YANGON UNIVERSITY OF ECONOMICS
MASTER OF PUBLIC ADMINISTRATION PROGRAMME

OPPORTUNITIES AND CHALLENGES OF LOCAL PHARMACEUTICAL INDUSTRY IN MYANMAR

(A CASE STUDY OF PHARMACEUTICAL FACTORIES IN YANGON)

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EMPA – 26 (16th BATCH)

AUGUST, 2019

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OPPORTUNITIES AND CHALLENGES OF LOCAL PHARMACEUTICAL INDUSTRY IN MYANMAR
(A CASE STUDY OF PHARMACEUTICAL FACTORIES IN YANGON)

A thesis submitted in partial fulfillment of the requirements for the
Master of Public Administration (MPA) Degree

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ABSTRACT

Myanmar pharmaceutical firms are small manufacturer and always try to survive in local markets due to the competition, lack of market access, complex regulatory pathway and not embracing the latest marketing strategies adopted by international companies. This study aims to analyze the opportunities and challenges of local pharmaceutical industry in Myanmar. The research method is a mixture of quantitative and qualitative approaches, the require data has been collected from the primary and secondary sources which together provided more comprehensive information. It was found that the local Pharmaceutical industries face the challenges of lack of ready accessibility to available pharmaceuticals, high prices for imported raw materials, and poor of laboratory facility for research and development. It also found that there are also many opportunities such as promote self-sufficiency, create new jobs, achieve independence from international suppliers, develop local industrial capacity and produce foreign exchange through exportation of domestically manufactured medicines for local pharmaceutical industry.

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LIST OF ABBREVIATIONS

ACTD	Asean Common Technical Dossier
AEC	ASEAN Economic Community
API	Active Pharmaceutical Ingredients
ASEAN	Associations of South East Asian Nations
cGMP	Current Good Manufacturing Practice
CIF	Cost, Insurance and Freight
COPQ	Cost of Poor Quality
CT Law	Commercial Tax Law
DAC	Drug Advisory Committee
DOH	Department of Health
EML	Essential Medicines List
FDA	Food and Drug Administration
FESR	Framework for Economic and Social Reform
GMP	Good Manufacturing Practices
GSPA	Global Strategy and Plan of Action
GxP	Good Practice guidelines
HRM	Human Resource Management
ICH	International Conference on Harmonization
IP Law	Intellectual Property Law
IPRs	Intellectual Property Rights
IS	Innovation System
ISO	International Organization for Standardization
JIT	Just-in-time
LEED	Leadership in Energy and Environmental Design
LMICs	Low and Middle Income Countries
MEHL	Myanmar Economics Holding Limited
MIC	Myanmar Investment Commission
MNEs	Multinational Cooperation and Enterprises
MOHS	Ministry of Health and Sports
MOPH	Ministry of Public Health

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MPMEEA	Myanmar Pharmaceutical & Medical Equipment Entrepreneurs' Association
ND Law	National Drug Law
NIS	National System of Innovation
PHC	Rural Primary Health Care
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PSC	Pharmaceutical Supply Chain
R&D	Research and Development
RFID	Radio-frequency Identification
RIS	Regional System of Innovation
SC Act	Sea Customs Act
SSI	Sectorial System of Innovation
TGA	Therapeutic Goods Administration
TIS	Technological Innovation System
TPE	Total Pharmaceutical Expenditure
TPM	Total Productive Maintenance
TQM	Total Quality Management
TTM	Time to Market
UNIDO	United Nations Industrial Development Organization
USD	US Dollar
WCM	World Class Manufacturing
WHO	World Health Organization
WWII	World War II

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CHAPTER 1
INTRODUCTION

1.1 Rationale of the Study

Medicines are lifesaving, lifestyle-changing, health improving magical potions taken to cure illnesses and maladies, alleviate moods, and generally set right, all that is going wrong physiologically and psychologically in the system. The purpose of medicine usage is a longer, improved quality of life, reduced pain and suffering, and of course, a huge monetary loss, since medicines are not cheap.

The healthcare industry is one of the fast growing, high potential sectors that needs reform, extension, and improvement to ensure better healthcare facilities so as to prevent the outflow of patients to other countries. The pharmaceutical sector is one part of the larger healthcare sector which incorporates all the drugs, medicines, tonics and injections needed for treatment and health improvement. The key to health and wellness in Myanmar also lies in access to medicines manufactured in one of the neighboring ASEAN nations or far off European countries. The era of globalization has helped many Myanmar Pharmaceutical companies to expand operations beyond traditional medicine. Changes in regulatory, patent and market trends will drive opportunities for generic drugs and hence very big opportunities for Myanmar pharmaceutical companies in local markets. Myanmar relies heavily on India, Thailand, Philippines, France, U.S., and China, for pharmaceutical products. The large share comes from Indonesia, which accounts for roughly half of all health-care imports, according to Government statistics. However many Myanmar pharmaceutical companies find it difficult to survive in local markets due to the competition, lack of market knowledge, complex regulatory pathway and not embracing the latest digital technologies adopted by global companies.

Myanmar local companies produce a substantial volume of active pharmaceutical ingredients (APIs). The Myanmar local pharmaceutical manufacturing sector is also moving toward comprehensive compliance with strict regulatory controls based on newly adopted government policies. Myanmar is focusing

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substantial resources on development of advanced research and development (R&D) capacity for new pharmaceutical products, including biological and plant-based products. Myanmar's strategy appears to include encouraging cooperation with foreign-based multinational originator companies investing in the establishment of research facilities.

The world relies to a large extent on the private sector and market dynamics to manufacture medicines that address public health needs. In this regard, a number of developing countries have encouraged the local production of pharmaceuticals as part of an industrial policy. Such being the case, this study focus on encouragement of local pharmaceutical firms to overcome the challenges by analyzing the potential benefits.

1.2 Objective of the Study

The principal objective of this study is to analyze the opportunities and challenges of local pharmaceutical industry in Myanmar.

1.3 Method of Study

The research method is a descriptive method with a mixture of quantitative and qualitative approaches. The required data has been collected from both primary and secondary sources which together provided more comprehensive information. Primary data was collected through distribution of questionnaire to the respondents in selected pharmaceutical production firms and distribution companies. A structured questionnaire has used to collect primary data. On the other hand secondary data such as the performance of production companies and distribution companies were collected from newspapers, published books and journals.

1.4 The Scope and Limitation of the Study

This study covers the challenges facing Myanmar pharmaceutical industry, and the chances as an opportunity bearing in mind that these challenges are not only facing Private but more specifically the Government pharmaceutical industry. These challenges emphasized on three categories; main challenges, external challenges, and self-challenges and opportunities focused on their economic future. In this study, it does not include the case concerning with the political impacts. The secondary data was used between the period of 2013 to 2018.

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1.5 Organization of the Study

This study is organized into five chapters. Chapter I is introductory chapter with rationale, objective of the study, method of study, scope and limitation of the study, and organization of the study. Chapter II presents the literature base on opportunities and challenges of Global pharmaceutical industry. These reviews provide deep insights into what constitutes an emerging market and list the major influences of these markets towards local manufacturing sites. Chapter III studies pharmaceutical industry in Myanmar, which includes the elements of local demand are analyzed and critically reflected within a pharmaceutical and emerging market context. Chapter IV analyses pharmaceutical industry in Myanmar, and the challenges and opportunities for local market. Chapter V summarizes the results of the study, drawing conclusions and recommendation with regard to opportunities and challenges of local pharmaceutical factories in Myanmar.

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CHAPTER 2
LITERATURE REVIEW

2.1 Global Pharmaceutical Industry

Pharmaceutical industry is one of the best sectors of the industry because of its contribution to keep the global population healthy by bringing down disease burden to the world. Pharmaceutical industry is intense capital and technology driven industry because of the intrinsic complexities like developmental challenges for new drugs, regulatory challenges for commercialization, huge capital requirement, longer gestation period, delay in return on investments and frequent changes in disease trends. This industry has been contributing to both human and financial health of the world.

Globalization is the tendency of investing funds and moves the business beyond domestic and national markets to other markets around the globe, thereby increasing the interconnection of the world (Albrow, Martin, King E. , 1990). It is the process of international integration arising from the interchange of worldviews, products, ideas and other aspects of culture.

The global pharmaceutical companies played a very important role in the area of development of new drugs which are very effective and safe. In spite of challenges from regulatory agencies, ethical committees for clinical trials, long gestation periods, one out of thousand success rates, billions of dollars investment for each molecules, companies continue to invest in research to bring new molecules for challenging diseases.

With a change in disease trends, emergence of latest technologies in diagnosis, increased average life of humans, increase in health conscious, implementing healthcare programs by the governments and access to newer drugs, the future of global pharmaceutical industry is bright. While in developed countries growth is flat due to the prevailing healthcare challenges, emerging markets continue to grow phenomenally (Kumra, 2015).

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2.2 Determinants of Operational Excellence (OPEX) in Pharmaceutical Industry

Starting with the determinants of Operational Excellence that shape the structure and purpose of any OPEX initiative, the chapter goes on to present the elements of Operational Excellence that translate strategic requirements into operational activities and defines the author's understanding of OPEX. Thereafter, OPEX is brought into the context of pharmaceutical manufacturing.

2.2.1 Manufacturing Strategy

On the regulatory side, the Food and Drug Administration (FDA) is well on the road to its transformation from an overhead intensive approach to quality to one that focuses more on scientific rigor than on compliance. While the outcome for brand name and generic pharmaceutical is still not fully understood, there can be no doubt that the entire industry recognizes that the levels of scientific rigor and document traceability will need to be higher than ever before (Chatterjee, 2010).

While change has always been a part of the life sciences landscape, the rapid pace and magnitude is significant, as it pertains to our quality and business paradigm. With the emergence of the BRICK (Brazil, Russia, India, China and Korea) countries comes their capability to supply low cost APIs that now extend to the global supply chain. And this underscores the need for more effective, far-reaching strategic planning.

The first involves extending the global supply chain, both up and down. Initially, many of the emerging markets presented an opportunity for low cost APIs. For many therapies this represents a significant factor of the overall standard cost. However, early attempts to measure these overseas manufacturers against ICH Q7A fell far short of what European and U.S. manufacturers were doing. Over the last ten years the sophistication of these API manufacturers has increased, with China alone supplying 80 percent of the world's APIs and over 40 percent of the U.S. market's APIs. Along the way there have been some very high profile missteps that have cost customers dearly. Despite the quality risks, there is little doubt that low cost API suppliers will remain a central strategy for most U.S. and European pharmaceutical companies.

In addition to API manufacturing, big Pharmaceutical is exploring the cost benefits of expanding manufacturing into these emerging markets. At this juncture,

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the business and regulatory considerations become inextricably intertwined. As an integral component to any Business Continuity exercise, the regulatory strategic and tactical plan will provide the key to leveraging available capacity and capability within an overseas operation. Leveraging a highly educated workforce and having access to lower cost capital makes good strategic sense. While the benefits of these new markets are undeniable, the complexities of project management escalate exponentially. Peculiarities with local building codes (when designing a facility in China, an old building code written during WWII required that we put a bomb shelter in the ground floor of the manufacturing building!), the influence of local unions and the constant vigilance required to ensure workmanship standards against design are just a few of the challenges to meet when trying to construct an overseas facility (Chatterjee, 2010).

While the advantages of these supply chain expansions are clear, industry is looking for other opportunities with less business risk. One rapidly growing area involves escalating outsourcing for the pre-clinical discovery process. The discovery process represents two strategic opportunities in terms of competitiveness. First, outsourcing the discovery activities allows parallel processing when evaluating time to market (TTM) reduction. Second, the GxP (Good Practice guidelines) overhead for this activity is less critical: it requires less compliance and due diligence. Even so, utilizing these outsourced pre-formulation services needs to be done thoughtfully, so there is confidence in the data and conclusions.

As the global supply chain expands globally, the need for control and visibility throughout the process is ever more critical. The FDA highlighted this in their 2006 guidance regarding e-pedigree. Regrettably, the industry has been slow to embrace this guidance and the agency has been reluctant to enforce it. Hand in hand with this expansion come the issues of information management and security of this information, central to ensuring supply chain integrity. As more stages of the drug development lifecycle are outsourced, the need for data integrity and knowledge management becomes more important. And this risk becomes more complicated as the emerging markets grapple with a steady stream of evolving Intellectual Property (IP) law. IP protection is often the lynch pin component to a competitive strategic plan and it factors prominently in the decision making process. Fortunately, technology has provided solutions which can quickly impart security and traceability. RFID and data encryption have become more commonplace for global deployments,

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particularly in mature organizations where sophisticated quality and costing principles, such as Cost of Poor Quality (COPQ) are integral to measuring business performance. Stealth technology exists that can be applied to a network to make it invisible to hackers or counterfeiters attempting to hijack data.

The final element that has become more prominent in the strategic thinking is sustainability. Over the past 30 years, the concept of sustainability has evolved to reflect the perspectives and expectations of both the public and private sectors. And they differ somewhat. A public policy perspective would define sustainability as the satisfaction of basic economic, social and security needs, now and in the future, without undermining the natural resource base and environmental quality on which life depends. From a business perspective, the goal of sustainability is to increase long-term shareholder and social value, while decreasing industry's use of materials and reducing negative impacts on the environment.

But what is common to both perspectives is recognition of the need to support a growing economy while reducing the social and economic costs of economic growth. To this end, Leadership in Energy and Environmental Design (LEED) based designs are growing as a foundation for any strategic business or facility plan expansion. As social responsibility creeps into the measureable objectives of an organization's strategic implementation, the ability to balance being a good corporate citizen with shareholder value become an essential element in any successful long-term plan. Although they may not share the same sustainability mindset, even the emerging markets recognize the value of sound energy management and effective use of natural resources to sustain business growth.

As our markets take shape, evolving an organization's strategic business plan to adapt to these new elements would be essential to continued success in a marketplace in flux. As regulatory professionals, we need to understand—not just be aware of—the impact and interplay of these elements. This allows a regulatory path that will not only ensure compliance, but also support the broader longer-term drivers for business performance there need to remain competitive in the years to come.

2.2.2 Manufacturing Output & Capabilities

Similar to the accepted number of strategic priorities – the elements to define the manufacturing strategy, scholars support different dimensions and terms for a factory's manufacturing output. Most researchers consider the four basic dimensions

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cost, quality, delivery, and flexibility, others have a more differentiated view. These discrepancies stem from insufficient definitions and differing levels of analysis. (Miltenburg, 2008)

Initially defined in the manufacturing strategy by ranking a set of competitive priorities, it is specified and measured to what extent a factory is ultimately capable of producing the required output. Obviously, the same dimensions are applied to control a manufacturing function's output and to assess its performance (Colotla, 2003). In turn, a factory's manufacturing capability is the ability to deliver output in accordance with a defined strategy (Kim, 1996). The level of manufacturing capability influences a factory's ability to improve or change. Existing capabilities build the foundation for new manufacturing capabilities. The larger the existing basis, the more opportunities exist to build on (Miltenburg, Setting manufacturing strategy for a company's international manufacturing network, 2009). A list of manufacturing outputs and appropriate capabilities as commonly discussed in the literature is illustrated in Table (2.1).

Table (2.1) Manufacturing Outputs & Capabilities

Manufacturing output	Manufacturing capability to …
Cost	➢ … control financial inputs to manufacture the product (e.g., material, labor, verhead, and other resources)
Quality	➢ … provide products whose features meet or exceed customers' specifications and expectations, and assure on-going conformance to meet assured specifications
Delivery speed and reliability	➢ … meet or exceed the expected delivery speed and keep delivery promises on-time and in-full
Product range and design flexibility	➢ … produce a wide range and mix of products, or conduct design changes quickly
Order size and delivery flexibility	➢ … change order sizes or delivery times quickly
Innovativeness	➢ … introduce innovative and novel products, processes, or products which enable the customer to be innovative

Source: Miltenburg (2009)

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While manufacturing capability need to control financial inputs on the products such as material, labor, verhead, and other resources, cheaper and effective medicine can distribute to market. Although quality maintain as a standard to world class, factories also must provide products whose features meet or exceed customers' specifications and expectations, and assure on-going conformance to meet assured specifications.

Meanwhile, factories often had a too simplistic view of manufacturing, having low costs as the only demand. This view, however, misses several dimensions of manufacturing, which leads to both missed opportunities and mismatch problems in the production. Areas related to content are manufacturing outputs while the process of manufacturing capabilities refers to the way the strategic manufacturing decisions are made.

2.2.3 Shaping the System: Manufacturing Levers

Decisions derived from the manufacturing strategy have both structural and infrastructural implications on the manufacturing system. However, a mere dichotomy between structure and infrastructure is too crude to sufficiently describe how decisions are translated into actions (Slack and Lewis, 2002). Several scholars have introduced categorizations of these decision areas (Hallgren and Olhager, 2006).

Miltenburg (2009) rephrased the term 'decision area' as 'manufacturing lever' in order to emphasize that managerial decisions shape the entire system. Each of these manufacturing levers is equally important and must not be marginalized or disregarded. The particular position of any lever is the result of several decisions that have been made in the respective area over the course of time. The current positions of all levers that are used for adjustments determine the type of the manufacturing system, its manufacturing capability, and finally its performance (Miltenburg, 2009).

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Table (2.2) Structural and Infrastructural Levers of a Manufacturing Site

Structural Levers	
Capacity	Capacity flexibility, shift patterns, temporary subcontracting policies
Facilities	Size, location and focus of manufacturing resources
Manufacturing process technology	Degree of automation, technology choices, configuration of equipment into lines, cells, etc., maintenance policies and potential of developing in-house processes
Vertical integration	Strategic make versus buy decisions, supplier policies
Infrastructural Levers	
Organization	Structure, accountabilities and responsibilities
Quality policy	Quality assurance and quality control policies and practices
Production control	Production and material control systems
Human resources	Recruitment, training and development, culture and management style
New product introduction	Design for manufacture guidelines, introduction stages, organizational aspects
Performance measurement and reward	Financial and non-financial performance measurement, recognition and reward systems

Source: Mills, Platts, Neely, Richards and Bourne, (2002)

2.2.4 Research and Development

The pharmaceutical sector is Research and Development (R&D) driven and it is strictly controlled. On the supply side, it can be stated that the sector is dominated mostly by originator chemical drugs and generic drugs (ITA, 2010). Originator chemical drugs (brand-name drugs) are based on substantial research and

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development (R&D) and are clinically tested both on humans and animals in order to be approved by the appropriate institution. The inventors of these drugs relies heavily on patents so that they can return their investments in R&D and be able to continue the development process of new medicines. Generic drugs (generics) are characterized as duplicates of the originator chemical drugs, which poses the same dosage form, strength, quality and performance characteristics. What differs from the two products is that generics are available in the following situations: after the patent protection given to the original innovator have expired; the patent owner gives the rights to another company, or it is authorized by the United States. On the demand side, the pharmaceutical industry is different from other sectors because the consumer (the patient) is not the one that makes the decision regarding the medicine that he/she needs to take due to the fact that the drugs are prescribed by the doctor (the decision maker). There is also a difference in regards to who is responsible for covering the medicine costs- it is common a national scheme to bear the costs (Commission, 2008).

There is a high tension between generic and originator companies especially, when most of the originators` drugs' patents are about to expire and as a consequence the market can be overwhelmed by generics. This phenomenon is known as the "patent cliff" in the pharmaceutical industry and affects significantly all the different parties involved in the market. In order to find a solution to the issue, originator companies have started using strategies such as "evergreening", which is defined as "weak" patents strategies that block generics companies from entering the market (Labs., 2010). Evergreening is a widespread practice by multinational cooperation and enterprises (MNEs) which aims to prolong the existing monopoly by slightly modifying an existing drug and seek a new patent (Stanbrook, 2013). Problems arise between MNEs and national governments especially in developing countries such as China, India and Brazil due to conflicts of interest. One of the most important things that divides the developed and developing country is not only the imbalance of resources but also the uneven level of knowledge, which is a crucial element for successful development (Stiglitz, 2008). From one side, MNEs pursue IPR protections of modified old drug in order to justify the investments spend on research and development. From another side, national governments in developing countries need to provide cheap medicine to the population which in most cases is under the average standards.

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2.2.5 Human Resource Management (HRM)

Modern approaches of human resource management (HRM) are seen as an enabler to increase operational performance (Inchniowski et al.,, 1997). Employees' knowledge about a company's products, processes and customers, rooted within the organization's routines and social interactions, can yield a competitive advantage (MacDuffie, 1995). Cua (2000) found that the concept of human resource management permeates TPM, TQM, and JIT, and thus constitutes an integral part of these programs' implementation (Armstrong, 2004).

Practices that are covered by HRM include teamwork, flexible job assignments, employment security, incentive payment, and training in multiple jobs (Ichniowski et al., 1997). Multiskilling requires extensive training but facilitates problem-solving and subsequently allows for job rotation within or across working teams (Macduffie, 1995). Cua (2000) later added a strategic perspective and referred to committed leadership, strategic planning, cross-functional training and employee involvement as important elements of HRM. She argued that implementing such practices is expected to create the requisite environment and motivation that is essential for organizational learning(Armstrong, 2004).

In order to ultimately contribute to an organization's performance, Macduffie (1995) lists three conditions that innovative human resource practices have to conform with:

- employees must possess knowledge and skills that managers lack,
- employees have the motivation to apply their knowledge and skills through discretionary effort, and
- the company's business or production strategy can only be achieved due to its employees' contribution of discretionary effort.

2.3 Pharmaceutical Supply Chain (PSC)

In order to describe a typical PSC, parties that form this supply chain should first be identified. According to Shah (2004) and Pedroso and Nakano (2009), a typical PSC includes, but is not limited to, the following parties: manufacturers, intermediaries, healthcare providers, and customers (Schwarz, 2011). A typical PSC is illustrated in Figure (2.1).

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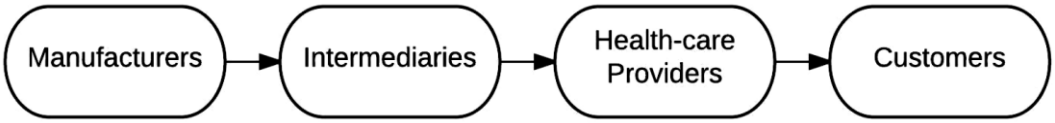
Figure (2.1) A Typical Pharmaceutical Supply Chain



Source: Own compilation based on literature

Manufacturers include, among others, pharmaceutical and biotechnology manufacturers, medical suppliers, and medical device producers. Intermediaries include wholesalers, mail order distributors, and group purchasing organizations. Healthcare Providers include hospitals, physicians, and pharmacies. Customers include government, employers, and individuals.

Manufacturers can be categorized into primary and secondary manufacturers. Primary manufacturers produce the active pharmaceutical ingredients (APIs) of the medications. Secondary manufacturers are responsible for transforming the active ingredients into usable drugs (e.g. tablets, capsules). After that, finished products are distributed to the healthcare providers through intermediaries (e.g. wholesalers, distributors). Some manufacturers deliver their products directly to healthcare providers and bypass intermediaries (Kritchanchai, 2012).

A distinct feature of a PSC is that final consumers (patients) do not fully understand the medical practice; hence, they have control neither over drug choice nor over the amount to be consumed. As a result, healthcare providers play an important role in PSC. Because they write prescriptions for patients, demand for drugs is dependent on healthcare providers (e.g. physicians and hospitals). This feature highlights the importance of technical information flow for demand creation in PSC as opposed to other industries' supply chains (Pedroso, 2009).

2.3.1 Innovation System's Boundaries

In the last twenty years, the number of different IS have emerged. From one side, it is possible to notice, that these approaches share similarities, but from another side, they concentrate on the various aspects of IS (see Figure 2.2) (Johnson, 2009).

The concept of National System of Innovation (NIS) can be used in various ways. A framework that helps to analyze processes of innovation (radical or incremental), actors and policy makers with a strong focus on learning and modes of innovation (STI and DUI), forms of knowledge and diffusion activities (Lundval, B.

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A & Johnson, 1994). This concept is gaining recognition also among the global organization, such as OECD and the European Union to study the production and innovation level of countries (Lundvall, 2007). The definition of NIS is an open, evolving and complex system that encompasses relationship within and between organizations, institutions and social-economic structures which determine the rate and direction of innovation and competence-building emanating from processes of science based and experience-based learning" (Lundvall, 2009). However, NIS faces several challenges, such as uneven distribution and access to education and knowledge, consequence, it has influence to country's welfare levels. To transfer the NIS approach from one country to another cannot always be successful, because of different country's institutions and characteristics (Lundvall, 2007).

The use of Regional System of Innovation (RIS) has been growing rapidly since the middle of the 90s. Cooke (1992) and Braczyk (1998) were one of the first that emphasized the significance of the RIS concept (Cooke, 2001). The RIS is defined as a set of interacting private and public interests, formal institutions and other organizations that function according to organizational and institutional arrangements and relationships conducive to the generation, use and dissemination of knowledge" (Doloreux, David, and Saeed Parto, 2004). To protect competitive advantage of regions, policy strategies should stimulate learning processes locally. The RIS elements (institutions, universities and public organizations) have a trustful relationship between each other and have common interests. Hence, the learning interaction and innovation is induced (Cooke, 2001).

The second innovation approach focuses on Sectorial System of Innovation (SSI), that was developed by Malerba (2002). The main building blocks are the institutions, knowledge, heterogeneous actors and networks.

The third innovation approach is Technological Innovation System (TIS) that was developed by Carlsson and Stankiewicz (1991). TIS is defined as the "dynamic network of agents interacting in a specific economic/industrial area under a particular institutional infrastructure and involved in the generation, diffusion and utilization of technology.

To conclude, emerged approaches (NIS, RIS, SSI, TIS) are important for the innovation process. They together are perceived as "focusing devices aiming at analyzing and understanding the process of innovation (rather than allocation) where agents interact and learn (rather than engage in rational choice)" (Lundvall, 2009).

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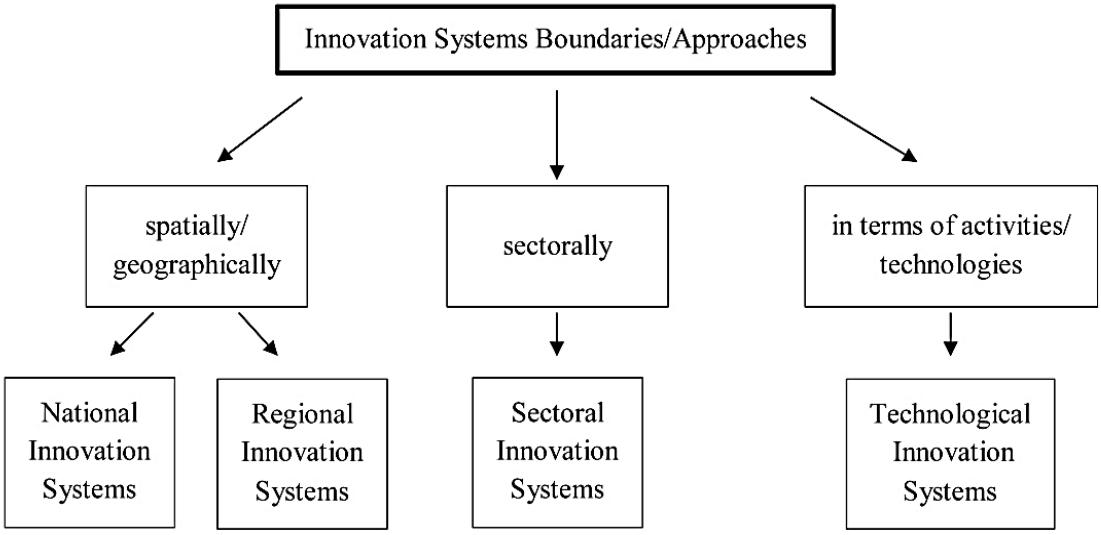
Figure (2.2) Innovation Systems Boundaries/Approaches



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2.3.2 World Class Manufacturing (WCM)

The World Class Manufacturing (WCM) project was initiated in order to identify successful practices of 'best' performing manufacturing sites. By comparing several manufacturing sites in advanced economies, Hayes and Wheelwright (1984) established the commonalities and manufacturing patterns which are common to successful sites. The researchers argued that building competitive strength is dependent on a set of manufacturing practices summarized in six world class dimensions such as

- Workforce skills and capabilities
- Management technical competence
- Competing through quality
- Workforce participation
- Rebuilding manufacturing engineering
- Incremental improvement approaches

Hayes and Wheelwright (1984) found that successful companies differ from less successful ones in the emphasis they put on competitive priorities, thus creating their own and unique strategic profile (Benito, 2005). They argue that it is not desirable to pursue each competitive priority with equal emphasis as "it is difficult (if not impossible), and potentially dangerous, for a company to try to compete by offering superior performance along all of these dimensions simultaneously, since it

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will probably end up second best on each dimension to some other company that devotes more of its resources to developing that competitive advantage." (Hayes R. a., 1984). Instead, companies should focus on specific dimensions to develop their unique capabilities.

The WCM perspective was also taken up by other authors having their own descriptions of the concept focusing on manufacturing practices like TQM and JIT. Schonberger (1986) listed 16 manufacturing principles that accounted for WCM, some of which are in line with the principles of Hayes and Wheelwright (1984), cited in (Friedli, 2013). The attributes of various world class organizations which are also in accordance with the work of Hayes and Wheelwright (1984), cited in (Friedli, 2013). Hall (1987) defined manufacturing excellence as a system that comprises JIT production, employee participation, standardized tools and machinery, supplier integration, and design-for-manufacturability (Friedli, 2013). Hayes and Pisano (1994) conclude that excellent companies consider their capabilities early on to set the right focus on practices that pave the road to a long-term success. The focus on superior organizational capabilities that have to be developed over time provide a sustainable competitive advantage to surpass competitors (Pisano, 1994).

2.4 Challenges in Pharmaceutical Manufacturing

Challenges in pharmaceutical manufacturing constitute the continuous pursuit of improvement of a production plant in all dimensions. Improvement is measured by balanced performance metrics comprising efficiency and effectiveness, thus, providing a mutual basis for an improvement evaluation.

2.4.1 Regulations Inhibit Innovativeness

The pharmaceutical industry is a highly regulated industry whose rules, guidelines, regulations and laws must be followed meticulously by manufacturers. This need for regulation stems from an information asymmetry between the manufacturers on one side, and the consumers on the other side. Both consumers and medical practitioners are not able to assess the products' safety, quality and effectiveness themselves, and thus have to rely on regulatory bodies to do so (Brhlikova, 2007).

In the late 1960s, the World Health Organization (WHO) prepared its first version of Good Manufacturing Practices (GMP). Specifically, GMP "is that part of

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quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization." (WHO, 2007).

The WHO's GMP guidelines have been adapted by individual countries, e.g., US FDA-GMPs, EU-GMP and regions, e.g., the areas of ASEAN and Mercosur. GMPs have also been acknowledged in the norms of the International Organization for Standards (ISO) and the International Conference on Harmonization (ICH). The enforcement of GMP standards, however, rests on individual national forces (Brhlikova, 2007). These standards govern the entire lifecycle of drug production; moreover, several regulatory bodies from the West are involved in the development of international guidelines (see Table 2.3). In this dissertation, the focus lies on the manufacturing of drugs and the associated challenges.

Table (2.3) Pharmaceutical Adaption Standards

Drug lifecycle	Guidelines	WHO	ICH	EU	UK	US
Drug discovery	Good Laboratory Practice	✓	✓	✓	✓	✓
Clinical trials	Good Clinical Practice		✓	✓	✓	✓
Manufacturing	Good Manufacturing Practice	✓	✓	✓	✓	✓
Distribution	Good Distribution Practice	✓	✓	✓	✓	✓
Post-marketing surveillance	Pharmacovigilance	✓	✓	✓	✓	✓

Source: (Brhlikova, 2007)

Regulations impact on the pharmaceutical industry's innovativeness and improvement. Compared to other industries where processes are improved on a continuous basis, the regulatory constraints within pharma inhibit innovation and freely conducted improvement activities (Basu, 2013). Thus, "many manufacturing procedures are treated as being frozen and many process changes are managed through regulatory submissions." (FDA, 2004). The fear of getting stuck in long and costly regulatory approval procedures causes many pharmaceutical manufacturing

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organizations to refrain from any changes throughout their processes' lifecycles, and to stick to inefficient operations and out-of-date processes (Basu, 2013).

2.4.2 Pharmaceutical Regulations in Thailand

Thailand is the neighboring country of Myanmar which is similar the system of medicinal production regulation but some policies and strategies are different between two countries. So, there were many lessons to be learned to improve as necessary for Myanmar.

The Food and Drug Administration (FDA), under the Ministry of Public Health (MOPH), is the main agency in charge of drug approval and registration. Its main sections relating to pharmaceutical registration are:

- Drug Products, under the Drug Control Division;
- Import Licenses, under the Division of Manufacturing and Import Facilities Control;
- Product Registration, under the Food Control Division, and
- Label Registration, which is also under the Food Control Division.

Thailand's regulatory environment for pharmaceuticals is not as well enforced as in other Western countries, leading to widespread bribery and corruption in the FDA and other agencies of the MOPH. The country's economic slump has only aggravated this problem by leaving the FDA understaffed and with an annual budget of only US $10 million (minus the $3 million spent on workers' salaries) – less than the budget of many provincial offices. Thus, the FDA has been taking quite a long time to fully consider drug approvals, often taking several years to complete the process.

Recently, the government made some revisions to the FDA's structure in order to minimize corruption and speed up approval. Two years ago, it decreed that only one FDA official should be in charge of the licensing approval process, instead of the previous arrangement where individual FDA officials controlled various parts of the licensing process (for example, one unit in a particular division of the FDA responsible for issuing licenses for product sales would have to wait for reports from authorities in another unit on inspection of the manufacturing site, as well as technical documents from yet another unit before it could give approvals).

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The change aimed to reduce bribery by cutting out FDA "middlemen" who would make sure that the documents of the products and the pharmaceutical firm under their responsibility moved faster from one unit to another. As a result, authorities are now able to trace back on work pending in the agency more easily.

The government also plans to focus the FDA's efforts only on monitoring and improving the quality of drugs in the market, steering the agency away from such previous (and distracting) responsibilities as overseeing the proper operation of drugstores in country. Instead, the latter will be transferred to the government's Pharmacy Council, and the government hopes that the switch will increase the speed and efficiency of the FDA's operations.

The government, however, has been slow to respond to claims that the FDA, in order to function effectively for the benefit of the public and free from political interference, should partly receive autonomy and be administered as an executive agency with a board of representatives from consumer groups, academics, the business sector, and the media.

Under this plan, only a part of the FDA would become "independent," and legislative sections of the FDA could stay in the bureaucratic system. Supporters of this plan, many of whom are in the FDA itself, claim that the greater administrative power the FDA would gain after being taken out from under the MOPH could greatly speed up drug approval. The FDA was notified in regulation in that cannot allow for import drug as can produce in local factory.

In late 1998, the FDA requested the Secretary for Public Health that it be allowed to become an independent executive agency, and urged public health administrators to reconsider their earlier decision against that plea. However, no decision has been made on this proposal yet.

Previously, the MOPH classified pharmaceuticals into "modern" and "traditional" (i.e. herbal) pharmaceuticals. Modern pharmaceuticals, which included generic and new drugs for human use as well as veterinary products, were further divided into three categories:

- Ready-packed pharmaceuticals, which are similar to those available in over-the-counter drug stores;
- Dangerous pharmaceuticals, which must be sold by a registered pharmacist; and
- Specialty controlled pharmaceuticals.

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However, the modern/traditional classification was too general, leading to multiple sub-categories for different drugs and creating general confusion over how certain drugs were to be treated in the market. For example, many drugs in the Thai market were misclassified as "dangerous drugs," and thus according to law kept off the National List of Essential Drugs (NLED, the standard drug price list in Thailand). As a result, manufacturers were prevented from advertising these products in media other than professional medical publications, ultimately lowering sales.

2.4.3 GMP in Emerging Markets

The WHO's Good Manufacturing Practices have also been implemented in emerging markets' regulatory systems. However, the standards in emerging markets are often less strict than those enforced by US and European regulatory bodies, and so enforcement mechanisms and sanctions across a drug's production cycle vary. The national differences in the jurisdiction and strength of regulatory codes reflect the interests and power of the various stakeholders and regulating authorities (Brhlikova, 2007).

The WHO suggest sanctions against manufacturers in emerging markets that fail to comply with GMP; however, it is in the hand of individual governments to monitor and enforce these guidelines (Brhlikova, 2007).

China, for instance, had enforced a policy requiring the country's pharmaceutical manufacturers to pass the GMP certificate by July 2004 at the latest. About 40% of Chinese manufacturers failed to pass the certification within time, leading to a significant reduction in the number of domestic pharmaceutical manufacturers. The remaining companies' competencies have since been lagging behind those of multinational manufacturers (Chan, 2011). Discussing country-specific GMP standards, Mrazek and Fidler (2004) argue that with regard to some emerging markets, and especially Russia, "it is important to note that these standards are less stringent than the GMP standards defined by WHO or those of the European Union." Brhlikova et al. (2007) researched GMP in India and found that some Indian companies try to acquire GMP certificates on the black markets; the introduction of GMP caused a significant barrier to market entry and growth to domestic manufacturing organizations. Achieving GMP compliance also poses a series of challenges to African pharmaceutical manufacturers, as summarized in Table (2.4).

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Table (2.4) Challenges for African Manufacturers towards Achieving Universal GMP Standards

Technical expertise	Financial considerations	Infrastructure requirements
▪ Access to know-how for designing, upgrading to and running GMP compliant facilities	▪ Access to export markets and their current fragmented nature	▪ Reliable utilities (implications for cost as well as compliance with GMP)
▪ Access to skilled human resources	▪ Competitive production given cost structure ▪ Variability in quality amongst market players ▪ Market context ▪ Policy incoherence ▪ Access to affordable investment capital	▪ Uncoordinated and/or vertical approaches to developing the sector ▪ Access to bioequivalence centers ▪ Lack of market data ▪ Regulatory oversight ▪ Underdeveloped supporting industries

Source: UNIDO (2012)

Focusing on multinationals from emerging markets, Bartlett and Goshal (2000) argue that multinationals usually enter the global marketplace at the lower end of an industry's value curve and have difficulties in moving upwards. Depending on companies' position in the value chain, and respectively their position in the global value curve, they have differing capabilities to manufacture their products compliant to international standards (UNIDO, 2012).

2.5 Global Drug Quality

Despite (some) country-level efforts to monitor and enforce GMPs, drugs manufactured by companies from emerging markets are known for their inconsistent quality. Not only is the quality of products occasionally poor, but China and India are also responsible for the vast majority of counterfeits that end up on the international health market (Lewis, 2009). Problems of product quality and product counterfeiting

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are not limited to these two countries – they affect all BRIC nations and a long list of Latin American nations (Bate, 2008).

Bate (2010) analyzed 1,838 drug samples of various pharmaceutical manufactures from advanced and emerging countries (see Table 2.5). The author found a substantial disparity in drug quality between large and small domestic Indian manufacturers. The highest variability in product consistency was found in African producers, followed bydrugs made in China and Vietnam (Bate, 2010). Assessing quality risks at offshore sites in emerging markets, Gray et al. (2011) found that also Western multinationals in emerging markets face difficulties in achieving similar quality risk levels compared to manufacturing in their home countries (Gray, 2011).

Table (2.5) Tested Drug Quality – Emerging vs. Advanced Countries

	Total samples tested	**Total Samples Failing Raman Spectrometry**	**Percent Failed**
Large Indian producers **a**	471	6	1.3%
Small Indian producers **b**	327	29	8.9%
Chinese producers	169	13	7.7%
Southeast Asian producers **c**	69	4	5.8%
Western producers **d**	438	1	0.2%
African producers	302	28	9.3%
Producers in mid-income nations **e**	62	7	11.3%
TOTAL	1,838	88	4.8%

Source: Bate (2010)

Note: a. more than $300 million in annual revenue; **b**. less than $300 million in annual revenue; **c**. countries include Thailand and Vietnam; **d**. countries include those within European Union, as well as Switzerland and United States; **e**. countries include Brazil, Turkey and Russia

Bate (2010) argues product quality is least consistent in drugs that are made by small pharmaceutical manufacturers for their domestic market and concludes that many domestic pharmaceutical companies of emerging markets are not able to manufacture drugs compliant with the standard of Western GMP. It is, however,

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important to note that while product quality may be found to be poor by international standards, it is often seen as relatively good in comparison with other local manufacturers and regarded as sufficient within an emerging market context (Bloom, 2013).

Quality defects in pharmaceutical products put patient lives at risk. From an economic perspective, quality defects entail a number of severe problems for an affected organization, e.g., loss of revenue, remediation costs, legal charges and fines etc. which can threaten business survival (Calnan, 2013).

2.6 Review on Previous Studies

Mya Mya Htay (2019) only focuses on the production activity of Insein Pharmaceutical factory, and also emphasizes on finding effective organization, wide policies make the sustainable development of the pharmaceutical production factory of Insein and fulfill the country's pharmaceutical need for public health sector. The objective of that study is to examine the important of drugs or medicines for both preventive and curative public health-care sector and to analyze the pharmaceutical production and products pharmaceutical factory (Insein) for public sectors in Myanmar (Htay, 2019).

Previously, Mohammed Al-Shakka was dwelt into the challenges facing Yemeni pharmaceutical industry, bearing in mind that these challenges are not only facing Yemen but more specifically the Arab pharmaceutical industry. These challenges could be divided into three categories; main challenges, external challenges, and self-challenges (Al-Shakka, 2016).

In that paper, was found these days, pharmaceutical industry thrives as one of the largest and exponentially expanding global industries. Nonetheless, millions of people in low income developing countries, have to suffer from the fatal consequences of the inaccessibility and non-availability of essential drugs. This is also happening in Yemen, where the pharmaceutical manufacturers sector have to face up to many challenges.

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CHAPTER 3
PHARMACEUTICAL INDUSTRY IN MYANMAR

3.1 Overview of Myanmar Pharmaceutical Industry

Myanmar has a significant growth in the pharmaceutical market started from the last decade, worth of US$ 160 m in 2010 to US 344 m in 2016 and the total pharmaceutical expenditure has been increasing at 11-12% per annum according to "the Trading Economics". Since Myanmar is free from the international sensation, the country is opening up and the investment of healthcare companies and the Market Expansion Services providers are expected to increase according to the ASEAN Economic Community (AEC). The estimated size of Myanmar's pharmaceutical industry is about US$ 100-120 million in Cost, Insurance and Freight (CIF) value. The Government has implemented the policies and long-term strategic plan for the healthcare system into action during 2017-2021. The Ministry of Health aims to enable every citizen to attain full life expectancy and enjoy longevity of life and to ensure that everyone is free from diseases.

The pharmaceutical market in Myanmar is mainly depended on the foreign imported medicines and drugs as Myanmar's domestic pharmaceutical industry is still small. Most of pharmaceutical products and drugs are mainly imported from other countries like India, Bangladesh, China, Indonesia, Pakistan, Thailand and Vietnam. The 85% of the drug market are imported products and India takes the lead with 40-45% of the market share. All imported medicines and supplies have to be registered and authorized by the Food & Drugs Administration (FDA). The FDA inspects the importers, pharmaceutical plants and the quality of drugs. Around 5000 types of medicines are currently imported.

According to the Myanmar Pharmaceutical & Medical Equipment Entrepreneurs' Association (MPMEEA), there are 1163 local companies, 26 foreign companies, 3214 individuals, 16 manufacturers in March 2017. The 60% of the total pharmaceutical product sales are made in Yangon and Mandalay. The major pharmaceutical companies which are leading in the Myanmar's drug market are

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DKSH Business Unit Healthcare, GE Healthcare, Sun pharmaceuticals, Dr. Reddy, Cipla and Ranbaxy respectively. Other local companies which mainly lead the market are Fame pharmaceutical, San Lwin Trading Company, AA medical product, GETZ Pharma limited and TAJ Pharma limited. Unlike other countries where the clinics, drug stores and pharmacies are around every corner, the number of such medical outlets is very few in Myanmar. The clinics and hospitals from private sectors have their own sources from the preferred medicine distributors.

Myanmar people's awareness in healthcare is increasing and the growing middle class is favoring on western drugs for quality and efficiency than traditional medicines. Price remains an issue but manufacturers know the limited paying capacity of local customers, and therefore keep their prices at lowest possible levels. Additionally, drugs that reach the market through cross border trade come at cheaper prices.

New hospitals with foreign private investments are under construction. The new law under the new government allow 70% foreign ownership in clinics and hospitals. Therefore, Myanmar pharmaceutical and healthcare industry is expanding over the time and Myanmar people can now have various choices such as having access to buy latest drugs in local markets and to take treatment in home country rather than travelling overseas for their health.

There are three parts to the sector: manufacturing, healthcare, and distribution. The government opened up the manufacturing sector in 2013, and there are now about ten factories under construction or that have started production, which is a good sign.

Myanmar is a member of the World Trade Organization and the World Intellectual Property Organization, but is legally exempted from the obligation to pass an intellectual property law until 2023. A copyright law is expected to come out soon, but the patent law will be introduced only after this temporary waiver comes to an end.

Myanmar's pharmaceutical market is estimated to be worth about US$600 million and is expected to grow to $1 billion in the next five years. If there is more investment in manufacturing, pharmaceutical companies will be able to sell their products competitively.

While there is significant potential, for the industry to grow the government needs to establish a solid national procurement policy that encourages domestic production. In many countries, there is a points-based, preferential system for local

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products. This would not necessarily only benefit Myanmar-owned factories if factories built with foreign investment were also considered domestic manufacturers.

Because import taxes are so low—the customs duty is only 1.5 percent—it is easy to do business by importing and selling products, which puts unnecessary pressure on the Myanmar currency, the kyat. Major investments are needed to stabilize the exchange rate, not just investments in sales and distribution.

Under World Health Organization Good Manufacturing Practice, all factories have their quality control, quality assurance and are regulated by the Food and Drug Administration, which inspects products produced by local factories quite frequently; more than imported products.

3.2 Challenges of Pharmaceutical Products and Infrastructure

Some problems that had been solved have re-emerged as the country undergoes political changes. One major challenge is the implementation of regulations at the directorate level. At the ministry, or policy level, there is much good will to improve business-friendly regulations, but there are challenges in implementing the policies down the line. For example, under the Union Tax Law, there is a commercial tax exemption for pharmaceutical products and medical devices, on which customs is not supposed to collect any import tax.

Now when we apply for an import license, an import recommendation letter or an approval letter from the FDA is required to identify it as a medical device. But customs officials may claim not to know if it is a medical device or not, or interpret the letter as not being addressed to them. This can cause delays up to two months to clear goods.

Air-conditioned transport is an issue in this country. Traffic congestion is common here. For products that need to be stored at less than 25 degrees, this poses a logistical challenge, as they can be exposed to high temperatures for many hours on the road.

The power supply is another challenge, especially for storage. This is because pharmaceutical businesses need up to three types of storage conditions, each at a different temperature, for their products. To create these conditions, we need air-conditioned rooms. The irregular electricity supply means we must have a backup diesel generator.

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As part of good storage practice, we need a contingency plan. When there are frequent power blackouts, backup generators are no longer for backup, but normal daily use. For distribution warehouses, we must be prepared for the backup generator's failure, which necessitates a secondary backup generator.

These are costs that add up, on top of the product cost. Companies that can afford this can invest, but retail outlets may find these conditions for storage challenging. In Yangon, companies can only build new generators behind buildings, due to the Yangon City Development Committee's revision of the law, and not all buildings have enough room to house such generators.

Under FDA standards, companies must have their storage facilities audited before they can begin importing pharmaceutical products, which improves storage conditions. The FDA also requires companies to have a backup generator— but not a secondary backup generator.

Problems occur at the retail level too. The FDA carries out inspections of outlets. But if they shut down all the pharmacies that don't have good air-conditioned storage, that would probably affect more than 90 percent of the pharmacies across the country.

3.3 Pharmaceuticals Market of Myanmar

According to market research agencies the total pharmaceutical expenditure in Myanmar has been growing at 11-12% per annum, and has increased from USD 390 million in 2014 to USD 440 million in 2015. However, these values are lower than most ASEAN nations including Singapore whose population is one tenth that of Myanmar. Growth prospects with governmental initiatives are high and the market is expected to touch USD 1.12 billion by 2023.

However, most of the pharmaceutical products sold come from countries like India, Bangladesh, China, Indonesia, Pakistan, Thailand and Vietnam. Research figures indicate that total pharmaceutical imports accounted for 85% of the drug market and India takes the lead with a strong 40-45% market share. All imported drugs have to be registered and authorized by the FDA that inspects pharmaceutical plants and importers and also tests the quality of drugs. At present, approximately 5000 drug varieties are imported into Myanmar.

There is a vast market for generic drugs and all types of prescription drugs including steroids and antibiotics can be purchased over the counter. This is

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responsible for big Indian companies like Sun Pharmaceuticals, Dr. Reddy's and Cipla capturing a significant market share of the local market. Another reason for the success of Indian companies is the lower price levels they can be procured at, compared to bigger international brands. When funding is not available and the patient has to pay out of pocket, cheapest options are sought – and this comes from Indian manufacturers. India also happens to be a neighboring country and trade across the border also takes place. Additionally, doctors and physicians are comfortable prescribing affordable Indian medicines since they are trusted for quality.

Currently the Myanmar pharmaceuticals market is dominated by imports. There are only a handful of domestic producers of pharmaceuticals, with most market demand instead met by products from neighboring countries, specifically India, China, Thailand and Bangladesh, as well as Pakistan and Vietnam. BMI Research reported that pharmaceutical sales totaled USD456 million in 2017, to grow around 7% to 2022. Currently the market for pharmaceuticals is very price sensitive, and generics dominate. Gradually there will be more space for brand-name products, as the economy continues to expand.

Imported pharmaceuticals must be registered with the Ministry of Health and Sports' Food and Drug Administration Department, though the body is understaffed and under-resourced, impacting its ability to test and approve drugs, as well as crack down on counterfeits. It has however successfully carried out some enforcement action. In addition, state-owned Myanma Pharmaceutical Industrial Enterprise is responsible Intellectual property rights are a major hurdle in encouraging pharmaceutical development. Many of Myanmar's IPR laws are outdated and spottily enforced, though the 1992 National Drug Law does outlaw counterfeit pharmaceuticals. A suite of four new IPR laws are being considered, including a Patent Law, which will shore up legal protections when passed. In addition, Myanmar's Competition Law came into force last year, though it remains to be seen in practice how it will be applied.

3.3.1 Domestic Production and the Distributor Network

The country's own pharmaceutical industry is grossly underdeveloped with most of the local supplies, accounting for only 20% of the demand, come from the state owned Myanmar Pharmaceutical Factory that comes under the purview of the Ministry of Industry. The factory has been set up to manufacture tablets, capsules,

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powders, lotions, injections, Biological and Vaccine Products to initiate the import substitution process. The factory produces about 190 items that are various types of medicine. A single private player named Fame Pharmaceutical has a GMP certified facility but produces herbal and organic medicines used to treat serious diseases like cancer and tuberculosis. Its product range includes 45 different kinds of herbal medicines that are exported to countries like Japan, Thailand, Singapore, Taiwan and South Korea.

There are over 100 pharmaceutical distributors operating in Myanmar, whose sales force manage to reach even the most remote corners of the country. Significant among these are distributors like the Swiss owned DKSH and Maxxcare which distribute both prescription and over the counter drugs. DKSH has a strong presence in many Asian countries and in addition to drugs, is also a distributor for medical devices. The company has been operating in Myanmar for 15 years, having established a network of 60 sub-distributors through whom its products reach 19000 retail outlets, has 7 warehouses, including 2 with cold chain capabilities. This reach of DKSH makes it the preferred choice for multinationals like Roche, Bayer and Sanofi to expand their sales without having to be concerned about compliance issues. Maxxcare has also created a towering presence in the pharmaceutical world and is the first distribution company that has received ISO 9001:2000 certification, and its sales force has access to the most remote parts of Myanmar. Some of the pharmaceutical brands under the company include Lupin, Novartis, Pfizer, GSK, MSD and Kalbe.

3.3.2 Opportunities: Pharmaceuticals-Promise of Growth

Awareness about health is increasing among the Myanmar people and the growing middle class is veering away from traditional medicines towards western drugs, due to their conviction about their quality and efficacy. This demand is being met through imports and the biggest volume of imports is of vitamin C tablets and antibiotics. Price remains an issue but manufacturers know the limited paying capacity of local customers, and therefore keep their prices at lowest possible levels. Additionally, drugs that reach the market through cross border trade come at cheaper prices.

International pharmaceutical companies are flocking into Myanmar since they see a barely tapped market of over 57 million people. Official figures indicate a USD 100- 120 million, but pharmaceutical specialists put the figure at USD 400 million

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since data available is based on customs value and not on the actual sales volume, and figures not incorporated are the illegal cross border trade and the under reporting of goods actually brought into the Myanmar market.

New hospitals with foreign private participation are coming up. Under the new rules formulated by the government the healthcare sector will permit 70% foreign ownership in clinics and hospitals. This has attracted private hospitals like Bumrungrad and Bangkok Hospital to set up representative offices and Samitivej Hospital has tied up with Parami Hospital to set up an international clinic which promises services that match international standards. Efforts are on to improve medical college education as well. The healthcare industry is getting an impetus from the government as well through increased allocations in the budget, and relaxation of rules for foreign investment.

The market is expanding in terms of the quality and range of drugs available, to include supplements and some of the newer, safer drugs. For the first time perhaps, the residents of Myanmar have the luxury of choice. It is only a matter of time before we see local manufacturing begin and people of Myanmar getting the entire range of the latest drugs in local markets, no longer needing to travel overseas for treatment, or having to carry back packages of medicines from trips abroad.

3.3.3 General Challenges faced by Pharmaceutical Sector

Long and healthy lives are one of the few matters that are equally perceived as crucial for everyone regardless of the culture. This is one of the most important sectors where innovation has a substantial impact on the health and wellness of millions of people. The pharmaceuticals are of high interest for both society and economy. The industry is defined as companies that are involved in various activities, such as research and development (R&D), manufacturing and marketing drugs and biological (ITA, 2010, p. 1). The market is highly competitive and it is dominated by large multinational corporations (MNEs). In the recent years though, there is an increase in the number of small specialized ventures in the sector. One of the main reasons for having large companies in the sector is the fact that sufficient investments are needed. It is estimated that the average cost of bringing a new drug to the market is more than $800 million (Boldrin and Levine 2005). Intellectual monopoly has dominated heavily in this sector.

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Lehman (2003) discussed that in some industries that are based on technological knowledge, inventors can wait until the last moment before sharing the idea to the market. This automatically gives them maximum patenting time of 20 years. It is different in the pharmaceutical industry due to the fact that the inventions should be revealed in the early stages because of government regulations. The knowledge regarding the new drug should be communicated between scientists and clinically tested in order to fulfill the safety and efficacy regulations.

(a) Legal Requirement

The Myanmar (Burma) government enacted the National Drug Law (the ND Law) in 1992. The basic purpose of the ND Law is to control and systematically regulate the manufacture, import, export, storage, distribution and sale of drugs.

The ND Law is administered by the Ministry of Health and Sports (the MOHS). In the MOHS, according with Health, there is composed of a total of 14 departments and institutes. They are: Office of the MOHS, Institute of Dental Medicine, Department of Health (DOH), Malaria Institute of Myanmar, Department of Health Manpower, Department of Health Planning, Department of Traditional Medicine, Department of Medical Research, Department of Medical Service, Institute of Medicine 1, Institute of Medicine 2, Institute of Community Health, Institute of Nursing and Institute of Pharmacy. The state-owned hospitals are also supervised by the MOHS.

Under section 4 of the ND Law, the Myanmar Food and Drug Board of Authority (the Board) was formed. The chairman of the Board is the Minister of Health. The Board consists of 19 members from various ministries. Section 5 of the ND Law gives the Board wide-ranging authorities and responsibilities.1 Section 6 of the ND Law confers on the Board the power to delegate to any organization or any person its functions and duties.

When the ND Law was implemented in 1992, Central Food and Drug Supervisory Committee and Food and Drug Supervisory Committees (the Supervisory Committees) in every Myanmar State, Division, District and Township were formed. Also, in accordance with section 29 of the ND Law, the Food and Drug Administration (the FDA) was formed under the DOH to administer all food and drug matters. The FDA plays a major role in monitoring food and drug registration.

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(b) The Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) was established in 1995 as one of the divisions under the Department of Health. The FDA division was upgraded to a separate department in April, 2013. The aim of the department is to ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country. FDA Headquarter is located in Nay Pyi Taw, the capital city of Myanmar, with five major divisions:

Administrative division, Drug Control division, Food Control division, Cosmetic and Medical Device Control division and Laboratory division while preexisting Yangon and Mandalay branches acting are still as major branches, control activities have greatly expanded with the establishment of new FDA branches in other Regions and State. In addition, FDA has also established branches in important border trade zones such as Muse, Kalthaung, Myawaddy and Tamu.

FDA is responsible for issuing GMP certificate for local food manufacturing businesses, import and export recommendation, import and export health certification. Drug control activities include marketing authorization for new product, variation of existing authorization, quality control laboratory testing, adverse drug reaction monitoring, Good Manufacturing Practice inspection and licensing of manufacturers, wholesalers, enforcement activities, drug promotion and advertisements. FDA issues notification and import recommendation of medical devices and notification of cosmetics.

(c) Regulatory

The country's Pharmaceutical Industry is just in its infancy. Reports available are very old and suggest the country has around 150 pharmacists, one state owned manufacturer besides 60 private small scale manufacturers. The trade has 275 wholesalers and 20 importers.

MFDBA: Lays down policies, provides guidance on production, distribution, importation, exportation, quality assurance, standard setting.

FDSCs: The State/Division FDSC, under the Director General of the Department of Health, licenses drug wholesalers and retailers. The CFDSC licenses local drug manufacturers and gives drug importation approval certificates to the importers. At township level the FDSCs are managed by the Township Medical Officers. The committees consist of the Township Medical Officer, the Commander

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of the Police, and the representatives of the City Development Committee and the General Administration Committee.

FDA: Established in 1995, responsible for issuing marketing authorization for pharmaceutical products, inspecting manufacturing plants and importers, and testing the quality of drugs.

DAC: Evaluates and registers drugs. Prior to submission to the DAC, applications are reviewed by staff from the registration section of the FDA - which consists of the Assistant Director of the Drug Control Section and two pharmacists.

Registration applies to imported as well as domestically manufactured products, and covers both the public and private sectors. Guidelines for drug registration have been formulated, and require that anyone applying for registration should be a resident of the Union of Myanmar. In the case of foreign companies, the applicant must be a legal representative domiciled in Myanmar but need not be the sole importer of the drug. Once a drug is registered, it can be imported into the country by anyone who has a license to import pharmaceuticals. Companies must pay US$100 for registration assessment fees, followed by US$300 for registration fees (registration of drugs).

Myanmar is to comply with the concept of ASEAN regulatory harmonization and ACTD format. In 1979, Myanmar developed and established the National List of Essential Medicines (EML) comprising of 254 items (122 essential, 132 complementary). The medicines in NLEM (2016) have been categorized as A = everyone (for any doctor) with first choice for the patient, B = Alternative to A, C = for experts (experienced doctors), D = Trained personnel with expert qualifications (drugs to be used in specialized centre), E1 = National Programme Drugs (eg. HIV, TB for Myanmar) and E2 = Specialist in specialized centre, kept by authorized body of the hospital, allowed by request (drug is expensive for some rare diseases or conditions, eg., liposomal amphotericin B, digoxin specific antibody) for central procurement. The numbers of items in each category are A = 217, B = 38, C = 139, D = 89, E1 = 41, and E2 = 13 and total of (486) medicines are included in NLEM (2016). Some of the items are included in one or two categories (eg. Ampicillin is in category A and C based on dosage form). Therefore, counting the items are (537) by category. [c] – symbol is placed next to an individual medicine or strength of medicine it signifies that there is a specific indication for restricting its use to children.

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(d) Commercial Tax and Customs Duties

Under the Commercial Tax Law a commercial tax is charged on all goods produced within the county or imported. The commercial tax payable is liable to be paid by the manufacturer or the importer. The government may grant exemption from tax with respect to any kinds of goods. The Sea Customs Act provides that the government may fix duties and tariff-values of any goods exported or imported on which customs duties are imposed. The government may also exempt any goods imported into, or exported from, the country from the whole or any part of the custom-duties leviable on such goods. In exercise of power conferred by the CT Law and the SC Act, the Ministry of Finance and Revenue has issued notification No. 1/93, in which 36 kinds of medicine are exempted from custom duty and commercial tax. The commercial tax payable on other medicines is 5% on the landed cost for imported goods or the sale receipt for that manufactured in the country. The custom duties payable on the other medicines is at rates ranging from 0% to 1.5% on tariff values.

3.4 Common Features of Pharmaceutical Industries in Myanmar

Because of the unstable socio-political atmosphere generated by crime and corruption in most developing countries, the economy still tends to show characteristic features of extreme capitalism and is still much consumer-oriented. Therefore, it has been clearly observed that indigenous industries in Myanmar whether pharmaceutical or otherwise have the same characteristics that can be summarized as follows:

a. A high percentage of the processed raw materials are imported that is, the industries are secondary types with no primary base.
b. Heavy machine and equipment used are mostly manufactured overseas and imported.
c. Labor is still very cheap.
d. The market is vast due to very high population in Myanmar.
e. Highly qualified indigenes, professionals and research experts in universities and research centers are now being recognized and consulted for technical services. Unlike before where foreign technical advisers or experts are often preferred and consulted.

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3.4.1 Levels of Pharmaceutical Manufacturing Industries

There are three different levels of production that pharmaceutical manufacturing industries can operate and they include the primary, secondary and tertiary levels (O'Connor, 2017).

(a) Primary Production

Primary production is the processing of raw materials to create Active Pharmaceutical Ingredients (APIs) and additives/ excipients or ancillary substances used in pharmaceutical formulation. The final APIs, which is the biologically active compound in the formulation that produces the therapeutic effect, should meet pharmacopeia or similar requirements. Primary manufacturing may involve either chemical or biological processes requiring different types of production facilities, technologies, skills and knowledge. The manufacture of active ingredients is the most expensive aspect of pharmaceutical production because of the necessary investment in capital equipment, process development and quality assurance systems. The more sophisticated the products, the greater the capability and skills required to develop and maintain the production processes.

(b) Secondary Production

Secondary production is the large-scale processing of finished dosage form such as tablets, capsules and injections, from raw materials or intermediate products, often from both local and imported sources. Production of sterile preparations (such as injections, antibiotics, and intravenous fluids) and non sterile preparations (such as oral solids, liquids and topical preparations) can be carried out with either locally produced or imported packaging materials. Although less technically demanding than primary production, this stage must be completed to precise specifications. It requires modern, high-speed, precision equipment to produce pills, capsules, and liquids, often in large quantities and at very low unit costs, which are targets that small facilities find difficult to achieve, especially while also meeting international GMP standards. They can be seen as factories registered by law to formulate and produce various dosage forms. The secondary industries depend entirely on the primary industries for their drugs and excipient raw material inputs. Similarly, both the primary and the secondary industries cannot function without the ancillary or support industries, i.e,

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the tertiary industries such as the engineering/ tool industries, paper, plastic, glass and metallic packaging unit industries.

(c) Tertiary Production

These include packaging and labeling finished products from primary and secondary sources into bulk packs, smaller dispensing packets, bottles, or course of therapy units for individual use. The initial quality of the pharmaceutical product established in the earlier phases of production must be maintained in the tertiary and final step, so ensuring high-quality standards through rigorous operational procedures is important. Tertiary production also addresses specific local needs for certain formulations, labeling, and packaging.

In addition to the above levels of production, pharmaceutical manufacturing industries can also be categorized into small, medium and large scale based on the overall production output. The small-scale industries are owned by private individuals while the medium scale is owned by a group of persons or shareholders. The so-called large scale industries are foreign controlled and made up of multinational corporations.

3.4.2 Current Opportunities and Challenges of Myanmar's Pharmaceutical Industry

The pharmaceutical industry traces its root from two sources; the first of these were local druggist that expanded from their traditional role of distributing botanical drugs such as quinine and morphine to wholesale manufacture in the mid-19th century. The function of the industry is to research, develop, produce and market drugs or pharmaceuticals for use as medications. Its aim is to produce safe and effective medicines with cost efficiency and productivity to the manufacturer. The potential for national or local production of quality assured, low-cost pharmaceuticals to meet national needs is an issue that has been debated and discussed for several decades. The justifications or challenges that initiated the need for local production of pharmaceuticals include;

a. The problem of lack of ready accessibility to available pharmaceuticals
b. High prices for imported raw materials
c. Inefficient regulatory policy

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These challenges have prompted public and political interests in considering local production of pharmaceuticals with the aim to

a. Promote self-sufficiency
b. Achieve independence from international suppliers
c. Develop local industrial capacity
d. Produce foreign exchange through exportation of domestically manufactured medicines and
e. Create new jobs.

Until the middle of the 20th century, most developing countries like Myanmar only imported finished pharmaceutical dosage forms such as suspensions, syrups, tablets, creams, ointments, suppositories, powders, capsules, and parenteral preparations all of which were imported by either multinational drug companies, government or some wealthy indigenous private entrepreneurs. Serious attention was not paid to the local production of raw materials, dosage forms or processing equipment. However, in recent times, the trend has changed and these are beginning to gain more attention especially the local production of dosage forms and some processing equipment.

Although a large proportion of dosage forms are still being imported or purported to be imported from industrially developed countries like India, China, USA, Europe, Parkistan, Taiwan, Brazil etc., government has also tried to encourage indigenous investors to move away from the sole importation of finished goods to the manufacture of simple products. This is an indication that serious effort still needs to be made in order for Myanmar to meet the drug and health needs of the citizens.

In this study, the National List of Essential Medicines (NLEM) which is now becoming very important not only for procurement but also for health care providers to do as a reference. Revision of NLEM was based the four important documents such as National List of Essential and Complementary Medicines and Vaccines for Myanmar (2010), Thai Essential Medicines List (2012), WHO Model List of Essential Medicines 18th edition, WHO Model list of Essential Medicines for Children 3rd edition.

In the National List of Essential Medicines, Complementary Medicines and Vaccines for Myanmar (2010), there were (4) categories such as:

E = Essential Medicines for basic health care system

E* = Essential Medicines recommended for tertiary referral level

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C = Complementary Medicines

C* = Complementary Medicines recommended for tertiary referral level. Total items were (341).

Normally, the NLEM should be updated two yearly according to the WHO guideline. The issue of updating was also discussed and considered based upon the information came out from various health sectors and programmes, such as updated treatment regime, drug resistant conditions, control drug policy, drugs from programme which were supported by WHO,NGOs, INGOs.

The medicines in NLEM (2016) have been categorized as follows:

A = everyone (for any doctor) with first choice for the patient

B = Alternative to A

C = for experts (experienced doctors)

D = Trained personnel with expert qualifications (drugs to be used in specialized centre)

E1 = National Programme Drugs (eg. HIV, TB for Myanmar)

E2 = Specialist in specialized centre, kept by authorized body of the hospital, allowed by request (drug is expensive for some rare diseases or conditions, eg., liposomal amphotericin B, digoxin specific antibody) for central procurement

The numbers of items in each category are as follow:

A = 217

B = 38

C = 139

D = 89

E1 = 41

E2 = 13

Total of (486) medicines are included in NLEM (2016). Some of the items are included in one or two categories (eg. Ampicillin is in category A and C based on dosage form). Therefore, counting the items are (537) by category. [c] – symbol is placed next to an individual medicine or strength of medicine it signifies that there is a specific indication for restricting its use to children.

c] – symbol is placed next to the complementary list it signifies that the medicine(s) require (s) specialist diagnostic or monitoring facilities, and/ or specialist medical care, and/ or specialist training for their use in children.

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3.4.3 Health and Development Challenges

Myanmar emerges from decades of isolation with much hope and support from the global and regional communities. The country has a high potential for rapid growth and development given its natural resources and youth representing nearly 40% of the population. Despite this, and consistent efforts for further development, Myanmar faces multiple constraints and risks that may limit its progress. For example, important disparities are apparent in access to benefits between rural areas, where about 70% of the population resides, and urban areas. In the health sector, constraints to improve the health status of the people include: access to basic health services; inequities and service availability; disparities in availability and affordability of essential medicines; adequate infrastructure and public expenditures; and trained health personnel.

The strong Government commitment to comprehensive development, including the health sector, is seen in the Framework for Economic and Social Reform (FESR), which outlines key parameters of the reform process. FESR is an essential tool to realize both the short- and long-term policy agenda of the Government over the three-year period starting in 2013, i.e. focusing on both immediate actions as well as on issues that require in-depth analysis and/or consensus-building. In the health sector, the Government will focus on a number of innovative measures in health financing. Particular attention will be paid to allocating more resources to rural primary health care (PHC), infectious disease control and maternal and child health, in view of the acute need to improve health indicators in all these areas.

Administratively, Myanmar is divided into 14 states and regions, with 69 districts, 330 townships, 82 sub-townships, 396 towns, 3045 wards, 13 276 village tracks and 67,285 villages. The country had an estimated total population of 61.3 million in 2011, spread among 135 ethnic groups. The major ethnic groups are Burma, Chin, Kachin, Kayah, Kayin, Mon, Rakhine and Shan. Buddhists represent 89.4% of the population, with Christian, Muslin and Hindu minorities.

The 15–28 age cohort currently represents 13 million people, 40% of the working population, who contribute and will continue to contribute their efforts and skills to enhancing productivity and competitiveness. People below the legal working age – a significant 25% of the population – will also provide in the years ahead, subject to proper schooling, skills or professional training, the human capital necessary to drive Myanmar's economic transformation. At the other end of the

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demographic spectrum, older age dependency ratio is low, with the share of people 65 and over equal to only 7.4% of the working age population.

Myanmar is currently in demographic transition; the trends in fertility and mortality would suggest that, while the current population is dominantly young, Myanmar is moving slowly towards an ageing population. The crude birth rate declined from 50 to 29 births per 1000 population in rural areas between 1988 and 2009, and the crude death rate plunged in rural areas from 9.9 to 5.8 per 1000 population in the same period. The population 0–14 years declined from 39% in 1980 to 29% in 2010. Conversely the population above the age of 60 increased from 2% to 9% in the same period. The urban population grew from 25% in 1990 to 34% in 2009; this modern economy is increasing the pressures on migration for seasonal work in rural areas of the country. The population is expected to reach 66 million by 2020.

3.5 Global Strategy as an Opportunity for Local Pharmaceutical Productions

At the request of World Health Organization (WHO) Member States and in connection with implementation of the Global Strategy and Plan of Action (GSPA), the Programme on Public Health, Innovation and Intellectual Property in WHO EMP has undertaken a series of studies and reports regarding local production of pharmaceutical products and related transfer of technology for developing countries. A principal objective of these strategies and reports is to assist other developing countries and regions – particularly in Africa – with promoting development of their local pharmaceutical production sectors. It examines the policies and practices of the Myanmar that have been used to encourage the local production of pharmaceutical products, the situation with respect to the pharmaceutical sector, and perhaps most importantly, how that set of policies is linked to access to medicines by the Myanmar population. While industrial policy objectives such as increasing employment opportunity and improving balance of payments are important to developing countries, WHO is primarily interested in local production and transfer of technology from the standpoint of how this may improve public health.

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CHAPTER 4
DATA ANALYSIS AND FINDINGS

4.1 Survey Profile

Myanmar Pharmaceutical and Medical Device Manufacturer Association (MPMDMA) was established in April 2018 with the permission from the Ministry of Planning and Finance in the announcement letter (SaBa/Si/Khant – 1/1 (3124/2018)) dated 26th April 2018 with the official registration number 187/2018/19(AhThin).

During the recent years, Myanmar had been developing in various sectors progressively and enormously. As social, Economic and Educational sectors are developing respectively. Health sector is the one need to be improved. To fulfill this crucial need, MPMDMA is established in April 2018 by inspired citizens who manufacture western Pharmaceutical Medicines and Equipment within the mother country, Myanmar.

As a survey area, eight manufacturing factories have been selected which qualified western medicines and equipment had been successfully inaugurated. Those provide a wide range of medicines and equipment on time making people accessible to cost effective quality medicines. Those factories are;

(a) Pharmaceutical Factory (Insein)

It is a state-owned Pharmaceutical Factories under the supervision of Myanmar Pharmaceutical Industrial Enterprise, Ministry of Industry. It is also the foremost and largest Pharmaceutical Factory in Myanmar interms of production capacity. The factory was founded in 1954 and Producing-Wide range of pharmaceutical products about 190 items including Tablets, Capsules, Oral Liquids, Ointments, Lotion, Sterile Products, Injections, Infusions and Biological Products (Vaccine and Snake Anti-venom). BPI received ISO 9001:2015 certificate for manufacturing and trading of pharmaceutical products and compile with WHO GMP, PIC/S GMP.

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(b) Alidac Healthcare (Myanmar) Limited

Backed by a legacy of 60 years of pharmaceutical manufacturing experience, Alidac Healthcare (Myanmar) Ltd., inaugurated it's state-of-the-art subsidiary plant on 6th of May 2018.The facility located at MJTD SEZ is currently capable of producing more than 40 million pills per month. With best-in-class quality processes, this world-class facility is compliant with global regulatory standards of WHO GMP & PICS (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme).The plant is ready to cater to the healthcare needs of the people of Myanmar and also export to select countries in Emerging Markets.

(c) Pacific Medical Industries Ltd

On July 23, 2017, we celebrate the official opening of Pacific Medical Industries Ltd (PMI) new US$20 million manufacturing facility in Yangon, a symbol of progress for the entire nation.

The result of a long-held ambition to provide affordable locally produced healthcare and pharmaceutical treatments, the PMI facility breaks new ground. It introduces new quality and safety standards according to globally recognized Good Manufacturing Practice (GMP) for WHO, European Union, USA and South Korea.

With these GMP in place, Pacific Medical Industries has received the ultimate accolade of Drug Manufacturing Establishment Registration No.3013492630 from US FDA. The first Myanmar organization to do so.

(d) Zifam Pyrex

Joint Venture between Pyrex Trading Co Ltd., Myanmar company was established national network and distribution setup since 1999 and Zifam Pinnacle Pty Ltd, that is an Australian company with manufacturing facility at Sydney which was approved by TGA (Therapeutic Goods Administration of Australia) since 1997. Zifam Pyrex Myanmar Co., Ltd facility is situated within Thilawa Special Economic Zone and will manufacture Beta Lactam antibiotics in all dosage forms; Oral Solids (Capsules, Tablets and Dry Syrup powders) and Sterile Injectable powders.

(e) Progress Biochem Company Limited

"Progress Biochem incorporated in Myanmar in year 2013 and obtained manufacturer license for oral liquid and topical preparation which comply with WHO

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GMP guideline on 19 Jan 2017. Advanced engineering design and facilities of factory leads to environmentally friendly and focus on quality products to deliver customer value".

(f) FAME Pharmaceuticals Industry Company Limited

All FAME products are manufactured in our own factory in Yangon since January, 2002. FAME has been producing capsules, caplets, tablets, powder, cream and liquid forms. All products of FAME Pharmaceuticals are natural, genuine and highly effective, most of them are organic. Over 80 items have already been introduced into the local and oversea markets. Our export market includes Asian countries such as Singapore, Malaysia, Thailand, South Korea, Japan, as well as Kuwait, Bulgaria, UK and Russia. In order to meet the international standards, all FAME products are manufactured according to WHO GMP, USDA, ACO, EU and ISO management guidelines. USFDA certifies that FAME Pharmaceuticals Industry since 2013, USFDA Registration No. 12155 128980. FAME has already received MIC approval license in 2016. FAME achieved the winner of ASEAN Energy Awards in 2013, Myanmar President's Excellence Performance Awards in 2014, Winner of ASEAN-OSHNET Excellence Award in 2016, Winner of ASEAN Business Awards for CSR in 2016, Winner of ASEAN Business Awards for Innovation in 2017 and Winner of Myanmar Employer Awards for Excellence in workplace category in 2017. Capacity: More than 376 M capsules, 132 M tablets/Caplets, 4,860 Kg of Cream and nearly 240,000 Liters of Liquid annually.

(g) RVK Meditech Company Limited

RVK Meditech Co., Ltd was founded in Myanmar since 27th May, 2015 and is a joint venture company with one of the Singapore companies and two local companies. On 1st July, 2015, Myanmar Economics Holding Limited (MEHL) handed over to RVK Meditech Co., Ltd for long term lease of in total 50 years. They always try to become one of the top pharmaceutical companies in Myanmar both in revenues and profits. They plan to achieve this by bringing innovative products to the market through quality manufacturing, responsible marketing and good distribution practices.

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(h) Yee Shin Pharmaceutical Company Limited

There was incorporated in 2015 and as sister Company of Yee Shin Co. Ltd, JDS Co., Ltd, and EMP Co., Ltd. A dedicated Intravenous Infusion, Oral Solid and Oral Liquid manufacturing facility under the name 'YSI Pharmaceuticals' commissioned in January 2017, designed to fulfill according to the PIC/S guideline. YSI is a Myanmar's 1st and only non-PVC IV soft bag producer (the latest IV technology) and aspire to be a WHO, ISO 9001-2015 compliant by 2019 and enter the Regulated market by 2021. Factory is located in Mawbi, 36 miles from Yangon downtown, built on 62 acres of land. The main production area is 193,885 sqft and administrative area is 73,485 sqft. Their productions are cGMP compliant production facilities for IVs, Tablets & Capsules, Oral Liquid. The new modernized QC and Microbiology labs equipped with latest technology equipment. Company was audited and approved by Myanmar FDA for cGMP compliance in January 2017.

4.1.1 Investment and Production Capacity of Pharmaceutical Factories

Myanmar's local pharmaceutical products manufacturing sector is hopeful it will experience significant growth after the new democracy government in 2010,the highest investment capacity factories are pharmaceutical Factory (Insein) US$ 99.4 million, YSI pharmaceutical factory US$ 39.82 million and Pharmaceutical Factory (Inyaung) US$ 32 million receptively, in Myanmar this year and the lowest investment capacity factory is Progress Biochem US$ 0.86 million, see Table (4.1).

Table (4.1) Pharmaceutical Factories Investment Capacity (Million-USD)

Factory Name	Pharmaceutical Factories Investment Capacity (Million-USD)
Pharmaceutical Factory (Insein)	99.4
YSI	39.82
Pharmaceutical Factory (Inyaung)	32
Alidac	25
RVK Meditech	25
AA Pacific	20
Zifam Pyrex	15
Fame	4
Progress Biochem	0.86

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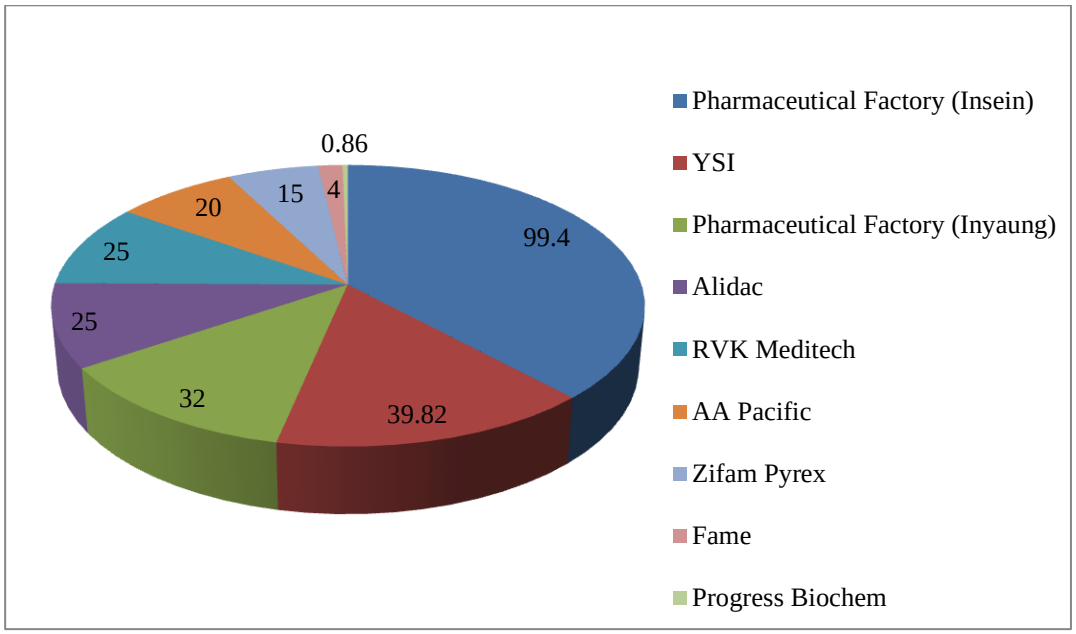
Figure (4.1) Pharmaceutical Factories Investment Capacity (Million-USD)



Source: Myanmar Pharmaceutical and Medical Device Manufacturer Association (MPMDMA) 2019

In production capacity, there can mainly be produced as 10 categories, some factories can be produced most of categories as essential, but some can be made one or two only. As the report of Myanmar Pharmaceutical and Medical Device Manufacturer Association (MPMDMA), the RVK Meditech pharmaceutical factory could be produced 3700 million table, 190 million capsule, 15 million liquid in 2018, then Pharmaceutical Factory (Insein) could be produced 1100 million table, 2.4 million capsule, 0.75 million liquid in 2018 respectively, as a least amount, Progress Biochem could only be produced 0.66 million liquid, annual overall production capacity can see as a figure (4.2) (Specific data showed in Appendix III).

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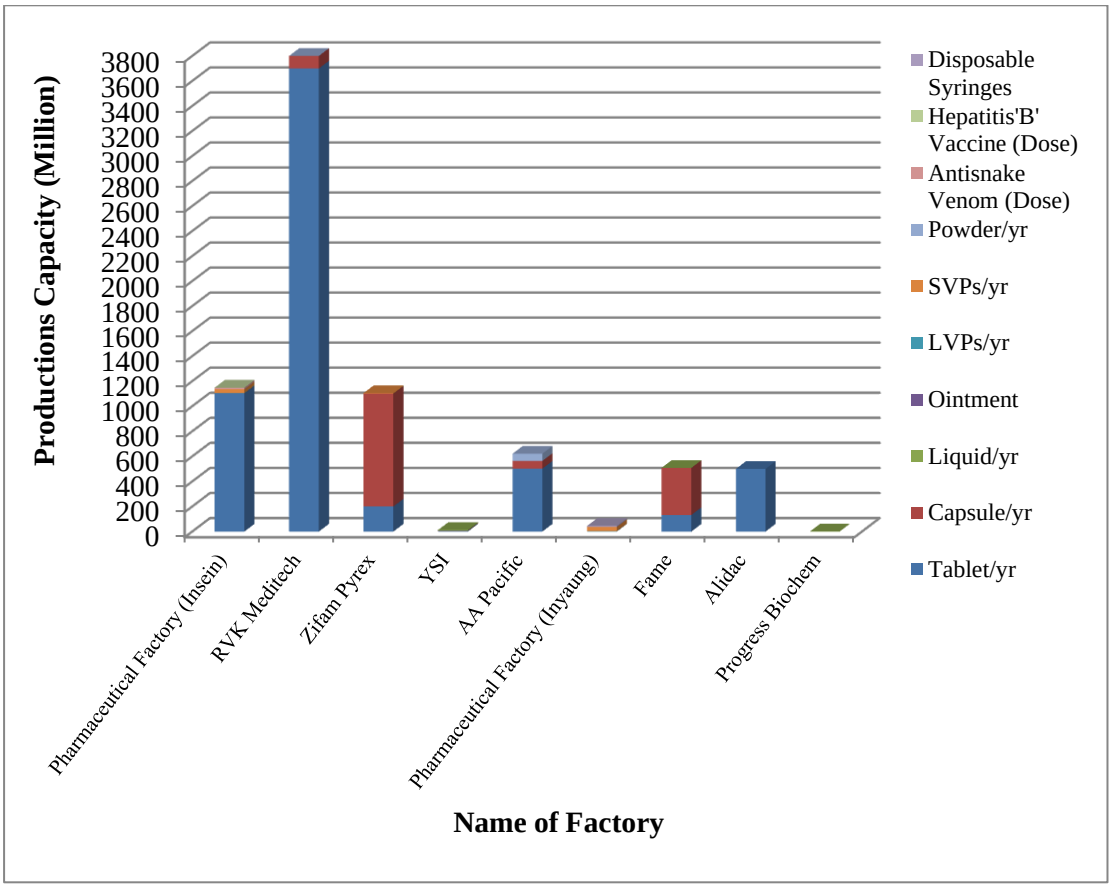
Figure (4.2) Pharmaceutical Factories Productions Capacity (2019)



Source: Myanmar Pharmaceutical and Medical Device Manufacturer Association (MPMDMA) 2019

4.2 Survey Design

A total number of 120 survey questionnaires were distributed to eight Local Pharmaceutical Industries within May to July 2019 but reflection of response was 94 answering so that it was 78 %, can assume that it was strongest. In the survey, there has indicated to challenges in local production sector, which included 5 categories, as well as; open answering for participants' opinion for further opportunities by in depth interview with key informants. In this survey, 5 types of challenges for local pharmaceutical industries were conducted and these items are categorized into facilities and industry, legal and regulation, control of illegal drug, research and development, and situation of citizens' interest in local products.

The respondents who are in various level of management (key informants) such as CEO/Chairman (Top Management Level), Director (Senior Management Level), Manager/Supervisor (Middle Administrative Level) and staffs from

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Government and private factories. By comparing the questionnaire survey result with the different survey result from level will be identified for challenges of local production.

4.3 Survey Findings

4.3.1 Demographic Characteristics of the Respondents

From the table 4.2, it reveals that 40 respondents occupy the largest number in the occupation level of Staff level (43%), followed by 26 respondents in the occupation level of Director level (28%), then 20 respondents in the occupation level of Manager/Supervisor level (21%) and the last 8 respondents in the occupation level of CEO/Chairman level (8%). Table also shows that 33 respondents occupy the largest number in the age group of 35-40 years old (35%), followed by 31 respondents in the age group of 45-60 years old (33%). In this study, out of the selected sample respondents, that represents the whole populations; (59 respondents or 63%) were females whereas (35 respondents or 37%) were males as shown in Table 4.1.

As of educational level, the majority of the respondents, 49 (52%), attained Master Degree education, followed by 24 respondents (26%) who attained Bachelor Degree education. In the study, there was included very few people, who attained Doctorate Degree.

According to the data analysis, it found out that most of respondents can discuss about the challenges and opportunities of local pharmaceutical factories, they know their facing problem, barriers, and way of their future. Most of response in survey, these can help to conclude and analyze for this study.

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Table (4.2) Demographic Characteristics of Respondents

Category	Number of Respondents	Percentage (%)
Position		
CEO/Chairman	8	8
Director	26	28
Manager/Supervisor	20	21
Staff	40	43
	94	**100**
Age		
35-40	33	35
40-45	28	30
45-60	31	33
60-above	2	2
	94	**100**
Education Level		
Bachelor Degree	24	26
Master Degree	49	52
Doctorate	21	22
Total	**94**	**100**

Source: Survey Data (2019)

4.3.2 Challenges of Local Pharmaceutical Industries

(a) Challenges Faced by Pharmaceutical Industries in Myanmar

Wholesale importation of finished products, as well as retail pharmacy business, has been a flourishing business in Myanmar. Accordingly the result of questionnaire from government and private pharmaceutical industries, there has been a parallel increase in the local drug manufacturing. However, the former still flourishes more than the later due to the following factors:

i. Very high demand of industrial conditions and standards required for both raw materials, dosage form processing, equipment and processing environment.
ii. Spiralling cost of business
iii. Poor marketing and administrative structure
iv. Control of global drug business by multinational co-operations that have overcome most of their initial development problems.
v. Unfair competition by imported products and multinationals.

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vi. Unfair government policies

vii. Illegal drug import from neighboring countries without approval from FDA

viii. Lack of effective research and development due to poor research support from the government and private companies.

ix. Brain drain that is, the ability to find experienced and skilled staff, particularly scientists and engineers.

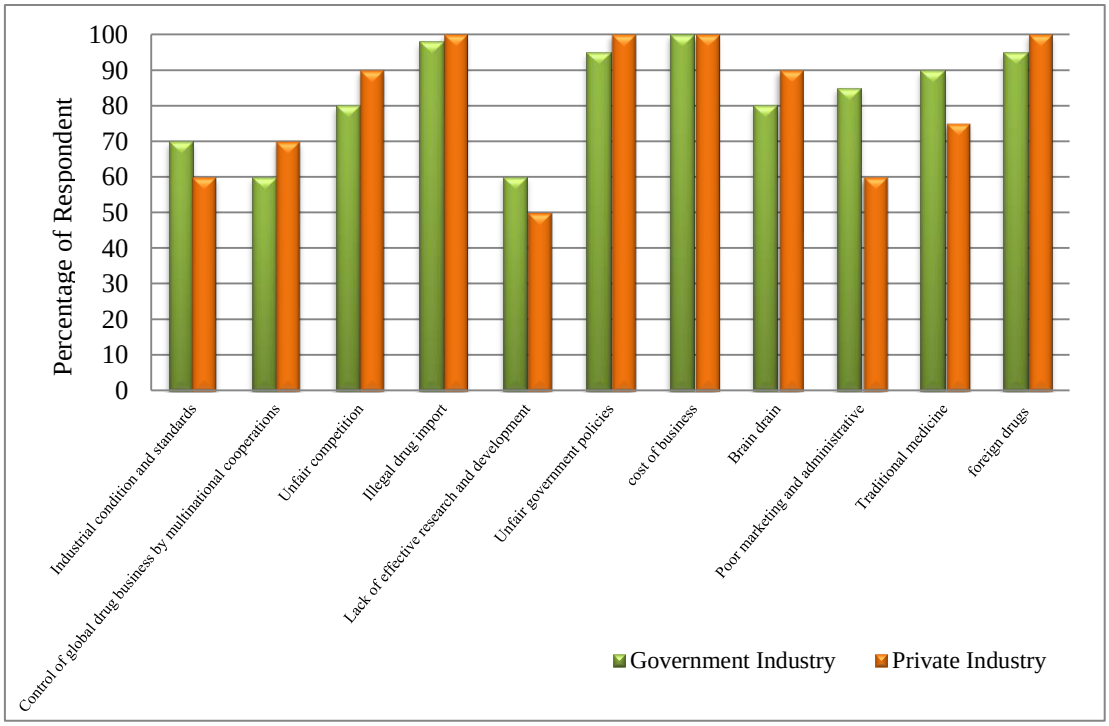
x. Most rural people are interested in traditional to cure their health.

xi. Citizens are more impressive in foreign drugs than local product.

Domestic production of pharmaceuticals and medical devices is limited. Although, there are a few companies who produce pharmaceuticals – such as Pharmaceuticals Factory, Insein (BPI) and FAME Pharmaceuticals – doctors often only assign prescriptions for foreign medicines. In terms of medical devices and equipment, foreign brands still dominate the market.

In addition to human resources, the reliability of water, power and environmental controls are central to the production decisions. If materials, equipment and spare parts are not available, items will have to be imported from countries with established pharmaceutical industries.

Figure (4.3) Challenges from Government and Private Pharmaceutical Industries



Source: Survey Data (2019)

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Figure (4.3) shows the result of questionnaires for pharmaceutical industry challenges of Government and Private Sector Factories, 2019. The major challenges for both private and government factories are their cost of business, illegal drug importing, unfair government policies and citizen trust in foreign drugs.

(b) Facility and Industry Challenges

The industrial condition and standards question from questionnaire was answered "yes" or "no" to clarify if the respondent's company has to import most of its raw materials, and also needs to more electricity support because national electricity was not sufficient 24/,7, then overall main question is target to the industrial condition and standards of pharmaceutical production factory that is facing the some barriers to improve. The result for this question described a percentage of 65% and 35% respectively. Most of the local pharmaceutical are trying to pass this problem, in that case the future local pharmaceutical should need to prepare how to solve this challenges to invest.

Table (4.3) Facilities and Industry Challenges of Respondents

Attribute	Category	No. of Respondents	Percentage (%)
Industrial condition and standards	Needs to improve	61	65
	No needs to improve	33	35
Total		**94**	**100**

Source: Survey Data (2019)

(c) Challenges in Legal and Regulation

As shown in table, it is very important that government need more to control and make more law enforcement in marketing strategy for corruption and need to change tax law and regulation for prevention local investor. The 85% of respondents agree to change law and regulations and to control on marketing strategy, in these survey, respondents are agreed with concerning their company has not equality for market competition (85%), National law and regulation are not satisfied for local

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productions (85%), and Government did not favored to Local company for investment and cooperation than foreign company, these mechanisms are not same as other country's national regulation (85%). So, there can be assumed that situation of Market demands is one of the challenges for local pharmaceutical factories.

Table (4.4) Legal and Regulation Challenges of Respondents

Attribute	Category	No. of Respondents	Percentage (%)
Situation of Market demands	Your company has equality for market competition	14	15
	Your company has not equality for market competition	80	85
		94	**100**
	National law and regulation are satisfied for local productions.	14	15
	National law and regulation are not satisfied for local productions.	80	85
		94	**100**
	Government favored to Local company for investment and cooperation than foreign company, these mechanisms are same as other country's national regulation	14	15
	Government did not favored to Local company for investment and cooperation than foreign company, these mechanisms are not same as other country's national regulation	80	85
	Total	**94**	**100**

Source: Survey Data (2019)

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(d) Control of Illegal Drug

The study sought to determine the illegal drug controlling system and law enforcement in which the coming from neighboring countries. The study revealed that majority (98%) of the respondents agreed cheaper medicines are coming inside from neighboring countries without permission. Although without permission medicines are coming inside, their quality has to be challenges our local product. In the other hand, government cannot effort on the illegal and black tax (local called) and still need to control Table (4.5). In their agreed, concerning with cheaper medicines are coming inside from neighboring countries without permission and although without permission medicines are coming inside, their quality has to be challenges our local product are as a one of the challenges for their factories.

Table (4.5) Challenges on Control of Illegal Drug

Attribute	Category	No. of Respondents	Percentage (%)
Control of Illegal Drug	Cheaper medicines are coming inside from neighboring countries without permission.	92	98
	Cheaper medicines are not coming inside from neighboring countries without permission.	2	2
		94	**100**
	Although without permission medicines are coming inside, their quality has to be challenges our local product.	92	98
	Although without permission medicines are coming inside, their quality has not to be challenges our local product.	2	2
	Total	**94**	**100**

Source: Survey Data (2019)

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(e) Research and Development

When the challenge of affording prescription drugs is raised, pharmaceutical manufacturers often argue that steps to reduce prices will lead to less innovation in the future. This response presumably applies to policies that use the market, such as shortening periods of exclusivity and making approvals of generics more rapid, as well as regulatory tools such as price controls. The manufacturers' argument has validity in that expectations of lower revenues will lead to less investment in research and development (R&D).

According to the data analysis on table and found out that 63 (67%) of respondents agree to improve as full scale-lab facility and need to make more research project and human resource development in local pharmaceutical factories and pharmaceutical education industry and 31 (33%) of the respondents disagree to improve.

Table (4.6) Research and Development (R&D)

Attribute	Category	No. of Respondents	Percentage (%)
Research and Development	Needs to improve as full scale-lab facility	63	67
	No needs to improve	31	33
Total		**94**	**100**

Source: Survey Data (2019)

(f) Citizen Interest

In the interest of Myanmar citizen on Local product medicines, all of respondents strongly agreed on most rural people are interested in traditional to cure their health and citizens are more impressive in foreign drugs than local product. As part of their response, additional question made to them "why?," all answers same way like that it depends on their experiences and critical facing concern. Therefore, citizen interest on local medicines is becoming one of the major challenges for local factories.

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Table (4.7) Situation of Citizens' Interest in Local Products

Attribute	Category	No. of Respondents	Percentage (%)
Citizens' trust	Most rural people are interested in traditional to cure their health.	94	100
	Citizens are more impressive in foreign drugs than local product	94	100
Total		**94**	**100**

Source: Survey Data (2019)

4.3.3 Opportunities of Local Pharmaceutical Industries

(a) Direct Opportunities

The study sought to find out the opportunities of the pharmaceutical industries, all of respondents strongly agreed on promoting their sufficient will become from local supplier company like SEZ improving, and vice versa there will be producing foreign exchange through exportation of domestically manufactured medicines and reflection of all improvement the big opportunity is, more product demands, more create new jobs. And the respondents generally also agreed they can reduce to relay on international supply, while there was electricity can be filled local industries, there will be filled local supplies and make more industrial technology capacity and additionally, there will be producing foreign exchange through exportation of domestically manufactured medicines.

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Table (4.8) Opportunities of Local Pharmaceutical Industries

Questions	Strongly agree (%)	Agree (%)	Neither agree nor disagree (%)	Disagree (%)	Strongly Disagree (%)	Mean
Promote self-sufficiency	9	59	18	9	5	3.8
Achieve independence from international suppliers	22	51	9	11	7	3.9
Develop local industrial capacity	28	26	10	24	12	3.6
Produce foreign exchange through exportation of domestically manufactured medicines	10	16	25	32	17	2.9
Create new jobs	30	57	12	0	1	4.4

Source: Survey Data (2019)

In Table (4.8), 59% of the respondents agreed that Promote self-sufficiency that will become self-sufficient and learn skills and necessary tools, 57% agreed that on when growing up their self-sufficiency, local people can get more job opportunities, but according to produce foreign exchange through exportation of domestically manufactured medicines, there have only 16 % agree.

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(b) Indirect Opportunities from Market are Rising in Rural and Suburban Areas

Although healthcare infrastructure expansion and the hiring of physicians have lagged, the net income and private healthcare expenditure of rural households have grown sharply over the past two decades. In 2018, the average annual net income was $1,490, 3 times that in 2014. The proportion of expenditure on healthcare and medical services rose from 3.2 percent to 7.2 percent over the same period. (Source: Health Expenditure 2018)

According to market research agencies the total pharmaceutical expenditure in Myanmar has been growing at 13 -14% per annum, and has increased from USD 391 million in 2015 to USD 409 million in 2016. However, these values are lower than most ASEAN nations including Singapore whose population is one tenth that of Myanmar. Growth prospects with governmental initiatives are high and the market is expected to touch USD 1.12 billion by 2023. However, most of the pharmaceutical products sold come from countries like India, Bangladesh, China, Indonesia, Pakistan, Thailand and Vietnam. Research figures indicate that total pharmaceutical imports accounted for 85% of the drug market and India takes the lead with a strong 40-45% market share. All imported drugs have to be registered and authorized by the FDA that inspects pharmaceutical plants and importers and also tests the quality of drugs. At present, approximately 5000 drug varieties are imported into Myanmar. Major shares of therapy wise segments in Myanmar are Anti Infective, Vitamins, and Analgesics, with the market share of 27%, 31%, and 13% respectively.

Aside from being a commodity that is required for service delivery, medicines also contribute significantly to government and household spending on health. Medicines account for over a quarter of total health expenditures with some Low and Middle Income Countries (LMICs) spending up to 67% of their total health expenditures on pharmaceuticals. In low and middle income countries, more than half and sometimes up to 90% of expenditures on medicines are out of pocket, putting the most vulnerable households at great risk of financial hardship and catastrophic health expenditures. While part of this spending brings good value for money, medicines contribute to the leading sources of health system inefficiency. This is mainly due to high medicines prices, the variable quality of medicines available on the market (i.e. substandard and falsified medicines) and the inappropriate use of medicines.

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Despite several challenges in the sector, the outlook for healthcare provision in Myanmar is positive. The government's ambition towards implementing Universal Healthcare Coverage, the relaxation of laws related to healthcare investment, expected increases in consumer spending power, along with the positive changes to the insurance industry, are all factors that create opportunity for local investors in providing Pharmaceutical products.

Major contributors in cities such as Yangon and Mandalay already have a large pool of middle-class consumers. Yet, as the consumer class grows, they will look for more domestic medicine products, as much as marketing can penetrate. Compared with international companies, local pharmaceutical production companies tend to have a better understanding of local culture, and are often perceived by Myanmar citizens as better at providing bedside manners and understanding of household medicinal requirements.

Table (4.9) Total Pharmaceutical Expenditure (TPE) in ASEAN Countries (2012-2018)

Total Pharmaceutical Expenditure			
Country	**Population**	**Growth Rate (%)**	**Expected Market (Annual)**
Singapore	5,804,337	87	USD 600 million
Thailand	69,625,582	91	USD 560 million
Malaysia	31,949,777	54	USD 520 million
Vietnam	96,462,106	47	USD 510 million
Philippines	108,116,615	55	USD 447 million
Indonesia	270,625,568	85.7	USD 420 million
Myanmar	54,045,420	92	USD 409 million
Cambodia	16,486,542	77.5	USD 180 million
Laos	7,169,455	83.5	USD 69 million
Brunei	433,285	20.8	USD 49 million

Source: WHO (TPE) 2018

According the data of WHO (TPE) 2018, the largest market can win for future year is Singapore but lower the local population, as well as Myanmar is rapidly increased in market group rate and also can be expected to market 409 million to gain in near future.

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Moreover, better employment opportunities are opened to citizen and also the country gain a lot of technical knowledge on Pharmaceutical manufacturing by expertise from various internationals. This is the great opportunities, network for medical, Pharmaceutical and Engineering Graduates to apply their knowledge and explore more experiences in such area.

More than such pride, the factories are life-saving support during disasters and outbreaks of communicable diseases by manufacturing the needful emergency medication in every limited time rather than import from other countries. It can save foreign currency loss due to fluctuations happened during tradeoff with other countries and help controlling budget deficit in the country. In the future, the factories have aim to import medicines and equipment to neighboring countries to gain more foreign revenue supporting development of country economic sector in a way.

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CHAPTER 5
FINDINGS AND RECOMMENDATIONS

5.1 Findings

Pharmaceutical Industry is an essential industry in any country. Myanmar has taken the initiative to start this valuable industry more than 60 years ago. Yet the outcome after these years, they are still importing 80% of their needs from the international manufacturers.

As the survey and literature of this studying, as well as the mentioned in Chapter 4, it was concluded that on the challenges and opportunities of local pharmaceutical factories. The study sought to analyze the Challenges of local pharmaceutical factories, the local pharmaceutical factories has to import most of its raw materials, also their big challenges is electricity support, their company complies the regulations of environmental conservation concerning about discharging the wastes, and they still need more laboratory equipment and production machine from best foreign products. Factories has not equality for market competition, most of the marketing team from foreign pharmaceutical product export company use the way of marketing by providing incentive to middle appointing of using (doctors) per amount. So, most of the market coverage are depended on private doctors and their prestige. And national law and regulation cannot be satisfied for local production company, more over government cannot be favored to Local company for investment and cooperation than foreign company, these mechanisms are not same as other country's national regulation, for example Thailand cannot allow to import while their local production can produce. Another challenges are, cheaper medicines are coming inside from neighboring countries without permission. Although without permission medicines are coming inside, their quality has to be challenges our local product. In the other hand, government cannot effort on the illegal and black tax (local called) and still need to control. And most rural people are initially try to treat their health problem by traditional ways and another step in more for overall country site, most of citizens are more impressive in foreign drugs than local product.

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Even though Myanmar local pharmaceutical factories have faced many challenges, there have big opportunities as a key to open the cave of challenges, as developed as country economic and as increased as foreign investment, when promoting their sufficient will become from local supplier company like SEZ improving, vice versa they can reduce to relay on international supply, while there was electricity can be filled local industries will be filled local supplies and make more industrial technology capacity. Additionally, there will be producing foreign exchange through exportation of domestically manufactured medicines and reflection of all improvement the big opportunity is, more product demands, more create new jobs.

5.2 Recommendations

Based on findings and survey result of this thesis, as the primary review, small-scale indigenous private or government manufacturing labs and research institutes are now beginning to compete favorably with the foreign-based companies even though we still depend on the imported raw materials and equipment.

Pharmacy schools should cater their curriculum to provide the necessary education and training to build the new workforce for this industry. This industry needs a lot of Pharmacist but also a lot of technical personnel. Training institutes for allied health also should take a lead in providing the necessary training as deemed necessary by the industry. Most of the highly educated Pharmacists provide education in the university, and they are providing limited laboratory research. The Universities has a social responsibility to support R&D and require that their staff should be involved in research and development as part of their career. We have a huge man force that can stand up the challenge of the new era, however, they are underutilized their main task is teaching the basic academic courses. The very same individuals were involved in research for major Pharmaceutical companies during their study abroad. For the business men, who are investing in the Pharmaceutical industry, they should have a broader vision for the future, they should encourage and support R&D because the outcome of developing a new molecule or formulation will be greatly rewarding. It takes patience and a lot of investment as well as comprehensive research to reach the goal.

With the ongoing training of more pharmacists in the country, enlightenment of the citizens, pharmacists, politicians and licensed patent medicine vendor through workshops and mandatory continuing education programmes, awareness has been

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created and now there is more reliance on good quality products including those manufactured in Myanmar.

There are now well qualified and registered pharmacists acting as consultants in drug product analysis and quality assurance. These analysts certify the genuineness or otherwise of locally manufactured or imported products.

There is also a number of growing local industries that manufacture good plastic containers, etc., and soon local manufacturers will no longer import most drug excipients. Many developing countries moved from mere packaging of finished products into the production of excipient raw materials formulation of dosage forms in commercial quantities for internal use and exports.

The combined effect of Myanmar's healthcare reform and growing market has been to offset continuing concerns about regulatory challenges and local industry protection, giving confidence to those local pharmaceutical companies that seek to take advantage of the opportunities presented by penetrating on market demand. Those opportunities comprise research, distribution, and technological subsector development, as well as the overall growth of Myanmar's market, and particularly rural and suburban market growth due to healthcare reform. As has been seen already, local companies are making the most of these opportunities by ramping up domestic product medicine marketing activity, as local companies enters its next and greatest phase of growth yet.

The Myanmar pharmaceutical market is big and the contribution is less than its potential. The focus on other than generic market is the need of the time and local pharmaceutical companies constantly searching for new avenues in the innovation driven sector. The constant increases in the size of the pharmaceutical market, due to a change in life style and high demand for quality health care. The regulatory policies need be improved, especially in the area of patent, tax for local industry, citizenship opportunities and price control, to boost the growth and create an impression as the destination for new generation pharmaceutical market.

For the further scope of study, there can be conducted focusing on the specific segments of the sector. The challenges in the import policies and foreign investments in Myanmar pharmaceutical sector can be further probed to improve the contributions. The innovative methods in marketing and sales of the drugs and the distribution, to penetrate into the rural area of Myanmar, can be studied. It improves the market share of local pharmaceutical companies and the availability of the needed medicines to the rural population.

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APPENDIX - I
Myanmar National Drugs Lists 2016

LIST OF MEDICINES IN NLEM (2016) BY THERAPEUTIC AREAS

SECTIONS	THERAPEUTIC AREAS
SECTION - 1	**ANAESTHETICS** • Halothane • Isoflurane • Sevoflurane • Nitrous oxide • Oxygen • Ketamine (hydrochloride) • Metaraminol • Propofol • Suxamethonium (chloride) (bromide) • Thiopental • Vecuronium • Bupivacaine (hydrochloride) • Lignocaine (hydrochloride) • Ephedrine • Lignocaine + Epinephrine (dental cartridge) • Atropine (sulphate) • Diazepam • Morphine • Midazolam • Glycopyrrolate
SECTION – 2	**ANALGESICS, ANTIPYRETICS, NON -STEROIDAL ANTI - INFLAMMATORY MEDICINES (NSAIMs), MEDICINES USED TO TREATE GOUT AND DISEASE MODIFYING AGENTS IN RHEUMATOID DISORDERS (DMARDs)** • Acetylsalicylic acid • Diclofenac (sodium/potassium) • Ibuprofen • Naproxen • Nitrous oxide+O2 • Paracetamol • Codeine phosphate • Fentanyl(citrate) • Morphine (sulfate/hydrochloride)

Sample output to test PDF Combine only

SECTION – 5	**MEDICINES FOR CENTRAL NERVOUS SYSTEM** • Carbamazepine • Diazepam • Lamotrigine • Levetiracetam • Lorazepam • Midazolam • Magnesium sulfate • Phenobarbital (sodium salt) • Topiramate • Valproic Acid (Sodium Valproate) • Trihexyphenidyl (Benzhexol) • Levodopa + Carbidopa
SECTION – 6	**ANTI-INFECTIVE MEDICINES** • Albendazole • Ivermectin • Levamisole • Mebendazole • Niclosamide • Praziquantel • Diethylcarbamazine • Amoxicillin (trihydrate) (sodium salt) • Amoxicillin with clavulanic acid (Co-amoxiclav) • Ampicillin • Benzathine penicillin • Benzyl penicillin G (sodium / potassium salt) • Cefazolin • Cefoperazone + Sulbactam • Cephalexin • Cefuroxime (sodium salt) • Cefaclor • Cefotaxime • Ceftriaxone (sodium salt) • Cefixime • Ceftazidime (pentahydrate) • Cloxacillin • Flucloxacillin (sodium) • Fortified Procaine Penicillin G • Imipenem + Cilastatin (monohydrate)

Sample output to test PDF Combine only

	• Meropenem • Phenoxymethyl penicillin • Piperacillin with tazobactam • Amikacin (sulfate) • Azithromycin (dihydrate) • Chloramphenicol (palmitate/sodium succinate) • Ciprofloxacin • Clarithromycin • Clindamycin • Co-trimoxazole (Sulfamethoxazole +Trimethoprim - 5:1) • Doxycycline(hydrochloride) • Erythromycin (stearate)(ethylsuccinate) (lactobionate) • Gentamicin (sulfate) • Levofloxacin • Lincomycin • Linezolid • Metronidazole (Benzoate) • Neomycin (sulfate) • Nitrofurantoin • Norfloxacin • Tetracycline • Vancomycin • Clofazimine • Dapsone • Ofloxacin • Rifampicin • Ethambutol (hydrochloride) • Isoniazid • Isoniazid + Ethambutol • Isoniazid + Rifampicin • Isoniazid + Rifampicin + Ethambutol • Isoniazid + Rifampicin + Pyrazinamide • 4 FDC (Fixed-Dose Combination) • Pyrazinamide • Rifabutin • Rifampicin • Streptomycin (sulfate) • Amikacin

Sample output to test PDF Combine only

	• Capreomycin • Cycloserine • Ethionamide • Kanamycin • Levofloxacin • Moxifloxacin • P-aminosalicylic acid • Amphotericin B (salt complex or lipid complex forms) • Caspofungin • Clotrimazole • Fluconazole • Griseofulvin • Itraconazole • Ketoconazole • Liposomal Amphotericin • Nystatin • Potassium iodide (KI) • Voriconazole • Metronidazole (benzoate) • Artemether • Artemether + Lumefantrine • Artesunate • Atovaquone + Proguanil • Chloroquine (phosphate/sulfate) • Dihydroartemisinin + Piperaquine • Doxycycline (hydrochloride) • Primaquine (diphosphate) • Quinine (sulfate) (dihydrochloride) • Abacavir • Abacavir + Lamivudine • Acyclovir • Atazanavir boosted Lopinavir • Efavirenz • Lopinavir • Nevirapine • Ribavirin • Ritonavir boosted Lopinavir • Tenofovir • Tenofovir + Emtricitabine + Efavirenz

Sample output to test PDF Combine only

	• Tenofovir + Lamivudine • Tenofovir + Lamivudine + Efavirenz • Valganciclovir • Zidovudine + Lamivudine • Zidovudine + Lamivudine + Nevirapine
SECTION – 7	**ANTIMIGRAINE MEDICINES** • Acetylsalicylic acid • Diclofenac (sodium /potassium) • Paracetamol • Propranolol (hydrochloride)
SECTION – 8	**MEDICINES AFFECTING THE BLOOD** • Erythropoietin (Epoetin) • Ferrous salt (sulfate, fumarate) • Filgrastim • Folic acid (sodium salt) • Granulocyte colony stimulating factor • Hydroxocobalamin • Oxymetholone • Vitamin B1 • Vitamin B6 • Enoxaparin • Heparin (sodium) • Phytomenadione • Protamine sulphate • Recombinant factor VIII • Recombinant factor IX • Tranexamic acid • Warfarin (sodium salt)
SECTION – 9	**BLOOD PRODUCTS AND PLASMA SUBSTITUTES** • Albumin (Human) • Gelatin Infusion
SECTION – 10	**CARDIOVASCULAR MEDICINES** • Carvedilol • Glyceryl Trinitrate (sublingual) • Metoprolol • Isosorbide Dinitrate (sublingual) • Isosorbide Mononitrate • Adenosine • Amiodarone (hydrochloride)

Sample output to test PDF Combine only

	• Atropine • Digoxin • Flecainide • Magnesium sulphate • Propafenone • Propranolol • Sotalol • Verapamil (hydrochloride) • Amlodipine (mesylate) • Chlorthalidone • Diltiazem (modified released) • Enalapril (maleate) • Felodipine • Hydralazine (hydrochloride) • Indapamide • Labetalol (hydrochloride) • Losartan (potassium) • Methyldopa • Metoprolol (tartrate) • Nifedipine • Perindopril • Prazosin (hydrochloride) • Carvedilol • Digoxin • Dobutamine (hydrochloride) • Dopamine (hydrochloride) • Enalapril (maleate) • Furosemide • Hydrochlorothiazide • Metolazone • Perindopril • Spironolactone • Dopamine (hydrochloride) • Dobutamine (hydrochloride) • Epinephrine (hydrogen tartrate) • Hydrocortisone • Norepinephrine • Acetylsalicylic acid (soluble/dispersible forms) • Clopidogrel (hydrogen sulfate)

Sample output to test PDF Combine only

	• Dipyridamole (extended release) • Enoxaparin • Heparin • Octreotide (as acetate) Terlipressin acetate • Streptokinase • Atorvastatin • Fenofibrate • Simvastatin
SECTION – 11	**DERMATOLOGICAL MEDICINES (TOPICAL)** • Benzoic acid + Salicylic acid • Clotrimazole • Ketoconazole • Miconazole • Nystatin • Tolnaftate • Clindamycin • Fusidic acid • Neomycin (sulfate) • Povidone Iodine • Potassium permanganate • Silver sulfadiazine • Acyclovir • Betamethasone (valerate) • Calamine lotion • Clobetasol • Fluocinolone acetonide • Hydrocortisone (acetate) • Coal tar • Fluorouracil • Imiquimod • Salicylic acid • Benzyl benzoate • Permethrin • Calcipotriol (Vitamin D analog) • Methoxypsoralen • Tacrolimus / pimecrolimus

Sample output to test PDF Combine only

SECTION – 12	**DIAGNOSTIC AGENTS** • Barium sulfate • Gadolinium • Iopamidol
SECTION – 13	**DISINFECTANTS AND ANTISEPTICS** • Chlorhexidine (digluconate) • Comprox AC + Solution dichlorometaxylenol • Eusol • Formaldehyde • Hydrogen peroxide • Hexanios • Methylated spirit • Povidone Iodine • Chlorine based Compound • Chloroxylenol • Glutaraldehyde
SECTION – 14	**DIURETICS** • Amiloride • Furosemide • Hydrochlorothiazide • Spironolactone • Mannitol • Metolazone
SECTION – 15	**GASTROINTESTINAL MEDICINES** • Aluminium Hydroxide • Aluminium hydroxide + Magnesium hydroxide • Magnesium hydroxide • Dimethicone • Omeprazole • Pantoprazole • Ranitidine (hydrochloride) • Cinnarizine (hydrochloride) • Dexamethasone • Domperidone (maleate) • Ondansetron (hydrochloride) • Prochlorperazine • Drotaverine • Hydrocortisone

Sample output to test PDF Combine only

	• Hyoscine (butylbromide) • Sulfasalazine • Bisacodyl • Glycerin suppositories • Lactulose • Magnesium Hydroxide • Magnesium sulphate • Poly ethylene glycol powder for solution • Rifaximin • Loperamide • Oral Rehydration Salts (Powder) (WHO formulation) • Zinc sulfate
SECTION – 16	**HORMONES, OTHER ENDOCRINE MEDICINES AND CONTRACEPTIVES** • ACTH • Dexamethasone (sodium phosphate) • Fludrocortisone (acetate) • Methylprednisolone • Prednisolone • Danazol • Testosterone ester • Ethinylestradiol + Levonorgestrel • Ethinylestradiol + Norethisterone • Levonorgestrel • Medroxyprogesterone (acetate depot) • Norethisterone enanthate • Copper Intra-Uterine Device (Cu-IUD) • Male Condoms • Levonorgestrel releasing implant • Oestrogen cream • Clomiphene citrate • Medroxyprogesterone • Bromocriptine • Acarbose • Glacagon • Insulin • Insulin glargine • Metformin

Sample output to test PDF Combine only

	• Pioglitazone • Repaglinide • Carbimazole • Levothyroxine (Sodium salt) • Propylthiouracil
SECTION – 17	**IMMUNOLOGICALS** • Antisnake venom serum (cobra antivenom) • Antisnake venom serum (viper antivenom) • Diphtheria Antitoxin • Immunoglobulin • Tetanus immunoglobulin (Human origin) • Rabies immunoglobulin (Human origin) • Anti D immunoglobulin • Hepatitis B immunoglobulin • BCG Vaccine • Diphtheria, Pertussis and Tetanus vaccine • Hepatitis B Vaccine • HPV vaccination • Measles Vaccine • DPT + Hep B + Hib Vaccine • Poliomyelitis Vaccine • Tetanus Vaccine • Cholera vaccine • Haemophilus Influenzae B Vaccine (HIB) • Hepatitis A vaccine • Human Papilloma Virus Bivalent Vaccine • Japanese Encephalitis Vaccine • Measles/Mumps /Rubella Vaccine (MMR) • Meningococcal Vaccine • Pneumococcal Vaccine • Rabies Vaccine • Rotavirus Vaccine • Typhoid, Paratyphoid A & B Vaccine with Vi antigen • Varicella Vaccine • Yellow Fever Vaccine • Ciclosporin • Cyclophosphamide • Methylprednisolone • Mycophenolate mofetil

Sample output to test PDF Combine only

	• Prednisolone
SECTION – 18	**MUSCLE RELAXANTS (PERIPHERALLY ACTING) AND ANTICHOLINESTERASE INHIBITORS** • Atracurium • Baclofen • Cisatracurium • Neostigmine (metilsulfate) • Suxamethonium chloride • Vecuronium bromide
SECTION – 19	**OPHTHALMOLOGICAL PREPARATION** • Acyclovir • Chloramphenicol • Clotrimazole • Framycetin (Sulfate) • Ganciclovir • Gentamicin (Sulfate) • Moxifloxacin • Netilmicin • Tetracycline (hydrochloride) • Voriconazole • Acetazolamide • Brimonidine • Pilocarpine (hydrochloride or nitrate) • Timolol (maleate) • Travoprost • Atropine • Tropicamide • Sodium chromoglycate • Dexamethasone • Flumethasone • Fluorometholone • Loteprednol etabonate • Prednisolone (sodium phosphate) • Tetracaine (hydrochloride)
SECTION – 20	**OXYTOCICS AND MYOMETRIAL RELAXANTS** • Ergometrine (hydrogen maleate) • Misoprostol • Oxytocin • Nifedipine

Sample output to test PDF Combine only

SECTION – 21	**PSYCHOTHERAPEUTIC MEDICINES** • Chlorpromazine (hydrochloride) • Haloperidol • Methylphenidate • Olanzapine • Risperidone (hydrochloride) • Amitriptyline • Escitalopram • Fluoxetine (hydrochloride) • Lithium carbonate • Valproic acid (sodium valproate) • Alprazolam • Clonazepam • Diazepam • Lorazepam • Clomipramine (hydrochloride) • Methadone • Tincture Opium
SECTION – 22	**MEDICINES ACTING ON THE RESPIRATORY TRACT** • Aminophylline • Bambuterol • Baclomethasone (dipropionate) • Budesonide (dipropionate) • Epinephrine (adrenaline)(as hydrochloride or hydrogen tartrate) • Fluticasone propionate • Fluticasone propionate and salmeterol combination • Hydrocortisone • Ipratropium bromide • Montelukast • Prednisolone • Salbutamol (Sulfate) • Theophylline • Tiotropium bromide • Benzoin Tincture • Carbocysteine • Dextromethorphan • Diphenhydramine (hydrochloride) • Nikethamide

Sample output to test PDF Combine only

SECTION – 23	**SOLUTION CORRECTING WATER , ELECTROLYTES AND ACID BASE BALANCE** • Magnesium oxide • Oral Rehydration Salts • Potassium Chloride • Sodium Chloride • Dextrose • Dextrose and Sodium Chloride • Physiological saline • Potassium chloride • Ringer Lactate • Saline • Sodium bicarbonate • 3% sodium chloride • Water for injection • Amino acid solution • Lipid solution • Total Parenteral Nutrition
SECTION – 24	**VITAMINS AND MINERALS** • Alfacalcidol(Hydroxycholecalciferol) • Ascorbic acid • Calcium gluconate • Ergocalciferol • Hydroxocobalamin • Multivitamin and Mineral Preparation • Magnesium Sulphate • Nicotinamide • Potassium Chloride • Pyridoxine(Hydrochloride) • Retinol(Palmitate) • Riboflavin • Sodium Fluoride • Thiamine (hydrochloride) • Vitamin B Complex • Vitamin K1
SECTION – 25	**MEDICINES USED IN CANCER CHEMOTHERAPY** • Bendamustine • Busulfan • Chlorambucil

Sample output to test PDF Combine only

	• Cisplatin • Carboplatin • Cyclophosphamide • Dacarbazine (DTIC) • Ifosfamide • Melfalan • Oxaliplatin • Capecitabine • Cytarabine • Fludarabine • Gemcitabine • Hydroxycarbamide • Methotrexate • Thioguanine • 5- Fluorouracil • 6 -Mercaptopurine • Docetaxel • Etoposide • Irinotecan • Paclitaxel • Vinblastine • Vincristine • Vinorelbine • Bleomycin C (Lyophilized powder) • Dactinomycin • Daunorubicin • Doxorubicin • Epirubicin • Idarubicin • Mitomycin - C • Mitoxantrone • Anastrozole • Bromocriptine • Flutamide • Letrozole • Leuprolide acetate (Lupron-Depot) • Tamoxifen • Arsenic trioxide

Sample output to test PDF Combine only

	• Asparaginase (Lyophilized powder) • Bevacizumab • Bortezomib • Dasatinib • Dexamethasone • Imatinib • Lenalidomide • Methylprednisolone • Prednisolone • Procarbazine • Rituximab • Sorafenib • Trastuzumab (Herceptin) • Thalidomide • Tretinoin/all trans retinoic acid • Antithymocyte globulin • Deferasirox • Deferiprone • Desferrioxamine mesylate • Eltrombopag • Erythropoietin (Epoetin) • Filgrastim • Folinic acid • Hydrocortisone • Mesna • Mycophenolate mofetil • Normal Immunoglobulin • Pamidronate • Rasburicase • Tacrolimus • Zoledronic -1A
SECTION – 26	**OTORHINOLARYNGOLOGICAL PREPARATION** • Boric acid /spirit • Chlorhexidine + Neomycin • Polymyxin + Bacitracin + Neomycin • Betamethasone + Neomycin • Clotrimazole • Fluticasone • Mometasone
	• Polymyxin B + Neomycin • Oxymetazoline(hydrochloride) • Sodium bicarbonate/ Glycerin • Bismuth subnitrate and Iodoform
SECTION - 27	**MEDICINES FOR UROLOGICAL SYSTEM** • Potassium Citrate • Finasteride

Sample output to test PDF Combine only

APPENDIX - II

SURVEY QUESTIONNAIRE

This is a survey questionnaire for my thesis. These answers will need to complete it probably takes 5-10 minutes. The information collected is "private and confidential" and will not be used for assessment. No part will be revealed without consent.

Section 1- Background Information

Choose the most suitable alternative by drawing a circle.

a. Gender: Male ☐ Female ☐

b. Age: _____

c. Education: _____

d. Position: _____

e. Work experience: _____

f. Company: _____

Section 2- Challenges of Local Pharmaceutical Factory in Myanmar

1. Facilities and Industry Challenges

a. Your company has to import most of its raw materials.

Yes ☐ No ☐

b. Your company needs to more electricity support because national electricity was not sufficient 24/7.

Yes ☐ No ☐

c. Your company always discharge wastes as per regulations for environmental conservation activity.

Yes ☐ No ☐

d. Most of laboratory equipment and production design machines has still need to import.

Yes ☐ No ☐

e. Based on above answering:

i. Your company faced challenge on very high demand of industrial conditions and standards required for both raw materials, dosage form processing, equipment and processing environment.

5 = Strongly Agree ☐

4 = Agree ☐

Sample output to test PDF Combine only

3 = Neither Agree nor Disagree ☐

2 = Disagree ☐

1 = Strongly Disagree. ☐

ii. Poor marketing and administrative structure of your company.

5 = Strongly Agree ☐

4 = Agree ☐

3 = Neither Agree nor Disagree ☐

2 = Disagree ☐

1 = Strongly Disagree. ☐

iii. General Comments:

_____

_____

_____

_____

2. Legal and Regulation

Situation of Market demands:

a. Your company has equality for market competition.

Yes ☐ No ☐

b. National law and regulation are satisfied for local productions.

Yes ☐ No ☐

c. Government favored to Local company for investment and cooperation than foreign company, these mechanisms are same as other country's national regulation .

Yes ☐ No ☐

d. Your answering mentioned above:

i. Control of global drug business by multinational co operations that have overcome most of their initial development problems.

5 = Strongly Agree ☐

4 = Agree ☐

3 = Neither Agree nor Disagree ☐

2 = Disagree ☐

1 = Strongly Disagree. ☐

Sample output to test PDF Combine only

ii. Unfair competition by imported products and multinationals.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

iii. Illegal drug import from neighboring countries without approval from FDA.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

iv. General Comments:

_____

_____

_____

_____

3. Control of Illegal Drug

a. Cheaper medicines are coming inside from neighboring countries without permission.

Yes ☐ No ☐

b. Although without permission medicines are coming inside, their quality has to be challenges our local product.

Yes ☐ No ☐

c. Government still needs to control forincreasing the illegal drug.

Yes ☐ No ☐

d. According your answering on above questions:

Sample output to test PDF Combine only

i. Illegal drug import from neighboring countries without approval from FDA.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

ii. General Comments:

_____

_____

_____

_____

4. Research and Development (R&D)

a. R&D requires that as part of production quality.

Yes ☐ No ☐

b. In your company, there have full-scale laboratory.

Yes ☐ No ☐

c. In your opinion, research and development activity can assist opportunities of productive drugs in market.

Yes ☐ No ☐

d. Government has responsibility to support research and development sector to implement local industry promoted.

Yes ☐ No ☐

e. As above question, government can fill the need of country's research sector.

Yes ☐ No ☐

f. In your company, staffs are always thinking about moving to other for their sufficient of live and opportunity.

Yes ☐ No ☐

Sample output to test PDF Combine only

g. As per your answering in above:

i. Lack of effective research and development due to poor research support from the government and private companies.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

ii. Brain drain that is, the ability to find experienced and skilled staff, particularly scientists and engineers.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

iii. General Comments:

_____

_____

_____

_____

5. Situation of citizens' interest in local products

a. Most rural people are interested in traditional to cure their health.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐
2 = Disagree ☐
1 = Strongly Disagree. ☐

b. Citizens are more impressive in foreign drugs than local product.

5 = Strongly Agree ☐
4 = Agree ☐
3 = Neither Agree nor Disagree ☐

Sample output to test PDF Combine only

2 = Disagree ☐

1 = Strongly Disagree. ☐

c. General Comments:

_____

_____

_____

Section 3- Opportunities of Local Pharmaceutical Factory in Myanmar

a. Degree

5 = Strongly Agree

4 = Agree

3 = Neither Agree nor Disagree

2 = Disagree

1 = Strongly Disagree.

		1	**2**	**3**	**4**	**5**
Sr.	**Description**	**Strongly Disagree**	**Disagree**	**Neither Agree nor Disagree**	**Agree**	**Strongly Agree**
	Promote self-sufficiency					
	Achieve independence from international suppliers					
	Develop local industrial capacity					
	Produce foreign exchange through exportation of domestically manufactured medicines					
	Create new jobs					

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b. General Comments:_____:

_____

_____

_____

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APPENDIX - III

Pharmaceutical Factories Productions Capacity (Year)

Factory Name	Tablet/yr	Capsule/yr	Liquid/yr	Ointment	LVPs/yr	SVPs/yr	Powder/yr	Antisnake Venom (Dose)	Hepatitis'B' Vaccine (Dose)	Disposable Syringes
Pharmaceutical Factory (Insein)	1100 million	100 million	0.75 million	0.05 million	3.5 million	28 million	0.62 million	12 million	0.3 million	
RVK Meditech	3700 million	190 million	15 million	7.5 million	7.2 million	12 million	55 million	-	-	-
Zifam Pyrex	200 million	900 million	0.7 million	-	-	4.2 million	-	-	-	-
YSI	1000 million	-	0.75 million	-	12 million	-	-	-	-	-
AA Pacific	502 million	61.6 million	-	-	-	-	57.7 million	-	-	-
Pharmaceutical Factory (Inyaung)	-	-	-	-	2 million	35 million	0.32 million	-	-	7.5 million
Fame	132 million	376 million	0.24 million	-	-	-	-	-	-	-
Alidac	500 million	-	-	-	-	-	-	-	-	-
Progress Biochem	-	-	0.66 million	-	-	-	-	-	-	-

Source: Myanmar Pharmaceutical and Medical Device Manufacturer Association (MPMDMA) 2019

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APPENDIX - IV

Result of Questionnaires for Pharmaceutical Industry Challenges of Government and Private Sector Factories

Challenges	Government Industry	Private Industry
Industrial condition and standards	70	60
Control of global drug business by multinational co-operations	60	70
Unfair competition	80	90
Illegal drug import	98	100
Lack of effective research and development	60	50
Unfair government policies	95	100
cost of business	100	100
Brain drain	80	90
Poor marketing and administrative	85	60
Traditional medicine	90	75
foreign drugs	95	100

Source: Survey Data (2019)

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