Pharmaceutical Market Potential of Southeast Asian Countries

By

Naresh Champalal Mali

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2015-2017

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

Pharmaceutical Market Potential of Southeast Asian Countries

By

Naresh Champalal Mali

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2015-2017

Blue Berry Pharma Advisory, Mumbai

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: www.iihmr.edu.in

INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

TO WHOMSOEVER MAY CONCERN

This is to certify that **Naresh Champalal Mali** of **MBA Pharmaceutical Management** from The IIHMR University, Jaipur has undergone internship training at **Blue Berry Pharma Advisory, Mumbai** from 14th February, 2017 to 14th May, 2017.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his future endeavors.

(Col.) Dr. Ashok Kaushik

Dean, Academics and Student Affairs
The IIHMR University, Jaipur

Dr. Saurabh Kumar

Assistant Professor
The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Near Sanganer Airport, Jaipur- 302029, Rajasthan, India.
Ph.: 0141- 3924700, 2791431- 32, Fax: 0141 3924738, E-mail: iihmr@iihmr.edu.in, Web.: www.iihmr.edu.in

Blue Berry Pharma Advisory

May 14, 2017

This is to certify that Mr. Naresh Mali student of MBA pharmaceutical management from THE IIHMR University, Jaipur has undergone dissertation from 14th February to 14th May 2017.

The candidate has successfully carried out the study designated during dissertation and his approach to the study has been sincere, scientific and analytical.

I wish him all the success in his future endeavor.

BLUE BERRY PHARMA ADVISORY ★ MUMBAI

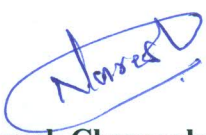
Subhash Seth
CEO
Blue Berry Pharma Advisory

703, KL Accolade, 6th Road, Santacruz East, Mumbai-400 055 Tel: +91-22- 2610600

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Pharmaceutical Market Potential of Southeast Asian Countries** submitted by **Naresh Champalal Mali** Enrollment No **IIHMR-U/01/2015-17/ 0039** under the supervision of **Dr. Saurabh Kumar** for award of **MBA in Pharmaceutical Management** of the University carried out during the period from **14th Feburary 2017 to 14th May 2017** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.



Naresh Champalal Mali
MBA Pharmaceutical Management
The IIHMR University, Jaipur

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that all ethical issues have been considered while collecting data for my dissertation titled **Pharmaceutical Market Potential of Southeast Asian Countries**

Naresh Chamapalal Mali
MBA Pharmaceutical Management
The IIHMR University, Jaipur

Acknowledgement

The satisfaction and euphoria that accompany the successful completion of the project would be incomplete without the mention of the people who made it possible.

First of all, I would like to extend my sincere thanks to **Mr. Subhash Seth**, Chief Executive Officer, Blue Berry Pharma Advisory for providing me an opportunity to learn and develop professionally.

I would like to express my sage sense of gratitude and heartfelt thanks to **Dr. Saurabh Kumar**, Assistant Professor, **The IIHMR University, Jaipur** for providing me an opportunity and all necessary facilities to accomplish this endeavor successfully. I am greatly indebted to him for providing his valuable guidance at all stages of the study, his advice, constructive suggestions, positive and supportive attitude and continuous encouragement, without which it would not have been possible to complete the project.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

Table of Contents

Review of Literature 10
Rational 11
Research Question 12
Objectives 12
Methodology 12
Analysis and Discussion 13
Southeast Asia Pest Analysis 15
Business Environment in Southeast Asia 16
Healthcare Sector in Southeast Asia 18
Global Pharmerging Market: Snapshot 23
Southeast Asian Pharmaceutical Market 28
Southeast Asia Generic Drug Market 30
Southeast Asia OTC market 31
Southeast Asia Import- Export 32
Clinical Trials in Southeast Asia 33
Regulatory Environment in Southeast Asia 34
Vietnam 44
Overview 44
Key Indicators 45
Pestle Analysis 46
Business Environment in Vietnam 49
Healthcare in Vietnam 50
Pharmaceutical Market in Vietnam 52
Regulatory Landscape 54
SWOT Analysis 56
Thailand 57
Overview 57
Thailand Key Indicators 58
Pestle Analysis 60
Business Environment in Thailand 61
Healthcare in Thailand 62
Thailand Pharmaceutical market 64
Regulatory Landscape 67

SWOT Analysis 68
Philippines 69
Overview 69
Philippines Key Indicators 70
Pestle Analysis 72
Business Environment in Philippines 74
Healthcare in Philippines 76
Pharmaceutical Industry in Philippines 78
Regulatory Landscape 82
SWOT Analysis 83
Malaysia 84
Overview 84
Malaysia Key Indicators 85
Pestle Analysis 86
Business Environment in Malaysia 88
Healthcare Sector in Malaysia 89
Pharmaceutical Market in Malaysia 92
Regulatory Landscape 94
SWOT Analysis 96
Myanmar 97
Overview 97
Myanmar Key Indicators 98
Pestle Analysis 100
Healthcare in Myanmar 103
Pharmaceutical Market in Myanmar 106
Regulatory Landscape 108
SWOT Analysis 110
Cambodia 111
Overview 111
Cambodia Key Indicators 112
Pestle Analysis 113
Business Environment in Cambodia 116
Healthcare in Cambodia 118
Pharmaceutical Market in Cambodia 120

Regulatory Landscape 123
SWOT Analysis 124
Conclusion 125
Recommendations 125
Limitations 126
References 127

List of Figures

Figure 1 Southeast Asian Country Population 14
Figure 2 Southeast Asian Courtiers GDP Growth rate 17
Figure 3 Southeast Asian Countries Life expectancy in 2016 19
Figure 4 Southeast Asian Countries Health Spending in 2016 20
Figure 5 Southeast Asia Disease Non- Communicable profile 21
Figure 6 Southeast Asia Healthcare development Stage 22
Figure 7 Pharmerging Market Map 23
Figure 8 Top Companies and Products in Pharmerging Market 25
Figure 9 Pharmaceutical Crime incident by region in 2015 27
Figure 10 Pharmaceutical Sales in Southeast Asia forecast 2020 28
Figure 11 Southeast Asian Countries Generic and Prescription Drug Sales in Southeast Asia 31
Figure 12 Southeast Asia OTC Categories market share 31
Figure 13 Southeast Asian Countries OTC Drug sales in 2016 32
Figure 14 Southeast Asian Courtiers Pharmaceutical Import in 2016 33
Figure 15 Southeast Asia Pharmaceutical Export in 2015 33
Figure 16 Top Countries Clinical trials 34
Figure 17 Pharmaceutical Distribution network in Southeast Asia 43
Figure 18 Vietnam GDP growth rate (%) 44
Figure 19 Vietnam Doing business environment 49
Figure 20 Vietnam Healthcare spending 2014-20. 50
Figure 21 Top 10 causes of death by rate in Vietnam 2015 51
Figure 22 Vietnam Pharmaceutical Sales forecast 2020 52
Figure 23 Vietnam Pharmaceutical Import-Export 53
Figure 24 Vietnam Pharmaceutical Market Segment 54
Figure 25 Thailand GDP growth rate (%) 58
Figure 26 Thailand Doing Business Environment 62
Figure 27 Thailand Healthcare spending 2020 62
Figure 28 Top 10 causes of death by rate in Thailand 2015 63
Figure 29 Thailand Pharmaceutical Sales forecast 2020 64
Figure 30 Thailand Pharmaceutical market segment 65
Figure 31 Thailand Pharmaceutical Import-Export 66
Figure 32 Philippines GDP growth rate (%) 70
Figure 33 Philippines Doing Business Environment 75
Figure 34 Philippines Healthcare spending 2020 76
Figure 35 Top 10 causes of death by rate in Philippines 2015 77
Figure 36 Philippines Pharmaceutical Sales forecast 2020 78
Figure 37 Philippines Pharmaceutical Import-Export 79
Figure 38 Philippines Pharmaceutical Market Segment 81
Figure 39 Malaysia GDP growth rate (%) 85
Figure 40 Malaysia Doing Business Environment 89
Figure 41 Malaysia Healthcare spending 2020 89

Figure 42 Top 10 causes of death by rate in Malaysia 2015 91
Figure 43 Malaysia Pharmaceutical Sales forecast 2020 92
Figure 44 Malaysia Pharmaceutical Market Segment 93
Figure 45 Malaysia Pharmaceutical Import-Export 94
Figure 46 Myanmar GDP growth rate (%) 97
Figure 47 Myanmar Doing Business Environment 103
Figure 48 Myanmar Healthcare spending 2020 103
Figure 49 Top 10 causes of death by rate in Myanmar 2015 104
Figure 50 Myanmar Pharmaceutical Sales forecast 2020 106
Figure 51 Myanmar Pharmaceutical Market Segment 107
Figure 52 Myanmar Pharmaceutical Import 107
Figure 53 Cambodia GDP growth rate (%) 112
Figure 54 Cambodia Doing Business Environment 117
Figure 55 Cambodia Healthcare spending 2020 118
Figure 56 Top 10 causes of death by rate in Cambodia 2015 119
Figure 57 Cambodia Pharmaceutical Sales forecast 2020 120
Figure 58 Cambodia Pharmaceutical Market Segment 121
Figure 59 Cambodia Pharmaceutical Import-Export 122

List of Tables

Table 1 Doing Business Ranking of Southeast Asian Countries 17
Table 2 Technical Document comparison amongst Southeast Asian Countries 35
Table 3 Comparison of Administrative documents requirements 36
Table 4 Product Approval timeline in Southeast Asia 36
Table 5 Medical tourism in Southeast Asia 41
Table 6 Medical niches in Southeast Asia 42
Table 7 Vietnam Pharmaceutical Import from India 53
Table 8 Thailand Pharmaceutical Import from India 66
Table 9 Philippines Pharmaceutical Import from India 80
Table 10 Malaysia Pharmaceutical Import from India 94
Table 11 Myanmar Pharmaceutical Import from India 108
Table 12 Cambodia Pharmaceutical Import from India 122

Acronyms

AMR- Antimicrobial Resistance

AMS- ASEAN Member States

ASEAN- Association of Southeast Asian Nations

BMI- Business Monitor International

DB- Doing Business Report

EML- Essential Medicines List

KHM- Cambodia

MYS- Malaysia

MMR - Myanmar

MoH - Ministry of Health

PHL - Philippines

SEARO- South-East Regional Office

THA- Thailand

VNM- Viet Nam

WHO- World Health Organization

EU- European Union

GDP- Gross Domestic Product

IMF- International Monetary Fund

IT- Information Technology

OECD- Organisation for Economic Co-operation and Development

Review of Literature

According to Economic intelligence unit, Seated in South-East Asia are emerging countries that will experience faster rates of healthcare spending growth over the next five years than those in BRIC economies. Emerging healthcare markets in Indonesia, Philippines and Vietnam are changing rapidly, as healthcare systems in these markets expand their capabilities to deliver healthcare to large populations of undiagnosed and untreated patients. According to Pricewaterhousecooper to capture opportunities found deep within emerging markets and its cities, a nuanced understanding of the region – the complex matrix of healthcare systems, government policies, epidemiological and socio-economic factors interacting and shaping the decisions of healthcare professionals and patients delivering and using drugs and medical devices, is critical.

According to report of ministry of health Communicable ailments keep on threatening the Region and whatever remains of the world. Flare-ups of extreme intense respiratory disorder (SARS) and avian flu demonstrate that recently rising irresistible illnesses can posture genuine general wellbeing dangers, with huge potential effect on social and financial advancement. Tuberculosis (TB) remains a noteworthy general medical issue in the Region on account of its high grimness and death rates. Tuberculosis control should be additionally fortified, with accentuation on tending to multidrug-safe TB and TB-HIV sweet.

PMMI says that pharmaceutical market in Southeast Asia is a complex and dynamic industry that is continuously evolving in response to a variety of market influencers. The landscape of the pharmaceutical market has changed significantly with the rise of generic drugs and the rapid expansion of mergers and acquisitions (M&A).according to pharmafocus Southeast Asia is a growing pharmaceutical market with an increase in clinical trials in recent years. With a population of about 646 million and a total area of 4.5 million kilo meters it contains the region's well-recognized study destinations of Malaysia, Singapore and Thailand, who are also members of PIC/S the Pharmaceutical Inspection Co-operation Scheme.

Rational

In a world struggling with low growth, the ten member countries, Southeast Asia represent a genuinely exciting prospect among other Pharmerging markets. It is expected high growth in the region, already the world's sixth largest economic bloc, to average 5.25% annually in the next five years. Much of this growth will come from ASEAN's urban hubs: the region currently has populations of over 646 million, which will continue to drive an overwhelming share of its economic development in the next decades.

For investors looking at the region, determining where exactly the greatest opportunities lie within these metropolises can be a struggle. This Study offer a wealth of data and analysis to clarify the prospects of these dynamic markets, enabling firms to pinpoint which market segments offer the most potential for growth.

Southeast Asia will be one of the few remaining growth regions for Pharmaceutical Multinational companies and it can be expected that business model changes and roll outs of infrastructure projects will accelerate. Further extended healthcare and improved health systems in the Southeast Asian countries will drive growth of domestic companies that will seriously compete with MNCs. This Study on Southeast Asian Market will uncover that which country will be the priority pharmaceutical market within the next Five years.

With a focus on Six countries—Vietnam, Thailand, Philippines, Malaysia, Cambodia, and Myanmar, this Study summarizes overall Southeast Asia Pharmaceutical and Healthcare Market and current scenario with major export-import countries and regulatory environment. The findings of a study aimed at providing tools and analysis for Pharmaceutical Companies to better engage with these markets and their local players for growing Business in Southeast Asia.

Research Question

What is the Pharmaceutical market potential of Southeast Asian Countries?

Objectives

- To Study the Pharmaceutical Market in Six Southeast Asian Countries (Vietnam, Thailand, Malaysia, Philippines, Myanmar, Cambodia)
- To Identify the most promising Southeast Asian Country for Pharmaceutical market

Methodology

Type of study

- Descriptive, Secondary / Desk Research

Data Collection Tool

- Information is collected from official databases on Healthcare and Pharmaceutical (i.e. WHO Country Profiles, CIA, IMS Health, World Bank) and official country documents such as Ministry of Health reports and country reports available in the public domain. and other government & regulatory published material, and paid data sources such as IMS Health and BMI.

Data Analysis

- Data from the accomplished from Research of individual Countries entered into a database using Microsoft Excel 2010 spreadsheet and analyzed.

Study Duration

- The Study was conducted over a period of 3 months from February 2017 to May 2017

Analysis and Discussion

South-East Asia Region (SEARO) consists of 10 countries. Archipelagic Southeast Asia comprises of Singapore, Indonesia, the Philippines, Brunei, and Malaysia. By and large, Southeast Asia amplifies more than 4,500,000 km^2. The Southeast Asian countries have a total population more than 646 million in 2017. Individual country populations vary from 0.43 million in Brunei to 263 million in Indonesia. Each country comprises of entirely different cultures, politics, languages, and levels of economic development, working collectively to expand their economic potential. Indonesia ranks fifth in world population.

The Southeast Asia will remain the most unique piece of the worldwide economy yet is confronting serious headwinds from a still powerless worldwide recuperation, moderating worldwide exchange, and the fleeting effect of development move. Still, the Southeast Asian Countries is very much situated them to address the challenges ahead, if it fortifies its change endeavors. To fortify its strength to worldwide risk and remain a wellspring of dynamism, policymakers in the district ought to push ahead with basic changes to raise efficiency and make financial space while supporting demand as needed.

As external demand remains relatively quelled and global financial conditions have started to tighten, residential request is relied upon to be a noteworthy driver of movement crosswise over the greater part of the district. Local request, especially utilization, will continue being driven by enthusiastic lower product costs, work financial circumstances and additional money advancement, nearby, in a couple of economies, macroeconomic lift.

Downside risks continue commanding the money related scene. Slower-than-anticipated global growth and tighter global financial conditions consolidated with high use in the region could have an adverse effect on regional growth. Specifically, the turning of the credit and money related cycles in the midst of high obligation represents a noteworthy hazard to development in Asia, especially because debt levels have increased markedly over the previous decade crosswise over the vast majority of the real economies in the area, including China and Japan.

It could be considered the smallest of WHO Regions. However, its Population ads up to one out of each four living individuals and between them, they, unfortunately, account for 40% of the burden of diseases worldwide. All 10 countries are members of the

World Trade Organization (WTO), however some of them are still spectators and there is one that is not yet included in any way. The three main players that are members of the WTO and that are at the forefront of the issues of health and trade in the Region happens to be Indonesia, Thailand, and Vietnam. They have certain things in like manner in the health and exchange field

In Southeast Asia, Philippines, Singapore, Malaysia and Nepal and Sri-Lanka have been classified as "partly free" countries. Cambodia, Laos, Vietnam, Brunei and Myanmar and Thailand have been categorized as "not free" countries. Majority government rules, management of law, and ensured human rights. Actually, honed types of financing and nepotism have prompted the improvement of littler and wealthier, and bigger and poorer portions of the populace in this area.

The population of Southeast Asia is marked by great ethnic and religious diversity. Influential ethnic and religious minorities live especially in Myanmar, Thailand, Malaysia, Singapore and the Philippines. In Myanmar, the ethnic-religious conflicts have been handed down since the British colonial period and are domestic in nature. The social rejection of Chinese minorities in all nations of Southeast Asia, except for the Philippines, is by all accounts in view of preference and envy of the budgetary achievement of the abroad Chinese.

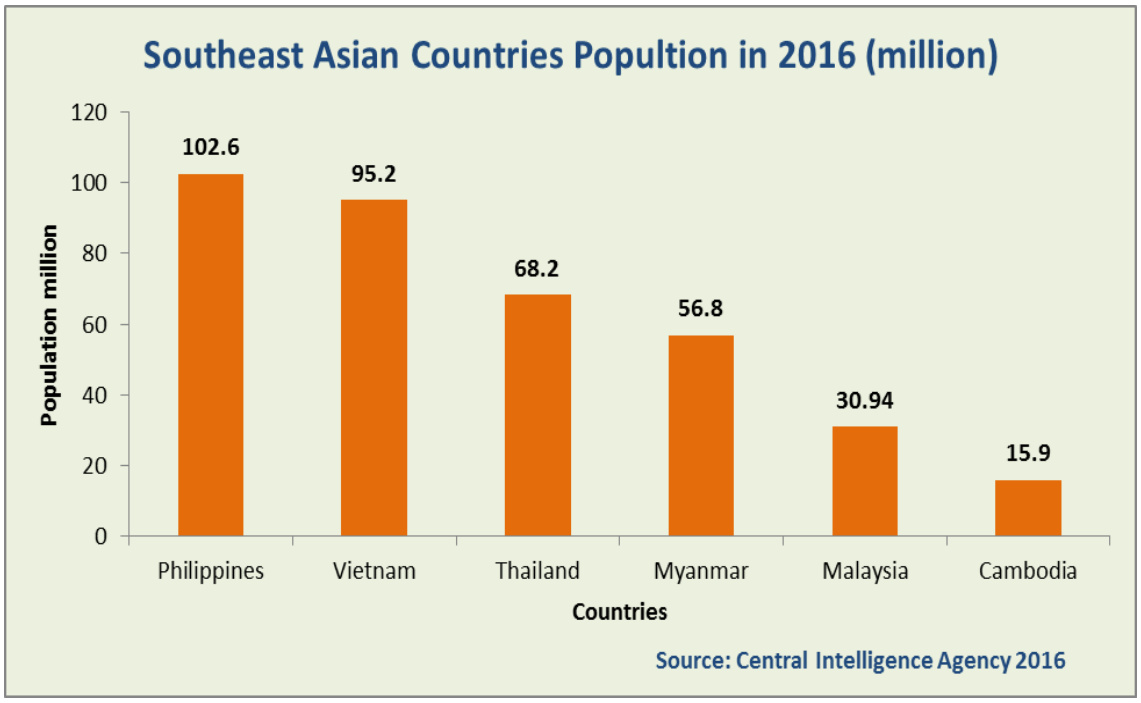


Figure 1 Southeast Asian Country Population

Since the mid-1990, Southeast Asia has undergone significant political and economic developments. Countries such as, Malaysia, Indonesia Singapore, and Thailand

experienced high economic growth rates until the mid-2000, which led to an improvement in the standard of living for their citizens. Thailand, Nepal, and Cambodia have overcome their isolation as a result of their position on the front lines in the conflict between East and West, have recruited foreign investors, and have participated in regional as well as other forums. Only Myanmar, which together with Laos joined the ASEAN Association in 1997, is still politically isolated. Myanmar has been internationally ostracized due to its slow process of democratization.

The Chinese community has played a large role in the development of the economies in the region. These business groups are associated through the bamboo network, a system of abroad Chinese organizations working in the business sectors of Southeast Asia that share regular family and social ties. The locale's economy extraordinarily relies on upon agribusiness; rice and elastic have for some time been conspicuous fares. Assembling and administrations are ending up noticeably more critical. A developing business sector, Indonesia is the biggest economy in this area. Newly industrialized countries include Malaysia, Vietnam, Thailand and the Philippines, while Singapore and Brunei are well-developed economies. The rest of Southeast Asia is still heavily dependent on agriculture, but Vietnam is notably making steady and slow progress in developing its industrial sectors. The region mainly manufactures textiles, rubber, electronic high-tech goods such as microprocessors and heavy industrial products such as automobiles. Oil reserves in Southeast Asia are plentiful. Tourism has been a key factor in economic development for many Southeast Asian countries, especially Thailand, Malaysia, and Cambodia.

Countries in Southeast Asia practice many different religions. Islam is the most practiced faith, numbering approximately 240 Population, concentrated in Indonesia, Brunei, Malaysia, and Southern Thailand and in the Southern Philippines. Indonesia is the most populous Muslim-majority country around the world. Buddhism is predominant in Laos, Cambodia, Vietnam, Thailand, Burma and Singapore. The culture in Southeast Asia is highly diverse: on mainland Southeast Asia, the culture is a mix of Indochinese (Myanmar, Laos, and Thailand) and Chinese (Vietnam). While in Indonesia, the Philippines, Singapore, and Malaysia the culture is a mix of indigenous Austronesia, Western, Indian, Islamic and Chinese cultures.

Southeast Asia Pest Analysis

Political

Political systems in Southeast Asian are vary from individual country. The Political system covers all the issues of government intervention

- Strong political commitment for Universal Health Coverage
- Struggles with the realities of implementation UHC systems
- Willingness to make more evidence-based decision making

Economic

Individual Southeast Asian countries has its own currency and exchange rates can be greatly affected by political changes

- Growth of middle population segment with disposable income
- Increasing cost pressures on health care budgets as cost of delivery and drugs risk outstripping budgets
- ASEAN Economic Community

Social

- Demographic changes –wealth and age distributions
- Epidemiological transitions (M&M is no longer driven by infectious diseases but rather NCD (diabetes, COPD, cancer etc.)
- Patient preference of branded products and private health sector, where affordable
- High-income patients cross country borders to seek high standard health care and technologies.

Technological

- Limited pharma technology, therefore the region relies on import for innovative drugs
- Limited requirements for technology transfer into the region
- Skilled physicians in Thailand, Malaysia, Vietnam which leads to medical tourism.
- ASEAN HTA agencies have limited technical capacity but actively developing.

Business Environment in Southeast Asia

Southeast Asia is Asia Pacific's third largest growth engine after China and India and saw resilient growth despite the global financial crisis. Favorable factors like rising

foreign direct investment, the region has experienced two decades of robust economic growth, which has successfully lifted millions out of poverty and created a middle class with newfound spending power. Consider the numbers: The combined GDP of Southeast Asian countries was close to $5.1 trillion in 2016 (CIA).

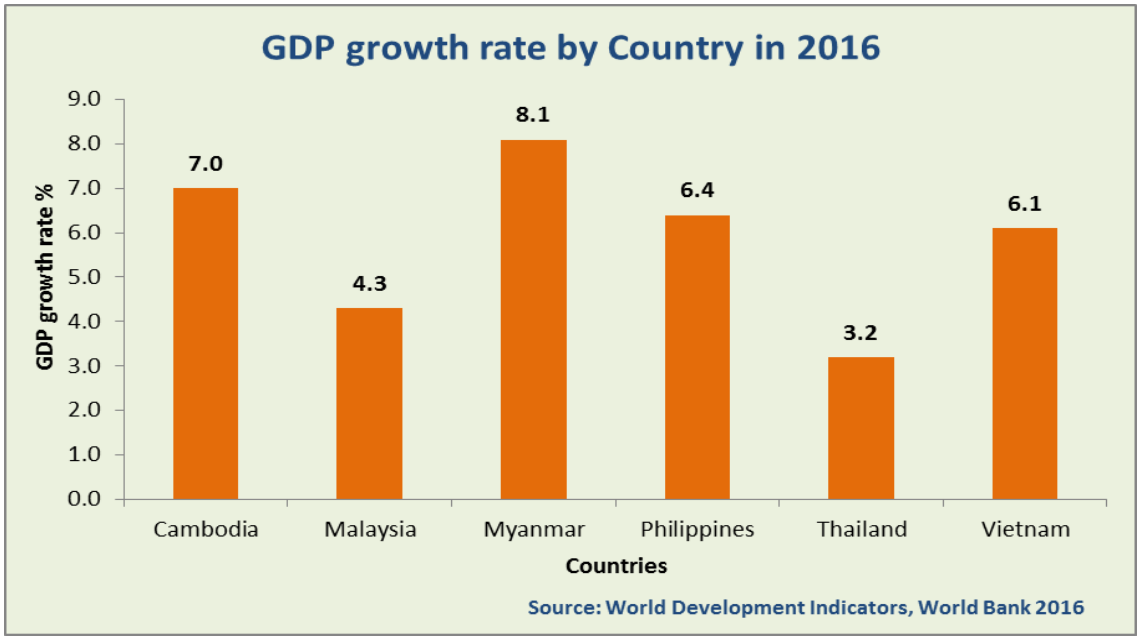


Figure 2 Southeast Asian Courtiers GDP Growth rate

Southeast Asia is home to more than 646 million people (about 60% of its population is under 35 years old). This young and large population translates into a large and dynamic workforce. Countries Growth is further supported by abundant land and natural resources, a wide range production capabilities and good intra-regional connectivity.

Countries	Doing Business 2017 Rank	Doing Business 2016 Rank	Change in Rank
Vietnam	82	91	↑ 9
Thailand	46	46	↔ 0
Philippines	99	99	↔ 0
Malaysia	23	22	↓ 1
Myanmar	170	171	↑ 1
Cambodia	131	128	↓ 3
Source: Doing Business Report, World Bank 2017			

Table 1 Doing Business Ranking of Southeast Asian Countries

Healthcare Sector in Southeast Asia

Good health is not restricted to an individual but encompasses an entire economy. Swift development of an economy is rare without substantial investment in human capital, and most Southeast Asian nations need to suitably recognize this fact. Healthcare is considered an integral part of national development across all Southeast Asian countries, from Singapore, a provider of world-class healthcare services, to Indonesia, the Philippines, and Vietnam, where the healthcare sector is still at a nascent stage.

Southeast Asia is described by differed statistic and monetary conditions that require a customized human services display for every nation. As revealed by WHO, Southeast Asia spends around 5.0% of GDP on human services versus created countries, for example, the US and Japan that burn through 17.6% and 9.2%, individually. This reflects colossal extension for improvement. Given the ascent in elderly and populace development, higher pay levels, expanding wellbeing mindfulness and interest for quality social insurance benefits, the district needs to connect the request supply hole by raising the extent of human services use as a rate of GDP.

As per research, Southeast Asia is balanced for development. The locale's social insurance market was near USD 120.58 billion and it is relied upon to develop by USD 176.6 billion by 2020 at a CAGR of 8.0%. The private area is probably going to keep being the overwhelming power, representing a 53% offer. The private medicinal services market is anticipated to achieve USD71 billion in 2020, almost twofold the size in 2010. General society and private human services markets are required to extend at CAGRs of 7.2% and 6.4%, individually, more than 2010–20.

A few elements are driving the social insurance showcase in Southeast Asia, especially the elderly populace (characterized as individuals more than 65 years). Southeast Asia is home to about 646 million individuals, with an elderly populace of 40 million. The elderly populace is required to reach 53 million by 2020. According to the World Bank's appraisals for the 10-year time span 2010–20,. The ascent in elderly populace implies more business for human services suppliers, as the elderly by and large look for more medicinal care and have more costly wellbeing profiles than the more youthful populace.

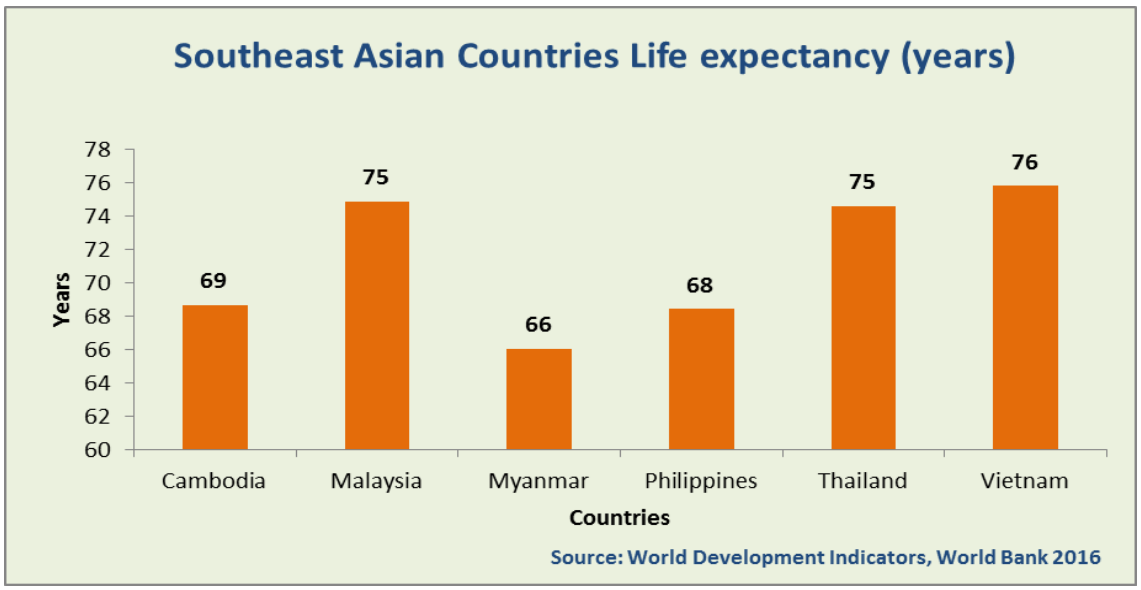


Figure 3 Southeast Asian Countries Life expectancy in 2016

Southeast Asia has a high prevalence of lifestyle-related diseases such as diabetes and heart disease. According to WHO report, the adult mortality rate due to cardiovascular diseases and diabetes has remained unusually high in Southeast Asia as compared to the rest of the world.

Southeast Asia's healthcare market also has supply side attractiveness in the form of inadequate healthcare infrastructure. The region lags behind developed countries in terms of bed count. Taking the US as the benchmark, calculations indicate that the Southeast Asia would need to add nearly 699,000 beds by 2020. The region is also far behind developed economies such as the UK, Germany, the United State and Japan in terms of availability of doctors and healthcare professionals. Our calculations indicate Southeast Asia would need to add nearly 958,000 physicians and 2.1 million nurses and midwives by 2020.

The lucrative healthcare market in Southeast Asia has attracted international private players. World-leading private hospitals have entered developed healthcare markets such as Singapore, Malaysia, and Thailand.

An aging population in the region will result in greater healthcare expenditure by the elderly - On an average, about 60-70% of the population in the Southeast Asia region is in the working age group of 15-64 years. Singapore and Thailand have among the highest percentage of the aging population in the above 65 years age group. This is expected to result in a greater demand for quality healthcare services for the elderly, especially in these two regions. The percentage of people over age 65 is expected to more than quadruple by 2050 in Southeast Asia. A report by the International

Osteoporosis Foundation indicated that the number of people at high risk for osteoporosis in the Philippines will reach 4 million by 2020 and reach 10.2 million by 2050. Also by 2050, more than 7 million Vietnamese women will be at risk of developing osteoporosis

Private health expenditure is high relative to government expenditure in the region - The private sector healthcare expenditure would continue to exceed public healthcare expenditure in Indonesia. The roll-out of national health insurance program (through 2019) is expected to increase the overall healthcare expenditure. In 2014, private expenditure in Malaysia represented just fewer than 42% of the total healthcare spending. The government health expenditure in the Philippines (4.7 of GDP in 2016), Malaysia (4.2 of GDP in 2016), Sri-Lanka (3.5 of GDP in 2016) and Myanmar (2.3 of GDP in 2016) falls short of the WHO standard of 5%. However, the government is now taking steps to boost public's access to healthcare and aims to provide universal health coverage by 2018. Due to the universal healthcare system in Thailand, government expenditure on healthcare as a percentage of total healthcare expenditure was more than 70% in 2016, although the funds were unequally distributed. In Vietnam, there will be a rise in the private healthcare expenditure as the government plans to increase public hospital fees. This expenditure will be borne by the patients due to low funding from the government

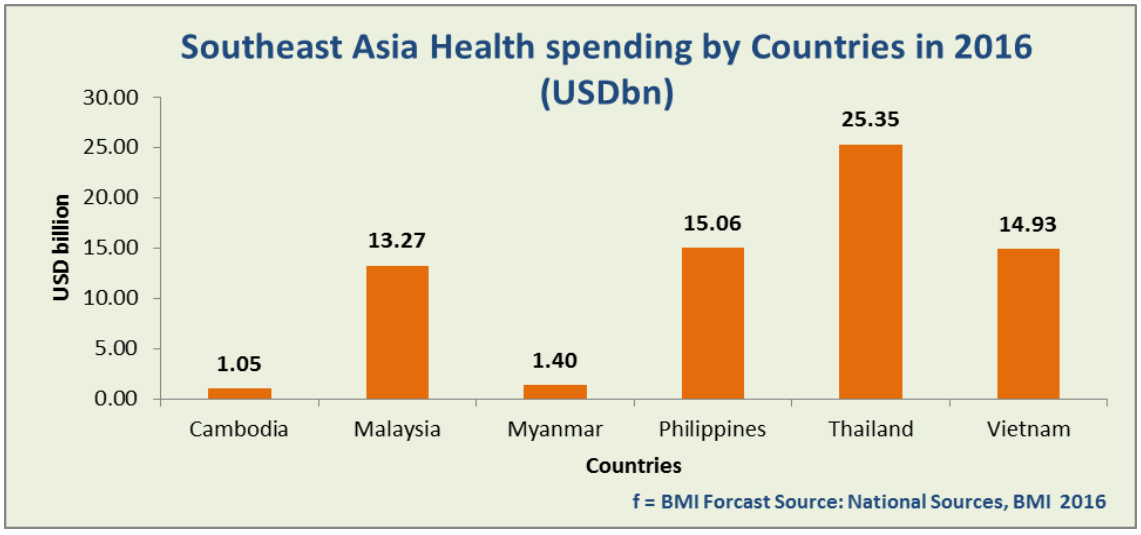


Figure 4 Southeast Asian Countries Health Spending in 2016

The rapid epidemiological change is also occurring, with the disease burden shifting from infectious to chronic diseases - About 62 percent of the deaths in Southeast Asian countries could be attributed to non-communicable diseases (WHO) and impact the productive 15-69 age group. In Region non-communicable diseases including cancer,

diabetes, cardiovascular, diseases, and respiratory diseases, all deaths from NCDs in the Region are below 70 years of age. Almost 190 million of the world's 370 million people diagnosed with diabetes live in Asia. Indonesia is among the top 10 nations with the most diabetics. In addition, Malaysia, Vietnam, and the Philippines are forecast to have increasingly high levels of diabetes diagnoses over the next two decades. Almost 61% of the 17 million annual cardiovascular-disease-related deaths occur in Asia (WHO). In Malaysia, approximately half of those over the age of 30 have hypertension.

Every year, more than six million Asians are diagnosed with cancer, and four million die from the disease. Among new cases of cancer globally, half are in Asia. The ASEAN nations are also experiencing increasingly high cancer rates. The most common cancers in Southeast Asia are lung, breast, liver, and colorectal cancers.

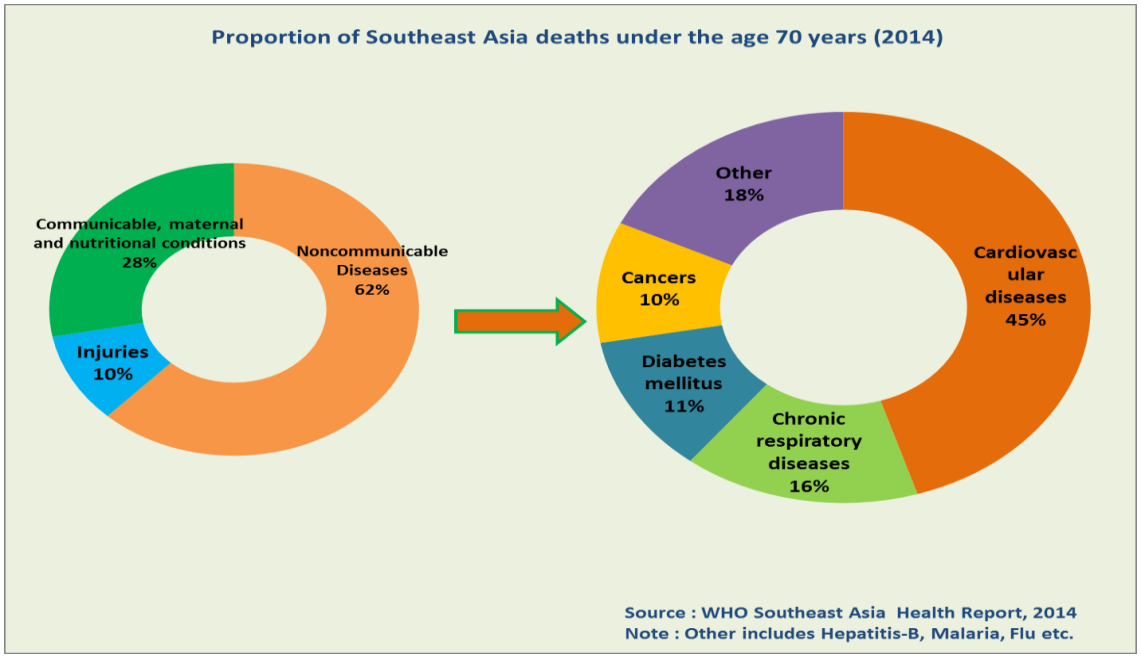


Figure 5 Southeast Asia Disease Non- Communicable profile

Tapping into South-East Asia's healthcare market requires understanding the vast economic, Socio-demographic and political differences in the ten countries that make up this region – from first world Singapore to third world Myanmar to identify the best growth opportunities for businesses.

Southeast Asia's healthcare sector will become third of the global market by 2020 Medical tourism, low costs, resilient economy & higher compliance to standards rising wealth, aging & growing population Demand for quality healthcare Increasing the level of access & affordability to medicines.

Development Stage of Healthcare in Southeast Asia

Southeast Asian healthcare market varies in structure and maturity, the healthcare sector in Southeast Asia varies widely in terms of maturity as well as structure. Singapore's healthcare market is represented by the advanced medical workforce and cutting-edge medical technology, while those of Indonesia, the Philippines, and Vietnam are represented by provision for basic healthcare needs.

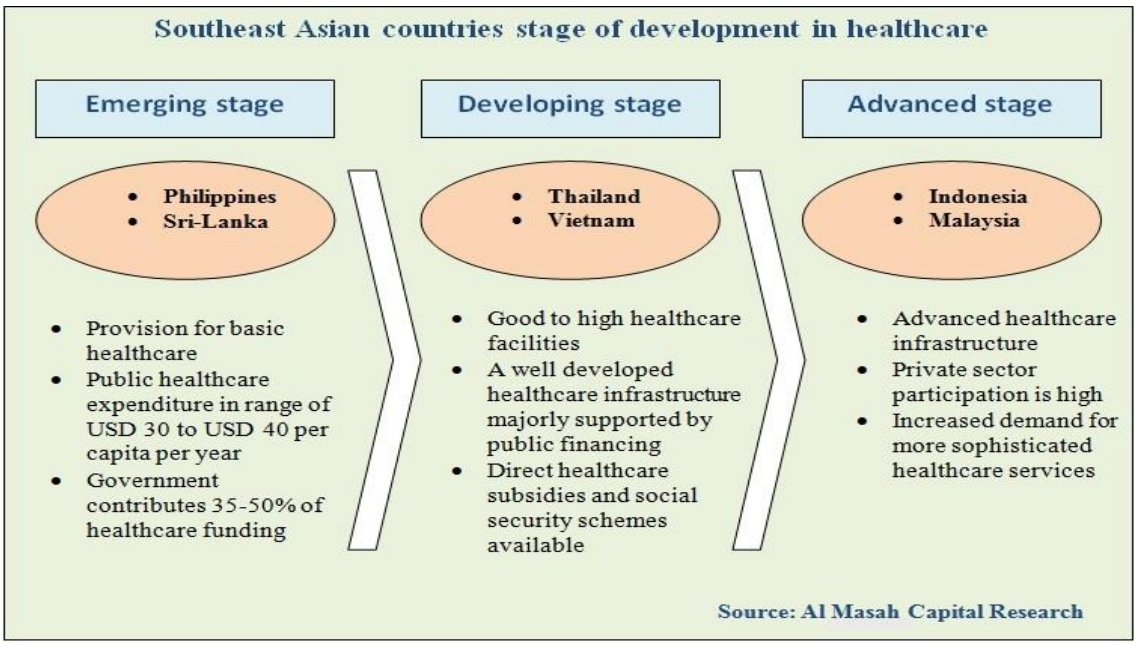


Figure 6 Southeast Asia Healthcare development Stage

Global Pharmerging Market: Snapshot

The global Pharmerging market is experiencing a significant growth, especially in the emerging economies across the world. The rising prevalence of aging population, increasing life expectancy, non-communicable diseases, escalating income, surging government expenditure on health care, free trade agreement, and the constant research and development are some of the key factors behind the growth of this pharmerging market.

Pharmerging markets can be segmented into three tiers based on pharmaceutical growth rate and market size. Tier-I includes China; Tier-II includes India, Russia and Brazil and Tier-III includes Turkey, Egypt, Indonesia, Thailand, Vietnam, South Africa and Mexico.

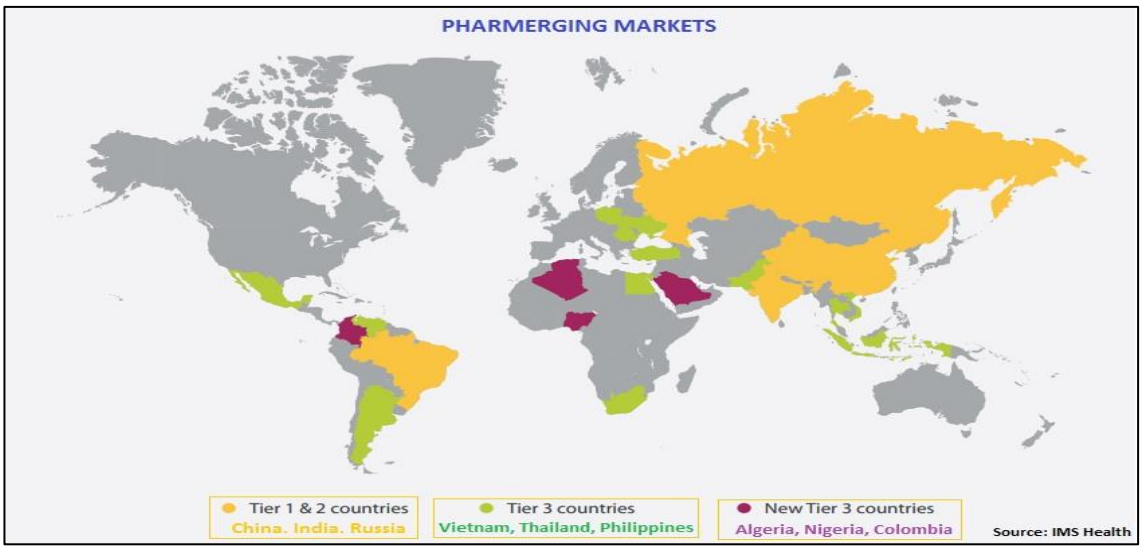


Figure 7 Pharmerging Market Map

The global market of 20 Pharmerging countries which stood at US$ 340.1 bn in 2015 and it is expected to rise at a CAGR of 13% between 2016 and 2020 and reach a value of US$626.6 bn by the end of 2020. The Tier I region (China) dominated the market during 2016, with a market share of 46%.

With the increasing incidence rate of various diseases, the demand for highly innovative and better outcome products is also increasing, which is likely to result in a substantial growth of this market in the future. The growth in innovation and advancements in the drugs for the treatment of diseases is also anticipated to drive this market over the next few years. Macroeconomic factors expected to influence Pharmerging market growth include greater awareness about drugs in semi-urban and rural markets, epidemiological changes coupled with age-related disorders, rapid development in the private hospital

industry. Also, increased government expenditure in the healthcare industry is expected to drive the Pharmerging market over the forecast period.

Emerging markets are likely to focus more on low-cost generic drug development, which is supposed to restrain the market growth in these regions. Regulatory policy changes are likely to curb the market as these changes are anticipated to have long-term impacts on pricing and medicine usage in various regions. Price sensitivity is another challenge likely to be faced by major players operating in the Pharmerging market.

China is likely to become a very complex market and is expected to focus on sophisticated operating models. Significant challenges likely to be faced by pharmaceutical industries planning to enter in Chinese market include shrinking price, complex distribution system, variation in commercial models in different provinces and regulations favoring domestic manufacturers.

Indian Pharmaceutical market is expected to be highly fragmented and competitive. Companies are supposed to adapt to local market trends and implement market entry strategies accordingly. The Brazilian market is anticipated to be commoditized in OTC segment as unmet medical needs are mostly satisfied by nonretail drugs. Establishment of CITEC, an economic evaluation agency is likely to act as a barrier for product inclusions in funding programs for the country. Innovation in Brazilian market is focused on niche private segments as demand for expenditure on complex therapies is usually avoided.

The Russian market is likely to be very volatile, due to the presence of price control on essential drugs. Also, a policy such as substitution of imported drugs with locally manufactured equivalents is likely to pose a challenge to major players.

After the U.S. and Japan's price cut system are considered to rebalance the spending priorities for pharmerging markets. Another major factor likely to restrain the pharmerging market is the inclusion of major drugs under Drug Price Control Order (DPCO) which will affect the retail and wholesale margins earned by Pharmacy. The pharmerging market is expected to be quite lucrative for major pharma MNC in order to succeed in pharmerging markets, major MNC companies are anticipated to tailor their portfolio according to local needs. Lower margins are further expected to lead to production rate cut. Some of the major pharmaceutical companies which have experienced a negative growth rate due to DPCO.

Major players in pharmerging markets are AstraZeneca, Sanofi, Merck, Pfizer, GlaxoSmithKline, Novartis, Abbott Laboratories, CSL Behring, Johnson &Johnson, Sun Pharmaceutical, Aspen, Teva Pharmaceutical, Bayer, Valeant Pharmaceutical, Biogen, Baxter, STADA, Mylan, Takeda Pharma, Alexion Pharmaceuticals, Endo Health Pharmaceuticals, etc.

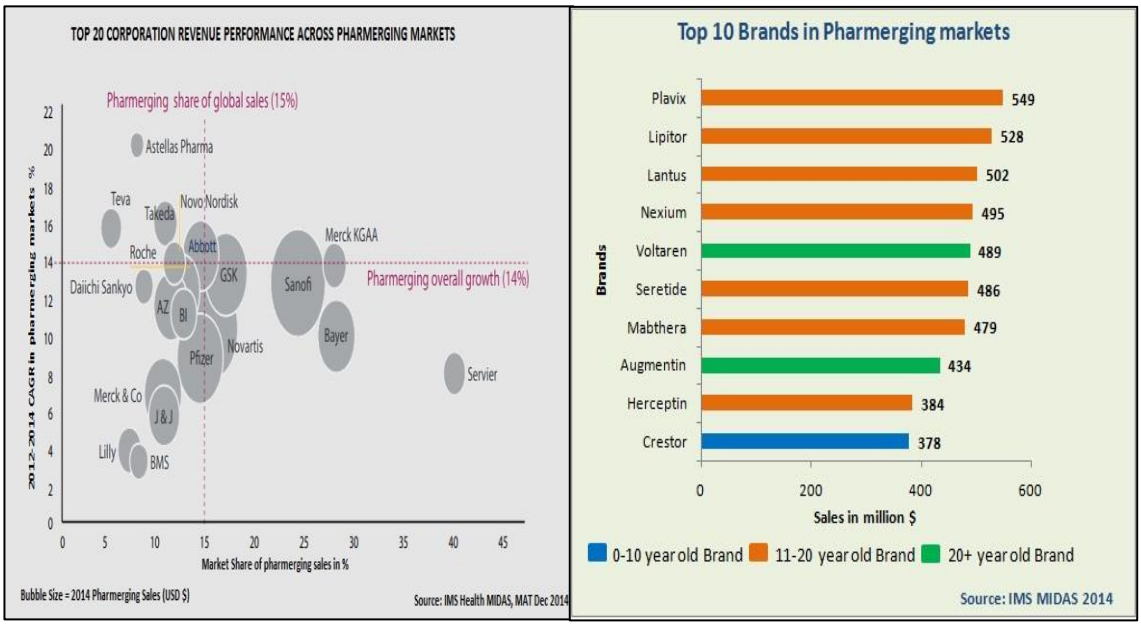


Figure 8 Top Companies and Products in Pharmerging Market

The pharmerging market is very fragmented due to the presence of small and medium size vendors. The market competition is likely to be dominated by product extensions, mergers & acquisitions, and technological advancements. A majority of pharmaceutical companies are expected to focus on merger and acquisitions to expand their market presence and increase their profits. In 2014, mergers and acquisitions in the healthcare industry were approximately around $50 Billion.

On the basis of the type of product, pharmaceuticals and Medical device are the two main segments of the global market for Pharmerging. The pharmaceuticals segment dominated the overall market in 2016 with a share of 65.2%. The scenario is expected to continue like this over the next few years, thanks to the significant rise in the demand for both, the branded as well as generic drugs.

Apart from this, the increasing number of innovative therapies for the treatment of various diseases at an affordable price is also projected to boost this segment in the years to come. On the other hand, the healthcare segment is likely to be driven by the growing emphasis on medical devices used in the treatment of a number of diseases.

Based on the indication, the worldwide market for Pharmerging has been classified into lifestyle diseases, cancers and autoimmune diseases, and infectious diseases. Among these, lifestyle-borne and cancer and autoimmune diseases are projected to offer lucrative opportunities for the growth of this market with attractiveness index over the forthcoming years.

Asia Pacific to Remain on Top

In terms of the geography, the global Pharmerging market reports its presence across Latin America, the, Asia-Pacific, North America, Middle East and Africa and Europe. With a share of 53%, Asia-Pacific led this market in 2016. Researchers expect this regional market to remain on the top, thanks to rapid urbanization, increasing patent expiration, and the surge in the investments for medical research. China has emerged as the key domestic market for Pharmerging in Asia Pacific.

Among other regional markets for Pharmerging, Europe, and Latin America are likely to witness healthy growth in the near future. Technological advancements, extensive research and development practices, and the increasing awareness regarding the treatment and the management of healthcare facilities are likely to propel the Latin America market. The Europe market is predicted to be driven by the large population size, growing disease prevalence, and the increasing health expenditure in the region.

Factors such as rising population due to low infant mortality rates and focus on developing innovative drugs are expected to boost the growth in the pharmerging market. Amongst the 21 emerging countries in the pharmerging market, China, India, and Russia are projected to hold a significant share of the market.

According to the WHO, 1 million deaths annually are linked to the counterfeit drug trade. These fake medicines threaten human safety, affect consumer perceptions of drugs and drug companies, infringe on IP rights, and act as a barrier to pharmaceutical industry growth. Legitimate drug manufacturers and distributors should continuously invest in countermeasures such as product traceability and authentication technologies. These efforts, however, can pose both financial and strategic challenges for pharmaceutical manufacturers, as they need to continuously update technologies and security along their distribution channels

In year 2016, Pharmaceutical Security Institute (PSI) recorded more than 3,000 pharmaceutical crime incidents in seven regions of the world. Every region experienced

a pharmaceutical crime incident. In total, there were 128 countries found to have been impacted by pharmaceutical crime.

It was found that 38% increase in the worldwide incident total compared to the previous year in 2014. Incidents impacting the Asia-Pacific region surpassed one thousand incidents annually for the first time in 2015. Also, incidents in North America increased over one hundred percent from the previous year. In the below chart, the regions are ranked in order from those experiencing the highest number of incidents to those with the lowest number of incidents.

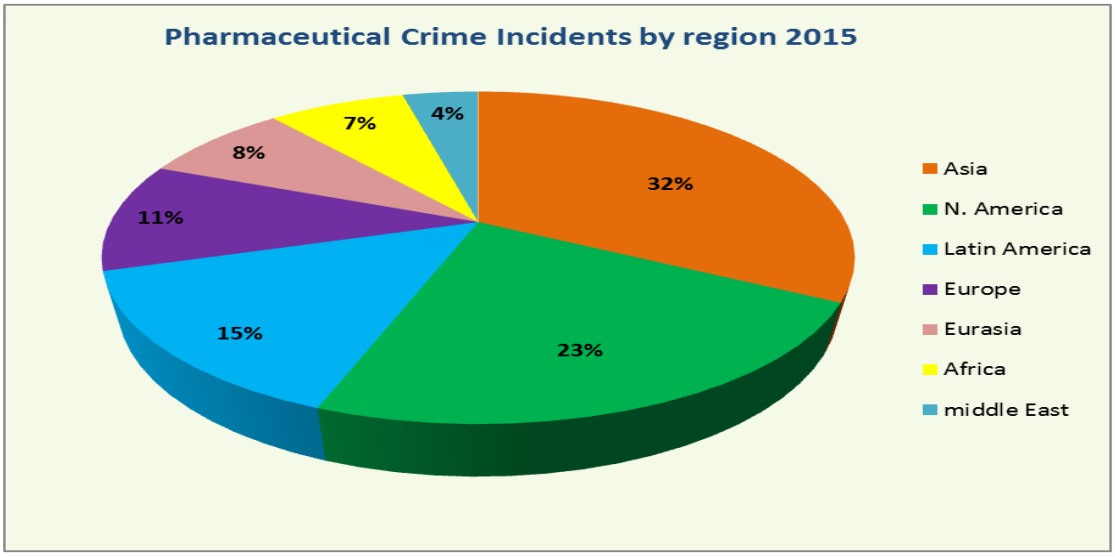


Figure 9 Pharmaceutical Crime incident by region in 2015

Those regions with seemingly low incident totals are not necessarily unaffected by or at a lower risk of pharmaceutical crime. Due to competing for law enforcement priorities, lack of funding or inadequate regulatory structures, in certain regions of the world, counterfeit medicines often go undetected. It is important to recognize these facts since they complicate region to region comparisons.

How big is the problem in Asia?

Counterfeit (fake) antimalarial drugs appear to be a particular problem in mainland South East Asia. In a recent study it was found that 38% to 53% of samples purchased from pharmacies and shops to be Counterfeits, with many packages bearing falsified security holograms.

Malaysia, a wealthier country with a relatively well-developed regulatory and legal environment has a Counterfeits medicine prevalence of roughly 3-5% of all medicines in circulation. By contrast, poorer countries tend to suffer from higher rates. For

instance, the International Pharmaceutical Manufacturers Group (IPMG) in Indonesia has estimated that Counterfeits drugs constitute 25% of Indonesia's US$2 billion pharmaceutical market

- 27% of anti-malarial drugs tested in Cambodia in 2006 were found to have incorrect levels of active ingredient (Lon, 2006).
- 7% of a sample of anti-malarial, TB and antibiotic drugs tested in major Indian cities failed quality testing (Bate, 2012).
- The Federation of Indian Chambers of Commerce claims that 15-20% of medicines on sale in India are Counterfeits.

Southeast Asian Pharmaceutical Market

At first glance, Asia appears to be an assured avenue of growth for pharmaceutical manufacturers. Southeast Asia is a fast growing & flourishing pharmaceutical market. And it is an attractive market for US & Japan. There is immense growth opportunity within pharma industry & huge untapped growth potential.

The pharmaceutical sales in Southeast Asia were USD 23.98 bn in 2016. And it is growing at CAGR of 7.0%. Rapid expansion in the economies of Southeast Asia, combined with government and private health care initiatives, is creating major opportunities for pharmaceutical companies in this region. In all of the countries described in this report, pharmaceutical market growth reached double digits over the past five years and is expected to remain strong well into the next century.

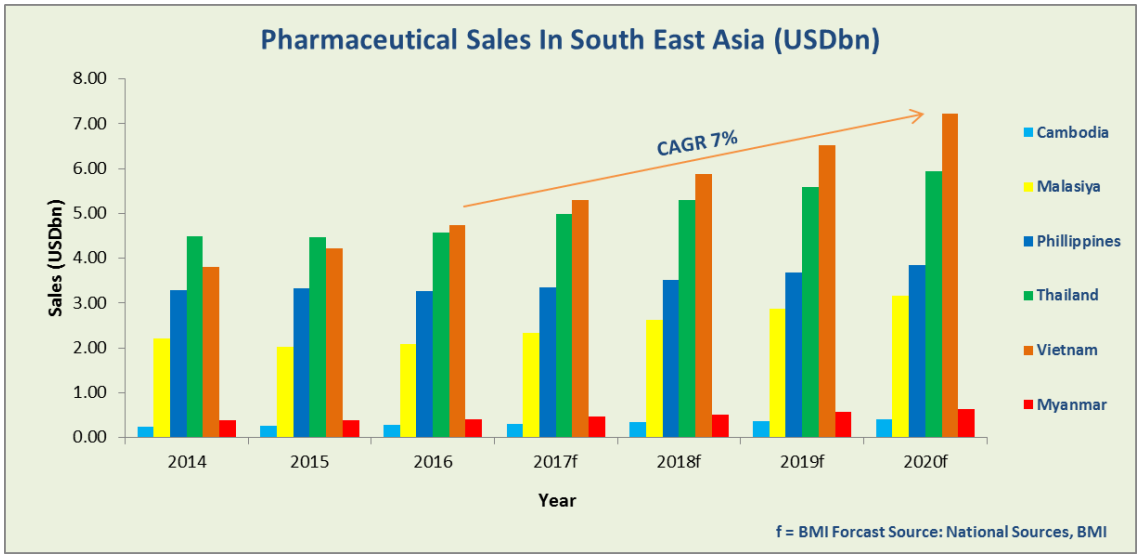


Figure 10 Pharmaceutical Sales in Southeast Asia forecast 2020

The markets in Thailand and the Philippines, each worth well over $4.57 billion and 3.27 billion, grew 5.39% and 3.2%, respectively, in 2016. Although growth has not been as dizzying in Cambodia, where sales reached $350 million in 2016, sales by foreign-based companies are expanding rapidly. In Malaysia, the government is expanding and privatizing health services and is offering incentives for foreign investment.

Market Drivers

Middle-income earners are on the rise across the South-East Asia, a demographic shift that is driving demand for better Pharmaceutical and healthcare that facilitate more efficient treatment. BMI forecasts this dynamic will help double the value of the Pharmaceutical market in the region — whose 10 members are Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam — from US$23.9 billion in 2016 to US$33.62 billion by 2020. Other factors, such as the implementation of new public health policies and an aging population, will further support the sector's growth in the mid-term. As a result, Pharmaceutical manufacturers are increasing their focus on Southeast Asia as a key growth market. Other positive factors include:

Some of the factors driving the market include:

- Southeast Asia has 646 million population and the world's 3rd largest labour workforce
- The region's economic output is US$2.1 trillion.
- Some 125 million households will enter the middle-income bracket by 2025, representing an increase of 87 percent (source: McKinsey Global Institute).
- There is increasing intervention by the public sector in terms of the investment in the healthcare sector and the level of spending.
- Steps being taken against counterfeit products
- Growth in over-the-counter market

Restraints

There are, however, some factors restraining the market as well. These include:

- Growing pressure on Pharma companies to cut costs
- Environmental concerns and recycling issues
- Increasing raw material costs
- Inflation
- Inadequate supply chains
- Government restrictions

- Uncertain consumer behavior
- Fierce competition from domestic retailers

The Vietnam's pharmaceutical industry, for example, has experienced high growth in recent years. There are a number of reasons for this. The market has a large (and growing) population (95 million according to a 2016 CIA report), a steadily growing economy, and rising rates of chronic diseases like diabetes, obesity, and cardiovascular disease. Increasingly, we are seeing rates of chronic diseases in developing economies that have historically plagued more developed countries. Estimates for India and China, for example, suggest that these countries have the largest diabetic populations in the world. In addition, the Vietnam's market has grown in part through the government's efforts to provide a system of universal healthcare. In its 2010 announcement, the government said that it would allow 100% foreign ownership of pharmaceutical companies. As a result, the pharmaceutical sector sales have experienced nearly twice the growth rate of gross domestic product (GDP).

Even though these countries contain fewer people than some of the others in the region, their demographics (e.g., higher incomes and increased life expectancy) may still make them attractive markets. In addition, characteristics like the fact the Singapore promote itself as a center for medical tourism can impact the market as well. Despite all the market potential, ASEAN remains a fiercely competitive region for pharmaceuticals. Part of the source of competition comes from the highly fragmented industry with literally thousands of smaller manufacturers.

Southeast Asia Generic Drug Market

Southeast Asia is a fast-growing market in generics; youthful populace and uninsured greater part speak to an incredible open door for generics in the pharmaceutical business. In spite of the fact that the generics market is right now very little, enhanced access to pharmaceuticals in the locale implies that it is developing quickly. The bland market in Southeast Asia was near 8.8 bn in 2016 (consolidated offers of main 5 nations). This reality is required to both heighten rivalry and pull in multinational pharma organizations to the range. Expanding utilization of generics in the locale is required because of both social insurance changes making drugs accessible to a greater amount of the populace – and legislative cost-control techniques. Generics pieces of the overall industry shift from nation to nation, displaying contrasting open doors for generics producers.

Figure 11 Southeast Asian Countries Generic and Prescription Drug Sales in Southeast Asia

Southeast Asia OTC market

Globally, over-the-counter (OTC) sedate deals have been expanding lately. This pattern is driven to some degree by forceful endeavors of worldwide pharma organizations to use the brand value that real items have accomplished amid the patent time frame. Other significant champs in the OTC classification incorporate items where patients keep on buying specific cures taking after an underlying specialist's remedy.

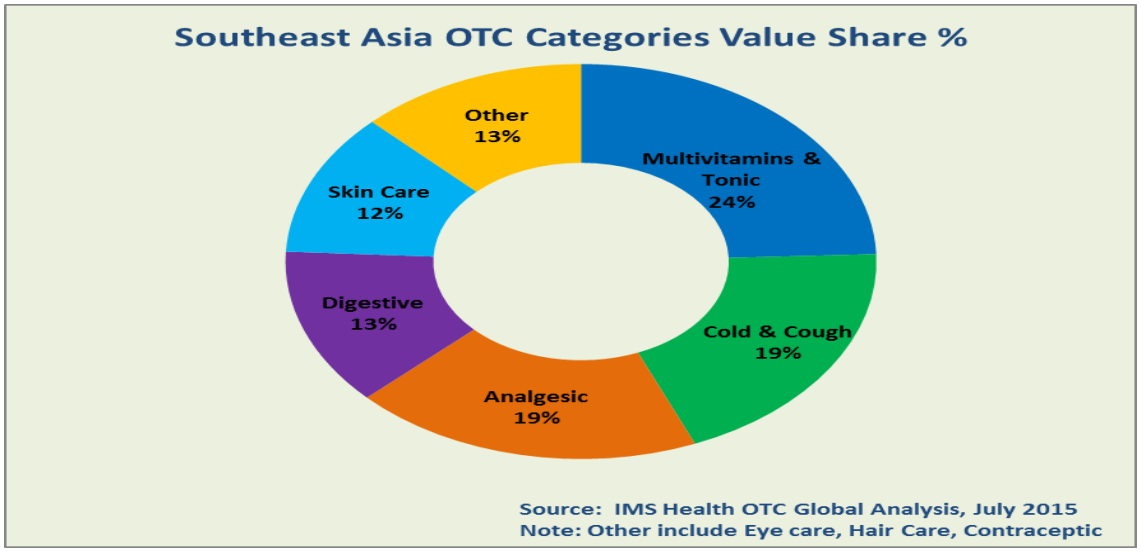


Figure 12 Southeast Asia OTC Categories market share

Key drivers of OTC market development will be for the most part constrained to volume, as buyers turn out to be better instructed and surer about self-pharmaceutical. OTC medications will likewise profit as buyers' spending power increments, and - on account of the low-salary populace - they may well swing to OTCs and customary

prescriptions to look for less expensive contrasting options to endorsed drugs. In any case, regardless of these difficulties, vitamins and dietary supplements are one of the quickest developing sections of OTC social insurance in Vietnam, with analgesics remaining the smash hits. Single vitamin supplements have turned out to be basic family unit items in the Southeast Asian Countries.

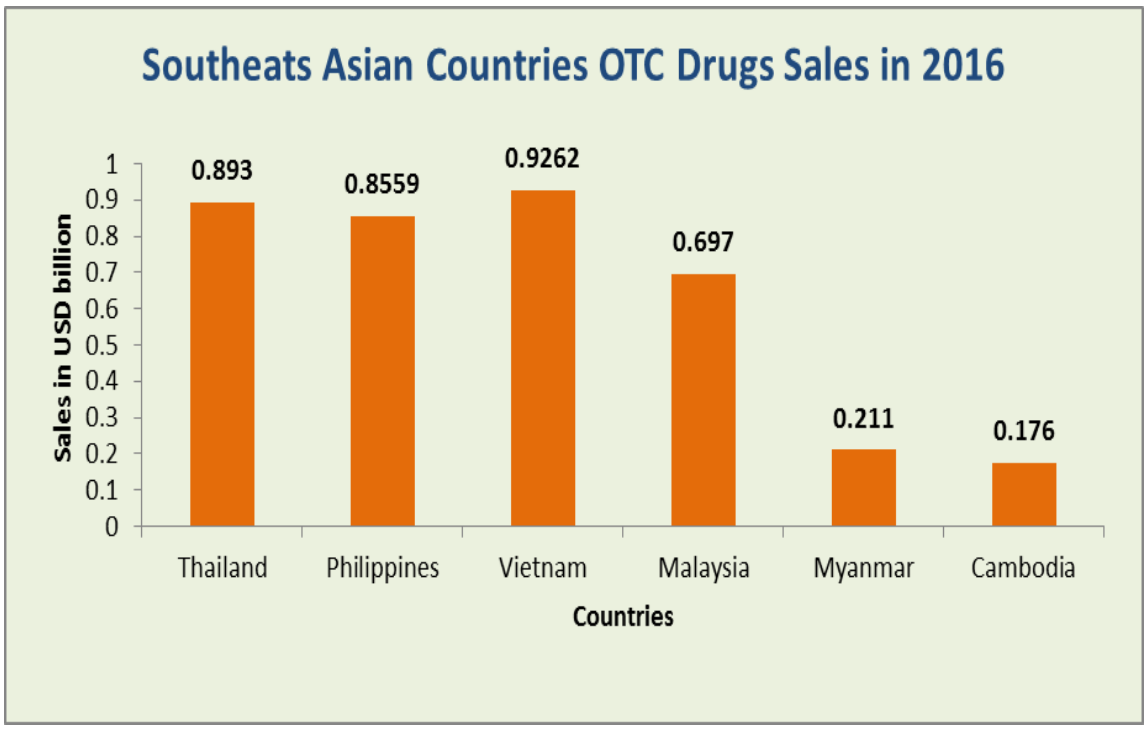


Figure 13 Southeast Asian Countries OTC Drug sales in 2016

The Government is now considering plans to expand the list of drugs which can be sold outside pharmacies since many common household remedies are more difficult to obtain in India than in other developing countries An expansion of the list would substantially increase the potential market opportunity in this segment.

Southeast Asia Import- Export

The pharmaceutical industry in Southeast Asia is based largely on imported Drugs which accounts for around 70-80% of Pharmaceutical products, while exports are estimated at only 20-30% of market volume. The exports is increasing year-on-year to double digit, pharmaceutical manufacture in Southeast Asian Countries very small.

Out of the imported pharmaceuticals, the biggest exporters are, India South France, Germany, Switzerland and Italy accounting together for around 55% of the whole import volume. Whereas the major exports of these countries are within the Southeast Asian region.

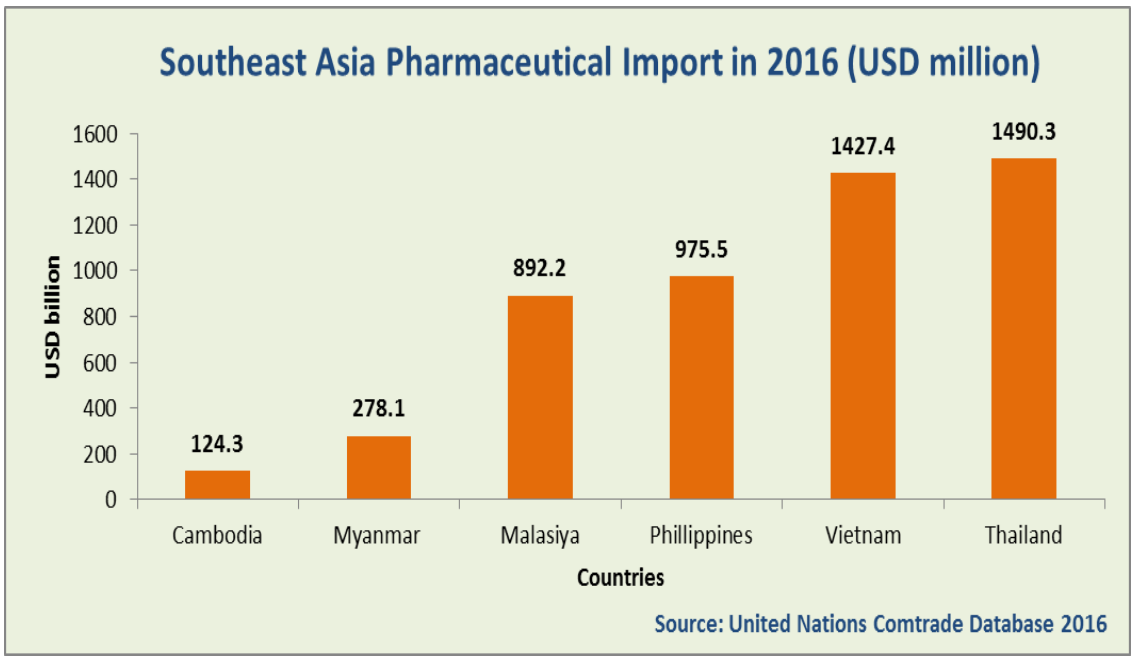


Figure 14 Southeast Asian Courtiers Pharmaceutical Import in 2016

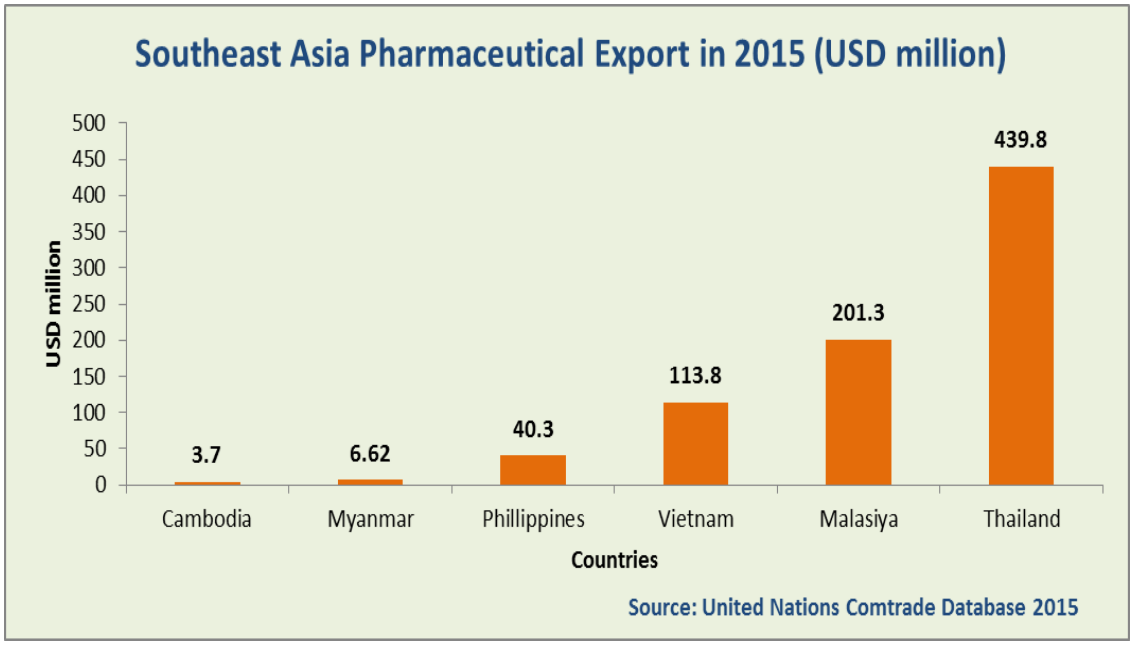


Figure 15 Southeast Asia Pharmaceutical Export in 2015

Clinical Trials in Southeast Asia

In recent years, the infrastructure available for conducting clinical trials in Southeast Asia has improved drastically. From 2002 to 2015 more than 4,917 trials are conducted in Southeast Asia, the Thailand leads the way with 2201 studies ongoing or completed (clinicaltrials.gov). While Singapore reported 1916 studies. Philippines are next with 1076 studies which cover oncology, autoimmune, cardiovascular and infectious disease.

Still establishing their credibility as clinical trial destinations, the rest of the countries in the region have fewer ongoing or completed studies; Malaysia (928), Cambodia (65), Myanmar (15), and Nepal (73).

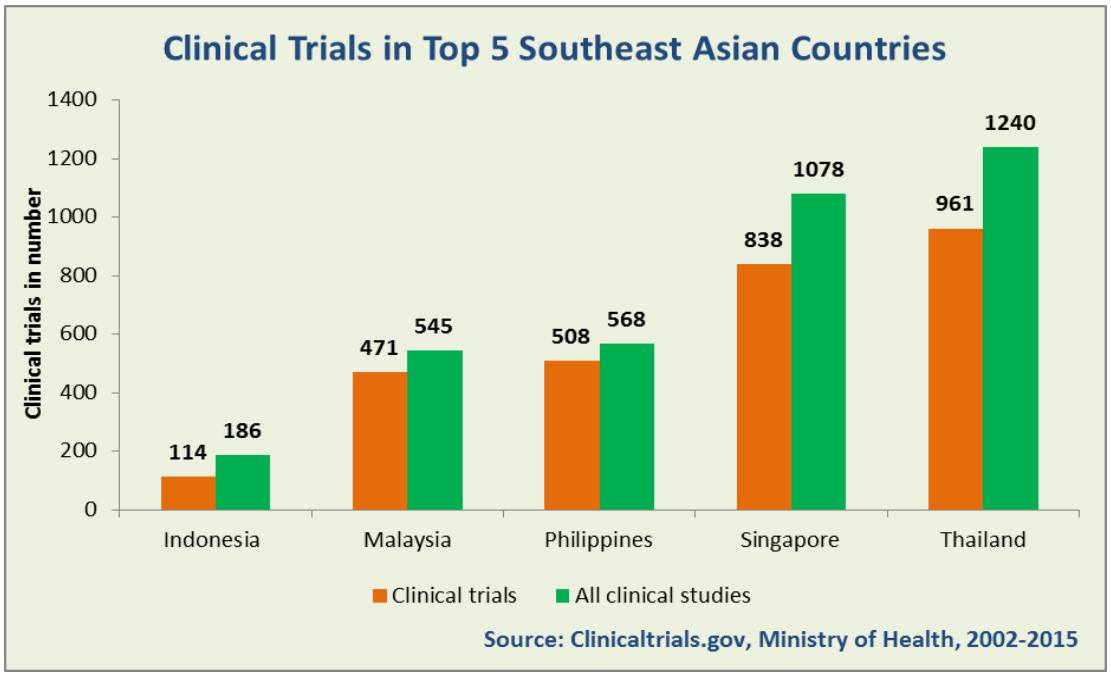


Figure 16 Top Countries Clinical trials

It is expected that the globalization in drug development and the emerging trend of Asia pacific trials will create increasing demands on Southeast Asian sites and fuel the growth of the clinical trial market in the region.

Regulatory Environment in Southeast Asia

As far as administrative, the Southeast Asian nations are winding up noticeably more structured in the administrative circle. Levies will be dispensed with and different obstructions between the nations will be eliminated. Take a shot at orchestrating norms started in 1997, with pharmaceuticals, restorative gadgets, and wellbeing supplements reserved as needs. In particular, ASEAN pioneers have consented to common acknowledgment of investigations of therapeutic items producers, including post-advertise evaluations. Southeast Asian countries required to fill an ASEAN Common Technology Dossier (ACTD) as the main administrative recording required for pharmaceutical organizations to pick up endorsement of their medications in the 10-part. When all is said in done, this institutionalization ought to decrease intricacy for producers keen on venturing into this locale. Harmonization of benchmarks will assist part nations with lowering expenses and increment the quality and accessibility of prescriptions in the locale. It likewise defines rules for bringing in medications to

guarantee quality medications for the area. Reviews or item cautions in one nation will be relevant for all the part countries.

Drug Registration Requirements in Southeast Asian Countries

ASEAN district is considered as "Developing business sector" for pharmaceutical fare and two-sided exchange. The comprehension of the enlistments &regulatory necessities of this district can be helpful for Pharmaceutical fare. The directions of ASEAN nations are empowering the import of value nonspecific items

Dossier requirements

- The dossier requirements for the ASEAN countries are in principle very similar to the requirements for the ICH countries.

- ASEAN Common Technical Dossier ACTD is common application format that will be submitted to ASEAN regulatory authorities for the registration of pharmaceutical products for human use.

Comparison of Administrative documents in Southeast Asian countries

Technical Document Comparison in Southeast Asian countries			
Sr.no	**Country**	**Validity**	**Format Followed**
1	CAMBODIA	5 Years	ACTD
2	MALAYSIA	5 Years	ACTD
3	MYANMAR	5 Years	Country specific & ACTD
4	PHILIPPINES	5 Years	Country specific & ACTD
5	THAILAND	5 Years	ACTD
6	VIETNAM	5 Years	ACTD

Table 2 Technical Document comparison amongst Southeast Asian Countries

Sr.No	ADMINISTRATIVE DOCUMENTS	MALAYSIA	THAILAND	VIETNAM	CAMBODIA	PHILIPPINES	MYANMAR
1	Application Form	✓	✓	✓	✓	✓	✓
2	Copy of valid certificate of brand Name clearance	✓	✓	✓	✓	✓	✓
3	Certificate of Pharmaceutical product	✓	✓	✓	✓	✓	✓
4	Free Sale Certificate	✗	✗	✗	✗	✗	✓
5	Good Manufacture Practice	✓	✓	✓	✓	✓	✗
6	License for pharmaceutical Manufacture	✗	✓	✓	✓	✗	✓
7	Site Master File	✗	✓	✓	✓	✓	✓
8	Permission for manufacturing & Marketing in country of origin	✗	✗	✗	✗	✗	✗
9	Letter of Authorization	✓	✓	✓	✓	✓	✓
10	Labeling Documents	✓	✓	✓	✓	✓	
11	Patent Information	✗	✓	✓	✓	✓	✓
12	Summary Product Characteristics	✓	✓	✓	✓	✓	✓
13	Patient Information Leaflet	✓	✓	✗	✗	✓	✓
14	Product Information Already Approved In Any State /country	✓	✗	✗	✗	✗	✓
Source: Country Specific Regulatory Agency							

Table 3 Comparison of Administrative documents requirements

Product Approval Timelines in Southeast Asia		
Countries	**Regulatory Agency/Responsible Government Department**	**Time taken for product approval**
CAMBODIA	Ministry of Health	New Chemical Entity- 1 year Generic/Establish Drug Formulation -3 Months
MALAYSIA	Drug Control Authority (DCA)	New Chemical Entity- 8-12 months Generic/Establish Drug Formulation - 3-6 Months
MYANMAR	Ministry of Health	New Chemical Entity- 1 year Generic/Establish Drug Formulation - 3-6 Months
PHILIPPINES	Food and Drug Administration (FDA)	New Chemical Entity- more than 1 year Generic/Establish Drug Formulation - 3-6 Months
THAILAND	Thailand Food and Drugs Administration	New Chemical Entity- 1-2 year Generic/Establish Drug Formulation - 3-6 Months
VIETNAM	Ministry of Health	New Chemical Entity- 1 year Generic/Establish Drug Formulation - 3-6 Months
Source: Country Specific Regulatory Agency		

Table 4 Product Approval timeline in Southeast Asia

Challenges and opportunities in the Southeast Asia regulatory landscape

The Southeast Asia region is currently undergoing a period of rapid growth. From the perspective of the pharmaceutical industry, the Southeast Asia region in APAC represents a large and rapidly expanding market. One such area demonstrating this growth is the Association of South East Asian Nations (ASEAN).ASEAN was established in 1968 with the aim of promoting regional growth, peace, and harmonization among member states by assisting each other in economic, social, cultural, technical, scientific and administrative matters. Five countries initially signed the ASEAN declaration, founding the association: Indonesia, Philippines, Thailand, Malaysia, and Singapore. Over the years, the organization expanded to include Brunei, Vietnam, Laos, Myanmar (Burma) and Cambodia. As of 2014, the region encompassed a population of over 646 million people and it is expected to grow to approximately 680 million people by 2020.

In 1999 ASEAN established the Pharmaceutical Product Working Group (PPWG) in an import to develop a more sophisticated regulatory framework, which is at varying stages of implementation across the region. PPWG is comprised of representatives from each of the ten member states' respective regulatory bodies (or government factions responsible for the regulation of pharmaceuticals), with attendance of each country being voluntary. The role of the PPWG has been to incorporate elements of the International Council for Harmonization (ICH), relevant to ASEAN, into regional guidance. The PPWG is tasked with creating committees to assess the opportunities for regional regulatory harmonization and to develop common guidelines; the findings of these committees are then reported back to the Consultative Committee for Standards and Quality (ACCSQ).

Challenges in Southeast Asia

One of the biggest challenges facing ASEAN is the harmonization of a diverse group of countries. The ten member states have large contrasts in a number of key fields, for example, different languages and vast ranges in population. The ASEAN region has a population of more than 646 million; however, distribution is uneven across the individual nations. For example, with a population of 252 million, Indonesia represents a potential market 610 times the size of Brunei Darussalam, which has a population of just 413,000 people. There is also broad economic diversity; in 2014 the urbanest member state, Singapore, had an average GDP per capita of US$ 87,100, one of the highest in the world, whereas Laos had an average GDP per capita of just US$5,700.

Consideration should also be given to the fact that the level of health insurance coverage is not uniform across the region. In most member states, a large proportion of the healthcare bill is paid for by the individual, rather than the state. More than 50% of healthcare spending in Cambodia, the Vietnam, and Singapore is paid for out-of-pocket, giving a clear sense of how the varying GDPs of the member states can have an impact on the overall size of the region's pharmaceutical industry.

Desirable healthcare products and services vary by country and are also impacted by the region's uneven distribution of wealth. For example, branded pharmaceuticals with a higher price tag may be more popular in the wealthier states of Singapore or Brunei than in the lower income member states, where generic products would be preferable. However, factors other than financial implications contribute to the type of pharmaceuticals companies in different member states. For instance, Cambodia's higher birth rate would suggest an increased demand for pediatric products and vaccines.

Variations in infrastructure cause uneven distribution networks, impacting the standard of healthcare available throughout ASEAN member states. Access to healthcare professionals and services tends to be concentrated in urban areas and it can be difficult for those residing in remote and rural areas to get access to quality pharmaceuticals and treatment

In addition to financial and social constraints, the Southeast Asian regulatory industry faces challenges due to a gap between the regulatory legislation issued by national governments, and the actual enforcement of these laws at a local level. The majority of pharmaceutical products in the region are imported, either as the final product or as base materials which are then manufactured into the finished product locally. There are serious problems with high volumes of counterfeit products making their way onto the market. Counterfeit products have been found to be more prevalent in the poorer economic states, such as Cambodia, where they often lack the funding to effectively enforce the regulations.

Intellectual property (IP) rights are another challenge within the Southeast Asian region. There is a high degree of variation in the legislation regarding IP and a general lack of expertise on the subject. This has created hurdles for the regulation of the pharmaceutical industry in terms of their ability to ensure the production of safe and efficacious products. In Indonesia, for example, patents are only extended to products that have been manufactured within the country; therefore, any foreign products that have been registered in Indonesia are at risk of local companies manufacturing the same

product and marketing it at a reduced price as a generic under a new name. The lack of clear pathways to IP protection in the region has led to a negative impact on the relationships between ASEAN regulatory groups and the international pharmaceutical markets.

Future regulatory opportunities for Southeast Asia

Despite the numerous challenges, ASEAN initiatives are already beginning to demonstrate a positive impact on the state of regulatory affairs. For example, at a meeting of the World Health Organization (WHO) in 2004, the representatives of ASEAN raised concerns about the stability zone assigned to their region. The ASEAN delegates highlighted that the existing zone IV stability designation (30°C/65%_RH) did not adequately meet the climatic conditions in their region. The WHO responded to the claims by sub-dividing zone IV into zone IVa (30°C/65%_RH) and zone IVb (30°C/75%_RH). All ASEAN member states were then assigned to stability zone IVb.

The impressive market growth statistics demonstrated across the ASEAN region, and the trend towards increased healthcare spending in many of the member states would suggest that ASEAN's regulatory affairs will continue to develop through increased industry awareness and investment.

In 2007, ASEAN member states committed to the creation of an integrated economic region known as the ASEAN Economic Community (AEC). The ASEAN pharmaceutical sector falls under the jurisdiction of the new AEC, through the AFTA, and the aim is that a single market would further increase the region's ability to compete globally, through improving its economic development. However, it has become evident that the original implementation date of 2015 was unrealistic and the move towards economic harmonization will need to be more of a gradual transition.

Traditional Medicine in Southeast Asia

The South-East Asian countries have a rich heritage of several systems of Traditional Medicine (TM), many of which are popular in use. World Health Organization has been assisting countries to promote the use of Traditional Medicine so that this valuable resource is utilized safely and effectively.

All nations in the South-East Asia Region of the World Health Organization (WHO) have a legacy of conventional frameworks of prescription. There are extensive quantities of customary solution experts who give assistance and administration to the evil and the destitute. It is critical that this special information frequently found in

antiquated writings, be used by nations to the most extreme degree conceivable without destroying nature and devastating the very plants which are the wellspring of the prescription.

More noteworthy utilize could be made of these restorative plants at the essential human services level so that all people could have response to natural medicine– particularly those living in regions with no allopathic social insurance scope. Additionally examine coordinated at a couple of the interminable sicknesses against which more medications are required, for example, diabetes, bronchial asthma, and joint pain, could prompt the revelation of new medications for these conditions. Directed and specific fare of some of these therapeutic plants being excitedly looked for after in different parts of the world could extensively upgrade the remote trade income of nations with this biodiversity. Watchful arranging is required so that such a program could be propelled without impediment to nature and without diminishing the accessibility of the therapeutic plants in the nations. The extensive quantities of prepared and semi-prepared experts of the conventional frameworks of pharmaceutical could turn out to be more required in the national human services frameworks of the nations. Such association can occur just thus of some direction of the frameworks being taken after, the items utilized for human services and the professionals of such frameworks.

It is critical likewise to find a way to guarantee that deceptive and unjustified misuse of these plants, which have been utilized for a considerable length of time, is prevented– particularly the licensing in western nations of these cures. In the meantime it is important to ensure the revelations being made in the nations of the Region by researchers and research specialists who are doing research and finding and recording the viability of the plants utilized.

Medical Tourism in Southeast Asia

Medical tourism is a rapidly growing industry in Southeast Asia. The treatment could include procedure like surgery, specialist treatments such as chemotherapy for cancer, major and minor surgeries or even routine health checks. Southeast Asia becoming one of the world’s regions with the largest inflows of international patients, the availability of lower-cost quality healthcare is the key driver of medical tourism in the region. Healthcare in Thailand is available at half the cost of similar care in the US. Estimates place revenues from medical tourism in Thailand, the world’s top medical travel destination, at US$3 bn.

Thailand, Singapore, and Malaysia are positioning themselves as medical tourism hubs and each enjoys a reputation for providing world-class treatments at internationally accredited hospitals Thailand and Singapore respectively has 30 and 15 private hospitals accredited by Joint Commission International (JCI).

Medical Tourism in Malaysia, Singapore and Thailand			
Countries	**Estimated Revenue**	**Number of patients**	**Origin of patients**
Malaysia	$650 million	0.583 million	Japan, India, Europe, Indonesia, Singapore
Singapore	$3.5 billion	0.856 million	Middle East, Indonesia, Malaysia,
Thailand	$4.3 billion	2.5 million	UK, Middle East, ASEAN countries, Japan
Source: Malaysia Healthcare Travel Council 2014			

Table 5 Medical tourism in Southeast Asia

Reasonableness is the key driver of restorative tourism. Malaysia Healthcare Travel Council look into demonstrates the cost of treatment in the US is seven-to-nine times higher than in Thailand, Malaysia or Singapore. Moreover, each of these three nations is creating itself as a focal point of greatness for particular medications. Thailand has earned a strong notoriety for restorative surgery and sexual orientation reassignment systems, and also having an extensive variety of reasonable properties and goals to decide for the strengthening time frame. Both Singapore and Malaysia are all inclusive perceived for heart and neurological surgery and joint substitutions. Thailand, Singapore, and Malaysia each had a clinic in the Top 10 World's Best Hospitals for Medical Tourists chosen by the Medical Travel Quality Alliance in 2014, with Malaysia taking shaft position. Medications canvassed in this examination are heart sidesteps, heart valve substitutions, angioplasties, hip substitutions, hysterectomies, knee substitutions and spinal combination.

Medical Niche	USA	India	Thailand	Singapore
Angioplasty	57K	5K–7K	13K	11.2K
Heart bypass	80K–130K	6.7K–9.3K	11K	16.5K
Heart valve replacement	160K	9K – 11K	10K	12.5K
Knee replacement	40K	6.2K–8.5K	10K	11.1K
Hip replacement	43K	5.8K–7.1K	12K	9.2K
Source: Malaysia Healthcare Travel Council, 2014 Note: All Value in USD				

Table 6 Medical niches in Southeast Asia

Singapore and Thailand, are facing increasing competition from emerging healthcare destinations in South Korea and India, Providers in Cambodia, Indonesia and Vietnam are also eyeing a piece of the medical travel market. Bali – Indonesia's prime tourist destination will see a new hospital equipped with world-class facilities, including an integrated cancer treatment centre open in 2017. Increased competition for the share of international medical travel seeking lower-cost care out of their home country is driving countries to find their niche among healthcare service offerings.

Pharmaceutical Distribution Network in Southeast Asia

Southeast Asia's geography has made it's very difficult to build and maintain a nationwide distribution network because of regional segmentations and local interest protection. Although a broad and efficient transportation infrastructure including railway system, highway network, and third-party logistics has been built all over Southeast Asia. A lack of efficient distribution service and effective supply chain management is still challenging Southeast Asia's Pharmaceutical Industry. The traditional state-owned regional distribution system which stems local service have few business connections with another regional network, so it is challenging for pharmaceutical manufacturers to set up a nationwide supply chain to distribute their products. Figure demonstrates the distribution network of Southeast Asia.

Figure 17 Pharmaceutical Distribution network in Southeast Asia

Vietnam

Overview

Vietnam is found to be the easternmost part on the Indochina Peninsula in Southeast Asia. It is bordered by Cambodia to the southwest, China to the north and Laos to the northwest. Vietnam is known as one-party communist state which consists of Southeast Asia's rapidly expanding economies as well as aims to become a developed nation by 2020. Record of past three decades reflects the remarkable development in Vietnam. The development and has molted Vietnam from world's poorest nations into a lower middle-income country.

Vietnam has taken the pleasure of robust economic growth. Since 2010, Vietnam's gross domestic product growth has found to be among the fastest Southeast Asia, with an average of 6.1% in 2016. Even if there is an ambiguity in the global environment, Vietnam's economy remains strong. Vietnam's medium-term outlook remains favorable; whereas the essential growth drivers of the country remain strong domestic demand and export-oriented manufacturing remain in force.

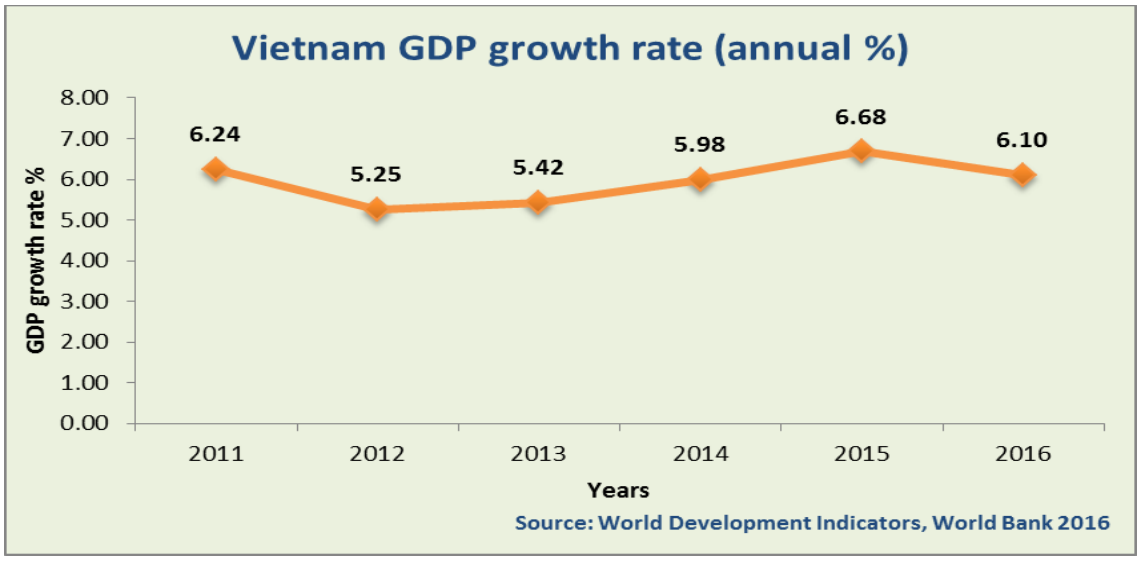


Figure 18 Vietnam GDP growth rate (%)

Part of the country population is living below the boundary of national poverty reached 13.5 percent in 2015. It decreases from 60 percent in 1993. The Vietnamese people are today is more educated (literacy rate 94.5%) and healthier in comparison to the data of past two decades and these overture has been appreciated across the society. The outcome of learning has increased rapidly, including in primary school. The mortality rates of infants as well as below five years aged children's have been significantly

reduced in the past two decades, and the life expectancy at birth has now increased and reached to 73.4 years. A substantial improvement has been noticed in terms of access to basic infrastructure. Due to which more than 78 percent of the population is now able to access the sanitation facilities.

Constant up gradation in the agriculture sector also plays a key role towards the success, as agriculture will continue to be an important accelerating growth factor as well as helps in reducing the poverty in Vietnam for the coming years.

The Government of Vietnam is committed towards the constant amendments in the law. The Socio-Economic Development Plan (SEDP) for the years 2016 to 2020, was approved in April 2016, acknowledges the gradual advancements on certain policy priorities as well as pay attentions towards the need to fasten the reforms.

Key Indicators

Demographic	Indicators
Location	Southeast Asia, edging the Gulf of Thailand, and the South China Sea, as well as China, Laos, and Cambodia
Total Area	331,210 sq. km
Climate	tropical in south; monsoonal in north with hot, rainy season (May to September) and warm, dry season (October to March)
Population	95.26 million (July 2016)
Age structure	**0-14 years:** 23.84% **15-24 years:** 16.69% **25-54 years:** 45.22% **55-64 years:** 8.24% **65 years and over:** 6.01%
Urban population	33.6%
Population growth rate	0.95%
Literacy	94.5%
Languages	Vietnamese (official), some French, Chinese, and

	English (increasingly favored as a second language)
Economic	**Indicators**
Currency	Vietnamese dong
GDP (official exchange rate)	$200.5 billion
GDP - growth rate	6.1%
GDP - per capita	$6,400
GDP - composition by sector	**Agriculture:** 17% **Industry:** 39% **Services:** 44%
Industries	food processing, garments, shoes, machine-building; mining, coal, steel; cement, chemical fertilizer, glass, tires, oil, mobile phones
Healthcare	**Indicators**
Health expenditures	7.1% of GDP
Hospital bed density	2 beds/1,000 population
Major infectious diseases	**Food/ Waterborne diseases:** hepatitis A, and typhoid fever, bacterial diarrhea **Vectorborne diseases:** malaria, and Japanese encephalitis, dengue fever
HIV/AIDS - adult prevalence rate	0.48%
Obesity - adult prevalence rate	3.5% (2014)
Source: Central Intelligence Agency 2016	

Pestle Analysis

Political

The Prime Minister of Vietnam leads the government, controlling over the council of ministers possessed of three deputy prime ministers and the heads of 26 ministries as well as commissions. The Communist Party maintains the political ambiance comparatively balanced since there have been few brawl. In 2014, Vietnam was ranked at 119 out of 175 countries being reported under Corruption Perceptions Index

(Transparency International 2014). Such influencing factor clearly reflects an uncontrollable impact over the business of foreign as well as non-state-owned organizations. The Government stability and Bureaucracy likely to Change in coming years for Vietnam

Economic

Vietnam's GDP purchasing power parity is $555 billion. The country falls in the lower-middle income group of countries. Its GDP growth rate was 6.1% in 2016. Therefore, it is harmless to state that Vietnam is a potential market for any business. The inflation rate of the country was measured 2.8 percent in 2016. Also the unemployment rate is recorded to be 3.7 percent in 2016 (The World Bank 2016, CIA), which projects comparatively very low percentage. It has very low per capita income and high health expenditure. Country's total import in the year 2016 was USD 161 billion; major imported products are machinery and equipment, steel products, raw materials, petroleum products.

Social

The population of Vietnam was 95.26 million in 2016; the official national language of Vietnam is Vietnamese. The style of living of Vietnamese people can be described as informal, relaxed and closed to each other. This can be one of the elements that companies in sharing economy can take as an advantage. On the other hand, there is an existence of a social issue which can heavily affect such businesses, because it is one amongst the most important principles of the peer-to-peer economy – trust. Presently, the media has been deliberately exposing frauds, crimes, rapes and robbery, which was also happening over the past years but currently it has gathered much better attention. 33.6 percent of the population is stay in urban areas, which implies most is still living in the countryside as well as rural areas, with a limited access to the technological facilities (CIA 2016). Hence, the sharing economy companies may find it difficult to enlarge their customer base as it majorly depends upon the high level technology.

Technological

The swift change as well as development in the technology might have an unexpected and unpredictable impact over the Vietnam. Vietnam has been ranked as the seventh among the countries with high usage of the internet in Asia, by Internet World Stats; the domestic manufacturers are still relatively new to the market. Vietnam will continue to implement tax cuts as part of its commitment under the information technological

agreement. This all illustrates a country open to adopting new technologies but lacking in knowledge and dependent on external expertise. The technology markets in Vietnam are currently growing but are still in the early stages of development, this provides an excellent opportunity for any company with a technological product or service to gain a good market share in an emerging marketplace.

Environmental

Hanoi is found to be the most polluted city in Vietnam and is counted among the most polluted cities in the Southeast Asia because of the large population density as well as excessive transportation. Increasing pollution remains an unsolved problem for Vietnam. However people in Vietnam are very much aware with the surrounding environment, natural disasters rarely hit most parts of Vietnam. On the contrary, cities resides the coastline located in the middle part of the country are continually demolished by storms and floods.

Vietnam is facing a combination of environmental challenges including air, water, and solid waste pollution. Most of the cities as well as provinces have no centralized wastewater, solid waste or hazardous treatment plants. Poor transportation connections and hilly areas may create links between north and south more challenging. Varied in weather conditions also need to be considered carefully. Many banks are creating a block by providing lack of funds to the companies; those are contributing in the pollution. Also banks are adjusting their policies by rejecting the clients on the basis of environmental blacklist. Such environmental problem opens lot of opportunities for exporters to Vietnam

Legal

Vietnam lacks an independent judiciary; as the country's judiciary is under the control of the CPV. Vietnamese legislation is still weak results in the legal system being inadequate and unstable. Vietnam's legal system is rapidly evolving. The legal framework is extremely inadequate in terms of the consistency, transparency and dependability. Ambiguity in the legal environment is the top concern for both local as well as for the foreign investors in Vietnam (The World Bank 2014). With the continuous efforts by the government to improve its institutional systems

Business Environment in Vietnam

The economy of the nation is directed by the state-claimed ventures, which catches for approximately 40% of the Gross National Product (GNP), the legislature has likewise broadcasted its dedication towards the financial progression and in addition the worldwide coordination. with a specific end goal to make nation's privatization more complete, the administration is pushing the development of household endeavors. Mainly, the Vietnam is a creating nation and, has experienced poor foundation. In any case, it has started to make noteworthy speculations from the remote financial specialists.

By 2018, the state tries to change the present imposing business model and in addition sponsored control circumstance with a focused power-era advertises. In seaport development, the Public-private Partnership (PPP) type of speculation has been upheld and is winding up plainly progressively prominent. Despite the fact that different measures have been taken keeping in mind the end goal to enhance the authoritative condition, this remaining parts an issue and has weakened the enthusiasm of remote financial specialists' in Vietnam's business condition.

Figure 19 Vietnam Doing business environment

Healthcare in Vietnam

The Healthcare spending in Vietnam will be worth close to $14.93 billion in 2016, Healthcare expenditure was 7.1% of GDP in 2014. Vietnam's healthcare expenditure may reach to as high as USD 20 billion by 2020 at CAGR of 7%, due to the rising incidences of NCD's, increasing aging populations.

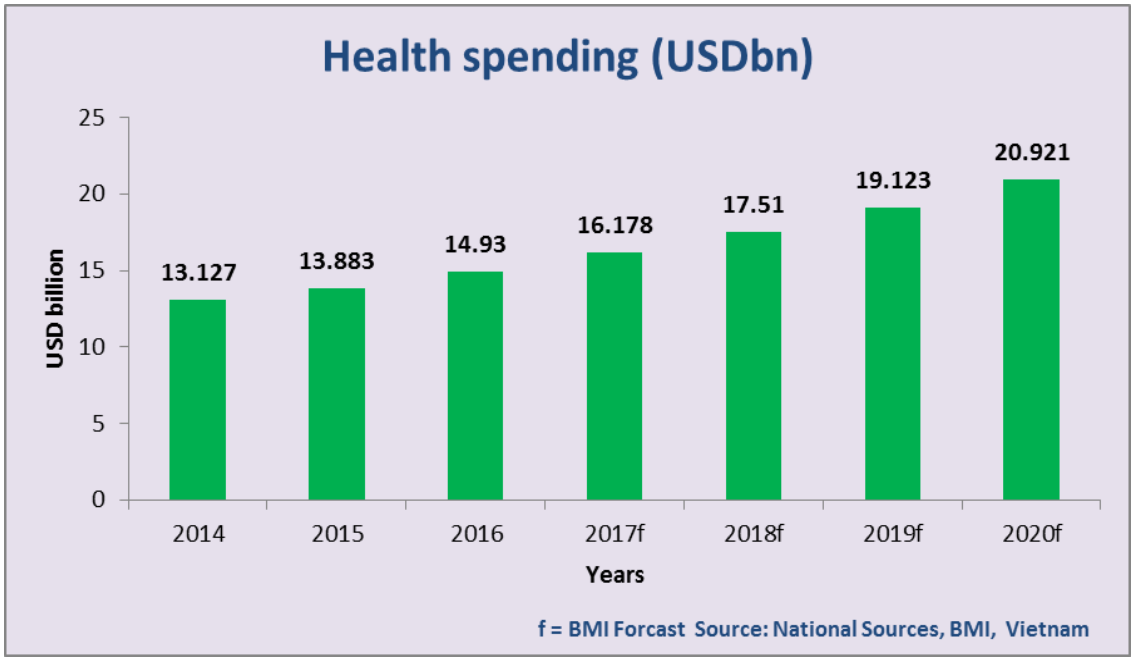


Figure 20 Vietnam Healthcare spending 2014-20.

Presently, 71.6% of the population having health care insurance. The government is currently subsidizes almost 80% of the hospital fees for the poor as well as near to poor, and 100% of poor people and ethnic minorities living in impoverished areas, and 30% to the farmers and fishermen who have an average living conditions.

The hospital sector in Vietnam still faces significant room for improvement: firstly, the number of facilities is rather small leading to constant overflow of visitors. Consequently, the hospital bed occupancy rate (BOR) exceeded 100% in 2011. In the same year, Vietnam had 1000 state hospitals, more than 120 local private hospitals and outside invested hospitals with a total of 145,550 beds.

Vietnam's healthcare sector, since despite the public's poor healthcare system, the economic development of the country is considered very positive. Recent years have seen a major influx of overseas investors and specialist medical service providers, largely drawn by the inability of local players to service growing demands.

Vietnam has experienced a rise in the number of patients with non-communicable diseases (NCDs). After the introduction of the antimalarial drugs and its treatment Vietnam was able to combat malaria out of the country. In 2014, currently, most commune medical clinics only have approximately 60% of the necessary medical equipment due to low financing.

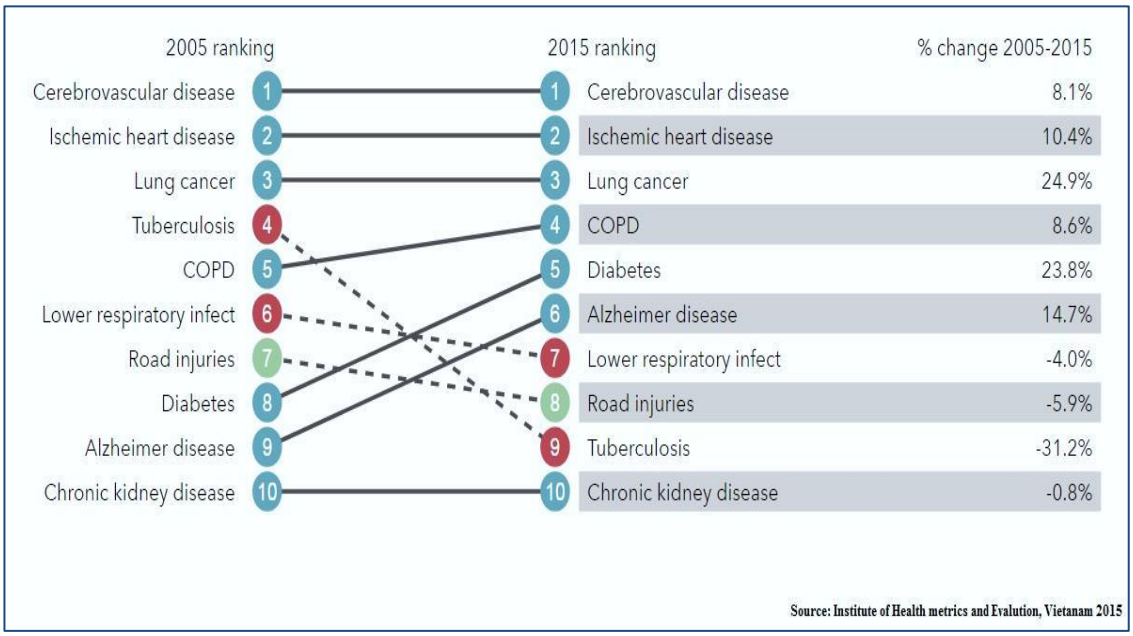


Figure 21 Top 10 causes of death by rate in Vietnam 2015

Pharmaceutical Market in Vietnam

The Vietnam's Pharma industry was valued at VND 105.6 trn (USD4.7 bn) in 2016 and it is expected to grow by 8.82 per cent per annum between 2016 and 2020, the market is expected to grow to US$ 7.21 billion by 2020.

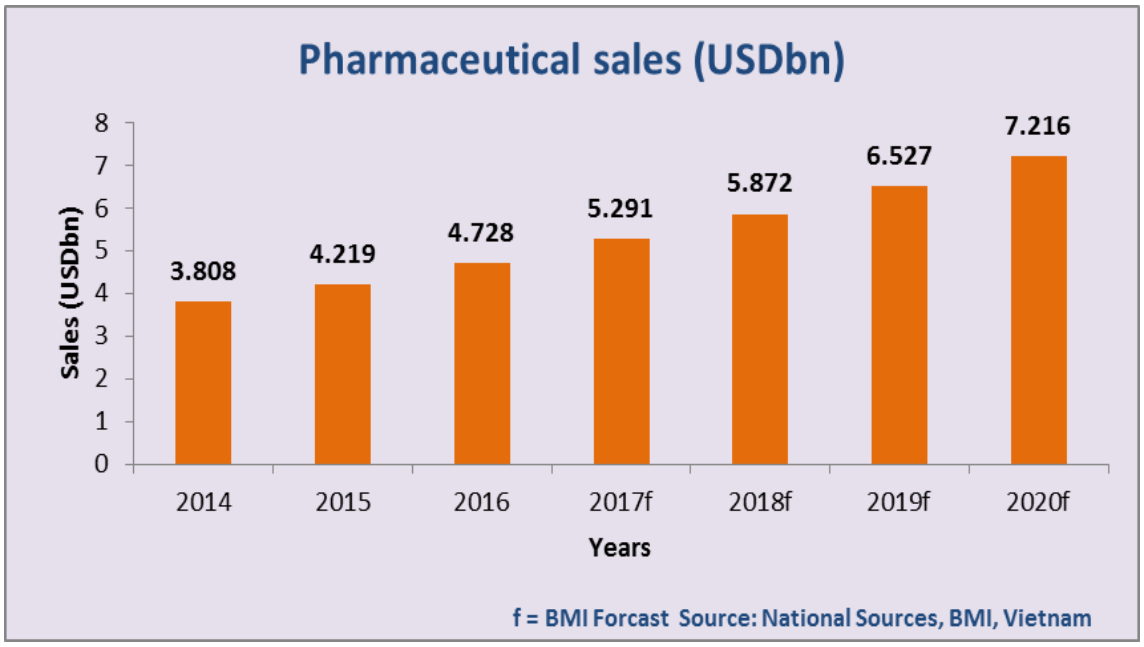


Figure 22 Vietnam Pharmaceutical Sales forecast 2020

Inflation is one of the major factors in these high nominal market growth rates. However, there is abundant scope for the increasing pharmaceutical consumption in the country where per capita drug expenditure is just USD $40.94. Assuming the required resources have put into the development of the healthcare sector. However, pricing still remains a key concern due to the lack of control, as well as regulatory bias against the foreign products.

In the present time, high demands for nutritional supplements and alternative pharmaceutical products are boosting chances for newly-born manufacturers and therefore creating a lot of competition between pharmaceutical companies. Meanwhile, much controversy is raging over the side effects of drugs and shady marketing strategies employed by those pharmaceutical companies. Despite the exports' year-on-year double-digit increase, pharmaceutical manufacture in Vietnam stays small. Out of the imported pharmaceuticals, the biggest exporters are France, India South Korea, Germany, Switzerland, and Italy accounting together for around 54% of the whole import volume.

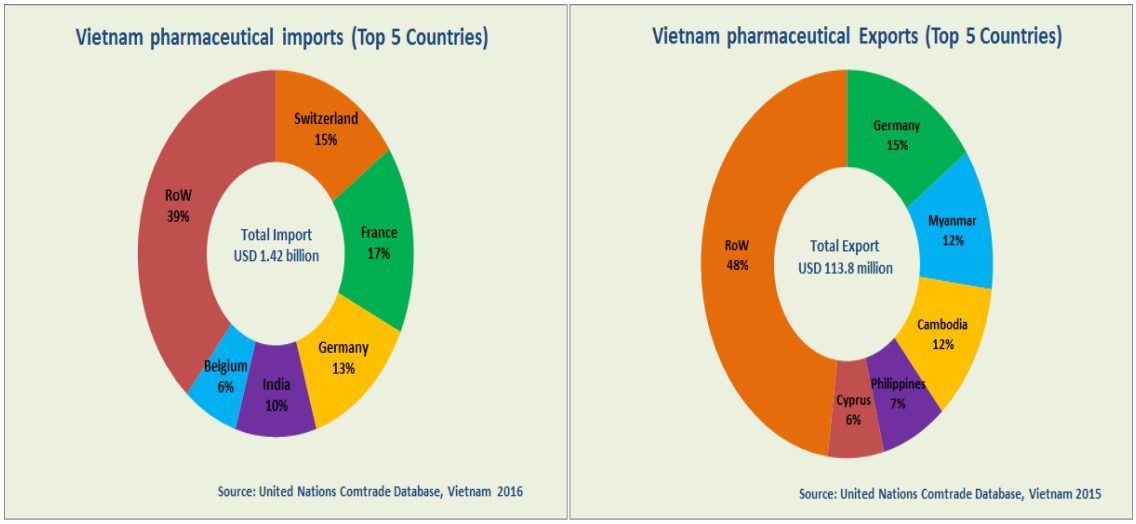


Figure 23 Vietnam Pharmaceutical Import-Export

Vietnam's local pharmaceutical industry will have a significant role to play in the expansion of the pharmaceutical market. Improvements in the manufacturing plants, adherence towards the international quality standards and partnerships with multinational firms are essential to ensure the overall quality of the product. Vietnamese firms can meet government plans to provide for 50% of domestic demand by 2020.

Commodity	Qty 2015-16 (Kg)	2015-16 Value (US $)	Qty 2016-17 (Kg)	2016-17 Value (US $)	Percentage Growth in Value (2017 over 2016)
AYUSH AND HERBAL PRODUCTS	11764900	12329443	10860647	16001642	29.78
BULK DRUGS, DRUG INTERMEDIATES	9777059	65549115	10928017	75671436	15.44
DRUG FORMULATIONS, BIOLOGICALS	5853750	152132265	5390676	139868000	-8.06
Total	27395709	230010823	27179340	231541078	0.67
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 7 Vietnam Pharmaceutical Import from India

Currently, there is presence of approximately 67,589 pharmacies in Vietnam region. One of the main issues is that patients can get most of the drugs without prescription form the physician. Furthermore, there is a lack of trained pharmacists and counterfeits are common. It is even reported that doctors are still illegally disburse medicines from their private clinics or offices. According to BMI, sales of the patented drug segment will achieve a CAGR of 10% from 2016 to 2020 and account for 20% of the market. The

market of generic drug is gigantic, consisting around $ 2.18 billion in 2016 equaling approximately 50% of the overall market's value.

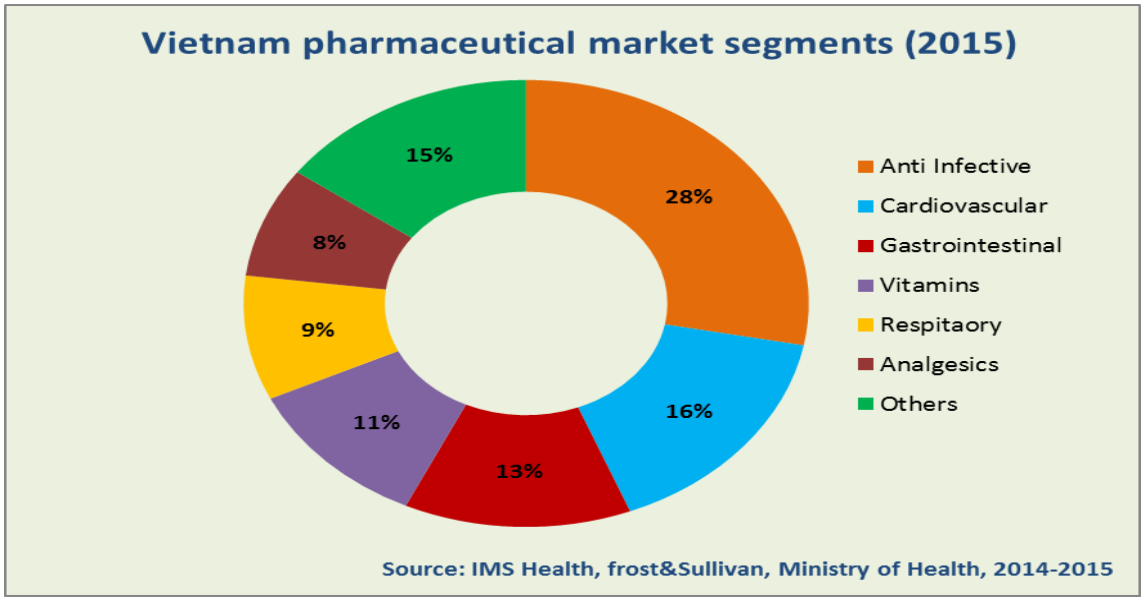


Figure 24 Vietnam Pharmaceutical Market Segment

Based on the government's economic plan, the regulation of drugs, food safety and hygiene and cosmetics will be strengthened and healthcare investment increased, supported by a substantial reorganization of the current network of treatment centers. In 2014, the Vietnamese Prime Minister issued Decision, approving the National Development Strategy of Pharmaceuticals in Vietnam (2020 - 2030) with an overall aim to ensure supply of essential medicines for the prevention and treatment of diseases.

Risk/ Reward Index

Vietnam's Pharmaceuticals Risk/Reward Index score at 48.3 out of a maximum of 100. Vietnam ranked 13th out of 20 countries. Vietnam's score is driven by a relatively large market size and robust sector value growth.

Regulatory Landscape

The Drug Administration of Vietnam (DAV), is working beneath the Ministry of Health, is the country’s primary drug regulatory authority. Regulations often can be unclear, and they frequently are implemented on a case-by-case basis. These uncertainties can pose a barrier to market entry for foreign pharmaceutical companies. Additionally, drug approval times often vary and long delays are typical.

Vietnam’s regulators are facing the biggest challenge with the country’s entrance to the WTO, which was achieved in January 2007. MNC’s have been provided the right to

open the branches in Vietnam and to import medicines directly, although they will still be blocked from distributing their products. Free trade agreements are seen as an obstacle to the use of domestic drugs due to patent conditions.

Major Domestic Player of Pharmaceutical Industry

The major pharmaceutical industries are located in Hanoi city.

1. DHG Pharma
2. Imexpharm Pharma
3. Pharmachem Vietnam Co., Ltd
4. Domesco Medical Import-export
5. Veterco Vietnam Limited
6. Pharbaco Vietnam
7. chaugiang co. Ltd
8. OPC Pharma JSC
9. Lam Dong Pharma
10. Vimedimex Pharma JSC

All above pharmaceutical companies are making generic as well as herbal products which cover higher market share in Vietnam.

SWOT Analysis

Strengths	Weaknesses
1. Commitment of the government towards the development of the health care sector 2. huge generics medicines sector 3. Strong segment of traditional medicines with an potential to improve the non-prescription medicines	1. Patent law relatively below international standards 2. Counterfeit drugs account for a significant amount of market consumption 3. Import-reliable market 4. Population focused in rural areas, rather than urban areas, preventing access to modern drugs
Opportunities	**Threats**
1. The ASEAN harmonization activity, including the appropriation of Western administrative principles, for example, ICH and WHO rules 2. Introduction of five-year restrictiveness for clinical dossier information empowering research-based multinationals 3. The end of the value solidify can possibly help values regardless of a conceivable fall in volumes 4. Radical rebuilding of the pharmaceutical business with an accentuation on remote	1. Government resistance to aligning patent lawfully with international standards deterring multinational sector expansion 2. The government increasingly interfering in the industry 3. Vietnam is highly susceptible to regional and global economic fluctuations 4. The legalization of parallel imports negatively impacting performance of patented drugs

Thailand

Overview

Thailand is based in the center of the Indo-china peninsula in Southeast Asia. It is surrounded to the north by Myanmar (Burma) and Laos, to the south by the Gulf of Thailand and Malaysia, to the east by Laos and Cambodia. Thailand consists a constitutional monarchy, which is led by the Vajiralongkorn, it is the world's longest-serving present leader of the state and the longest-reigning monarch in the history Thai. At present, Thailand is known as the newly industrialized country and a major exporter. Tourism also contributes a significant role in the Thai economy. It is ranked as 20th most populous country, with around 68 million people registered in 2016. Bangkok is the capital as well as the largest city, which is also Thailand's commercial, industrial, political and cultural hub. The official language commonly spoken in the country is Thai. Thailand is known as the nerve center for automotive productions as well as manufacturing sector which generates and contributes into 1/3rd of the GDP of the country's economy.

Thailand is recognized as an upper-middle income Country. Over the last few decades, Thailand has shown a phenomenal breakthrough in the political as well as economic development, which has helped it to step up from a lower-income country to an upper-income country in less than one decade of time span.

There is a significant decline in the poverty over the last three decades from 67% in 1986 to 12.2% in 2016. However, poverty and inequality continues to pose significant challenges with vulnerabilities results in the faltering economic growth, falling agricultural prices, and ongoing droughts. The growth in economy has been a fundamental driver and has helped in the reduction of poverty in Thailand. On the other hand, the growth in GDP was less than 3.2 percent in 2015 and 2016. Despite of the

pressure, Thailand is the only Southeast Asian nation which never has been colonized.

Figure 25 Thailand GDP growth rate (%)

The economy of Thailand is heavily export-dependent, with exports accounting for more than two-thirds of gross domestic product (GDP). Thailand exports over US$190 billion in 2016 worth of goods and services annually. Major exports include rice, textiles and footwear, fishery products, rubber, jeweler, cars, computers, and electrical appliances. The Thai automotive industry was the largest in Southeast Asia and the 9th largest in the world. The Thailand industry has an annual output of near 1.5 million vehicles, mostly commercial vehicles. Thailand Tourism makes up about 17% of the economy. Thailand was the most visited country in Southeast Asia,

Thailand Key Indicators

Demographic	Indicators
Location	Southeastern Asia, bordering the Andaman Sea and the Gulf of Thailand, southeast of Burma
Total Area	513,120 sq. km
Climate	Cool, dry northeast monsoon (November to mid-March), warm, rainy, cloudy southwest monsoon (mid-May to September)
Population	68,20 million (July 2016)
Age Structure	**0-14 years:** 17.18% **15-24 years:** 14.47% **25-54 years:** 46.5%

	55-64 years: 11.64% **65 years and over:** 10.21%
Urban population	50.4%
Population growth rate	0.32%
Literacy	96.7%
Languages	Thai 95.9%, Burmese 2%, other 1.3%
Economic	**Indicators**
Currency	Thai baht
GDP - exchange rate	$390.6 bn
GDP - growth rate	3.2%
GDP - per capita	$16,800
GDP - composition by sector	**Agriculture:** 8.9% **Industry:** 35.9% **Services:** 55.3%
Industries	textiles and garments, tourism, agricultural, beverages, tobacco, automobiles and automotive parts, agricultural
Healthcare	**Indicators**
Health expenditures	6.5% of GDP
Hospital bed density	2.1 beds/1,000 population
Major infectious diseases	**food or waterborne diseases:** bacterial diarrhea **vectorborne diseases:** dengue fever, Japanese encephalitis, and malaria
HIV/AIDS - adult prevalence rate	1.12%
Obesity - adult prevalence rate	9.2%
Source: Central Intelligence Agency 2016	

Pestle Analysis

Political

Thailand has embraced a parliamentary, majority rule type of government, with the King as Head of State under the Constitution, practicing the sovereign power in the organization. The present coalition government headed by Prime Minister Prayut Chan-o-Cha means to improve the intensity of Thailand by widening market access for organizations as a feature of its monetary arrangement, advancing exchange and speculation, taking part in facilitated commerce assertions and co-operation structures to extend universal financial linkages, giving answers for the danger of medications, avoiding and battling debasement, raising the way of life of the Thai individuals through wage increments and expense help, and building up the health care coverage framework. The danger of further developing of the political division and the nation and prompts Myanmar's style dictatorship.

Economic

Thailand's GDP was close to $1.161 trillion in 2016, with a growth rate of 3.2%. Furthermore, with the slowdown in the growth of private investment over the past five years, there exists a significant need for investments and a higher skilled workforce. the increasing fiscal deficit is worrying. The banking sector plays a significant role in the economy. The national budget for 2015-16 was $76.2 billion. Tourism makes up about 17% of the economy. The economy of Thailand is export-dependent, with exports accounting for more than two-thirds of GDP. Major exports include fishery products, rubber, rice, textiles, footwear, cars, computers, and electronic products.

Social

The urban population of Thailand is 50.4% as of 2016; and the official language of Thailand is Thai. Thailand follows majorly Buddhism religion. Thai culture has been influenced by Indian, Cambodian, Lao, Burmese and Chinese. The escalating economic growth in as well as around the Bangkok has further marginalized the country's under developed regions. High rates of literacy imply the presence of large educated peoples. While, Thailand has a strong social security system, increasing income, and the developmental disparity is a reason for concern. The government will also seek to maintain the quality as well as raise the funds for social security services. However, there are certain income and development inconsistency present with in the country.

Technological

Thailand has invariably making scientific as well as technological advancements. The foremost goals of development is to create an valuable knowledge bases which can be well adopted and can extend local Thai wisdom into commercial benefits, as well as increase the level of research and development activities as mechanisms to drive forward economic and social development, via efficient use of resources and research networks. Research and development expenditure in the country is growing, but weak intellectual property rights protection is an issue. The country has IPR protection and enforcement as key influencing issues.

Environmental

Arranged amidst terrain Southeast Asia, Thailand's geological components incorporate high mountains, valleys, and an upland level. Focal Thailand is the heartland. Arrive subsidence in significant zones coming about because of the exhaustion of the water table; dry spells. Thailand's fast mechanical development and populace development have brought about expanded contamination levels. Thailand is having a moderate however steady execution in the worldwide Environmental Performance Index (EPI) with a rank of 91 out of 180 nations in 2016.

Legal

Thailand's legislature has an exceptionally liberal state of mind towards worldwide business and exchange. The Export-Import Bank of Thailand is dynamic in helping exporters by furnishing them with financing choices and the liquidity expected to extend and build up their business sectors. The administration concedes certain benefits to outside and household organizations working and sending out from its assigned modern zones, which extend from diminishments in tax assessment, brought import obligations down to exception from certain work laws. It has powerless IP law.

Business Environment in Thailand

Thailand's foundation is viewed as one of the best in SEA after Malaysia and Vietnam. Thailand has a very much created roadway organize, various conditions of the-craftsmanship seaports and an effective present day broadcast communications and Internet framework. The administration is focused on expanding framework improvement and a 5 year spending arrangement on the foundation of over USD 700 million has been affirmed. The ventures incorporate new between city street joins, urban mass travel frameworks, port development, another rapid rail arrange (running amongst Thailand and China) and extension of Suvarnabhumi air terminal."

The administration has decreased the corporate wage impose rate from the recorded 30% to 23% in 2013 and 20% in 2014/15. Along these lines, Thailand has the second-most reduced corporate expense rate in Southeast Asia, only somewhat above Singapore's.

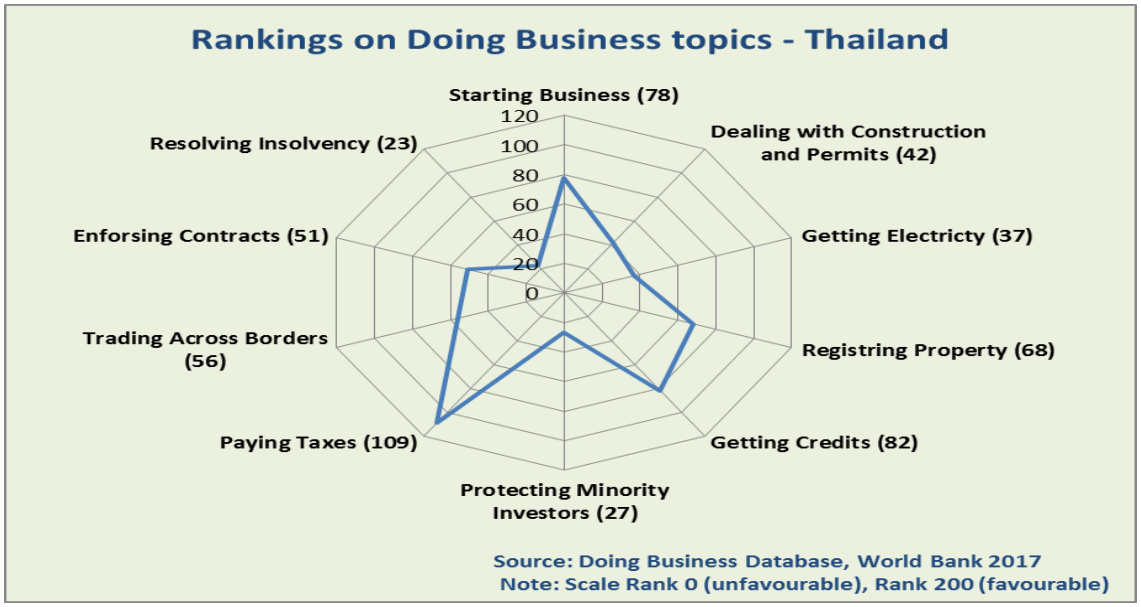


Figure 26 Thailand Doing Business Environment

Healthcare in Thailand

The healthcare spending in Thailand will be worth close to $25 billion in 2016, it is expected to grow at CAGR of 5.82%. Healthcare expenditure was 6.5% of GDP in 2014. Thailand's healthcare expenditure could rich to USD 34 billion by 2020 due to the rising incidences of NCD's, increasing Medical tourism.

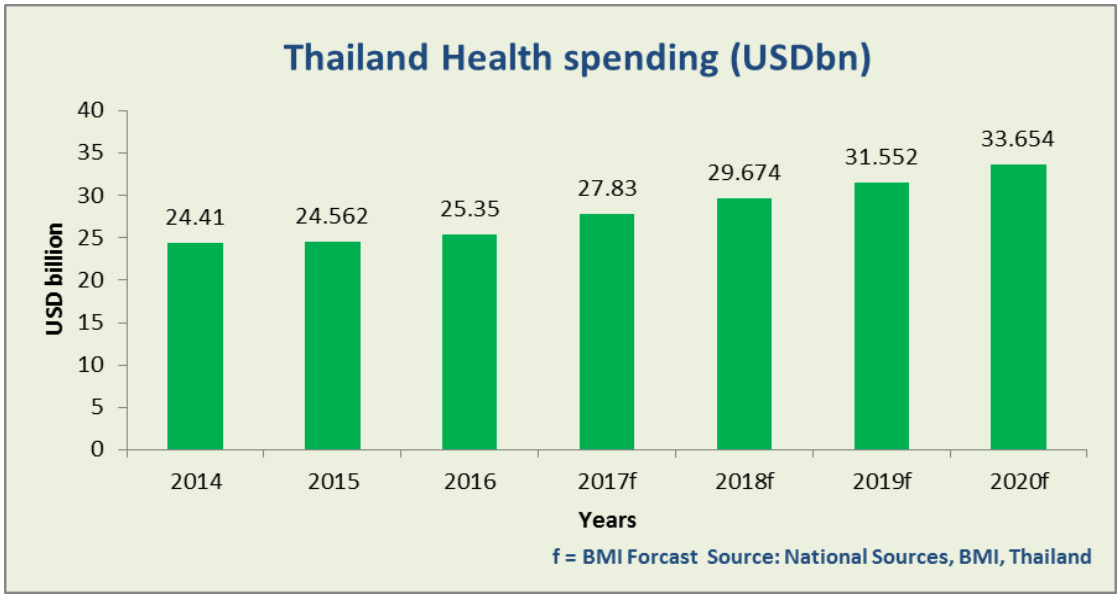


Figure 27 Thailand Healthcare spending 2020

The majority of healthcare services in Thailand are delivered by the public sector. Thailand has the significant medical infrastructure, with a total of 17,014 health care facilities as of October 2015. Of these, 56% are sub-district health promotion units, 28% are private clinics and 7% are primary care units. Thailand is a healthy society. The introduction of universal health care has been to a great degree responsible for the drop in mortality rates, while public-health efforts and vaccination campaigns have greatly reduced the prevalence of disease. Life expectancy in 2016 was 74.7 years.

Non-communicable diseases (NCDs) remain a problem in the country, 73% of deaths in Thailand are caused by NCDs, compared with 63% globally (WHO). The country has a high rate of tuberculosis and still has cases of malaria, though mainly in remote and mountainous areas. An increase in dengue fever cases is expected in 2017. Cardiovascular diseases and cancer are the leading causes of mortality. Western and lifestyle diseases have also been increasing. About 9% of Thai adults have diabetes, while approximately 25% have hypertension. Obesity is increasing.

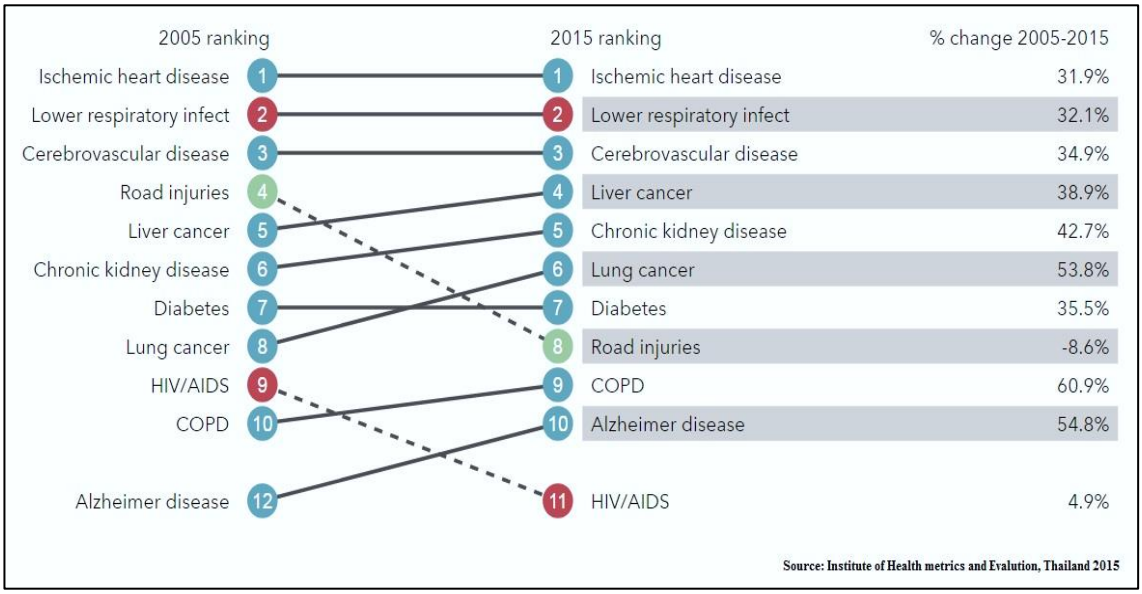


Figure 28 Top 10 causes of death by rate in Thailand 2015

Thailand population is aging faster than the rest of the world; according to the CIA about 11% of the population is above 65 year age and 12% are between 55-64 year age group. An aging population will create many business opportunities for the healthcare sector.

Thailand has a strong private health care sector, with eight exchange-listed hospital groups: Krungdhon Hospital, Krungdhon Hospital, Mahachai Hospital, Aikchol Hospital, Bangkok Dusit Medical Services, Ramkhanhaeng Hospital, Vibhavadi Hospital and Samitivej Hospital. Many of these groups are actively investing in the

growth of the sector. The government is encouraging private hospitals to make a greater investment in research and development so the country can maintain its position as a leading medical tourism destination and develop into a medical centre for the Southeast Asian region.

In Thailand, health tourism has been on the rise in recent years. It is estimated that 2.81 million people came to Thailand in 2015 for medical treatment, up more than 10% from 2014. Thailand's health sector is doing extremely well in places but is starting to feel the pressures of success. Health tourism is beginning to have an impact on the domestic market; both in terms of pricing and expectations, and necessary policy reforms are under way.

most likely through the creation of a co-payment system. The limited benefits of the program have also been brought into question, and like many other developing countries Thailand is beginning to question the cost of prescription medicines. The greater costs are also the result of the interplay between the private hospital system, which gets higher rates because of demand from international patients, and the public hospital system, which is struggling for funds.

Thailand Pharmaceutical market

The Thailand's Pharma industry was valued at THB161 bn (USD4.6 bn) in 2016 and it is expected to grow by 5.39 percent per annum between 2016 and 2020, the market is expected to grow to US$ 5.947 billion by 2020.

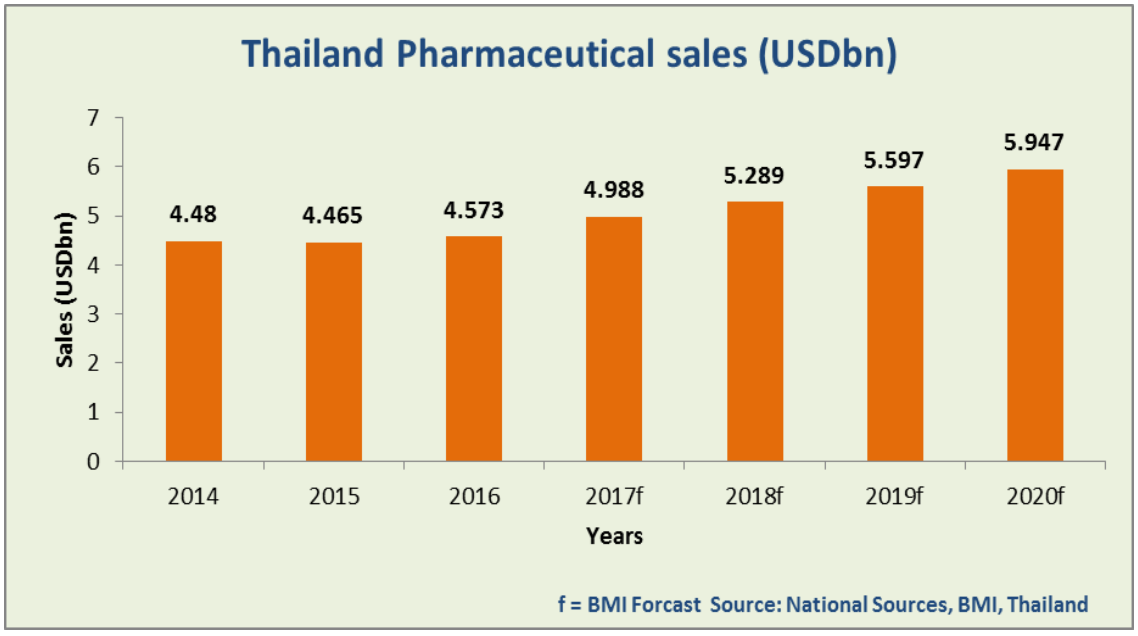


Figure 29 Thailand Pharmaceutical Sales forecast 2020

Thailand's pharmaceutical market is considered as the largest and most developed after Vietnam and Indonesia in the region and is projected to achieve the rank of the eighth largest market in the Asia.

The quantity of Thai household sedate organizations has been becoming rapidly over the previous decade since the presentation of the UHC. The legislature is currently subsidizing more R&D, empowering the neighborhood sedate industry to climb the esteem chain. The Thai government is right now chipping away at a revision to the nation's Drug Act that will refresh the pharmaceutical directions.

Prescription medicines make up for 80 percent of the pharmaceutical market in Thailand and will continue to dominate the market. In coming years, prescription drug sales will continue to be boosted due to improving healthcare conditions and the country's universal coverage.

Antibiotics will remain to be among the leading areas, although there is a growing trend of restricting sales of these treatments due to rising resistance to such drugs. Cardiovascular drugs will become more important, due to the aging population and the rising prevalence of unhealthy lifestyles. The use of herbal medicines is on the rise. The use of traditional medicines is being promoted by the government and there is an increasing trend towards the use of them in hospitals and health stations across the country.

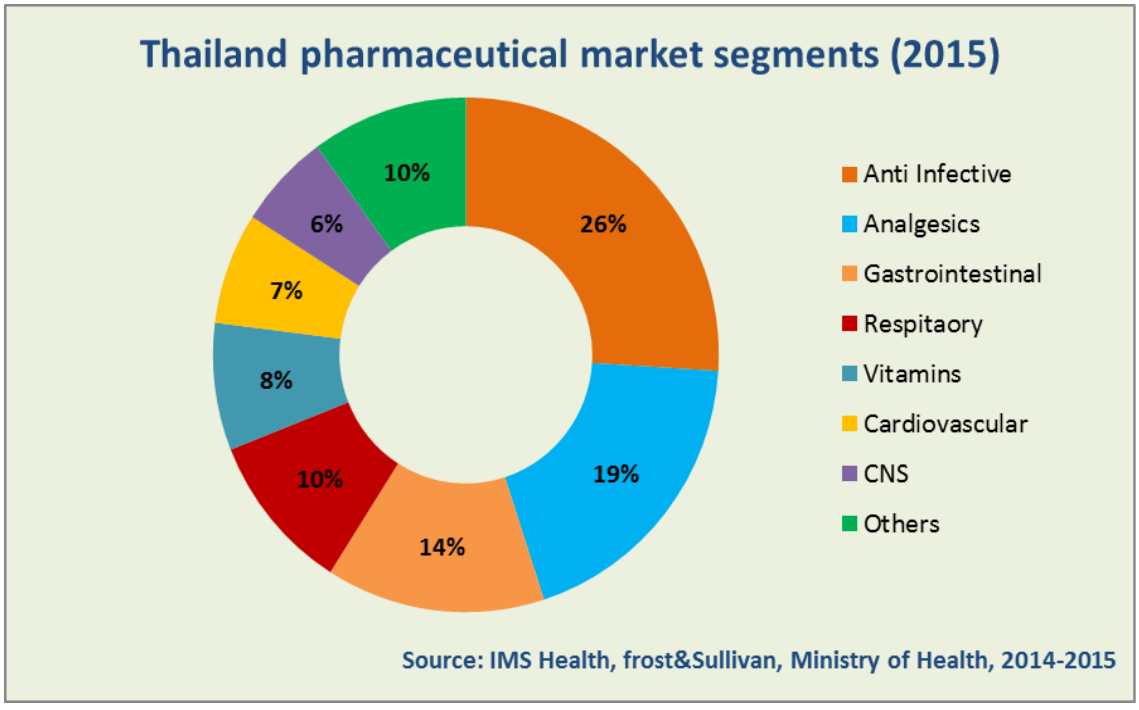


Figure 30 Thailand Pharmaceutical market segment

The market for API in Thailand has been largely dominated by the import of bulk drugs from other countries. The local player's inability to produce bulk drugs at costs much lesser than the prices charged by export nations is a major factor for the underlying situation. The industry comprises of more than 175 manufacturers of which approximately 75% are accredited with the Good Manufacturing Practices (GMP). Around 60% of the drug manufacturing companies operating from Thailand are the domestic players. More than $1.49 billion worth of medicinal products are imported from outside each year. Companies based in the United States, Germany, France and Switzerland altogether accounts about 61% of all imported drug sales.

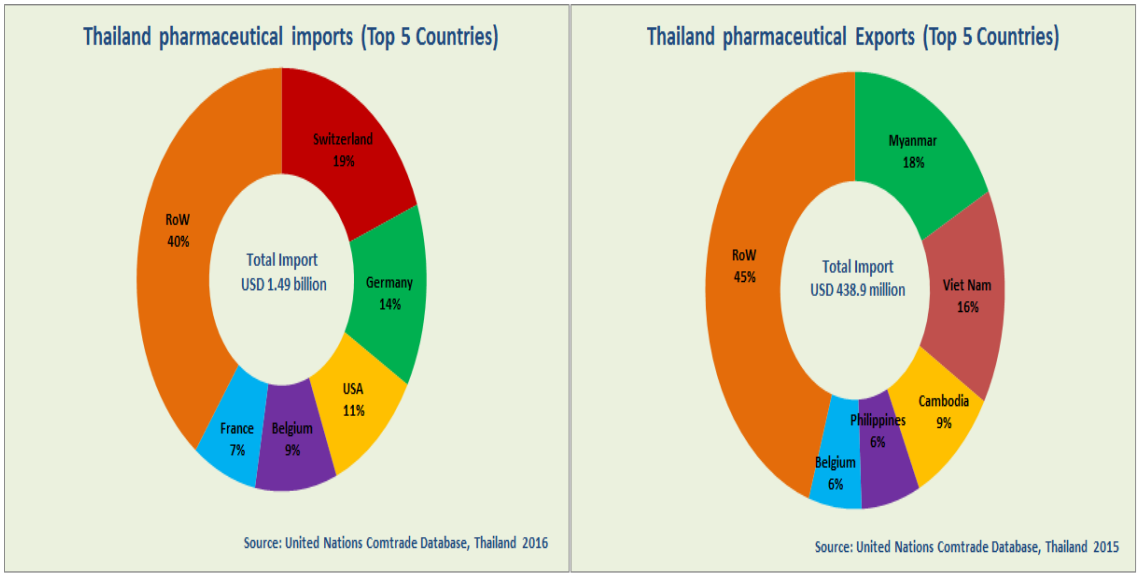


Figure 31 Thailand Pharmaceutical Import-Export

Commodity	Qty in 2015-16 (Kg)	Value in 2015-16 (US $)	Qty in 2016-17 (Kg)	Value in 2016-17 (US $)	Percentage Growth in Value (2017 over 2016)
AYUSH AND HERBAL PRODUCTS	867461	2132189	1028643	2796449	31.15
BULK DRUGS, DRUG INTERMEDIATES	3453347	66656324	4808831	58391589	-12.4
DRUG FORMULATIONS, BIOLOGICALS	2523309	96274100	2189645	89891152	-6.63
Total	6844117	165062613	8027119	151079190	-8.47
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 8 Thailand Pharmaceutical Import from India

Thailand carries various benefits to the MNC companies looking to manufacture or source their products in Thailand including a skilled workforce, strong medical training, a friendly regulatory environment and a well-established infrastructure.

Risk/Reward Index

Thailand remains in the lower half of the Pharmaceutical Risk/Reward Index table that assesses the attractiveness of 20 countries in the Asia-Pacific region, with a score of 49.3 out of 100. While Thailand offers relatively attractive revenue-earning opportunities in a regional comparison for multinational investors, increasing pharmaceutical expenditure is somewhat overshadowed by the prevalent risks in the country including low levels of patent protection.

Regulatory Landscape

In Thailand, the Ministry of Public Health (MoPH) is the summit body which oversees the pharmaceutical business through the Food and Drug Administration (FDA). The FDA gives mandatory directives in areas such as drug approvals, registrations, and licensing, pricing and marketing activities at various levels of value chain. All tasks are coordinated in conjunction with the Drug control division; Division of manufacturing and import facilities control; Department of Internal Trade and the Food control division.

The utilization of nonspecific drugs ought to incorporate parameters on quality control, general item data, and in addition item fabricating. New nonexclusive medication applications ought to incorporate a full arrangement of the dossiers and in addition bioequivalence examine information and writing that backings adequacy and security. New medication applications ought to incorporate data on security, viability, and quality, including process approval and solidness thinks about. Item licenses would be legitimate for a long time and sustainable. State-possessed medication organizations would likewise need to consent to permitting and item enlistment prerequisites. Item obligation would be presented, and fines for not following directions would be fundamentally expanded. The Thailand government is right now chipping away at a correction to the nation's Drug Act that will refresh the pharmaceutical controls.

Major Domestic Player of Pharmaceutical Industry:

The major pharmaceutical industries are located in Bangkok city.

1. Paradigm Pharma (Thailand) Co. Ltd

2. Thai Meiji Pharmaceutical Co. Ltd
3. Thai Otsuka Pharmaceutical Co. Ltd
4. Thai Meiji Pharmaceutical Co. Ltd
5. Greater Pharma Company Limited
6. Kaspa Pharmaceutical (Thailand) Co. LTD
7. T. C. Pharmaceutical Industries Co., Ltd
8. Berlin Pharmaceutical Industry Co. LTD
9. R. X. Company Limited
10. Atlantic Laboratories Corp. Ltd

All above pharmaceutical companies are making generic as well as herbal products which cover higher market share in Thailand.

SWOT Analysis

Strengths	**Weaknesses**
1. Market consolidation with leading developers having advantages easy access to project financing, brand reputation, economies of scale. 2. High quality medical professional workforce 3. Hospitality and service mind 4. Low cost of medical treatments	1. Rising salary and minimum wage rates and Lack of foreign language skills 2. Policy incoherence and lack of cooperation among key stakeholders Weak medical malpractice law 3. Most Pharmaceutical API's and medicines are imported 4. High energy dependence Political instability Lack of funding, especially for SMEs
Opportunities	**Threats**
1. Growing domestic economy and people's rising incomes. 2. Limited healthcare supply in Thailand and overseas markets. 3. Thailand being a value-for-money destination for medical tourism. 4. Demographic change, rising prevalence of chronic diseases and cost escalation in developed countries	1. Regulatory risk 2. Political risk and natural disasters. 3. Emergence of new players such as Malaysia 4. Lack of support from the population and prevalence of inequities 5. European sovereign debt crisis

Philippines

Overview

The Philippine islands comprise of more than 7,000 islands lying around 806 km off the southeast shoreline of Asia. The general land area is for all intents and purposes indistinguishable to that of Arizona. Just around 7% of the islands are greater than one square mile, and only a solitary third have names." The greatest are Luzon in the north (104,687 sq. km), the islands are of volcanic origin, with the greater ones crossed by mountain ranges. The most lifted zenith is Mount Apo (9,690 ft.) on Mindanao.

The Philippines' overall relations rely on upon trade with various nations and the success of the 10 million abroad Filipinos living outside the country." As a building up and dynamic individual from the United Nations, the Philippines have been picked a couple times into the Security Council. Carlos P. Romulo was a past President of the United Nations General Assembly. The country is a dynamic part in the Human Rights Council and what's more in peacekeeping missions, particularly in East Timor despite enlistment in the United Nations, the Philippines is moreover a building up and dynamic individual from ASEAN (Association of Southeast Asian Nations), an affiliation planned to fortify relations and progress financial and social improvement among states in the Southeast Asian range.

The Philippine economy is the 36th greatest on the planet, with a normal 2016 aggregate national yield (apparent) of $311.687 billion. Fundamental admissions consolidate semiconductors and electronic things, transport equipment, bits of attire, copper things, oil based merchandise, coconut oil, and common items. Genuine trading associates join the United States, Japan, China, Singapore, South Korea, the Netherlands, Hong Kong, Germany, Taiwan, and Thailand. Its unit of cash is the Philippine peso

A recently industrialized nation, the Philippine economy has been transitioning from one in light of farming to an economy with more accentuation upon administrations and assembling. Of the nation's aggregate work compel of around 40.813 Million, the rural segment utilizes 30% of the work constrain and represents 14% of GDP. The modern segment utilizes around 14% of the workforce and records for 30% of GDP. In the interim, the 47% of laborers required in the administrations part are in charge of 56% of GDP.

Figure 32 Philippines GDP growth rate (%)

The unemployment rate in 2014 stands at 16% in the interim, because of lower charges in essential necessities, the expansion rate facilitates to 1.7% in 2016. The economy has been moderately strong to worldwide financial stuns because of fewer introductions to agitated global securities; bring down reliance on fares, generally versatile residential utilization, extensive settlements from around 15 million abroad Filipino specialists and vagrants, and a quickly growing outsourcing industry.

Philippines Key Indicators

Demographic	Indicators
Location	Southeastern Asia, archipelago between the Philippine Sea and the South China Sea, east of Vietnam
Total Area	300,000 sq. km
Climate	tropical marine; northeast monsoon (November to April); southwest monsoon (May to October)
Population	102,62 million (July 2016)
Age structure	**0-14 years:** 33.71% **15-24 years:** 19.17% **25-54 years:** 36.86% **55-64 years:** 5.89%

	65 years and over: 4.38%
Urban population	44.4%
Population growth rate	1.59% (2016)
Literacy	96.3%
Languages	Filipino (official) and English (official)
Economic	**Indicators**
Currency	Philippine peso
GDP (exchange rate)	$311.7 billion
GDP - growth rate	6.4%
GDP - per capita	$7,700
GDP - composition by sector	**Agriculture:** 9.7% **Industry:** 30.5% **Services:** 59.8%
Industries	electronics assembly, food processing, petroleum refining, fishing, garments, footwear, pharmaceuticals, chemicals, wood products
Healthcare	**Indicators**
Health expenditures	4.7% of GDP (2014)
Hospital bed density	1 beds/1,000 population
Major infectious diseases	**food or waterborne diseases:** bacterial diarrhea, hepatitis A, and typhoid fever **vectorborne diseases:** dengue fever and malaria **water contact disease:** leptospirosis
HIV/AIDS - adult prevalence rate	0.08%
Obesity - adult prevalence rate	4.7%
Source: Central Intelligence Agency 2016	

Pestle Analysis

Political

The Philippines have seen great years of political solidness. Around couple of decades prior, there was a fascism in the nation however now there is just framework and a political gathering is in government. The nation has built up its industry and it has built up a decent reputation of business. The legislature was spending low on its R&D part and they need to rely on upon the outer variables for the arrangement of new innovation and it has the feeble foundation of streets and railroads.

After the rebuilding of the equitable framework in the nation, the nation has gained ground in the administration segment and it has done a decent execution in different parts. The legislature has presented different new political changes in the administration and individuals turn out to be more mindful of their rights and their duties. At the point when the legislature of Dictator Marcos was toppled, then his tremendous measure of cash was kept in the banks of western nations particularly Switzerland, which was reclaimed to the nation and it, was utilized as a part of the economy of the nation and now there is no indication of political turmoil.

Economic

Philippine has experienced fast auxiliary changes and is moving towards a more steady and creating economy. The informed workforce, gigantic household request, nearly youthful workforce, rich common assets, great business condition and high remote trade hold is probably going to drive the Philippians economy to supported development amid 2016-2020. The administration has arranged different business venture and market passage in the wake of presenting a different comprehensive perspective of the nation. Presently they have an entire comprehension of political circumstance inside the nation in which key figures and administration pointers are incorporated. They have a comprehension about the statistic of the nation and they are making strides in human services and instruction.

The GDP of the nation is making development and it is required to reach to $372 billion by 2018. There is monetary advancement in the legislature and different fast basic changes are being attempted to make its economy stable. It is moving towards globalization and it is getting profits by its economy. Their financial approaches demonstrate that they are presently concentrating on their FDI and FII and they have

appealing venture strategies and support to the business and exchange exercises by the legislature

Social

The Philippine constitution perceives English, and it is the dialect of the law, alongside the local Filipino, as the official dialect. This nation has given extraordinary accentuation to instruction and now you can discover taught individuals, its prepared and expert workforce is available in the legislature and they are participating in all money related and social exercises. Individuals have religious flexibility and they can take an interest in their religious ceremonies. Their constitution perceives English yet Filipino is additionally utilized as social dialect and furthermore in the courts. It's the vast majority of the general population moved from agribusiness to industry and they are making strides in making some great items in different businesses. The administration has executed its approaches for the welfare and prosperity of its populace, which has gotten certain progressions the nation. The approaches and directions of the nation are presently executed at the fitting level and it additionally demonstrated a definitive objective of the administration to make monetary advancement in the nation.

Technological

The nation has made huge improvement in the innovative field. Different innovative improvements have been presented in the nation and individuals will have most recent and crisp data about their venture and key choices with the goal that they can make their interest in this nation. The nation is utilizing most recent gear and items to develop their industry and agribusiness. It has presented most recent IT advancements in the nation and the greater part of the general population have their own phones with the web offices. It has given the budgetary exchanges to the general population over the cell systems and about portion of the number of inhabitants in this nation is utilizing the mobile phones

Environmental

The Philippines is situated in the West Pacific sea isolated from different nations of the world and its biological condition is interesting. There is no major issue of contamination, as this is the agrarian nation and now it began setting up businesses. The legislature is making new directions for the security of the earth and it is likewise actualizing it in its actual soul keeping in mind the end goal to safeguard the common

environment and its biodiversity. The modern area and exchanging offices and organizations are consenting to the directions and controls administering the natural assurance.

Legal

The legislature is concentrating on the powerful enactment in each field particularly in the business. It has presented the laws for the assurance of their base wages, their working time, offices of wellbeing and training to all native of the nation and for the ecological security. The administration is holding fast to the strict arrangements with the goal that they can keep up the great lawful foundation of the nation. Presently individuals have more privileges of their life, training and work and they are happy with the arrangements of the administration and they are making strides in the improvement and prosperity of their nation. The parliament is the fundamental wellspring of planning new enactments and it is reliably making strides for the making of new laws and controls, which can likewise secure the remote speculation and it has a decent climate for the venture of their riches.

Business Environment in Philippines

The financial framework is open and market-arranged, despite the fact that estimating instruments stay directed in a couple of divisions to secure buyers. The Philippines has experienced huge auxiliary changes in the previous decade. Framework is immature in many parts of the nation yet thought to be satisfactory in real metropolitan territories. The legislature is focused on expanding foundation ventures.

Figure 33 Philippines Doing Business Environment

Healthcare in Philippines

The healthcare spending in the Philippines will be worth close to $15.06 billion in 2016, it is expected to grow at CAGR of 7.82%. Healthcare expenditure was 4.7% of GDP in 2014. Philippines healthcare expenditure could rise as high as USD 22.0 billion by 2020 due to the rising incidences of NCD's, and Medical tourism.

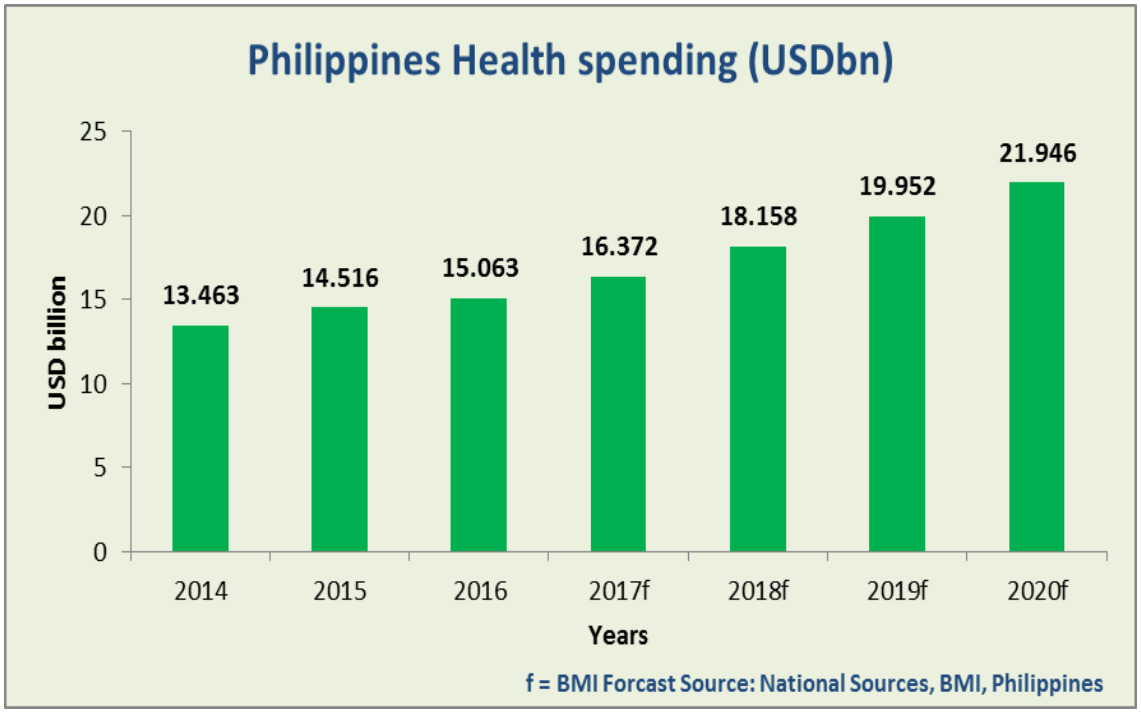


Figure 34 Philippines Healthcare spending 2020

The Philippines performed well in the UN's 2000-15 Millennium Development Goals (MDGs), accomplishing five of eight MDGs. It was judged impartially in one yet did not meet two objectives: enhancing maternal wellbeing and accomplishing all inclusive fundamental training. Following on the MDGs, work on achieving 17 targets of sustainable development goals (SDGs) has been agreed by nations around the world. But given the Philippines' limited resources and its lack of success on two of the MDGs Communicable diseases continue to be major causes of morbidity and mortality in the Philippines, infectious diseases such as tuberculosis and pneumonia are leading causes of death.

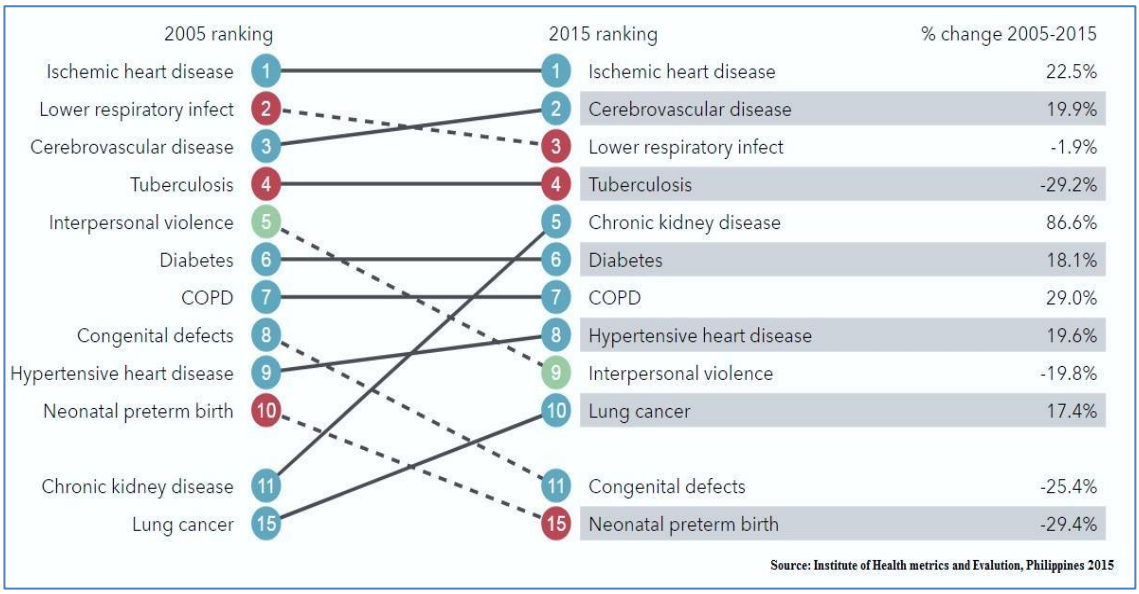


Figure 35 Top 10 causes of death by rate in Philippines 2015

The Universally Accessible and Affordable Quality Medicines Act of 2008 pronounced it government arrangement to secure general wellbeing and to receive measures to elevate and guarantee access to reasonable bunk powerful and quality medications solutions for all subjects, while the Food and Drug Administration Act of 2009 gives access to both licensed and non-protected life-sparing quality meds. Both of these demonstrations support the National Drug Policy.

Not at all like the human services divisions in Vietnam and Thailand, medicinal services in the Philippines are basically private. In private Filipino healing centers, specialists assume a considerable administration part and regularly have a possession intrigue. The national Department of Health buys medicates just for the moderately couple of territorial open clinics (around 40) that stay under its control. the Department of Health keeps on regulating the national medicinal services framework by setting up and upholding least gauges for offices and administrations, advancing the improvement of doctor's facilities, and keeping up specialist over neighborhood administration endeavors.

The human services part in the Philippines has seen dynamic development in mergers, organizations together, and acquisitions in the previous year. A remarkable illustration is Metro Pacific Hospital Holdings; Health offices in the Philippines incorporate government and private doctor's facilities, and essential and tertiary medicinal services offices, for example, centers and strength mind units. As indicated by the DoH, the private area contains half of the nation's wellbeing framework. Wellbeing status and access to administrations is the absolute most vital medical issue in the Philippines. This

disparity emerges from auxiliary deformities in the fundamental building squares of the Philippine wellbeing framework, including the low level of monetary insurance offered – issues which up to this point have been insufficiently tended to by change endeavors.

Pharmaceutical Industry in Philippines

The Philippines's Pharmaceutical industry was valued at PHP 156.19 bn (USD3.26 bn) in 2016 and it is expected to grow by 3.42 per cent per annum between 2016 and 2020, the market is expected to grow to US$ 3.854 billion by 2020.

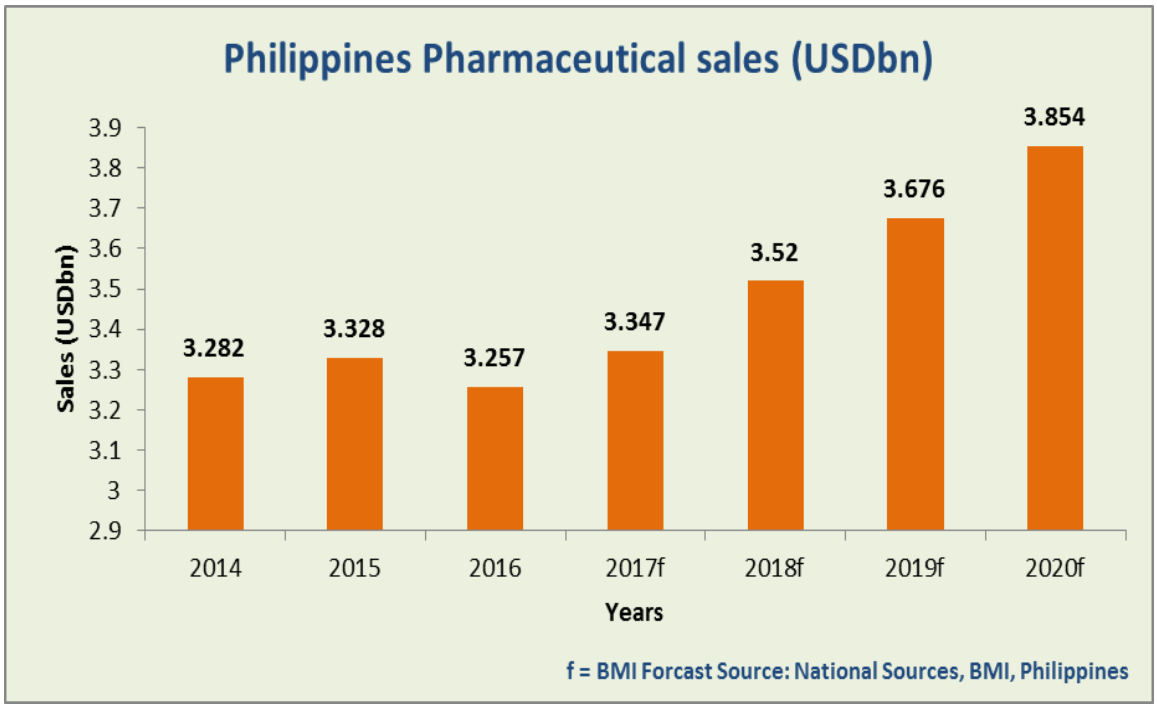


Figure 36 Philippines Pharmaceutical Sales forecast 2020

The Philippines' pharmaceutical market is growing at its quickest pace in decades. Its market has been developing at a rate of 4–5 percent yearly. outside pharmaceutical organizations caught 70 percent of the Filipino market. That is not exactly in earlier years when piece of the pie was 80 percent. GlaxoSmithKline, Novartis, and Sanofi are among the biggest outside pharmaceutical organizations working together in the Philippines. Among residential medication organizations, GC International, Pascual Laboratories, and Natrapharm are the biggest.

Household sedate organizations are making their most noteworthy picks up in generics. Customarily, even poor Filipinos looked down on nonexclusive medications. Specialists – lured by motivating forces from pharmaceutical organizations – infrequently endorse generics, and patients intermittently don't trust non-marked medications. Be that as it

may, late laws ordering the utilization of generics out in the open settings have prompted a continuous acknowledgment among Filipinos.

Nonspecific substitution in both the general population and private divisions, which has been a driver for the fabricate of bland medications - Increased consumption on solutions by Local Government Units (LGUs) - Government activities for the aversion and administration of ceaseless maladies - an enhanced and refreshed administrative condition. The generics portion is progressively essential in the Philippines. Notwithstanding nearby makers, numerous outside makers are entering the market. To rival these nonexclusive and off-brand items, numerous multinational organizations are diminishing the costs of some brand name sedates by as much as 50 percent. Not very many remote pharmaceutical organizations do their own assembling in the Philippines. Rather, they import and disseminate completed pharmaceutical items, or they import sedate fixings and outsource generation to neighborhood producers

The Philippines Pharmaceutical industry depends mostly on import. Not very many outside pharmaceutical organizations embrace their own particular assembling in the Philippines. Rather, they import and disseminate completed pharmaceutical items, or they import medicate fixings and outsource generation to neighborhood makers.

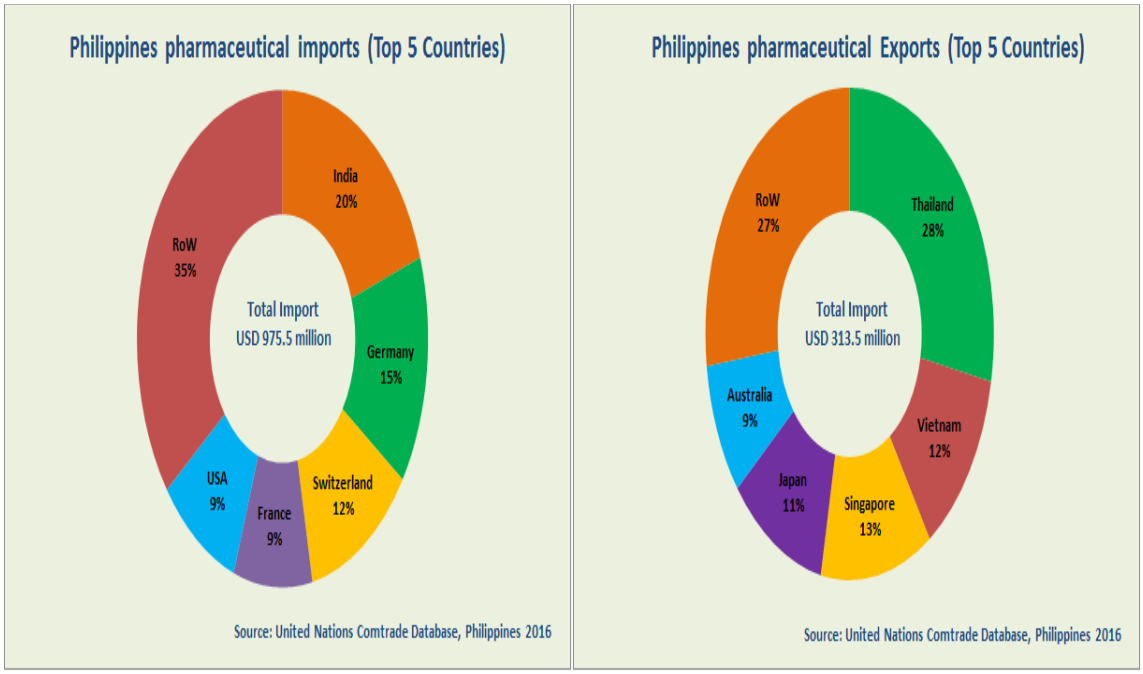


Figure 37 Philippines Pharmaceutical Import-Export

Commodity	Qty 2015-16 (Kg)	2015-16 Value (US $)	Qty 2016-17 (Kg)	2016-17 Value (US $)	Percentage Growth in Value (2017 over 2016)
AYUSH AND HERBAL PRODUCTS	2371487	3514766	781596	3096925	-11.89
BULK DRUGS, DRUG INTERMEDIATES	917117	16837954	1236905	16767173	-0.42
DRUG FORMULATIONS, BIOLOGICALS	6571291	178849221	6756035	196962150	10.13
Total	9859895	199201941	8774536	216826248	8.85
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 9 Philippines Pharmaceutical Import from India

The Philippines Pharmaceutical Manufacturers Association (PPMA) is a non-stock, non-benefit affiliation set up on September 30, 1950. It was composed for the basic role of uniting elements occupied with the make and additionally showcasing of pharmaceutical items for the accomplishment of persistently update the guidelines of the pharmaceutical assembling industry in the Philippines, advancing and empowering pharmaceutical research and innovation improvement with a view to using indigenous material and participating with the therapeutic and partnered callings for the advancement of the social insurance conveyance framework in the nation.

Outside pharmaceutical organizations control around 66% of aggregate industry deals, with pieces of the overall industry of individual remote organizations going in the vicinity of 1% and 6%. One hundred and forty-three European organizations order a consolidated piece of the pie of 39%, and 77 % U.S. organizations control a consolidated piece of the overall industry of 28%. Japanese organizations have to a lesser degree nearness in the Philippines than in numerous other Southeast Asian nations.

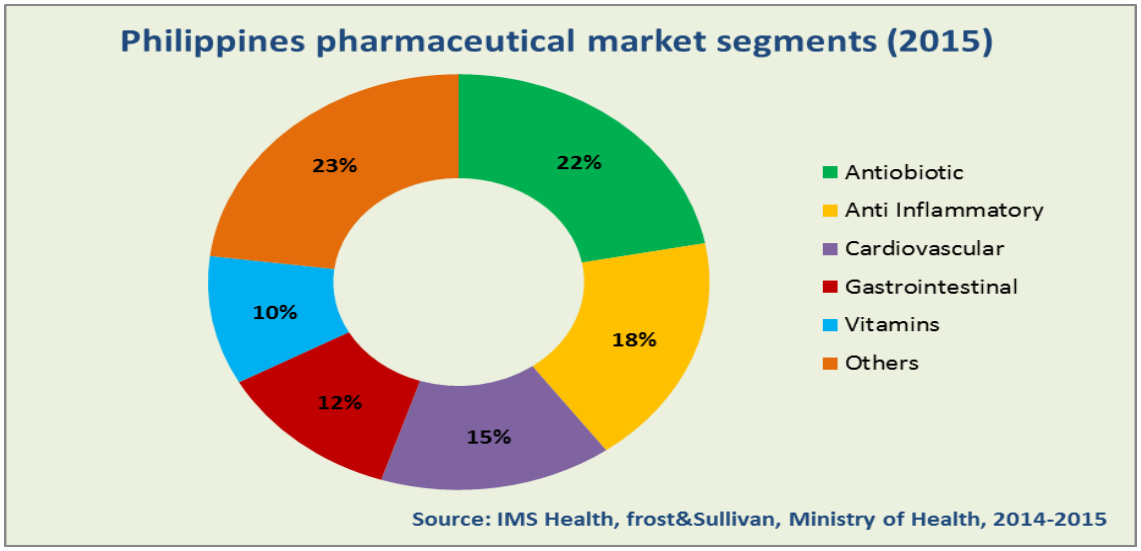


Figure 38 Philippines Pharmaceutical Market Segment

The Generics Act of 1988 required the production of medicines identified by their generic names and required providers to write out prescriptions using generic terminology. The act has been credited with spurring the creation of a market for generic pharmaceuticals, shifting the balance of power from physicians to pharmacists and consumers. Consumers now have a choice of drugs to purchase, and many are choosing generics because they save as much as 85% versus the price of brand-name medicines. The Generics Act and the emergence of many private sector retail drugstore chains focused on generic medicine have expanded access to quality drugs.

Moving away from the geographical dimension of the Philippines, there are a number of factors that present the Philippines as a viable investment candidate in the Pharmaceutical market. The Filipino Pharmaceutical market is set to grow rapidly and be valued at $ 4 billion by 2020. The Foreign investment already accounts for 70% of pharmaceutical manufacturing and distribution in the Philippines. Secondly, it is evident that there is a large discrepancy between generic and branded drugs in the Philippines.

Risk/Reward Index

The Philippines is ranked in 14th place out of the 20 pharmaceutical markets assessed in Asia Pacific (scoring 45.0 out of 100), the Philippines's Risk/Reward Index score is dragged down by industry characteristics such as policy enforcement (policy enforcement score of 2.8 out of 7) and per capita spending (score of 2.4 out of 12). Despite scoring below the regional average in many categories, there are plenty of future opportunities and rewards. There are indications that the market is maturing further, with the progressive implementation of a universal healthcare system.

Regulatory Landscape

In the Philippines, there are legitimate arrangements setting up the forces and obligations of the Medicines Regulatory Authority (MRA). The MRA is a piece of the Ministry of Health. Under the Philippines FDA is permitted to hold stores it gets from organizations, notwithstanding the spending it gets from the legislature. This will enable it to extend its capacities later on. The body will likewise have new powers that its forerunner did not, for example, the capacity to seize imperfect pharmaceuticals and crooks that offer them by equipped constrain and without a court arrange. The Philippines FDA is in total control of the produce, importation, fare, dispersion and offer of pharmaceuticals, nourishment, beautifying agents and medicinal gadgets.

The Philippines healthcare and Pharmaceutical Association (PHAP) made its own directions for pharmaceutical advancement, contained in the 'Code of Pharmaceutical Marketing Practices.' Although the code is relevant just to part organizations of the PHAP, it plays a noteworthy part in the reasonable and moral advancement of pharmaceuticals in the Philippines. The PHAP Code requires particular.

In the same way as other administrative offices, BFAD takes after the activities of the US Food and Drug Administration (FDA) nearly. In the Philippines, there are lawful arrangements in the Medicines Act that accommodate Pharmacovigilance exercises as a feature of the MRA command. Legitimate arrangements additionally exist requiring the Marketing Authorization holder to consistently screen the security of their items and answer to the MRA Laws with respect to the observing of Adverse Drug Reactions (ADRs) exists in the Philippines.

Major Domestic Player of Pharmaceutical Industry:

The major pharmaceutical industries are located in Makati city.

1. Eon Pharmatec, Inc.
2. Aspen Philippines
3. Philippine Pharma Procurement Inc
4. Khriz Pharma
5. Raquel Abbas
6. Pharex-Pascual Laboratories, Inc.
7. Marzan Pharma
8. Pasteur Pharma
9. All-Bio Pharma

10. Medicamenta Inc

All above pharmaceutical companies are making generic as well as herbal products which cover higher market share in Philippines.

SWOT Analysis

Strengths	**Weaknesses**
1. Large and developing populace combined with as of now low levels of medication utilization. 2. Government sense of duty regarding the enhance access to pharmaceuticals. 3. Steady interest for outside made therapeutic gadgets. 4. A moderately created nearby industry.	1. One of the most noteworthy territorial rates of private wellbeing spending as a rate of the aggregate wellbeing consumption 2. Only 33% of the populaces have satisfactory access to pharmaceuticals. 3. Counterfeiting, absence of requirement and poor patent and information insurance are the principle administrative issues 4. The market is dependent on remote medications, which applies impressive and unwelcome weight on government social insurance funds
Opportunities	**Threat**
1. ASEAN harmonization initiative. 2. The adoption of Western regulatory standards such as ICH and WHO guidelines. 3. Need for cost cut down and new legislation 4. Investment incentives for foreign players.	1. Government has acquired domestic patent law with international standards 2. Legislation allowing faster and easy entry of generics into the market 3. Increase of the number of medicines under the controlled-price drugs list. 4. Government’s cost-cutting policy

Malaysia

Overview

Malaysia comprises of islands and the biggest of them all is shared by Malaysia alongside two neighboring nations Singapore, and Indonesia. It is isolated by the South China Sea into two likewise estimated districts, Peninsular Malaysia and East Malaysia. The capital city is Kuala Lumpur. Malaysia is a government protected in Southeast Asia, comprising of thirteen states and three elected domains. Malaysia has embraced the political arrangement of a parliamentary vote based system. The law entirely forbids utilize or ownership of medications and there is a punishment of death for somebody who is discovered liable. The Social religion is Islam yet there are minorities too which incorporate Christianity, Hinduism, and Buddhism. The political scene has been described by an uncommon level of political solidness and coherence through an all-encompassing national coalition of political gatherings. Malaysia's legitimate framework depends on English Common Law.

Malaysia is a middle-income country; Malaysia is vulnerable to a fall in world commodity prices or a general slowdown in global economic activity. Malaysia has experienced strong economic growth over the last decade; the 2016 estimates for GDP amounted to US$ 863.8 billion, and it is growing at rate of over 4.3 % between 2015 and 2016. Malaysia´s economic growth slowed down in 2016 due to lower oil prices and decreased demand from China. Malaysia has once been the largest producer of rubber and palm oil in the world. Malaysian economy majorly dependent on export goods; the government has pushed to increase tourism to Malaysia.

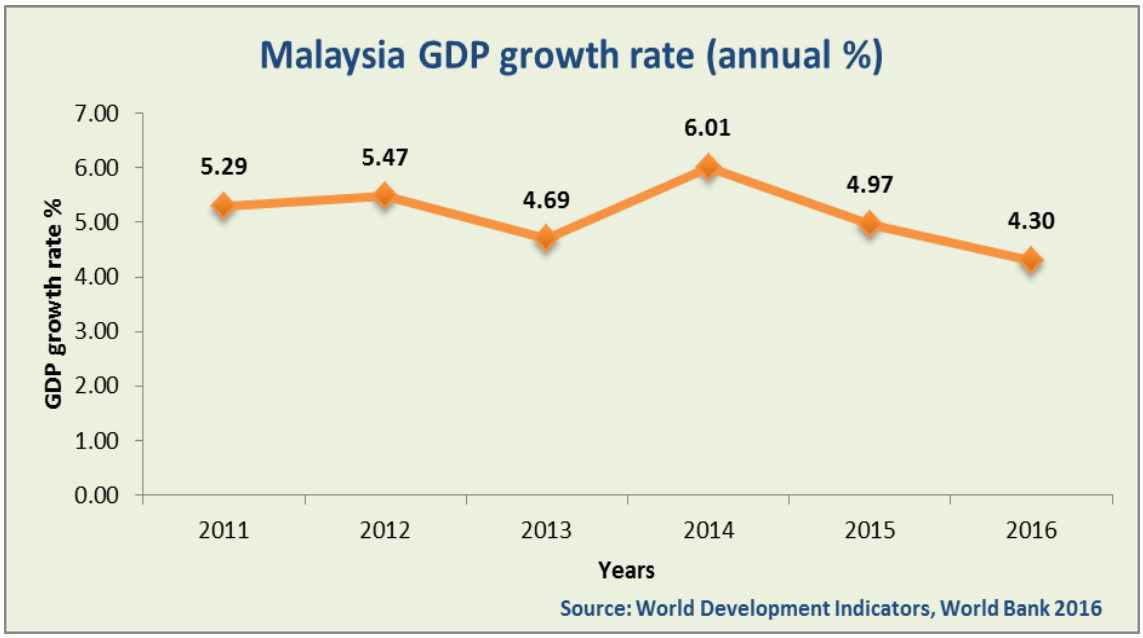


Figure 39 Malaysia GDP growth rate (%)

The NAJIB organization is proceeding with endeavors to lift local request and decrease the economy's reliance on fares. By and by, fares - especially of gadgets, oil and gas, palm oil, and elastic - remain a huge driver of the economy. Malaysia has the world's sixteenth biggest gaseous petrol saves and 28th biggest raw petroleum holds. consolidated with managed spending deficiencies, has constrained Kuala Lumpur to start to address financial deficits, through introductory decreases in vitality and sugar endowments and the declaration of the 2015 usage of a 6% merchandise and ventures impose. Falling worldwide oil costs in the second 50% of 2014 have stressed government funds, contracted Malaysia's present record surplus and put descending weight on the ringgit.

Malaysia has a very much created money related part, with all around promoted banks, great credit quality and a low offer of non-performing advances (around 1%). Be that as it may, a hazard element is the abnormal state of private obligation, which could turn into an issue if loan fees rise significantly.

Malaysia Key Indicators

Demographic	Indicators
Location	Southeastern Asia, peninsula bordering Thailand and Borneo, bordering Indonesia, Brunei, and the South China Sea.
Total Area	329,847 sq. km
Climate	tropical; annual southwest (April to October) and northeast (October to February) monsoons
Population	30,94 million (July 2016)
Age structure	**0-14 years:** 28.16% **15-24 years:** 16.86% **25-54 years:** 41.06% **55-64 years:** 8.06% **65 years and over:** 5.86%
Urban population	74.7%
Population growth rate	1.4%

Literacy	94.6%
Languages	Bahasa Malaysia (official), English, Chinese (Cantonese, Mandarin), Tamil, Telugu, Malayalam, Panjabi, Thai
Economic	**Indicators**
Currency	Malaysian ringgit (MYR)
GDP - exchange rate	$302.7 billion
GDP - growth rate	4.3%
GDP - per capita	$27,200
GDP - composition by sector	**Agriculture:** 8.2% **industry:** 37.8% **Services:** 54%
Industries	Rubber and palm oil, petroleum and natural gas, pharmaceuticals, medical technology, electronics and semiconductors, timber processing, agriculture.
Healthcare	**Indicators**
Health expenditures	4.2% of GDP
Hospital bed density	1.9 beds/1,000 population
Major infectious diseases	**food or waterborne diseases:** bacterial diarrhea **vectorborne diseases:** dengue fever **water contact disease:** leptospirosis
HIV/AIDS - adult prevalence rate	0.4%
Obesity - adult prevalence rate	12.9% (2014)
Source: Central Intelligence Agency 2016	

Pestle Analysis

Political

Since independence, Malaysia has adopted the political system of a parliamentary democracy. Legislative power is divided between the federal and state legislatures. Parliament consists of the Lower House. The political leadership of the country has been focusing on two key long-term goals: cementing national unity and economic development with equity. NSC bill gives more power to authority's to tackle violent

extremism, increasingly progressive government policy aimed at attracting international investment and World trade agreements e.g. further gives expansion to the EU. Malaysia's foreign policy is based on the principle of neutrality and maintaining peaceful relations with all countries, regardless of their political system. Economic relations and incentives play a major role in shaping foreign affairs. Furthermore, Malaysia seeks to develop relations with other countries in the region and portray itself as a progressive Islamic nation.

Economic

The Gross domestic product per individual is around $27,200 in 2016, however like the various economies that were intensely depending on China for their fares they have additionally confronted troubles when Chinese economy backed off. Malaysian money has downgraded against the dollar to this degree without precedent for history. Most exceedingly bad of all circumstances is the political amongst present and previous Prime Minister which has settled on speculators reexamine about their choices. The legislature has attempted to enhance the nation's economy by concentrating on tourism, science projects, and managing an account.

Social

Malaysia is a mainstream state with Islam as the state religion. The official dialect of Malaysia is Malaysian and English remains a dynamic second dialect. It has a multi-ethnic, multicultural, and multilingual society. Most of the populace is of Muslims, Buddhists, and Christians are not in careless numbers which offer ascent to these contentions esp. among youth. Malaysia has encountered years of financial development and advancement with dynamic authority, where an administration with its painstakingly focused on strategies supported urbanization. Social issues, for example, destitution, unemployment, and abuse of laborers by vast partnerships don't exist in Malaysia; however racial separation and clashes are deteriorating with the progression of time. It is the exceptionally alluring position for tourism.

Technological

Malaysia is actually propelling nation, Improvements in nearby advances e.g. accessibility of Digital TV. Real firms on the planet have outsourced their assembling in Malaysia in light of its entrenched framework and all around prepared workforce who are beneficial and gifted. The railways, recreational parks, lofts and shopping centers are all furnished with optical strands to give web network to all individuals.

Environmental

he earth of Malaysia is profoundly affected by deforestation and contamination. The urbanization, setting of dams, agribusiness and so on are the immense intentions behind deforestation. Malaysia is an extensive exporter of elastic and palm oil. Thus, logging is still completed in Malaysia in spite of the fact that on paper they have the best rainforest assurance approaches. Air contamination has increased profound roots in the nation as the dangerous gasses from vehicles and businesses are being radiated into the air. These urban areas deliver 1.6 million tons of strong waste every year. In the wake of considering the land in utilization, Malaysia has been positioned fourth on the planet on the terms of transmitting most measures of nursery gasses per capita.

Legal

Malaysian has an expansive impact of Britain. The law was built up in the early settlements of Malaysia. Malaysia picked up its autonomy from the British in 1956. The Islamic sharia law is likewise executed in specific locales of Malaysia. The Malaysian criminal code was made after Indian criminal code and Malaysian land law depends on Australian Torrens framework. The government ward made by the parliament of Malaysia is rehearsed all through the nation.

Business Environment in Malaysia

Malaysia has an open and industrialized market economy. The state plays a noteworthy however declining part in controlling financial action through macroeconomic arrangements. The legislature has set out various changes with the point of proceeding with the progression of the economy, particularly in the administrations division. Malaysia was one of the establishing individuals from the WTO and is effectively required in both multilateral advancement and local and respective participation. The nation has seven worldwide ports and 200 modern parks, including specific stops, for example, Technology Park Malaysia and Kulim Hi-Tech Park. Improvement has generally been amassed in monetarily intense urban areas. Subsequently, while provincial ranges have as of late been the concentration of advancement, despite everything they fall behind the real urban areas.

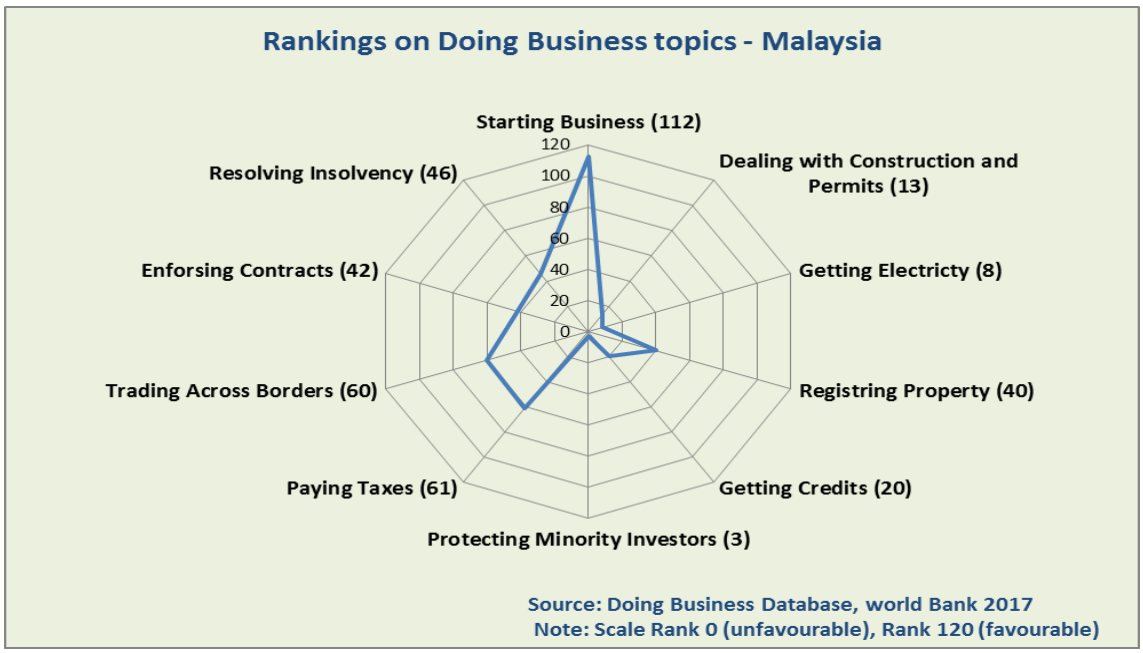


Figure 40 Malaysia Doing Business Environment

Healthcare Sector in Malaysia

The healthcare spending in Malaysia will be worth close to $13.27 billion in 2016, it is expected to grow at CAGR of 9.58%. Healthcare expenditure was 4.2% of GDP in 2014. Malaysian healthcare spending could rise as high as USD 20 billion by 2020 due to the rising incidences of chronic diseases like diabetes, increasing healthcare costs and medical tourism.

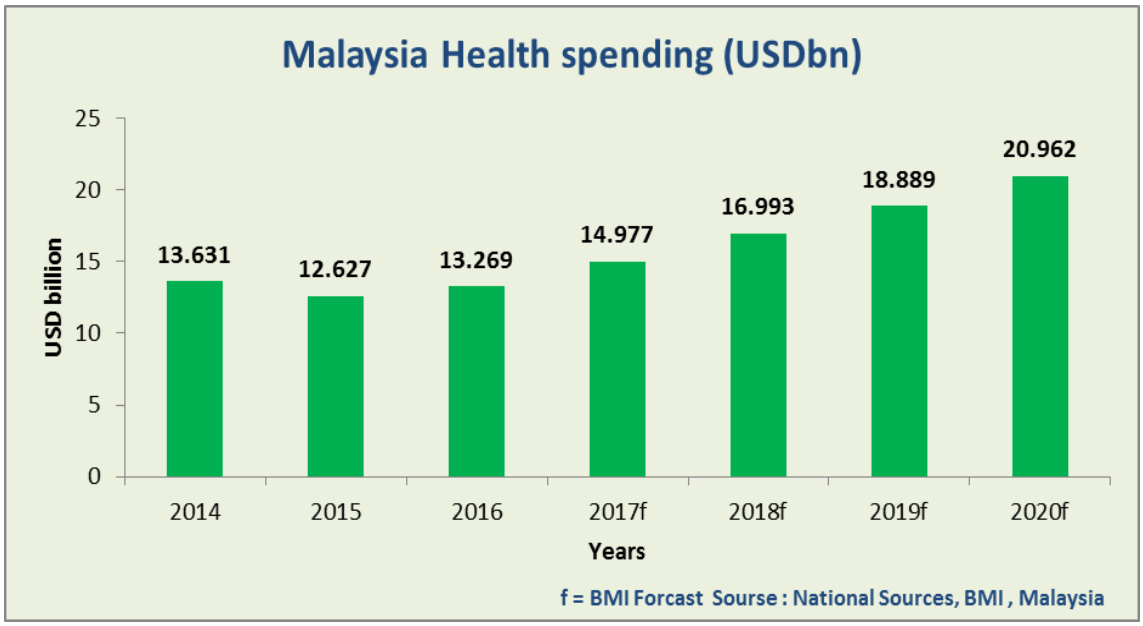


Figure 41 Malaysia Healthcare spending 2020

Malaysia, as one of Asia's most perceived creating nations regarding medicinal services, Healthcare in Malaysia has experienced radical changes. It has ascended to its monstrous potential as a favored medicinal services travel goal for the world. Social insurance in Malaysia is an appealing recommendation, offering world-class quality medicinal services, which is effectively available and intensely reasonable, for patients' genuine feelings of serenity. It has a broad arrangement of social insurance. It executes a widespread human services framework, which exists along the private social insurance framework. It is a standout amongst the most ethnically differing Asian nations. Accordingly, satisfactory human services arrangement for every statistic trademark is an unpredictable suggestion.

Social insurance framework in Malaysia is for the most part under the obligation of the administration's Ministry of Health. Medicinal services in Malaysia works on a proficient and far reaching two-level framework, comprising of an administration run general social insurance framework that serves Malaysian residents, and an existing together private human services framework that obliges natives and universal patients alike. By far most of the populace is secured by open human services protection, which is especially essential for the country poor. Minimal effort taxpayer driven organizations are financed by duties and other open incomes, in spite of the fact that they keep on suffering staff deficiencies. The administration circles 150 open doctor's facilities (MOH).

General society segment is hampered by impediments in human services spending plan and the capacity to hold experienced ability, the private part is equipping to address focused difficulties with a more grounded, more imaginative play that is focused to give both money related and social returns. One of the key ranges for improvement is further open and private medicinal services mix and a social medical coverage stage that can empower a more adjusted human services condition inside the nation. Non-Communicable Disease (NCDs) is progressively common in Malaysia. Just about 70% of Malaysian grown-ups have a NCD. 4.6 million Malaysians over the age of 18 will have diabetes, an increase of 1 million over 2014. Malaysians will soon be an aging society.

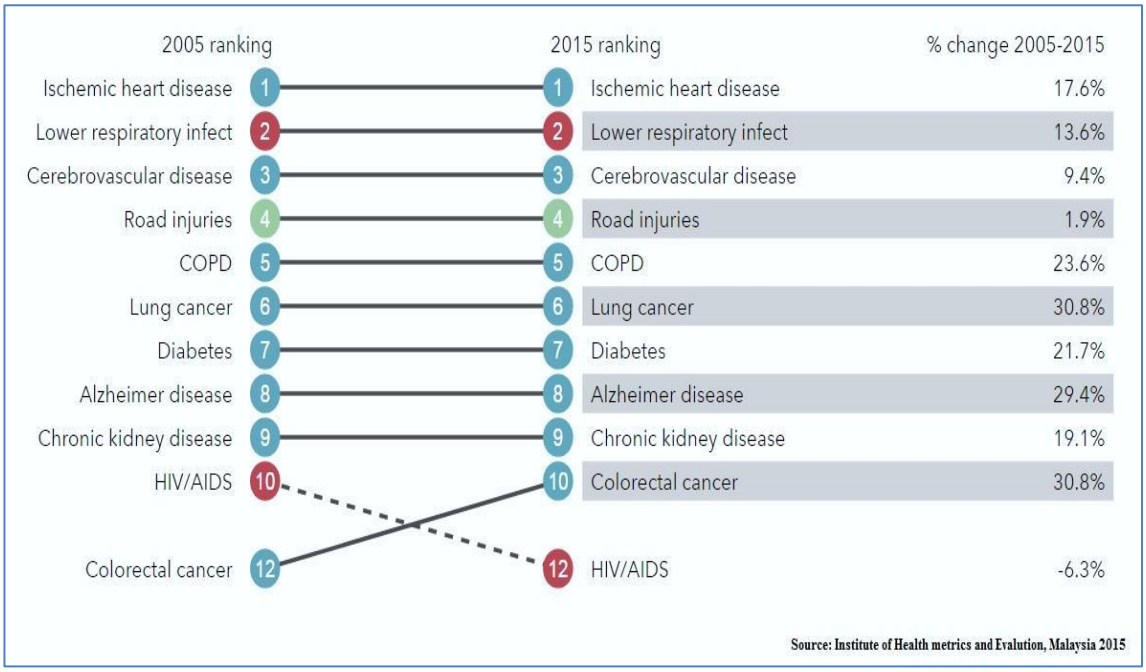


Figure 42 Top 10 causes of death by rate in Malaysia 2015

Pharmaceutical Market in Malaysia

The Malaysian Pharma industry was valued at MYR 8.58 bn (USD2.09 bn) in 2016 and it is expected to grow by 8.62 per cent per annum between 2016 and 2020, the market is expected to grow to US$ 3.164 billion by 2020.

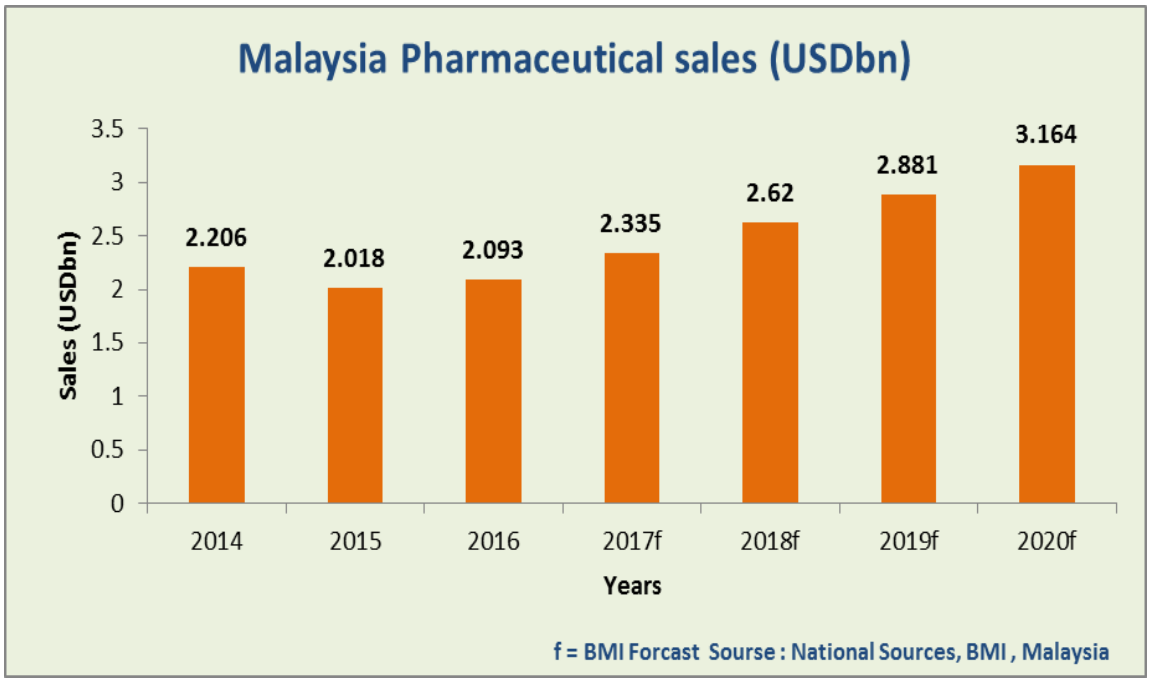


Figure 43 Malaysia Pharmaceutical Sales forecast 2020

The pharmaceutical business in Malaysia has indicated huge development in the course of the most recent decade, reliably expanding 7 to 9 percent every year. The market depends on a solid residential nonexclusive division and imports of marked and licensed solutions. The items produced by the Malaysian pharmaceutical industry fall into four classes:

1. Health and food supplements
2. Prescription medicines
3. Over-the-counter (OTC) products
4. Traditional medicines

As of now, the nearby business is creating around 30 percent of the local request. Malaysia's pharmaceutical requirements for protected and concentrated medications are foreign, which is assessed to represent over 80% of the nearby pharmaceutical market. As indicated by the Drug Control Authority (DCA) of the Ministry of Health Malaysia, a sum of 264 pharmaceutical producers with great Manufacturing Practices (GMP) affirmation have enrolled with the DCA. The GMP accreditation guarantees that items

are reliably created and controlled by quality models. Of the 265 makers, 80 are authorized to create present day meds involving predominantly analgesics, stomach settling agents, hostile to hypertensive, diuretics, anti-toxins, and against histamines. Another 180 makers are authorized to create neighborhood conventional and home grown pharmaceuticals while the remaining are veterinary premises. The Malaysian pharmaceutical makers are spoken to by the Malaysia Organization of Pharmaceutical Industry (MOPI). MOPI has just 37 individuals on the grounds that not all assembling organizations authorized by DCA are a part. MOPI assessed that their individuals can create 80% of the medications on the Malaysian National Essential Drugs Lists (NEDL).

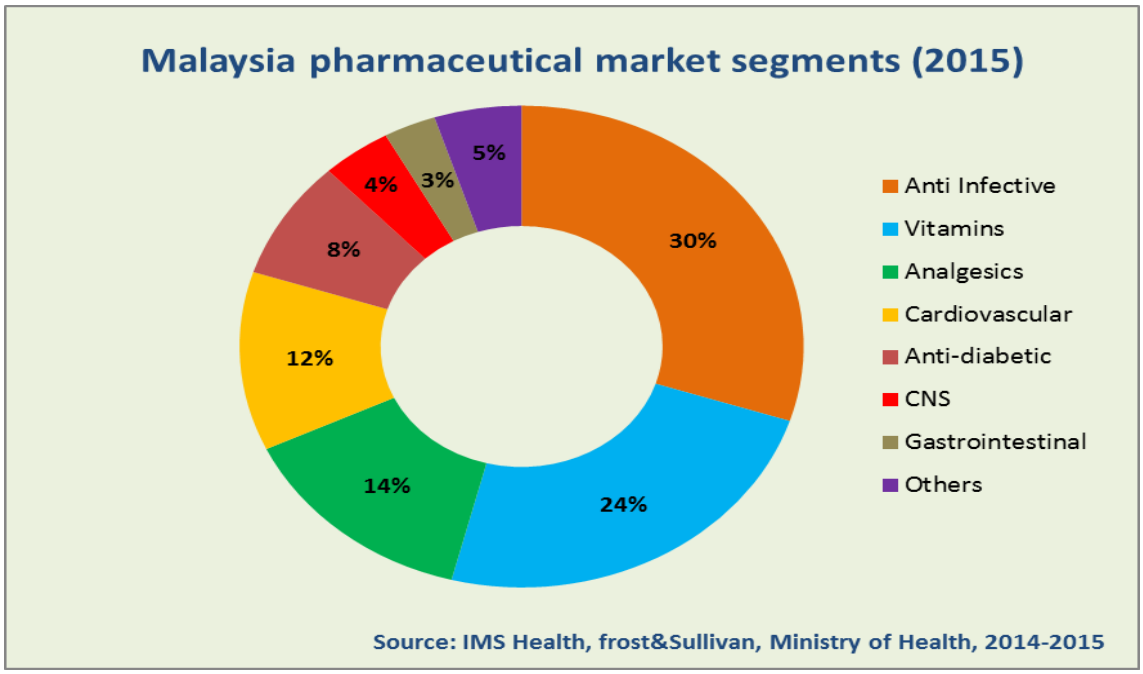


Figure 44 Malaysia Pharmaceutical Market Segment

The generics producing industry in Malaysia has been becoming over the previous decade; there are roughly 80 present day medicate makers authorized by the administration, are as yet important to take care of household demand. Local Malay makers are presently beginning to build R&D speculation and create higher esteem included nonexclusive medications like oncology prescriptions and biologics.

MOPI evaluated nonspecific medications solution represent 70% (in unit terms) of the medications utilization in the nation and 44% in esteem terms because of the cost-adequacy of the nonspecific medicines. Nonspecific medications in Malaysia are more financially savvy than the trend-setter item proportionate, as a rule 20-90% more affordable.

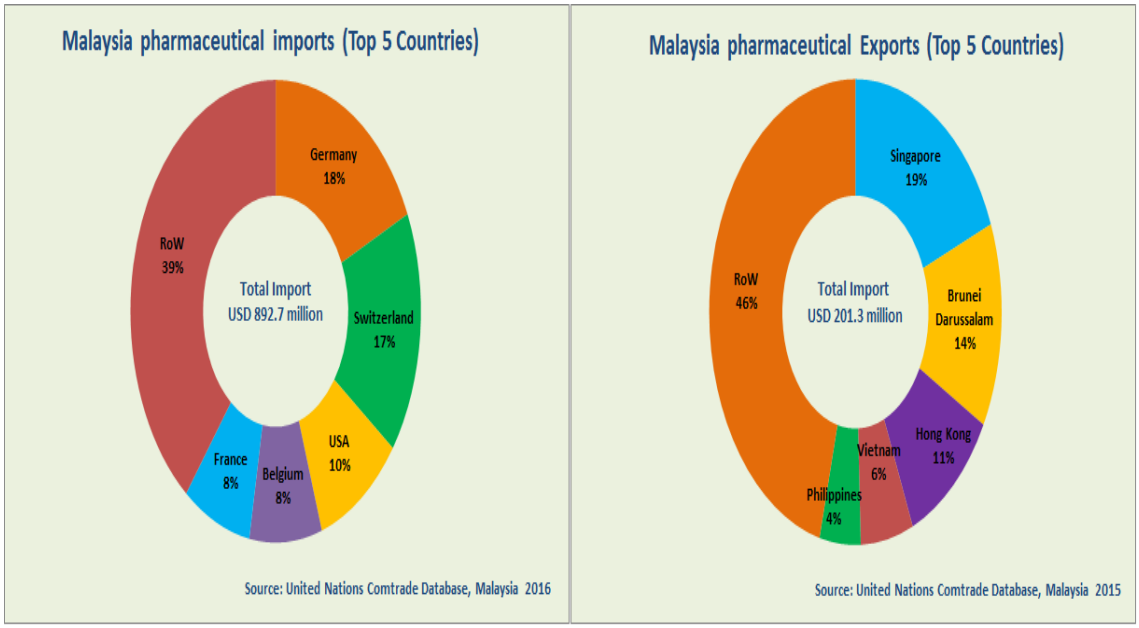


Figure 45 Malaysia Pharmaceutical Import-Export

Commodity	Qty 2015-16 (Kg)	2015-16 Value (US $)	Qty 2016-17 (Kg)	2016-17 Value (US $)	Percentage Growth in Value 2017 over 2016
AYUSH AND HERBAL PRODUCTS	1651117	7673476	1759601	8936020	16.45
BULK DRUGS, DRUG INTERMEDIATES	2574228	18308322	3310392	17937049	-2.03
DRUG FORMULATIONS, BIOLOGICALS	1731923	48531632	1209394	37821735	-22.07
Total	5957268	74513430	6279387	64694804	-13.18
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 10 Malaysia Pharmaceutical Import from India

Risk/Reward Index

Malaysian Pharmaceutical Risk/Reward Index score is 59.0 out of 100 in 2016, unchanged from the previous year's score. The country is ranked as the eighth most attractive pharmaceutical market in the Asia Pacific region, just below Singapore (62.1). Malaysia's above-average score is a reflection of its strong market growth potential.

Regulatory Landscape

The key regulatory pro in Malaysia is the Drug Control Authority (DCA). Pharmaceuticals industry are govern by the DCA, which is supervised by the official

general of prosperity, head of pharmaceutical organizations, head of the National Pharmaceutical Control Laboratory, and seven other assigned people. The standard obligation of the DCA is to ensure the security, quality, and sufficiency of pharmaceuticals in Malaysia. DCA-asserted secretly made pharmaceuticals are moreover recognized in Organization for Economic Co-operation and Development (OECD) countries, demonstrating the way of nonexclusive meds made in Malaysia.

All neighborhood pharmaceutical producers must be authorized by the DCA. Controls with respect to outside speculation have made the foundation of pharmaceutical joint endeavors troublesome before, however this procedure is ending up plainly to some degree simpler. Organizations wishing to build up assembling operations in the district have had a tendency to pick neighboring Singapore rather, which offers a more extensive scope of venture motivators, despite the fact that the Malaysian government is attempting to change this adjust.

Major Domestic Player of Pharmaceutical Industries

The major pharmaceutical industries are located in Kuala Lumpur city

1. CCM Pharmaceuticals Sdn. Bhd.
2. Hovid Berhad
3. Kotra Pharma (M) SdnBhd
4. Pharma NiagaBerhad
5. Hoe Pharmaceuticals SdnBhd
6. Antah Healthcare Group
7. Apex Healthcare Bhd
8. Bio-Pharmaceuticals SdnBhd
9. SG Global Biotech SdnBhd
10. Yung Shin Pharmaceutical (Y.S.P.) Industries

All above pharmaceutical companies are making generic as well as herbal products which cover local market share in Malaysia.

SWOT Analysis

Strengths	Weaknesses
1. Progressively dynamic government approach, gone for pulling in global speculation. 2. Improving neighborhood fabricating principles, with a guarantee to biotech improvement. 3. Sizeable generics showcase, given low patient buying power and remiss patent laws. 4. OTC and generics markets is very strong position	1. The week patent law remains conspicuously below international standards. 2. The Recent reform aimed at increasing generic product development 3. Stringent government drug pricing policy heavily biased towards local drug producers. 4. Local manufacturing only manufacture Generic, basic medicines.
Opportunities	**Threats**
1. Generics drug as an integral factor of market growth. 2. Exports is growing very fast 3. Increasingly pharmaceutical demand and Government law to prevent disease outbreaks. 4. Malaysia becoming more attractive country for medical tourism	1. Government resistance to aligning domestic patent lawfully with international standards. 2. Existence of a significant counterfeit drugs sector 3. Increased focus on internationally recognized norms and legislation to disadvantage local players 4. Possible introduction of price ceilings on essential medicines 5. Government seeking compulsory licenses for patented drug

Myanmar

Overview

The Union of Myanmar (or more commonly known as Burma) has an area of 676,578 square kilometers, making it the second biggest nation in Southeast Asia, The capital city is Naypyidaw. It imparts outskirts to Bangladesh, China, India, Laos, and Thailand. The Myanmar comprises of different ethnic gatherings. Myanmar's authentic money is the Myanmar kyat (MMK). Myanmar's economy is upheld by inexhaustible characteristic assets and wares. Myanmar is a rich in oil, gaseous petrol, and other mineral assets, its biggest fare is flammable gas, which is giving an inexorably essential income stream.

Myanmar is a lower middle-income country; In 2016 GDP amounted to be US$ 311.1 billion, and it is growing at an average annual rate of over 8.1 %. Myanmar has largely missed the enormous progress in growth, productivity, and poverty spreading across Asia. But as long as Myanmar stays the course on reform and transformation, it has a number of intrinsic assets and a highly supportive external environment on which to build.

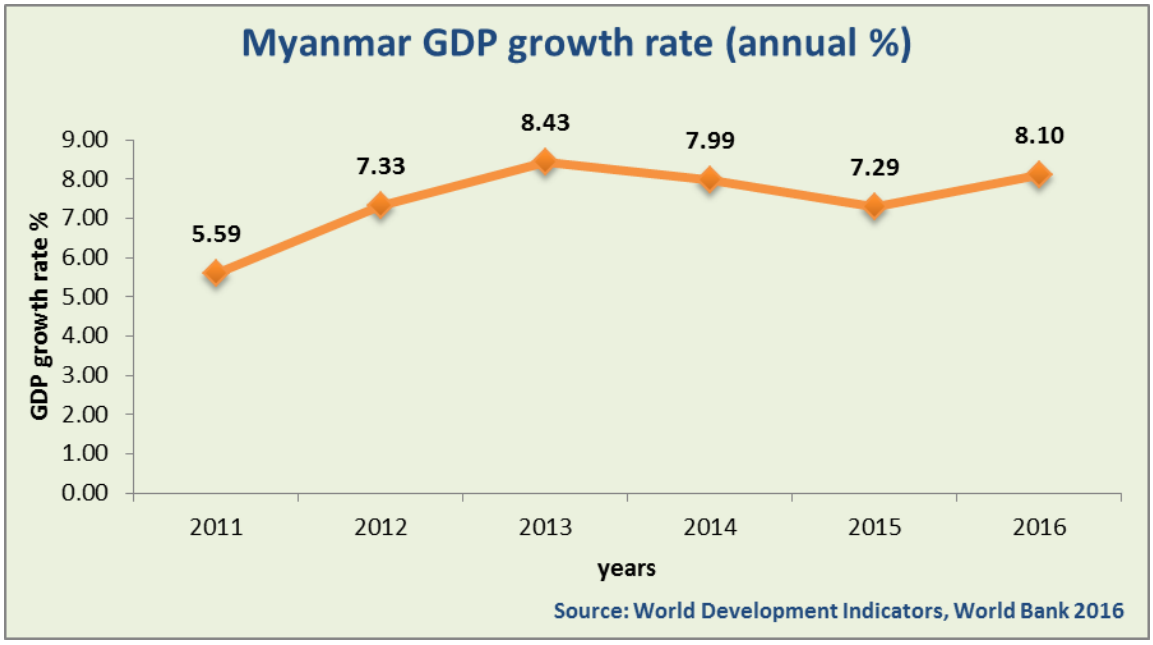


Figure 46 Myanmar GDP growth rate (%)

Government arrangement creators taking office in April 2016 have focused on proceeding with change, which is important if Myanmar is to accomplish its development potential, evaluated at 8% every year. The new organization is required to press for more straightforwardness and deregulation, less formality, enhanced

instruction and preparing, and more powerful and productive taxpayer supported organizations.

As the biggest nation in terrain Southeast Asia, Myanmar has one of the most minimal populace densities in the locale, with fruitful grounds, critical potential to build its generation, yields, and benefits in horticulture, and a rich blessing of characteristic assets. Myanmar needs satisfactory foundation. Products traverse the Thai outskirt (where most illicit medications are sent out) and along the Irrawaddy River. The unwinding of outside trade controls is relied upon to move imports upward and add to an extending of the present record shortfall. Facilitating of monetary approvals forced on Myanmar by modern nations ought to prompt larger amounts of exchange and venture, and in addition the resumption of help and concessionary financing, both from these nations and from worldwide money related establishments.

Myanmar has a financial and exchange concurrence with Turkey and monetary concurrences with China, Malaysia, and Singapore and so on. It additionally has exchange concurrences with Bangladesh, India, Israel, Malaysia, Pakistan, the Philippines, Sri Lanka, Thailand, and Vietnam. Myanmar is an individual from the ASEAN Free Trade Area (AFTA), a signatory to the ASEAN Framework Agreement on Services (AFAS), and a gathering to the Framework Agreement on the ASEAN Investment Area (AIA). As an individual from ASEAN, Myanmar is a gathering to the ASEAN-China Free Trade Agreement, the ASEAN-Korea Framework Agreement on Comprehensive Economic Cooperation.

While the Myanmar government has great monetary relations with neighbors, for example, China and Thailand, huge upgrades in the business and political atmosphere and financial administration will be required to pull in genuine, long haul venture, especially from western economies.

Myanmar Key Indicators

Demographic	Indicators
Location	Southeastern Asia, bordering the Andaman Sea and the Bay of Bengal, between Bangladesh and Thailand
Total Area	676,578 sq. km
Climate	tropical monsoon; cloudy, rainy, hot (southwest monsoon, June to September); less cloudy, lower

	humidity during winter (northeast monsoon, December to April)
Population	56,89 million (July 2016)
Age structure	**0-14 years:** 25.77% **15-24 years:** 17.73% **25-54 years:** 43.54% **55-64 years:** 7.49% **65 years and over:** 5.47%
Urban population	34.1%
Population growth rate	1%
Literacy	93.1%
Languages	Burmese (official)
Economic	**Indicators**
Currency	Burmese kyat
GDP - exchange rate	$68.28 billion
GDP - growth rate	8.1%
GDP - per capita	$6,000
GDP - composition by sector	**Agriculture:** 26.3% **Industry:** 27.5% **Services:** 46.2%
Industries	Agricultural, tungsten, iron; cement, pharmaceuticals; wood, copper fertilizer; oil and natural gas; garments; jade and gems
Healthcare	**Indicators**
Health expenditures	2.3% of GDP
Hospital bed density	0.6 beds/1,000 population
Major infectious diseases	**food or waterborne diseases:** bacterial and protozoal diarrhea, hepatitis A, and typhoid fever **vectorborne diseases:** dengue fever, malaria, and Japanese encephalitis

	water contact disease: leptospirosis **animal contact disease:** rabies
HIV/AIDS - adult prevalence rate	0.76%
Obesity - adult prevalence rate	2.9%
	Source: Central Intelligence Agency 2016

Pestle Analysis

Political

Myanmar is administered by the military junta and still, assumes a high part with loaded with compulsion and no vote based system. His administer gone on for twenty-six years. Amid this time San Suu Kyi ascended as the unmistakable pioneer yet she was imprisoned and after that later house captured for over 15 years. Following quite a while of discretionary disconnection and monetary and military approvals, and the US loose checks on outside guide to Myanmar in November 2011 and declared the resumption of conciliatory relations on 13 January 2012. She got opportunity in 2010 and battled the presidential decisions of 2016; nonetheless, she lost to Htin Kyaw yet regardless she will hold a position in get together and proceed with her tranquility development for which she won Nobel Prize also.

The Myanmar military junta has been utilizing hostile to subversive and interior security constitution to destruct the democratization procedure. What's more, in 2008 constitution choice guaranteed to hold races in 2010 and perform majority rule government later on. The EU has put authorizes on Myanmar, including an arms ban, end of exchange inclinations, and suspension of all guide except for compassionate guide.

Economic

In mid sixty's Myanmar was a financially wealthiest nation in Southeast Asia and the world's biggest exporter of rice. In any case, since it begun to get represented by junta administration, the normal rate of yearly GDP development just stayed 2.9%, GDP per capita slipped to $233 and expansion rate reach in the vicinity of 30 and 60%. In 2015 Myanmar had surges and avalanches in its pinnacle farming months accordingly of which products were annihilated and economy got a huge hit. Swelling shot up as costs of products went up because of a deficiency of provisions. The administration called for

support from global groups as it couldn't deal with this without anyone else. The underlying foundations of every single monetary issue lie in the arrangements of 1960. These strategies made nation vigorously agrarian and absence of fulfillment and market neglected to give motivators to enterprises to create. (Asian Development Outlook 2015 Update: Enabling Women, Energizing Asia, 2015)

Social

There are ethnic social affairs, with 108 vernaculars, and Bamar is the best ethnic, with over 87% of people and Buddhism is the best religion. A different extent of indigenous social orders exists in Myanmar. The military organization abused people and did not give them the privilege to talk unreservedly not only this they in like manner filled ethnic violence and put a limitation on lessons of other ethnic feelings. The repression approach in like manner covered a robust part of their social issues like enrolling underage children in the military as a result of lacking work available to smother the nation, usage of children in illegal occupations. Various Muslims were killed along these lines various others were made desperate. Preparing and prosperity are undeveloped as an important portion of the monetary support is relegated to military and less on other social regions.

Technological

Since 2010 Myanmar's economy started opening up and with that development trade began, disregarding the way that the convenient invasion is at 40% and the web at 21.9% in 2016, Myanmar was beforehand the world's greatest rice exporter and group for piece of attire collecting yet military organization and US sanctions expelled the status from them. By and by when the best approach to headway and progress has opened by the day's end then Myanmar should endeavor to benefit however much as could be normal from the condition.

Environmental

The most pressing environmental issue with the country is deforestation and illegal logging with the worldwide associations preceding the issue is depended upon to take off up significantly higher. Capability rate and straightforward passage to information have made people fragile and careful about the rich inheritance of their country and the hazard it is in.

Legal

The true blue and legitimate structure is deteriorating to the inside and in no state of securing the inhabitants and outside budgetary authorities. The economy can flourish when people have trust in the structure that whatever has a place with them won't be taken away by urge or preposterous means and they will be given help and support to create. New government needs to guarantee that it gains ground and make approaches that are critical to win back everyone's trust.

Business Environment in Myanmar

Myanmar is one of the slightest created nations on the planet, with an abnormal state of destitution (26%) in Southeast Asia. It has experienced many years of stagnation, botch, and disengagement. Foundation in major urban ranges is simple, best case scenario and practically non-existent in most rustic zones. The nature of the training framework has weakened over numerous years, bringing about a serious lack of talented specialists, also qualified people to deal with the economy. The monetary part is primitive, with an old-fashioned saving money framework. The nation experiences a conversion standard approach that is neither uniform nor bound together. This has not just brought about contortion in the market and in costs yet has additionally contrarily influenced fares and imports.

Myanmar also lacks many of the basic business and commercial laws and regulations required for a functioning business environment. Outside of the agricultural sector, much business activity is concentrated in state-owned enterprises or enterprises controlled by former regime members. Crony capitalism is rampant.

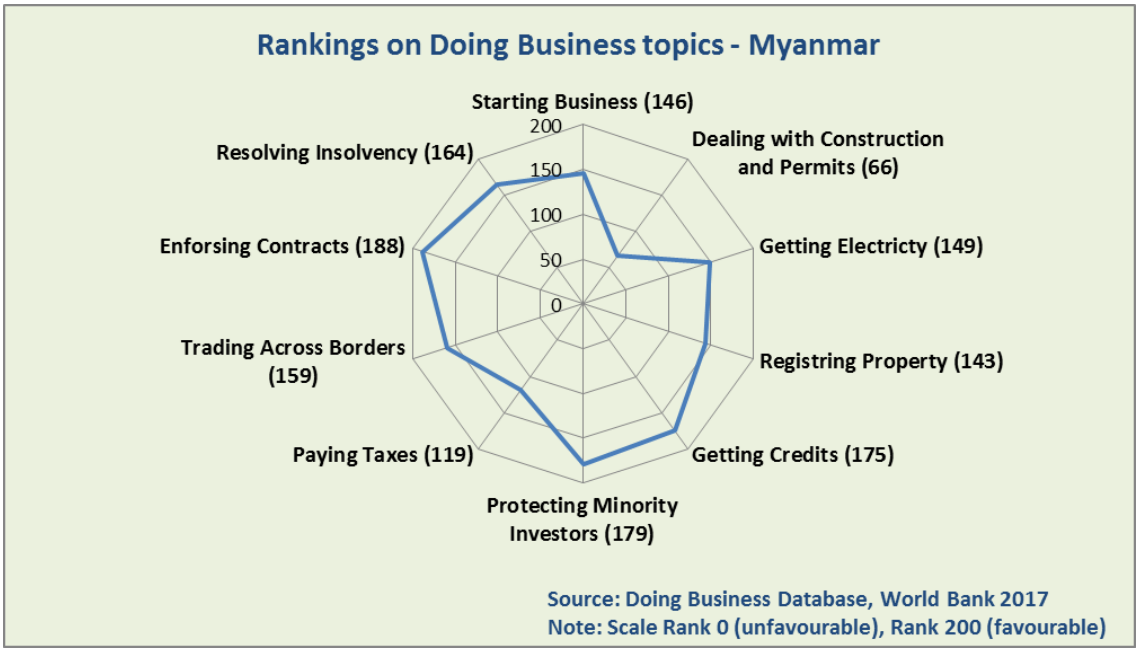


Figure 47 Myanmar Doing Business Environment

Healthcare in Myanmar

The healthcare spending in Myanmar was worth close to $1.39 billion in 2016, it is expected to grow at CAGR of 8.0%. Healthcare expenditure was 2.3% of GDP in 2014. Myanmar healthcare expenditure could reach to USD 2.04 billion by 2020 due to the rising incidences of chronic diseases, increasing healthcare cost.

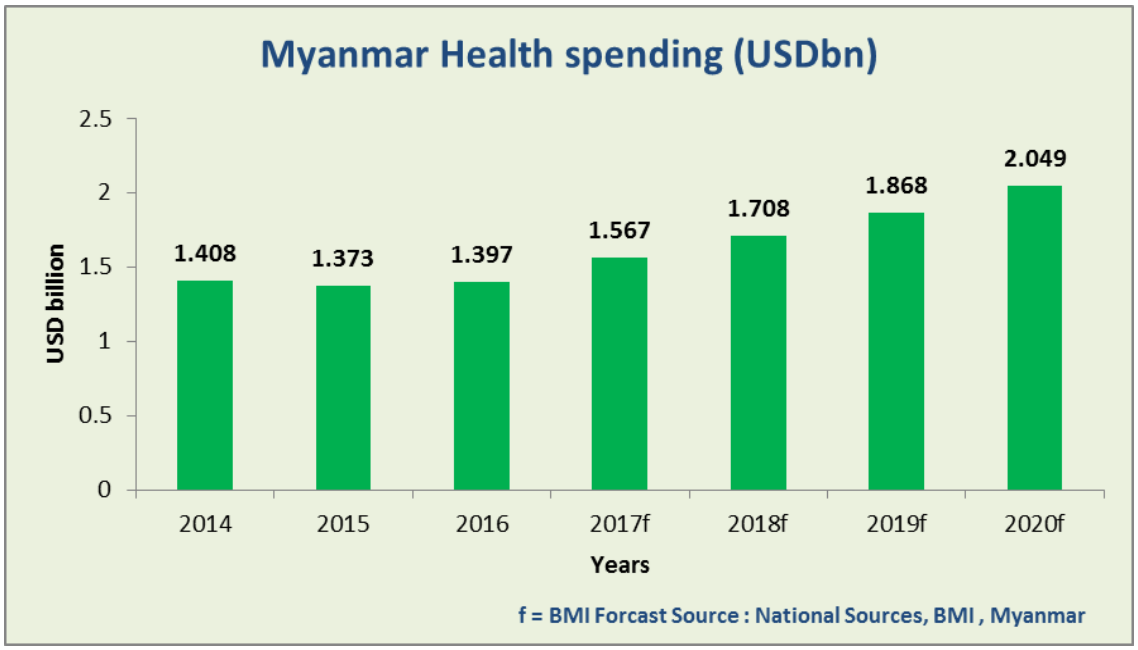


Figure 48 Myanmar Healthcare spending 2020

With a population of over 57 million people, Myanmar's healthcare sector represents a huge area with enormous opportunities. Myanmar health care system evolves with changing the political and administrative system and relative roles played by the key providers are also changing although the Ministry of Health remains the major provider of comprehensive health care. Myanmar is left behind by international development and is scrabbling to achieve the government's ambitious plans. The challenges surrounding the healthcare sector are rooted in the mismanagement of the previous administration, the military regime. The current government has indicated that one of its first priorities will be improving and expanding basic health care provision. Other aims include reducing out-of-pocket spending on medical treatment and permitting the opening of more private healthcare centers, to augment public health systems. In recent years, the military-backed civilian government and the new administration have both prioritized the healthcare sector with increased budget allocations. The sector has also seen increased foreign investment by regional and global players.

HIV/AIDS recognized as a disease of concern by the Myanmar Ministry of Health, is most prevalent among sex workers and intravenous drug users. In 2014 the estimated adult HIV prevalence rate in Burma was 0.8%. Non-communicable diseases (NCDs) are increasingly in Myanmar. Myanmar's Health Vision 2030 encompasses the long-term objectives. This includes: eradication and elimination of communicable diseases.

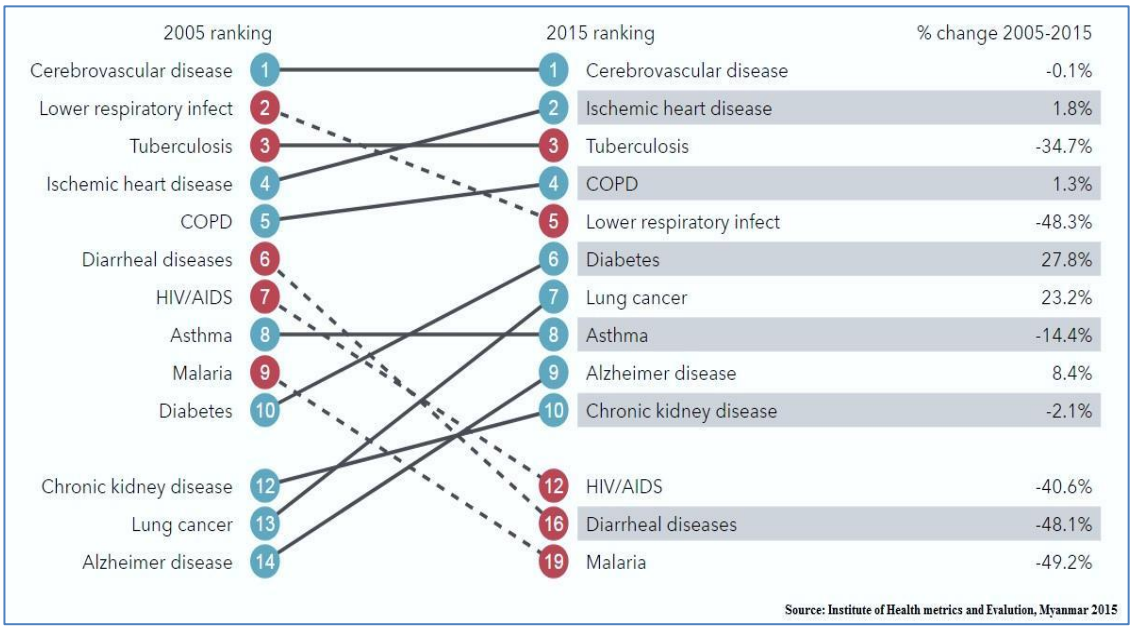


Figure 49 Top 10 causes of death by rate in Myanmar 2015

Myanmar's healthcare sector is serviced by both the private and public sectors. The Ministry of Health & Sports is the union-level ministry implementing the National Comprehensive Development Plan (NCDP); and the Department of Health – a department of the Ministry of Health & Sports serves as the main regulatory body for healthcare providers as well as stakeholders in the fields of pharmaceuticals, medical devices, and capital investment. Myanmar Medical Association (MMA) is the facilitator between different healthcare providers and ensures that private practitioners are integrated into public healthcare activities.

Since 2011, the government has been gradually increasing the budget allocation for the healthcare and education sectors. Total government health expenditure in 2016 was USD 1.39 billion. The funds will be earmarked for the purchase of advanced medical equipment, including electrosurgical technology; the provision of free medical treatment for government employees; and training medical professionals. The major source of finance for healthcare services is the Union Government, with other sources consisting of foreign aid and community contributions and donations.

The state of health in Myanmar is gradually improving, with significantly higher levels of funding being allocated by the state, and foreign donors and private investors looking to participate. To ensure its 57 mn people have access to better care, and mindful of the challenges, the administration is increasingly open to assistance from foreign governments, NGOs, and private firms. The newly installed government has also put education at the heart of its reform agenda, recognizing its potential for lifting the country out of poverty. More money is being channeled into the sector as officials seek to build a 21st-century education system to help push Myanmar into the ranks of the upper-middle-income nations by 2030.

Pharmaceutical Market in Myanmar

The Myanmar's Pharmaceutical industry was valued at MMK525 bn (USD409 mn) in 2016 and it is expected to grow by 8.7 percent per annum between 2016 and 2020, the market is expected to grow to US$ 0.622 billion by 2020.

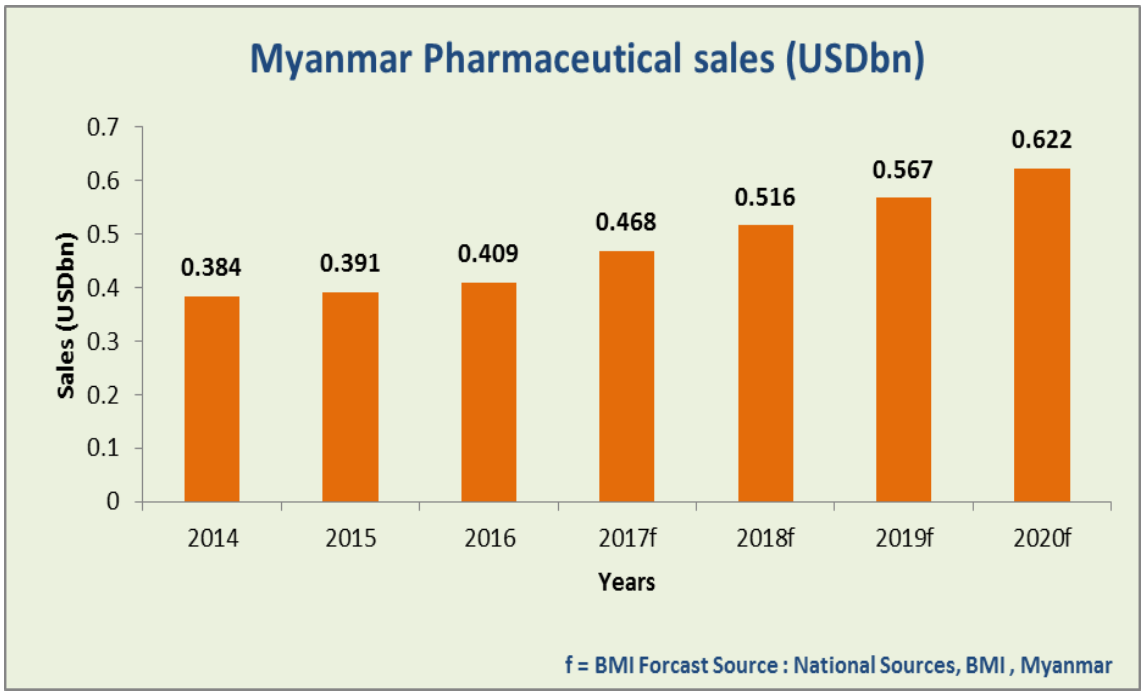


Figure 50 Myanmar Pharmaceutical Sales forecast 2020

Myanmar pharmaceutical market is immature. A lion's share of the nation's pharmaceutical supplies was foreign made or delivered by the Myanmar Pharmaceutical Factory, the main state-claimed pharmaceutical plant in the nation under the Ministry of Industry. Western nations organizations are presently starting to demonstrate some enthusiasm for the market. At present India's bland organizations are the fundamental remote organizations in the nation. Ranbaxy, Cipla and Wockhardt are the principle organizations from India. In December 2013, STADA Arzneimittel announced that its items are currently accessible in Myanmar, with neighborhood accomplices offering both nonexclusive and marked items through in-authorizing. STADA remarked that the item go on offer will be progressively extended, and noticed that the move makes it one of the main Western pharmaceutical organizations to take up exercises in Myanmar. They Plan to begin creation in 2015.

Anti-Infective Lead Market Share of Myanmar about 35 Percentages which has higher market share than others. Vitamins have led market with market share of 30% and analgesic's market share is about 11%.

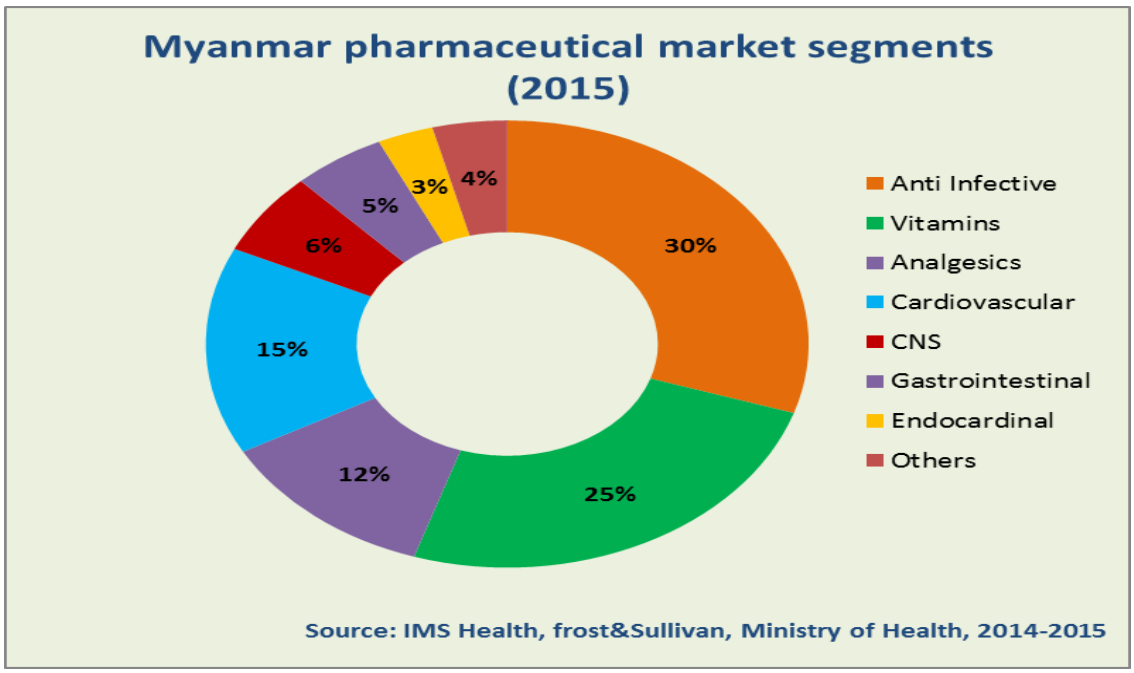


Figure 51 Myanmar Pharmaceutical Market Segment

The country holds only 4 local pharmaceutical production units as the domestic industrial production for all the sectors is in its nascent stages. In sharp contrast, there are 100 odd distributors of foreign drug companies, importing over 5000 kinds of allopathic formulations. Inevitably local demand for medicines & health supplements is fed by imports. A lot of Myanmar's interest for pharmaceuticals is filled by imports, as Myanmar's residential pharmaceutical industry is little and immature. As indicated by information from UN Commodities Trade pharmaceutical imports achieved US$278.1 mn in 2016.

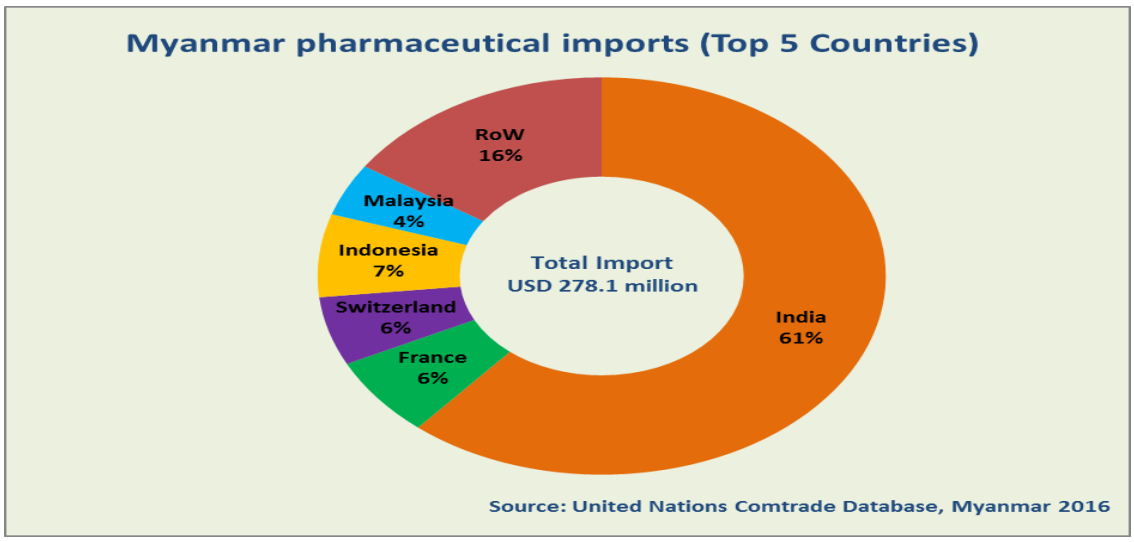


Figure 52 Myanmar Pharmaceutical Import

Commodity	Qty 2015-16 (Kg)	2015-16 Value (US $)	Qty 2016-17 (Kg)	2016-17 Value (US $)	Percentage Growth in Value (2017 over 2016)
AYUSH AND HERBAL PRODUCTS	366603	911970	407364	1166886	27.95
BULK DRUGS, DRUG INTERMEDIATES	446612	653377	468474	991494	51.75
DRUG FORMULATIONS, BIOLOGICALS	10026763	176632695	9647573	191449056	8.39
Total	10839978	178198042	10523411	193607436	8.65
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 11 Myanmar Pharmaceutical Import from India

Risk/Reward Index

Myanmar is ranked last out of the 20 key markets in the Southeast Asia region, the country scored 27.8 out of 100, below the regional average. Due to its small pharmaceutical market and the lack of general infrastructure to support health care and still-fragile macroeconomic and political outlook

Regulatory Landscape

The principle administrative expert in Malaysia is the Food and Drug Administration (FDA), under the protection of the Ministry of Health. The Food and Drug Administration (FDA) was built up in 1995 and is in charge of the wellbeing and nature of sustenance, medications, medicinal gadgets and beauty care products issued in the nation. Exercises of the organization incorporate endorsement for new items, changes to existing items, quality control research facility testing, antagonistic medication response observing, great assembling hone investigation, authorizing of producers, wholesalers, requirement exercises, tranquilize advancement, and ads. The Myanmar FDA works with the Customs Department, the Directorate of Trade and the Myanmar Police Force. The organization takes essential measures to ensure just enrolled medications are foreign made into Myanmar. The FDA likewise issues wellbeing suggestions for neighborhood sustenance fabricating, imported nourishments, and sent out sustenance's.

Enrollment applies to foreign and also locally fabricated items and spreads both general society and private segments. Rules for medication enlistment have been figured, and

require that anybody applying for enrollment ought to be an occupant of the Union of Myanmar. On account of outside organizations, the candidate must be a lawful agent domiciled in Myanmar however require not be the sole shipper of the medication

As Myanmar opens up and the government pursues its ambitions towards enhancing healthcare services and extending universal healthcare to the country's 57 million people, there has been a high inflow of foreign direct investment (FDI) in the healthcare sector. Multinational companies (MNCs) like General Electric (GE), as well as companies from regional markets, have invested in Myanmar, especially in the areas of medical equipment and pharmaceutical products.

Major Domestic Player of Pharmaceutical Industry:

The major pharmaceutical industries are located in two cities which are in Yangon and Mandalay from where 60 percentages of pharmaceutical product sales are made.

- FAME PHARMACEUTICAL
- SAN LWIN TRADING COMPANY
- A A MEDICAL PRODUCT
- GETZ PHARMA LIMITED.
- TAJ PHARMA LIMITED

All above pharmaceutical companies are making generic as well as herbal products which cover higher market share in Myanmar.

SWOT Analysis

Strengths	Weaknesses
1. Global sales and marketing network 2. Brand awareness in medical field 3. Skilled sale and marketing staff with medical knowledge background 4. Reasonable price and Japan product in the market	1. Unfamiliar brand with the market 2. High price compared to low-quality brands 3. Unskilled workforce
Opportunities	**Threats**
1. Growing Myanmar market 2. Technology aid and produce in Myanmar can freely trade with the rest of the ASEAN countries without tax (Products of Myanmar under Japan technology)	1. Lower Price of other similar products 2. Counterfeit Products in the market - Blocked by strong competitors 3. Counterfeits drugs and Product Errors

Cambodia

Overview

Cambodia is situated on the Indochinese peninsula; it is bordered by Laos and Thailand on the north and Vietnam on the east and south. The size of Missouri, country consists chiefly of a large alluvial plain ringed by the mountains with the Mekong River to the east. Cambodia is an agrarian country like India. Approximately 80 percent of the Cambodian population is involved in agriculture on a full-time or part-time basis, though it is doing extremely well in various sectors like a garment, tourism, and construction or real estate sectors, Cambodia has experienced speedy increment in economic status over the last decade.

Cambodia is a lower middle-income country. It has an experienced of robust growth of economy over past decade; the Gross Development Product is sprouting at an average yearly rate of about 7% between the years 2010 and 2016. The construction, agriculture sectors, garment, real estate, and tourism together contribute for the majority of the growth. Over 0.7 million population majorly women's, are working in the garment as well as footwear sector. Additionally, fifty thousand Cambodians are on the payroll in the tourism sector and around sixty thousand people are working in the construction sector. Tourism has sustained to rise swiftly with the foreign influx more than 2 million per year since 2007 and had reached somewhere around 5 million visitors in 2015. One more attracting sector for the payers is mining and the Cambodian government has also praised opportunities for the mining of bauxite, gems, gold, and iron.

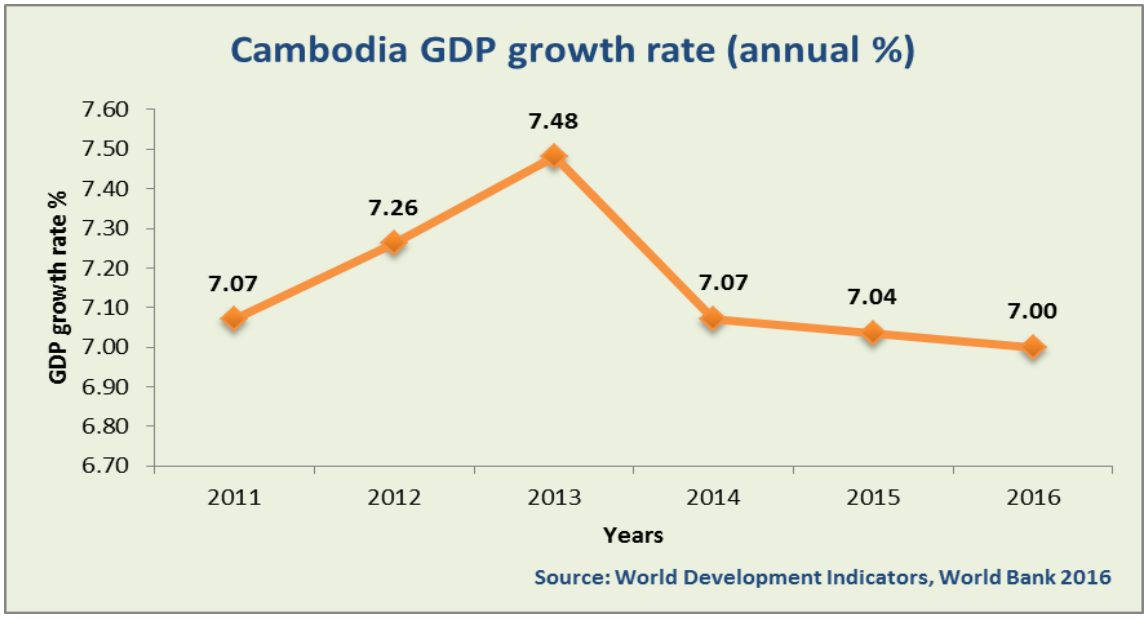


Figure 53 Cambodia GDP growth rate (%)

Cambodia continued to be one of the poverty-stricken countries amongst other Asian countries and long duration development of economic conditions lasts as a daunting objection, occupied by the regional corruption, narrow human resources, large differene in the income pattern, and poor prospects of job.

Cambodia Key Indicators

Demographic	**Indicators**
Location	Southeastern Asia, between Thailand, Vietnam, and Laos
Total Area	181,045 sq. km
Climate	Tropical; rainy, monsoon season (May to November); dry season, little seasonal temperature variation
Population	15,957,223 (2016)
Age structure	**0-14 years:** 31.24% **15-24 years:** 19.02% **25-54 years:** 40.18% **55-64 years:** 5.43% **65 years and over:** 4.14%
Urban population	20.7% of total population
Population growth rate	1.56% (2016)
Literacy	77.2%
Languages	Khmer (official) 96.3%, other 3.7%
Economic	**Indicators**
Currency	Riels (KHR)
GDP (official exchange rate)	$19.37 billion
GDP - real growth rate	7%
GDP - per capita (PPP)	$3,700
GDP - composition by sector	**Agriculture**: 26.7% **Industry**: 29.8%

	Services: 43.5%
Industries	construction, tourism, garments, rice milling, fishing, wood and wood products, rubber, cement, gem mining, textiles
Healthcare	**Indicators**
Health expenditures	5.7% of GDP (2014)
Life expectancy	64.5 years
Hospital bed density	0.7 beds/1,000 population
Major infectious diseases	**Food or Waterborne diseases:** bacterial diarrhea, hepatitis A, and typhoid fever **Vectorborne diseases:** dengue fever, Japanese encephalitis, and malaria
HIV/AIDS - adult prevalence rate	0.63% (2015)
Obesity - adult prevalence rate	2.9% (2014)
	Source: Central Intelligence Agency 2016

Pestle Analysis

Political

Cambodia is in the developing phase, having a constitutional monarchy with a multiparty democracy and an elected government. Political risk and instability in Cambodia are relatively high, compared with other developing countries and emerging markets. Currently, the Cambodian People's Party is in government. According to the Economist Intelligence Unit (EIU) country report (September 2014), the Prime Minister Hun Sen and his Cambodian People's Party (CPP) will continue to hold power until 2018

United States-Cambodian bilateral relations have been strong and broadened from the past years. US have helped the country around $62 million by varied USAID mission welfare programs. Cambodia is a constitutional monarchy. After 2013 election, there were two main political entities: named CPP and CNRP. Transparency International (TI) has ranked Cambodia on 156th place in the list of perception about corruption index

in the year 2016. Government of Cambodia made an effort to deduce the level of corruption throughout the nation, registration of company is also become simplified as well as automatic in nature. Its aim is to provide applicants to register a new company on the online forum in comparatively less time, which in turn reduces the face-to-face interaction.

Economic

Identified as an 'Olympian of Growth' by the World Bank, Cambodia has made major economic progress after decades of civil war. Cambodia has a GDP of $19.7 billion with a growth rate of 7%, Per Capita GDP of $3700 and inflation of 2.8% in 2016. shoe manufacturing, rice milling, Garment, Textile, tobacco, fisheries and fishing, wood and wood products, cement, rubber, papers and food processing are a major industrial sector of the country which holds 29.8% of GDP (2016).

The main driver for Cambodia's economic performance depends on a narrow base of four sectors: agriculture, tourism, garment manufacturing and construction. 100% shareholding FDIs allowed towards the investment has attracted growing number of investors. Cambodia's economic situation is dependent and exposed to exchange rates, which causes a high risk to the country's export competitiveness and developing economic stability. Cambodia's macro-economic position is expected to remain stable and moderate safe, according to the World Bank (2015)

Social

The number of inhabitants in Cambodia is 15.9 million and 95% of those have confidence in Theravada Buddhism and rest Islam, Christian and so on. Nation is a blend of Khmer 97.6%, Cham 1.2%, Chinese 0.1%, Vietnamese 0.1%, other 0.9% ethnic gatherings. Cambodia has a proficiency rate (2016) of 77.2% and Khmer is a first dialect talked by 95% of the populace and English is expanding as a moment dialect. Cambodia is a prevalently female culture, setting a higher incentive on individuals, personal satisfaction and supporting than on profession, cash, and achievement. Cambodians for the most part eat rice and fish and they are known for silk and cotton weaving, silverwork, silver and gold adornments, and basketry. Piece of clothing enterprises for the most part involve female workers and the work cost is low $ 50 - 80 every month (NPRS PRF article). Cambodia has a moderately solid and youthful workforce that particularly benefits the attire creation area. Be that as it may, the insufficient instructive frameworks and low inspiration and hard working attitude of specialists keep Cambodia from building up a talented work constrain and continue

fabricating powers as generation quality, profitability, innovation, and advancement restricted

Technological

Cambodia is far behind in their technological sector. Cambodia's current electricity supply does not meet the basic demand of the country. Cambodians do not have regular access to electricity and the distribution of electricity infrastructure remains disproportionate between rural and urban areas. Furthermore, the major demand of electricity is covered through imports from Thailand, Vietnam, and Laos. Cambodia's capital, Phnom Penh, alone consumes about 70-80% of Cambodia's total electricity demand. An electricity expansion to rural areas – majority of most households in Cambodia – is still limited. Poor infrastructure is among the main factors that are limiting Cambodia from significant economic development. The especially weak quality of electricity supply, high electricity costs and a further increase in electricity demand, cause industry sectors to face major difficulties, due to decreasing inflowing FDI's.

Environmental

Cambodia has 181,035 km^2 and counts as one of the major forest countries in the world. Today around 40% of the land are tall forest covered, Cambodia's climate is tropical and subject to southeast and northwest monsoons. Energy resources are relatively low in Cambodia. Therefore the country is highly reliable on imports from neighboring countries. Cambodia's main environmental offsets are immense deforestation rates, illegal logging, and strip mining. Cambodia as one of the countries that are put on highest risk looking at influences of climate change, Cambodia recently received additional financial support from the EU, Sweden and the United Nations Development Programed (UNDP) to tackle threats evolving through climate change. The EU alone provides over 50% of the committed financial contribution for the second phase of Cambodia Climate Change Alliance (CCCA) plan by 2019. Cambodia is highly reliant on external financial support in order to receive necessary resources to cope with upcoming climate changes.

Legal

The legal law is a week as compare to other Southeast Asian countries; the current significant competitive advantage of duty-free exports to the European market could be threatened in the future, by countries such as Vietnam. a future duty-free access

between Vietnam and the EU would most likely see buyers and factory owners relocation to Vietnam Minimum wage exists only in the garment sector.

ASEAN Free Trade Area (AFTA) agreement which leads to in Reduction/limitation of intra-regional tariffs through Common Effective Preferential Tariff (2018), Implementation of Open Trade Policy allows 100% foreign ownership benefit, 0% Tax Rate, and Promoting industrial growth by increasing the share of manufacturing rising from 15% of GDP in 2012 to 20% in 2024. Cambodian Trade Integration Strategy (by World Bank): supporting trade development and integration into world economy

Business Environment in Cambodia

The long haul headways of the economy of Cambodia stay to mirror an overwhelming test following quite a while of war. The region is experiencing a remote fundamental framework in the field. The legislature is working with both two-sided and in addition the multinational supporters or the funders, which incorporates the World Bank and IMF, to address the nation's major having necessities. Right now, the legislature of Cambodia has expected to bring the advancement up in the foundation segments which comprise the extension of street, street upkeep, and development of the scaffold, in order to encourage the transportation with in the nation.

The chief economic challenge faced by the Cambodian government is that the coming decades will develop an economic habitat in which the private sector can create ample amount of job opportunities which will in turn handle the demographic imbalance in the country. More than 50% of the Cambodian population is under the age of 25 years. Also, the population lacks in necessary education as well as the skills, especially in the poor class of the countryside.

The government is also making initiatives in order to provide a favorable situation for the private sector. Particularly, the government is trying to lower the cost of practicing the business by reducing the corruption and also by mobilizing resources in order to increase the development of social as well as economical and physical infrastructure.

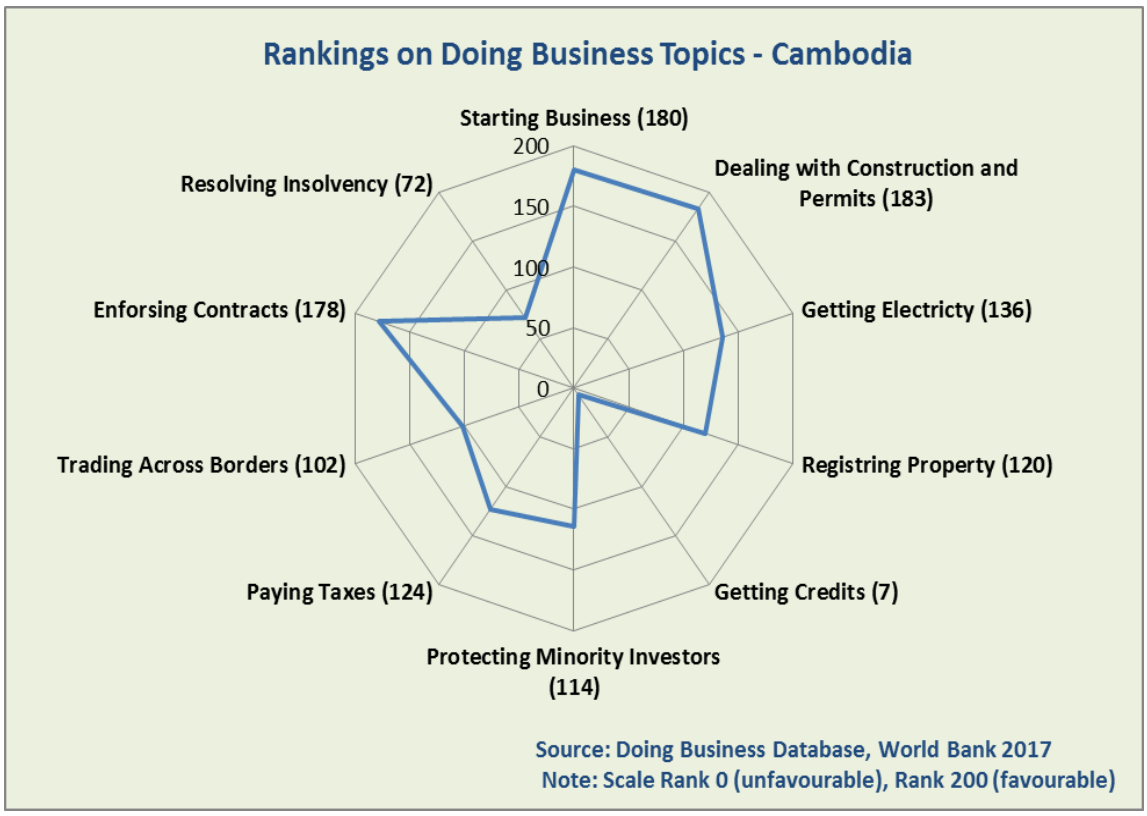


Figure 54 Cambodia Doing Business Environment

Healthcare in Cambodia

The healthcare spending in Cambodia will be worth close to $1.1 billion in 2016, it is expected to grow at CAGR of 4.2%. The market is expected to grow to US$ 1.279 billion by 2020. Healthcare expenditure was 5.75% of GDP in 2014.

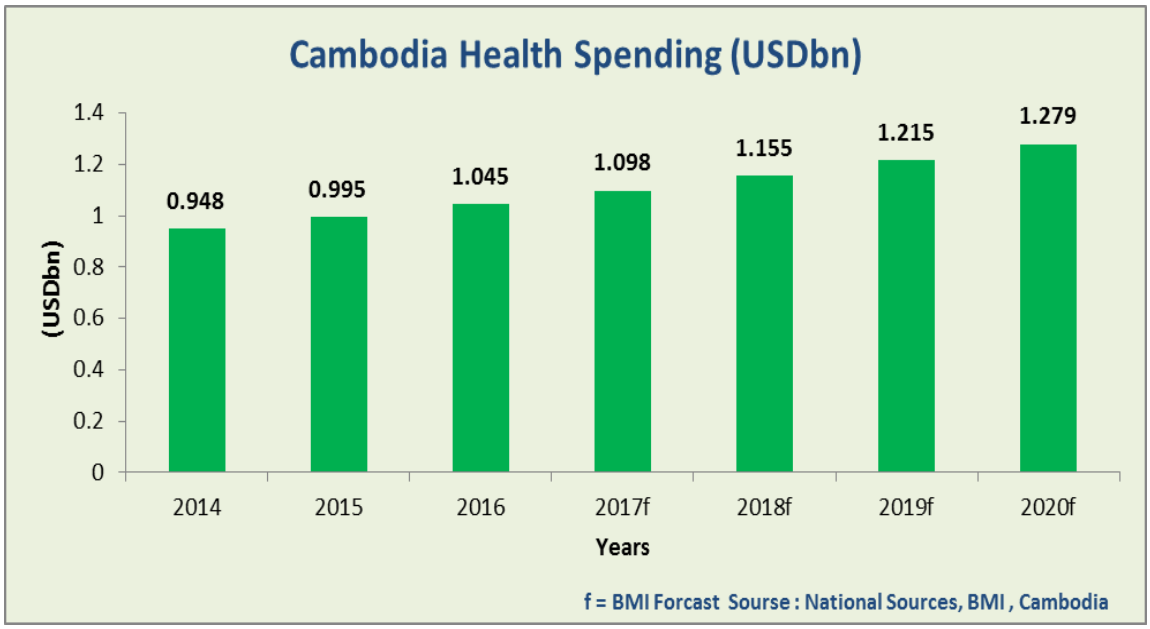


Figure 55 Cambodia Healthcare spending 2020

A nation of 15 million individuals, as the Cambodian economy creates; social insurance spending has been growing all through the nation. In spite of the fact that still littler and more hard to work together in than a large portion of its neighbors, Cambodia's medicinal market is on a positive direction that ought to soon pull in more consideration from Western restorative gadget and pharmaceutical organizations.

While transferable sicknesses like tuberculosis and jungle fever are as yet the essential driver of death, Western illnesses like hypertension and diabetes are progressively predominant. In the course of recent years, irresistible malady rates have fallen fundamentally with progressively high rates of vaccination and national sickness control programs. Actually, Cambodia had a year-on-year 60% drop in instances of dengue fever in 2014.

The medicinal services quality in Cambodia is expanding alongside the developing economy of the nation. As there is increment in the economy, the Cambodian government has begun of across the country changes in social insurance which has started in the 1990s, and outstandingly has enhanced the soundness of the Cambodian

populace, putting it at stake with a specific end goal to fulfill the Millennium Development Goal (MDG) targets set by the United Nations (UN).

Alongside the start of Cambodian wellbeing change, Ministry of Health of Kingdom of Cambodia has been playing the main part in wellbeing framework arranging and advancement. The Royal Cambodian Government arrangements to build the nature of social insurance in the nation by bringing issues to light of HIV/AIDS, intestinal sickness, and different maladies. Furthermore, in 2015, 61% of the aggregate wellbeing consumption had been assessed to be furnished with out-of-pocket installments, which may be unreasonably expensive to poorer section of the populace in the nation.

The most occurring infectious diseases gather a very high risk of food or waterborne diseases including bacterial and protozoal diarrhea, hepatitis A & B, and typhoid fever and dengue fever, Japanese encephalitis, and malaria.

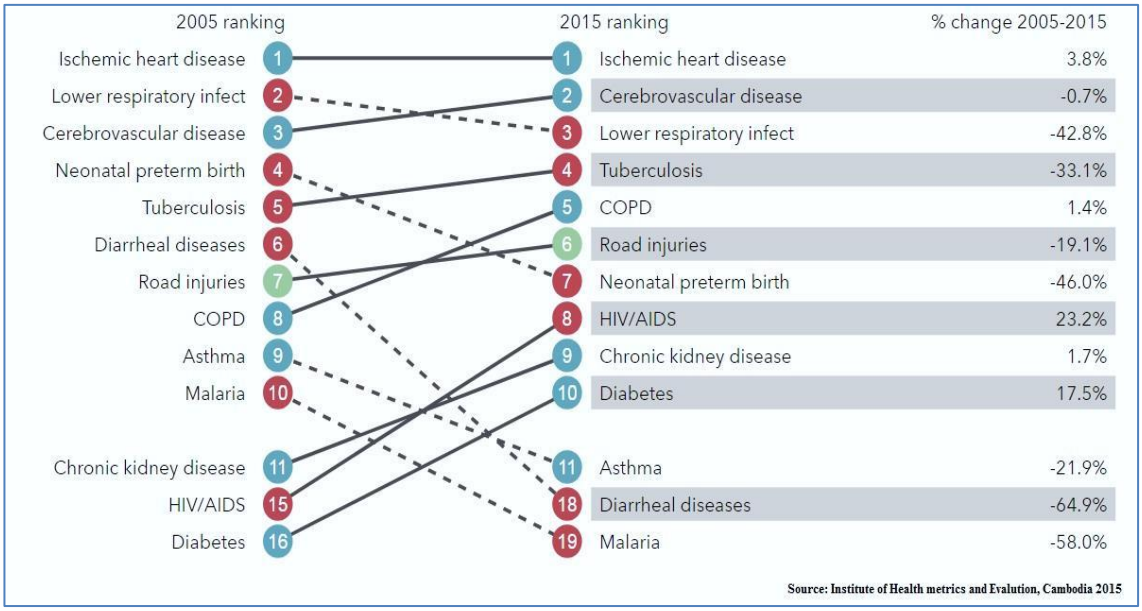


Figure 56 Top 10 causes of death by rate in Cambodia 2015

Healthcare service demand continues to steadily grow in Cambodia. The uptrend has been driven by Cambodia's lack of a gatekeeper system, easy and inexpensive access to medical treatment, aging demographics and a lack of long-term care facilities However, consistently low levels of government health expenditure mean that there has been, and will continue to be, a lack of healthcare resources available for the development of the sector. Until the government shows more concrete commitment towards the sector, the progress of healthcare provision to the population will be hindered. Cambodia is becoming an aging society in which people 65 or older account for at least 4.14% of the population in 2016. It is currently projected to become an aged society (10%) in 2025

and a super-aged society (20%) in 2030. Cambodia's fast aging population will increase demand and opportunities for long-term care and related services in the future, but these latest projections also present significant challenges for public healthcare policy.

Pharmaceutical Market in Cambodia

The Cambodian Pharmaceutical industry was valued at KHR 1113.5 bn (USD278 mn) in 2016 and it is expected to grow by 7.92 per cent per annum between 2015 and 2020, the market is expected to grow to US$ 0.407 billion by 2020.

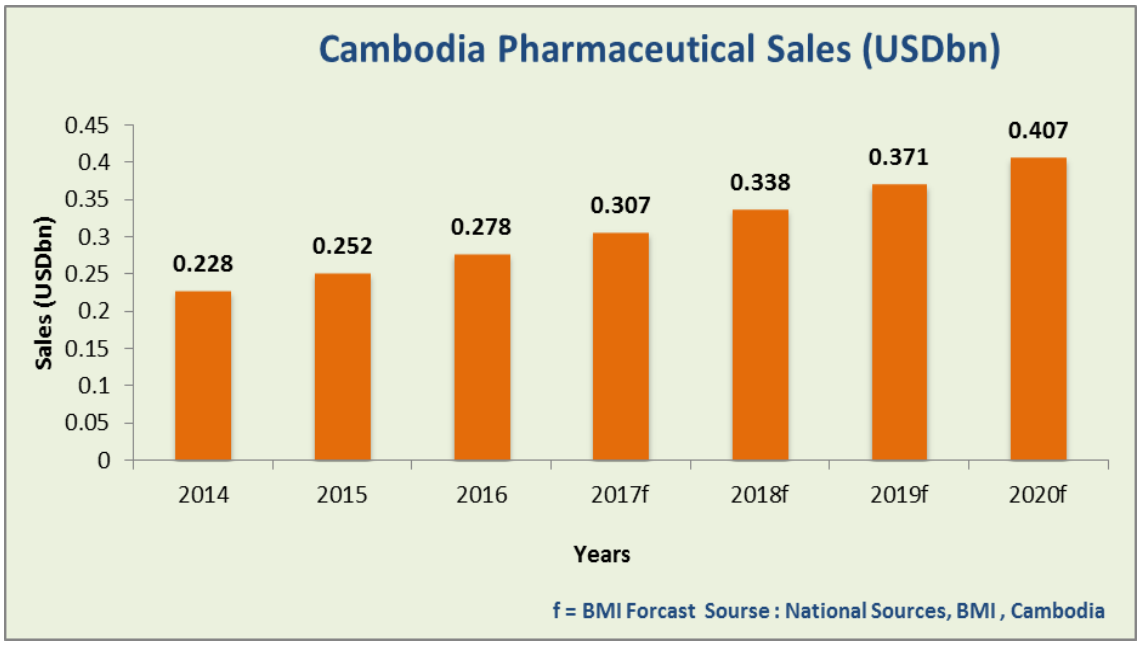


Figure 57 Cambodia Pharmaceutical Sales forecast 2020

Pharmaceuticals are to a great degree effortlessly open in Cambodia, being purchased over the counter as a rule. Be that as it may, the nature of drug stores shifts significantly. The offer of fake pharmaceuticals keeps on being a noteworthy issue in Cambodia. In spite of the fact that the circumstance is enhancing, it stays critical to pick drug stores painstakingly as some fake prescriptions are incapable and hurtful.

The standard of processing plants creating drug likewise should be considered. Low gauges of practice in the medication processing plants mean a significant number of these less expensive medications may not be beneficial to take since they don't meet certain criteria of the benchmarks of practice. For example, some have been sullied with different pharmaceuticals amid creation or harmed by presentation to the sun or dampness. Numerous drug stores don't utilize qualified staff and store pharmaceutical at wrong temperatures.

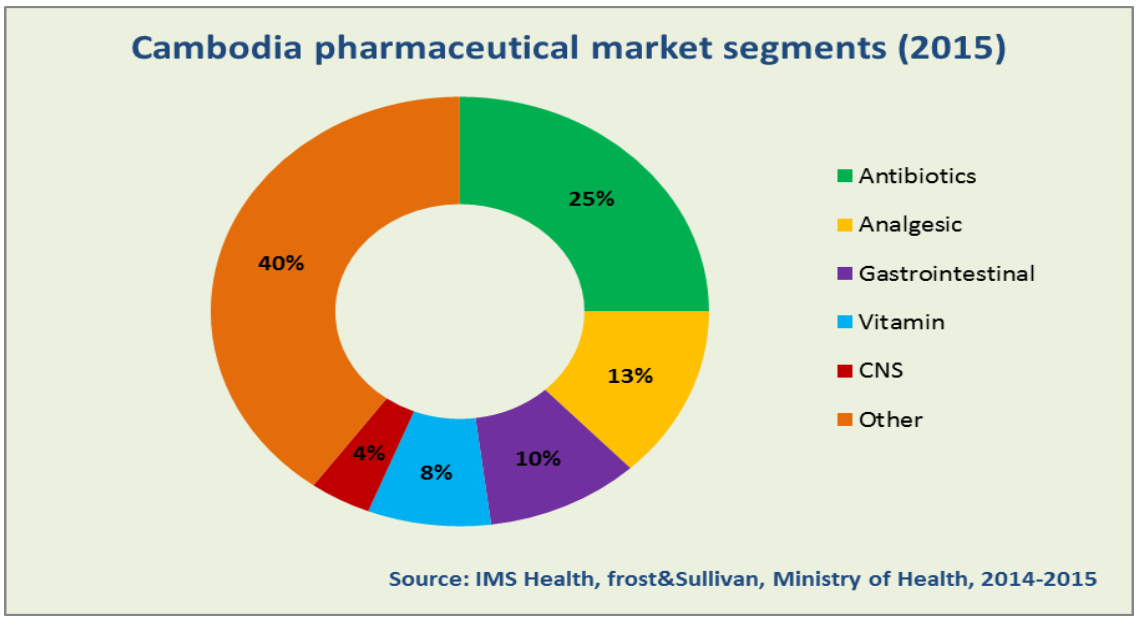


Figure 58 Cambodia Pharmaceutical Market Segment

The use of pharmaceuticals in Cambodia is growing as more of the country change from traditional to western medicines, And the pharmaceuticals industry looks set to strengthen with global brands such as Germany's Bayer, France's Sanofi and Britain's GlaxoSmithKline entering the market. Due to factors such as Small pharmaceutical market size, corruption, the poor legal framework and the economic structure of the country, In Cambodia multinational pharmaceutical firms like Pfizer, AstraZeneca, Merck & Co, and Roche does have representative offices in the country.

Pharmaceutical distribution in Cambodia is challenging when one takes into consideration the low urbanization rate 20.7% in 2016. Japan and Cambodia signed a memorandum of understanding on Japanese provision of sophisticated medical systems. Many locally-operated pharmacies in Cambodia also lack trained staff meaning customers run the risk of being prescribed the wrong medicine, and given unqualified advice.

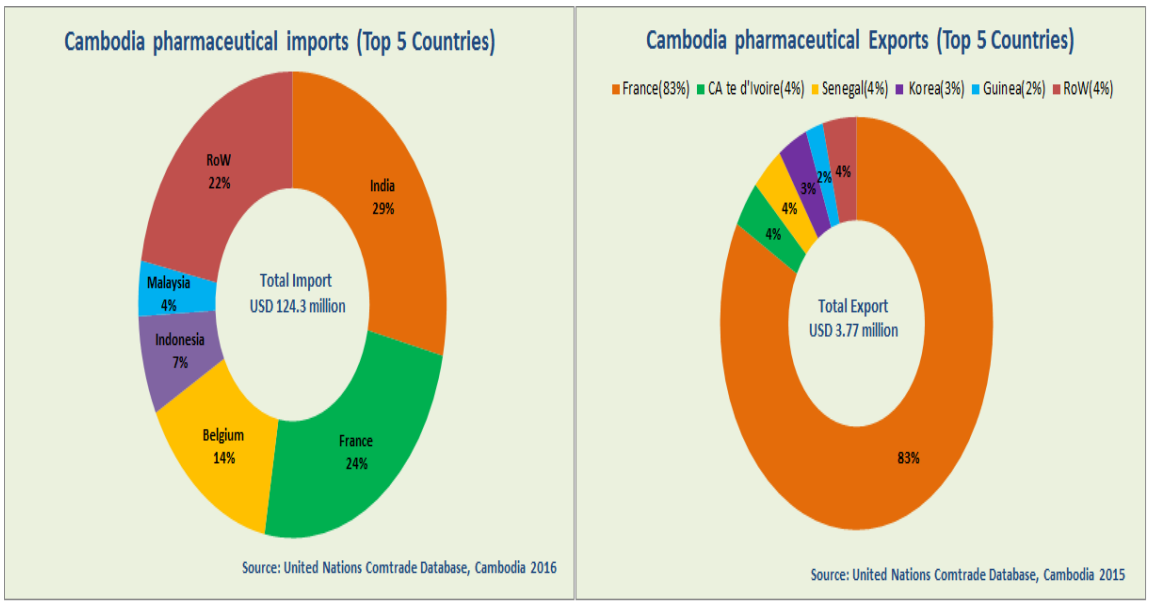


Figure 59 Cambodia Pharmaceutical Import-Export

Commodity	Qty 2015-16 (Kg)	2015 to 2016 Value (US $)	Qty in 2016-17 (Kg)	2016 to 2017 Value (US $)	Percentage Growth in Value 2017 over 2016
AYUSH AND HERBAL PRODUCTS	28340	231184	37118	254349	10.02
BULK DRUGS, DRUG INTERMEDIATES	24313	736997	22725	544438	-26.13
DRUG FORMULATIONS, BIOLOGICALS	1816879	41645891	1893771	39151251	-5.99
Total	1869532	42614072	1953614	39950038	-6.25
Source: Directorate General of Commercial Intelligence and Statistics 2017					

Table 12 Cambodia Pharmaceutical Import from India

The combination of economic growth, raising disease awareness and gradual improvements in healthcare provision will underpin Cambodia's growing demand for healthcare and Pharmaceutical over a multi-year horizon. The pharmaceutical market will see high headline growth rates, with low-cost generic drugs to remain dominant due to low affordability. The poor operating environment of Cambodia will continue to pose challenges to MNC due in part to the entrenched use of traditional medicines and the resistance of counterfeit drugs.

Risk/Reward Index

Cambodia's Pharmaceutical Risk/Reward Index (RRI) score in 2016 was 32.9 out of a maximum of 100. Cambodia's score is driven by high sector value growth but is dragged down by the relatively small market size, low per capita spending on medicine and industry and country risks.

Regulatory Landscape

Regulatory Agency in Cambodia which looks after all the regulatory environment is Department of Drugs and Food, Ministry of Health, Cambodia (MOH); The Department of Drugs and Food under the MOH is in charge of the quality and control of pharmaceuticals. Medicate item enlistment takes after ASEAN necessities, is moderately modest and takes just a year. There are no administration controls or repayment frameworks for medications. Right around 80% of pharmaceutical deals are in Phnom Penh and the encompassing area, making dissemination moderately basic. The Department is made out of five agencies each with their own claim to fame:

- The Narcotic Control and Pharmaceutical Trade Bureau
- The Drug Regulation Bureau
- The Registration and Cosmetics Bureau
- Essential Drugs Bureau
- Food Safety Bureau

The Registration and Cosmetics Bureau is responsible for registering all drugs and cosmetics coming into the country. Registration is the main mechanism for controlling the country’s pharmaceutical product quality. Registration involves evaluating documents using the following criteria:

- Administrative-application, summary of product info, GMP, Certificate of Pharmaceutical Product (CPP)
- Qualitative and quantification formulation, manufacturing process, certificate of analysis of ingredients, control procedures of ingredients, stability, bioavailability, and bioequivalence
- preclinical-pharmacokinetics, toxicology and clinical trials

Major Domestic Player of Pharmaceutical Industries

The major pharmaceutical industries are located in Phnom Penh city

1. Dynamic Pharma Co., Ltd
2. Khunaco Import Export Co., Ltd.
3. Rypharm Co., Ltd.
4. PPM International
5. VE (Cambodia) Ltd
6. Royal Nyta Pharma Co., Ltd
7. Greenhill Inc.
8. Ly Hok Singh Pharma Co., Ltd.
9. MNU Pharmaco Limited
10. E.L.E.A.N Limited

All of above pharmaceutical companies are making generic as well as herbal products which cover local market share in Cambodia

SWOT Analysis

Strengths	**Weaknesses**
1. Distribution of medicines is centralized in the CMS 2. Regional integration and ASEAN Economic Community 3. Inter-country production chain strategy potential in Cambodia 4. Favorable investment environment for FDI and future prospected growth	1. Political Instability, corruption, lack of transparency and unclear bureaucratic procedures 2. No effective tax policy in Pharmaceutical 3. Many drug outlets are not licensed and Poor infrastructure facility 4. poor drug prescription trend
Opportunities	**Threats**
1. Development of healthcare and Pharmaceutical sector 2. Supplying medicine, diagnostic, and scientific & testing products to the Cambodian market 3. Global production costs will further increase, which in turn increases the demand for cheap labor in developing countries like Cambodia	1. Major threat from Counterfeit Drugs 2. Increasing competition from other low-cost production countries, such as Myanmar 3. Due to Import of Raw material price fluctuation occurs 4. Increasing costs of health care expenditure

Conclusion

- Despite of various challenges like Patents and Intellectual Property Rights, Regulatory Reforms and R&D spending and the relative average economic growth in Southeast Asia, the overall Pharmaceutical market is expected to raise approximately $33.36 billion by 2020. Such trajectories of future growth remain too compelling for foreign pharma companies to retreat from the market, who are instead opting to adapt their strategies in line with local conditions.
- Vietnam is most promising country today followed by Thailand and Malaysia in Southeast Asia amongst other countries described here but in near future by 2020 Malaysia will become most promising country followed by Vietnam and Thailand because of increasing disease burden, economic growth, expanding Medical tourism and improved regulatory environment

Recommendations

To capture the immense opportunities in Southeast Asian markets, pharmaceutical companies require highly targeted strategies. Each country in Southeast Asia presents a unique set of socioeconomic and geographic, regulatory issues characteristics, and government, and local competitors. And what works in developed markets won't necessarily work in emerging economies like Southeast Asia.

The payoff for getting a targeted emerging-market strategy right is significant. By 2020, emerging markets will account for more than 30% of pharmaceutical sales growth worldwide. It is crucial for pharmaceutical companies to tap into this wellspring of growth as health systems mature.

Southeast Asia alone is expected to generate $40 billion in pharmaceutical sales by 2020. The diverse countries in this region can serve as case studies to help companies develop strategies for success in other emerging markets.

To establishing a strong foothold in Southeast Asia, Pharma Companies can do much more than sell pharmaceuticals—they can build a robust presence within the region's pharmaceutical value chain. Companies should take the following actions to secure big wins in emerging markets such as Southeast Asia.

Establish public-private partnerships: Strategic partnerships with local Government authorities' help Pharma Companies to gain greater access to previously underserved populations. Companies can engage in a public-private partnership (PPP) that addresses health challenges among Southeast Asian rural population.

Develop targeted, region-specific R&D: R&D in Pharmerging markets is rarely adapted to local Companies. MNCs import and distribute the same types of drugs in those markets that they created for developed markets. But pharmaceutical needs and preferences in Pharmerging markets are differ from mature market. Pharma companies has to tailor their R&D programs to address these differences will have much greater success than their counterparts that do not. By localizing R&D efforts, companies also have an opportunity to build up the region's infrastructure and capabilities.

Differentiate from unbranded generics: Pharma companies need to establish superior brand images to differentiate their products from unbranded generic competitors in Southeast Asia. This can be achieved by shaping their product portfolios to address unmet needs and by focusing on innovative, difficult-to-replicate products.

Build a strong local distribution network: To secure full market coverage over countries, it is essential to establish local manufacturing and distribution networks. Strategic placement of manufacturing hubs and strong collaboration with local distributors—particularly those with extensive networks and existing relationships—are important for the timely delivery of high-quality drugs. Inefficient manufacturing networks can create complex supply chain issues and damage an MNC's reputation.

Explore joint ventures: A long-term partnership with a local organization through a joint venture or acquisition can be a quick way to build manufacturing and distribution capabilities in Southeast Asia.

Limitations

- The current study has its own limitations. The study confined to the English language for the publically available secondary data, reports and other published documents.
- Regulatory Environment in Southeast Asia as a subject is vast and requires lot of resources to have a detailed analysis on this topic. There is lot of scope to further study in depth on each derived model.

References

1. Jayapala Reddy AV, B. Madhusudhan Rao. Business Model Based Pricing Strategy for Pharma Products In Southeast Asian Region. Journal ff Pharmaceutical Research Vol.15. No.4, Oct. - Dec. 2016 : 115
2. World Health Organization, World Health Statistics 2015, 2015.
3. World Health Organization, GLOBAL STATUS REPORT on non-communicable diseases 2014
4. IMS Institute for Healthcare Informatics. Understanding the Pharmaceutical Value Chain. 2014.
5. Economist Intelligence Unit business, South-East Asia: The New Emerging Healthcare Market Challenge, 2016
6. Deloitte, Medical Tourism: The Asian Chapter, 2016
7. PricewaterhouseCoopers, "Pharma 2020: The vision" – Which path will you take? (June 2015).
8. PricewaterhouseCoopers, "Pharma emerging markets 2.0", 2015
9. Business Monitor International, Southeast Asia Pharmaceuticals & Healthcare Report Q117 2016.
10. Business Monitor International, Myanmar Pharmaceuticals and Healthcare Report Q117 2016.
11. Business Monitor International, Vietnam Pharmaceuticals and Healthcare Report Q117 2016.
12. Business Monitor International, Thailand Pharmaceuticals and Healthcare Report Q117 2016.
13. Business Monitor International, Malaysia Pharmaceuticals and Healthcare Report Q117 2016.
14. Business Monitor International, Cambodia Pharmaceuticals and Healthcare Report Q117 2016.
15. Business Monitor International, Philippines Pharmaceuticals and Healthcare Report Q117 2016.
16. IMS Institute for Healthcare Informatics, Understanding the Pharmaceutical Value Chain. 2014.
17. PricewaterhouseCoopers, Southeast Asia Investment opportunities, Tax and others(August 2016
18. IMS Institute for Healthcare Informatics, Pharmerging markets Picking a pathway to success 2016

19. Economist Intelligent Unit report. 'Asia Competition Barometer Pharmaceuticals', The Economist, 2015.
20. Frost & Sullivan, The Asian CMO Market, 2015
21. World Bank, Doing Business in Vietnam, 2017
22. World Bank, Doing Business in Thailand, 2017
23. World Bank, Doing Business in Malaysia, 2017
24. World Bank, Doing Business in Philippines, 2017
25. World Bank, Doing Business in Myanmar, 2017
26. World Bank, Doing Business in Cambodia, 2017
27. Ministry of Health Malaysia, Health Informatics Centre, Planning & Development Division. Health Facts, 2015
28. Health Intelligence Asia, "Healthcare in Myanmar" Myanmar Pharmaceutical Market & Devices Market Survey Report, 2015