accordance with - premises, equipment, furniture and fixture, personnel) – that is necessary for quality management in pharmacies,

- (ii) current performance of the pharmacies (how to operate the pharmacy whether they have training process or not, procurement and inventory, documentation, storage, prescription handling and dispensing practice) for accessible and safe and
- (iii) current quality intervention (how to operate the pharmacy in accordance with quality policy and service strategy in addition to the regulation) for maintaining pharmacy capacity.

From the phase I study, the gaps are identified from differences between the real situations and standard legislation which provide evidence base information. These evidence-based outcome data are used to include the participation of key stakeholders in processes of GPP guidelines development. The semi-structured interview guide is employed in focus group discussion (FGD) with key expert persons from each stakeholder for exploration of facilitators and barriers in guideline development. Then the study is conducted the priority-setting aspects on GPP contents for policy implementation in accordance with available resources based on timeline.

Figure 2 Conceptual framework of the study



## CHAPTER 2

### LITERATURE REVIEW

#### 2.1. The Good Pharmacy Practice (GPP)

The core activity of pharmacy practice is to provide medicines, other health-care products and consistent professional services. The pharmacy practice ensures to secure good health and avoiding ill health in the population thereby helping the individual and society to improve health. Those practices in pharmacy should be assured appropriate drug therapy outcomes and patient safety through managing patient care (Joint FIP/WHO guidelines on Good Pharmacy Practice). The provision of quality medicines and care service in safe and effective is, therefore, a priority for healthcare. However, many countries had noticed that the pharmacy practice reflected a high degree of variations in practice which can lead to several tangible and intangible effects on public health. Any practice performed in poor performance or slapdash practice or inattentive to the standards of care could threaten or jeopardize the safety of patients (Gill *et al.*, 2013).

International Pharmaceutical Federation (FIP) initiated the standards of pharmacy services at 1992 as Good Pharmacy Practice (GPP). In 1996, World Health Organization (WHO) endorsed this document under the heading of “GPP in community and hospital settings” and published it officially. The underlying principle of GPP guidelines was based on pharmaceutical care provided by pharmacists. This document was intended to improve practices of pharmacy and meet the changing circumstances by developing the elements of service they provide. As a consequent, the needs of the people can be responded by providing optimal, evidence-based care.

The goal of good pharmacy practice (GPP) is to improve standard and practice of pharmacy services, drug distribution and use and education to the community and contribute to the health and well-beings of the population. Therefore, to meet the mission of these practices, these guidelines were urged to develop as a reference by national pharmaceutical organizations, national authorities, and other relevant bodies providing guidance on specific roles, functions and activities of care providers.



### **2.1.1. Pragmatic agenda for policy to implement GPP guidelines for community**

#### **pharmacies**

The philosophy of pharmaceutical care was integrated into the practice of pharmacy in order to meet the world's healthcare needs and expectations. FIP takes the roles in global healthcare decisions and actions by advancing pharmaceutical education, pharmaceutical sciences and pharmaceutical practice (FIP, 2008). FIP recommended a strategy for implementing of national standards of GPP and provided a framework for every country and suggested the corresponding national pharmaceutical organizations to set up the criteria and its own standards that are relevant and achievable within its timescale (WHO, 1996).

The standards of GPP are often exceeded those provided by national legislation. The national legislation seldom gives precise instructions about how the services should be produced to meet the requirements. However, at the beginning step, FIP recommended that the basic pharmaceutical services and relevant standards should be affiliated with national regulatory framework. Then the education system of pharmacy should be changed for dynamic healthcare system. The pharmacists, as care providers, needs more in-depth knowledge of pharmacotherapy, sociology and communicative skills to meet the need of patients in modern age. Then the last stage is towards the provision of more sophisticated professional services. FIP suggested that a baseline should be established for practice and below which the activity cannot considered the pharmacy practice at all. Since standards are an important part in the measurement of quality service to the consumer, there is a need to develop, adopt and enforce minimum standards of GPP to assess pharmacy practice (FIP, 1997).

For the national level, the WHO and FIP suggested that the minimum standards for a legal framework, a workforce framework and an economic framework should be established. In a legal framework, it was strongly recommended that a pharmacy staff and the scope of pharmacy practice should be defined. It makes ensure the integrity of supply chain and quality of medicines. A workforce framework has to ensure the competence of pharmacy staff and define the personnel resources that needed to provide GPP. Finally, an economic framework has to provide sufficient resources that are effectively used to ensure the activities undertaken in GPP process.

As the minimum level, the national standards of GPP recommended the several roles for community pharmacists. The responsible person in pharmacy should be obliged to ensure the service they provide and be appropriated quality to every patient. The roles for pharmacists are to be:

- prepared, obtained, stored, secured, distributed, administered and disposed of medical products
- provided effective management of medication therapy
- maintained and improved professional performance
- contributed to improve effectiveness of the healthcare system and public health (FIP, 1997).

Since there is inequity in economic situations, cultures, natures, and resources among countries, the scope of pharmacy practice and requirements are inappropriate to set equally for all member countries to achieve the mission of pharmacy practice. However, in order to implement the policy agenda in pragmatic approach, each country should take account the key policy considerations based on their own. They should be aligned with macroeconomic and political stability, major stakeholder involvement, knowledge development, political commitments, and professional development and collaboration among them. Generally, for developing countries and countries in transition, the joint FIP and WHO has introduced the design and method of some simple recommendations according to available resources of individual country and focused on areas in applicable and most relevant pharmacy practice. In that case, WHO and FIP strongly suggested that the national pharmaceutical associations should have a role in setting standards required for GPP, which includes a *quality management framework* and a *strategic plan* for developing services.

This recommended design and method were intended for step-by-step implementation of proper pharmacy practices and emphasized on four major areas. With the step-wise approach, progress would be upward, forwards to next level of health institution to final ideal condition. They were

- Personnel – with the aim of access to a qualified pharmacist or, even when it is not possible to direct access to pharmacists in somewhere, a person who should have an adequate pharmaceutical service.

- Training – with the aim of focusing on training the pharmacy personnel for self-sufficient within country. It is recognized that the level of training must be appropriate to the level of service provided and medicine used through well-established standards and curricula for ensuring consistency and appropriate for each level of training.
- Standards – with the aim of focusing to guarantee the integrity and quality of pharmaceutical products, services and the premises where the service is provided and minimize the risk of dispensing errors.
- Legislation and National drug policy – with the aim of establishing a national GPP policy that must be adequately enforced and establishing a national drug policy to ensure equitable access to safe, effective and good quality of drugs.

## **2.2. Background of Republic of Union of Myanmar**

### **2.2.1. Geographic and Sociodemographic Information of Myanmar**

The republic of Union of Myanmar, located in South-East Asia, has estimated population of 51,419,420 persons by 2014 provisional census results. Administratively, the country is divided into Nay Pyi Taw Council Territory and 14 States and Regions. 70 percent of population resides in rural areas while the rest population lives in urban areas. The average population density for whole country was 77 persons per square kilometer and it can vary whether the highest densely populated area or hard to reach areas from 666 persons to 88 persons per square kilometers of land respectively (IHLCA Project Technical Unit, 2009-2010).

### **2.2.2. Health System Overview**

Myanmar healthcare system had changed along with political and administrative system. However, the Ministry of Health and Sports is the major provider for comprehensive healthcare services through seven functioning departments all over the country (Ministry of Health, 2014-2015). They raise the health status of people by covering all activities in health promotion, diseases and ill-health prevention, cure and rehabilitation (Tun *et.al.*, 2014). Healthcare is organized and provided by public and private providers. Provision of health services

is extended down to rural settings via a network of healthcare facilities at different administrative levels. The public healthcare facilities in Myanmar are mainly for provision of curative and rehabilitative services (Latt *et al.*, 2016). The profit private sectors are mainly for ambulatory care and is regulated in conformity with the Public Health Law (1972). Currently, Yangon, Mandalay and other large cities had some private institutional care.

### **2.2.3. Health Expenditure**

The government is the major source of finance for healthcare services and external aids and community contributions are other minor sources. The provision of service was used to be virtually free until 1993. When user charges were introduced in the form of cost sharing, then private out-of-pocket (OOP) payment became the main source of finance. In the period of Military regulation, a poor economic condition of country leads to very limited public expenditure on basic services that causes inaccessible to basic health needs by a majority of people and resulted in unfulfilled protection for health-for-all. According to 2010 United Nations Development Programme survey, a quarter of the population lacks the resources to meet basic needs. The government expenditure was less than 0.2 USD/person/year between 2001 and 2011 on pharmaceuticals which is extremely low by global and regional standards. The government spent a large share on curative and rehabilitative services in 2006 until 2011 and spent 10-20% on prevention and public health services from 2001 to 2006. This spending was increased to 2432% between 2007 and 2011. In 2014-2015, the expenditure on healthcare was increased in terms of 3.65% of general government expenditure. Although delivery of medicines is free to the vulnerable patients in public sectors, the government funding was still insufficient in supporting the required quantity of essential medicines. As a result, there was too frequent stock-outs in public hospitals that leads to the percentage of OOPs expenditure was high (Myanmar National Health Plan (2017-2021), 2016). All the patients have to purchase their medicines either from private pharmacies outside the hospitals or operating within hospital compounds. As a result, utilization of services is much more relied on outside the public health services.

#### **2.2.4. Health seeking behaviour of public**

By 2008 surveyed data of Ministry of Health and Sports (MOHS) conducted in 3 large cities from Yangon, Mandalay and Mon regions, 18% of outpatients assessed pharmacies for primary care as self-care, 72% of patients assessed the healthcare in private sector, only 6% used public sector and the remaining percent of patients assessed traditional methods and others. Therefore, pharmacies are the second most commonly used health facility by the consumers in Myanmar (Health in Myanmar, 2008).

#### **2.2.5. Human resources in healthcare system**

The Ministry of Health is not only for service provision but also for training and producing all categories of health professionals and workers through medical, dental, nursing and related universities and institutes. The total health workforce has increased for 20% between the fiscal years 2006-2007 and 2010-2011. The ratio of doctors, nurses and midwives per 1000 population increased from 1.27 to 1.49 from 2006-2007 to 2010-2011 respectively. According to the WHO data, the density of doctors from both public and private sectors was 0.5 in 2010, the density of nurses was less than 1 in 1000 population and those of dentists was 5 per 100,000 while pharmacists and other technicians were quite below than the density of doctors because their production has less than 500 graduates per year (Tun *et.al.*, 2014). As a result, the number of healthcare workers in Myanmar was still far below the global standard of 2.28 health workers per 1000 population. Furthermore, the distribution of work force is inequity among urban, rural areas and remote less-secure areas. Therefore, there was a big challenge in accessing health services in remote, broader and less-secure areas.

#### **2.2.6. Regulation and governance of pharmaceutical sectors in Myanmar**

In terms of regulation and governance of pharmaceutical sectors in Myanmar, the Ministry of Health and Sports (MOHS) launched the Laws relating to the drug safety. They are the Public Health Law (1972), National Drug Law (NDL) (1992), Law relating to Private Health care Services (2007) and Consumer Protection Law (2014). The Myanmar Food and Drug Administration (MFDA) Department under the MOHS is a responsible key for enforcing these laws. Among these laws, NDL is the major law concerning the regulation of pharmaceuticals

from manufacturing to distribution and selling of medicines to the customers (Thida & James, 2000). This law is aimed to ensure safe, efficacious and assured quality of the medicines in the local pharmaceutical markets. Though the law concerning the secure of product safety and services for the consumers has imposed as Consumer Protection Law (2014), under the auspices of the Ministry of Commerce, it was still underdeveloped implementation (Yee, 2016).

### **2.2.7. Pharmaceutical law, legislation and pharmacies in Myanmar**

The Ministry of Health Myanmar (MOH) launched the National Drug Law (NDL) in 1992. The basic purpose of it is to control and systematically regulate the manufacture, import, export, storage, distribution and sale of drugs. For someone who wish to manufacture, import, export, store, distribute and sell the pharmaceutical raw materials or drugs, he or she must register in FDA. The law specified that all the applicants must be residents of Myanmar. If the producer is a foreign company, the applicant must be a resident representative of the foreign company and was given an authorization letter by the foreign company. The Ministry of Health (MOH) issued the notification in 1993 that contains the procedure for the sale of pharmaceuticals. According to this notification, a person who would like to obtain a licence whether wholesale or retail must apply to the relevant Township Supervisory Committee (TSC). The licence issued by TSC is subjected to the confirmation by the District Supervisory Committee (DSC). The licence period is validated for 3 years from the date of issuance. If a person wished to renew the licence he or she can apply 90 days before its expiry date or if the licence is not renewed again at expiration date, it will be invalid.

The requirements for premises for selling the pharmaceuticals must have adequate space for receiving, inspection, storage and issuing of pharmaceuticals, adequate light, good ventilation, required storage temperature and specified moisture for pharmaceuticals with neat and clean storage manner. Moreover, necessary arrangements must be done in the building and the area must be prevented from the entry of rodents and insects. There must be separated in areas for resting, dinning, washing and changing for employees. The vendor must guarantee the quality and efficacy of the drugs that are not deteriorate due to the premises and equipment used.

Again, the personnel qualification as supervisors at the pharmacies require proper experience and minimum age of 20 for an applicant. He or she must not be convicted as drug users in narcotic or psychotropic substances or otherwise the person is not qualified to be a supervisor. The vast majority of pharmacies in Myanmar has no pharmacists to supervise the pharmacy staffs where the former is most responsible for the safe and effective running of the registered pharmacy.

### **2.2.8. Good Pharmacy Practice Guidelines for retail pharmacies in Myanmar**

The Myanmar's Good Pharmacy Practice (GPP) Guidelines was aimed to set standards for practice of pharmacy and regulate the staffs' practice within the pharmacy. The guidelines was being developed (in Myanmar version only) during this study, in 2017 for registered retailed pharmacies. The central state has a vision to implement the GPP guidelines in near future, beyond 2020. The contents in the Myanmar GPP Guidelines were conducted to summarize. The present version of Myanmar guidelines has 10 main domains with many subdomains under each one.

The first domain is aimed to specify the five basic requirements to implement GPP guidelines for retail pharmacies. They are

- (i) To prioritize the patients and their health
- (ii) To sell the medicines with good quality, and contribute the necessary information related to the medicines to the customers and supervise the medication that sold from drug stores also.
- (iii) To help patients with self-medication regarding the OTC drugs
- (iv) To sell medicines that are suitable, meaningful, cost-effective, harmless and potent and supervise according to doctors' prescription letter
- (v) To have pharmacist(s) in pharmacies for providing suitable, economical, safe and efficacious medicines correctly in accord with prescription letters

The second domain is mainly specified about necessary accommodation regarding the space and layout requirements and contains 8 subdomains describing appropriate space management for easy arrangement in the building and acquire necessary temperature, light and ventilation for medicines that could have impact on the potency of medicines. The guideline

emphasized on the separate area within pharmacy for convenient working, for communication with patients and for storage of medicines in a dispensing area and a separate area for counselling with patients if necessary. The guideline recommended the way to keep the controlled drugs (CDs), and prohibited entry to the dispensing area for those of people who are not related to work. The guideline ruled out any disturb volume that can cause distraction in a pharmacy. Moreover, the guideline strictly specified about installation of required equipment and facilities regarding security system, washing and cleaning purposes, temperature and humidity measuring devices, and adequate power supply. This domain is intended to facilitate safe and effective delivery of pharmacy services.

The third domain is aimed to ensure having necessary equipment for adequate operation within a pharmacy such as a dispensing board having 2 ft x 8 inches size at least, clear and concise written labels, tablet counting devices, a well-functioning refrigerator, adequate number of shelves, cupboard and cabinet and clean repacking materials. This domain is intended to facilitate in dispensing process, effective storage of medicines, including OTCs and cold-chain medicines, and necessary statutory documents.

The fourth domain regards with personnel hygiene of pharmacy staffs. It specified a pharmacist should always wear a coat and a name badge for notice of professional staff in pharmacy who could help the patients and customers for their medications. It specified all the pharmacy staffs including pharmacist(s) and assistant staff(s) were needed to be conscious about health and personnel hygiene. The drugs are prohibited to handle with bare hands and use clean gloves or spoons instead. The guideline suggested that any person with open wound in skin was not allowed to dispense directly to customers. But if there is any cut or abrasion on skin, that person must be used a water-resistant cover. And be informed to responsible person in pharmacy if any staff was suffered from skin diseases. Moreover, the pharmacy staffs are prohibited the activities of smoking and eating in pharmacy compound.

The fifth domain is intended to store medicines and medical products as stipulated by the manufacturers in order to maintain the quality of them. The products should be stored as original containers if possible and if there is exception, the contents must be stored carefully to avoid contamination and all relevant information must be clarified on the new container. For example, the generic names of medicines, the strength, quantity of product,



manufacture date, batch number and expiry date and so on. There is instruction for storage of medicines that used for external and internal. They should be stored as same classification via alphabetically. The storage condition of pharmacy should be neat and tidy.

The sixth domain is instructed about receiving the order of prescription letter to ensure accurate dispensing process. It was stated that a pharmacist should confirm the prescription completeness and also check the prescription that is issued by authorized professional or not. The pharmacist is also authorized to check the appropriateness and duplication of medications. A pharmacist can determine for customers whether the medication is appropriate or not and if necessary, a pharmacist is instructed to contact the respective prescriber and amend the situation and record those conditions. The law instructed that the pharmacy should provide all the information related to products such as dosing instruction, generic and proprietary name, dosage form, strength and quantity, storage condition and if necessary, provide the name, address and telephone number of pharmacy to customer(s). For this condition, the pharmacy should provide information in legible and understandable condition.

The seventh domain is related about documentation for qualification of drug store applicant regarding premises licence, seller's licence, retailer's licence and control drug licence. They all must have to display at main entrance of a drug store. There is also needed to be maintained for some documents such as personnel details, addresses, medical records, prescription letters, sale and purchase invoices related to controlled drugs and every medicines according to batch number, expiry date, stock balance. These all documents are stated as easily accessible whenever required.

The eighth domain instructs about procedures details for

- displaying the medicines on counter and shelves to avoid wrong choose of medicines during dispensing
- careful read of prescription letter in order to dispense correctly medicines to patients or customers and if it is uncertainty in prescription letter, contact to respective prescriber and confirmed again
- management of medicines before and after expiration dates and records of those medicines on computer or written form should be maintained

- checking to identify for prescription letters to avoid medication errors. The law specified that all of the above procedures must be performed by a pharmacist.

The ninth domain states about accountability of a pharmacist and the owner of a drug store. A pharmacist must take account for supervision of staffs for correct dispensing process or doing it by him/herself. The owner of a drug store must take account for licencing processes and make sure that they are not to be expired.

The tenth domain as well as the last domain of GPP document instructs for purchasing of medicines. All purchased medicines must be registered to the FDA and from the sources of official distributors. All those official invoices and vouchers are instructed to be documented.

### **2.2.9. Implementation a policy in a country and stakeholder participation**

The effectiveness of a policy and pursuance of long-term goals in an active and adaptive manner are linked with how do stakeholders be engaged and participated into policy design and implementation. The stakeholder participation is referred to as various stakeholders are affected by or they can affect the results of policy-making and decision-making processes (Pisano *et.al.*, 2015). So they are the persons directly or indirectly involved in the policy process such as individual citizens, civil society, academia, business organization, admins and top-level policy-makers. They can support the policies to be sustained along with synergies through harnessed. The negative emergent behaviour are mitigated through increased transparency, accountability, a richer understanding of the in-process. The multiple-stakeholders have a right to be involved in the decision-making process. In turns, the processes should recognize and communicate the needs and interest of all stakeholders, define how the stakeholders participate in it. They should be provided information and capacity to participate and communicate to them how their input affected the decisions (ICAT, 2020).

As it is regarded as “*no one is less important*”, everyone has a unique area of expertise in experience, knowledge and skills, they have equal chances in contributions. It must have to recognize the public values and their concerns in making decisions regarding the barriers and facilitating factors in early stage of policy development and along with its implementation process. The core principles are equal collaborative involvement of community and researchers,

therefore they can understand the situations, reshape their knowledge on political, social, economic and familial contexts in communities and they evaluate themselves thereby improve practices (Baum *et al.*, 2006 and McIntyre, 2002).

The participatory action research (PAR) applies two approaches in collecting (through participation) and analyzing data for action purpose (through action) and making change by generating practical knowledge (Gillis & Jackson, 2002). Attwood's explained his evince about the philosophy of PAR that "*people have a right to determine their own development and recognizes the need for local people to participate meaningfully in the process of analyzing their own solutions, over which they have (or share, as some would argue) power and control, in order to lead to sustainable development*" (MacDonald, 2012).

PAR has seven key components that have been summarized some of the principal features of it. The first feature declared that the problems are originated in the community itself and it can be defined, analyzed and solved by the community. Secondly, the people are engaged in examining their knowledge (understanding, skills and values) and interpretive categories (the ways in which they interpret themselves and their action of social reality). The sense of participatory is people can only do action research "on" themselves but not done "on" others. Therefore, community members are the primary beneficiaries of the research. Thirdly, PAR engages the people to participate fully and actively at all levels of the entire research process. Fourthly, PAR aims to help people recover and release themselves from the constraints of irrational, unproductive, unjust and unsatisfying social structures. PAR encompasses a range of powerless groups of individuals (the exploited, the poor, the oppressed and the marginalized).

The fifth is PAR has the ability to create a greater awareness in individuals' own resources (their language, their modes of work and social relationships of power) that can mobilize them for selfreliant development. The sixth component of PAR is reflexive. PAR is more than a scientific method in that community participation in the research process investigates reality in order to change it and facilitates a more accurate and authentic analysis of social reality. It is a deliberate process, through which people aim to transform their practices through learning by doing that leads to changing the ways in which we interact in a shared social world. Lastly,

PAR allows the researcher to be a committed participant, facilitator, and learner in the research process which fosters militancy rather than detachment (MacDonald, 2012 and Kemmis, 2007).

The origin of action research is attributed to Kurt Lewin (1948). At first, PAR was mainly used in low-income countries for needs assessment, planning and evaluating health services (Baum, 2006). It was reported that in the early 1970s, PAR was applied as a research method in the field of popular education. The popular education supports oppressed people through “problem-posing approach”. Firstly, the educators must have familiarized themselves with the history and situation of community before enter a community. Then they co-operated with community to identify their aspirations, their daily-lives problems and systemic causes of these problems via public meetings. Problem-posing education had achieved in not only to change oppressed people’s knowledge of their situation but also to transform those aspects of their own values, practices and internalized psyches from oppression (Paradis, 2009). In 1990s2000s, the employing of participatory processes was reported in homelessness research across a range of disciplines in nursing, social work, health promotion, psychology, geography and drama (Stoecker, 2003).

Research using PAR is increasingly applied in health research in 21<sup>st</sup> century (Baum *et al.*, 2006). MacDonald (2012) extracted the PAR methodology for research that suited in best way for a number of disciplines such as education, health, community development, adult education, organizational development, agriculture, industry, university-community development and research with groups of oppressed or marginalized individuals. Participatory research thus support the empowerment of participants and communities in feeling more capable and confident, helping them exercise real political influence and building skills to self-initiate projects (Paradis, 2009).

Importantly, because of the characteristics of PAR, i.e., sharing the power and mutual respect among all team members, make advantage in effective participation during design and implementation processes. Therefore, PAR can be used as an effective “tool” to address a problem and engage the participants and the researcher(s) to participate in the process thereby improve their practices and their situations.

In spite of having a number of strengths, some limitations are present in using the PAR method for researchers and participants. They are time consuming and it cannot specify

the time for the process because the iterations continues until the problem is resolved. In addition, involvement cannot always be predictable because of local people are not so easy to engage for participation in the research. In general, not everyone in the community will willingly participate in research particularly who survived within oppressed economies and local people may be skeptical about the perceived benefits of the research and as a result, most of them may not want to invest their time and energy (Walter, 2009). It also requires knowledge of community and sensitivity on the part of the researcher to participants' agenda (MacDonald, 2012). It was pointed out that the important issues that must be addressed in employing PAR method in research are power imbalances, misunderstanding regarding the participants' perceptions, social issue, uncertainty or lack of agreement regarding the direction that can lead to the wrong questions being asked. These issues can be resulted in irrelevant data (MacDonald, 2012).

Regarding methods to collect data when used PAR can have various types. It should at least three selected methods be used to transcend the limitations of each individual one. It was suggested that focus groups, participant observation and field notes, interviews, diary and personal logs, questionnaires, and surveys are effective methods of data generation in PAR. It was recommended that to strengthen the data and more effective problem-solving.

To sum up, PAR is an action research methodology in systematic inquiry that focuses on social change. It is a collaborative process among participants and researchers. It empowers the participants and promote their capacity development and capacity building for every participants. In spite of its challenges, it is a valuable methodology in this research because the current situation requires action taking and make changes the condition.

#### **2.2.10. RELATED RESEARCH STUDIES**

Researches regarding the pharmacy practice are important because the services or practices in pharmacy that we delivered make sure an evidence-based service. From these evidences, we can alarm the current conditions, inform the policy makers for effective policies, regulations, guidelines, support and adapt services to better provision for the health and pharmaceutical needs of its people, and educate quality and train the health care professionals such as knowledge and competency of the pharmacists. As quality improvement and medicine

usage in society are very much dependent on the overall quality of healthcare and pharmaceutical system.

Research based in pharmacy practice has been undertaken to explore the relations of various aspects of pharmacy practices to the different key factors such as economic, regulatory, socio-demographic, and pharmacy professional factors etc. Many research works are conducted to explore the pharmacy practices in selling, dispensing, educating and training aspects with regards to policy and regulation and standard guidelines. For instance, a study regarding inadequate regulation and weak enforcement on community pharmacies has shown that cause of death in hospitals by self-medication was 2.9-3.7% due to inappropriate use of drugs that leads to drug-drug interactions (Yadav & Rawal, 2015).

Similarly, many studies in developing countries had proclaimed about poor performance of pharmacy practice. They were (i) illegal selling the wide range of prescription medicines without professional supervision, (ii) insufficient history taking before dispensing the medicines, (iii) lack of referral patients who require medical attention, (iv) sale of medicines that are either clinically inappropriate and/or in doses that are outside of the therapeutic range, (v) sale of incomplete courses of antibiotics and (vi) limited provision of information and counselling to the patients (Miller & Goodman, 2016, Hardon *et al.*, 2004 and Akinyandenu, 2014). These studies showed that inadequate knowledge and training, profit incentives and inadequate enforcement were the main factors that led to inappropriate practice among them.

A study conducted by Kafle *et al.*, 2013 proved that a strategy for training intervention for the individual staffs has significantly impacts on their selling practice for common health problems. They regarded that the basic orientation program should encompass the history taking, advice giving, referral skills and key recommendations about sales practice for common health problems (Kafle, 2013). Therefore, the practice of pharmacy is influenced by many factors and these factors are in turn affected by the organizational context of the pharmacy; trained staffs, counselling, facilities, and the external pharmacy environment; number of trained staff in the research, relevance of pharmacy education to the needs of pharmacy practice, competitive business environment, policy environment (Brata, 2016).

Moreover, a study in Iran investigated the pharmacy systems to evaluate the practice towards GPP (Hanafi *et al.*, 2013). They found that the current situations of Iranian community pharmacists' knowledge, attitude and practice were still need in improvement and they suggested that educational programs should be provided for local community pharmacists by National Pharmaceutical Organizations. A study of Kamuhabwa and Ignace, 2015 was conducted in urban areas of Tanzania for assessing the dispensing skills of drug sellers (regarding about doses, frequencies, side effects, drug-drug interactions and other relevant information on specific tracer drugs) by patient simulation approach method. This kind of research can predict the pharmacy and medicine related services and can obtain the quality of evidence available for pharmacy. They used a list of variables to determine the levels of dispensing skills ranged from low to medium. The results showed that a quarter of the dispensers had low dispensing skills, the majority of them had medium and only small percentage of them had high dispensing skills. This study highlighted about personnel qualification and training programmes on them to uplift their capacity with changing technology, new drug information and treatment guidelines.

In other way, some studies found out various aspects of community pharmacy activities to cover whole pharmacy practices. By Wiryanto *et al.* (2014), the study in Indonesia designed some standard elements of community pharmacy practice to align some more comprehensive pharmacy practice standards intended to use as guidelines for pharmacists in performing profession. They categorized the various aspects of pharmacy's activities from their national legislation and rules of profession into 5 components which were validated as instruments to accommodate standards elements contained in the legislation and the new code of ethics. The aspects of pharmacy activities were professionalism, managerial, dispensing, pharmaceutical care and public health service activities.

On the one hand, some studies approved that setting a set of standards in accordance with step-wise approach can be well-established good practice of pharmacy within certain timeline. For example, the Pharmaceutical Society of Malaysia has prepared a set of benchmarking guidelines to meet the goals of good pharmacy practice in community pharmacies as well as to estimate the timeframe required for these guidelines to be adopted to implement. The guidelines cover five main areas: premises, equipment and accessories, personnel, references

and SOPs with the purpose of promoting the professional standards of practice (Siang *et al.*, 2008).

Another 2 studies have alluded in capacity for the provision of facilities in that a space is essentially required for consultation with the self-medicated patients who met difficult in counselling due to lack of space for this purpose (Brata *et al.*, 2016). Additionally, by Wijesinghe *et al.* (2007), the quality assurance of pharmacy practice was determined through standards such as availability, displaying the pharmacy business license and physical environment statements (adequacy of floor, ventilation, light and availability of water supply).

Nevertheless, adoption of good pharmacy practice principles can solve some of problems and gain some benefits. A study in Thailand announced and proved that implementation of GPP principles could gain benefits in terms of saving cost from different aspects of stakeholders. As a patient, they will gain advantages from pharmaceutical care services and saving cost by reducing drug-related problems. For the regulators, the implementation of this program will be saved the cost of surveillance in 50% and also reduced the workload to inspect pharmacies. For the owners of pharmacies, the benefits will be gained as cost saving in reducing the waste of expired drugs each year (Wuttipanich and Kitisopee, 2015).

All the discussed researches are exploring the interplay between practice and policy. These evidences can inform decisions taken at both countrywide level by policy makers and at the individual level by the healthcare providers in partnership with the patients. Therefore, these researches are aimed to support evidence-based policy and practice of pharmacy. Although the researches based on quantitative approaches regarding to the pharmacy practices and services are many and varied, a few studies were employed qualitative way to explore the pharmacy practice. Since the nature of the present study is also new initiatives for policy implementation, it is necessary to find out the major consequences and implications of new guidelines on community pharmacy.

Therefore, this study uses both quantitative and qualitative methods to investigate the current situations and to explore the different perspectives on new regulation including unforeseen problems and benefits. Since, the current study is trying to develop the GPP guidelines and establish the principles of GPP to local retail pharmacies, the study uses participatory approach for bringing a unique area of expertise in skills, knowledge and



experiences of everyone who concern the using of health service. With the inclusive, it is believed that they can understand the situations in which they find themselves by constructing of new knowledge along with the process and thereby improving their current situations.



## CHAPTER 3

### METHODOLOGY

#### 3.1. INTRODUCTION

As the present study aims to develop the GPP guidelines and its implementation plan in near future at Myanmar for retail pharmacies, it is necessary to address the current situations of pharmacy contexts with all its strengths and weakness. However, there is little studies for pharmacy practice of drug sellers regarding their knowledge, attitude and practice and no study to examine the stakeholder perceptions on pharmacy services that can shape the pharmacy practices. This chapter is organized into three sections. The first section describes a general overview of pharmacy practice in quantitative way. Therefore, the situational analysis was carried out on drug sellers' pharmacy practices. The second section explains how different stakeholders understand the pharmacy roles and practices and how they think the GPP guidelines development and implementation processes. Therefore, the stakeholders' attitudes and experiences towards community pharmacy services, drug-related problems and perceptions towards pharmacy practice is required to investigate for better understanding reasons towards the context of pharmacy health services. As a result, all aspects of pharmacy practices and services from the baseline situation were gathered by qualitative approach and further presented to selected key stakeholders for exploring the facilitators and berries for the development of contents of good pharmacy practice (GPP) guidelines. The last section highlights the way to identify and confirm the optimum conditions for practical implementation of Myanmar's GPP contents which was based on available resources. As a consequence, the contents of GPP for Myanmar were set the priorities with key participants to support the policy implementation of government. The focus group discussion method was used to address the aims of the thesis. This chapter describes different data collection methods used in the study. It explains each method used, explains how the data-collection activities and discusses the choice of participants for each data-collection activity.

## **PART I : Quantitative method**

### **3.2. SURVEY METHOD: USE OF PILOT STUDY FINDINGS TO EXPLORE**

#### **BASELINE INFORMATION OF PHARACY PRACTICE**

Quantitative, descriptive, cross-sectional study was chosen for this initial phase. This pilot study aimed to obtain baseline information of pharmacy practice of retail pharmacies. Information obtained from this phase of the research was then used to develop a questionnaire for qualitative interview in the next phase of the study. This phase is based on 43 registered community pharmacies from three areas of Mandalay Region in Myanmar *viz.*: Pyin Oo Lwin town, Chan Mya Tharsi township (Mandalay) and Kyaukse town.

In order to conduct a survey study in the selected areas, the permission was firstly asked for from the Department of Public Health, Mandalay Region in 2017. After getting the permission, the researcher contacted to the head of each Township Health Department to get a list of all registered pharmacies. With the purpose of recruiting different sizes of pharmacies *i.e.*, large-sized, medium-sized and small sized ones, the samples were collected from both downtown and outskirt areas. With the purpose of covering the entire dry zone, hilly and metropolitan regions, this study chose three different areas from Mandalay Region. Any private registered retail pharmacy that was selling the modern medicines for human target was purposively selected as a participant. With their permission, the potential participants, retail registered pharmacies were contacted and informed in advance. Moreover, in order to invite as many participants of stakeholders as possible, the principal researcher asked a support letter from a non-government organization “Myanmar Retailers Association, Mandalay Regional Office” with the aim of having the private registered retail pharmacies engaged in the research with clear understanding of the purpose of study. As a result, all those who participated in this study and the researcher got rapport before the study was conducted. They were thus willing to answer without feeling frightened. Nevertheless, there were nearly ten pharmacies who have neither a desire to participate in this study nor an interest to have conversation about the study, meaning a denial to participate in. Therefore, our study excluded such kinds of pharmacies. All the participants in this study were informed and contacted in advance before the field visit.

### 3.2.1. Sample area

The Mandalay Region, the center of the country, consists of 31 townships which are organized into seven districts. The regional capital is Mandalay which is the second largest city in Myanmar. According to 2014 census, it has population of 1.225 million people. One of the selected townships assigned as study area I, Pyin Oo Lwin township, is more suburb in character. It is located 42 miles east of Mandalay. It is well-known as a scenic hill-resort with an estimated population of around 255,000 and the area is 1978 square kilometers. It is the largest size of township among study areas. The 37.9% of population resides in rural areas while 62.1% populace in urban areas. It is a good economic center. It also has a temperate climate cooler than the area II and III. People who live in that area could assess health-related services and commodities from Pyin Oo Lwin general hospital, rural health centers, small and large private clinics and retail pharmacies. The assigned area II, Chan Mya Tharsi, is located in south-central area of Mandalay. It is urban in character and a more cosmopolitan character. But it is the smallest area among three selected townships having 25.8 square kilometers. In 2014, this township had a population of 283,781 with 100% urbanization. The weather condition of that area was 21°C in the coolest months of the year, normally in January and February while in April and May, the hottest months in Myanmar, the temperature ranged from 35°C to 40°C. As this area is one part of Mandalay city, it is a major center for health facilities for Upper Myanmar with large public hospitals and private hospitals. It also has the highest number of pharmaceutical outlets, compared to other townships in the Mandalay Regions. The assigned area III, Kyaukse township, is a more rural but easily accessible township of medium size having 1878.5 square kilometers. It was the capital of Kyaukse District in central Myanmar of Mandalay Region. It is about 26 miles far away from Mandalay and also has the same weather as Mandalay. A population of 257,907 resides in that area with 16.1% urbanization. This area has one general public hospital, a rural health center and quite a number of private clinics (Department of Population & Ministry of Labour, Immigration and Population, October 2017).

### **3.2.2. Sample size**

The study population was 43 registered pharmacies from three aforementioned areas.

### **3.2.3. Study period**

The data were collected between a period of three weeks from July to August 2018.

### **3.2.4. Measurement tools**

The owners or their representatives were asked to answer a set of structured questionnaires related to the pharmacy layout, atmosphere of pharmacy, the staff employment and their personnel status, the practices of pharmacy staffs and quality assurance process of pharmacy's structure. A checklist of quality audit indicators as per good pharmacy practice guidelines was also used to assess current situation of pharmacy practice in local retail pharmacies. It was designed and formulated by reviewing literature on pharmacy practices of different countries and Myanmar National Drug Law (1992). The GPP guidelines was mainly based on WHO/FIP framework. The checklist used in this phase was mainly referred to Nepal's Pharmacy Practice guidelines. This was used as a major prototype because the situations of both Myanmar and Nepal are in similar cultural habitats, geographic locations and socio-economic status. Nevertheless, prior to the study, all the questionnaires were evaluated by two academic researchers in Silpakorn University, Thailand; qualitative and quantitative experts for validity and reliability, and for the effective capture of the topic under investigation. This formulated checklist was used as a tool for evaluating the current situations of pharmacy practices and for comparing standards to identify some gaps. From this baseline information, the study figured out which practices needed uplifting to meet the international standards.

### **3.2.5. Data collection method Pharmacy Visits:**

With regard to data collection, a personal visit to each registered retail pharmacy was performed during their normal working hours in order to survey how they were running the

pharmacies and to acquire the physical facilities and equipment in pharmacies. The samples recruited in this section were located near hospital, markets and business hub with the purpose of capturing a comprehensive picture of pharmacies that are distributed across different locations. Fulfilling this objective of the study and establishing the rapport with them, the principal researcher had visited more than one time and introduced herself before starting the study. On the day of the interview, the researcher and the colleague asked the participants to give their spare time. Then the purpose of the study was explained to facilitate the process and a neutral environment was created without a feeling of tension. Once they understood the purpose of the study, then interview was started. Some interviewees were pharmacy owners while others were the responsible persons while their respective owners were absent in the pharmacies. They were interviewed further to get more information on personnel qualification, staff employment, training process on staffs and how they managed their pharmacies. Two pilot studies were conducted to test the understanding of questionnaires and revised them whenever necessary. Those pilot study samples were skipped and thus not included in the study result.

The surveying time for each pharmacy normally took from half an hour to one hour. The interpretation of results was done by objectivity or subjectivity of things accordingly. If the domains in checklist were noted as objectivity, it was remarked in the checklist whether in compliance or not. The subjectivity of each pharmacy practice was observed independently between researcher and colleagues. If the results were agreed by both, then it was taken as confirmed data. Otherwise, the unclear results were confirmed by third person's observation. She herself independently observed and made the situation clearer. However, there was not having too many things disagreement between principal researcher and the colleague. In this way, the baseline study was conducted to analyze the current situations of pharmacy practice in local retail pharmacies in Myanmar. The checklist questionnaires and consent documents are presented in Appendix.

### **3.2.6. Data collection tools**

In order to determine the current practice of each pharmacy, a standard checklist containing questionnaires, field note and an audio-recorder were used as data collection tools. Permission for recording was firstly requested and the consents were obtained. However, most of the participants did not grant permission to record the interview and, therefore, only field notes

were taken down on paper. Along with the principal investigator, there was one pharmacist and a non-pharmacist research assistants who had sound backgrounds of science and underwent repeated practice for observation of pharmacy practice by using the questionnaires. They were trained for over an hour to understand the questionnaires. Not only the questionnaires, the principal investigator and the colleagues served as one part of research tools to collect the data.

### **3.2.7. Data Analysis**

The data collected from the study were conceptualized into four aspects according to the WHO guidelines; (i) the facilities of pharmacy, (ii) the personnel and training of pharmacy staffs, (iii) the practices of staffs and (iv) quality assurance process of pharmacy. They were tabulated into an excel worksheet and descriptive analysis was performed. They were then assigned into three groups depending on the extent to which the drug stores comply with the standard audit checklists. The first group shows frequency and percentage of drug stores which comply with the standard of good pharmacy practice guidelines whereas the second group goes into the group of those trying to keep good practice with their available resources and it can be regarded that their practices were acceptable to a certain level but still have not met the good pharmacy practice standards. The final group represents those drug stores that do not comply with the good pharmacy practice at all.

### **3.2.8. Ethical issues**

The ethical issues of this study were verified and approved by the Ethics Review Committee from Department of Medical Research under the Ministry of Health and Sports of Myanmar with the ethical review no. Ethics/DMR/2018/098 issued on 6 July, 2018.

## **PART II : Qualitative methods**

This research employed two types of qualitative research methods; semi-structured interviews and nominal group discussion. First, a numbers of in-person semi-structured interviews were used to explore the role of retail pharmacies in each local area encompassing the advantages and disadvantages of their practices, the events within pharmacy atmosphere regarding the drug-related problems of participated stakeholders and their perceptions towards pharmacy practices, GPP guideline development in Myanmar and its implementation. Second, a

nominal group discussion was used to select and prioritize several recommendations which were developed from the findings of the previous interviews. The qualitative group discussion method was chosen in this study to explore social interactions with retail pharmacy settings and gain an understanding of the human experience, attitudes and behaviour of the stakeholders such as pharmacy staffs, owners, pharmacists, professionals and patients as well as the underlying factors influencing their attitudes and behaviours.

### **3.3. CONDUCTING IN-PERSON INTERVIEWS: EXPLORING THE ROLE OF RETAIL PHARMACIES INCLUDING ADVANTAGES AND DISADVANTAGES OF PRACTICES, THE EVENTS OF DRUG-RELATED PROBLEMS AND PERCEPTIONS TOWARDS PHARMACY PRACTICES AND THE IMPLEMENTATION OF GPP GUIDELINES**

A cross-sectional qualitative approach was conducted with 62 informants, during July to September in 2018, to understand the stakeholders' experiences and their perceptions towards (a) role of pharmacies in Myanmar, (b) drug-related problems and (c) practices of pharmacy staffs. Individual in-person interviews were conducted by using semi-structured interview guide to collect data. From the personal interviews, it was found out how they perceived and expected the roles of pharmacy and how important the practices of pharmacy was to them, how they felt on service provision from the pharmacies and how much they expected the pharmacies to be good ones. They included regulators (administrator, inspectors), professionals (prescribers, pharmacists, nurses), lay people (customers, patients and patient attendants), pharmacy owners and staffs from pharmaceutical companies. The details sociodemographic data of each stakeholder were listed in table 6. The number of participants from respective town is 18 from Pyin Oo Lwin, 32 from Mandalay (Townships of Chan Mya Tharsi, Mahar Aung Myae and Chan Aye Thazan, Aung Myae Thazan and University of Pharmacy) and 12 from Kyaukse.



### 3.3.1. Sample area

#### Area I : Pyin Oo Lwin

A total of 18 participants were recruited from this area I, including such kinds of stakeholders: 12 patient attendants, 1 administrator, and 5 pharmacy owners. From the previous visit at Pyin Oo Lwin town, the data recorded by Township Health Committee showed there were approximately 50 registered private retail pharmacies in 2016. On the first day of visit for interview during March 2018, the researcher and her colleague went to administration office of Department of Public Health, Township and District level of Pyin Oo Lwin, Mandalay Region to meet the head of local administrator in order to clearly understand the current situations of law enforcement and regulation and to share his experiences and opinions. He was around 39 years old and he takes the roles of execution of public health measures and planning process for public health crisis control. The team of administration also takes the role of issuing the licensing process for retail pharmacies and regulatory inspection visits of pharmacies' activities together with cooperation of members of Food and Drug Supervisory Committee. When we met, he managed the place to sit our interview. He was active and discussed anything with him willingly so far. So we did not face any problem during the interview. The interview took around one hour to complete because no new issues was emerged during our conversation.

At another day, the researcher and her colleagues (one colleague for one time visit) went to a chief of retail pharmacies (informal administrator) who takes the roles of maintenance of social norms and as a point of liaison between local retail pharmacies groups and state institutions such as providing information awareness of FDA and local administrative office to other people. He was over 55 years old. He said he did not want to take this role for these years because he was too old now. He assumed this position when he was a young. He has completed the high school level and currently his experiences for running the retail pharmacy was over 40 years. He is kind and hospitality. His pharmacy was a small size one, around 8ft x 10ft having a small front counter open to main road near the corner of the street. It was located near a bizarre. He displayed all the medicines in shelves with glass windows and a counter to keep clean and tidy. When we explained about the purpose and scope of the study, he seemed eager to appoint a date for a meeting with other potential participants from pharmacy owners. With the help of him, I make a connection with other five local pharmacy owners who enable to give opinions and

interest to participate in the study. According to his sayings, more than half of the pharmacies were concentrated in downtown area and the rest were uneven distribution across the local area. He also said there were many unregistered vendor shops and groceries that sell drugs illegally in this town and it could be difficult to collect the data and persuade them to commit to participate in interview. Therefore, this group of unregistered shops was excluded from the study.

Again, to reflect accessing the pharmaceutical services of local people, a purposive sampling technique was used to include diverse stakeholders such as patients, customers. As a result, many days later, we contacted to the 300 bedded District hospital through local Township Committee with the permission letter from the Department of Public Health, Mandalay Region. It is the largest hospital in center of the town for provision of health care to patients in need. Another small circuit hospitals localized in outskirts of town are the major health care facility for local people in its region and vicinity. We went to see the director of that hospital to ask oral consent for conduction of interview with patients in hospital. So, we explained the purpose and scope of the study. She was in a sociable mood on our visit to hospital and she let an officer of hospital to manage the interview section for us. Then the officer arranged a very comfortable room for interview section with patients who currently attending the hospital. She invited around 20-30 patients who enable to share their spare time and interest in interview study. However, the patients themselves could not participate in interview study. Instead, their relatives and family members came to join the interview section. They were from surgical ward, OG ward and medical ward. There were initially 12 patient attendances joined the interview who were willingly to participate and shared their spare time. I informed the participants that there were no special legal relationships between researcher and government offices. We shared the purpose of study in order to facilitate the process and explained this study was not to find fault but to provide better conditions for pharmacy atmosphere and contribution of everyone was important in data provisions. After they agreed, every participant was given a consent form to read and sign. However, they concerned that they were unfamiliar with audio recordings of interviews. They afraid that their responses on questions might be wrong or be actioned when they revealed anything negative attitude towards questions in confidence. As a result, we conducted the interviews with them in a friendly and non-threatening environment to feel ease more and talk freely without recording. The participants have been told in advance that the interviews would be lasted

around 30 to 40 minutes. All the interviews were engaged to anonymously answer questions and to explore opinions to get the full picture of the phenomenon. All the interviews were conducted with the assistance of my colleague and filed notes were recorded during and after interviews. So we needed many more time to do for record for each participant. On the twelfth participant, we stopped interview as we thought the data were saturated because no new ideas and information were obtained from the data collection.

### **Area II : Mandalay area**

A total of 32 participants were contacted and recruited as potential informants from this area II, including such kinds of stakeholders: 10 patients, 9 prescribers, 2 nurses, 4 pharmacists, 1 drug inspector, 2 pharmaceutical company staffs, 2 pharmacy owners and 2 special cases of pharmacy owners. From the previous visit at Chan Mya Tharsi Township, the data recorded by Township Health Committee showed there were approximately 200 registered private retail pharmacies in 2016. On the first day of visit to Township Health center, we met township officer at her office. We explained about the purpose and scope of the study, she agreed to conduct the study in this township. She recommended some pharmacy owners who might have potential informants for my study. So we noted the addresses and names of retail pharmacies that she recommended. We also included the pharmacy owners from Chan Mya Tharsi Township who once participated in the previous pilot study for interview section. We therefore contacted to potential pharmacy owner either on phone or in person individually. Two owners from the recommended pharmacies and one owner from pilot study were therefore recruited as potential informants for my study. They all were willingness to response to interview. Other owners from Chan Mya Tharsi Township were reluctant to participate in the interview and they said they were too busy to spare their times and not interested to have conversation. Therefore, this study excluded such kinds of participants who had not reached consensus. In addition to current location, two additional pharmacy owners from Chan Aye Thazan Township were contacted to participate in the study. They have complied with the standards as they were trying to establish the GPP concepts in their pharmacies in their own ways. One of the owners was a pharmacist who trying to provide the quality service to his customers.

Again, to reflect accessing the pharmaceutical services of local people, a purposive sampling technique was used to include diverse stakeholders such as patients,

customers. In this area, the research team tried to contact private clinics located in Chan Mya Tharsi Township. Unfortunately, we did not get any connection with many private clinics near a month and it was unable to reach a consensus on the best way to collect the outpatients for interview. However, we luckily got a chance to conduct the interview with patients from a nonprofit private clinic which was funded by charity funds run by religious based society. It gave permission to conduct the interview study. From this small clinic, a total of ten outpatients were recruited as potential informants during their wait for the prescribers. They were asked to participate in the study based on their own willingness and their spare time, and to provide detail information about the role of pharmacies and their experiences on using it. The participants were informed that participation was voluntary and they could withdraw from the study at any stage. To understand the professional attitude towards roles of retail pharmacies, some of the specialists, general practitioners and nurses with different working experiences were also contacted to contribute their experiences regarding the drug-related problems of patients and perceptions towards pharmacy services. Our study recruited the healthcare providers from both private and public sectors. The prescribers and nurses from private sector were recruited from both a profit hospital and a non-profit clinic. During the visit to a privately owned non-profit clinic, we had met a prescriber who voluntarily worked for 3 or 4 years in this clinic. After he had gone off duty, we had a chance to interview with him after receiving the oral consent. We friendly talked rather than formal interview. Another visit to public hospital in Chan Mya Tharsi Township area, we went to a 300-bedded Teaching hospital during the office hour to ask oral consent for conduction of interview with some prescribers in hospital. We waited their free times in hospital where they provided a room to us then after they free, we could meet. There was a total of seven potential participants from prescribers who working in public hospital. However, we could not meet all potential participants who has already contacted with telephone. As they were busy and they worked at different duty roster, they did not provide their time in hospital for interviews. Instead, they asked the interview guidelines to take home and made an appointment with them on telephone later. As a result, in this study, we could interview with only one prescriber in-person at hospital. Another six prescribers from public hospital were conducted interviews on phones. Furthermore, on the day of visit to a private hospital during April 2018, we had formerly contacted on phones to ask oral consent for conduction of interview with prescribers and nurses in

that hospital. A prescriber and two nurses with different working experiences were recruited based on their own will. We appreciated them for sparing their valuable time, experiences and revealing their perspectives and suggestions. However, this study site was not included in the proposed areas previously. Nevertheless, this private hospital has contacted to research team and they informed that they agreed to participate in the study. It was located in Mahar Aung Myae Township. As a result, the permission to collect the data and ethical issues for this area were further approved from the office of Department of Public Health, Mandalay Region and Ethics Review Committee from Department of Medical Research under MOHS respectively, with extended ethical review no. Ethics/DMR/2018/098A/2018 issued on 17 August, 2018.

Moreover, in order to include pharmacists' attitudes towards current pharmacy services and their experiences and perceptions regarding the pharmacy practices of retail pharmacies, 5 pharmacists from academic section were contacted to invite to participate in the interview. However, 2 pharmacists replied that they were busy to spare their times and one of them said she was not interested to have conversation for this topic. She said she felt that it was sensitive topic for her and the questions were reluctant to respond as anything negative attitude towards questions in confidence might be affect to her. So she did not accept the invitation for interview. Both of them were excluded from this study because they had not reached consensus for this study. The recruited academic pharmacists were with different designations and working experiences. They were willingly to participate to share their opinions on pharmacy services, current situations of pharmacy education and pharmacists' role in Myanmar. Furthermore, the pharmacists from a private hospital and a community pharmacy were purposively selected for this study. As a result, the researcher contacted to each pharmacist and invited on phone to join the interview. After they all agreed to participate in the interviews, the appointment dates were fixed for individual participant.

One of the stakeholders, the administrator(s) or drug inspector(s) were purposively recruited for the study to clearly understand the current situations of law enforcement and regulation on retail pharmacies and to share his or her experiences and opinions towards pharmacy practices in his or her local area. Before the study was conducted, the researcher and colleagues contacted all regulators from each township (totally 4 townships in Mandalay area) in person to get their consent for the interview. However, three of them refused to participate in the

study, giving the reasons that they were busy. Besides, they refused three times to make appointments for the interview. Therefore, they were excluded from the study. The only one participant taking the role of drug inspector as well as administrative assistant from the township health center from Aung Mye Thazan had agreed to join the interview. The participant of that township health center provided the current situation of pharmacy registration system and current trend of enforcement and regulation regarding the pharmacy practices.

In order to explore the attitudes of pharmaceutical companies towards the current

trend of pharmacy service, the researcher contacted to a manager of big pharmaceutical company at Aung Myae Thazan Township. We explained the purpose and scope of the study. He allowed to conduct the interview with his staffs including pharmacist and non-pharmacist. As a result, it was luckily to get a chance to interview with staffs and grabbed about their experiences and perceptions regarding the pharmacy practices of local shops. After the participants agreed to participate in the interviews, the appointment dates were fixed for individual participant. However, the interviews were conducted through phones as we cancelled two times to make in-person meet for the interview.

### **Area III: Kyaukse area**

A total of 12 participants from this area were participated in the interview study. The study was conducted within the end of March and first week of April in 2018. Initially, we contacted 15 participants and recruited as potential informants from this area III, including such kinds of stakeholders: 10 customers, 1 local administrator, 1 pharmacist and 5 pharmacy owners. However, during the visits to pharmacies, many customers were reluctant to participate in the interview and denied without giving any reason. Therefore, only 5 customers were included in this study who offered oral consent. The research team also contacted to Department of Public Health, Kyaukse District. On another day, we went to the administration office of Department of Public Health which is located in the General hospital compound. It administered the Township and District level of Kyaukse area in Mandalay Region. The chief local administrator was busy during our arrived time and he allowed the local drug inspector to take part in interview. She was recruited as potential informant who provided information relating to current situation of local practices of pharmacy and current trend of enforcement and regulation of that area. She was

willingly to response to interview and she also helped us to meet some pharmacy owners who were potential to take part in our study. Therefore, she went with us to some pharmacies which based on the inclusion and exclusion criteria of the sample that we previously explained our objective of the study. She introduced the pharmacy owners of local people and we explained the purposes of the study. Some pharmacy owners were once participated in the previous pilot study. So they were invited to participate again in the study. We had formerly contacted to ask oral consent for conduction of interview with them. However, some owners felt reluctant to have conversation with strangers. They refused to take part in study as they said they were too busy to spare their times and not interested to have conversation. As a result, we visited another pharmacies until we reached consensus. The participants were informed that participation was voluntary and they could withdraw from the study at any stage. Finally, a total of five local owners were recruited as potential informants for this study area. We also had a chance to meet a pharmacist who working in that hospital. So we contacted to a pharmacist and invited on phone to join the interview. She agreed to participate in the study and provided the information concerning drug-related problems and pharmacy practice of that area.

### **3.3.2. Measurement tools**

Semi-structured in-depth interviews were conducted with the aim to clear understanding of stakeholders' experiences towards pharmacies' role in healthcare section, pharmacy services, knowledge of local health practices of pharmacy staffs and drug-related problems among them. A great benefit was obtained through direct contact between interviewer and interviewees while collecting the data. From the personal interviews, it was found out how they perceived and expected the roles of pharmacy and how important the practices of pharmacy were to them, how they felt on service provision from the pharmacies and how much they expected the pharmacies to be good ones. Before starting the interviews, the permissions for recording were requested first and then consents were reached. If not permitted, field notes were taken down on paper in order to help in analyzing the gathered data. Each interview lasted approximately for 20-30 minutes. During conducting the interview, the participants felt comfortable and friendly, and thereby conversations flowed smoothly and they freely expressed their experiences and views.

### **3.3.3. Data collection tools**

During the interviews with the participants, the semi-structured interview guide, field notes, audio-record and sketches were used as collection tools. However, most of the participants did not grant permission to record the interview and, therefore, only field notes were taken down on paper. The principal investigator and the colleagues served as one part of research tools to collect the data. The interview guide will be focused on the role of pharmacies in Myanmar, the history or experiences of drug-related problems caused by dispensing practices of pharmacy, perceptions towards current situations of pharmacy and its practice and principles of good pharmacy practice. Before conducting the study, the questions were evaluated with two academic researchers, qualitative and quantitative experts from Silpakorn University (Thailand), for validity and reliability and assessed for whether the questions effectively captured the aim of the topic under investigation.

### **3.3.4. Data Analysis**

During the period of June to September 2018, the data were analyzed together with two researchers from Faculty of Pharmacy, Silpakorn University at Thailand. Thematic content analysis was used to analyze the data. The recorded field notes were used as information to analyze the themes and disseminating the findings. The interviewed verbatim were translated into English and transcripts were verified by the two persons of experts in English and pharmaceutical terminology from Myanmar. For the validation of data, the contents of interview transcripts were reviewed repeatedly for familiarizing the data in its entirety. The transcripts were read more thoroughly, analyzed line by line to make notes of thoughts and writing summaries of each transcript. The initial codes of themes were applied to each section, sentence or word as they emerged in the data. Then all the data were condensed into key themes. Correlation and links between and among themes were identified and reviewed repeatedly for every category assigned to the data. For reducing and interpreting the data, the identified themes were organized into logical and meaningful categories (Bader, 2017). The data were analyzed over and over to get agreement on the content identification with expert researchers from faculty of Pharmacy, Silpakorn University, Thailand. They all assessed the content validity of the context and then



agreed the finalized themes. The results were transcribed as a draft report of findings to provide a baseline information for next step of the study.

### **3.3.5. Ethical issues**

The ethical issues of this study were verified and approved by the Ethics Review Committee from Department of Medical Research under the Ministry of Health and Sports of Myanmar with the ethical review no. Ethics/DMR/ 2018/098A/2018 issued on 17 August, 2018. All the participants were informed about benefits of the study by their participation rather than provision of incentives. All participants were served a meal during their time for rewarding their effort. Some participants were compensated travel expenses while some pharmacy owners were provided the technical support and advices. They also received the feedback about results of the study and reference books related to good practice of pharmacy. The research was started only after ensuring grants in written consent form from all participants. As they were part of the research process, they were important to honor the rights and freedom of all individuals. They were thereby regarded as co-investigators for sharing their ideas rather than subjects.

### **3.3.6. Confidentiality and data security**

The valuable collected data, both soft and hard copies, were stored privately and safely to ensure the confidential issues throughout the data collection and usage. Completed questionnaires, recordings and transcripts of study sites were securely stored and not left openly in any place. They were prevented from easy access to other people. It ensured safekeeping the data during the research process. Reduced risks of data loss hence increased verifiability. At the end of the study, the data of fieldwork were destroyed in a safe way. In case of paper, they had been shredded and in case of computer file, they had been permanently deleted from all recorded systems.

### **3.4. FOCUS GROUP DISCUSSIONS (FGDs)**

#### **3.4.A. A Qualitative Study**

##### **3.4.1. Round 1: Ascertainableness of GPP contents**

To address the objectives of the phase II study, a qualitative study was performed with different groups of selected stakeholders encompassing customers, regulators, pharmacy owners from rural and urban areas and academics. Group discussions were conducted during January and February 2019 as the first time for identifying the issues that associated with GPP implementation process.

The focus group method was chosen for this study because it allowed access to express views, opinions, experiences and attitudes of the participants which helped the researcher understand how they interpret their perceptions. The stakeholders were purposively recruited from both formal health sector (pharmacists and regulators) and informal health sector (pharmacy owners and customers). A total of eight focus group discussions; of which four were conducted as group discussions with 7 customers, 9 pharmacy owners and 6 academic staffs including non-pharmacists and pharmacists. Another four were conducted as individualized interviewed with 2 key regulators and 2 owners during January and February 2019. The interview topic guide was based on a collection of most frequent identified issues from previous interview phase. They were asked to clarify the factors that effect on the implementation of GPP guidelines in Myanmar and propose the optimum conditions of the guidelines in implementation stage.

##### **3.4.1.1. Sample area**

The participated pharmacy owners were recruited from Mandalay Region and Pyin Oo Lwin town. They were participated since pilot and previous interview studies. They had eager to participate in focus group discussion. The customers were collected from Chan Mya Tharsi township of Mandalay Region. For special case studies 1 and 2, the key informants were recruited from Chan Aye Thazan Township of Mandalay Region. The University of Pharmacy was also one of the places.

### **3.4.1.2. Sample size**

A total of 26 participants were purposively collected for focus group discussions with the aims of exploring the barriers and facilitators in a set of GPP guidelines development. The discussion sections were conducted eight times with separate groups based on similar experiences and backgrounds to minimize the power differences. Each focus group discussion group contained between 5 and 7 participants; however, some group discussions were individualized interviews rather focus group discussions as in regulators and a special case of pharmacy owners. The discussions were lasted from 30-50 minutes.

### **3.4.1.3. Study period**

A period of nearly 2 months (from January to February 2019)

### **3.4.1.4. Sampling techniques**

Sampling was purposive for pharmacy owners, academics and regulators while for customers, convenient sampling was employed with inclusion criteria of participants with experiences of using pharmacy. Inclusion criteria of participants comprised any customers, pharmacy owners, academics and regulators with willing to participate in the study and in addition, those for who enable to give their spare time, opinions and suggestions were regarded as sampling units. The selected participants were initially contacted by phone and invited to take part in group discussions. Arrangements were made with those who agrees. The discussion sections were organized in a private, comfortable place to feel ease more and talk freely with minimum risks of threatening feelings. Each participant received a summary of the previous study.

### **3.4.1.5. Measurement tools**

Semi-structured interview guide was constructed based on identified gaps from previous step which was analyzed the current situations of retail pharmacy contexts in Myanmar. Prior to the group discussion, the contents of semi-structured interview guide were evaluated by two academic researchers from Faculty of Pharmacy, Silpakorn University in Thailand for effective capture of the topic under investigation. The interview guide covered the

optimum ways to achieve GPP implementation and analyze the barriers and facilitators in implementation process of GPP guidelines. Using this semi-structured interview guide, each stakeholder' ideas on planning of GPP establishment was explored and identified the contents of GPP guidelines from their point of views with the guidance of GPP principles.

#### *3.4.1.5.1. FGD questioning plan for pharmacy owners*

The focus group questions for pharmacy owners were assessed particular aspects of their expectations if the government run the GPP in practice and what can they do for these changes. The following semi-structured questions summarize the focus group questioning plan for pharmacy owners and explores their attitudes, beliefs, motivations and barriers associated with GPP implementation.

1. *How do you think that which steps should be implemented (perhaps the government may start immediately or not) and could be started now, later and future? Please specify them!*
2. *How would you like to get support from government for GPP program?*
3. *How would you like to suggest the government to achieve GPP in Myanmar?*

#### *Recruitment*

A total of four focus group discussions were conducted with pharmacy owners from both rural and urban areas of Mandalay Region. The four group discussions were (i) one with owners from suburban area and consisted of 4 participants, (ii) one with owners from urban area containing 5 participants, (iii) one with the owner from urban area who has established the GPP concepts without professional view and (iv) the last one with the pharmacist owner who has established the GPP concepts with professional view. The research method for those individual cases can be said in-depth interview rather than group discussion. The selected pharmacy owners from suburban and urban areas were invited for focus group discussion from the previous interview section who had still willing to join the study. The additional question guidelines for two special cases of owners were aimed to explore the experiences of their journeys and attitudes towards established good system of their pharmacies. The first person can be said he was the pioneer to establish the GPP system for his pharmacy. The second owner was a pharmacist and he was trying to improve his pharmacy service for customers. He was currently

acting as a secretary member of Myanmar Pharmaceutical Association (MPA) as well as a secretary general of Myanmar Retailers Association. The additional question were:

1. *What is your inspiration to run your pharmacy like this?*
2. *Why did you run your DS this way? Other people are easy to run it but you don't. Why?*
3. *In real situation, there are many kinds of customers. You can face the customers like "I need these and I will pay right now and get my medicines". How can you deal with that kind of customers?*
4. *If the patients will prioritize the price first, then many DS are jumping into the price world. What do you think about this?*
5. *How do you think about Pharm care? Do you think that all DS can provide Pharm care to customers?*

#### *3.4.1.5.2. FGD questioning plan for customers*

The focus group questions for customers assessed their expectations on what kinds of pharmacy do they want to be in future and what kind of service do they want to get from the pharmacies and their opinions on how government should regulate on pharmacies. The following semi-structured questions summarize the focus group questioning plan for customers and explores their attitudes, beliefs, and perceptions towards quality pharmacies.

1. *Which aspects of personnel / staff quality status would you like to be in pharmacy?*
2. *What would you like to pharmacy (drug store) to be in your mind? How they can become quality drug stores?*
3. *How would you like to government should be regulated on pharmacies? Why?*

#### *Recruitment*

Only one focus group discussion was conducted with customers from Chan Mya Tharsi Township, Mandalay area in this study. The stakeholder for customers were recruited from the neighbours who had experiences of using pharmacies (drug stores) with different purposes. In this study, there was seven participants in a group discussion. It was difficult to persuade a customer during their pharmacy visit because they felt reluctant to have conversation with strangers. Moreover, it was quite hard to schedule an interview appointment

together on the same date and time. That is why the participants were purposively selected with three inclusion criteria that was based on willing to join the study, enable to give their experiences and suggestions and beings users of pharmacy services with different purposes. They were invited to interview by asking the oral consent and the approval of the request is valid for 2 weeks. Then the selected participants were encouraged to schedule the group appointment as soon as the request is approved.

#### *3.4.1.5.3. FGD questioning plan for academic pharmacists*

The focus group questions for pharmacists were assessed their expectations on barriers for roadmap of GPP implementation and their opinions for filling the gaps and suggest the ways to achieve GPP in Myanmar. The following semi-structured questions summarize the focus group questioning plan for pharmacists and explores their attitudes, perceptions and suggestions towards establishment of GPP principles.

- 1. How can you fill the gaps about Human Resource (HR) as a University of Pharmacy?*
- 2. How university can support in GPP guidelines implementation process?*
- 3. How can suggest the government to achieve GPP in Myanmar?*

#### *Recruitment*

Only one group discussion was conducted with six members of academic staffs from University of Pharmacy Mandalay in this study consisting of one rector and four pharmacists and one non-pharmacist teaching staffs with different designations and working experiences. The academic pharmacists were recruited as key participants for group discussion section because the identified gaps from analysis of previous phase I study were related to the human resource, current situations of pharmacy workforce and pharmacists' roles in Myanmar. Under the Department of Human Resource for Health, the two Universities of Pharmacies were important sources to produce healthcare providers for healthcare system and technical supporters for GPP implementation, who are pharmacists. Since the identified gaps were mainly related to the places where human resource production, the academic pharmacists were recruited for provision of better information for clarify the factors that effect on the implementation of GPP guidelines in Myanmar and propose the optimum conditions of the guidelines for implementation. All of them had reached consensus for this study. They were invited to interview by asking the

oral consent and the approval of the request is via the official letter before setting the group discussion. Then the selected participants were encouraged to schedule the group appointment as soon as the request is approved.

#### *3.4.1.5.4. FGD questioning plan for regulators*

The research method for the regulators can be said merely individual in-depth interviews rather than focus group discussions. The interview guidelines for regulators from FDA were clarified the roles of FDA for GPP program in support of pharmacies, the barriers of practical ways to implement the GPP program and how do they plan to establish, develop and sustain this program. The following semi-structured questions summarize the interview questioning plan for regulators and explores their attitudes, perceptions and plans towards establishment of GPP principles.

1. *What are the roles of FDA in support of DS for GPP program?*
2. *What is your opinion on classify the DS? What difficulties will be met when classified them?*
3. *How would you like to establish, develop and sustain GPP standards?*

#### *Recruitment*

Since the beginning of the study, the research team contacted to regulators from Department of Food and Drug Administration who were in the administrative level from Central and Lower Myanmar. They were acting as administrators as well as policy advocates for GPP program. Since they were in the upper level of administration, it was quite hard to schedule an interview appointment together on the same date and time. As a result, informal individual in-depth interview was requested for each participant to interview by asking the oral consent. A privately two interviews were conducted for this stakeholder. The approval of the request is valid for 2 weeks before setting the interview date. Then each interview was scheduled as soon as the request is approved.

#### **3.4.1.6. Data collection method**

A qualitative method of small group discussions was adopted. This approach employed the situational analysis of current situations from the phase I study and informed identified gaps to the selected stakeholders for exploring and capturing feedback, took the agreement on situational analysis and perspectives of them towards development of contents

in GPP guidelines. From these group discussions, the barriers and facilitators were analyzed in guideline development and performing good practice.

#### **3.4.1.7. Data collection tools**

During small group discussions, filed-notes, sketches and audio-records were used in case of agreement for analysis. The researcher and the research assistant were also one of the research tools to collect data.

#### **3.4.1.8. Data Analysis**

Thematic content analysis was used to analyze the data and the steps involved in analyzing the data were the same as previous interviewing section.

#### **3.4.B. A Quantitative Study**

#### **3.4.2. Round 2: Prioritization the issues and develop an implementation plan of good pharmacy practices in Myanmar**

During June and July 2019, five FGDs consisting of pharmacies owners, regulator and academic pharmacists were held as a second round for setting the priority to develop an implementation plan of GPP guidelines that incorporates contextualized strategies in accordance with findings from previous step. This study phase was aimed to develop strategic planning for implementation of Myanmar GPP guidelines in registered retail pharmacies. Similar criteria were employing when choosing the participants for the focus groups. The priority setting methods were based on the guidance of WHO's national health strategies concept (Schmets, 2016), Montorzi *et al.*, (2010) and similar studies (Vogel *et al.*, 2016, Kaporiri and Norheim, 2004, Baltussen and Niessen, 2006, Azeredo *et al.*, 2014, Youngkong *et al.*, 2012, Schey *et al.*, 2017), to ensure the implementation of guidelines in Myanmar. Relevant local approvals were obtained in each group. The contents of GPP were prioritized in terms of importance and practical ways along with the expected timeline then ask them to assign weights to each element. Then these elements were ranked based on stakeholder values. The participants qualitatively appraised, deliberated and reached consensus on which strategic plans should be adopted based on timelines. This document



was assumed to be a draft protocol with local adaptation where required aiming to propose it to responsible authorities for review and approve it.

#### **3.4.2.1. Research design**

To address the objective of the phase II study; ascertainableness of GPP contents, prioritization the issues and develop an implementation plan of good pharmacy practices, second round of focus group discussions (FGDs) were conducted with selected stakeholders from formal health sector in three different groups; regulator, academics from pharmacy and pharmacy owners.

All the selected key stakeholders were being invited from the previous interview section. A mix-methods (qualitative and quantitative) study design was used to conduct for a total of five focus groups discussions comprising 5 pharmacy owners from urban area, 6 pharmacy owners from rural area, and 2 academic pharmacists while 1 key regulator and 1 pharmacy owner were individualized interviewed during June and July 2019. Demographic data of the participants are shown in Table-13. The majority of the participants were male (66.67%). The participants were middle-aged adults (range 38-63 years) had a high-school level of education to graduation with basic sciences or pharmacy or medical degrees.

#### **3.4.2.2. Sample area**

The participated pharmacy owners were recruited from Chan Aye Thazan Township of Mandalay Region and Pyin Oo Lwin town. The University of Pharmacy was also one of the places.

#### **3.4.2.3. Sample size**

A total of 15 participants from formal health sectors were purposively collected for focus group discussions with the aims of identifying priorities, discussed factors affecting the implementation process and developing an implementation plan that incorporates contextualized strategies in accordance with findings from previous step. Each, in-persons, focus group discussion group contained between 2 to 6 participants and discussions were lasted from 1 hour to 1 and a half hours each. Some exception focus group discussions were conducted with individualized discussion rather than group discussions as in a regulator and a pharmacy owner.

#### **3.4.2.4. Study period**

A period of nearly 2 months for data collection process (from June to July 2019)

#### **3.4.2.5. Sampling techniques**

##### *Recruitment*

Key participants were identified through purposive sampling from previous FGDs section with the aim of incorporating the perspectives from a diverse stakeholder including academics (Upper Myanmar), pharmacy owners from rural and urban areas and an administrator (higher level from Central Myanmar). However, some of participants of regulator, owners and pharmacists from previous FGDs were dropped out from the study because they were not willing to attend on. As a result, a total of five focus group discussions were conducted with 2 groups of pharmacy owners from both rural and urban areas of Mandalay Region, one group discussion was held with 2 participants from University of Pharmacy, Mandalay, one with a pharmacist owner and one with an administrator who were in high level.

#### **3.4.2.6. Measurement tools**

Focus group discussions (FGDs) provide the opportunity to explore issues in more depth than can usually be achieved through a survey. In round 1 qualitative focus group discussions, stakeholders' perspectives were gathered to plan the contents of GPP guidelines and understand challenges of implementation. Round 2 FGDs were conducted to prioritize strategic planning for implementation, focusing on identifying priorities, barriers, and facilitators for adapting and implementing guideline recommendations. Data collection involved 33 proposed strategic plans developed from an extensive review of international literature and thematic analysis of the previous interviews. These plans were assessed using the Multi Criteria Decision Analysis (MCDA) framework to aid in the development of policy plans for GPP guideline implementation. Likert scales ranging from 1 to 5 were used to assess statements, with the timeline scale having 4 points. The scales measured the initiation timeline, impact of the program, feasibility of implementation, and agreement on statements. Participants ranked the prioritization criteria based on timeline, practicality, agreement level, and impact. To ensure a

balanced discussion, separate focus groups were conducted at different times with participants from similar fields and backgrounds. The discussions were moderated by the primary investigator and an assistant moderator, who took notes and summarized the discussions. Each group consisted of around five to six participants and efforts were made to create a homogeneous environment to encourage open and comfortable expression of experiences and views. Permission for recording was obtained, and if not permitted, field notes were taken. Each discussion lasted approximately 45-60 minutes, with equal opportunities for participants to contribute. Dominance in the conversation was discouraged, and less talkative participants were invited to share their thoughts. The research facilitators ensured a neutral and welcoming atmosphere, carefully wording key questions. Session summaries aimed to reflect stakeholders' opinion evenly and fairly.

#### **3.4.2.7. Data collection method**

Prior to the commencement of group discussion, informed consent was obtained and participants received information on the objectives of the group discussion as well as a summary of previous data regarding the current situations of pharmacy context. The main methods of data collection during round 1 focus group discussions included audio recording, note-taking and participant observation. For round 2 study, participants were having to allocate the pre-defined priorities. Findings from the previous interviews were presented to provide additional information from other stakeholders to consider when deliberating priority recommendations for implementation. For each group, a draft protocol was prepared containing a list of 33 proposed strategic plans which were developed from the findings of the focused scan of the international literature, and thematic analysis of the interview and survey conducted in round 1 (see the Appendix). These strategic plans were formulated in terms of four criteria regarding importance, agreement, feasibility for implementation in local context and timeline schedules. The participants were asked to complete an anonymous individual ranking exercise to which a list of strategic plans with recommendations for implementation of the GPP guidelines and identified the factors affecting to the uptake of guidelines in their practical setting. With this system, each participant is able to vote anonymously in real time with results presented immediately. The participants were given time to rank each attribute before going to same small discussion groups. Participants have to rank the priority recommendations in terms of importance, agreement,

feasibility and timelines for implementation in the local context. When responses for a given recommendation were highly disparate, discussion took place to understand the perspective views of each stakeholder. Participants were encouraged to link proposed implementation strategies back to the underlying barriers that would be addressed, and leverage identified facilitators.

The MCDA approach was used in this phase. By MCDA method, it was allowed to take account the different perspectives for the preferences of the criteria and their relative importance in policy formation. The statements were grouped under four sections, using a conceptual framework developed for the Myanmar context: (1) Timeline for Initiation (when?); (2) Practical way (how?); (3) Agreement (what extent) and (4) Impact (how severe?). Participants were also asked to provide reasons for their ratings of each statement via a comment box/separate relevant area. When responses for a given recommendation were highly disparate, discussion had been taken place. Participants reconvened in small groups to identify potential strategies for implementing the prioritized recommendations in their practice settings. The dummy matrix for ranking exercise on pre-defined statement was stated in Appendix.

#### **3.4.2.8. Data collection tools**

During small group discussions, filed-notes, sketches and audio-records were used in case of agreement for analysis. The researcher and the research assistant were also one of the research tools to collect data.

#### **3.4.2.9. Data Analysis**

During the period of May to June 2019, the data for round 1 study were analyzed together with two researchers from Faculty of Pharmacy, Silpakorn University at Thailand. Thematic content analysis was used to analyze the data as conducted in previous phase. During the period of February and May 2020, descriptive statistics were calculated on quantitative survey data for round 2 study. The pre-defined 33 statements were asked to rate in five-point Likert items which were group under four sub-domains: 1) Timeline for initiation (when?), 2) Practical way (how?), 3) Agreement (what extent?) and 4) Impact (how importance?). The responses were analyzed using Microsoft Excel 2016. To be efficient in priority-setting process against counterbalance of consuming scarce resources, some simple mechanisms were used to identify the important topics in the process of setting assessment priorities. The scores

were calculated by adding all the scores (according to scales) and dividing by the total number of scores. The prioritized items were ordered by using the prioritization matrices which is useful for applying a systematic approach to weighing criteria towards evaluating solutions against the criteria. The use of the matrix helps to decide what strategic plan should be implemented first. Finally, a policy work plan was developed in accordance with timeline and available resources such as budgets, human resource, technique and equipment.

#### **3.4.2.10. Ethical issues**

The ethical issues of this study were verified and approved by the Ethics Review Committee from Department of Medical Research under the Ministry of Health and Sports of Myanmar with the ethical review no. Ethics/DMR/ 2018/098A/2018 issued on 17 August, 2018. All the participants were informed about benefits of the study by their participation rather than provision of incentives. All participants were served a meal during their time for rewarding their effort. Some participants were compensated travel expenses while some pharmacy owners were provided the technical support and advices. They also received the feedback about results of the study and reference books related to good practice of pharmacy. The research was started only after ensuring grants in written consent form from all participants. As they were part of the research process, they were important to honor the rights and freedom of all individuals. They were thereby regarded as co-investigators for sharing their ideas rather than subjects.

#### **3.4.2.11. Confidentiality and data security**

The valuable collected data, both soft and hard copies, were stored privately and safely to ensure the confidential issues throughout the data collection and usage. Completed questionnaires, recordings and transcripts of study sites were securely stored and not left openly in any place. They were prevented from easy access to other people. It ensured safekeeping the data during the research process. Reduced risks of data loss hence increased verifiability. At the end of the study, the data of fieldwork were destroyed in a safe way. In case of paper, they had been shredded. In case of computer file, they had been permanently deleted from all recorded systems.

## CHAPTER 4

### RESULT

#### Findings from Quantitative Survey of Pharmacies

##### 4.1. Evaluation of current pharmacy practice of local retail pharmacies

A set of questionnaires was used as indicators to facilitate review of pharmacy practice. They were noted as quality audit and categorized into four domains according to the WHO guidelines; (i) the facilities of pharmacy, (ii) the personnel and training of pharmacy staffs, (iii) the practices of staffs and (iv) the quality assurance processes of pharmacy. The results of finding were grouped into three categories of standard according to the extent to which the pharmacies comply with the standard criteria in audit checklists. Each category of standard was expressed in frequency and percentage of pharmacies in each area. The results of cross-sectional study were analyzed in descriptive way and the data were charted in an excel worksheet into a framework matrix. Each row represents a check point of pharmacy practice to facilitate a detailed view of each stage. Each column being the frequency and percentage of sample population (n=43) that complied with standards in different extents. As a result, those pharmacies that follow the standards of quality audit regarding the good pharmacy practices were designated as group A. For those pharmacies that did not meet the standards of quality audit but were trying to keep good practice with their available resources were assigned as group B. In this case, their practices could be regarded as acceptable to a certain level. The last group C was assigned for those pharmacies whose practices were frail and did not meet the standards of quality audit at all.

##### 4.1.1. Socio-demographic characteristics of participants

A total of forty-three licensed pharmacies in three different areas were visited and surveyed the pharmacy practices of staffs. The samples recruited in this section were located near hospital, markets and business hub with the purpose of

capturing a comprehensive picture of pharmacies that are distributed across different locations. The socio-demographic characteristics of participants are presented in Table 1.

*Table 1 Socio-demographic characteristics of participants (n=43)*

No	Characteristics	Frequencies	Percentage
<b>1.</b>	<b>Numbers of study population in assigned areas</b>		
	Pyin Oo Lwin : Area I (sub-urban area)	12	28
	Chan Mya Tharzi : Area II (urban area)	21	49
	Kyaukse : Area III (rural and sub-urban areas)	10	23
<b>2.</b>	<b>Owner status of pharmacies</b>		
	Pharmacist	2	5
	Non-pharmacist	41	95
<b>3.</b>	<b>Person met in pharmacy during visit</b>		
	Owner	30	70
	Seller	13	30
<b>4.</b>	<b>Gender of pharmacy's staffs</b>		
	Male	26	60
	Female	17	40
<b>5.</b>	<b>Age (years)</b>		
	19-29	4	9
	30-39	18	42
	40-49	16	37
	50s and above	5	12
<b>6.</b>	<b>Educational status</b>		
	Passed high school	17	40
	Graduated rather than pharmacy degree	22	51
	Bachelor of Pharmacy	4	9
<b>7.</b>	<b>Working experience of staffs</b>		
	< 6 months	1	2

	1-5 years	10	23
	6-10 years	8	19
	11-15 years	9	21
	16-20 years	6	14
	21-25 years	2	5
	>26 years	7	16
<b>8.</b>	<b>Duration of operation of pharmacy (years)</b>		
	≤ 5	5	12
	5-10	15	35
	>10	23	53
<b>9.</b>	<b>Number of persons working in the shop</b>		
	1	10	23
	>1	33	77
<b>10.</b>	<b>Size of pharmacies (Specified based on legal requirement* - at least 10' x 10')</b>		
	Small (10')	15	35
	Medium (10'-15')	20	46
	Big (>15')	8	19

In this phase, 12 retail pharmacies were selected from area I, 21 pharmacies from area II and 10 from area III with 28%, 49% and 23% respectively. From the spot assessment, it was found that most of the drug stores have a maximum visit of 200 customers per day and the least visit of 50 per day. Those pharmacies getting big customers were big and medium-sized ones with a variety of products available. They were mostly located near hospitals and in the downtown area.

It was found that a vast majority of the pharmacies were owned by non-pharmacists in 95% while only 5% were possessed by pharmacists. In 70% of the pharmacies, the owners and sellers were the same persons. 60% of the pharmacy staffs were male and the remaining population were female with the age ranging from 19 to above 50 years. The most prominent working age group was in the range of 30-39 with 42%.



In the rural and sub-urban areas, 40% of respondents were found to have passed the matriculation examination in their education without graduation. However, the majority in the urban areas, around half of the respondents were graduates and only 9% of them graduated with bachelor of pharmacy. The working experiences of the staffs in pharmacies ranged from 6 months to more than 30 years and the obvious groups were found to have staffs with working experiences of 1-5 years and 11-15 years, comprising 23% and 21% respectively. Around one-third of the pharmacies were in operation for 5-10 years. However, mostly in rural and sub-urban areas, the long-running retail pharmacies had been in existence for more than 10 years which was accounted for 53%.

It was noticed that 23% of the pharmacies were run with single person while 77% of the pharmacies had two-to-eight staffs depending on the size of pharmacy and affordability of the owner. Interestingly, most of the pharmacies belonged to families whose members took the roles of drug sellers also. The sizes of recruited sample were categorized based on the specification of legislation of Myanmar government. The minimum requirement of space for pharmacy business was a building having an area of ten square feet at least. Therefore, based on that specification, it was noted that half of the sample population were medium-sized business and mostly found in urban and sub-urban areas. Nearly one-third of the sample were small-sized business and they were found mostly in some parts of sub-urban and rural areas.

#### **4.1.2. Facilities of pharmacy**

Under the domain of facilities of pharmacy includes premises and equipment issues. The results related to the pharmacy layout and the environment around pharmacy are checked with checklist and described in terms of frequencies and percentage as shown in Table 2.

Regarding the pharmacy layout, it was generally found that the majority of drug stores has clear mark of pharmacy name so it could be visible and noticeable from the street. They were also labeled the word “Pharmacy” either in English or in Myanmar language accounting for 70%. However, unnoticeable signage was found in rural area of Area III. A good standard of pharmacy is specified by having enough

space for displaying shelves, counters and information for patients. This fact was well observed in 70% of sample population especially in sub-urban and urban areas while 30% of total sample located in outskirts areas of sub-urban and rural areas had acceptable level of standard with just enough space for shelves and counters but not for displaying the information for patients.

Significantly, in all areas, the lowest percentage of compliance with standards guidelines was found in the criteria of compounding area. This is because extemporaneous preparations was seldom prescribed in present days. Therefore, it was not specified inside the pharmacies. In addition, the majority of pharmacies have no separate area for counseling purpose which accounted for 95% of sample population. Only 5% of the sample provided a separate counseling area for patients who wanted to ask for more drug information. This type of pharmacy mentioned that they were intended to provide the best service in their area.

It was only in 5% of study population that pest control measurement was available from time to time. These pharmacies were found to be aware of practicing good hygiene. The majority of study population was unaware of pest control process. They stated that there were neither rodents nor insects in their pharmacies and so it is not necessary for them to control the pests all the time. Some of them claimed that they were too busy to take care of cleaning process and to control the pests or rodents. Therefore, 79% of respondents were found to poorly comply with pest control measurement. In addition, 72% of the retail pharmacies were poorly designed for disabled people using wheelchair and pushchairs. They claimed that the setting up of aisle was not necessary because they were mostly located beside the pavement for the pedestrians and no disabled person would come to buy the medicines, but his or her family members.

Regarding the furniture and equipment inside the pharmacies, slightly over 80% of pharmacies have well-placed, neat shelves for storage of medicines particularly in sub-urban and urban areas. In addition, nearly half of the pharmacies had adequate protection against temperature, dust, moisture, excessive heat and light. The participants from the area II and III mentioned that the weather of the area II and III were very hot and dusty in the summer season. Therefore, the more provision of furniture was provided to protect the medicines from heat, light, dust and moisture.

As a result, these two criteria were found to be in compliance with the standards guidelines. Contrary to these areas, most of the participants in the area I stated that it was not necessary for them to have refrigerators to store the medicines except for cold-chain medicines. They perceived that the area I has cool climate and the temperature below 30°C of this area was optimum to store the medicines without needing further protections. Therefore, weather was found to be one of the significant factors that affect the practice of pharmacy. Significantly, a small proportion of pharmacies had refrigerated facilities (21%) to sell the cold-chain medicines while the others stated that the processes of maintaining the cold-chain medicines was a burden in investment with little profit. They claimed that they had to buy refrigerators and generators in case of outage period and it was hard for them to keep such kinds of medicines. Therefore, the majority of pharmacies (79%) did not sell the cold-chain medicines.

In a truthful way, the vast majority of pharmacies were intended to run for a business. Therefore, they took solely the role of count-and-pour practice. As a result, they did not provide patient care processes like provision of patient information leaflets (PILs), monitoring the patients' blood pressure, height and weight measurement with 93%, 88%, 91% respectively. Moreover, 93% of pharmacies did not have computerized system to maintain the records on inventory control and stock management and 91% have no reference resources for pharmacy. A majority of participants in urban and rural areas mentioned that their business is small and family business so they don't need to install computer system. However, the participants in the area I and III, on the contrary, stated that it was difficult for them to find someone with necessary computer skills and they could not pay high salary for them. Therefore, these criteria did not meet the standard guidelines in all areas.

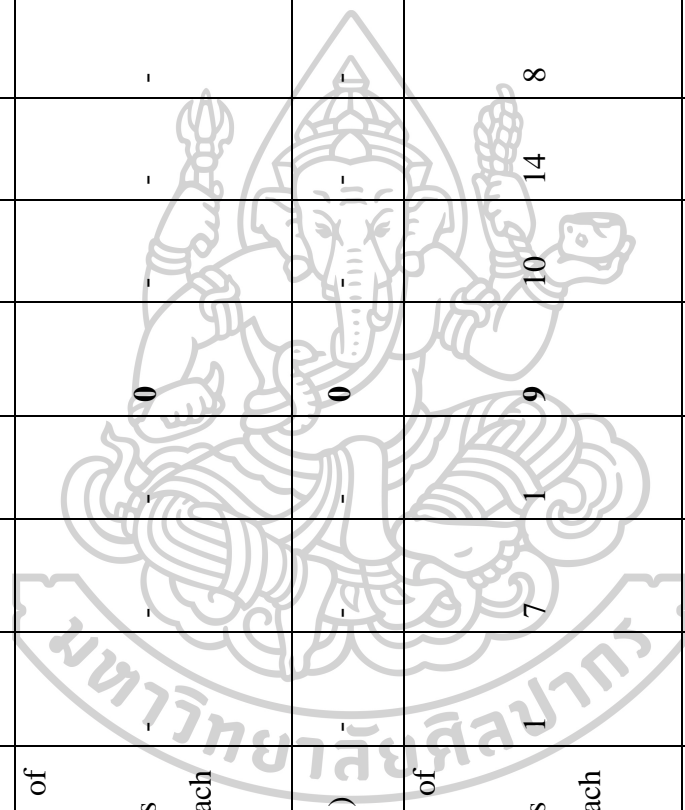


*Table 2 Facilities of pharmacy (n=43)*

Criteria	Distribution of Study Population	Group A			Group B			Group C					
		I	II	III	Total	I	II	III	Total I	I	II	III	Total I
<b>2.1. Premises</b>													
1. Having clearly marked sign/word of Pharmacy	No. of sampled pharmacies from each area	7	18	5	30	5	3	4	12	-	-	1	1
	Percent (%)	16.28	41.86	11.63	69.77	11.63	6.98	9.30	27.90	-	-	2.33	2.33
2. Enough space inside pharmacy for displaying shelves, information and counters	No. of sampled pharmacies from each area	7	19	4	30	5	2	6	13	-	-	-	0
	Percent (%)	16.28	44.19	9.30	69.76	11.63	4.65	13.95	30.23	-	-	-	0
3. Hygiene	No. of	1	3	1	5	9	13	7	29	2	5	2	9

around environment	sampled pharmacies from each area	2.33	6.98	2.33	11.63	20.9	30.2	16.2	67.4	4.65	11.6	4.65	20.9	
	Percent (%)					3	3	8	4		3		3	
	No. of sampled pharmacies from each area	2	10	3	15	6	9	5	20	4	2	2	8	
	Percent (%)	4.65	23.25	6.98	34.88	13.9	20.9	11.6	46.5	9.30	4.65	4.65	18.6	
	No. of sampled pharmacies from each area	-	4	1	5	1	2	1	4	11	15	8	34	
	Percent (%)	-	9.30	2.33	11.63	2.33	4.65	2.33	9.30	35.5	34.8	18.6	79.0	

											8	8	0	6	
6. Keeping premises Clean	No. of sampled pharmacies from each area	2	7	1	10	3	8	2	13	7	6	7	20		
	Percent (%)	4.65	16.27	2.32	23.25	6.98	18.60	4.65	30.23	16.28	13.95	16.28	46.51		
7. Service area (Dispensing area)	No. of sampled pharmacies from each area	1	5	1	7	1	6	1	8	10	10	8	28		
	Percent (%)	2.33	11.63	2.33	16.28	2.33	13.95	2.33	18.60	23.25	23.25	18.60	65.11		
8. Counselling area	No. of sampled pharmacies from each	-	2	-	2	-	-	-	0	12	19	10	41		



area																	
9. Compounding area	Percent (%)	-	4.65	-	4.65	-	-	-	-	-	0	27.9 1	44.1 9	23.2 5	95.3 5		
	No. of sampled pharmacies from each area	-	-	-	0	-	-	-	-	0	12	21	10	43			
10. Enough space for patients to stand while waiting	Percent (%)	-	-	-	0	-	-	-	-	0	27.9 1	48.8 4	23.2 5	100			
	No. of sampled pharmacies from each area	1	7	1	9	10	14	8	32	1	1	-	1	2			
11. Aisles for people who use	Percent (%)	2.33	16.28	2.33	20.94	23.2	32.5	18.6	74.4	1	2.33	-	2.33	4.65			
	No. of sampled	-	3	-	3	5	6	0	1	9	10	12	9	31			



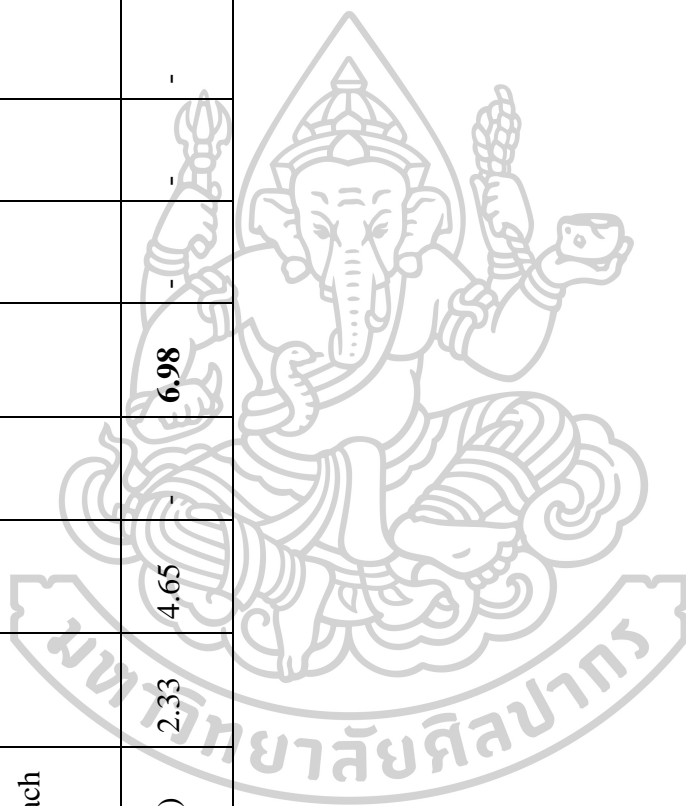
wheelchairs or prams	pharmacies from each area	-	6.98	-	6.98	4.65	13.95	2.33	20.93	27.91	23.25	72.09
	Percent (%)	-	6.98	-	6.98	4.65	13.95	2.33	20.93	27.91	23.25	72.09
<b>2.2. Furniture, Fixtures and Equipment</b>												
1. Providing drinking water and separate waste collection baskets/boxes	No. of sampled pharmacies from each area	1	2	1	4	1	1	-	2	10	18	37
	Percent (%)	2.33	4.65	2.33	9.31	2.33	2.33	-	4.66	23.25	41.86	86.04
2. Neat and well-placed shelving and storage	No. of sampled pharmacies from each area	8	20	7	35	2	1	2	5	2	-	3
	Percent (%)	18.60	46.51	16.2	81.38	4.65	2.33	4.65	11.6	4.65	-	6.98

3. Storing at prescribed temperatures and conditions	No. of sampled pharmacies from each area	4	15	2	21	3	2	2	2	7	3	5	4	6	15
	Percent (%)	9.30	34.88	4.65	48.83	6.98	4.65	4.65	4.65	16.2	8	11.6	9.30	13.9	34.8
4. Have furniture for protection of medicines from dust, moisture, excessive heat and light	No. of sampled pharmacies from each area	5	10	5	20	3	6	1	10	4	5	4	5	4	13
	Percent (%)	11.63	23.25	11.6	46.51	6.98	13.9	2.33	23.2	6	9.30	11.6	9.30	30.2	
5. Equipped with refrigerators	No. of sampled pharmacies from each	2	5	2	9	-	-	-	0	10	16	8	34		





11. Patients information leaflets (PILs)	No. of sampled pharmacies from each area	1	2	-	3	-	-	-	0	11	19	10	40
	Percent (%)	2.33	4.65	-	6.98	-	-	-	0	25.58	44.19	23.25	93.02



#### 4.1.3. Personnel and training of pharmacy staffs

Relating to the staff education, few number of pharmacy can hire pharmacist and it was found that only three pharmacies (7%) had 4 total pharmacists and two of them were owners and two pharmacists were sale staffs of pharmacies. The majority of pharmacies were staffed with graduated persons (54%) and, therefore, this group of participants was considered to be at the acceptable level of standards. Among 54% of pharmacies, 26% of pharmacies employed the staffs holding certificate of pharmacy assistant from private training sector. The remaining 39% of pharmacies were employed staffs with high school education level especially in rural areas and family business type of pharmacy. They reported that it was hard for them find graduated persons who were interested in selling medicines and even if they found graduated persons, they could not pay high salary for them. As a result, the quality of staff education in this group did not meet the standard criteria.

Regarding the staff employment rule, nearly half of the sampled pharmacies (47%) hired their staffs who could show their fit certificate. Moreover, proper working experience related to medical field, moral judgment and credentials criterion were all considered in employment procedure. However, pharmacies run by a person singly and of family business type were found without such a procedure which accounted for 53% of population. Significantly, there was no pharmacy that underwent periodic immunization process for staffs and document on staff's health data. Most of them said that they were unaware of immunization process and maintenance of documents about staff's health profiles. Moreover, some of them were concerned about the costs of immunization. Surprisingly, all study population was found to be in noncompliance with establishment of the documents and assigning clearly described roles and responsibilities of their pharmacy staffs. All the staffs take all the roles of dispensers, cashiers and store keeper as well.

In terms of training process, only two pharmacy owners (5%) had met the standard level. They can manage the appropriate training programmes with professional representative and external trainers while the majority of sampled pharmacies trained their apprentice staffs by the owners or experienced senior staffs which accounted for 84% of the entire population. The remaining percent of

pharmacies are run by family members, and so these pharmacies had not achieved such activity. However, only one pharmacy was found to have training policy for its pharmacy to give the best services. Surprisingly, all pharmacies have no procedure, reference books and curriculum for training process and no document on their training process. Therefore, there was little chance to review periodically and updated. Relating to this topic, a few participants received training two to three times provided by government organization and NGOs. However, they stated that the trainings they received were not related to dispensing and storage practices.



Table 3 Personnel and training status of pharmacy staffs (n=43)





Criteria	Distribution of Study Population			Group A			Group B			Group C		
	I	II	III	Total	I	II	III	Total	I	II	III	Total
<b>3.1. Personnel of pharmacy staffs</b>												
2. Education of pharmacy staffs	-	3	-	3	6	11	6	23	6	7	4	17
		6.98	-	6.98	13.95	25.58	13.95	53.48	13.95	16.28	9.30	39.53
<b>3.2. Staff employment</b>												
1. Hiring a staff by medical examination	4	14	2	20	-	-	-	0	8	7	8	23
	9.30	32.56	4.65	46.51	-	-	-	0	18.60	16.27	18.60	53.48
2. All staff undergo	-	-	-	0	-	-	-	0	12	21	10	43

periodic immunization	pharmacies from each area	-	-	-	-	-	-	-	-	-	-	27.91	48.84	23.25	100
	Percent (%)	-	0	-	-	-	-	-	-	-	-	0	48.84	23.25	100
3. Systems for archiving staff's health data	No. of sampled pharmacies from each area	-	0	-	-	-	-	-	-	-	-	12	21	10	43
	Percent (%)	-	0	-	-	-	-	-	-	-	-	27.91	48.84	23.25	100
4. All activities carried out as per well-documented guidelines or procedures	No. of sampled pharmacies from each area	-	0	-	-	-	-	-	-	-	-	12	18	10	40
	Percent (%)	-	0	-	-	-	-	-	-	-	-	27.91	41.86	23.25	93.02
5. Clearly allotted	No. of sampled	1	3	-	-	-	-	-	-	-	-	11	19	10	40

responsibilities	pharmacies from each area																	
	Percent (%)	2.33	4.65	-	6.98	-	-	-	-	-	25.58	44.19	23.35	93.0	2			
<b>3.3. Training process of pharmacy staffs</b>																		
1. Trained with appropriate external trainers	No. of sampled pharmacies from each area	1	1	2	9	18	9	36	2	2	2	1	5	11.6	3			
	Percent (%)	2.33	2.33	-	4.65	-	20.93	41.86	20.93	83.72	4.65	4.65	2.33	11.6	3			
2. Training policy	No. of sampled pharmacies from each area	-	1	-	1	10	5	20	7	10	5	22	51.1	6				
	Percent (%)	-	2.33	-	2.33	23.25	11.63	46.51	16.28	23.25	11.93	51.1	6	5	1			
3. Adequate practical	No. of sampled	-	-	0	11	18	9	38	1	3	1	5						

training of staffs in a pharmacy	pharmacies from each area	-	-	-	-	25.58	41.86	20.93	<b>88.37</b>	2.33	6.98	2.33	<b>11.63</b>
	Percent (%)	-	-	<b>0</b>	-	-	-	-	-	-	-	-	-
4. Any reference resources, curriculum and training manuals for training process	No. of sampled pharmacies from each area	-	-	<b>0</b>	-	-	2	-	<b>2</b>	12	19	10	<b>41</b>
	Percent (%)	-	-	<b>0</b>	-	4.65	-	-	<b>4.65</b>	27.91	44.19	23.25	<b>95.34</b>
5. trained about hygiene in storage and handling	No. of sampled pharmacies from each area	-	-	<b>0</b>	-	10	18	8	<b>36</b>	2	3	2	<b>7</b>
	Percent (%)	-	-	<b>0</b>	-	23.25	41.86	18.60	<b>83.72</b>	4.65	6.98	4.65	<b>16.28</b>
6. well	No. of	-	-	<b>0</b>	-	-	-	-	<b>0</b>	12	21	10	<b>43</b>

documented on training process	sampld pharmacies from each area	-	-	-	-	-	-	-	-	0	27.81	48.84	23.25	100
	Percent (%)	-	-	-	-	-	-	-	-	0	27.81	48.84	23.25	100



#### 4.1.4. Practices of staffs

Interestingly, all the participants responded that they had checked the name(s) of medicines, potency, dosage and total amount of medication of customers who came with prescription letters. They also stated that they provided clear instruction to the customers on how they should take their medications and refill when necessary. They also mentioned that they provided appropriate counseling regarding the usage of medication. Concerning with dispensing practice, three-quarter of sample population used clean containers or plastic envelopes to pack the dispensed medicines and clearly labeled on it. But, nearly one-fourth of population applied clean containers without a clear label on it. They just provided information verbally to customers. Only a negligible amount of pharmacies (2%) utilized the reused paper bags for packing.

Nevertheless, according to the nature of pour-and-count practices of pharmacy and non-pharmacist staffs, they were found to have limited abilities on prescription review, confirming identification of clients, checking prescribers and patient profiles, patients' history of drug used all in detail. Moreover, they were found to be less conscious to keep document when any changes were made by a prescriber on his prescription. It was noticed that the majority of staffs can perform the checking the correctness of dispensed medicines, checking some points of prescribers' profiles such as the name of prescriber, signature and the registration number and correct delivery to the right customers. However, the pharmacists who took the role of dispensers were able to identify the medication correctness, side effects and drug interactions among prescribed medication (7%). They could give appropriate suggestion and counseling to the patients. A considerable poor practice was also found at pharmacies that sold the cold-chain medicines. It was found that around one-third of population complied with the standard practice in selling the cold-chain medicines i.e., they provided the medicines with iced-packs or cold-chain boxes to maintain the required storage condition 2-8°C during transport period. While the majority of pharmacies (67%) were not able to provide required conditions for that kind of medicines. Those pharmacies claimed that the costs of iced-packs and boxes were relatively high, compared to iced-cubes.

Regarding the storage practice, all the pharmacies checked the correctness of ordered products before storage. As a result, they all adhered to standard guidelines for it. All surveyed pharmacies had return system if the products were unused and unopened yet before specified expiry date (normally 3 months before expire). Regarding the management system for nearly or already expired products, it was found that the majority of pharmacies checked the shelves periodically to ensure the removal of expired products (86%). While 14% of pharmacies admitted that they were too busy to check the expiry dates of products periodically. However, the majority of participants were found to be managing in their own ways, i.e., they used either first-in-first-out system or returning the products back to suppliers or disposed them into waste bins. 95% of participants had poor practice on storing those expired products or nearly expired products in separate areas with locked system. Majority of participants responded that they did not have enough space for keeping the expired products in separate ways. Another poor compliance of storage practice was found in keeping the documents of purchase and sale vouchers according to the legal requirements. It was noticed in 77% of surveyed pharmacies especially in rural and sub-urban areas. They stated that they had limited space to keep these documents and no longer need to keep them after paying their debt obligations.



Criteria	Distribution	Group A	Group B	Group C
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Table 4 Pharmacy practices of staffs (n=43)



	of Study Population	I	II	III	Total	I	II	III	Total I	I	II	III	Total I
<b>4.1. Prescription handling and dispensing practices</b>													
1. Check the name(s) of medicines, potency, dosage, total amount of the medicines	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	0	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	0	-	-	-	0
2. Instruction to the patients	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	0	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	0	-	-	-	0
3. Refill information if necessary	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	0	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	0	-	-	-	0

4. Giving appropriate counseling regarding usage of medication to	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	0	-	-	-	-	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	0	-	-	-	-	-	-	-	0
5. solid dosage forms are packed in a clean container or envelop and neatly labeled	No. of sampled pharmacies from each area	10	17	5	32	2	4	4	10	-	-	-	-	-	1	-	-	1
	Percent (%)	23.25	39.53	11.63	74.41	4.65	9.30	9.30	23.25	-	-	-	-	-	2.33	-	-	2.33
6. Final review of prescription and the correctness of dispensed medicines	No. of sampled pharmacies from each area	-	3	-	3	8	15	6	29	4	3	4	3	4	11	-	-	11
	Percent (%)	-	6.98	-	6.98	18.60	34.88	13.95	67.44	9.30	6.98	9.30	6.98	9.30	25.58	-	-	25.58
7. Provide cold-	No. of	1	1	1	3	1	4	1	6	-	-	-	-	-	0	-	-	0



council registration number	Percent (%)	-	-	-	0	2.33	6.98	2.33	11.63	25.58	41.86	20.93	88.37
11. Check the name, address, age, sex of the patients	No. of sampled pharmacies from each area	-	-	-	0	-	-	-	0	12	21	10	43
12. Take the history of drug used	Percent (%)	-	-	-	0	-	-	-	0	27.81	48.84	23.25	100
13. Record any changes by the prescriber on the prescription	No. of sampled pharmacies from each area	-	-	-	0	2	3	1	6	10	18	9	37
	Percent (%)	-	-	-	0	4.65	6.98	2.33	13.96	23.25	41.86	20.93	86.04

	Percent (%)	-	-	-	-	-	-	-	-	-	0	27.81	48.84	23.25	100
14. Extemporaneous preparations	No. of sampled pharmacies from each area	-	-	-	-	-	-	-	-	-	0	12	21	10	43
	Percent (%)	-	-	-	-	-	-	-	-	-	0	27.81	48.84	23.25	100
<b>4.2. Storage practices</b>															
1. Check for correctness before storage	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	-	0	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	0	-	-	-	0
2. Return the unused and unopened medicines	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	-	0	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	0	-	-	-	0
3. Check the shelves to	No. of sampled	10	19	8	37	-	-	-	-	-	0	2	2	2	6





10. Store separately in a locked shelf for already expiry	No. of sampled pharmacies from each area	1	-	2	11	20	10	41	-	-	-	0
	Percent (%)	2.33	-	4.66	25.58	46.51	23.25	95.34	-	-	-	0
11. Record the temperature in pharmacy	No. of sampled pharmacies from each area	-	1	1	-	-	-	0	12	20	10	42
	Percent (%)	-	2.33	2.33	-	-	-	0	27.91	46.51	27.91	97.67
12. Keep the controlled drugs under lock and key if they sell (n=1)	No. of sampled pharmacies from each area	-	1	1	-	-	-	0	-	-	-	0
	Percent (%)	-	100	100	-	-	-	0	-	-	-	0

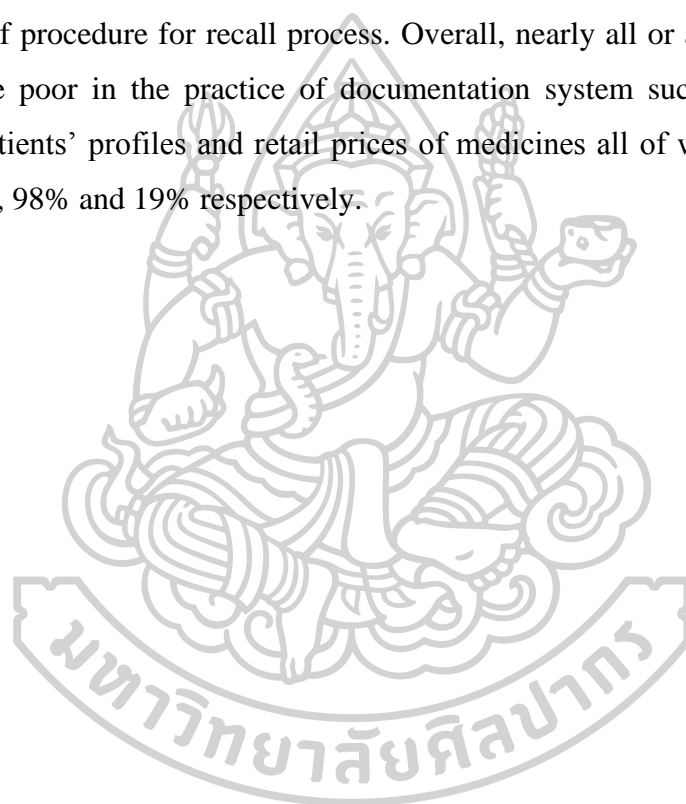


#### 4.1.5. Quality assurance process of pharmacy

For determination of quality assurance of pharmacy, two issues were used to analyze the situation. Regarding the procurement process, all surveyed pharmacies adhered to good practice of pharmacy, i.e., 100% in compliance. All of them claimed that they purchased medicines from authorized sources only and, in general, they checked the correctness of products against invoices before accepting them to ensure that the quality of product met the acceptable level of standard. However, there was no pharmacy who met the standard guidelines in recording the details information of suppliers. Some stated that they merely recorded the name of the company or wholesaler and their contact numbers. Some responded that they were unaware of addresses of all suppliers and the names of the contact persons of the suppliers. In addition, only 9% of the sampled pharmacies kept the written communication documents in systematic ways. While the vast majority of pharmacies (91%) had no record nor document of communication with suppliers in writing regarding the list of authorized representatives of the suppliers. Interestingly, but not surprisingly, the vast majority of pharmacies hardly checked the reliability of suppliers' chain and sent the designated persons to visit the suppliers' premises for conducting audit of their premises and system. The majority of participants responded that they were unaware of and also unknown about such requirements to check the reliability and they had no chance to visit the suppliers' premises or factories. It is normal for inspectors or regulators to check the quality of processes and products. In this country, this practice was hardly accepted from traditional point of view.

Concerning with the documentation system on operational process, it was found that all selected pharmacies adhered to the standard practice in maintaining necessary statutory and operational documents. These practices were mandatory to follow as specified by laws. Nevertheless, only 9% of the pharmacies were found to comply with the standard practice according to the audit records. The majority of participants (91%) complained that they were small business or family business and thus, they did not consider it necessary to get audit document. Likewise, an extensive number of pharmacies had no quality manual and policy documents.

However, there was one pharmacy in area II that had document of quality policy. It was claimed that they would like to offer quality service to customers. Regarding the nationwide recall process, only 5 pharmacies (11.63%) had experienced such cases for a long time ago but issues were not the same for each pharmacy. The remaining participants (88.37%) claimed that they had never experienced or heard about recall process. They mentioned that they had received authentic information and alarms from FDA as well as pharmaceutical companies. Unfortunately, no one documented when that happened. Interestingly, a total of 43 pharmacies stated that they were unnoticed of procedure for recall process. Overall, nearly all or all pharmacies were found to be poor in the practice of documentation system such as SOPs, service strategy, patients' profiles and retail prices of medicines all of which accounted for 100%, 93%, 98% and 19% respectively.



Criteria	Distribution	Group A	Group B	Group C
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Table 5 Quality assurance process of pharmacy (n=43)

	of Study Population	I	II	III	Total	I	II	III	Total	I	II	III	Total	
<b>5.1. Procurement process</b>														
1. Maintain reliable supplier(s) for procurement and inventory management	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	43	-	-	-	0	
	Percent (%)	27.81	48.84	23.25	100	-	-	-	100	-	-	-	0	
2. Check the products against invoices for correctness of quantity, price, physical conditions before accepted	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	43	-	-	-	0	
	Percent (%)	27.81	48.84	23.25	100	-	-	-	100	-	-	-	0	
3. Purchase from authorized sources only	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	43	-	-	-	0	

	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	0	-	-	0
4. Records on detailed information of suppliers	No. of sampled pharmacies from each area	-	-	-	0	12	21	10	43	-	-	-	-	0
	Percent (%)	-	-	-	0	27.81	48.84	23.25	100	-	-	-	-	0
5. Keep the document on written communication with suppliers	No. of sampled pharmacies from each area	1	3	-	4	11	18	10	39	-	-	-	-	0
	Percent (%)	2.33	6.98	-	9.30	25.58	41.86	23.25	90.96	-	-	-	-	0
6. Check for reliability of suppliers' chain	No. of sampled pharmacies from each area	1	1	1	3	-	-	-	0	11	20	9	40	
	Percent (%)	2.33	2.33	2.33	6.98	-	-	-	0	25.58	46.51	20.93	93.02	
7. Send designated persons to visit the	No. of sampled	-	-	-	0	-	-	-	0	12	21	10	43	

suppliers' premises	pharmacies from each area																			
	Percent (%)	-	-	-	-	-	-	0	0	27.81	48.84	23.25	100							
8. Review and Update the list of medicines periodically	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0
<b>5.2. Documentation system on operational processes</b>																				
1. Maintain adequate necessary statutory documents	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0
2. Accessible to operational documents	No. of sampled pharmacies from each area	12	21	10	43	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0
	Percent (%)	27.81	48.84	23.25	100	-	-	-	-	-	-	-	-	0	0	-	-	-	-	0

3. Maintain product list with retail price	No. of sampled pharmacies from each area	6	10	4	20	4	7	4	15	2	4	2	8
	Percent (%)	13.95	23.25	9.30	46.51	9.30	16.28	9.30	34.88	4.65	9.30	4.65	18.60
4. Audit records	No. of sampled pharmacies from each area	1	2	1	4	-	-	-	0	11	19	9	39
	Percent (%)	2.33	4.65	2.33	9.31	-	-	-	0	25.58	44.19	20.93	90.69
5. Keep the document on quality manual and policy	No. of sampled pharmacies from each area	-	1	-	1	-	-	-	0	12	20	10	42
	Percent (%)	-	2.33	-	2.33	-	-	-	0	27.91	46.51	23.25	97.67
6. Record of narcotic	No. of	-	1	-	1	-	-	-	0	-	-	-	0

and psychotropic drugs (n=1)	sampled pharmacies from each area	-	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0	-	-	0	
	Percent (%)	-	100	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0
7. Keep the documents of profile, records	No. of sampled pharmacies from each area	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	0	12	20	10	42
	Percent (%)	-	2.33	-	2.33	-	-	-	-	-	-	-	-	-	-	-	-	0	27.91	46.51	23.25	97.67
8. Specify the location of products along with the list	No. of sampled pharmacies from each area	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	0	12	20	10	42
	Percent (%)	-	2.33	-	2.33	-	-	-	-	-	-	-	-	-	-	-	-	0	27.91	46.51	23.25	97.67
9. Other documents (SOPs, protocols,	No. of sampled pharmacies	-	-	-	0	-	-	-	-	-	-	-	-	-	-	-	-	0	12	21	10	43
	Percent (%)	-	-	-	0	-	-	-	-	-	-	-	-	-	-	-	-	0	27.91	46.51	23.25	97.67



procedures)	from each area	-	-	-	-	-	-	-	-	-	-	-	-	27.91	48.84	23.25	100
	Percent (%)	-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
10. Record on cleaning and maintenance processes	No. of sampled pharmacies from each area	-	-	-	-	-	-	-	-	-	-	-	-	12	21	10	43
	Percent (%)	-	-	-	-	-	-	-	-	-	-	-	-	27.91	48.84	23.25	100
11.Service strategy	No. of sampled pharmacies from each area	-	-	-	-	-	1	2	-	-	-	-	3	11	19	10	40
	Percent (%)	-	-	-	-	-	2.33	4.65	-	-	-	-	6.98	25.58	44.19	23.25	93.02
12. Records on errors of supplier-notice and rectify (n=1)	No. of sampled pharmacies from each area	-	-	-	-	-	-	1	-	-	-	-	1	-	-	-	0
	Percent (%)	-	-	-	-	-	-	100	-	-	-	-	100	-	-	-	0

13. Records on complaints	No. of sampled pharmacies from each area	-	-	-	-	-	-	-	-	-	-	-	-	0	12	21	10	43
	Percent (%)	-	-	-	-	-	-	-	-	-	-	-	-	0	27.91	48.84	23.25	100
14. Receive authentic information and alarms for all recalls (n=5)	No. of sampled pharmacies from each area	2	2	1	5	-	-	-	-	-	-	-	-	0	-	-	-	0
	Percent (%)	40	40	20	100	-	-	-	-	-	-	-	-	0	-	-	-	0
15. Well document on all the process in recall (n=5)	No. of sampled pharmacies from each area	-	-	-	0	-	-	-	-	-	-	-	-	0	2	2	1	5
	Percent (%)	-	-	-	0	-	-	-	-	-	-	-	-	0	40	40	20	100
16. Receive immediate address or suitable action on	No. of sampled pharmacies	-	-	-	0	1	1	1	1	1	1	1	1	3	1	-	1	2
	Percent (%)	-	-	-	0	-	-	-	-	-	-	-	-	0	40	40	20	100



## **Findings from In-depth Interviews**

### **4.2. Current situation of pharmacies in Myanmar**

Data were collected from six townships around Mandalay city located in Mandalay Region. Table 6 gives an overview of the socio-demographic characters of numbers of respondents in each township and per stakeholder group. All the stakeholders were hereafter designated according to the area they came from: stakeholders in area I, II (A), (B), (C), (D) and III etc. Points of view on the role of pharmacy were quite similar within the majority of lay people, pharmacy owners and pharmaceutical companies and quite different between professional and administrator stakeholder groups from the three areas. It can be generally summed up that the pharmacies had a positive contribution among many customers, pharmacy owners and pharmaceutical companies while it had a pessimistic outlook on pharmacy services among many administrators and professions.

#### **4.2.1. Role of Pharmacies in Myanmar**

##### **General overview**

Except all townships in area II, the remaining two areas were suburb and rural in natures. As a result, local people from some rural areas were found to be difficult to go to see a doctor or rural health centers because of geographic locations and low economic status. Hence, many pharmacies in those areas take the role of healthcare and a source of necessary drug information. The townships from area II were urbanization and sub-urbanization in nature, with a more cosmopolitan character. People from these areas were found to be chosen private clinics or private hospitals first if they had illness and used pharmacies for their health promotion, prevention and prescription filling purposes rather than their treatments.

### **The views of pharmacy users including customers, patients and patient attendants**

The pharmacy users across all areas agreed that the pharmacy was a convenient place for them to get their medicines they want. Pharmacies were considered as an available resource of medicines as well as alternative choice on economic factors with additional reasons such as accessible location, lots of choice and saving time etc. They mentioned that the pharmacies were important for majority of people in rural areas and people with low economic status. The following sentiments shows the social roles perceptions of pharmacies among pharmacy users in this study.

#### **4.2.1.1. Social Roles of pharmacies**

*“in my point the drug stores are the places where we can buy our medications easily without expensive prices and we have lots of choices of drug stores if we do not satisfy about their service or prices”* (customer 1, area III)

*“drug stores are our reliable health outlets since we are poor, we do not afford to go clinics. They gave some pills that made me feel relieve”* (customer 4, area III)

*“drug stores are good for us, medicines they gave are matched for me and my family. Every time we felt ill, I bought medicines from this shop. They can give right medicines for us and provide information about medicines”* (customer 2, area III)

*“The drug store is near my house so it is okay for my family. The medicines that we always taking can get from there”* (patient 1, area II)

*“a fair number of drug stores can provide medicines that we need. We relied on them because the opening hours are suitable for us”* (patient 7, area II)

*“we lived in village where there is no drug store, far from 12 miles and difficult to access medicines so drug stores are important to access medicines in our area. We faced difficulties when we have health problems”* (patient attendant, farmer 1, area I)

*“Sometimes drug stores are useful for me to relieve my symptoms but not always. As we are low-income people, we always do not afford to see a doctor so we rely on nearest drug stores”* (patient attendant, housewife 5, area I).

*“I think the existence of DS is good for public to get their medicines. People with minor symptoms do not need to go clinic or hospital. They can get their medicines in drug stores so it is economic for low-income people”* (patient attendant, farmer 2, area I)

### **The views of pharmacy owners and staff**

In this study, only one pharmacy staff was included as a participant for two reasons. The first one was the owner was declined due to lack of time and permitted his staff to interview on behalf of him. The second reason was that most of the owners had capacity to influence the workers or staffs. No one dare to participate in interviews without permission from owners. Moreover, most of the owners were found to be working as sellers in this study. As a result, most of the participants from pharmacy were pharmacy owners. The pharmacy owners across areas mentioned themselves as being a useful buffer when people need to buy the medicines either on self-medication or prescription. They proudly stated that the pharmacies were fulfilling the needs of people and helping people in economical ways to solve their health problems. The following sentiments shows the social roles perceptions of pharmacies among pharmacy owners in this study.

#### **4.2.1.2. Social Roles of pharmacies**

*“we provide the medicines that they want. The role of drug store in my opinion is usual and not so strange to say. We provide correct medicines according to patients asking and prescription letter.”* (owner 4, area I)

*“we provided the medicines that the people need so we felt glad and we think that we could fill up the people needs in good ways”* (owner 1, area II)

*“normally people who do not dare to buy medicines from hospitals, bought medicines from drug stores. For this purpose, I open this drug store”* (owner 1, area III)

*“I would like to help people who needs their medication especially those people who poor and cannot afford to go clinics. Drug stores are places to get their medication easily, right?” (owner 2, area III)*

*“the people here are mostly inhabit in rural areas, they can buy their medication course day by day according to their wages” (owner 3, area III)*

However, some owners mentioned themselves being a family business and a poised nature of business with dignity and fame. Some of their perceptions of pharmacies in this study were:

#### **4.2.1.3. Business Roles of pharmacies**

*“we are running drug store as business to provide quality medicines to customers but there are many unregistered drug stores in our area, we cannot compete with them because they sell a variety of things rather than the medicines only people prefer to buy all things in one shop so I would like to government must take action on them thereby we can stand a unique role in our society” (owner 1, area I)*

*“the role of drug stores should be in a unique position, standing with dignity. Now we are survived among unregistered drug stores. So our roles are lost and it makes us lower our dignity to run the drug stores” (owner 2, area I)*

*“My main income get from cars dealing and this is my second job for extra money. As for me this is normal business to get money” (owner 2, area II)*

*“we are running this pharmacy for our family business. So it doesn't mean special for us” (owner 3, area II)*

#### **The views of pharmaceutical company staffs**

Two company staffs were interviewed and their views about role of pharmacy in Myanmar were quite similar that the pharmacy and pharmaceutical companies were business partners and channels for distribution of medicines to public. Their mutual role perceptions of pharmacies in this study were:

#### 4.2.1.4. Mutual partnership roles of pharmacies

*“Drug stores and pharmaceutical companies are worked in partnership. They are some part of channels for distribution of company products”* (company staff 1, area II)

*“Drug stores are media for delivering our medicines to customers in right ways”* (company staff 2, area II)

#### The views of local administrators and professions

The local administrator and regulator generally viewed the pharmacies as a private business rather than a source of medicine supplier. Moreover, the majority of professions remarked that the pharmacies were sheer business for profits without professional knowledge and ethics. They viewed the pharmacies as frail compliance of rules and regulations. Their perceptions of business roles of pharmacies were:

#### 4.2.1.5. Business Roles of pharmacies

*“most of pharmacies are just for business but few are running for welfare of people”* (administrator 1, area I)

*“I think the running of pharmacies in Myanmar is just a business. They all sell the medicines for their profit”* (regulator 2, area II)

*“for me they are nothing. They all sell the medicines for their profit. They sell the border-trade drugs”* (academic pharmacist 1, area II)

*“the pharmacies in Myanmar are running as business. I cannot say exactly what their role is”* (nurse 2, area II)

*“the pharmacies in Myanmar are just like shops for buying commodities”* (doctor 1, area II)

Nevertheless, there was some participants from professions had an optimistic view on pharmacy that some pharmacies played essential role for making public accessible to health commodities. Their perceptions of social roles of pharmacies were:



#### 4.2.1.6. Social Roles of pharmacies

*“they are good for easy access to public. The pharmacies can be reached a certain level of supportive to health service only when they are upgraded in knowledge, attitude and practice of sellers”* (nurse 1, area II)

*“important places for public to get right medicines because they might bring a gap between prescription of doctor and dispensing of medicines by seller”* (doctor 2, area II)

*“let’s imagine if there was no drug stores in this town, how could people can get their medicines? They support the people with their affordable resources (times, spaces, staffs”* (pharmacist 2, area II)

#### 4.2.2. Advantages and Disadvantages of Current Pharmacy Services and Practices

##### General overview

Perceptions regarding the current situations of pharmacy practices with respect to pharmacy services were found to be diverse among stakeholder groups. It was noticed that the general people who use the pharmacy services had a poor understanding of roles of pharmacists in pharmacies because the majority of people were found to be lack of expectation of services from pharmacists. However, most of them were a slightly positive views towards the services with respect to the pharmacy practices.

##### **The views of pharmacy users including customers, patients and patient attendants**

Most of the pharmacy users were found to be defined pharmacy practices and services in different ways based on their experiences and socio-cultural context such as emotional feelings and judgments on physical condition. The emotional feelings were found to be friendliness (warmly treated), the ways the pharmacy staffs treated to them (social dealings, patiently and kindly treated) and satisfaction (informative responses and prices). The judgments on physical condition were found to be on tangible things such as cleanness or dirtiness of pharmacy layout

and availability of a wide variety of medicines they wanted. Depending on their experiences, they defined thereby pharmacy practices and services as what is good and/or what is bad. The following sentiments shows the social perceptions of pharmacy practices and services among pharmacy users in this study:

#### **4.2.2.1. Social construction of reality: Advantages and disadvantages of services and practices**

*“they can explain me very well about products. They suggested me which product is better and good to use. I like current situation” (patient 3, area II) (advantage)*

*“we prefer more on good communicated drug stores. We would like to get the information and assist to us how should we take these medicines. We want that kind of drug stores” (patient 4, area II) (advantage)*

*“they can give counselling to us and explain how to take the medicines and we satisfied with their counselling practices” (customer 2, area III) (advantage)*

*“most of the drug stores are neat and tidy, few drug stores have well-trained staffs who can give complete information of drugs” (patient attendant, student, area I) (advantage)*

*“I had seen the dusts in the drug stores, I don’t like it. They do not keep their medicines in clean way. Some drug sellers are not skilled persons” (patient attendant, housewife 5, area I) (disadvantage)*

*“sometimes when we asked a medicine from drug store, they did not explain about medicine and sold without giving any information” (patient 2, area II) (disadvantage)*

*“the weak point of them is they cannot provide well service when they had large number of customers. In that time, they are not patient” (patient 7, area II) (disadvantage)*

*“if we requested the specific product they did not provide any information about it. They think that we (the customer) will definitely know about requested medicines. In fact, it’s not. I don’t want to them (pharmacy staffs) to*

*assume all customers will have medical knowledge” (customer 3, area III)*  
(disadvantage)

### **The views of pharmacy owners and staff**

It was found that most of the participants from retail pharmacies perceived good pharmacy practices when they perform good things such as helping people to get the medicines and filling the people desires. In later case, some people with low economic status have desire to buy their medications in day-by-day. They proudly declared that they were tried to meet the need of patients and customers as much as they can. Lastly, they proclaimed that a good practice was dispensing without errors in line with doctors’ prescriptions. Their attitudes towards advantages of pharmacy practices and services were as follows:

*“Good point is pharmacies are places where we can deliver medicines to patients on their needs” (owner 1, area I) (advantage)*

*“as for me, I instructed all of my staffs to check the prescription letter whether it was correct or not. We counseled the patients what they asked” (owner 1, area II)*

*“the sale rate of drug stores and preference of customers are depended on decoration of these drug stores so every drug store might prepare in good ways to persuade their customers. For my drug stores, I managed first-in-first-out system for medicines, cleaned my drug store every once a month” (owner 4, area III)*

On the other way, they perceived the disadvantages of their pharmacy practices and services that selling the illegal (non-registered) drugs in pharmacies was malpractice of pharmacy. However, they claimed that this malpractice was happened for a number of reasons such as customers’ demands, prescribers’ prescriptions and market decisions. For the first reason they said that people only accepted the medicines that the doctor prescribed where it was expensive or not, whether it has cheap and effective alternative brands or, whether these products has been stock-out in the market or not, or, whether these products were registered or not. As a result, they could not give generic drugs as an alternative to stock-out brand

name medicines. People complained and only asked the medicines that the doctors' prescribed. For the second reason, doctors were said to be recognized solely on promoted company products. So they prescribed repeatedly on that products and sometimes, that was happened to stock-out conditions. Some doctors, in another way, still prescribed unregistered medicines to patients. In such cases, some prescribed medicines were like orphan-drugs and they had no similar trade names in the market and as a consequence these medicines were still useful to some patients. Another reason was some doctors did not notice on drugs whether they were registered and not. Because there are many duplications in the market and they only recognized on the medicines that were commonly used and familiar products. As a result, they confessed that they tried to practice in line with rules and regulations but those forces like customers' demands, prescribers' behaviours, market decisions, and business matters drove them to sell illegal products. Thus, they highlighted that the problems shaped by customers and prescribers' behaviours were likely to impact on their pharmacy practices. Their perceptions of malpractice and pharmacy services were as follows:

*“I think the practice of pharmacy is also related to selling of border-line products. We sell these products because of customers' demand and prescriber's instructions. We don't want to sell these illegal products. We have lots of competition if we don't sell, we can lost our clients” (seller, area I) (disadvantage)*

*“the disadvantage of the practice is we cannot give the generic drugs to patients. People insisted on medicines that was identical to their old package or prescribed medicines. We cannot explain if these products are running out of stocks” (owner 1, area I) (disadvantage)*

*“I know that our practice may be wrong but some patient did not afford to buy the full course of their medications especially antibiotics. They can pay for only one day, can spend on medicines in day-by-day” (owner 1, area II) (disadvantage)*

*“my drug store cannot check expiry dates and stocks regularly. We have no time but if we saw expiry products during our sale, we removed them and put in separate area” (owner 1, area III) (disadvantage)*

*“many drug stores sold mix pill packs because of customers’ demands. How we ever tried to explain the side effects of medicines, people do not listen to us. If we do not sell mix pills, the buyers blame me and they think we are not experts and do not know everything about medicines so even though we don’t want to sell illegal or pack medicines, we still selling because of demands from patients” (owner 3, area III) (disadvantage)*

### **The views of pharmaceutical company staffs**

The pharmaceutical company staffs said that they have known for some drug store owners for a couple of years and those owners were experts at getting pharmaceutical knowledge and they could explain all drug information to customers. As a result, the current situations of advantages of pharmacy services were said to be recognized as health care services for public and they were necessary sources of medicines supply for the public. Their attitude towards advantages of pharmacy practices and services were as follow:

*“some drug stores have experienced persons and they like expert. They can tell all drug information like pharmacists because they have many (many) experiences from practice and deal with customers. So they got trust from people” (company staff 1, area II) (advantage)*

*“the good point is pharmacies are located everywhere so we can get medicines easily without time consuming. They have a variety of products and brand names. No one come to buy a pharmacy with limited items” (company staff 2, area II) (advantage)*

On the other hand, their perceptions on disadvantages of pharmacy practices and services were (i) pharmacies were selling the POM medicines freely to anyone in unlimited amount and (ii) lack of counselling practice to public. Their perceptions towards disadvantages of practices in pharmacies were:

*“Sometimes, some drug stores are selling of POMs freely and giving mixed pills (ready to use for self-medication) and can buy as much as you afford”*

*“the communication. They need to give kindness, warmness and practice of counseling. Currently, they run the business commercially without giving customers any pharmaceutical care”* (company staff 2, area II) (disadvantage)

### **The views of local administrators and professions**

The majority of this group of stakeholders accepted that the pharmacies were having more disadvantages rather than advantages. They mentioned the service of pharmacy has advantage only no advantage for practice of pharmacy. The only one thing they regarded as advantage of pharmacy was pharmacies were easy access of medicines and can get a variety of drugs including prescribing only medicines (POM) and over-the-counter medicines (OTC) for people. They mentioned that:

*“we can get any drug easily so this makes us advantage as well as disadvantages depending on the practices”* (doctor 6, area II)

However, some professions worried about these advantages were turned into disadvantages when the drug sellers have poor practice of selling in case of they sold the POM freely to public without having proper pharmaceutical knowledge. Their perceptions towards disadvantages of pharmacy practices were:

*“pharmacies sold POM drugs freely, focus on profit. Malpractice because of low level of thinking”* (administrator 1, area I)

*“most of the pharmacies have no competent ones. Sometimes they selling POMs freely and give mixed pills without prescribe”* (administrator 2, area II)

*“there is not so many good things in current practices because they are businessmen, they have business-minded. They run business only without giving pharm care to customers”* (academic pharmacist 1, area II)

*“they do not take responsibility and do not have accountability on their faults. Many of them employ staffs who do not pass the high school level of education”* (doctor 5, area II)

*“there is no proficient staff in pharmacies. They just sold what the customers asked for. Sometimes they prescribed directly to customers” (doctor 3, area II)*

#### **4.2.3. Experiences of Drugs-related Problems (DRPs) among Stakeholders**

##### **General overview**

Regarding the experiences of DRPs, the phenomena could be categorized into three main types. The majority of participants, the first group, had no experience about DRPs. This group comprised of 24 persons; mainly were lay people including 6 patients, 2 customers and 5 patient attendants, 3 pharmacists, 2 regulators, 2 company staffs and 4 pharmacy owners. The second group of participants believed that they would not have DRPs experiences because they said they use only medicines with less potent and familiarity or sold the medicines of having the prescription and registered number. This group consisted of 14 persons; 7 patient attendants and 7 pharmacy owners. The final group who experienced the DRPs cases, mainly consisted of prescribers (n=9) and nurses (n=2) having experiences of clinical and hospital fields and other groups of stakeholders (4 patients, 3 customers, 1 owner, 1 regulator and 1 pharmacist). Two other pharmacists who working in the public hospital and the owner of pharmacy mentioned about DRPs in hospital but so these cases were skipped because of it was not related to community pharmacy. For those who can detect DRPs were identified according to their own experiences and the professional knowledge.

##### **The experiences of pharmacy users including customers, patients and patient attendants**

The first group of this stakeholder clearly claimed that they had no experience of DRPs. Their perceptions towards DRPs were:

*“I have never experienced about drug problem” (patient attendant, housewife 5, area I)*

*“I have never been suffered any problems about my medications” (patient 1, area II)*

*“no. I'd never experienced about drug allergy even and heard about drug problems of others (customer 2, area III)*

The second group of this stakeholder expressed that they would not have DPRs events because they always used the familiar medicines and less potent medicines. They also stated that the medicines they used were compacted to them, cured their symptoms and improved their health. So the medicines they used might not harm to their body. Their perceptions towards DRPs as follow:

*“we take medicines for minor symptoms so we don't have drug problems” (patient attendant, housewife 1, area I)*

*“medicines that we take are not potent and strong so we don't have drug problems” (patient attendant, housewife 2, area I)*

*“we used usual household drugs and traditional medicines so we are nothing to happen” (patient attendant, housewife 3, area I)*

*“we got medicines from rural health center so we don't have any drug problems” (patient attendant, farmer 1, area I)*

The last group stated that they could detected the DRPs based on their own experiences and signs and symptoms of their physiological responses such as felling of unwell. However, some participants had heard DRPs events from their friends and neighborhoods although they had never been experienced themselves. Their experiences towards DRPs were:

*“I'd never been suffered side effects but one day I took analgesics for 3 times and one dose was taken with coffee then I suffered hot burn” (patient 1, area II)*

*“sometimes, nausea, loss of appetite and fatigue. Do not suffer too serious conditions” (customer 1, area III)*

*“I'd experiences from other people when they took pack medicines (sold by drug stores), they fell down then dead” (patient 8, area II)*



### **The experiences of pharmacy owners and staff**

The first group of this stakeholder has no experiences on DRPs cases. They claimed that DRPs has never happened due to the dispensing errors or prescription errors because they said that they always checked dispensed medicines in line with the prescriptions. Their perception towards DRPs were:

*“I haven’t experienced or heard about drug-related problems caused by medication error or dispensing error. We always check the medicines and prescription letter” (owner I, area I)*

*“no. I never have experienced the problems that related to medicines. Most of the patients come to buy medicines by showing the sample that they are taking or bringing the prescription letter” (owner I, area III)*

*“ahh! this will not happen because we have been selling according to the prescription letter brought by patients and sometimes they bring empty strips” (seller, area I)*

The second group of this stakeholder stated that they would not experience towards DRPs in customers because they sold the medicines in accordance with prescriptions and sometimes filled for long-term used customers. They also accepted that the medicines they sold frequently were multivitamins, analgesics and antitussive like medicines. So they thought that the medicines are frequently and commonly used for people and these drugs might not have possible side effects to people. They believed in another way that the quality of medicines was already guaranteed by FDA and therefore they thought that they do not need to concern whoever dispense the medicines. Their perceptions towards the DRPs were:

*“no, I don’t have any experienced or heard about DRPs. We always sell the OTC medicines and counsel customers how to take these. Normally we sell most in analgesics, multi-vitamins and anti-flu” (owner 2, area I)*

*“no, most of the patients come to buy only when do not get all items of medicines from hospitals. They usually bring prescriptions from hospitals. I have no experience on any problem related with drug quality like substandard medicines or*

*counterfeit medicines because the medicines in my pharmacy are all registered drugs” (owner 2, area I)*

The third group of participants, one pharmacy owner had heard about experiences from people with self-medication. The friendly customers told their experiences to pharmacy owner or staffs. Their experiences towards DRPs were:

*“sometime I heard from other people who take analgesics and suffered abdominal pain. One of my friend bought prednisolones from my shop and self-medicated. After a week, she told to me she felt unwell during her course so I suggested her not to take if any symptom occurs” (owner 3, area I)*

#### **The experiences of pharmaceutical company staffs**

The group of this stakeholder clearly claimed that they had no any experience of DRPs and never heard about DRPs of others.

#### **The experiences of local administrators and professions**

The first group of this stakeholder had no experience of DRPs. They claimed that:

*“I haven’t experienced or heard about DRPs caused by medication error or dispensing error from pharmacies” (academic pharmacist 1, area II)*

*“we haven’t heard about DRPs in our area but we have problems of unregistered products. We confiscated the unregistered drugs from some drug stores” (drug inspector, area II)*

*“I worked in administrative department as I am not healthcare professional so I have no experiences of drug problems of patients” (regulator, area III)*

In third group stakeholder, the regulator stated that they had heard about dispensing errors of community pharmacies. However, he explained that he did not think this is not a DRPs event because the pharmacy staffs making a minor mistake of dispensing error such as giving a look-alike or sound-alike drug to patients. His perception towards this experience as follow:

*“all problems are minor. Drug sellers make mistakes in selling because they cannot read the handwriting of prescribers” (regulator, area I)*

However, in pharmacists' point of view, many drug-related problems were initiated from wrong medications because of incomplete statement of dosage form by prescriber and their illegible handwriting. They felt sadly that the evidences of those cases were no opportunity to record them because pharmacists are less opportunities in hospital and clinical fieldworks.

*“I concerned the knowledge of sale persons as they are not pharmacists. As you know there are lots of similar trade names with different compositions. They gave wrong drug mistakenly to patients. The drug sellers just follow the prescription and sell exactly what the doctor prescribed. As they are not experts in medications, they don't know whether it is wrong drugs or dosage forms. Sadly lack of record on these events” (pharmacist in private hospital, area II)*

Nevertheless, one pharmacist mentioned that she had experienced of one event of DRPs of her friend. This was because an unskilled pharmacy staff gave a substituted medicine, having similar effect, to her friend. As a result, her friend suffered side effects of that substituted drug. She remarked on that case was there was no specific report system for such kind of error to take action. Her experience towards DRPs was:

*“my friend experienced about that she went to a pharmacy to buy some Aminophylline tablets for her asthma. That time the Aminophylline tablets were stock out in market. So the seller sold Salbutamol tablets to her. The pharmacy staff didn't give any information about drugs. When she took the first time medication, she suffered restlessness, palpitation and arrhythmia so she did not dare to take this medicine for second medication” (academic pharmacist 2, area II)*

The prescribers and nurses having experiences of clinical and hospital fields revealed that they have seen a lot of consequences of medications either in self-medication and prescribed medicines. According to the nurses, they had experienced some DRPs events range from minor to major cases especially in children and housewives who frequently used OTC medicines for long time without being counseled by professionals. They remarked that the DRPs were related to the patients' habits of retrieving the retained memory about their previous sufferings

together with the drugs that relieved them. Public were said to be little background knowledge about medicines because they requested the medicines by telling the colour, shape, appearance and even the price range of medicines. As a result, errors were found to be in dispensing process. Common problems they found were abdominal pain, abortion or bleeding in some patients. In such cases they knew from the patients was pharmacies are selling these medicines without giving drug information and counselling on medicines. Their experiences towards DRPs were:

*“patients generally buy their medication in their own ways, self-medication, they will come to hospitals/clinics only when they suffered side effects like bleeding from OC pills” (nurse 2, area II)*

*“some pharmacies do not counsel on medicines that should not be taken daily or regularly and neither do they give drug information” (nurse 2, area II)*

*“we have experienced some cases of side effects of NSAIDs such as haematemesis and melena and G6PD deficiency in children because some drug stores sold these OTC medicines freely without taking patients’ history and underlying diseases. Patients as well they retained the memory of their previous sufferings together with the drugs that relieved them” (nurse 1, area II)*

According to prescribers, they stated that the side effects of patient suffered in prescribed medicines were expected untoward effects of medicines and unavoidable. It was simply to treat the patients’ symptoms by giving the appropriate treatments. In this way, they treated the DRPs of patient’ symptom better. However, the prescribers and nurses admitted that they had no records on DRPs case because of they have no time to investigate any reason further for DRPs.

*“most are minor cases like nausea, vomiting, abdominal pain. So we gave appropriate treatments to their symptoms. We have no records on these cases because these are our daily work and it is not strange anymore, and as they are patients they can have many (many) complaints. We don’t think too detail for each case whether this is psychological or drug problems...so gave them medicines that matched for them” (doctor 7, area II)*

*“there are many cases we found everyday in hospitals. We normally experienced on cushions syndrome because of steroids effects, drug induced GI bleeding and dry cough because of side effects of ACEIs and many (many) other problems in patients” (doctor 8, area II)*

#### **4.2.4. Perceptions towards Better Pharmacy Services and Practices**

##### **General overview**

Regarding expected quality of pharmacies and ways to upgrade them, the majority of different group of stakeholders thought that pharmacy staffs are key players of service provision in pharmacies. As a result, they suggested that the pharmacy staffs with appropriate pharmaceutical knowledge should be recruited in pharmacies and they should be trained with suitable training courses. Some pharmacy users suggested that government should be strictly enforced on pharmacies to comply with rules and regulations. However, few participants from pharmacy owners and pharmacists pointed out that the quality of pharmacies could be improved by refining the health care system management rather than individual approach such as using the classification system for pharmacy either by rating the standard of pharmacy or limited selling items of medicine based on staffs' qualification and extending the strict enforcement on all distribution channels of pharmaceuticals rather than private retail pharmacies.

##### **The perceptions of pharmacy users including customers, patients and patient attendants**

Many pharmacy users suggested that all the pharmacy staffs should be kind, warm and proper counsel to patients because they have noticed that the majority of pharmacy staff lacked good communication skills. They also mentioned that good communication of pharmacy staffs was important for them to relieve their symptoms when they discussed about health problems to pharmacy staffs. Their perceptions towards better pharmacy services and practices were:

*“people are buying medicines to relieve their pain and illness so every drug store should explain completely about medicines like side effects, drug information and ways to use it” (patient attendance, farmer 2, area I)*

*“drug stores with not well communication should not exist, drug store should have skilled persons with good social dealing skills” (patient attendant, student, area I)*

*“people who buy the medicines are really ill. As they are patients, whether they are familiar to medicines or not, the drug stores should explain carefully to all of customers” (patient 4, area II)*

*“they should have good friendliness to regular customers because I think that it can help making the patients better” (patient 7, area II)*

Some users commented that all the pharmacy staffs should be received trainings for improve their practice and knowledge. They stated that their health problems relied on knowledge of staffs therefore employing the qualified staffs was important to provide the better service of pharmacies for them. Their perceptions towards better pharmacy services were:

*“A suitable training course is needed for drug stores to enhance their practice and knowledge (if possible) for not selling unregistered drugs and expired drugs” (patient attendant, farmer 1, area I)*

*“drug stores should employ qualified staffs (if possible) as we need to take suggestions from drug sellers sometimes, it would be better and safe if we could get suggestions from competent person” (patient attendant, worker 1, area I)*

*“I would like drug store to have trained staffs because I noticed that they are not skilled at all” (patient attendance, merchant 1, area I)*

### **The perceptions of pharmacy owners and staff**

For the pharmacy owners and staff, the majority of them perceived that the services and practices of pharmacy were improved by receiving the regular training courses from government. Some suggested that government should be strictly enforce through all areas to minimize the variations in pharmacy practices. Their perceptions were:

*“I would like to get official training from government regularly or hold meeting regular like once every six months or something like that” (owner 1, area I)*

*“Well, the government let us change our practice, we would like to get training regularly and we would like to get recognition from the government. We want rules and regulations uniformity” (seller 1, area I)*

*“All the pharmacies should be received regular training or hold meeting for the staffs' professional development. If the government offers training, i will let my staffs to attend it thereby i could get qualified (or certified) staffs” (owner I, area III)*

*“the government should enforce the law strictly in fair and square way. If the law specifies "No license is issued when there is no compliance", then we will follow” (owner 5, area III)*

Contrarily to the above ways, some owners perceived that individual approach solely might not solve the current situations of pharmacy context. They believed that the current situations could be improved through the classification of the pharmacy shops in accordance with their standard practice or the staffs' qualification. Moreover, one of the owners, a pharmacist as well, claimed that the quality of pharmacies could be improved by extending the strict enforcement on all distribution channels of pharmaceuticals rather than private retail pharmacies. He claimed that however hard pharmacies tried to store the medicines in best way, it is useless as long as the potency of medicines was not fully maintained in their initial stages such as during transportation and storage at warehouses of pharmaceutical companies. So he expressed a desire to put emphasis on regulation and management of pharmaceutical companies and their warehouses. Moreover, he revealed their unethical market practices. These pharmaceutical companies initiated and persuaded the prescribers to prescribe their products. This has led to malpractices of prescribers and this, in turn, affects pharmacies because drug stores stood as middleman between companies and prescribers. Therefore, he expressed a desire that all drugs should be prescribed in generic name/chemical name by corresponding prescribers. He suggested that the GPP guidelines should cover whole supply chain rather than retail pharmacies only, encompassing supply chains, wholesale distributing sector, private retail sector, prescribers and the public. He also suggested that role of FDA is

important because the support and appreciation of FDA would motivate pharmacy business to comply with the standards. He believed that appreciation of the pharmacy activities can lead to raise public awareness about quality pharmacy and this in turn, persuade pharmacies to compensate their efforts. Their perceptions were:

*“it needs to change the whole sector of health system. The only way to solve the current problems is to change the situations of the whole health sector. Health system must be developed. It needs change in individual's beliefs, perspectives, opinion to a higher level for a situation” (owner 2, area I)*

*“I suppose it cannot solve the problems when the FDA only highlight in one sector. So in my point, the quality of drugs can be maintained only if all the drugs are in accordance with the standards from starting points to the end (along the supply chain). You should keep in mind from the starting point of the supply chain, distributors in the middle, drug stores in the lower level and the public as end users at the last” (owner-pharmacist, area II)*

*“even if the customers have no awareness on quality, FDA should promote or appreciate the pharmacies that follow and comply with standards. FDA should specify grading or ranking system for good ones. By doing so, all the drug stores will realize they can get compensation for their efforts” (owner-pharmacist, area II)*

### **The perceptions of pharmaceutical company staffs**

This group of stakeholders perceived that the services and practices of pharmacy were improved by complying the rules and regulations of government. One participant suggested that government should frequently upgrade the capacity of pharmacy staffs through education campaign like knowledge sharing programme. Their perceptions were:

*“they should not sell the medicines that are not allowed by FDA such as fake drugs, substandard drugs. They should sell those medicines that are accordingly essential for public and patients’ needs” (company staff 1, area II)*



*“knowledge sharing should be frequently performed to pharmacy staffs for uplift the capacity of staffs. If possible, every pharmacy should have pharmacist’ supervision” (company staff 2, area II)*

### **The perceptions of local administrators and professions**

The local administrators and professions also perceived that pharmacy staffs are key players of service provision in pharmacies who directly contact the patients and customers. Moreover, the professions concerned that the staffs are mediators who can either precise or deviate in dispensing practice in line with prescription letters. For such a case, the professions suggested that the personnel qualification is important criteria for manipulations of prescription letter and proper counselling to the patients. Therefore, giving training to pharmacy staffs and specifying the personnel qualification were important for improving the pharmacy context. Their perceptions towards the better services and practices of pharmacy were:

*“the most important thing is the knowledge of the sellers. They need to be trained well. As they directly contact patients, they should have a good knowledge on drugs” (administrator 2, area II)*

*“if the pharmacies have skilled drug sellers, it will be better. If there is a will to improve the pharmacy practice, the staffs should be well-trained. The government should specify (in details) for education of drug sellers” (nurse 1, area II)*

*“The current practice needs more qualified staff because the medicines nowadays are more complicated and too many duplications. Besides, the treatment processes are too complicated and this cannot be handled by persons who can only read in English. They have not enough skills of interpreting prescription letters and counseling to patients” (doctor 6, area II)*

*“The current statement was not sufficiently described on qualification of personnel. The drug stores should employ staffs who have acceptable level of knowledge in pharmaceutical fields”(doctor 2, area II)*

Some professions thought that strict enforcement only could control the quality of pharmacies. Their perceptions were:

*“established the rules and laws on pharmacy can improve pharmacy Practice. Effective law can control the pharmacies” (nurse 2, area II)*

*“ways to improve pharmacy practices in my views are the existing law should be activated, government must permit only skilled persons to sell and dispense medicines and license for opening of drug stores should be strictly controlled and those selling mixed pills should be severely punished” (doctor 7, area II)*

However, some prescribers and local regulator eagerly discussed that the application of classification system might solve many pharmaceutical problems such as dispensing freely the prescribed medicines without prescriptions and illegal selling of medicines. Their perceptions towards improvement of pharmacy practice were:

*“I would like to classify the drug stores that based on pharmaceutical knowledge level of a person. If the person gets higher pharmaceutical knowledge, they will get a license for all kinds of drugs, otherwise the less knowledge they have the less items they should sell” (doctor 1, area II)*

*“if the drugs in pharmacies are classified into OTC and POM according to sellers' education, this is a good idea. But we do not have enough human resource to inspect the pharmacies” (administrator 1, area I)*

*“Okay! I want to suggest 2 things: the first one is that there should be law that specifically classified the POM drugs. The second is that the law describes required quality of personnel to run a drug store. That means it should not allow any graduate to run the drug stores who do not have enough pharmaceutical knowledge” (doctor 2, area II)*

**4.2.5. Perceptions towards Good Pharmacy Practice (GPP) implementation and possible barriers and facilitators for implementation process and possible outcomes from implementation of GPP guidelines**

### **General overview**

Regarding this section, a semi-structured questionnaires was used to explore the stakeholders' attitudes and understanding on the principles of good pharmacy practice (GPP) and the consequences of its implementation process. The vast majority of participants have neither heard about principles of good pharmacy practice (GPP) nor familiar with the terms of GPP. Only a few participants such as regulators and a non-pharmacist pharmacy owner had familiarly with the GPP terms but with limited understandings on the principles of good pharmacy practice. Pharmacists are exceptions in this case and they perceived that the principles of GPP were necessary for safe use of medicines of public and better health outcomes of patients.

### **The perceptions of pharmacy users including customers, patients and patient attendants**

All the pharmacy users were found to be little or no knowledge on practice level about GPP. They had never heard or familiar with the terms GPP or pharmacy practice. Moreover, they had never touched the rules and regulations of current existing laws. However, their attitudes towards the practice levels about GPP were positive. Some users expected that pharmacies with no selling unregistered and expired medicines were complied with good practices. While some users expected towards good practices that it was good compliance to laws.

### **The perceptions of pharmacy owners and staff**

The majority of pharmacy owners and staff had never heard about terminology of GPP and its principles. GPP terms was found to be a new thing to majority of this stakeholder.

*“I have no heard about GPP principles so how should we learn it? Is it a new one? What is it for? Do we need it?” (owner 2, area II)*

However, they could imagine that GPP was good for pharmacies or good for everyone because the guideline and practice of GPP were set by government.

*“I have never heard about GPP. So I cannot give my opinion on GPP principles. But if the government thinks that this is necessary for us, we have to accept it” (owner 1, area III)*

*“As for me, I welcome GPP. But if the government wants us to follow and practice it, please show us how to do it in right way” (owner 2, area III)*

Regarding the implementation of GPP guidelines in retail pharmacies if the government would promulgate the laws relating to GPP, they simply agreed that they would follow the guidelines because they were be inclusive in this process. However, they explored their perceptions and difficulties relating to the implementation of GPP guidelines. The first thing that some owners of rural areas claimed that practicing the GPP principles might not be matched with socio-cultural and socio-economic status of their local people. Some of them confessed that if the GPP implementation was to be adapted voluntarily, they did not want to change by them alone. They concerned that most of the local people were not rich enough to buy expensive medicines as well as demand the quality service. Their perceptions towards implementation of good pharmacy practice were:

*“the barriers for GPP implementation will be that customers may feel reluctant to get into a decorated building. They usually think the big shops are increase in prices. Besides, communication gap can occur as barriers between the sellers and buyers. It is not easy to change the situation because of our culture” (owner 2, area III)*

*“if this situation becomes compulsory, we have to follow. If it is a voluntary change, I don't want to change alone as this is a small rural area, many people are not rich enough. If I decorate my shop according to standards, people will feel reluctant to buy from me if government enforce it as mandatory law for whole country, we are ready to change it” (owner 2, area I)*

The second thing that some of the owners from rural area who could not afford to follow such condition commented that they would give up their business at that time and change to another business. They revealed their difficulties as

barriers for GPP implementation that they could not afford to employ a pharmacist and invest for facilities which were beyond their limits.

The majority of owners mentioned the third thing of barriers for GPP implementation. It was mindsets of people. Some owners stated that people are hard to change their status quo and do not have desire to change into different situation. Because people think that changing the situation might be more difficult for them than the previous condition. They also admitted that they were accustomed to immoral practice for long (long) time. That means they tried to blame others for their general weakness.

*“Unless changing the situations that based on individuals and public perception towards good quality and practice become high, it would be difficult to initiate the GPP principles in retail pharmacies” (owner 2, area III)*

*“Umm, there is malpractice everywhere because we used to live in comfort zone for several years. They don’t have right concept. This leads to low level of their practices so it is not possible to change at once” (owner 5, area II)*

Regarding the expectations of pharmacy owners to overcome the difficulties in complying the GPP guidelines, the first thing claimed from some owners was they have desired to be compensated for their activities with some kinds of rewards such as appreciations from government such as ranking or rating their pharmacies for attention of public if they have to adapt it voluntarily. They also stated that government should announce in official channels like newspapers for expressing the guarantees of their services and making people appreciate their efforts.

*“I suppose without motivation and description about the standards of drug stores, everyone will barely change. They need pressure when you want to them to start the GPP. The best thing to bring them along is that the government gives motivation and acknowledgement to them. Just let them know they are important for people’s lives” (owner 2, area II)*

The second thing to overcome the difficulties in GPP implementation was some owners perceived that they could practice the GPP in right way if the government shows the ways how to practice it. They expected that if the government

provide necessary training to them, they could get qualified staffs even if they could not employ the pharmacists.

*“well, we do not understand about GPP principles if government tell us what is GPP and how should we follow it, it will be the best thing I think”(owner 1, area II)*

The third thing of their expected ways to solve the difficulties in GPP implementation was changing the mindsets of stakeholders. Some participants suggested that the mindset of retail pharmacies could be changed by encouragement and appreciation from government which are essential for good attitude towards changes to come. Some owners said that increasing the public awareness on standard complying pharmacies was one of the important facilitators for GPP implementation.

*“I would like to suggest ranking or rating system for our pharmacies. FDA should promote or appreciate the drug stores that follow and comply with standards. By doing so, all the drug stores will realize they can get compensation for their efforts”(owner 1, area II)*

*“I think if we change our practice according to rules and regulations but public is still not notice about that and this can lead to a strange way to them. So education of public is the first thing and most important I think” (owner 3, area III)*

However, one of the owners, who had already initiated the principles of GPP, explored his positive attitudes towards GPP implementation process. He is a non-pharmacist. He perceived the practicing of GPP was provision of quality medicines to public in a safe way. Though he did not know the principles and scope of GPP like a profession, his good intentions brings the concepts of good practice to practice it in his pharmacy such as employing a pharmacist to manage the pharmacy as well as doctors to counsel in free of charge for customers. His perceptions towards GPP implementation were

*“As I am the pioneer of initiation of GPP to my drug store, I’ve already experienced those conditions both facilitators and barriers. I understand that GPP can guarantee the service that we provide. So in my opinion, if all the drug stores follow the principles of GPP, the public who use the pharmacy service can get*

*quality medicines in safe way. I am so pleased to give the best quality of service to customers and public and I am so proud of my work” (owner 1, area II)*

As a general overview, the majority of owners had known about current rules and regulations of existing National Drug Law. However, the current regulations related to pharmacy practice were found to be perceived differently in each participant. They had limited understandings on the principles and practices of pharmacy. Regarding the knowledge about current existing law, some of their responses were:

*“I have known about penalties. We know what the punishment or penalty liable for infringement of law. So I do not sell mixed pills, expired drugs and fake-drugs to patients” (owner 1, area III)*

*“I know the regulations that are promulgated by FDA. They notify how to store the medicines, how to keep the documents specified by law, something like that” (owner 2, area I)*

#### **The perceptions of pharmaceutical company staffs**

Similarly with above stakeholders, they also did not familiar with regulations relating to retail pharmacies. No special comments and suggestions about GPP implementation process, barriers and ways to overcome from this group of stakeholders.

#### **The perceptions of local administrators and professions**

From the points of local regulator and inspectors as an administrative role on GPP implementation process, the current context of pharmacy was too far to reach the national agenda. One of the regulators made some pointed facts that despite the principles of GPP were good, the establishment was depended on the community perceptions and their value on quality services and products. He also stated that the implementation process could be successful only with good educational level of public, high economic status and clear perspectives towards quality services with high moral standards. Otherwise, he did not think the situation of pharmacy atmosphere was neither worse nor better when there is GPP in Myanmar. He expressed that there was less clear-cut between punishments for law-breaking versus

award for compliance. As a result, the vast majority of private retail pharmacies were weak compliance in rules and regulations. Some perceptions of a local regulator were:

*“in my opinion, if there is GPP in Myanmar, it would be neither worse or better than this situation. Because the vast majority of private pharmacies are weak compliance in rules and regulations. No clear-cut between punishment for law-breaking and reward for compliance. There are lots of factors that influence on pharmacy practice such as people who struggled in lives have no time to demand for high quality service. So I think unless the majority of public asking high quality, it is not easy to solve these problems. Then fair educational level and good economic conditions can only persuade the community to interest these things to implement it”* (regulator, area I)

Regarding the barriers relating to the implementation of GPP guidelines in Myanmar, the participants from a group of regulator and inspectors pointed out that poor human resource regarding pharmacists and regulatory teams and budgets were barriers for government. They said that not only the regulatory teams at every level of different states and regions had insufficient staffs to cover all the areas but also the pharmacists do not meet the needs. Two local inspectors stated that:

*“the hard thing is FDA has no capacity to check all the things at now. So we including FDA do not cover all shops. Township level also do not have enough man power to train the pharmacies. Another thing is investment is the barrier for the drug store owners. Employment of pharmacist is high cost for drug store owner and the quantity of pharmacists is also not enough to employ and the costs for maintenance and decoration of pharmacies”* (local inspector, area II)

*“I don't know too much in detail about implementation and its process. but i can say that in current situation we do not have enough staffs so we cannot visit regularly to cover all shops. If we will implement another criteria "GPP", the first barrier for us is human resource. This can be extra work for us. The second will be the budget and the third is our knowledge about GPP. I'm afraid that*



*even we don't know detail about GPP, how will we transfer this message to drug store owners and sellers then to customers. I think all the steps can have many barriers” (local inspector, area III)*

In addition, a regulator mentioned about socio-economic factors of general people and perceptions of pharmacy staffs, which were identified barriers in GPP implementation. He concerned that people from rural areas do not think further for quality of drugs and services because middle-class people and low-income people were struggle for survival. As a result, they have little or no chance to demand for high quality services of health care and their perception towards medication safety was low because they considered only on costs and self- efficacy. So he remarked that unless those general people asking the quality services, the GPP implementation was not possible to establish especially in rural areas. Regarding the perceptions of pharmacy staffs, he assumed that the majority of pharmacies were weak compliance with the law and a few pharmacies could provide high quality service. He said the pharmacies were complying the statement only when there was inspection. So he remarked that the good practice would be seen neutrally if a person concerns for welfare of others and perceives his or her service is for well-being of human. He also remarked that the GPP implementation will be achieved possibly when people changing their ways of thinking and perceiving safe practice is for their welfare. Moreover, increasing number of communities who can afford the quality service and who value the quality and appreciate the good practice could be a driving force for GPP implementation. He suggested for community pharmacies who would resist to follow the GPP guidelines should be appreciated for their efforts by the government. His perceptions towards difficulties for GPP implementation process was:

*“if the socio-economic condition of public is saturated to a certain level, there can have demands for quality service otherwise it cannot establish. Then we gradually upgrade their concepts and perceptions. And for the pharmacies, they should be appreciated for changing and be received certificate for their efforts” (regulator, area I)*

All the participants from the group of prescribers and nurses did not familiar with the terms of pharmacy practice, GPP and current rules and regulations relating to pharmacies and pharmaceuticals as well. The perceptions of prescribers about GPP principles and its implementation process were found to be beyond their knowledge and interests. So they cannot imagine about principles and scope of GPP. However, they perceived that an efficient regulation relating to pharmacy launched by government or relevant organizations such as FDA could control the activities and practices of pharmacies and then could bring the positive outcomes and benefits to all stakeholders.

*“This is beyond my knowledge. So I have no idea on GPP. That’s why I have nothing to give suggestions or opinions but I have desire to improve the pharmacies in Myanmar” (doctor 4, area II)*

*“I suppose the GPP guidelines will be pretty perfect for pharmacies. It can bring benefits to all. There needs a control of prescription drugs and all OTC products” (doctor 5, area II)*

*“If there is a good regulation related to pharmacy practice, I think it will be safe for general public. If government wants to implement it, they should apply effective laws and regulations” (doctor 3, area II)*

A few prescribers expected to include a certain issue in the context of GPP guidelines such as limited selling of POM medicines and proper dispensing of OTC medicines. They recommended that the POM medicines should be sold only with prescription letter and thereby it could help in improving the rational use of medicines and proper use of antibiotics.

*“I expect that the law must contain some conditions like POM drugs can be sold only with prescription letter and all the OTC drugs should be sold with legal requirements” (doctor 5, area II)*

*“Government should permit the skilled persons only to sell and dispense medicines and strictly controlled on licensing system of opening the drug stores” (doctor 7, area II)*

Nevertheless, some of them concerned that upgrading the standards of pharmacies seemed to be difficult in current situations. They commented that the quality of pharmacy staffs is less satisfactory for public and the pharmacy owner would face difficulty to renovate his shop. Therefore, they suggested that pharmacy staffs should be trained well by upgrading their capacity and strict rules and regulations should be applied to enforce the pharmacies to follow and comply the standards.

*“I think the GPP is good for pharmacies. However, they could not follow it. They might fail to comply it because of budgets, investments if they are not landlord or high costs because of maintenance fees and something like that” (doctor 5, area II)*

*“There can be little compliance in rural areas I think. Besides, in downtown areas, there will be rare pharmacists in pharmacies. And I don’t think all pharmacies will follow it” (doctor 7, area II)*

However, all of the stakeholders from this group did not provide their expected ways to overcome the difficulties in complying the GPP guidelines and any special comments on it. But they gave their opinions about current regulation related to pharmacy practice that the current situation seemed lack of effective regulatory mechanism and less guarantee practice for public. So their opinions on existed regulations were:

*“I think the current situation lacks effective regulatory mechanism to take action against rule infringement” (doctor 1, area II)*

*“though I don’t know much about the current regulation, I concern about that it was not safe practice for public in pharmacies so I think a new regulation is necessary for improving the pharmacy practice. The current regulation is weak” (doctor 5, area II)*

*“the current practice needs more qualified staffs because the treatment processes are too complicated so this cannot be handled by persons who can read only in English” (doctor 6, area II)*

The pharmacists from academic section, public hospital and private pharmacy perceived that the principles of GPP are important for good practice and it could contribute the promotion of rational and economic prescribing of medicines.

*“These guidelines are intended to provide the safe and effective medicines to be used properly and appropriate ways to achieve welfare of public health outcomes. It is the core of pharmacy activities and requires to provide patients make the best use of medicines. The medicine use process is also important for well-being of patients” (academic staff 1, area II)*

When they were asked about implementation of GPP standards in Myanmar, they affirmed that the scopes of GPP were too far to adapt and wide to adopt for current situations because the pharmacy staffs were thought to be non-professionals and not proficient in pharmaceutical backgrounds. They also concerned about how pharmacies would run with little or no pharmacists to harmonize well with GPP standards and who would take responsibility for these tasks. So they remarked that the plan of GPP implementation would be a big challenge for retail pharmacies to initiate unless the government enforce a fact that at least one pharmacist must be employed in each pharmacy.

*“The real situations of drug stores are so far to touch the good pharmacy practice. I think GPP is too high for them. I think they cannot follow GPP. They cannot follow even the current regulations. Perhaps they know the current regulations but they don't follow unless regulations enforce on them” (academic staff 3, area II)*

All the pharmacists agreed to say that financial resource and the criteria of standards were barriers for current situations such as professional practices, recruitment of pharmacist resource, staff employment, roles and responsibilities of pharmacy staffs. Currently, pharmacists were less frequently found in community pharmacies because of little job satisfaction, unclear allocation of responsibilities between pharmacist and non-pharmacist staffs and small amount of salary comparing with pharmaceutical companies. Therefore, they remarked that the gaps between standard and current practice were too wide to bridge and it could take

a long time to make all the pharmacy staffs work in harmonious way. Therefore, as the government, the FDA should have a strategic plan to implement GPP and start it in step-by-step.

*“The gaps between standard regulation and real practice are too wide to initiate it. GPP is mainly for pharmacists. Now we all are not working in drug stores. How can we initiate this guideline without us? Right? Who will take responsibility for this GPP? So I think we are hardly to adopt these guidelines unless the government specifies that a pharmacist must be worked/supervised in each drug store”*

The first academic pharmacist remarked that the pharmacy owners and staffs would struggle to follow those standards with limited abilities since majority of them were non-pharmacists. Their current practices were not aligned with GPP concepts. But she expected that the difficulties could be reduced by providing the appropriate level of trainings, designing the relevant training courses for staffs and education campaign to distribute required knowledge to public thereby people would become aware of rational use of medicines. All stakeholders should be understood what GPP principles are and why GPP is important for them.

*“frankly say that there is no concept about GPP for owners, sellers and regulators. All these will be barriers for GPP. The owners and drug sellers also will be struggled to follow the standard GPP at first. The public as well, the process of education to them is quite hard. So we must persuade them about benefits of health care provision regarding how importance of care and why they need for them. We need to give education to the public so that they understand the GPP principles. Along with this, there need to enforce rules and regulations compulsorily. So the drug stores as well as the public should be well knowledge. Their awareness and demands are important”*

The second academic pharmacist commented that the implementation process could be difficult for policy makers as well as baseline levels of staffs at the very first beginning steps and during the sustaining process. Her point of view was that the pharmacy staffs were enjoying the comfort zone and they did not want to

struggle out of there. So it could be difficult for policy makers to control them to change to a new setting. As a result, law enforcement and public awareness is essential for establishment of GPP principles. So she urged that the healthcare system was needed to change in right ways such as employment of qualified staffs who would well-knowledge on OTC products, provision of public education to raise awareness on how benefits of healthcare and utilization of pharmacists in health care system. She recommended that knowledge of GPP principles, concepts and awareness, regulatory enforcement and encouragement were facilitators for the implementation of guidelines.

*“There could be difficult from policy makers to general workers. Because there will be needed to change a whole (health) system. People dislike the current situations but (if there will be changed) they do not want to struggle from comfort zone. They do not follow the laws even if they know this is good for them.”*

*“There could be more effective only if all the (health) sectors change together. It is necessary to follow the rules and regulations if we want to activate right system. In order to change from chaos system to right system, the very first thing is our compliance. At the same time, it is necessary to be well-educated. The current situations should be changed with authority (by force) as well as education”*

The third academic pharmacist stated that pharmacists have no chance to make assessment and comment on doctors' prescriptions and less opportunity to deal with prescribers. So she thought that little or no collaboration with prescribers was one of the barriers in establishment of GPP principles. Her suggestion to solve this problem was the government should engage to all prescribers to support the GPP. Therefore, her expectation to reduce the barriers was government has responsibility to reconcile the gaps between specialists, GPs, pharmacist and non-pharmacist staffs.

*“Barriers are assessments of the prescription by the pharmacists. We have no chance to assess social background of patients, legally registered drugs or not, economic aspects of patients, and therapeutic aspects of medications... how to deal with physicians/doctors/GPs to understand GPP. The society of doctors does not*

*believe in pharmacies and the pharmacies have no authority or chance to provide feedback to doctors so we need technical ways to communicate them”*

A pharmacist from pharmacy owners gave his impressions on curriculum of pharmacy education. He suggested that the curriculum should be upgraded to prepare pharmacy profession to handle diverse responsibilities in different practice settings. He said that the current education trend was not matched with the practical settings in different areas, for example, the curriculum were focused only on the basic pharmaceutical sciences such as formulation and industrial-oriented subject matter. Moreover, he commented that the problem of human resource could be reduced by doubling the amount of production of graduated pharmacists at each year from both universities.

*“Even bachelor degree of pharmacy graduated students cannot work immediately in drug stores without having any exposure of clinical experience. The knowledge that we’d learnt from university is not matched with jobs in everywhere...for example, marketing art. In university we hadn’t had a chance to learn it. We should produce double amount of bachelor students. Even within 5 years, the produced pharmacists cannot meet the required amount”*

They expected the outcome of GPP implementation in positive way that there could be decreased number of unstandardized retail shops that would not comply with the standard guidelines. Another points of positive outcome were patients and customers would receive safe use of medicines, the national standard of healthcare sector would be built up and the relation between pharmacists and other professionals could be promoted to get better health outcomes for public.

*“Unstandardized drug shops may be withdrawn as they will inconvenient to follow the standard guidelines. The GPP is very good guidelines to provide safe use of drugs for patients and customers. I believe it can promote the relationship between pharmacists’ role and pharmacy services of other professionals to be better health outcomes of the public. It can also promote standard of our nation in health care sectors. The standard operating procedures of drug supply system can*

*be established and foreseeable changes in pharmacy practice.” (academic staff I, area II)*

### **Ascertainableness of GPP contents**

#### **Contents derived from the group discussion with Customers**

In order to be a good pharmacy and its practice, from the point of customers, most the customers defined it that the pharmacy staffs can provide correct medicines that the doctors prescribed, quick delivery service of medicines to customers, inexpensive prices and can provide a complete information of medicines that they asked. So, with the group discussion with customers, most of the customers prioritized that good communicated ability of pharmacy staffs is important for assisting them to get medicines and information that they wanted. Good communication that they mentioned was staffs' patience with customers on asking the medicines. The customers prioritized secondly that personnel qualification of pharmacy staffs and they want a graduated person who is knowledgeable in pharmaceuticals or who got a certificate of training on pharmaceuticals. Then they proposed to include in prioritization that strict rules and regulations are necessary to consistent nationwide and commented that reward-punishment system is required for compliance of rules and regulations. Therefore, they discussed that announcement or appreciation about quality drug stores or pharmacies from the government in official channels was crucial for their awareness on choice of quality shops. Lastly, they gave suggestions that provisions of educating and training programs to pharmacies in regards to customers' care and services, and proper storage of medicines were essential for establishment of a better quality pharmacy.

*“the sellers should be patient when we asking them. They should explain until we understand the medications. Most of the drug stores didn't provide customers' services. They all are just doing selling and buying”*

*“a good pharmacy can provide right medicines to us, and without too delay because I don't want to spend too much times to get medicines and I want to relieve immediately”*



*“I think government should educate to drug stores. They should use reward-punish system. Nationwide! The majority of people might follow the rules and regulations if they get reward/profit from someone/government. Otherwise, I don’t see they will change”*

Table 6 shows a summarized 6 contents proposed by pharmacy users;

*Table 6 Proposed contents for optimum condition of GPP guidelines implementation (n =7)*

No	Propose Contents for establishment of GPP principles to retail pharmacies
1.	Pharmacy staffs should have good communication and kind treating to customers and patients
2.	Government should enforce strictly on retail pharmacies with existing regulations
3.	Government should specify the qualification of pharmacy staffs who is knowledgeable in pharmaceuticals or who got a certificate of training on pharmaceuticals
4.	Government should announce publicly for the quality of pharmacy practices knowing the people what are differences between quality and general drug stores
5.	Government should award to quality pharmacy in order to encourage the compliance of rules and regulations
6.	Drug store owners and staffs should have to be trained on customer care, customer services and good practices of pharmacy

### **Contents derived from the group discussion with Academic staffs**

Based on the analyzed, identified gaps from previous interviews, the current situations of retail pharmacies context in Myanmar showed that pharmacy staffs were limited ability for prescribing and counseling to the patients and customers because the majority of them were not professionals. Moreover, the pharmacist number was short off in private and public health care system and the retail pharmacies were run with trade-off culture without pharmacists. The roles of pharmacists were generally thought to be in a subordinate position to other professionals in health care system.

As a result, job satisfaction for pharmacists was lacking among pharmacists and this is why the pharmacists did not work in public as well as private health sectors.

Regarding the first interview guidelines, two of academic staffs proposed that the annual intake of undergraduate pharmacy students should be increased numbers and it should be planned as a long-term goal in order to reduce inadequate number of pharmacists in working fields. Academic staffs then suggested to fill another gap as a short-term goal was upgrading the qualification of pharmacy staffs with provision of trainings on pharmaceuticals. One of the pharmacist academicians pointed out that a person with limited knowledge on pharmaceuticals must have difficult to perform all principles of good pharmacy practice in one time. So she suggested that very first basic requirements of good practice should be started for a normal person who working in the retail pharmacies such as good storage practice and good dispensing practice. And then she said the scope of good pharmacy practice should be expanded in phase by phase in each year. Being a place of human resource production as well as a site of teaching, a pharmacist academician proposed that the University of Pharmacy should provide supportive training for good pharmacy practice to pharmacists as well as pharmacy assistants.

*“As the number of DS was more than 10000, our produced amount had not met that DS amount. So the first solution to fill the gaps is we should increase the intake of pharmacy students. But this may be long-term to meet the objective” (Chief administrator)*

*“The second, for the short-term, we can provide trainings as at least 1 year course like 1-2 years diploma. The training program should always go as Continuous pharmacy education (CPE). We can also conduct the Continuous professional development (CPD) for pharmacists and pharmacy staffs. So what can we do now as university is we should take responsibility to train the other staffs how to do good practice, get good dispensing practice and counsel the patients” (Pharmacist Academician 4)*

*“the scope of GPP is too wide. So for a lay person to obtain good practice as well as professional relationship was too difficult for him/her” (Pharmacist Academician 1)*

Corresponding to the second interview guideline, the chief administrator of University gave a comment that collaboration should be established among professionals to get professionals relationship and pharmaceutical care concept. Another academician also agreed that collaboration is crucial for professional development and provision of pharmaceutical care to patients and customers. They all remarked that the current situation of pharmacy atmosphere is not meet with standard criteria regarding the personnel qualification of staffs. As a result, pharmaceutical care concept is hardly to initiate for those kinds of staffs and collaboration is also far-off process. They believed that the University can bring the gap of collaboration among professions and thereby supporting the in-process and sustainable implementation of GPP guidelines.

*“we can help them to get professional relationship and pharm care concept. Right now the pharm care concept is important because nowadays the trend is changing to patient care” (Pharmacist Academician 3)*

*“For my opinion, I think collaboration should be started from awareness. It can be obtained through holding seminars or workshops frequently. For awareness about prescription practice also, we should conduct seminars for (many) many times to understand how importance of good prescribing practice” (Chief administrator)*

Regarding the suggestions to government to achieve GPP in Myanmar, the participants highlighted that the government should assign the Universities of Pharmacy to provide training program to drug sellers and pharmacists. They agreed that Law and legislation should clarify the roles of Universities in upgrading the human resource capacity. Moreover, they also pointed out that the National Policy should be extended for utilization of pharmacists in right ways. This means the laws should specify at least one pharmacist must be working in retail pharmacies. This criterion is said to be essential for collaboration of profession to provide pharmaceutical care to patients and to perform the tasks of good pharmacy practice.

One of the pharmacist academicians concerned that the meaning and principles of good pharmacy practice should be clear understood and be trained among regulators. Because they concluded that the regulators are the first persons who work hand in hand for GPP principles to owners and sellers. They suggested that the specific responsibility should be allocated for each level of government staffs who involved in GPP implementation and pharmacy staffs and owners who implement the GPP in practical way. Therefore, based on the previous sections of interviews, they suggested that the responsible regulatory body should adjust and negotiate settings on different GPP meanings among stakeholders before implementation. Lastly, they remarked that enhancement or encouragement is necessary for differentiation of quality and general drug stores.

*“I would like to suggest that Government should specify law on Universities of Pharmacy must provide training program to drug sellers and pharmacists”*

*“the Universities should take doubling intake for pharmacy students or the law should notify that if there is quality staffs in DS, they can provide quality service and run with effectively, or something like that. Only law can strengthen/ clarify our role in upgrading the human resource capacity” (Chief administrator)*

*“Government should reconsider on rules and regulations and if necessary, edit and amend it regarding the utilization of pharmacists” (Pharmacist academician 2)*

*“I would like to say in short 3 points that must have to be balance in order to establish GPP:*

*(1) rules of laws (as other people stated) the government should coordinate the registration that they must push the owners to employ the pharmacists by applying law and bylaw...*

*(2) professional development should be conducted for continuous learning. As our rector said we can hold seminar, talk, and so on” (Non-pharmacist academician)*

*“Concerning the regulator, they should try first to understand very well on GPP principles themselves. Then they should show the way and their vision to owners and sellers. If they really want to start it, please train the regulators themselves first then*

*allocate the specific responsibility and let the regulators (themselves) to read to understand GPP principles clearly” (Pharmacist academician)*

Regarding the sustainable process of GPP implementation, some academicians pointed out that the university should highlight the government’s policy planning by doing the research on “need analysis”, on “comparing the services with or without pharmacists in patients’ medications” and on “assessing the educational status of pharmacy assistants”.

*“we need the research on “Man power analysis for GPP” or “need assessment”. From this, we can point out the policy planning” (Pharmacist academician 1)*

*“we should point out the policy planning that we need to assess the educational status of pharmacist assistant (trained from private business sector).” (Pharmacist academician 2)*

*“we should compare between the services without pharmacists and services with pharmacists in adjusting the therapeutic drug monitoring” (Chief administrator)*

Table 7 presents a total of 18 contents proposed by academician groups including chief administrator, pharmacist professors and non-pharmacist professor.

*Table 7 Proposed contents for optimum condition of GPP guidelines implementation (n =6)*

No	<b>Propose Contents for establishment of GPP principles to retail pharmacies</b>
1.	The Universities (of Pharmacy) should produce doubling amounts of pharmacists and the authority should be affirmed by Law and Legislation
2.	The Laws should update the standards in step-by-step annually
3.	The scope of GPP should be specified and initiated from the simple feasible tasks which is important for patients’ safety because the scope is too wide to achieve
4.	The Universities (of Pharmacy) should be assigned to provide supportive training and certification for good pharmacy practices to drug stores (such as good dispensing practice, patient care practice, counseling practice etc)

5.	Drug store owners and staffs should have to be trained on pharm care process and good practices of pharmacy
6.	The government should recognize the roles of pharmacists in drug stores and specify rules and regulations on pharmacists to supervise the community pharmacies
7.	Government/FDA should understand clearly about pharmaceutical care principles
8.	Universities (of Pharmacy) should educate to undergraduate students on principles of pharmaceutical care
9.	The responsible regulatory body should adjust and negotiate settings on different GPP meanings within stakeholders before implementation
10.	The government should negotiate among drug stores, prescribers and companies and let them to collaborate each other
11.	The government should announce publicly for quality of practices to the people knowing what are differences between quality and general drug stores
12.	The Universities (of Pharmacy) should take the roles of conducting research (need-based analysis, role of pharmacists among general people and professions, role of pharmacists in healthcare system etc.) to strengthen the GPP principles
13.	The research should be conducted on need analysis studies for stakeholders which can provide trainings that can respond to customers'/stakeholders' needs
14.	The research should be conducted for evaluation of practices of drug stores as well as customers' behaviours to assess the awareness on GPP principles
15.	The GPP principles should be strengthened by exploring evidence base research data
16.	Getting increase awareness to all stakeholders by showing strong evidence base on "only pharmacies with GPP can bring the drug safety to them"
17.	The education campaign should provide information or awareness on how importance of roles of drug sellers in dispensing practice, counselling practice and storage management etc.
18.	The rules and regulations should be updated which relate to roles of professionals in drug stores (pharmacists workforce)

### **Contents derived from the group discussion with Pharmacy owners (Urban area)**

When a discussion section was carried out with a group of pharmacy owners from urban area about the most feasible steps in GPP implementation, they thought that training programs can be initiated in short duration. They also believed that the training could upgrade their capacity in short-term. They mentioned that it is more suitable when the types of training are matched with government's roadmap. However, they said that they need effective trainings on storage practice, communication, dispensing and patient care service.

Another expectation that can be started in short-duration was provision of education to public and drug stores. However, they supported that education campaign should be planned for long-term goal and sustained along with implementation process. They believed it because many times of education campaigns can change the awareness of public and set the mindset about quality, safety and risks of pharmaceuticals. Some of them suggested that collaboration between retail pharmacies, distributors and prescribers is important for participation in the process of GPP to smooth the journey.

*“So if you want me to run with professionally, you (as a government) must provide diploma course. It can start within short period” (owner 4 from Urban area)*

*“Kind of training is depend on what they want us to do. We need technical training that really help to us. We would like to get trainings that relate with customer service or quality care or something that match with their roadmap” (owner 2 from Urban area)*

*“So as for me, I think we can do upgrade our staffs in short term. So we need training. We willing to accept it” (owner 5 from Urban area)*

*“collaborate from companies and FDA is good for us. We can go straight with support from companies and FDA. We need regular meeting with FDA and companies to discuss about our problems like shortage of medicines in market, banned products, recall products, something like this...” (owner 4 from Urban area)*

They remarked that applying the classification system to retail pharmacies is not suitable for current situations. They thought that if the government would apply classification system, the retail pharmacies will be separated into two parties; one party that could follow the rules and regulations and the other that could not follow those ways. So they mentioned that no one would get benefit from the way of classification system. They worried that public still might not ready to accept on restricted items of medicines if there will be classified pharmacies and they might have limited accessibility to a variety of medicines.

*“classifying the drug stores based on drug system is not suitable for now I think. It’s too far from ground situation. We can separate as 2 parties. So no one can get benefit if the DS are separated into two parties” (owner 3 from Urban area)*

Based on their discussions, they needed and requested that standard operation procedures (SOPs) for all pharmacy activities are required to uniform their actions. They highlighted that government should encourage to pharmaceutical companies and wholesale distributors to participate in implementation of GPP process and they mentioned that they need technical and moral support from FDA. They urged that government should use reward-punish system to improve the current situation.

*“So we need to know procedures and standard thereby we can avoid our staffs’ errors. Right now, we have no format and we put medicines on shelves according to the customer’s demands and sometimes we arrange them in convenient way. Not knowing standard procedure or format” (owner 5 from Urban area)*

*“Please tell to government – not only enforce but also support and reward! We understand enforcement is important for controlling a certain condition but supporting as well can improve the situation” (owner 5 from Urban area)*

*“Support us whatever based on their design/vision. Not only enforce us but protect us (friendly relationship). Thereby we can discuss frankly our conditions” (owner 3 from Urban area)*

Table 8 shows a total of 16 contents proposed by pharmacy owners from urban area;



*Table 8 Proposed contents for optimum condition of GPP guidelines implementation (n =5)*

<b>No</b>	<b>Propose Contents for establishment of GPP principles to retail pharmacies</b>
1.	The government/FDA should provide trainings on rules and regulations of pharmaceutical marketing to wholesale suppliers, pharmaceutical companies and retail suppliers
2.	The government should provide information of GPP implementation to prescribers and specialists through Medical associations (both NGOs and GOs)
3.	Drug store owners and staffs should have to be trained on pharmaceutical care process and good practices of pharmacy by professionals
4.	In order to establish GPP principles, prescribers should prescribe with clear hand writing on generic drugs only in order to minimize dispensing errors on lookalike/sound-alike drugs and avoid the stock-out problems/unnecessary expensive trade products
5.	The pharmaceutical companies should practice ethically regarding dealing with prescribers and support to drug stores in their affordable ways for GPP achievement
6.	The FDA should collaborate with drug stores to encourage them and share up-to-date knowledge and information
7.	The government should engage pharmaceutical companies to support drug stores in their affordable ways for GPP achievement
8.	The collaboration should be effective and transparent between government as well as pharmaceutical companies and prescribers in order to understand the real situations of drug stores
9.	The government should support to drug stores in technically and morally
10.	The retail pharmacies should be awarded in order to compensate their efforts (money and time)
11.	The government should encourage the prescribers to write prescription letter rationally and correctly
12.	Regulation should be covered to all levels of stakeholders (e.g. supply chains,

	distribution outlets, prescribers and consumers)
13.	The government should apply reward system rather than punishment system (Recompense)
14.	The pharmacy business should have registration system for sellers to provide guarantee of institutions
15.	The prescribers need to aware that their roles is also important for implementation of GPP principles (e.g. prescribers' attitude and ethics in prescribing habits)
16.	The pharmaceutical companies need to avoid unethical marketing behaviours

### **Contents derived from the group discussion with Pharmacy owners (Rural area)**

When a discussion section was carried out with a group of pharmacy owners from rural area about the most feasible steps in GPP implementation, they requested the training programs that should be started in short-term period before GPP implementation. They suggested that the training program should be designed for different course levels based on the experience of workers and that would match with GPP way. They claimed that the staffs' qualification and experiences were too varied and if a worker has experienced then he or she left the job. So they are not easy to train a new worker again and again and if the government set a training program for them, the pharmacies could employ trained and qualified staffs.

*“the training level should have classified for non-experience persons and experience person. Because the education status and experiences are very diverse”*  
(owner 1 from Rural area)

*“for GPP program, we need training. Right now I have no idea about the kind of training. But we would like to get the training that is matched with GPP way”*  
(owner 1 from Rural area)

*“training is important for us because if we train our staffs for nearly 6 months to 1 year, they got experience and then quit the job. We had to train repeatedly to new staffs. But no one stayed more than 2 years”* (owner 2 from Rural area)

*“So we cannot train anymore. If government will give training, we can get benefits like we get a certain level of qualified staff. Not every graduate persons are interested in working at DS” (owner 2 from Rural area)*

Another criterion they proposed in priority setting was intensive legislation on every section that involve in pharmaceutical distribution, prescription and utilization. They felt that the current regulation is unfair and the law is rubbery scope and inconsistent application among prescribers, pharmaceutical companies and retail pharmacies. They deemed that they were discriminated and neglected from prescribers and pharmaceutical companies. But these two stakeholders have thought to be strong relationships. So another criterion they proposed was collaboration and support from government (like FDA and PH), prescribers and pharmaceutical companies. They felt that the encouragement from government was far from merely seen. They wanted to use reward-punishment system as previously mentioned in owners from urban area. But they want to extend this system on prescribers because they perceived that the prescribing behaviours of prescribers can affect on their pharmacy practice.

*“we can feel that the current regulations and laws is not equity among doctors, companies and us. So it is necessary to strong enough for everyone. Some people deceived laws. So we would like to propose that please make the law strong enough to cover every section” (owner 3 from Rural area)*

*“And I can feel also we are left / separated from others (doctors and companies). The companies, they tried to make profits from collaboration with doctors” (owner 3 from Rural area)*

*“I think collaborate with companies and doctors is also important. Without their understanding on real situations, the DS is still running in difficulty state” (owner 4 from Rural area)*

*“I would like government to support (in positive way) and enforce (in negative way) to doctors to write prescription letter correctly and rationally. This process is related to our work” (owner 5 from Rural area)*

They then suggested that government should intensively control the registration process of pharmaceuticals to minimize too duplication of products in markets and these make many prescribers to confuse and uneasy to recognize the brand names. They concluded that the consequence of duplication happens medication errors as the doctors could commit. They also remarked that too many me-too products cause a waste of valuable resources. Another suggested criterion that should be in prioritize list was controlling the quality of medicines at the supplier chains. They want to control the distributors, a very first beginning step of importation. They remarked that the government regulation was weak at this site and the distributors are also the key players. Their attributions are likely to impact on the drug quality regarding the storage and transportation conditions. So, they want to suggest the government that the retail pharmacies should not be criticized merely rather than irrational prescribing of prescribers and unethical marketing of pharmaceutical companies.

*“I would like to suggest government to intensive control on import process. That means, as a consequence of duplication, doctors cannot recognize the brand name and makes them confuse and complicate. Duplication in markets makes I feel that it is a kind of waste” (owner 4 from Rural area)*

*“if government want to run GPP, they should control the quality of drugs at the very beginning step (companies). Not only force the drug stores to follow to be a quality one, but they have to control since the beginning” (owner 1 from Rural area)*

*“if government want to implement GPP in drug stores, please do not criticize only on drug stores. We are related with people, doctors, hospitals, companies as well. So, the problems are not only happened by drug stores alone. I would like to suggest that please look at all sites that can have impact on GPP project” (owner 5 from Rural area)*

The last thing they proposed in priority setting was changing the mindset of government and public. The attitude of government towards retail pharmacies be suggested that government neglected the role of pharmacies among people and lacked of cooperation with pharmacies. The government is said to be enforced to

pharmacies with “rule of law” rather than providing support and cheer up. Moreover, the government be suggested that they should find a way to change the mindset of people in rural areas. The people were thought to be underprivileged, and poor education and knowledge on pharmaceutical products. So the owners worried that people in rural areas were mostly self-medication on advertised products via TV and social media. They thought that government should lift up their socio-economic status and ways of thinking.

*“I would like to suggest that mindsets of government (FDA, PH) should be changed. We need cooperation. But I see they don’t want to cooperate with us. They do not encourage us. So mindset should be first changed” (owner 5 from Rural area)*

*“we have to change the people mindsets also. But I think mindsets alone is not solving the problems but in rural areas, they have not enough knowledge, not enough money to go to clinics. So the only one to solve their health problem is coming to drug stores. Most of them are self-medication. They asked directly the medicines that advertise on the TV and social media. They don’t know about this medicine is effectiveness or not” (owner 3 from Rural area)*

*“The government have to lift up their socio-economic status. Most of customers here are farmers and workers. They are poor. How could they afford quality services or expensive medicines? There is no one who doesn’t want the best things in the world but it is hard to distribute to general people especially to the poor” (owner 2 from Rural area)*

Table 9 presents a total of 17 contents proposed by pharmacy owners from rural area;

*Table 9 Proposed contents for optimum condition of GPP guidelines implementation (n =4)*

No	<b>Propose Contents for establishment of GPP principles to retail pharmacies</b>
1.	The government/FDA should provide trainings on rules and regulations of pharmaceutical marketing to wholesale suppliers, pharmaceutical companies and retail suppliers
2.	The training programs should provide well-trained pharmacy assistants
3.	The government should provide information of GPP implementation to prescribers and pharmaceutical companies (both NGOs and GOs)
4.	Drug store owners and staffs should have to be trained good practices of pharmacy
5.	The government should collaborate with universities to design the training modules on context of pharmacy activities based on capacity of pharmacy staffs (both pharmacists and non-pharmacists)
6.	The pharmaceutical companies should practice ethically regarding dealing with prescribers and support to drug stores in their affordable ways for GPP achievement
7.	The FDA should collaborate with drug stores to encourage them and share up-to-date knowledge and information
8.	The collaboration should be effective and transparent between government as well as pharmaceutical companies and prescribers in order to understand the real situations of drug stores
9.	The government should negotiate among drug stores, prescribers and companies and let them to collaborate each other
10.	The government should apply reward system rather than punishment system (Recompense)
11.	The FDA should intensively control on registration of duplicated drugs to minimize the prescribing errors
12.	The government should encourage the prescribers to write prescription letter rationally and correctly
13.	Regulation should be covered to all levels of stakeholders (e.g. supply chains,

	distribution outlets, prescribers and consumers)
14.	The prescribers need to aware their role which is also important for implementation of GPP principles (e.g. prescribers' attitude and ethics in prescribing habits)
15.	The pharmaceutical companies need to avoid unethical marketing behaviours
16.	The government should change the mindsets first before implementing the GPP program (e.g. appreciate and encourage rather than enforce and punish)
17.	The public need to aware about safety of medication and health education

### **Additional cases with pharmacy owners who has established GPP**

The initial questionnaires in interview guide regarding asking their expectations on GPP establishment and their journey experiences were same as other pharmacy owners from urban and rural areas. Their sharing and suggestions were found to be focused on entire health system rather than on one sector only. They remarked that solving the problems and barriers in pharmacy practices with single factor was not enough to solve all the daily problems. For example, applying the strict regulation on retail pharmacies barely cannot control the pharmaceutical market. So they pointed out that an effective cooperation between major stakeholders was importantly necessary for problems solution. The first person, non-pharmacist owner said that effective cooperation between major five key players can reduce many problems they faced in nowadays.

*“I would like to say we can go further only when the 5 stakeholders unite together and collaborate each other. They are (i) FDA (ii) drug stores (iii) Ministry of Health (iv) Pharmaceutical companies and finally (v) doctors/prescribers”*

He pointed out that all the stakeholders who concerned with pharmacy services should consolidate for greater efficiency and do their jobs without hindrance rather than working separately and disconnected networks. To be added, a pharmacist owner suggested that Universities of Pharmacy should also provide official training course and hold registration exam if they have enough human resources or if they not, they should specify a standard for private sectors at least. For example, the University of Pharmacy should take part in setting the curriculum and criteria for

private training sectors. He commented that the level of examination should be designed on current educational status to match the conditions. As a result, he suggested that a strategic planning on human resource, and level of training should be prepared for short-term and long-term durations before starting the GPP project.

Moreover, as a pioneer in initiation of good pharmacy practices for retail pharmacies, he claimed that recognition from government sector and rank the shops were crucial and it was deserved for his efforts and it will be the courage to go further even if he was still alone. He thought that the appreciation will highlight the difference between ordinary shops and good practiced shops thereby general people will notice the safe practice shops. Therefore, based on his experiences, he requested that applying the highlight system for reward and punishment is crucial for long journey.

*“I would like to get ranking or rating system for our pharmacies. In doing so, people can easily notice our practice. I changed voluntarily for 7 or 8 years ago but the government did not recognize and appreciate officially. So it doesn't make differ from other shops”*

*“Only government announces in newspaper can guarantee our service and appreciate our effort. I want this only. Just one. We need encouragement and appreciation from government. I can follow all the rules and regulations”*

According to their experiences, the investment cost was too high to run such a good service and quality pharmacy. They both employed pharmacists and experienced staffs to provide good quality service without anyone acknowledged their efforts. Moreover, the shop of non-pharmacist owner employed doctors with the aimed of helping customers who want to get information of medicines. He ignored the lost and only focused on the provision of quality services and guarantee the quality of medicines. He was trying to prove that he can run a pharmacy that could provide guarantee for all kinds of drugs including cold-chain medicines. With his indomitable spirit, his pharmacy was currently well-known for reliable supply of cold-chain medicines beyond eight years of hardship.



*“Although I’d known that the investment cost is too much to consider, I go with my indomitable spirit i.e., my drug store must be safe, really effective and helpful for people. If I looked up only on profits, I cannot go to the way that what I’d decided. So I didn’t put lose and win in my head. So from my experience, I’d known that doing a business with humanistic mind never lose”*

Regarding with their suggestions to achieve GPP in Myanmar, the pharmacist owner suggested that all the factors need to be in balanced and synchronized along with GPP process as the journey of GPP is long way. His opinion was the standard of living and quality of care can be increased only when the public has purchasing power. So, he remarked that the level of standard should be set up according to the spending power of public. Moreover, GPP cannot be accomplished without balancing the dominant factors relating the GPP development rather than emphasizing the role of drug stores only. For example, socioeconomic status of country, cooperation of key players who involved in health care system, human resource factors, governance of the law, etc. should be concerned during GPP process running. He also suggested that the mindsets of stakeholders were also crucial role in establishing the good practice system. All stakeholders should bear the concept of responsibility for safety rather than showing the power of authority and resistance. In this way, he believed that GPP seem achievable if all the stakeholders were regarded as responsible persons for health care safety and unsafe practice risks.

*“the drug stores should perceive they are responsible health care providers and this concept should be attributed by anyone who involved in health care services. This issue should put first and foremost title in GPP”*

*“for the public, their mindset should be changed with education. We should let them know about how GPP drug stores are! How GPP drug stores run with which criteria and those GPP drug stores can provide that kind of service” like that.*

*“we can go further only when we are in balance nationwide. All the factors should be linked together. I would like to say GPP will not be developed by doing nothing but it also cannot be accomplished by going GPP alone. We should think other dominant factors which relate to GPP development. We should point out the*

*whole system, identify the groups of stakeholders who are responsible for GPP and finally to anyone who involved in GPP implementation”*

In addition, being a secretary member of Myanmar Pharmaceutical Association (MPA) as well as a secretary general of Myanmar Retailers Association, he answered as a different role that Pharmacy Council Law is essential for initiation of GPP process and then set up the objective about GPP, develop and sustain process. He suggested that the MPA should develop the license system and classify the pharmacies into high-, middle-, and low-class by assessment or suitable ways to reveal their quality and capacity. MPA should take the role of support and help to pharmacies in putting the GPP mindsets to everyone.

*“if council law is activate in future, this committee will force to initiate the GPP process and push the committee members to set up the objective about GPP. We will plan how to initiate, develop and sustain the GPP process. We (council) can develop the license system such as classify the pharmacy level as high-, middle- and low-class by exam/assessment”*

*“we are not verifying them by our authority but we are assessing and revealing their quality only. We will say to people that the association would like to help you and just want to support you. We should put GPP mindsets to everyone”*

Regarding the suggestions to achieve GPP in Myanmar, the non-pharmacist owner mentioned again that the key five stakeholders should unite together and collaborate between them. They should be effective cooperation and be ethical in their respective filed. He supported that if the pharmacies in local areas could be upgraded by GPP program, those pharmacies could provide safe and quality medicines and then local pharmacies could keep abreast in developed and developing countries.

Table 10 provides a total of 26 contents proposed by pioneers of pharmacy owners practicing the good practice;

*Table 10 Proposed contents for optimum condition of GPP guidelines implementation (n =2)*

<b>No</b>	<b>Propose Contents for establishment of GPP principles to retail pharmacies</b>
1.	The Universities (of Pharmacy) should produce doubling amounts of pharmacists
2.	Drug store owners and staffs should have to be trained on pharmaceutical care process and good practices of pharmacy by professionals
3.	The principles of GPP should be trained to staffs who all involve in GPP implementation, those in pharmacies, professionals, suppliers and the public
4.	The Universities (of Pharmacy) should be assigned to provide supportive training and certification for good pharmacy practices to drug stores (such as good dispensing practice, patient care practice, counseling practice etc)
5.	The registration system should be established for pharmacists and pharmacy assistants for attaining the guarantee of institutions
6.	Government/FDA should understand clearly about pharmaceutical care principles
7.	The government should recognize the roles of pharmacists in drug stores and specify rules and regulations on pharmacists to supervise the community pharmacies
8.	The government should announce publicly for quality of practices to the people knowing what are differences between quality and general drug stores
9.	The accreditation and certification system should be established for pharmacy's activities by showing the role model
10.	All stakeholders should be aware by showing strong evidence base on "only pharmacies with GPP can bring the drug safety to them"
11.	The education campaign should provide information or awareness on how importance of roles of drug sellers in dispensing practice, counselling practice and storage management etc.
12.	The government should negotiate among drug stores, prescribers and companies and let them to collaborate each other
13.	The collaboration should be effective and transparent between government as well as pharmaceutical companies and prescribers in order to understand the real situations

	of drug stores
14.	In order to establish GPP principles, prescribers should prescribe with clear hand writing on generic drugs only in order to minimize dispensing errors on lookalike/sound-alike drugs and avoid the stock-out problems/unnecessary expensive trade products
15.	The pharmaceutical companies should practice ethically regarding dealing with prescribers and support to drug stores in their affordable ways for GPP achievement
16.	The government should apply reward system rather than punishment system (Recompense)
17.	The FDA should intensively control on registration of duplicated drugs to minimize the prescribing errors
18.	The government should encourage the prescribers to write prescription letter rationally and correctly
19.	Regulation should be covered to all levels of stakeholders (e.g. supply chains, distribution outlets, prescribers and consumers)
20.	The prescribers need to aware their role which is also important for implementation of GPP principles (e.g. prescribers' attitude and ethics in prescribing habits)
21.	The pharmaceutical companies need to avoid unethical marketing behaviours
22.	The government should change the mindsets first before implementing the GPP program (e.g. appreciate and encourage rather than enforce and punish)
23.	The public need to aware about safety of medication and health education
24.	The pharmacy council should be supported as an active and functioning body
25.	The mindset of pharmacy staffs should be changed from market-orientation to service-orientation
26.	The added value of pharmacist's role in the pharmacies should be proved by comparing between pharmacies to get public awareness

### **Contents derived from the individualized in-depth interviewed with key regulator 1 (Central level) and regulator 2 (Regional level)**

Before starting the interview questionnaires, the regulators revealed the administrative structure of governance for private sectors focusing on retail pharmacies. FDA department is responsible for enforcement tasks and they joined with Public Health Department (DPH) which is responsible for issuing the license to drug stores. The structure of FDA could not be extended to decentralized level because of insufficient human resource. They have regional level constitution. Therefore, in order to implement GPP, FDA department requested a team that composed of 5 members (including FDA, PH, Police, City Development Committee and Department of administration) to check a pharmacy's activities and take action on pharmacies who break the laws. The regulators said the FDA gave training about GPP for 2 or 3 times per every month in 2 or 3 townships nationwide. However, there was inequity in many factors like socio-demographic, economic, technology and human resource. As a result, both regulators remarked that GPP program could not run full extent in nationwide at current situations. So they planned GPP should be started from the most feasibility areas for infrastructure, human resource, technical resource and most importantly investment.

*“If GPP project will run in Myanmar, we cannot run in whole country because there is inequity in everywhere. We can just start from big cities like Yangon, Mandalay, Nay Pyi Taw”*

At the current days of 2018, the FDA advocated regulations about GPP to retail pharmacies in urban and sub-rural areas to reform gradually through education punishment programme. Besides, FDA tried to promote public awareness about health and medicines through frequent education campaigns.

Regarding the roles of FDA in support of DS for GPP program, the FDA department said that they distributed GPP guideline booklets and provided trainings to those regional areas that was set to implement GPP program. Both regulators said that before going to GPP roadmap, the retail pharmacies must comply the most basic rules and regulations such as avoid selling the substandard medicines or fake

medicines and mixing the medicines without recommendation from specialists or prescription letter. They remarked that without any fulfill the conditions of pharmaceutical rules and regulations, the ongoing GPP might be a challenge for all. They felt little satisfaction on provided trainings and education campaigns for effectiveness because public were hardly changed their old behaviours about self-medication and misuse medicines. The government realized that the mindsets of public need to be changed along with upgrade healthcare system.

*“One of the way to achieve FDA activities is all the members have to be active participation. For GPP program, we also distributed the GPP booklets (GPP rules and regulations). During 2015-2018, we gave many (many) trainings (uncountable). We used many budgets for those activities. Sometimes, they did not come. Although we gave (training and knowledge), they did not take it. They are not willingly to do this”*

*“We hired many voluntary people and trained them then let them to distribute knowledge to lay people. But the program is not very effective as we expected. I think this is because of mindset status!”*

Moreover, the FDA believed that providing frequent trainings and taking uniform action in nationwide could start GPP program in near future quickly. However, with insufficient human resource and budgets were believed to be reasons of ineffective extent as they (the FDA) expected. Insufficient human resource leads the less frequent checking and taking actions. As a result, the retail pharmacies were uncared for good practices and neglected the rules and regulations. Therefore, the FDA proposed that employing enough staffs for FDA department was essential for effective enforcement.

*“Until end of 2019, we will train them and take action to them. No one afraid unless taking action. We have to check the DS frequently if we have enough staffs. We have enforcement plans till to 2023”*

It was found little or no encouragement from FDA site about GPP implementation because they remarked that the retail pharmacies must follow the basic 33 instructions in the GPP guidelines. And if the retail pharmacies broke any

statement in the GPP guidelines, they will be taken action in accordance with existing laws. The regulators said that the FDA would give notifications to retail pharmacies through official channels like newspaper and corresponding website pages. Therefore, it was only retail pharmacies' faults if they did not know or notice about notifications from FDA because the FDA has already provided continuous education program to retail pharmacies for more than three times about GPP training.

*“we started to control the quality of drug stores since 2015. From 2016, we advocated to them, at 2017, we warned them and take action but not so tough. At 2018, we started to take action and punishment. As they are planned to do this job, they must know rules and regulations without any advocacy”*

*“We'll provide instruction. The instruction is already announced in Notification. They must follow precisely. If they will break the laws, they will be taken action in accordance with existing laws. So we will let them notify via official channel or in Newspaper”*

Based on the proposed suggestions from pharmacy owners about accreditation or applying ranking system to pharmacies, the regulators from FDA said that they are not solely taking the roles of regulation to retail pharmacies and they have to adjust and work together with other administrative members like Public Health (PH) and City Development Committee (CDC) and so on. Moreover, the accreditation body in Myanmar was still needed to develop well. Therefore, the FDA body could not appreciate to those pharmacies which were already started GPP ways. In addition, the capabilities and situations of retail pharmacies in rural areas and urban areas were not equal in chance. As a result, it was quite hard to apply accreditation system to retail pharmacies. Therefore, accreditation to retail pharmacies was not only administrative structure issue but also it was policy issue. Similarly, applying the classification system to pharmacies was big issues to policy makers as well as retail pharmacies. Because of less feasible employment of graduated persons in pharmacies and different perceptions towards accept obedience to the laws, the classification of retail pharmacies was believed to be hard and complicated conditions. Therefore, the regulators from FDA department supposed

that applying the accreditation system and ranking system for pharmacies will be implemented in the future and the classification of pharmacies will be initiated phase-by-phase also. In the present time, they tried to push the retail pharmacies to meet the minimum standards as much as they can.

Regarding the roles of establish, develop and sustain GPP standards, the regulators mentioned that the number of pharmacists was not enough in retail pharmacies. As a result, the FDA could not enforce fully the running process of retail pharmacies. The regulator 1 gave the opinion that the pharmacist is not necessary for selling medicines but necessary for supervise the pharmacies to confirm the prescription letter. However, one of the problems in current situation was the pharmacists have no registration system and this could be the problem to provide responsibility and accountability for the pharmaceutical processes. As a result, the FDA, regulation body could enforce towards the pharmaceutical practice for pharmacy staffs and the draft GPP guidelines was focused only on pharmaceutical practices such as how to sell medicines, how to store medicines in proper ways and how to read prescription letter correctly. The current situation could not focus on patient care services and it was easy to handle the practices of pharmaceuticals for the FDA. Therefore, the pharmaceutical care or patient care concepts were believed to be initiated in future after preparing many factors that can affect the pharmaceutical care processes such as upgrading the knowledge of people, cooperation with universities, encouraging the changing of people mindsets and so on. To sustain the GPP process, the FDA has desired to collaborate with Universities of Pharmacy for providing the trainings to retail pharmacies. At the current time, the private business sectors were providing trainings to people who wants to run the pharmacies and work in the pharmacies. The FDA disliked the current situations of it. They believed that those private business sectors will be disappeared then the government universities provide the official trainings to retail pharmacies. As the FDA body, they only take the roles of regulations and enforcement. By producing the different levels of training staffs from official channels, the retail pharmacies were believed to be classified according to the levels of knowledge of pharmacy workers.



Table 11 provides a total of 9 contents proposed by the regulator from central area and Table 12 provides a total of 8 contents proposed by the regulator from regional area;

*Table 11 Proposed contents for optimum condition of GPP guidelines implementation (n = 1)*

<b>No</b>	<b>Propose Contents for establishment of GPP principles to retail pharmacies</b>
1.	Drug store owners and staffs should have to be trained on pharm care process and good practices of pharmacy by professionals in order to minimize the potential risks
2.	Public should have increase awareness on benefits of pharm cares and risks of safety
3.	Health education should be provided to public
4.	Universities of Pharmacy should provide supportive training for good pharmacy practices to drug stores (such as good dispensing practice, patient care practice, counseling practice etc)
5.	Universities of Pharmacy should establish the registration system for pharmacists and pharmacy assistants to provide guarantee of institutions
6.	Universities of Pharmacy should produce increase amounts of pharmacists
7.	Universities of Pharmacy should provide well-trained pharmacy assistants
8.	The mindsets of people and pharmacies should be changed first before implementing the GPP program
9.	The responsible person or organization should be assigned to the GPP program implementation

Table 12 Proposed contents for optimum condition of GPP guidelines implementation (n =1)

No	Propose Contents for establishment of GPP principles to retail pharmacies
1.	Universities of Pharmacy should provide supportive training for good pharmacy practices to drug stores (such as good dispensing practice, patient care practice, counseling practice etc)
2.	Universities of Pharmacy should produce increase amounts of pharmacists
3.	Universities of Pharmacy should provide well-trained pharmacy assistants
4.	Health education should be provided to public to increase public awareness on safety issues
5.	The mindsets of people and pharmacies should be changed first before implementing the GPP program
6.	Drug store owners and staffs should have to be trained on pharm care process and good practices of pharmacy by professionals in order to minimize the potential risks
7.	The well-functioning accreditation body should be established
8.	The FDA body should extend collaboration with other organization like universities of pharmacy and funding agents

#### 4.3. Prioritization the contents and develop a strategic plan of Good Pharmacy Practice in

##### Myanmar

The main objective of this study is to develop the GPP guidelines and a plan to implement it in Myanmar context. The study aims to find out the optimum conditions for GPP guidelines implementation which are suitable for local context and the condition having little or no pharmacists. The development process consists of conducting the situational analysis of pharmacy context, generating the contents from interviewing with multiple stakeholders and reaching a consent to set priority and a strategic plan to implement the guidelines.

The current situations of Myanmar faced many factors in implementation of good pharmacy practice such as a limited number of human resources regarding the pharmacists and well-trained manpower for pharmacies, weak at law enforcement and professional collaboration and so on. There is also noted that the distribution of human resource is highly inequitable in different geographical areas and differ levels of socioeconomic conditions in study areas. As a result, the national strategic plan is needed to design to address these challenges in an effective, consolidated and sustainable manner.

The proposed conditions for GPP guidelines implementation are 6 contents from pharmacy users, 18 contents from academia, 16 contents from pharmacy owners from urban area, 17 contents from pharmacy owners from rural area, 26 contents from pharmacy owners who live in urban area and they have established the principles of good pharmacy practice. From the policy-maker and officer from enforcement level, they proposed 9 contents and 8 contents respectively.

There are a total of 100 proposed contents from multi-stakeholders during first round of focus group discussions through a total of eight FGDs and four individual interviews. From these contents, similar contents were merged, rearranged and grouped into same elements and put under main themes that defines as strategies. Again, the second round of group discussions were conducted through three FGDs and two individual interviews based on findings of first round section. They are prioritized by four scales of timeline, five levels of easy to very difficult steps in practical way, five degrees of level of agreement and five degrees of level of impact on implementation cycle.

Regarding the practical way, the level of easy versus very easy and difficult versus very difficult were quite hard to predict. So according to the agreement of analyst, we redefined very easy as everyone can do it without any barrier or difficulty and easy is defined as everyone can do the stated conditions but with condition. That means a condition could not be performed by single factor alone and it needs cooperation or collaboration with other factors. As for difficult condition, a condition could be performed by taking complicate technical ways and much time. But for very

difficult condition, we redefined it as a task that could be carried out in difficult with conditions such as more complicated solutions might be needed and step-by-step long-term plans were required to meet and achieve the aim and objectives of the study. Then prioritization of elements was ranked.

The priority of the elements was determined based on their score average and frequency score average and is presented in Table-13. The proposed timeline was established by considering the average scores of the timeline criteria and divided into four categories. T 1 represents the highest average score range of 3.4 – 3.8, indicating the need for immediate implementation. T 2 corresponds to an average score range of 2.8 – 3.3 and is intended for short-term goals. T 3 refers to an average score range of 2.4 – 2.7 and is intended for mid-term goals. Finally, T 4 encompasses scores between 1.5 and 2.3 and is designated for long-term goals. During the discussions with stakeholders, it was proposed that the assigned immediate criteria should be implemented in prompt ways if there is initiation of GPP implementation process. The short-term goals should commence after six months of implementing the GPP guidelines. The mid-term goals should follow the successful implementation of immediate and short-term targets, approximately 2-3 years thereafter. The long-term goal is intended to be sustainable over an extended period and is expected to start when T 1, T 2 and T 3 are functioning effectively and in balance. Consequently, it is suggested to initiate the long-term goal approximately 5 years into the implementation process of GPP guidelines.

Following the second round of focus group discussions, the identical components are categorized into overarching themes, which are defines as strategies. As a result, the 33 suggested components will be organized under seven main themes of strategies, outlined as follow:

- 1. Education and training for the stakeholders on understanding the meanings of GPP and risks of safety** : with the objective of educating and training to all stakeholders for clear understanding of GPP principles and getting aware of risks of unsafe healthcare

2. **Management for Human Resource** : with the objective of producing adequate number of qualified pharmacists and trained staffs for pharmacy to establish the GPP principles
3. **Effective communication and collaboration to implement GPP standards** : with the objective of establishing the efficient network within stakeholders and healthcare professionals to reform and to strengthen enforcement of GPP principles
4. **Persuasion, support and encouragement to follow GPP standards** : with the objective of providing the pharmacies with moral, physical and technical support necessary to follow the GPP standards and to make them know that only pharmacies with GPP can bring the drug safety to public
5. **Governance and regulations** : with the objective of enforcing effective National Policy to apply GPP principles
6. **Sustainable processes for GPP implementation** : with the objective of establishing, disseminating and sustaining the GPP principles that respond to the safe use of medicines for people and lastly,
7. **Changing Mindsets** : with the objective of advocating and engaging all stakeholders to strengthen the implementation of GPP process.

*Table 13 A scorecard determines the level of impact, level of practical way, degree of agreement, timeframe for implementation process (n=15)*

**For Strategic Plan 1: Education and training for the stakeholders on understanding the meanings of GPP and risks of safety**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeliness</b> (Rating x Wt)	<b>Basic Priority Rating</b>
Weight of Degree	Severe – 5 Major –	Very difficult – 1	Strongly disagree – 1	Long-term – 1 Mid-	

	4 Modera te – 3 Minor – 2 Insignif icant - 1	Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	term – 2 Short- term – 3 Immedia te - 4	
1.1	10 x 5=50	7 x 2= 14	8 x 4 = 32	9 x 3 = 27	<b>140</b>
	4 x 4 = 16	7 x 4 = 28	7 x 5 = 35	6 x 4 = 24	
	1 x 3 = 3	1 x 3 = 3			
<b>Average</b>	<b>4.6</b>	<b>3</b>	<b>4.5</b>	<b>3.4</b>	<b>232/15=15. 5</b>
1.2	9 x 5 = 45	4 x 1 = 4	8 x 4 = 32	9 x 2 = 18	<b>118</b>
	5 x 4 = 20	10 x 2 = 20	7 x 5 = 35	6 x 3 = 18	
	1 x 3 = 3	1 x 3 = 3			
<b>Average</b>	<b>4.5</b>	<b>1.8</b>	<b>4.5</b>	<b>2.4</b>	<b>198/15=13. 2</b>
1.3	7 x 5 = 35	4 x 1 = 4	8 x 4 = 32	10 x 2 = 20	<b>108</b>
	4 x 4 = 16	9 x 2 = 18	7 x 5 = 35	4 x 3 = 12	
	1 x 3 = 3	1 x 4 = 4		1 x 4 = 4	
	2 x 2 =	1 x 0 = 0			

	4				
	1 x 0 = 0				
<b>Average</b>	<b>3.9</b>	<b>1.7</b>	<b>4.5</b>	<b>2.4</b>	<b>187/15=</b> <b>12.5</b>
1.4	6 x 5 = 30	7 x 1 = 7	3 x 3 = 9	2 x 1 = 2	<b>90</b>
	3 x 4 = 12	7 x 2 = 14	7 x 4 = 28	6 x 2 = 12	
	6 x 3 = 18	1 x 4 = 4	5 x 5 = 25	6 x 3 = 18	
				1 x 4 = 4	
<b>Average</b>	<b>4</b>	<b>1.7</b>	<b>4.1</b>	<b>2.4</b>	<b>183/15=12.</b> <b>2</b>
1.5	4 x 5 = 20	5 x 1 = 5	3 x 3 = 9	8 x 2 = 16	<b>90</b>
	7 x 4 = 28	9 x 2 = 18	7 x 4 = 28	5 x 3 = 15	
	4 x 3 = 12	1 x 4 = 4	5 x 5 = 25	2 x 4 = 8	
<b>Average</b>	<b>4</b>	<b>1.8</b>	<b>4.1</b>	<b>2.6</b>	<b>188/15=12.</b> <b>5</b>

**For Strategic Plan 2: Management for Human Resource**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeline</b> (Rating x Wt)	Basic Priority Rating
Weight of Degree	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
2.1	4 x 5 = 20	5 x 1 = 5	4 x 3 = 12	3 x 1 = 3	<b>80</b>
	5 x 4 = 20	8 x 2 = 16	5 x 4 = 20	7 x 2 = 14	
	5 x 3 = 15	2 x 4 = 8	6 x 5 = 30	2 x 3 = 6	
	1 x 2 = 2			3 x 4 = 12	
<b>Average</b>	<b>3.8</b>	<b>1.9</b>	<b>4.1</b>	<b>2.3</b>	<b>183/15=12.2</b>
2.2	5 x 5 = 25	4 x 1 = 4	3 x 3 = 9	1 x 1 = 1	<b>104</b>
	4 x 4 = 16	8 x 2 = 16	5 x 4 = 20	1 x 2 = 2	
	6 x 3 = 18	2 x 4 = 8	7 x 5 = 35	6 x 3 = 18	



	18			18	
		$1 \times 5 = 5$		$7 \times 4 = 28$	
<b>Average</b>	<b>3.9</b>	<b>2.2</b>	<b>4.3</b>	<b>3.3</b>	<b>205/15=13.7</b>
2.3	$5 \times 5 = 25$	$8 \times 2 = 16$	$3 \times 3 = 9$	$5 \times 2 = 10$	<b>95</b>
	$5 \times 4 = 20$	$4 \times 3 = 12$	$6 \times 4 = 24$	$4 \times 3 = 12$	
	$5 \times 3 = 15$	$3 \times 4 = 12$	$6 \times 5 = 30$	$6 \times 4 = 24$	
<b>Average</b>	<b>4</b>	<b>2.7</b>	<b>4.2</b>	<b>3.1</b>	<b>209/15=14</b>
2.4	$3 \times 5 = 16$	$5 \times 2 = 10$	$2 \times 2 = 4$	$4 \times 2 = 8$	<b>94</b>
	$5 \times 4 = 20$	$2 \times 3 = 6$	$2 \times 3 = 6$	$6 \times 3 = 18$	
	$5 \times 3 = 15$	$7 \times 4 = 28$	$7 \times 4 = 28$	$4 \times 4 = 16$	
	$2 \times 2 = 4$	$1 \times 0 = 0$	$4 \times 5 = 20$	$1 \times 0 = 0$	
<b>Average</b>	<b>3.6</b>	<b>2.9</b>	<b>3.9</b>	<b>2.8</b>	<b>199/15=13.3</b>

**For Strategic Plan 3: Effective communication and collaboration to implement GPP standards**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeliness</b> (Rating x Wt)	Basic Priority Rating
Weight of Degree	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
	14 x 5 = 70	5 x 1 = 5	14 x 5 = 70	5 x 1 = 5	<b>168</b>
3.1	1 x 1 = 1	7 x 2 = 14	1 x 3 = 3	7 x 2 = 14	
		1 x 3 = 3		2 x 4 = 8	
		1 x 4 = 4		1 x 0 = 0	
		1 x 0 = 0			
<b>Average</b>	<b>4.7</b>	<b>1.7</b>	<b>4.9</b>	<b>1.8</b>	<b>197/15=13.1</b>
3.2	12 x 5 = 60	12 x 2 = 24	14 x 5 = 70	3 x 2 = 6	<b>181</b>
	2 x 4 = 8	2 x 4 = 8	1 x 4 = 4	9 x 3 = 27	
	1 x 1 = 1	1 x 0 = 0		2 x 4 = 8	

				$1 \times 0 = 0$	
<b>Average</b>	<b>4.6</b>	<b>2.1</b>	<b>4.9</b>	<b>2.7</b>	<b>216/15=14.4</b>
3.3	$10 \times 5 =$ 50	$12 \times 2 =$ 24	$9 \times 4 = 36$	$2 \times 2 = 4$	<b>134</b>
	$3 \times 4 =$ 12	$1 \times 3 = 3$	$6 \times 5 = 30$	$7 \times 3 =$ 21	
	$1 \times 3 =$ 3	$2 \times 4 = 8$		$6 \times 4 =$ 24	
	$1 \times 2 =$ 2				
<b>Average</b>	<b>4.5</b>	<b>2.3</b>	<b>4.4</b>	<b>3.3</b>	<b>217/15=14.5</b>
3.4	$6 \times 5 =$ 30	$7 \times 1 = 7$	$1 \times 3 = 3$	$2 \times 2 = 4$	<b>116</b>
	$7 \times 4 =$ 28	$7 \times 2 =$ 14	$6 \times 4 = 24$	$5 \times 3 =$ 15	
	$1 \times 3 =$ 3	$1 \times 4 = 4$	$8 \times 5 = 40$	$8 \times 4 =$ 32	
	$1 \times 2 =$ 2				
<b>Average</b>	<b>4.2</b>	<b>1.7</b>	<b>4.5</b>	<b>3.4</b>	<b>206/15=13.8</b>
3.5	$9 \times 5 =$ 45	$10 \times 1 =$ 10	$1 \times 3 = 3$	$8 \times 1 = 8$	<b>99</b>
	$5 \times 4 =$ 20	$5 \times 2 =$ 10	$8 \times 4 = 32$	$6 \times 2 =$ 12	
	$1 \times 2 =$ 2		$6 \times 5 = 30$	$1 \times 3 = 3$	
<b>Average</b>	<b>4.5</b>	<b>1.3</b>	<b>4.3</b>	<b>1.5</b>	<b>175/15=11.7</b>

**For Strategic Plan 4: Persuasion, support and encouragement to follow GPP standards**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeliness</b> (Rating x Wt)	Basic Priority Rating
Weight of Degree	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
	12 x 5 = 60	3 x 1 = 3	1 x 4 = 4	2 x 2 = 4	<b>179</b>
4.1	2 x 4 = 8	9 x 2 = 18	13 x 5 = 65	3 x 3 = 9	
	1 x 0 = 0	2 x 4 = 8	1 x 0 = 0	9 x 4 = 36	
		1 x 0 = 0		1 x 0 = 0	
<b>Average</b>	<b>4.5</b>	<b>1.9</b>	<b>4.6</b>	<b>3.3</b>	<b>215/15=14.3</b>
	12 x 5 = 60	4 x 1 = 4	1 x 2 = 2	9 x 2 = 18	<b>158</b>
4.2	2 x 4 = 8	10 x 2 = 20	2 x 4 = 8	4 x 3 = 12	
	1 x 1 = 1	1 x 0 = 0	12 x 5 = 60	1 x 4 = 4	

	1		60		
				$1 \times 0 = 0$	
<b>Average</b>	<b>4.6</b>	<b>1.6</b>	<b>4.7</b>	<b>2.3</b>	<b><math>197/15=13.2</math></b>
4.3	$13 \times 5 =$ 65	$3 \times 2 = 6$	$5 \times 4 =$ 20	$2 \times 2 = 4$	<b>195</b>
	$1 \times 4 =$ 4	$3 \times 3 = 9$	$10 \times 5 =$ 50	$2 \times 3 = 6$	
	$1 \times 3 =$ 3	$9 \times 4 =$ 36		$11 \times 4 =$ 44	
<b>Average</b>	<b>4.8</b>	<b>3.4</b>	<b>4.7</b>	<b>3.6</b>	<b><math>247/15=16.5</math></b>
4.4	$9 \times 5 =$ 45	$4 \times 2 = 8$	$1 \times 2 = 2$	$1 \times 1 = 1$	<b>144</b>
	$5 \times 4 =$ 20	$6 \times 3 =$ 18	$3 \times 4 =$ 12	$5 \times 2 =$ 10	
	$1 \times 3 =$ 3	$5 \times 4 =$ 20	$11 \times 5 =$ 55	$8 \times 3 =$ 24	
				$1 \times 4 = 4$	
<b>Average</b>	<b>4.5</b>	<b>3.1</b>	<b>4.6</b>	<b>2.6</b>	<b><math>222/15=14.8</math></b>
4.5	$4 \times 5 =$ 20	$4 \times 1 = 4$	$1 \times 2 = 2$	$9 \times 2 =$ 18	<b>103</b>
	$5 \times 4 =$ 20	$10 \times 2 =$ 20	$5 \times 4 =$ 20	$6 \times 3 =$ 18	
	$4 \times 3 =$ 12	$1 \times 3 = 3$	$9 \times 5 =$ 45		
	$1 \times 2 =$ 2				
	$1 \times 1 =$ 1				
<b>Average</b>	<b>3.7</b>	<b>1.8</b>	<b>4.5</b>	<b>2.4</b>	<b><math>185/15=12.4</math></b>

4.6	7 x 5 = 35	11 x 2 = 22	3 x 3 = 9	2 x 1 = 2	<b>111</b>
	4 x 4 = 16	3 x 3 = 9	6 x 4 = 24	8 x 3 = 24	
	2 x 3 = 6	1 x 4 = 4	6 x 5 = 30	5 x 4 = 20	
	1 x 2 = 2				
	1 x 1 = 1				
<b>Average</b>	<b>4</b>	<b>2.3</b>	<b>4.2</b>	<b>3.1</b>	<b>204/15=13.6</b>

**For Strategic Plan 5: Governance and regulations**

<b>Strategic plans</b>	<b>Impact (Rating x Wt)</b>	<b>Practical way (Rating x Wt)</b>	<b>Agreement (Rating x Wt)</b>	<b>Timeliness (Rating x Wt)</b>	<b>Basic Priority Rating</b>
<b>Weight of Degree</b>	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
<b>5.1</b>	7 x 5 = 35	9 x 2 = 18	6 x 4 = 24	3 x 3 = 9	<b>146</b>

	8 x 4 = 32	3 x 3 = 9	9 x 5 = 45	12 x 4 = 48	
		3 x 4 = 12			
<b>Average</b>	<b>4.5</b>	<b>2.6</b>	<b>4.6</b>	<b>3.8</b>	<b>232/15=15.5</b>
5.2	4 x 5 = 20	9 x 1 = 9	4 x 3 = 12	7 x 1 = 7	<b>81</b>
	3 x 4 = 12	5 x 2 = 10	4 x 4 = 16	5 x 3 = 15	
	7 x 3 = 21	1 x 4 = 4	7 x 5 = 35	3 x 4 = 12	
	1 x 2 = 2				
<b>Average</b>	<b>3.7</b>	<b>1.5</b>	<b>4.2</b>	<b>2.3</b>	<b>175/15=11.7</b>
5.3	6 x 5 = 30	4 x 1 = 4	1 x 2 = 2	1 x 1 = 1	<b>126</b>
	8 x 4 = 32	10 x 2 = 20	4 x 4 = 16	2 x 2 = 4	
	1 x 2 = 2	1 x 4 = 4	10 x 5 = 50	5 x 3 = 15	
				6 x 4 = 24	
				1 x 0 = 0	
<b>Average</b>	<b>4.3</b>	<b>1.9</b>	<b>4.5</b>	<b>2.9</b>	<b>204/15 = 13.6</b>
5.4	12 x 5 = 60	11 x 1 = 11	1 x 2 = 2	2 x 1 = 2	<b>173</b>
	2 x 4 = 8	4 x 2 = 8	14 x 5 = 70	2 x 2 = 4	
	1 x 3 = 3			3 x 3 = 9	

				$8 \times 4 =$ 32	
<b>Average</b>	<b>4.7</b>	<b>1.3</b>	<b>4.8</b>	<b>3.1</b>	<b>209/15=13.9</b>
5.5	$2 \times 5 =$ 10	$4 \times 1 = 4$	$4 \times 3 =$ 12	$7 \times 2 =$ 14	<b>85</b>
	$5 \times 4 =$ 20	$8 \times 2 =$ 16	$4 \times 4 =$ 16	$4 \times 3 =$ 12	
	$1 \times 2 = 2$	$1 \times 3 = 3$	$7 \times 5 =$ 35	$3 \times 4 =$ 12	
	$7 \times 0 = 0$	$1 \times 4 = 4$		$1 \times 0 = 0$	
		$1 \times 0 = 0$			
<b>Average</b>	<b>2.1</b>	<b>1.8</b>	<b>4.2</b>	<b>2.5</b>	<b>160/15=10.7</b>
5.6	$13 \times 5 =$ 65	$5 \times 1 = 5$	$2 \times 4 = 8$	$7 \times 2 =$ 14	<b>170</b>
	$2 \times 4 = 8$	$8 \times 2 =$ 16	$13 \times 5 =$ 65	$2 \times 3 = 6$	
		$2 \times 4 = 8$		$6 \times 4 =$ 24	
<b>Average</b>	<b>4.9</b>	<b>1.9</b>	<b>4.9</b>	<b>2.9</b>	<b>219/15=14.6</b>



**For Strategic Plan 6: Sustainable processes for GPP implementation**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeliness</b> (Rating x Wt)	Basic Priority Rating
Weight of Degree	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
6.1	5 x 5 = 25	4 x 1 = 4	1 x 3 = 3	5 x 1 = 5	<b>87</b>
	6 x 4 = 24	9 x 2 = 18	8 x 4 = 32	5 x 2 = 10	
	3 x 3 = 9	1 x 3 = 3	6 x 5 = 30	2 x 3 = 6	
	1 x 2 = 2	1 x 4 = 4		3 x 4 = 12	
<b>Average</b>	<b>4</b>	<b>1.9</b>	<b>4.3</b>	<b>2.2</b>	<b>187/15=12.5</b>
6.2	6 x 5 = 30	4 x 1 = 4	4 x 3 = 12	3 x 1 = 3	<b>84</b>
	4 x 4 = 16	7 x 2 = 14	7 x 4 = 28	6 x 2 = 12	
	5 x 3 = 15	1 x 3 = 3	4 x 5 = 20	2 x 3 = 6	

	15			6	
		$2 \times 4 = 8$		$3 \times 4 = 12$	
		$1 \times 0 = 0$		$1 \times 0 = 0$	
<b>Average</b>	<b>4.1</b>	<b>1.9</b>	<b>4</b>	<b>2.2</b>	<b><math>183/15=12.2</math></b>
6.3	$4 \times 5 = 20$	$4 \times 1 = 4$	$3 \times 2 = 6$	$3 \times 1 = 3$	<b>76</b>
	$5 \times 4 = 20$	$3 \times 2 = 6$	$2 \times 3 = 6$	$4 \times 2 = 8$	
	$4 \times 3 = 12$	$4 \times 3 = 12$	$5 \times 4 = 20$	$5 \times 3 = 15$	
	$2 \times 2 = 4$	$4 \times 4 = 16$	$5 \times 5 = 25$	$3 \times 4 = 12$	
<b>Average</b>	<b>3.7</b>	<b>2.5</b>	<b>3.8</b>	<b>2.5</b>	<b><math>189/15=12.6</math></b>



**For Strategic Plan 7: Changing Mindsets**

<b>Strategic plans</b>	<b>Impact</b> (Rating x Wt)	<b>Practical way</b> (Rating x Wt)	<b>Agreement</b> (Rating x Wt)	<b>Timeliness</b> (Rating x Wt)	Basic Priority Rating
Weight of Degree	Severe – 5 Major – 4 Moderate – 3 Minor – 2 Insignificant - 1	Very difficult – 1 Difficult – 2 Neither – 3 Easy – 4 Very easy - 5	Strongly disagree – 1 Disagree – 2 Neutral – 3 Agree – 4 Strongly agree - 5	Long-term – 1 Mid-term – 2 Short-term – 3 Immediate - 4	
7.1	2 x 5 = 10	8 x 1 = 8	5 x 3 = 15	1 x 1 = 1	<b>82</b>
	7 x 4 = 28	7 x 2 = 14	6 x 4 = 24	8 x 2 = 16	
	4 x 3 = 12		4 x 5 = 20	2 x 3 = 6	
	2 x 2 = 4			4 x 4 = 16	
<b>Average</b>	<b>3.6</b>	<b>1.5</b>	<b>3.9</b>	<b>2.6</b>	<b>174/15=11.6</b>
7.2	3 x 5 = 15	5 x 1 = 5	3 x 3 = 9	5 x 1 = 5	<b>82</b>
	6 x 4 = 24	9 x 2 = 18	6 x 4 = 24	5 x 2 = 10	
	6 x 3 = 18	1 x 3 = 3	6 x 5 = 30	3 x 3 = 9	

	18			9	
				2 x 4 = 8	
<b>Average</b>	<b>3.8</b>	<b>1.7</b>	<b>4.2</b>	<b>2.1</b>	<b>178/15=11.9</b>
7.3	2 x 5 = 10	4 x 1 = 4	4 x 3 = 12	3 x 1 = 3	<b>83</b>
	5 x 4 = 20	11 x 2 = 22	6 x 4 = 24	6 x 2 = 12	
	8 x 3 = 24		5 x 5 = 25	4 x 3 = 12	
				2 x 4 = 8	
<b>Average</b>	<b>3.6</b>	<b>1.7</b>	<b>4.1</b>	<b>2.3</b>	<b>176/15=11.7</b>
7.4	3 x 5 = 15	5 x 1 = 5	1 x 3 = 3	1 x 1 = 1	<b>91</b>
	6 x 4 = 24	9 x 2 = 18	7 x 4 = 28	7 x 2 = 14	
	5 x 3 = 15	1 x 3 = 3	7 x 5 = 35	4 x 3 = 12	
	1 x 2 = 2			3 x 4 = 12	
<b>Average</b>	<b>3.7</b>	<b>1.7</b>	<b>4.4</b>	<b>2.6</b>	<b>187/15=12.5</b>

The final results of implementation strategic plans for priority recommendations were proposed in high to low order based on average score as below (Table – 14).

Table 14 Prioritized strategic plans in accordance with high to low average score

No	Criteria	Average score	Rating score	Timeline	
				Average score	Assigned goals
1.	4.3. To give necessary trainings to the pharmacy staffs to strengthen the appropriate pharmaceutical knowledge	16.5	195	3.6	T 1
2.	5.1. To develop a set of terms of reference (TOR) and to assign to the project-owner (the one who is responsible to drive the GPP implementation)	15.5	146	3.8	T 1
3.	1.1. To introduce GPP concept to a number of administrators and enforcement staffs to visualize policy goals as they will be the ones who work hand in hand for GPP principles	15.5	140	3.4	T 1
4.	4.4. To establish accreditation and certification system for	14.8	144	2.6	T 3

	appreciation of pharmacy's activities by showing role model				
5.	5.6. To establish a national taskforce composed of right persons	14.6	170	2.9	T 2
6.	3.3. To practice collaboration between FDA and Universities of Pharmacies to support and empower the roles of pharmacies in healthcare service provision	14.5	134	3.3	T 2
7.	3.2. To implement good distribution practices of suppliers	14.4	181	2.7	T 3
8.	4.1. To make the important role of pharmacies in patient's safety known to pharmacies	14.3	179	3.3	T 2
9.	2.3. To recruit drug inspectors from pharmacists	14	95	3.1	T 2
10.	5.4. To make sure extensive coverage of regulations; i.e. all stakeholders from	13.9	173	3.1	T 2

	importer, suppliers, through distributors, prescribers to end users (consumers)				
11.	3.4. To practice negotiation among pharmacies, prescribers and pharmaceutical companies for smooth collaboration, to recognize and support the role of one another	13.8	116	3.4	T 1
12.	2.2. To establish registration system for pharmacists and pharmacy assistants for attaining the guarantee of institutions	13.7	104	3.3	T 2
13.	4.6. To highlight the role of pharmacies by conducting researches (evidence-based research data) on customers' needs thereby strengthen the establishment of the GPP principles	13.6	111	3.1	T 2
14.	5.3. To update the rules and regulations for standards to meet the	13.6	126	2.9	T 2

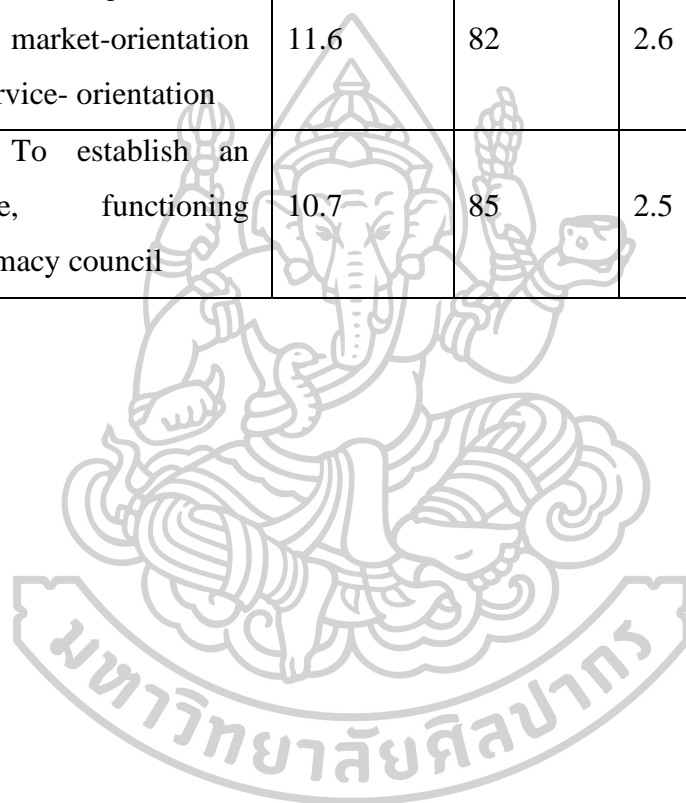
	international requirements				
15.	2.4. To increase the number of pharmacy student intake as well as pharmacy faculty	13.3	94	2.8	T 2
16.	1.2. To educate and train on principles of GPP to staffs who all involve in GPP implementation, those in pharmacies, professionals, suppliers and the public	13.2	118	2.4	T 3
17.	4.2. To provide pharmacies a transitional period necessary to reform and change to fully implement GPP	13.2	158	2.3	T 4
18.	3.1. To implement good prescribing practices of prescribers	13.1	168	1.8	T 4
19.	6.3. To involve pharmacists in improving public health and to promote their roles (of community pharmacist)	12.6	76	2.5	T 3
20.	7.4. To raise	12.5	91	2.6	T 3



	professional attitudes				
21.	1.5. To review and revise the curriculum of training programs regularly for pharmacies by all stakeholders	12.5	90	2.6	T 3
22.	1.3. To raise the public awareness about harms, safety concerns and benefits of proper use of pharmacies by using a variety of channels (campaign, meeting, radio, newspaper, social media)	12.5	108	2.4	T 3
23.	6.1. To assess and evaluate the practices of pharmacies and customers' behaviours to make necessary modification for better ongoing activity	12.5	87	2.2	T 4
24.	4.5. To raise public awareness on quality service of pharmacies and to organize public campaign on pharmacy profession awareness	12.4	103	2.4	T 3
25.	1.4. To improve health knowledge of the public	12.2	90	2.4	T 3

	and raise awareness of benefits of pharmaceutical cares and safety risks				
26.	2.1. To support pharmacists in the tasks of raising public awareness of pharmaceutical care processes in the role of community pharmacists	12.2	80	2.3	T 4
27.	6.2. To conduct supportive research to sustain the fruitful practice of GPP principles	12.2	84	2.2	T 4
28.	7.2. To change perception of the role of pharmacist among stakeholders	11.9	82	2.1	T 4
29.	7.3. To raise public awareness of the added value of the role of pharmacists in community pharmacy	11.7	83	2.3	T 4
30.	5.2. To implore government to approve GPP guidelines and support the implementation (make	11.7	81	2.3	T 4

	the issues as national agenda)				
31.	3.5. To empower and reinforce participatory engagement of communities and lay people network	11.7	99	1.5	T 4
32.	7.1. To change mindset from market-orientation to service- orientation	11.6	82	2.6	T 3
33.	5.5. To establish an active, functioning pharmacy council	10.7	85	2.5	T 3



## CHAPTER 5

### DISCUSSION AND CONCLUSION

#### 5.1. Current Practice and Determinants of Pharmacy Practices in Local Retail Pharmacies of Myanmar

From the study regarding the demographic data of pharmacies, it was noticed that the retail pharmacies were established at last 40-50 years ago and the trend was more popularized around previous 10 years. It was confirmed by little or no research before or around 2010. But many local studies were conducted in 2013 and afterwards, showing the significant growth of pharmacy business and endorsed by increasing change in health care demands. The situation was affirmed by many local studies conducted throughout Yangon, Mandalay and Nay-Pyi-Taw areas (May Myat Noe Swe, 2019) (May In Gyin Lwin, 2019) (Win Lae Phyu, 2016) (Sandar Oo, 2016) (Kyaw Khine San, 2013). It was agreed with previous studies that the distribution of pharmacies was not even in each area and they were concentrated in the city areas particularly near hospitals, clinics, markets and main roads. It was observed that the large number of pharmacies were observed in studied urban sites particularly in Mandalay area which was more than in public or private health facilities such as hospitals, clinics and public health care centers. This means that the retail pharmacies were predominating places for the potential purchase of prescription and over-the-counter medicines.

Therefore, this finding was partly in accord with report from Nigeria by Liu *et al.*, 2016. That study pointed out that the accessibility of pharmacies might have a chance to provide primary care services for public. Moreover, this condition was supported by many early studies that had been described by Goodman *et al.*, 2007. They stated that the existence of pharmacies was in order to response consumer demands with friendly manner and provide faster service thereby accessed them in

convenient way. Therefore, this fact makes easy approach to pharmacies than formal healthcare facilities when there was stock-out of medicines happened.

Regarding the infrastructure and facilities requirements, the layout of pharmacy have complied with requirements where there was appropriate space for easy arrangement in the building such as receiving, inspection, storage and issuing of pharmaceuticals. This might be part of requirements of Myanmar National Drug Law. However, well designated areas for dispensing and waiting purposes were hardly found in majority of pharmacies. The respondents explained that a quick dispense without delay and wait to get the medicines was one of the reasons for being a good pharmacy. Another reason behind was lack of additional space and most of them were not landlords. As a result, they could not renovate themselves without owners' agreement. Some of the respondents claimed that they had budget constraints. Therefore, they said that the waiting area were not necessary for customers.

From this study, it was confirmed that the general people had less sought pharmaceutical advice from a pharmacist. Public awareness of the availability of pharmacists was still subordinated to medicines and other health related topics in retail pharmacies. This is due to the inadequate numbers of pharmacists working at retail pharmacies who takes the role of primary health care services. In Myanmar, the retail pharmacies were set and seemed as merely a convenient first point of assess for medicines and other medical related products rather than provision of health care at a community level. Some owners from study areas responded that many people are just came and bought the medicines they want and no one was interested in looking for pharmacists to discuss about their medications and diseases. This situation was more confirmed by the facts that nobody was interested in the information displayed in the nearby posters or took the information leaflets provided on the counters or asked a pharmacist who stood by to help the customers with the necessary drug information concerning the diseases. Obviously, the number of pharmacists at the time of fieldwork were found to be critically low. The rest of other staffs were non-pharmacists who may be able to deliver pharmaceutical services like provisions of appropriate suggestions, proper dispensing and correctness of dispense medicines

based on their working experiences. As a result, the public currently has low expectations of the pharmacists in retail pharmacies. This condition was significantly low compliance with WHO and FIP guidelines in which at least one pharmacist must supervise or work in pharmacy to provide services related to health and medicines. This could be the context of Myanmar National Drug Law in which the ownership of a pharmacy and staffs were not mandatory to be a pharmacist. A large number of sale staffs in pharmacies had little or no formal training relating to the pharmacy practices. They were getting knowledge and experiences related to pharmaceuticals through ample working years. Some of them stated that their pharmacies were operated for more than 30 years since the pharmacy business was not well-functioned. These results were partly aligned with many abroad studies conducted in Pakistan by Khan *et al.*, 2012 and Hussain *et al.*, 2011 in which a small number of pharmacy attendants was pharmacists and a large number were nonqualified and untrained staffs.

With dispensing practices, all respondents revealed that they were practiced perfectly in correct dispensing for prescribed medicines concerning checked the name, potency, dosage and total amount of medication in line with prescription. These conditions were regarded as pros aspects of pharmacy practices. Therefore, it could be considered as easiest way to fill the gap(s) and improve the situation with less barriers when the standards of pharmacies will be upgraded. Nevertheless, the practices related to prescription handling of staffs were considered to be limited abilities because their dispensing practices were no more than count-and-pour practices i.e., preparing and giving medicines. One of the factors that relate to this practice was the legislation statement of the government of Myanmar in which any person who had graduated rather than a pharmacy degree was allowed to operate pharmacy business. Similar practices at pharmacies were also reported from a study conducted in Nigeria by Ogbonna *et al.* in 2015. They revealed that the dispensers were unable to perform the processes of prescription validation, drug labeling and patient counseling with professional way which are the key components of effective management for patients in community pharmacies.

With regards to staff recruited pattern, validation of supplier chains and documentation system of pharmacies, the context of Myanmar and culture of local people were significantly differed from the guidelines of other countries in that the owners of pharmacies usually considered to employ their staffs with proper working experiences related to previous same field, moral judgement, fit certificate and credentials criterion. These are traditional ways and most probability to get a job for a pharmacy. The traditional views of employment were found to be mismatched from framework of WHO and FIP and these procedures were normally not observed in pharmacies operated by a person singly and family members.

By interviewing with owners of pharmacies on training issues, they revealed that the majority of staffs were not received official trainings relating to pharmacy practices from government sectors. They said they had learnt through apprenticeship from owners or senior staffs from work. For those pharmacies run by owners who had qualification, they do not hire another person and their family members assist in dispensing the drugs. Most of them had found to be limited abilities in dispensing medicines in that they had poor documentation system, insufficient checking of prescriptions and only count-and-pour practice. However, in Pyin Oo Lwin, interestingly, there was only one pharmacy owner who has training policy for his pharmacy to give best services. There was no other studied pharmacy has annual training policy issue for their pharmacies. These were the notable practices of staffs in pharmacies and they were important features related to the necessity to establish the implementation of GPP principles. One of the pitfalls related to pharmacy practice was lack of documentation on working procedure, recording on special issues such as complaints, recall and ADRs, curriculum for training process and in-training processes. These could be the reasons of low levels of awareness for recording and documentation of pharmacy practice among pharmacy staffs. The training of staff issue was therefore required and recommended by WHO and FIP for the implementation of patient-oriented services rather than product-oriented trend, the basic principle of GPP (WHO, 2011). Similar situations were found in Nigeria, a study reported by Ogbonna *et al.* in 2015. They reported that the dispensers were

untrained people though they learn from owners of vendors and gathered information from medical representatives of pharmaceutical companies. As a result, their storage, dispensing and labeling practices were inappropriate and documentation was also poor. They also lacked adequate pharmacists who could perform good pharmacy practice.

Moreover, in many developing countries and developed countries, the personnel qualification was found to link with competency and skillfulness of staffs to perform various activities associated with safe practices such as reporting the adverse drug reaction(s), recording the complaint(s) from customers, reviewing the prescriptions, providing the appropriate counselling regarding to medications and so on. However, the vast majority of pharmacies in Myanmar were found to be lacking documentation on their daily practices, the problems they encountered and complaints they had as a record systematically. It was noticed that the critical elements of the concept on documentation was lacking. Moreover, all study population were lacked in clear assign of roles and responsibilities within pharmacies. As a result, all the staffs had to take the roles of dispensers, cashiers and store keepers as well. Overall, the pharmacy staffs were practiced the count-and-pour nature and they have limited abilities on prescription review and correctness and identify side effects and drug interactions among prescribed medication. They did not fulfill their obligations as pharmacists, who can identify medication correctness, side effects and drug interactions among prescribed medication. These lack of knowledge about stated elements can contribute to the irrational use of medicines in public and become unprofessional pharmacy services. These could be the reasons of educational and professional level of pharmacy staff that lead to poor pharmacy practices. Therefore, some drawback features were necessary to manipulate to match the standard levels by providing training programmes and specifying staffing levels.

By doing so, all the staffs might able to provide patient-oriented services only when they have appropriate pharmaceutical knowledge and awareness of safe practices.



## **5.2. In-depth Interviews : Current situations of Retail Pharmacies Role in Myanmar**

### **5.2.1. Different meanings of Pharmacies for stakeholders**

By understanding the different dimensions on value of a pharmacy's roles among stakeholders in different geographic areas, the description of retail pharmacies is critical in planning the implementation of Good Pharmacy Practice Principles towards provision of quality healthcare services and better assist in health care system.

Pharmacies were socially meaningful to general people and found to be having shared values. Some significant roles they play were easy access to drug in a location, a variety of choice of medicines and shops, time saving and most importantly by social interaction among customers and pharmacy staffs. Most of the customers said that they trusted the sellers for helping them to get a medicine without any delay in an economic way and also without making a mistake. Therefore, in general, people can directly request any kind of medicines that they want if they felt they had enough experiences and they could choose the retail pharmacies depending on their experiences and social interactions.

Communication is one of the important facts in the customers' mind because they could trust the sellers' skills or believed them to be trained staffs by smooth communication skills. This relieved the patients' sufferings emotionally. The retail pharmacies in different localities played different social roles to general people. However, among the findings of the study, there was no one that mentioned the importance of a pharmacist's presence in pharmacies. The professional knowledge and of sellers were not concerned as much as communication between sellers and customers and availability of variety of products in reasonable prices. It could be said that pharmacists were still uncommon in pharmacies, got low recognition as health care professionals and, consequently, this could lead to a culture of trade-off without pharmacists.

According to the findings in this study, the roles of pharmacies in Myanmar by the views of the pharmacy owners were to deliver pharmaceutical

products to public in correct ways and to fulfill the needs of patients in economic ways. Therefore, they proudly said that the pharmacy business was a great job that brought them prestige because they served for the welfare of people. This situation brought the win-win negotiation among pharmacy owners and customers and enhance the shared values among them. It was confirmed by staffs of pharmaceutical companies, business partners of retail pharmacies. They emphasized that the pharmacies could bridge the gaps between private clinics and patients where the prices of drugs in private clinics were relatively higher than lone pharmacies. According to the findings of the study, the retail pharmacies in Myanmar thought to have mutual benefits both in relation with the public and also with pharmaceutical companies.

However, the importance of employing skilled staffs or trained staffs for non-pharmacists and pharmacists were emphasized by the stakeholders in many professional fields and administrative sites. The pharmacy owners in this study seemed to agree that the pharmacies were operated as a sheer business for profit without professional ethics rather than playing public access to health commodities. As a result, the pharmacies were seen by the stakeholders merely as a channel for distribution of pharmaceuticals and related products. They appeared to have no more value than that.

#### **5.2.2. Experiences, Perceptions and Attitudes towards Drug-related Problems**

##### **(DRPs)**

When investigating the DRPs reports developed in retail pharmacies, the DRP categorization systems are needed to clarify in professional ways. The basis classification for DRPs as per definition of the Pharmaceutical Care Network Europe (PCNE) was “A *drug-related problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes*” (The PCNE Classification V 8.01). However, in the present study, different ways of interpreting DRPs were noticed because of the different ways of perceptions in the identification of DRPs among stakeholders. DRPs were interpreted and understood in

different ways among lay people and even by some pharmacy owners. The DRPs were unidentified in majority of pharmacy users and were not clearly explained by some owners. They perceived that the familiar and commonly used medicines were quite safe and compact to them. The pharmacy users perceived that the common drugs used in minor illness such as fever and pain killers would not have effects too much and that such drugs were usually less potent and harmless. These constructed concepts push the lay people to use familiar drugs again and again without consultation with medical doctors. In addition, the pharmacy owners perceived that the medicines would not have DRPs if they provided in line with prescriptions, sold the registered drugs in line with regulations and direct proposed drugs or commonly used drugs. They accepted that the quality of medicines was guaranteed by registration processes of government and the safety of medicines was guaranteed by the prescribers' prescriptions. As a consequence, they believed that DRPs would never happen in their normal routine tasks unless they sold unregistered products. However, it could not be said that DRPs were absent among lay people and pharmacy owners who were unable to identify them. The professions could identify a case when it occurred and would expect the possible and unavoidable side effects of prescribed medicines based on their medical knowledge and experiences. They realized that they had to accept the consequences of medications along with the effectiveness of medicines. So, they simply treated the inevitable outcomes of prescribed medicines by providing the appropriate treatments and making the patients' symptoms relieved. Nevertheless, there was no recorded data of the cases of DRPs in both clinical and hospital settings as they perceived that the cases were unavoidable normal cases and they were too overloaded with treatment to record them. In Myanmar, the adverse drug reaction (ADR) reporting system was established in 2002. However, May, L.M *et al.*, explored a study that was conducted in eight teaching hospitals in Yangon at 2017. The study reported that a great number of assistant surgeons were neither aware of ADR reporting system nor ADR reporting form. They also did not know how to report ADRs and where. A year later, another local study which has conducted in 2018 reported that nearly half of the study population had poor awareness of ADR

reporting system and they observed many barriers to report ADR cases among postgraduate students and specialist clinicians in teaching hospitals at Yangon (Lwin Moe May *et al.*, 2020). These databases were highlighted the poor reporting practices about drug-related problems and therefore, there were crucial needs to raise awareness among health professionals and authorities about initiation of strong pharmacovigilance system in clinical and hospital settings to protect patient safety and increase the quality of healthcare. The reporting practice should be incorporated gradually as an essential part of the regular professional duties of health professionals. This should also be coordinated between the responsible regulatory bodies such as regional FDA departments where drug-related problems were encountered. An active educational program and awareness campaign should be provided regarding the importance and technical aspects of the pharmacovigilance program and ADR reporting to professionals (Datta, 2015). In addition, the awareness campaign regarding drug-related problems should be disseminated to the public and community.

### **5.2.3. Perceptions and Attitudes towards Pharmacy Practices and its Principles**

Regarding this dimension, it was significantly observed that good pharmacy practice was quite differently defined by different stakeholders, each holding his or her own definition.

Firstly, the vast majority of customers and patients defined a good pharmacy as warm social relation and provision of the information they want. It did not matter whether a seller was a pharmacist or not. They defined a pharmacy as a bad one if it lacked the abovementioned conditions. They were satisfied with the information that the sellers responded, not knowing whether it was true or not, and whether it was scientifically right or wrong. They justified a pharmacy as a good or bad one depending on its physical conditions like cleanness, with cheap prices comparable to other pharmacies and availability of variety of items that makes them one stop service. Most of them said that good communication skills of pharmacy staffs were important for them to discuss about their health problems and to help them feel better. Some of them pointed out that the knowledge of the sellers was important for people to have good pharmaceutical services and the pharmacy staffs should

receive regular trainings to improve their practice and knowledge. The principles of good pharmacy practice were crucial for the public to make safe use of medicines with the aim of better health outcomes of patients. However, it was found in this study that general people used pharmacy without having little or no knowledge of what is good or bad about pharmacy practice. They simply thought that not selling unregistered and expired drugs and following the rules and regulations of Laws are good pharmacy practice.

Secondly, the majority of owners perceived that a good practiced pharmacy was the one run in-line with rules and regulations such as not selling unregistered drugs, making sure dispensing in accord with prescription letters and filling people's gaps concerning drugs. Most of them remarked that their pharmacy practices could be improved by getting regular trainings from government and the strong enforcement of drug law in order to reduce the variations of their practices. Many non-pharmacist owners perceived that the GPP guidelines were hoped to be good enough to apply in their daily practice because these guidelines were set by government. This means that they were not familiar with GPP process and could not imagine the scope and responsibilities in the principles of GPP. In addition, they believed that they had no other choice but to follow the government's rules and regulations if the government would promulgate the GPP rules. Therefore, it could be taken from the discussion section that their perceptions towards implementation of GPP guidelines and possible barriers, facilitators and outcomes from it were only their imaginary expectations. They thought that the renovation of pharmacy and staffing of qualified staffs were unaffordable for them to do and it was beyond their limits when the GPP guidelines were to be implemented in Myanmar. Moreover, the socio-cultural nature and socioeconomic status of local people would not match with quality pharmacies. People would reluctant to use the expensive, quality service of pharmacy. The last barrier was mindsets of people who were accustomed to immoral practice that might be difficult to change within short period. However, they supposed that the first barrier could be overcome if the government publicly made appraisal or gave official document of proper recognition when a pharmacy met the needs of the

set standards. If trustworthiness of a pharmacy was made known by the government to the public, then it would relatively cause people to make subsequent mindset change. This might encourage them to adapt good pharmacy practice voluntarily. In order to gain good practice, they assumed that the government should provide roadmap to follow and show the practical ways to apply GPP concepts in pharmacies. The last possible barrier, mindsets was expected to overcome by persuasion to the retail pharmacies towards good attitude through encouragement, appreciation and raising public awareness on quality pharmacies from government. Contrary to these suggestions, a few owners tried to analyze the situations and assumed that a single approach might not achieve to solve the current situations of pharmacy context in Myanmar. To establish good pharmacy practice principles, a pharmacist owner and a non-pharmacist owner who initiated GPP already suggested some approaches to overcome the current problems in pharmacy practice. They had desires to apply classification system on pharmacies, extension of GPP principles on all related distribution channels of pharmaceutical products encompassing warehouse conditions of pharmaceutical companies and wholesalers, prescription practices of prescribers, public education and most importantly, appreciation of pharmacy activities by FDA and related organizations regarding regulation and enforcement.

Thirdly, the pharmaceutical companies, the partners of pharmacies, supported that some pharmacies running for a long time could respond all drug information and they had expertise as much as pharmacists. They believed that those pharmacies could deal with customers and achieve trust from people. They recommended that enforcing the rules and regulations from government and upgrading the capacity of pharmacy staffs might improve the pharmacy practice within retail pharmacies. Since the staffs had not familiar with rules and regulations relating to pharmacy practices, any special comments and suggestions about GPP implementation process could not be mentioned.

Finally, the regulators and professionals remarked that the pharmacy practice in retail pharmacies were not much satisfactory because of malpractices like selling the POM drugs freely and unlimitedly to public without having proper

pharmaceutical knowledge, having no competence staffs, giving medicines without pharmaceutical care concepts and having no accountability and taking no responsibilities for their faults. In order to give good pharmacy service and show good practice, most of them remarked that employing qualified staffs was critical for dispensing prescribed medicines and proper counseling to patients. Therefore, the training issue was important for improving the pharmacy context among regulators and professional stakeholders. With few exceptions, some stakeholders discussed about application of classification system on medicines or that many pharmaceutical problems in pharmacies could be solved by staffing a person with acceptable level of pharmaceutical knowledge. Therefore, as a consequence, a qualified person should be specified by laws for the running of a pharmacy.

Regarding the GPP principles and its scope, the vast majority of stakeholders except academic pharmacists have neither heard nor familiar with the terms and principles of good pharmacy practice (GPP) and it was found to be beyond their knowledge and interest. Although very few participants from regulators and non-pharmacist pharmacy owner had heard the GPP terms, they were found to be with limited understanding of GPP principles. The understanding of GPP and its concepts was found to be diverse. This might be due to transfer of knowledge to corresponding stakeholders who differently and hardly received it. Moreover, in order to implement GPP guidelines in Myanmar, most of the stakeholders in this groups did not expect a proper success unless perceptions of community were directed towards values of quality services and products. The implementation process could be successful when the public's cognitive level on safe practice, socio-economic status and moral standards were high enough to accept the safe practice for their welfare. The expected barriers that the regulators discussed about were insufficient human resources of pharmacists and regulatory teams and limited budgets from government site. The number of pharmacists could not be expected to fill the posts for every pharmacy and those in government service to fill all the posts in regulatory teams of township level to lead the inspection of the local pharmacies. The common complaints and discussions from some prescribers included little satisfaction with the quality of

pharmacy staffs, lack of effective regulatory mechanism in current situation and little guaranteed practice of pharmacy for public. The academic pharmacists affirmed that the scopes of GPP were wide enough to be adapted in Myanmar situations such as economic status of country, people education and mindsets of each stakeholder. The implementation process of GPP could have a big challenge because of the limited foundation knowledge and skills of pharmacy staffs to follow the GPP concepts. As a result, the academic pharmacist tried to discuss barriers for GPP implementation. The scopes of GPP would need to be specified for each level of pharmacy staffs such as pharmacist, pharmacist assistants through provision of appropriate level of trainings to them. In conclusion, functions of GPP should be started and implemented step-by-step with great care, proper preparation for the barriers and challenges, and expecting the adaptability of the stakeholders already discovered in this study.

While searching a condition for guideline implementation, the GPP implementation might be a bit challenge in practical ways with limited resources and the abilities of pharmacy staffs to follow it. However, based on a collection of most frequent identified issues from previous interview phases, the retail pharmacies were the only unit that would execute the GPP guidelines. It was significantly noticed that some of the multi-stakeholders' roles are being underrepresented in the GPP guidelines document such as pharmacist's supervision, prescribers' behaviours and pharmaceutical companies' ethics. They are marginalized people or groups who are affected too little or no influence over new regulation.

From the government site, the drug stores are to be regulated and complied regulatory requirements. The government has announced its intention to initiate GPP programme through advocacy for legislation and regulation. However, there does not appear to be any plans for an accreditation and reward system to recognize the efforts of drug stores. Government representatives believe that by establishing and enforcing rules and regulations, they are guiding drug stores towards improvement. They aim to provide the best practices for drug stores, and as a result, drug stores are expected to comply with the rules and regulations without resistance. This approach is akin to a paternalistic role adopted by the government.



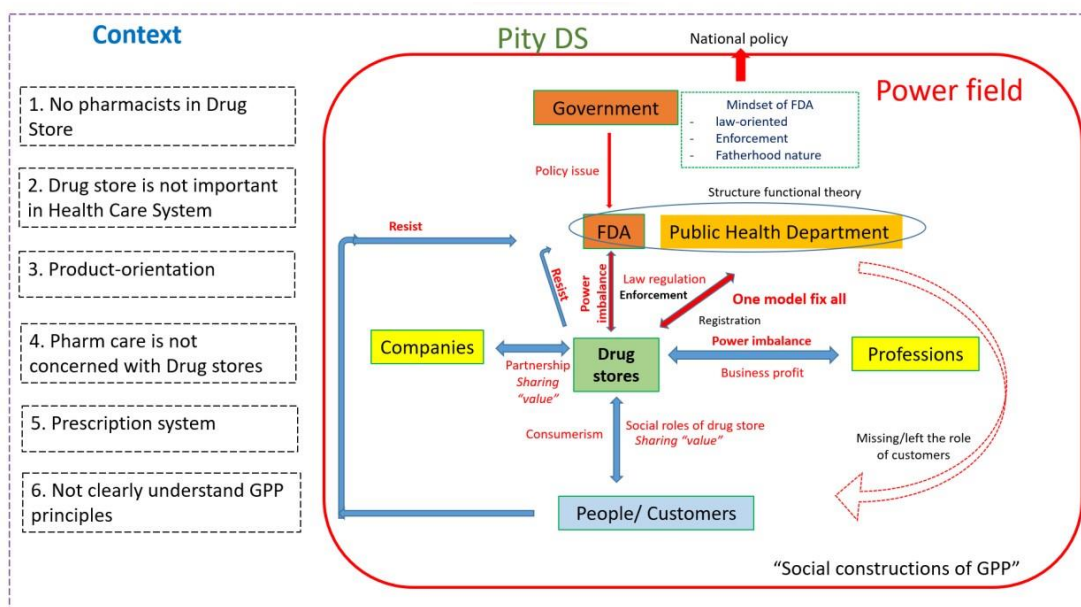
From the views of prescribers, pharmacy users and pharmaceutical companies, they perceived the drug stores as accountability for new regulations of pharmacy practice. They even do not notice themselves that they are involved and influenced in the pharmacy practice. Customers have a choice on any drug store that can help them to get a medicine without any delay. Customers' demands, prescribers' prescribing behaviours and market decisions drove the drug stores to have great impact on the pharmacy practices. They criticized on correct dispensing processes for prescribed medicines and if this is correct ways, they defined it as good pharmacy practice.

However, the pharmacy profession, most of the pharmacists and pharmacy owners concerned that the policy of GPP principles initiation is inextricably linked to multiple-stakeholders and they concluded that it is quite hard to sustain and achieve without proper interaction with other components of the organization. Pharmacists pointed out that no pharmacist in drug store and as a consequence, it is uncertain to conduct the principles of good pharmacy practice in drug stores.

Therefore, from the qualitative study, the drug stores are basically seemed liked a victim for implementation of GPP guidelines. All stakeholders perceive that no one concern about GPP as they are not directly related to it. They put the blame for each other. They regard that the journey without GPP can go through smoothly. Hence, extra regulation like GPP guidelines was not needed for them. The objectives of GPP principles could not be imagined because it is beyond their limits. However, if the GPP rules are promulgated by the government, they believed that they had no other choice but to follow the government's rules and regulations. The results of the study clearly indicate that there is a hierarchy regulation at government site and pharmacies are powerless communities. It was also found that some stakeholders from pharmacy field refuse to accept the changes in pharmacy. They would show the resistance to power of regulation. A possible conclusion for these results may be power imbalance and hierarchy relationship between pharmacy stakeholder and the government.

The themes identified in this study were summarized in a diagram followed:

Figure 3 The themes identified in this study



The current situations of pharmacies in Myanmar can be effectively analyzed using a strength, weakness, opportunity and threat (SWOT) analysis, which will provide a clear understanding of the potential advantages, limitations, opportunities and challenges associated with the establishment of the GPP guidelines.

### Strength

In Myanmar, Pharmacies were:

- Abundant source for easy access to medicines
- Important role in accessibility of medicines to public especially in rural areas
- Fulfilling the needs of people and reducing the burden of financial difficulties
- In good social relationship with general public (e.g. friendliness, good communication, satisfaction on fulfillment of their needs)

### Weakness

- Retail pharmacies are neither considered nor recognized as outlets of healthcare service by professionals
- Pharmacy staffs are non-professions

- Inequity of resources in geographically and socio-economically different areas (e.g. budget, investment, human, professional)
- Count-and-pour practice
- Product-oriented selling practice (business type)
- The knowledge, understanding, and application of definition, description and scope of Good Pharmacy Practice are limited on product-oriented practice

### **Opportunity**

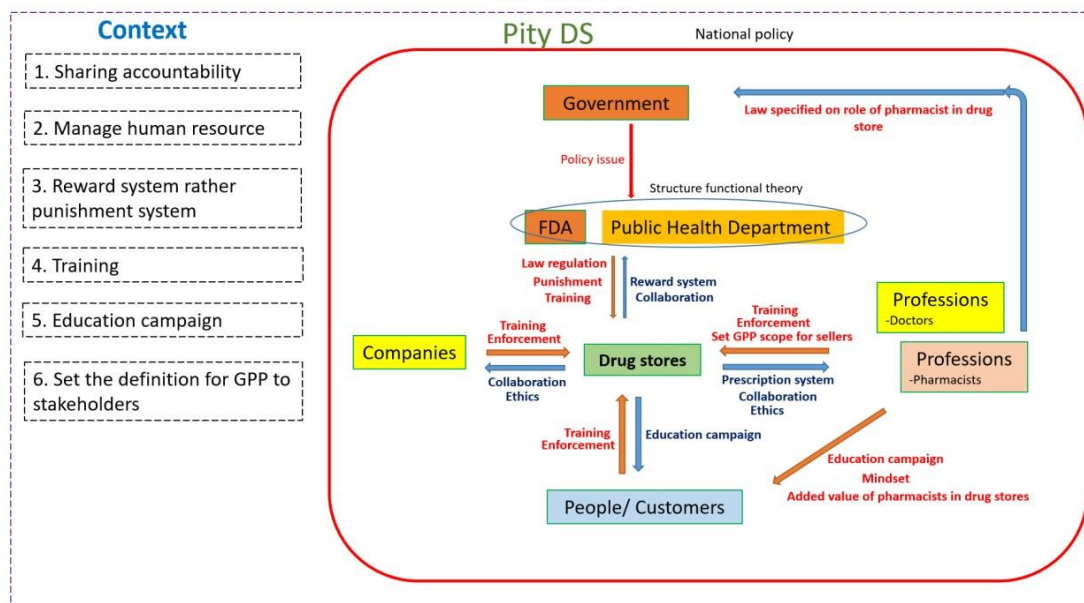
- If GPP can be implemented in Myanmar, we can establish a system that can improve pharmacy practices and services regarding the patient-oriented system
- Classification and accreditation system can be established in Myanmar
- Partnership with other health professionals can be achieved

### **Threat**

- Challenges in establishment of GPP principles with limited skills of staffs
- Low investments and budgets
- Unethical dispensing practice of sales staffs
- Other ways for common people to get medicines rather than GPP pharmacies (e.g. black market, online shopping)
- Rarity of human resource for training, inspection, education to public and pharmacists

The possible solutions suggested from multi-stakeholders were summarized in a diagram followed:

Figure 4 The possible solutions suggested from multi-stakeholders



Every stakeholder provided a single possible solution to every single problem (cause and effect problem solution). Each solution they gave can only solve in one problem and could not solve for all conditions. The condition needs root-cause analysis to identify appropriate solutions for underlying issues rather than just solving one condition in one statement. For example, most of the multiple-stakeholders regard that the capacity of pharmacy staffs could be upgraded through training alone, the awareness of the public towards safety of their medicines could be raised by education campaign etc., regardless of the socio-demographic factors, economic factors, regulatory factors, health system factors and inequity factors and so on.

Nevertheless, the stakeholders participate in designing the implementation cycle and eager to suggest solutions to the current situations. There is no single panacea for national level policy and this situation require evaluation with a system thinking lens rather than fragmented programme thinking. The government should explore the problems from a system's perspective, promote dynamic networks of diverse stakeholders rather than solving one problem, foster more system-wide planning, evaluation and research (WHO, 2009). Moreover, the multiple-stakeholders should be engaged to participate and appreciated for how they have helped to shape rules. Because policy makers' treatment upon stakeholders' input can have impact on stakeholders' involvement in future either encourage or discourage.

When the society is involved in making decision in policy planning, there will be better rules and regulations (Pisano *et.al.*, 2015). Therefore, system thinking should not be overlooked in complex, real-world settings in order to operate more successfully and effectively.

Through the best effort to fulfil the aim of study, a total of eight focus group discussions containing 26 stakeholders is conducted for first round to collect the contents for optimum condition of implementation process and then conducted a second round of FGD containing a total of 15 stakeholders. They are finally selected from formal health sectors and participated in prioritizing the contents and discussed factors affecting the implementation of GPP guidelines in Myanmar. The participants qualitatively appraised, deliberated and reached consensus on which strategic plans should be adopted based on timelines.

### **5.3. Development of Myanmar GPP guidelines from Focus Group Discussions (FGDs)**

The literature review provided a complete description of the Myanmar FDA department's Good Pharmacy Practice (GPP) guidelines. While the GPP guidelines drew on the framework of the National Drug Law (NDL), they included additional details such as customer communication and counseling, personnel hygiene, handling and dispensing of prescription medications, documentation of prescription records (especially for controlled substances), pharmacist accountability and procurement of medicines from official trade channels. However, the NDL or GPP guidelines did not explicitly require the employment of pharmacist in drug stores or community pharmacies in terms of pharmacist accountability. Therefore, this study recommends updating current laws and regulations to meet international standards, including the employment of pharmacists in drug stores. Additionally, it proposes raising awareness among the public about the role of pharmacists in the healthcare system to emphasize their added values. To ensure the effective implementation of GPP principles, it is necessary to establish an active and

well-functioning Pharmaceutical Council. Furthermore, the practicality, feasibility, and sustainability of the guidelines, particularly in relation to the concept of good pharmacy practice for stakeholders, have not been evaluated.

Obtaining the necessary dataset to determine the optimal conditions for GPP implementation has been challenging due to the lack of a shared goal among stakeholders. The GPP process is closely tied to drug stores, but no one takes responsibility for it. Currently, the government's focus on GPP is primarily for retail pharmacies in the private sector, without sufficient input from customers, professionals and pharmaceutical channels. These stakeholders are unaware of the role of pharmacies in daily life, as drug stores are perceived solely as profit-driven businesses and not as places for pharmaceutical care services. Therefore, it is crucial to communicate the goals of GPP to all stakeholders before and during the implementation phase.

However, the primary observation that arises from this study is the limited and diverse understanding of the meaning and principles of GPP. Additionally, the government intends to use the top-to-bottom approach for new policy implementation process, which could make the implementation process challenging in practical terms. To soften this difficulty, it is recommended to incorporate a bottom-to-top approach during the implementation phase, as stakeholders' engagement and appreciation play a crucial role in shaping the rules. One of the findings of this study suggests introducing the GPP concept to the multi-stakeholders encompassing a number of administrators, enforcement staffs and pharmacy staffs. This would help minimize diverse interpretations of GPP and enable stakeholders to grasp the depth and breadth of GPP and risks of safety. Importantly, the principles of GPP should be disseminated by highly competent professionals to minimize any deviation. As a result, these conditions are closely intertwined with the findings of the second phase of this study. Four strategic plans, designated as T 1, should be promptly implemented to mitigate difficulties in the implementation process. These plans include (i) initiating the

dissemination of appropriate pharmaceutical knowledge, (ii) establishing a project team with defined terms of reference (TOR) to drive the GPP process, (iii) introducing the GPP concept to collaborative members to align with policy goals and (iv) promoting negotiation and collaboration among stakeholders (pharmacies, prescribers and pharmaceutical companies) to recognize and support each other's role. The remaining short-term, mid-term and long-term goals should be started sequentially, with continuous evaluation and periodic planning as needed.

The second significant aspect is the hierarchy management within organizations. Considering the power dynamics among stakeholders involved in organizational change initiatives, the government holds the most influential position, akin to a parental figure. The prescribers (physicians, clinicians) hold the highest level of power among professionals. Customers possess purchasing power. The drug stores, on the other hand, represent a relatively powerless stakeholder group tasked with executing the GPP roadmap. As a result, a power imbalance is observed among multi-stakeholders. However, relying solely on power strategies does not guarantee compliance and may even lead to resistance. Demonstrating authority and enforcing strict measures can further provoke anger and potentially sabotaged the desired change (Boohene, 2012).

The evidences from this study suggest that the pharmaceutical care concept is underestimated in perspectives of multi-stakeholders. Their responses seemed to emanate resistance behaviour to organizational change. This can be concluded that people are afraid to change the new environment because of they are unfamiliar with the process and concept of pharmaceutical care; they do not properly equipped with the skills required to perform as well under the new regime; and lack of technical and resources to implement the project. The collaboration among multi-stakeholders was then found to be segregated and the drug stores are existed as an independent and unrelated to the healthcare system in Myanmar.

To summarize, the findings of the study indicate that in order to bring about change, it is crucial to ensure that the human resources involved are properly trained and equipped with the necessary tools to acquire the required skills and knowledge. The structure and function of the organization, as well as the systems for rewarding and punishing, need to be redefined. It is important to evaluate the pharmacy practices and the roles of pharmacy staffs, and clearly define the responsibilities and accountabilities of those driving the implementation of Good Pharmacy Practice (GPP). Implementing a reward system is essential to motivate target units, as it allows them to see the significant benefits of the changes rather than focusing on the associated risks. Additionally, the rewards given reflect how the system values the outputs and practices of the staff during the implementation of the initiatives. Therefore, the government should provide support and actively involve all stakeholders who are directly or indirectly impacted by the policy, adopting a system thinking approach rather than solely focusing on individual units.

#### **5.4. Limitations of the study**

In this study, several limitations were identified that should be taken into consideration when interpreting the results. These limitations are –

(1) firstly, the study was conducted in some geographic location, which may limit the generalizability of the findings to other regions. Factors such as cultural differences, regulatory requirements and healthcare systems can vary widely between regions and these differences could impact the implementation of pharmacy practice. Therefore, caution should be exercised when extrapolating the results of this study to other areas.

(2) secondly, participants may have provided socially desirable responses or may have over- or under- reported their experiences with pharmacy practice field. Future studies could consider incorporating objective measures, such as pharmacy workflow analyses, needs analysis, to complement the resulted data.



(3) thirdly, the study did not attain the perspectives of other stakeholders in the implementation of pharmacy practice, such as physicians, nurses and patients as the concepts of pharmacy practice were beyond their interests. However, pharmacy practice implementation is a complex process that involves collaboration and communication among multiple healthcare providers and patients. Including these perspectives could provide a more comprehensive understanding of the challenges and facilitators of pharmacy practice implementation.

(4) fourthly, the study did not assess the feasibility, practicability of pharmacy practice implementation and long-term sustainability of them. The implementation of new pharmacy practices can be resource-intensive and it is important to consider whether these practices can be successful implementation over long-term period. Future studies could consider evaluating the sustainability of pharmacy practice implementation and identifying strategies to support long-term implementation.

Finally, the study did not consider the potential impact of external factors such as changes in healthcare policy or funding on the implementation of pharmacy practice. These factors can have a significance impact on the implementation of healthcare practices and future studies could consider incorporating these factors into their analysis.

In conclusion, this study on the findings of optimal conditions for GPP guidelines implementation identified several limitations that should be considered when interpreting the results. Future studies could consider addressing these limitations to provide a more comprehensive understanding of the challenges and facilitators of pharmacy practice implementation.

#### **5.5. Suggestions for further studies**

In order to successful implementation of good pharmacy practice principles, here are some suggestions for further studies:

1. investigating the impact of collaborative care model: explore collaborative care models involving pharmacy owners, pharmacists, physicians and pharmaceutical companies. Assess the effectiveness of team-based approaches in harmonizing the organization workflow, optimizing medication therapy, improving patient outcomes and reducing healthcare costs.

2. studying the role of pharmacists in public health initiatives: impact of pharmacist- led interventions in improving patient outcomes and patient education.

3. evaluating the barriers and facilitators: investigate the barriers and facilitators that affect the implementation of pharmacy practice interventions in various healthcare settings. Identify key factors that hinder or promote successful implementation and explore strategies to address these issues.

4. gathering the stakeholder perspectives: conduct further qualitative research to gather the perspectives of different stakeholders involved in pharmacy practice implementation such as policy makers, administrators, healthcare providers, and patients. Understand their views on the challenges and opportunities associated with implementing the pharmacy practice interventions.

5. examining the organizational factors: examine the impact of organizational factors including the human factors on the implementation of pharmacy practice interventions. Investigate how organizational culture, collaborative models, leadership, resources, policies, socioeconomic and geographical aspects and workflows influence the successful adoption of pharmacy practice interventions in healthcare settings. Explore the unique challenges and opportunities associated with implementing these interventions in different contexts.

6. implementing the frameworks and models: evaluate the government's planning implementation frameworks and models in the context of pharmacy practice. Assess their applicability and effectiveness in guiding

the root-cause analysis of implementation failures or successes in pharmacy practice research.





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