

**THE COMPETITIVENESS OF THE
PHARMACEUTICAL INDUSTRY IN MALAYSIA:
AN APPLICATION OF EXTENDED PORTER'S
DIAMOND MODEL**

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DIAMOND MODEL**

by

CHONG HOOI YING

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LIST OF ABBREVIATIONS

APIs	Active Pharmaceutical Ingredients
ASEAN	Association of Southeast Asian Nations
DCA	Drug Control Authority
GDP	Gross Domestic Product
IFDI	Inward Foreign Direct Investment
IO	Industrial Organization
MIDA	Malaysia Industry Development Authority
MNCs	Multinational Corporations
MNHA	Malaysia National Health Account
MOH	Ministry of Health
MS	Market Share
MyCC	Malaysia Competition Commission
NCEs	New Chemical Entities
NPRA	National Pharmaceutical Regulatory Agency
OCED	Organisation for Economic Co-operation and Development
OFDI	Inward Foreign Direct Investment
OTC	Over-The-Counter
PCT	Patent Cooperation Treaty
RBV	Resource-Based View
RCA	Revealed Comparative Advantage
ROA	Return on Assets
ROS	Return on Sales
R&D	Research and Development
SMEs	Small and Medium-sized Enterprises
WHO	World Health Organization

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DAYA SAING INDUSTRI FARMASEUTIKAL DI MALAYSIA: APLIKASI MODEL PELANJUTAN PORTER'S DIAMOND

ABSTRAK

Industri pembuatan farmaseutikal Malaysia menghadapi beberapa masalah daya saing. Antaranya termasuk penurunan keuntungan, peningkatan jumlah pesaing, prestasi eksport yang tidak baik, kapasiti pengeluaran yang terhad, dan kurangnya kemampuan inovasi. Kajian daya saing sebelumnya menunjukkan bahawa faktor persekitaran perniagaan negara asal memainkan peranan penting dalam menentukan daya saing industri. Namun, aspek ini jarang diterokai dalam konteks farmaseutikal. Maka, kajian ini dijalankan untuk mengkaji hubungan antara faktor persekitaran perniagaan negara asal dan daya saing syarikat bagi sampel 30 syarikat pembuatan ubat preskripsi yang beroperasi di industri farmaseutikal Malaysia dari tahun 2004 hingga 2018. Teori penyelidikan diubahsuai khas untuk Malaysia berasaskan model Porter's Diamond. Kaedah regresi panel statik digunakan untuk menganggar hubungan antara faktor persekitaran perniagaan negara asal dan daya saing syarikat dari industri pembuatan farmaseutikal Malaysia. Hasil kajian menunjukkan bahawa jumlah perbelanjaan penjagaan kesihatan negara, kecekapan pelaburan modal, eksport farmaseutikal, usia dan saiz perusahaan penting dalam meningkatkan daya saing syarikat dalam industri pembuatan farmaseutikal Malaysia. Sebaliknya, hasil penyelidikan menunjukkan bahawa sumber daya manusia yang mahir, jumlah paten, pembentukan modal tetap kasar, keluaran kasar industri kimia, keamatan jualan, am dan pentadbiran, perbelanjaan penjagaan kesihatan kerajaan, pelaburan langsung asing masuk dan keluar bertindak

balas negatif terhadap prestasi persaingan perusahaan farmaseutikal. Manakala, hasil penyelidikan bercampur ditemui untuk bilangan perusahaan yang bersaing terhadap prestasi persaingan perusahaan farmaseutikal. Sebaliknya, krisis ekonomi tidak memberi kesan ketara terhadap daya saing syarikat pembuatan farmaseutikal. Penemuan ini memperluas pengetahuan mengenai aplikasi teori dalam menjelaskan hubungan antara faktor persekitaran negara asal dan daya saing syarikat dalam konteks farmaseutikal. Di samping itu, kajian ini memberikan bukti kritikal bagi pembuat polisi dan pengurus dalam industri farmaseutikal untuk merangka strategi yang lebih baik. Mereka boleh memperuntukkan sumber negara dengan lebih tepat dan memutuskan pelarasan atau perubahan dasar yang sesuai untuk meningkatkan daya saing syarikat farmaseutikal.

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ABSTRACT

The Malaysian pharmaceutical manufacturing industry is facing several competitiveness issues. Among the issues are declining profitability, an increase in the number of competitors, poor export performance, limited production capacity, and a lack of innovation capabilities. Previous pharmaceutical competitiveness literature demonstrates that home country business environment factors play an important role in determining the industry competitiveness in international trade. However, the relationship between home country business environment factors and pharmaceutical firm competitiveness in terms of profitability and market share remains largely unexplored. Therefore, the purpose of this study is to investigate the influences of national business environment factors on pharmaceutical firm competitiveness for a sample of 30 prescription medicines manufacturing firms operating in Malaysia from 2004 to 2018. The theoretical foundation for this research is primarily derived from Porter's Diamond Model. Static panel regression method is used to estimate the relationships between home country business environment factors and the firm competitiveness of the Malaysian pharmaceutical manufacturing industry. The findings suggest that country's healthcare expenditure per capita, capital investment efficiency, pharmaceutical exports, firm age, and size are important in improving the firm competitiveness of Malaysia's pharmaceutical manufacturing industry. In contrast, the research results indicate that skilled human resource, patent count, gross fixed capital formation, chemical industry

gross output, selling, general and administration intensity, government healthcare expenditure inward and outward foreign direct investment respond negatively to the firm competitive performance. While mixed findings are discovered for number of competing firm in affecting the firm competitiveness of pharmaceutical manufacturing industry. However, the economic crisis has no significant impact on the industry's firm competitiveness. These findings extend knowledge of the applications of underlying theory in explaining the relationships between home country environment factors and firm competitiveness in the pharmaceutical context. In addition, this study provides critical evidence for policymakers and managers in the pharmaceutical industry to formulate better strategies, make more informed allocations of national resources and decide appropriate policy adjustments or changes to improve the firm competitiveness in the pharmaceutical manufacturing industry.

CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter describes the research's introduction, which starts with competitiveness, pharmaceutical industry in Malaysia and the competitiveness challenges as well as firm competitiveness models and studies. The problem statement, research objectives and research questions are then presented. Besides, the definition of key terms for major variables are taken into account. The significance of the study is discussed at the end of this chapter as well as the summary of the chapter.

1.2 Background of the Study

The concept of competitiveness has been widely discussed and has become a major concern for governments, industries, and businesses around the world when developing policies because it is closely related to economic success (Bhawsar and Chattopadhyay, 2015; Camison and Fores, 2015; Chikan, 2008; Dvouletý and Blažková, 2020; Fagerberg and Srholec, 2017; Falciola et al., 2020; Kalim et al., 2019; Nunes et al., 2018; Voulgaris and Lemonakis, 2014). Competitiveness, as defined by Fagerberg and Srholec (2017) and Falciola et al. (2020), is the ability to enter new markets, outperform competitors, attract investment, and expand. The notion of competitiveness is complex and multidimensional. It can be defined according to the scale, context and objective of its application (Dvouletý and Blažková, 2020; Fang et al., 2018; Jarungkitkul and

Sukcharoensin, 2016; Bhawsar and Chattopadhyay, 2015; Delbari et al., 2015; Lee et al., 2014; Voulgaris and Lemonakis, 2014; Dogl et al., 2012).

Globalisation and increased business competition both nationally and internationally are driving the increased emphasis on competitiveness (Bhawsar and Chattopadhyay, 2015; Chikan, 2008). In the past decades, there is widespread of interest in defining and measuring competitiveness with different perspectives (Bhawsar and Chattopadhyay, 2015). Extensive competitiveness studies have been conducted at multiple scales, including international (Cai et al., 2018; Galovic, 2015; Lakner et al., 2019) nation and region (Afzal et al., 2019; Castro-González et al., 2016; Fainshmidt et al., 2016; Rusu and Roman, 2018) as well as industry (Cho and Lee, 2020; Fang et al., 2018; Guan et al., 2018; Hoang, 2021; Irfan et al., 2019; Jarungkitkul and Sukcharoensin, 2016; Kaliszewski et al., 2020; Kuik et al., 2019; Kuo et al., 2020; Song et al., 2017; Vu and Pham, 2016), and firm (Bamel and Bamel, 2021; Camison and Fores, 2015; De Montreuil Carmona and Gomes, 2021; Cong et al., 2021; Delbari et al., 2016; Elgazzar and Ismail, 2021; Falciola et al., 2020; Hua, 2020; Kuo et al., 2017; Lanyi et al. 2021; Markus and Rideg, 2021; Sukumar et al., 2020; Tambade et al., 2019; Valdez-de la Rosa et al., 2021), with various methodologies used to empirically operationalize the concept.

Among the competition scales, firm level competitiveness is increasingly emphasised in the recent years (Falciola et al., 2020; Voulgaris and Lemonakis, 2014) as economic and business literatures recognise Porter's (1990, 1998) claim that firms are the one compete in international markets, not country. The firms create economic values and contribute to the competitiveness of industries and, as a result, of countries. Based on various definitions provided by scholars (Chikan, 2008; D'Cruz and Rugman, 1992;

Dvoulet and Blaková, 2020; Falciola et al., 2020; Porter, 1998), firm competitiveness is generally defined as a firm's ability to compete, develop, and be profitable in a competitive environment.

Pharmaceutical manufacturing industry in Malaysia has demonstrated strong imitation capabilities in generic medicines production (Hassali et al., 2015). However, the industry is encountering several competitiveness challenges, including declining industry profitability, limited domestic pharmaceutical manufacturing capacity, firms lacking in innovation capabilities to develop and produce innovative medicines, an increasing number of competing firms, and poor export performance (Babar et al, 2011; Fitch Solutions, 2019; Hassali et al., 2015; MIDA, 2019; MyCC, 2017)

The pharmaceutical industry has changed tremendously recent years due to dynamic forces in the competitive as well as regulatory environment (Shabaninejad et al., 2014). Enhancing pharmaceutical competitiveness is critical for the survival and growth of pharmaceutical manufacturing firms in both domestic and international markets in response to the new competitive environment (Mishra and Jaiwal, 2017; Shabaninejad et al., 2014). Therefore, improving the pharmaceutical manufacturing industry's firm competitiveness is a pressing but critical problem for Malaysia's economic and social growth as well as responding to new competitive environment. A comprehensive study is required to examine the factors determining the firm competitiveness of the pharmaceutical manufacturing industry.

According to the literature (Barua et al., 2012; Cai et al., 2018; Chong and Chan, 2014; Das and Das, 2015; Galovic, 2015; Lakner et al., 2019; Mishra and Jaiwal, 2017; Mahajan et al., 2018; Rentala et al., 2014; Voulgaris and Lemonakis, 2014), a competitive pharmaceutical industry or firm has a high international trade performance, is efficient, productive, profitable, and has a large market share growth. Notably, in previous pharmaceutical competitiveness studies (Barua et al., 2012; Chong and Chan, 2014; Das and Das, 2015; Mahajan et al., 2018; Mishra and Jaiwal, 2017; Rentala et al., 2014; Sharma and Gunawardana, 2011; Voulgaris and Lemonakis, 2014) as well as pharmaceutical firm performance research (Amin and Aslam, 2017; Escandón Barbosa et al., 2016; Jaisinghani, 2016; Kim et al., 2017; Pal and Soriya, 2012; Rahman et al., 2020; Sharma, 2012), a strong emphasis has been placed on the investigation of the effects of industry-related and firm-related factors on pharmaceutical competitiveness and performance in terms of international trade, firm profitability, export performance, efficiency, productivity, and firm innovation performance.

Resource-Based-View (RBV) and Structure-Conduct-Performance (SCP) paradigm are frequently used in the aforementioned studies to investigate the effects of firm and industry related factors on the competitiveness or performance of pharmaceutical firms. However, the investigations of the influences of national business environment factors underlying Porter's Diamond model is limited to pharmaceutical international trade competitiveness (Cai et al., 2018; Lakner et al., 2019), firm export performance (Bouet, 2014), and innovation performance (MacPherson and Boasson, 2004). The role of national business environment factors in determining pharmaceutical firms' profitability and market share has yet to be studied.

Firms from developed countries can use their home countries' competitive advantages to increase their productivity and competitiveness (Porter, 1990). The economic environment varies from country to country, with emerging and developing countries markedly different from developed countries (Jaisinghani, 2016). Despite the importance of pharmaceutical competitiveness issues, no clear study has been found to investigate the relationship between the national business environment and pharmaceutical manufacturing firm competitiveness in Malaysia.

Porter's Diamond Model is a paradigm that connects competitiveness at the national and firm levels (Chikan, 2008). The model emphasised the role of both microeconomic and macroeconomic in determining a firm's competitive advantage (Zhao et al., 2012). In contrast to other firm competitiveness theories such as SCP and RBV which mainly focused on the industry and firm related factors without capturing the macroeconomic condition. The government's role is critical in the pharmaceutical industry, which is heavily regulated. Given the nature of the industry and the relationship between national business environment factors and pharmaceutical firm competitiveness, particularly in terms of profitability and market share, which is largely unknown, the present study uses a panel data technique based on Porter's Diamond model to analyse the directions and effects of home country business environment determinants on the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.

1.3 An Overview of Pharmaceutical Industry in Malaysia

Pharmaceuticals are a class of newly discovered organic compounds that have helped to improve our standard of living (González Peña et al., 2021). While the pharmaceutical industry is a group of businesses that in charge of the research, development, manufacturing, marketing and distribution of both branded and generic pharmaceuticals (González Peña et al., 2021; Galovic, 2015). According to Fitch Solutions' Malaysia Pharmaceuticals and Healthcare (2020), Malaysian pharmaceutical sales was estimated to be worth USD 2.33 billion in 2019, as shown in Figure 1.1, while the nation's per capita spending on medicines was around USD73 in 2019. The pharmaceutical sales in the country has more than doubled from USD 1.06 billion in 2007 to USD 2.33 billion in 2019. Despite the economic downturn in developed countries has led to global financial and economic crisis in 2008, the sales of Malaysia's pharmaceutical seems was not highly affected by the crisis. The country's sales growth rate between 2008 and 2009 was witnessed a decline of 0.08 per cent as compared to the previous year between 2007 and 2008. Interestingly, the declined of sales growth rate didn't prolonged. In fact, the pharmaceutical sales growth continued to pick up in year 2010 and 2011 in a row. Malaysia's pharmaceutical demand is generally on the rise and is still growing despite the economic downturn, as medicines are one of the most basic human needs (OIC Health Report, 2019; 2017; Galovic, 2015). Moreover, a variety of factors influence pharmaceutical demand, including income level, price fluctuations, distribution, population age, healthcare system, and so on (Galovic, 2015).

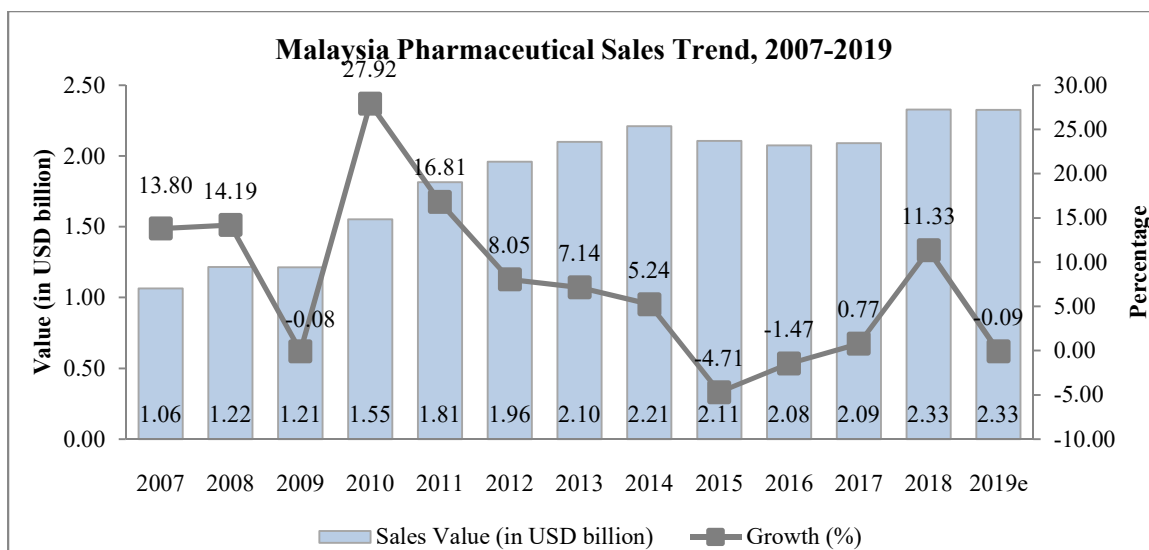


Figure 1.1: Malaysia Pharmaceutical Sales Trend, 2007-2019

Source: Author own construction based on data extracted from Fitch Solutions' Malaysia Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2011-Q4 2019).

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions

Pharmaceutical market comprises the sales of both prescription medicines and non-prescription medicines. Over-the-counter (OTC) medicines are generic terms for non-prescription medications. Under Malaysia's Poison Act 1952, prescription medicines are referred to as "controlled medicines." However, the term "prescription medicines" is used in the current research in line with the international pharmaceutical and healthcare publications such as books, journals and reports. Malaysia's pharmaceutical market is dominated by prescription medicines (Hassali et al., 2015). As shown in Figure 1.2, prescription medicines accounted for 72-80 per cent of the pharmaceutical market share in terms of value from 2007 to 2019. Over-the-counter (OTC) medicines, on the other hand, accounted for the remaining market share of 20 per cent to 28 per cent during the same time period. Fitch Solutions' Malaysia Pharmaceuticals and Healthcare (2020)

reports that the country's prescription medicines were estimated to be worth USD1.87 billion in 2019, while over-the-counter medicines were worth USD 0.47 billion.

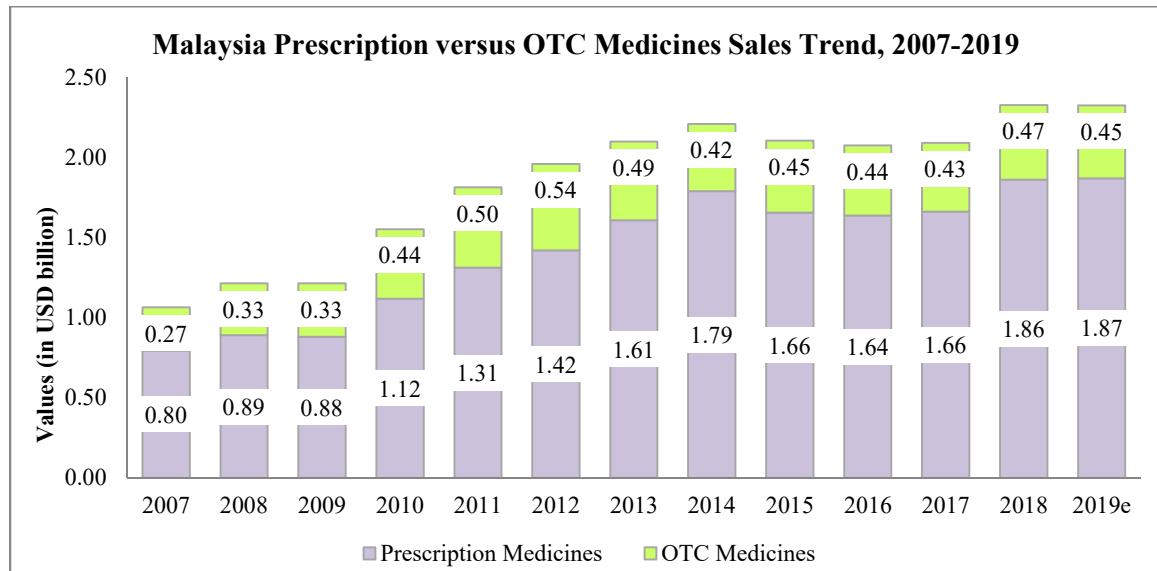


Figure 1.2: Malaysia Prescription versus OTC Medicines Sales, 2007-2019

Source: Author own construction based on data extracted from Fitch Solutions’ Malaysia, Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2011- Q4, 2019)

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions

The prescription medicines market is based on a robust domestic generic medicines sector as well as patented and generic medicines imported from other countries (Hassali et al., 2015). Prior to 2010, patented medicines had a strong presence in the Malaysian pharmaceutical market, but generic medicines began to outperform patented medicines in 2011. As shown in Figure 1.3, the market share of patented medicines has steadily declined from 67 per cent in 2007 to 47 per cent of total prescription medicines in 2019. On the contrary, the market share of generic medicines has increased from 33 per cent in 2007 to approximately 53 per cent in 2019.

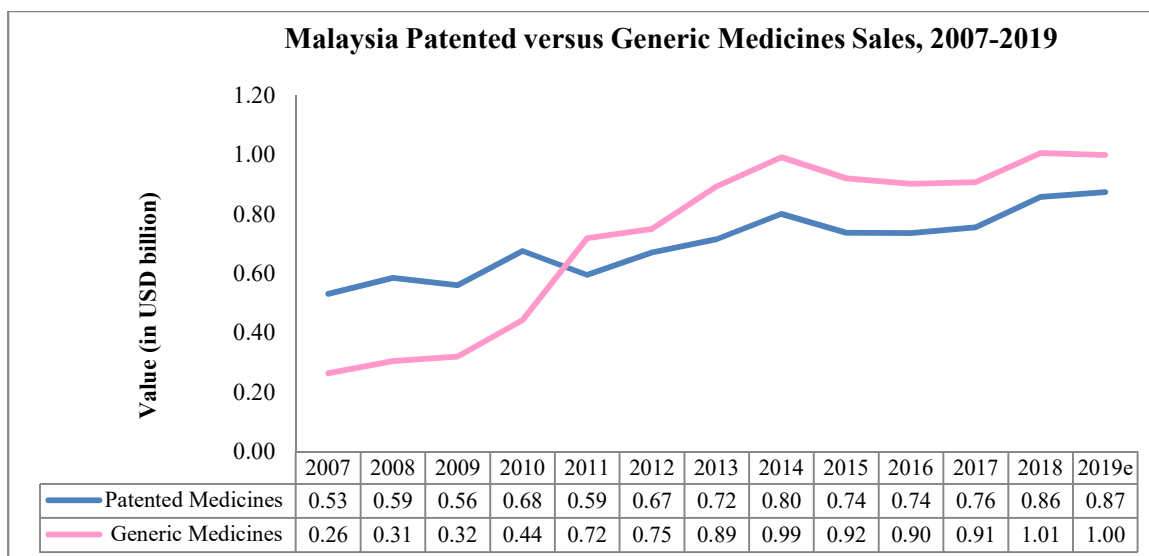


Figure 1.3: Malaysia Patented versus Generic Medicines, 2007-2019

Source: Author own construction based on data extracted from Fitch Solutions’ Malaysia, Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2011 – Q4, 2019)

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions

With respect to the pharmaceutical trade, Figure 1.4 shows that Malaysia pharmaceutical export value witnessed some growth and rose from USD 134.10 million in 2009 to USD 224.55 million in 2019. Nevertheless, the value of pharmaceutical imports is several times that of exports. Indeed, it has been increasing from USD 708.50 million in 2007 to USD 1438.87 million in 2019 signifying Malaysia is highly dependent on the imported medicines in the past decade while export is still far behind to catch up the gap (Fitch Solutions, 2020). As a consequence of highly reliance on the imported medicines, Malaysia has recorded deficits in pharmaceutical trade from 2007 till 2019. It is expected not to be reversed for a long time (MyCC, 2017).

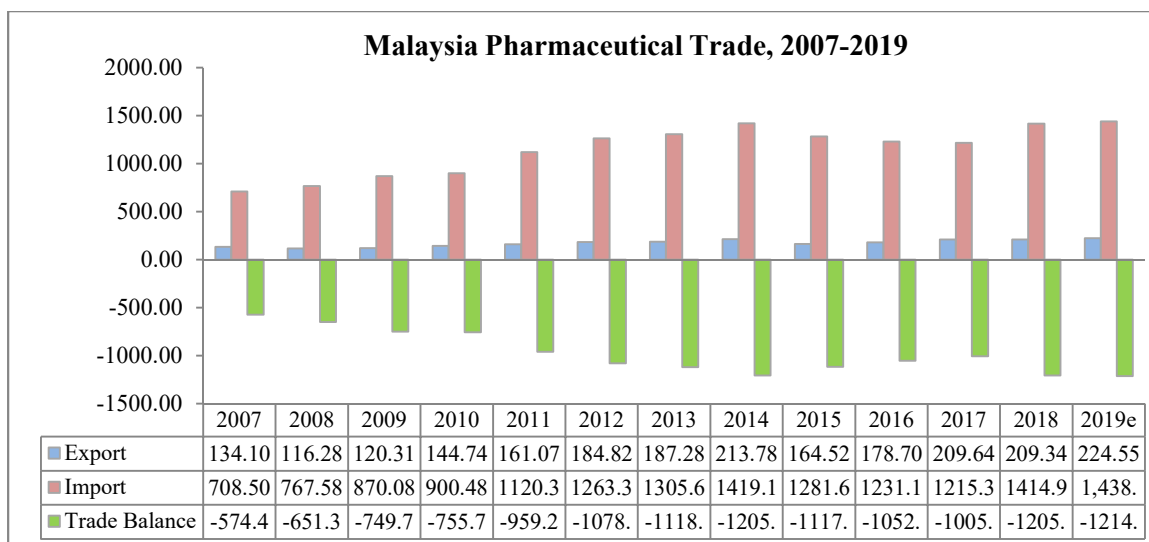


Figure 1.4: Malaysia Pharmaceutical Trade, 2007-2019

Source: Author own construction based on data extracted from Fitch Solutions' Malaysia, Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2011 – Q4, 2019)

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions.

Malaysia has a dual public-private healthcare system. The Ministry of Health (MOH) is the country's primary legislative and policy-making agency for healthcare sector. It is also the largest provider of healthcare services and the largest purchaser of medicines in the public healthcare sector (Aigbogun et al., 2014; Ali et al., 2013; Hassali et al., 2015; Jaafar et al., 2013; Tan et al., 2014). As illustrated in Figure 1.5, government health spending has accounted for 51-57 per cent of total country health spending over the years. Pharmaceutical industry is a highly regulated industry due to the safety concern of the medicines. Medicines, unlike most ordinary goods, are vital goods that can be life-saving or life-threatening depending on the level of regulatory control. The pharmaceutical industry is highly regulated because of the safety concerns about medicines. In Malaysia, the Drug Control Authority (DCA) under the Ministry of Health (MOH), with its secretariat at the National Pharmaceutical Regulatori Agency (NPRA), is

the primary drug regulatory authority in charge of product registration and issuing licences for pharmaceutical manufacturing, importation, and sale (including health supplement, traditional medicines and veterinary products) (Hassali et al., 2015; MyCC 2017).

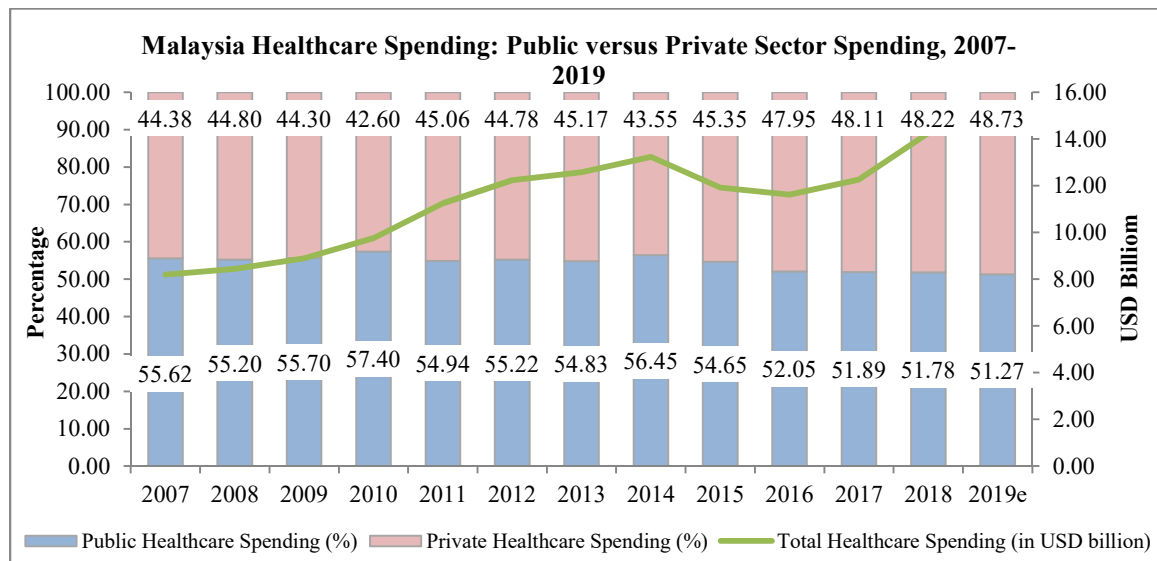


Figure 1.5: Malaysia Healthcare Spending: Public versus Private Sector Spending (2007-2019)

Source: Author own construction based on data extracted from Fitch Solutions’ Malaysia Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2011-Q4 2019)

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions.

MOH regulates and procures medicines at lower costs in the public healthcare sector. MOH employs these price-control measures to ensure that the price of medicines in the public healthcare sector is equal, rational, affordable, and secure (Hassali et al., 2015; Tan et al., 2014). According to Tan et al., (2014), pharmaceutical firms must provide proof of medical benefit combined with a low price offering in order to be included in the MOH Drug Formulary. Following inclusion in the MOH Drug Formulary, a price-controlling measure is introduced, which includes an arrangement between

pharmaceutical firms and the MOH that no price increases will be made for one year, and any subsequent price increases must be justified.

On the contrary, Malaysia's private healthcare sector is based on free market principles, with no price controls and pricing determined by market forces (Babar et al., 2007; Babar et al., 2005; Hassali et al., 2015; Hassali et al., 2013; Tan et al., 2014). All parties in the pharmaceutical supply chain, including manufacturers, wholesalers, dispensing doctors, and retail pharmacies, are free to set their own selling prices under the open market economy model (Hassali et al., 2013; Tan et al., 2014). Malaysia's pharmaceutical industry is not subject to industry competition law. According to a pharmaceutical study conducted by McCC in 2017, more research is needed for the pharmaceutical industry supply chains, which should investigate the structure of importers of patented medicines, as well as distributors and wholesalers to justify the need for competition law in the pharmaceutical industry.

Malaysia's pharmaceutical industry has a three-level supply chain (Hassali et al., 2015; MyCC, 2017), as depicted in Figure 1.6. The first level includes generic medicine manufacturers as well as originator and generic medicine importers. The second level is made up of wholesalers and distributors who operate under four different wholesale licence classes, while the third level is made up of public and private healthcare providers who dispense medications to patients or end users. Some of the players, especially the larger ones, are vertically integrated and have NPRA manufacturing, importing, and wholesale licences.

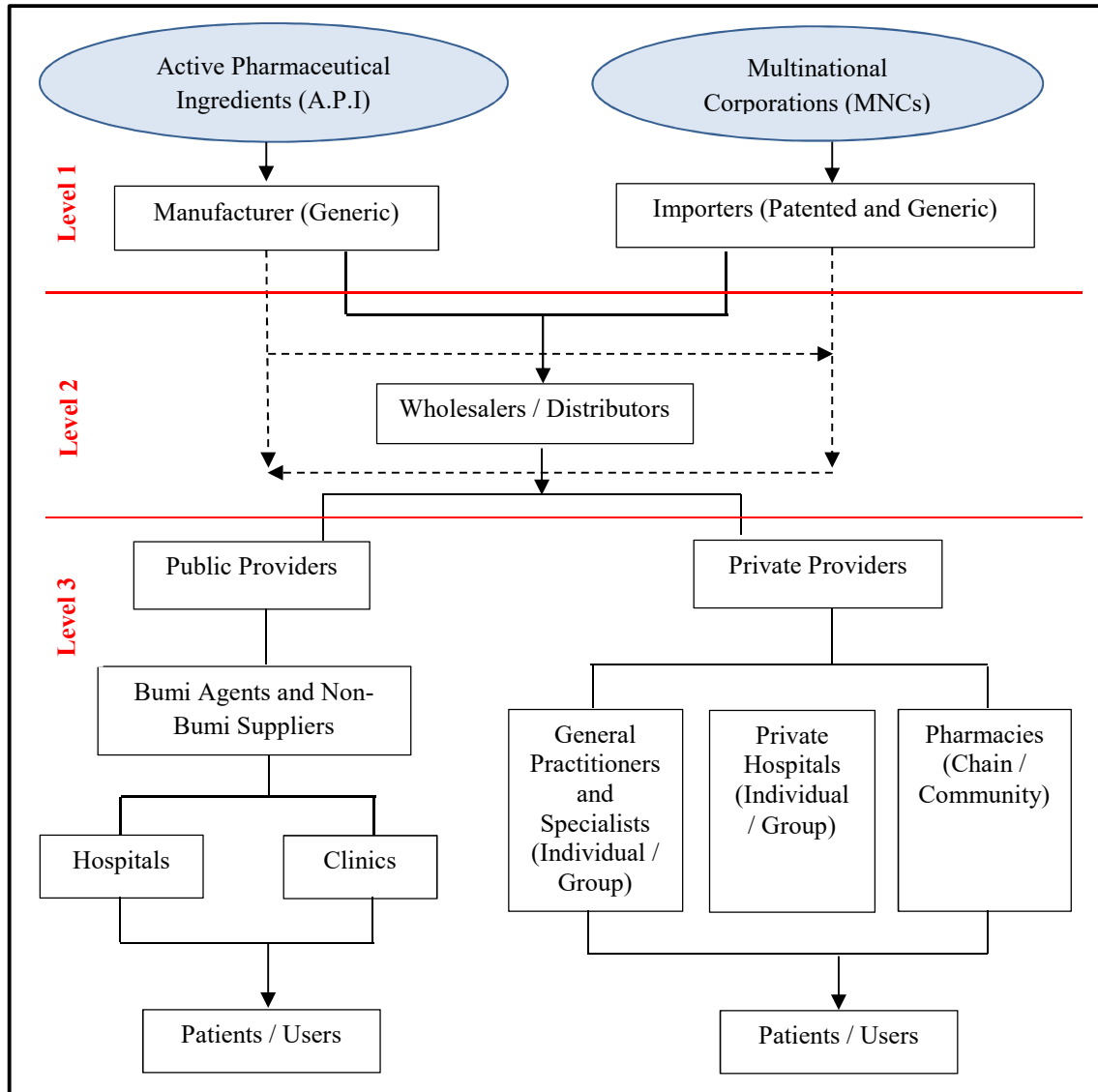


Figure 1.6: Overview of the market structure and supply chain of the pharmaceutical industry in Malaysia.

Source: Reproduced from MyCC 2017: Market Review on Priority Sector under Competition Act 2010: Pharmaceutical Sector

1.3.1 Development of Malaysian Pharmaceutical Manufacturing Industry

As illustrated in Figure 1.6, pharmaceutical manufacturers are the primary parties that play a significant role in producing and supplying medicines across the entire Malaysia pharmaceutical supply chain. Based on the list of licensed manufacturers published and updated as of July, 2019 by NPRA, there are 257 GMP certified pharmaceutical manufacturing firms registered with DCA. A total of 75 firms have been granted licences to manufacture modern medicines. There are 42 prescription medicines manufacturers and 33 over-the-counter medicine manufacturers among these firms. Another 135 licenced manufacturers produce modern and herbal medicines, 10 manufacturers hold license for producing health food supplements, 26 of them are licensed manufacturer of both traditional medicines and health supplements while remaining 11 manufacturers are licensed to produce veterinary pharmaceuticals (see Table 1.1).

Table 1.1: Categories of Pharmaceutical Manufacturing Licenses issued by NPRA, July 2019

Categories of Pharmaceutical Manufacturing Licenses issued by NPRA, as of July 2019	Number of Firms
A - Poison (Controlled/Prescription Medicines)	42
X - Non-Poison (OTC/Non-Prescription Medicines)	33
T - Traditional Medicines	135
HS - Health Supplements	10
TMHS - Traditional Medicines Health Supplements	26
Vet – Veterinary	11
Total	257

Source: Author own construction based on data from NPRA website (accessed 15 May 2020).

The prescription medicine segment is particularly important among the categories because it accounts for 70-80 per cent of the country pharmaceutical sales (refer Figure 1.2). In 2019, there are 42 GMP certified pharmaceutical manufacturing firms registered with DCA and granted licences to manufacture prescription medicines. According to the company profile of these firms, only 30 of the 42 firms are pharmaceutical manufacturers whose primary activity is the production of prescription medications. The remaining 12 companies are not engaged in the manufacture of prescription medicines as their primary business. They are a medical device manufacturer, a private hospital, independent prescription medicine distributors, a packaging company, a government research institute, a logistics service provider, OTC and veterinary producers who produce a small number of prescription medicines or involve in repackaging of prescription medicines.

Malaysia's local prescription medicines manufacturing is dominated by the leading generic manufacturers with greater finance resources whereas majority of the remaining firms are small and medium-sized producers that specialise in generic and low-tech pharmaceuticals, as well as traditional medicines and herbal supplements (Aigbogun et al., 2014; Fitch Solutions, 2017; Hassali et al., 2015). According to MIDA (2019), the local pharmaceutical manufacturing industry in Malaysia produces approximately 30 per cent of domestic demand, with the remaining 70 per cent consisting of imported pharmaceuticals that are not available locally. Their output is primarily for the domestic market while the larger firms are orienting towards export markets. This posits that the capacity of local pharmaceutical manufacturing industry in Malaysia is still not able to

meet the country demand and imports account for the vast majority of the Malaysian pharmaceutical industry, rendering the nation a net importer (MyCC, 2017).

Fitch Solutions' Malaysia Pharmaceuticals and Healthcare Reports (2020) reports that Malaysia's pharmaceutical industry remains closed to the international market, as the Malaysian government implicitly discourages an open and competitive market for international pharmaceutical compounds by favouring locally produced products in procurement. The involvement of MNCs with manufacturing operations in the country is restricted through restrictive regulatory policies in order to protect domestic manufacturing. As a result, Malaysia is still home to a small number of pharmaceutical MNCs from developed countries (MyCC, 2017). Surprisingly, according to the NPRA's list of manufacturers, there are only 6 foreign-owned prescription medicines manufacturing firms present in Malaysia.

Interestingly, despite the country's increasing pharmaceutical sales over the years (refer Figure 1.1), as well as the Malaysian government's implementation of a generic policy and patent cliffs to encourage the use and production of generic medicines (Fatokun et al., 2013), the average net firm profit margin of Malaysia's prescription medicine manufacturing firms has decreased from 15.97 per cent in 2004 to 9.35 per cent in 2018 as shown in Figure 1.7. On the other hand, the number of competing prescription medicine manufacturers in Malaysia has increased slowly from 2004 to 2018, implying that competition intensity is increasing. When the market concentration of the prescription medicine manufacturing industry is examined further, the Herfindahl-

Hirschman Index (HHI) value HHI value is below 1500 and decreases between 2004 and 2018 as depicted in Figure 1.8. In accordance to the Merger Guidelines by U.S. Department of Justice and Federal Trade Commission, 2010, it can be concluded that the market structure of prescription medicines manufacturing industry in Malaysia is classified as low concentration. According to Cherchye and Verriest (2016), a fragmented market with a large number of comparatively small firms competing against each other. The fragmented market leads to more intense competition

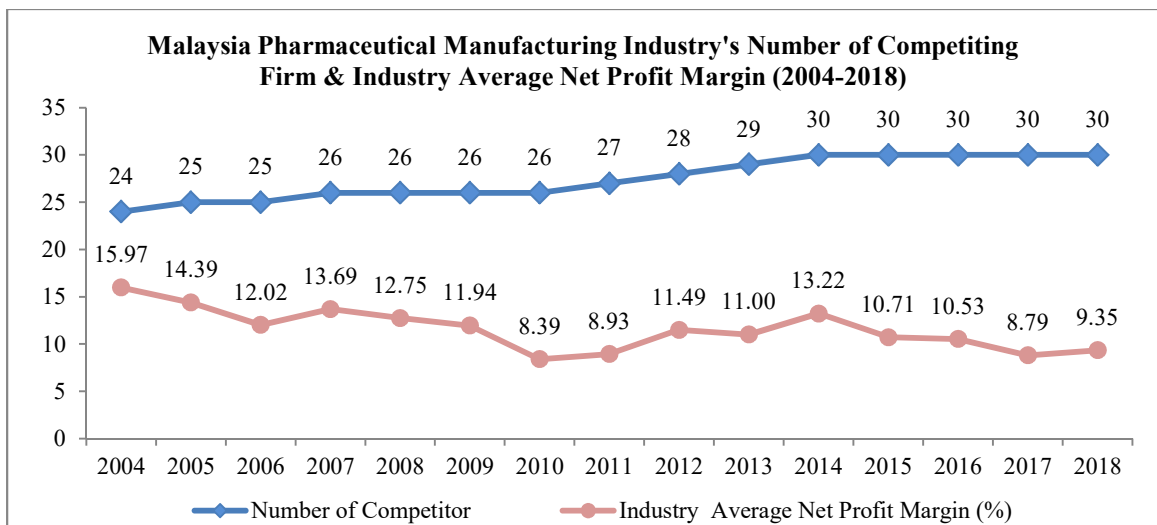


Figure 1.7: Malaysia pharmaceutical manufacturing industry's number of competing firms and industry average net profit margin (2004-2018)

Source: Author own construction based on data extracted from firm annual financial statements from 2004 to 2018

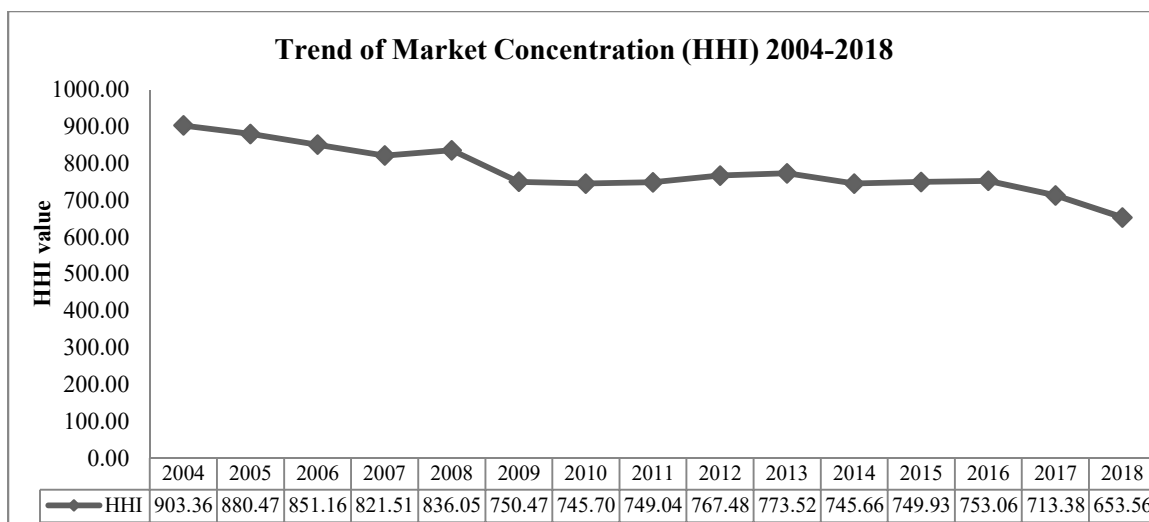


Figure 1.8: Trend of Market Concentration (HHI) 2004-2018

Source: Author own calculation based on annual firm data from 2004-2018

Malaysian prescription medicines manufacturing industry is mainly based on strong domestic generic or imitator medicines production as opposed to the imported of patented or originator given their limited technological capacity for advanced research and high technology development of innovative or patented medicines (Hassali et al., 2015; MyCC2017). The research and development capabilities of the prescription medicine producers are limited to developing processes for manufacturing generic medicines rather than inventing new medicines (MyCC, 2017). Based on the Organisation for Economic Co-operation and Development (OECD) patent database, it is discovered that number of patent applications filed under Patent Cooperation Treaty (PCT) for pharmaceutical in 2018 is 8.6 in relative to country total patent application of 131.3 indicating a 6.55 per cent of patent from the pharmaceutical industry. A patent is an incentive for pharmaceutical innovation because it grants the original medicines

manufacturers monopoly status for a set period of time, allowing them to recoup the high investment cost, particularly R&D funds that are tied up over a long development time horizon (Sloan and Hsieh, 2012).

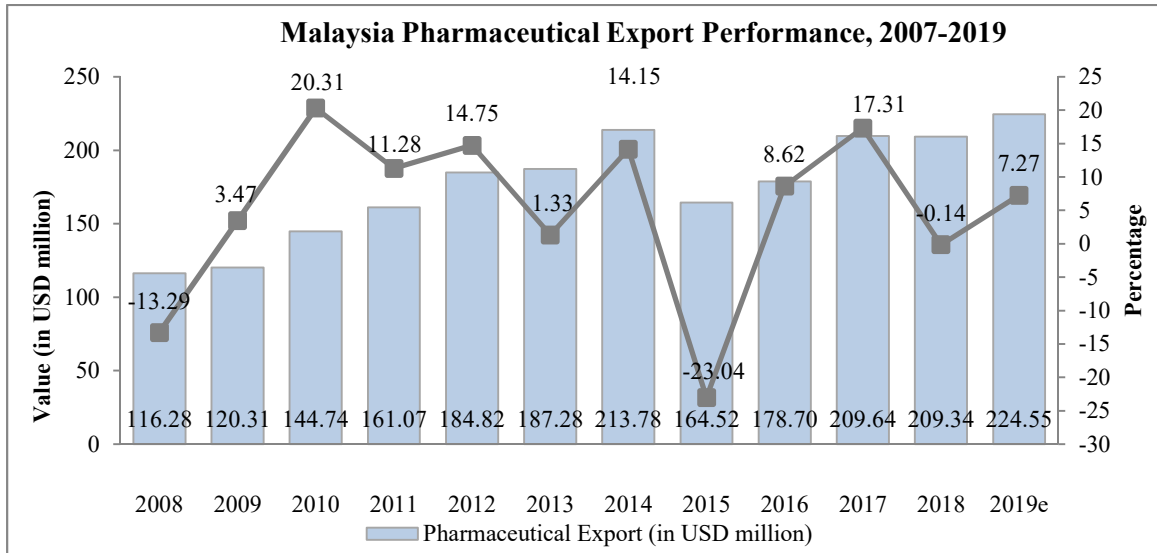


Figure 1.9: Malaysia Pharmaceutical Export Performance, 2007-2019

Source: Author own construction based on data extracted from Fitch Solutions’ Malaysia Pharmaceuticals and Healthcare Reports (Q2, 2020; Q4, 2019 – Q4, 2013)

Note: e= Fitch Solutions estimate based on sources from Ministry of Health, national health accounts, and Fitch Solutions

Switching the lens to the pharmaceutical export performance, Figure 1.9 shows that pharmaceutical exports increased from USD116.28 million to USD224.55 million over an 11-year period, from 2008 to 2019. There is some increase in the pharmaceutical export value in the past decade but the growth rate progressed in slow manner. According to MyCC (2017), larger prescription manufacturing companies are increasingly turning to exports for a variety of reasons. These include a small domestic market, a preference for Bumiputera companies in securing government procurement contracts, and government

efforts to promote pharmaceutical exports such as generic exports under Entry Point Projects (EPP3), halal pharmaceuticals to penetrate the Middle East and other Muslim countries. Other factors, such as Malaysia's membership in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and high regulatory standards, are advantageous for entering the export market. Despite policies aimed at encouraging exports, the slow progress in pharmaceutical exports reflects the ineffectiveness of export policies.

1.4 Problem Statement

The pharmaceutical manufacturing industry is critical to national health, social and economic development, and national security (Cai et al, 2018). Malaysian government has identified pharmaceutical manufacturing as one of the important industries in the manufacturing sector that should be further developed and promoted due to its potential to contribute to the sector's future growth and exports (Malaysian Investment Development Authority, MIDA, 2020; Ministry of International Trade and Industry, MITI, 2019). Prescription medicines, on the other hand, have dominated most of the pharmaceutical markets around the globe including Malaysia because it is the major inputs in the production of good health. Malaysia's pharmaceutical manufacturing industry particularly the prescription medicines manufacturing is encountering several competitiveness challenges.

The pharmaceutical industry has long been one of the world's most competitive and profitable industries (Shabaninejad et al., 2014). Profitable pharmaceutical companies are competitive (Voulgaris and Lemonakis, 2014). However, the profitability of Malaysian prescription medicine manufacturing firms has declined from 2004 to 2018 (refer Figure 1.7), indicating the industry is not competitive. Profitability is critical for businesses to remain viable in highly competitive industries. Any abnormal profit is unsustainable and may jeopardise the firm's survival (Jaisinghani, 2016).

Domestic pharmaceutical manufacturing firms have lacked technological innovation capabilities for advanced research and high-technology development of patented medicines and APIs (Hassali et al., 2015; MyCC2017). The number of pharmaceutical patents in Malaysia has remained low over the last decade (see Figure 1.8). Indeed, patents have become major barrier to the entry of generics for Malaysian prescription medicine manufacturers (MyCC, 2017). Furthermore, Malaysia's prescription medicines manufacturing industry is still underdeveloped (MyCC, 2017). The industry does not produce enough prescription medicines to meet the needs of the country. Although pharmaceutical demand in the country is constantly increasing, as shown in Figure 1.1, domestic prescription medicine production capacity remains limited, with only about 30 per cent of total country pharmaceutical consumption captured. The remainder is sourced from other countries. Due to the small domestic generic market, larger local prescription medicine manufacturers are shifting their focus to export (MyCC, 2017).

According to United Nations Industrial Development Organization (UNIDO) statistics, Malaysia's chemical industry gross output decreased as a percentage of total manufacturing gross output for the majority of the time between 2004 and 2018. Furthermore, World Bank data show that value added has decreased as a percentage of total manufacturing value added since 2006, falling from 14.66 in 2006 to 9.52 in 2018. Both manufacturing gross output and value added reflect a manufacturing industry's competitiveness level (Fafaliou and Polemis, 2013). This indicates that the Malaysian chemical industry's competitiveness is deteriorating. If the relevant and supporting industries of a country have competitive advantages or are globally competitive, the country's industry is likely to be competitive (Porter, 1990). Hence, incompetent local chemical supplier performance may have an impact on Malaysian pharmaceutical manufacturing firms' competitive performance.

On the other hand, the number of new prescription medicine manufacturers entering the market gradually increased between 2004 and 2018 (see Figure 1.7). Competition is becoming more intense as the number of competitors grows (Porter, 1990). The industry competition may be heightened further as local generic manufacturers are less active in the development of patented medicines, resulting in a low entry barrier. Additionally, the patent cliff initiative facilitates the entry of imported branded generic medicines (Hassali et al., 2015; MyCC, 2017). According to Porter (1990), the intensity of competition has a significant impact on firms' innovation processes and their ultimate prospects for international success. In contrast, Chong and Chan (2014) demonstrated

that increasing the number of competing firms reduces market concentration and, as a result, firm profitability, resulting in low firm competitiveness.

The Malaysian government bears half of the country's total health spending, as illustrated in Figure 1.5. MOH is the largest provider of healthcare services and the largest purchaser of medicines in the public healthcare sector. MOH implemented a price control strategy and purchased medicines at a lower price from pharmaceutical firms in order to reduce costs and ensure medicine accessibility (Aigbogun et al., 2014; Ali et al., 2013; Hassali et al., 2015; Jaafar et al., 2013; Tan et al., 2014). Increased government healthcare spending improved the pharmaceutical manufacturing industry's international trade competitiveness (Cai et al., 2018). Nonetheless, the government's role as buyer can either help or hurt a country's industry's competitiveness (Porter, 1990). Occurrences beyond a firm's control such as global economic crisis are significant because they can cause discontinuities that lead to changes in competitive position (Porter, 1990). Malaysia's pharmaceutical sales did not severely affected during the global economic crisis period from 2007-2009 (refer Figure 1.1), but the average net profit margin of pharmaceutical manufacturing firms' profitability declined during the same period.

Export oriented pharmaceutical firms are more profitable (Jaisinghani, 2016) and competitive in gaining a larger market share growth (Voulgaris and Lemonakis, 2014). However, slow growth in Malaysia's pharmaceutical export performance, as shown in Figure 1.9, suggests that the country's pharmaceutical manufacturing industry's ability to compete in the international market remains low. Foreign direct investment, on the other

hand, is effective in raising international trade competitiveness in the pharmaceutical manufacturing industry (Sharma and Gunawardana, 2011). The involvement of MNCs with manufacturing operations in Malaysia is still limited (Fitch Solutions, 2020; MyCC, 2017).

The aforementioned phenomenon has revealed that pharmaceutical manufacturing firms in Malaysia are less competitive both nationally and internationally. If competitiveness is not improved, the growth and sustainability of the domestic pharmaceutical manufacturing industry will be jeopardised, affecting the nation's well-being, social and economic development.

1.5 Research Objectives

The main purpose of this research is to determine the factors underlying Porter's Diamond model that influence the competitiveness of pharmaceutical manufacturing firms in Malaysia. Porter's Diamond Model is a paradigm for connecting firm and national business environment perspectives (Chikan, 2008). The model is widely acknowledged as one of the most useful models for assessing industry and firm competitiveness (Zhang and London, 2013; Zhao et al., 2012). Unlike other firm competitiveness theories such as SCP and RBV, which focus primarily on industry or firm-related factors, Porter's Diamond took into account both micro and macroeconomic perspectives (Zhao et al., 2012).

However, in today's globalised businesses, the classic Porter's Diamond is insufficient, and several modifications and extensions are required (Cartwright, 1993; Dunning, 1992, 1993; Grant, 1991; Rugman and D'Cruz, 1993; Stopford and Strange, 1991). Given that the pharmaceutical industry is heavily regulated (Duflos and Lichtenberg, 2012) and highly globalised (Shabaninejad et al., 2014), the current study attempts to enhance the classic Porter's Diamond model by assessing the direct effects of government and chance factors rather than the indirect effects in the original model. Additionally, the model is expanded by incorporating a component of multinational business activities. Panel regression analysis is used to validate the relationships between the influencing factors and pharmaceutical firm competitiveness.

- (1) To assess the influence of national business environment factors on the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.
- (2) To investigate the role of government in the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.
- (3) To explore the impact of chance factor on the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.
- (4) To scrutinise the effect of multinational business activities on the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.
- (5) To examine the impact of firm specific variables on the firm competitiveness of the pharmaceutical manufacturing industry in Malaysia.