



DECLARATION

I hereby declare that the project is based on my original work except for quotations and citations which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted for any other degree at USM or any other institutions.

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DATE: 10 JULY 2009

Halal Certification Issues in Pharmaceutical Products-CCM
BERHAD

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Research report in partial fulfillment of the requirements
for the degree of MBA

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TABLE OF CONTENTS

| | Page |
|---|--------|
| ACKNOWLEDGEMENTS | i |
| TABLE OF CONTENT | ii - v |
| LIST OF TABLES | vi |
| LIST OF FIGURES | vii |
| ABSTRAK (MALAY) | viii |
| ABSTRACT | ix |
| | |
| CHAPTER 1: INTRODUCTION | |
| 1.0 Background of The Case | 3 |
| 1.1 Problem Statement | 3 |
| 1.2 Issues To Be Examined In The Case | 4 |
| | |
| CHAPTER 2: LITERATURE REVIEW | |
| 2.0 Pharmaceutical Industry | 5 |
| 2.1 History | 5 |
| 2.2 Definition | 7 |
| 2.3 Global Economy | 7 |
| 2.4 Industry Revenues Year 2006 | 9 |
| 2.4.1 Market Leaders In Terms of Revenue | 9 |
| 2.4.2 Market Leaders In Term of Sales | 11 |
| 2.4.3 Market Leader Growth(%) By Year 2006 | 13 |
| 2.5 Malaysia Pharmaceutical Industry | 14 |
| 2.6 Pharmaceutical Industry In Term of Market Share | 18 |
| 2.7 Drug Application Process | 19 |
| 2.8 Halal Industry | 21 |
| 2.9 CCM Pharmaceutical Sdn Bhd Industry Analysis | 24 |
| 2.10 Company Profile | 27 |
| 2.10.1 Company History | 27 |

CHAPTER 4: CASE WRITE-UP

| | |
|--|----|
| 4.0 Halal and Haram Concept in Pharmaceutical Industry | 62 |
| 4.1 The Important of Halal Certification | 63 |
| 4.2 Pharmaceutical and Halal issues in Industry | 64 |
| 4.3 CCM Berhad as Pharmaceutical Company in Halal Industry | 68 |
| 4.4 Pharmaceutical as High Regulated Industry | 72 |
| 4.5 HDC versus JAKIM Roles | 76 |
| 4.6 Development of the Halal Industry | 79 |
| 4.6.1 Global Halal Market | 80 |
| 4.6.2 Market Development in Halal Certification | 81 |
| 4.6.3 Government and Non- Government Roles | 83 |
| 4.7 CCM Berhad with Market Development in Halal Industry | 85 |
| 4.8 Marketing Concept in Halal | 86 |

CHAPTER 5: CASE ANALYSIS

| | |
|--|-----|
| 5.0 Case Analysis | 90 |
| 5.1 Internal and External Factor | 90 |
| 5.1.1 Strengths | 90 |
| 5.1.2 Weaknesses | 91 |
| 5.1.3 Opportunities | 91 |
| 5.1.4 Threats | 91 |
| 5.2 SWOT Analysis on A Chemical Company of Malaysia Berhad | 92 |
| 5.2.1 Strengths | 93 |
| 5.2.2 Weaknesses | 94 |
| 5.2.3 Opportunities | 96 |
| 5.2.4 Threats | 97 |
| 5.3 TOWS Matrix Analysis | 98 |
| 5.4 TOWS Matrix on A Chemical Company of Malaysia Berhad | 100 |
| 5.5 TOWS Matrix strategies | 101 |
| 5.5.1 Strengths & Opportunities (Maxi-Maxi) | 101 |

| | |
|--|-----|
| 5.5.2 Weaknesses & Opportunities (Mini-Maxi) | 102 |
| 5.5.3 Strengths & Threats (Maxi-Mini) | 103 |
| 5.5.4 Weaknesses & Threats (Mini &Mini) | 104 |
| 5.6 Implementation Plan | 105 |
| 5.6.1 Short Term Planning | 105 |
| 5.6.2 Long Term Planning | 106 |
| CHAPTER 6: CONCLUSION | |
| 6.0 Case Summary | 108 |
| 6.1 Recommendation | 112 |
| 6.1.1 International Halal Certificate | 112 |
| 6.2.2 Build Exclusive Line of Halal's Pharmaceutical Products in Halal's Industry | 113 |
| 6.1.3 CCM Needs Focus to Research Effort and Development | 115 |
| 6.2 Conclusion | 116 |
| References | 118 |
| Appendix A (Industry Information) | 123 |
| Appendix B (CCM Company Information) | 134 |
| Appendix C (Cover Letter and Questionnaire) | 145 |
| Appendix D (News Paper Articles) | 152 |
| Appendix E (Forms and Letters) | 158 |

LIST OF TABLES

| | Page |
|--|------|
| Table 2.1 Total Revenues of Market Leaders Year 2006 | 9 |
| Table 2.2 Market Leader in Terms of Sales Year 2006 | 11 |
| Table 2.3 CCM Pharmaceuticals Sdn Bhd: Competitive Position 2007 In Term of Value Share | 25 |
| Table 3.1 Schedule are dealing with HDC | 57 |
| Table 3.2 Schedule are dealing with CCM | 58 |
| Table 4.1 Rate of Service Fee for Product for 2 Year Period | 74 |
| Table 4.2 Criteria of Industry | 74 |

LIST OF FIGURES

| | Page |
|--|------|
| Figure 2.1 Total Revenues of Market Leaders 2006 | 10 |
| Figure 2.2 Market Leaders in Terms of Sales 2006 | 12 |
| Figure 2.3 Market Leader Growths (%) in Percentage 2006 | 13 |
| Figure 2.4 Market Leaders in Term of Market Share (%) 2006 | 13 |
| Figure 2.5 Categories of Pharmaceutical Products in Malaysia | 16 |
| Figure 2.6 CCM Pharmaceutical Sdn Bhd Competitive Position In-term of Value Share 2007 | 26 |
| Figure 2.7 CCM Berhad Subsidiaries | 29 |
| Figure 2.8 CCM Halal Council Charts | 36 |
| Figure 2.9 Halal Journeys of CCM Products | 37 |
| Figure 3.0 Halal Management Hierarchy | 38 |
| Figure 3.1 Turnover for Years 2007 & 2006 Each Division | 39 |
| Figure 3.2 Profitability on 2007 & 2006 Each Division | 40 |
| Figure 3.3 Group Turnovers and Profit before Tax Year 2003 – 2007 | 41 |
| Figure 3.4 Key Performance Indicator (KPIs) | 43 |
| Figure 4.0 Business Cycle of CCM Berhad in Consumer Life | 69 |

ABSTRAK (MALAY)

Kajian ini melibatkan isu sijil halal dalam industri farmaseutikal di Malaysia. Syarikat yang dipilih untuk dikaji adalah Chemical Company of Malaysia Berhad (CCM Berhad). Syarikat tersebut merupakan sebuah syarikat farmaseutikal yang terbesar dan merupakan syarikat yang berada dibarisan hadapan dalam pensijilan Halal produk farmaseutikal di Malaysia. Dalam pembacaan yang telah dijalankan oleh pengkaji, syarikat CCM lebih bertumpu kepada memperolehi kelebihan persaingan di antara pesaing di dalam pasaran tempatan dan pasaran antarabangsa. Tujuan kajian ini adalah: (1) Membentuk barisan eksklusif ubatan preskripsi dan ubat-ubatan yang Halal untuk bersaing dengan pesaing (2) Untuk memohon kebenaran dari JAKIM / HDC bagi membolehkan produk di bawah CCM Pharmaceutical S.B dilabelkan dengan logo Halal pada pembungkusan produk. Kajian ini melihat kaedah kajian kes menggunakan produk farmaseutikal didefinisikan sebagai ubatan yang dilesenkan oleh Badan Penggubalan Undang-undang Perubatan yang memerlukan preskripsi sebelum memperolehinya. (1) Data premier seperti temuramah semi-struktur, analysis tinjauan pasaran. (2) Data sekunder seperti dokumen bertulis, laporan tahunan, laporan analisis industri (GMID), laman web rasmi yang berkaitan (seperti Kementerian Kesihatan Malaysia, lain-lain syarikat dan pesaing dalam pasaran) dan jurnal artikel yang diterbitkan. Kaedah diagnosis yang digunakan dalam kajian ini adalah model SWOT dan TOWS. Kajian ini, diharap dapat menyumbangkan strategi yang terbaik yang boleh diadaptasi oleh CCM Berhad untuk menyelesaikan masalah yang dihadapi sekarang. Di samping membolehkan organisasi ini memperluaskan faedah konsep Halal kepada pelanggan produk farmaseutikal. Akhir sekali, kemungkinan di masa hadapan dengan hasil dari kajian ini boleh digunakan sebagai piawaian untuk memberi cadangan kepada CCM Berhad untuk mengambil langkah seterusnya bagi menyelesaikan masalah berkaitan kebenaran memaparkan label logo Halal pada pembungkusan produk.

ABSTRACT

This research explores the application of Halal certification issues in the pharmaceuticals industry in Malaysia. The company that had been chosen for this study is Chemical Company of Malaysia Berhad (CCM Berhad). The CCM is the biggest pharmaceutical company and also at the forefront of Halal (“حلال”) application initiatives involving pharmaceuticals products in Malaysia. The company was concentrates to gaining market competitiveness in the local market as well as the foreign markets. The purpose of the study are: (1) to create an exclusive Halal certified prescription drugs or medicines line against its competitors (2) The key research is intended to focus on Halal “حلال” application on pharmaceuticals product. This research employs a case study methodology. The key research is intended to focus on Halal “حلال” application on pharmaceuticals product. A pharmaceutical product is defined as a licensed medicine that is regulated by legislation to require a prescription before it can be obtained. The data collection involves are: (1) primary data such as semi-structured interviews, market survey analysis. (2) Secondary data such as company’s record, annual reports, industry analysis report GMID (Global Marketing Information Database), relevant website such as Ministry of Health Malaysia (MOH), other companies in the industry and published journals articles. The diagnostic tools to be need in the SWOT and TOWS models. It is hoped this research will contribute towards a better implementation of halal labeling for CCM’s pharmaceutical in order to in addition this can be expand the benefits of the Halal (“حلال”) concept their customers. Finally, it is envisaged that the outcome of this study can be used to recommend to CCM Berhad on regarding the next steps of Halal “حلال” logo on their products packaging.

CHAPTER 1

INTRODUCTION

1.0 Background of the Case

Currently in Malaysia, everybody is busy to talking about global Halal-hub after the Halal Industry Development Corporation (HDC) was a lunched in September 2006. Global Halal-hub is the mission that HDC is trying to achieve and that is also their main objective. When we talk about Halal many things will be in our mind. It might be ours perception of Halal, current issues about Halal, Halal products the controversy that the company faces about Halal issues and so on influence our minds. Because of these reasons, that study Halal Certification Issues in Pharmaceutical Products was chosen as a topic to be studied.

The main issue is about guideline or Halal certification procedure in Halal pharmaceutical product. Under pharmaceutical products categories one of the category is medicines. Medicine has been categories as a consumable product which is can be taken to eat or apply at human body. The current scenario that happening in market is most of the kinds of pharmaceutical products had displays Halal logo at product packaging and at the same time those product has obtain Halal certification. As a Muslims consumer, the consumer will find the Halal pharmaceutical product that has been certified Halal product. It also is fulfilling the requirement of Syariah laws of Halal. But in the guideline and procedure in JAKIM/ HDC stated, pharmaceutical product (medicines) will be rejected for Halal certification application.

Firstly, this study will focus on the Chemical Company of Malaysia Berhad (CCM) as a reference and benchmark of a pharmaceutical company. By using CCM, the main study is to determine the issues that arise regarding Halal certification in Halal pharmaceutical products. With reference to Manual Prosedur Pensijilan Halal Malaysia book (2005) 1st edition, published by Jabatan Kemajuan Islam Malaysia (JAKIM), application for Halal Certification by (JAKIM) will be rejected if it does not follow the requirements they as stated in the manual. One of the requirements stated was related to pharmaceutical products. All kinds of drugs or medicines that are categorized as pharmaceutical products by the Ministry Health of Malaysia (Kementerian Kesihatan Malaysia) will be rejected for the application.

If these conditions were to be applied in the Malaysian industry, then how do the pharmaceutical companies run their business without the halal logo? And how do we determine and categorize whether the pharmaceutical products are listed under the under Ministry of Health (MOH) and will all those products be rejected? This question is more relevant to CCM itself. Then the next issue is the role of JAKIM. As we known HDC has taken over the JAKIM the in terms of Halal certification. The main question is why is it that, JAKIM/HDC could not accept the application from producer's pharmaceutical of products. Pharmaceuticals products are also consumable products that are categorized as Halal products in market.

In the market some of the pharmaceutical products display the Halal logo on the packaging but some do not. This will cause confusion among the consumers. For example some of the CCM, products listed under the HDC have the Halal logo on the packaging but some do not. So this study will focus on these issues and try to find the

answers to all the questions that arise. Hopefully this study will find the reasonable answers and to eliminate confusion regarding the issue among in consumers generally. Consumer has been confused because some of the pharmaceutical products in market had displays Halal logo and some not displaying. This brings more confused if the consumer check and refer to HDC website which is has a listed of pharmaceutical products that has been certified Halal by HDC. When the consumers refer to that lists some of the products that were listed at market not displaying the Halal logo whether the product has Halal certification.

1.1 Problem Statement

The problem in these studies can be divided into two. First the problems, related to CCM Berhad and the second related to HDC. The main issue that these two companies faced is related to Halal certification of pharmaceutical products in-term of guideline and procedure, but in this study or case the main issue will be highlighted towards to CCM Berhad Company. The main focus is to look in depth toward to CCM Berhad Company business activities that related with Halal issues. This study will try to focus on the best strategy that can adopted by CCM Berhad to solve their problems regarding Halal certification of their products and at the same time to emphasize their opportunities in the industry and market by giving them competitive advantage among the rivals. This strategy may perhaps help the company to expand their business effectively and efficiently through the entire world of Halal pharmaceutical products. HDC is the organization as a reference (body authority) that control Halal certification in Malaysia.

1.2 Issues to Be Examined In the Case

1. To know why the Halal certification application for all kinds of medicinal products under the Ministry of Health (MOH) list will be rejected. What is the reason?
2. To recommend JAKIM/HDC that they should allow the pharmaceutical company displaying Halal logo on product packaging if the product was certified Halal by JAKIM/HDC.
3. To determine the responsibility of HDC after having taken over the role from JAKIM in terms of Halal certification? (What is the function, rules, procedure, integrity and etc).

CHAPTER 2

LITERATURE REVIEW

INDUSTRY PROFILE

2.0 Pharmaceuticals Industry

2.1 History

The pharmaceutical industry is highly regulated. Companies in this industry are subjected to a variety of laws and regulations relating to their products such as the research and development activities, testing methods, manufacturing processes, marketing, sales and distribution. Pharmaceutical industry provides innovator drugs, generics and health/dietary supplements. Innovator drugs are those with patent protection for their active ingredients or process. Generic drugs contain the same active ingredients as that of innovators' but may not necessarily be of the same formulation. Pharmaceutical companies also produce medicine. Medicine define as a substance used to prevent or cure disease or to relieve pain, anxiety or any form of perceived discomfort categories as prescriptive (ethical) and over-the-counter.

The pharmaceutical industry started in the 19th century. At that time, humans believe that plants, animals and minerals contained medicinal properties, which is the intuition and trial and error was the methods that have been used. The oldest records of medicinal preparations made from plants, animals or minerals are those of the early Chinese, Hindu and Mediterranean civilizations. Meanwhile for Alexandria, Egypt era in the 2nd century relatively purified inorganic chemicals such as lead carbonate, arsenic and

mercury. In the previous century 1st one of Greek physician has found a few medical agents example verdigris and cupric sulfate as prescribed as medicinal medicine.

For the earliest drugstore was found in Middle Ages was opened by Arabian pharmaceuticals in Baghdad in 754. Starting from this point, many stores soon began operating throughout the medieval Islamic world and also Europe. During 1950s and 1960s numerous new drugs were developed this included first oral contraceptive (The pills), Cortisone, blood pressure drugs and other heart medications. At the same time, legislation was enacted to test/examine and approve drugs required for labeling. The medicine also was classified as prescription and non-prescription drugs became legally pharmaceuticals product.

In 1964, the World Medical Association was established to set standards for clinical research and demanded that subject give their informed consent before enrolling in an experiment. Pharmaceutical companies at that time were required to prove efficacy in clinical trials before marketing drugs. Entered to the 1980s, pressure by economics and a new regulations body or institute both safety and environmental but also transformed new DNA chemistries and new technology was growth in proper ways. Pharmaceuticals industries also get a new impact whereby a dramatic increase in the use of contract research organizations for clinic development and even for basis R&D.

So from the history, the medicine was developing from raw material (plants) and to drug medicine product with scientific name. Until today, the sources are still being used and the physician are still doing researches to explore content of that sources that might be have other medical agents which can be used to cure or make as a new medicine- get the new potential. Drug development was in progress from hit and mass

approach to rational drug in laboratory design and natural product. Lately after many technologies that have been used producers are producing and creating products that are demand by consumers such as nutritional supplements otherwise known as alternative medicine. According to the latest figure there are now more than 200 major pharmaceutical companies in industry. Source from:

(
.)

2.2 Definition

According to Wikipedia, “Pharmaceutical Company is a commercial business whose focus is to research, develop, produce to market and distribute medicines. Pharmaceutical companies can deal in generic and/or brand medications. They are subject to a variety of laws and regulations regarding the patenting, testing and marketing of drugs.” Source from: ()

2.3 Global Company

On the year 2007, the companies which were listed as the top 5 Pharmaceutical Company are: **(1) Johnson & Johnson (J&J)** which comprises the world’s premier consumer health company, the world’s largest and most diverse medical devices and diagnostics company, the world’s third-largest biological company and the world’s sixth-largest pharmaceutical company. Johnson & Johnson was incorporated in 1887 and its

Worldwide headquarters is in New Brunswick, New Jersey, USA. J&J have more than 250 operating companies and employing 119,400 who are people engaged in research and development, manufacture and sale of a range of products in the healthcare field. The company operates in three different segments: (1) consumer, (2) pharmaceutical and (3) medical devices and diagnostics.

Pfizer Inc is the second world's largest pharmaceutical company. The company operates in consumer healthcare and animal health products in addition to its core pharmaceuticals. Pfizer's consumer healthcare division operates in OTC healthcare market worldwide across all major sectors. The company's key product is cough, cold and allergy (hay fever) remedies brands such as Benadryl and Sudafed. The company also holds large value share in Nicorette brand, Zantac (digestive remedies, Rogaine / Regaine in medicated skin care and Visine in eye care. Recently its New York based company produced high selling medicines and drugs which include the famous Viagra pills.

The third is **Bayer AG** Company whose headquarters is located at Bayerwerk, Leverkusen Germany. The company produces diversified chemicals, pharmaceuticals, dietetic products and hygiene products. Fourth is **GlaxoSmithKline (GSK)** Company based in UK, London. GSK has been as a leading research based Pharmaceutical Company operating in consumer healthcare, cosmetics and toiletries and non-alcoholic drinks in addition to its core pharmaceuticals. The company has its operational headquarters in the US and operates in over 117 countries and sell products in over 140 countries. The key product is Panadol in analgesics for its healthcare business and the last is **Novartis AG** based at Basel, Switzerland. Novartis has been merger with the Swiss pharmaceuticals companies CIBA-GEIGY and Sandoz. In 1996, Novartis was formed and has

since become one of the world's leading manufacturers of pharmaceuticals and consumer healthcare products. Novartis business activities are manufacture of pharmaceuticals, agricultural chemicals, hot drinks and packaged foods. (Source from:

)

2.4 Industry Revenues Year 2006

2.4.1 Global Market Leaders In Terms of Revenue

The table below shows a list of large pharmaceutical and biotech companies ranked by healthcare revenue in (USD million) worldwide.

Table 2.1

Total Revenues of Market Leaders (USD Million) Year 2006

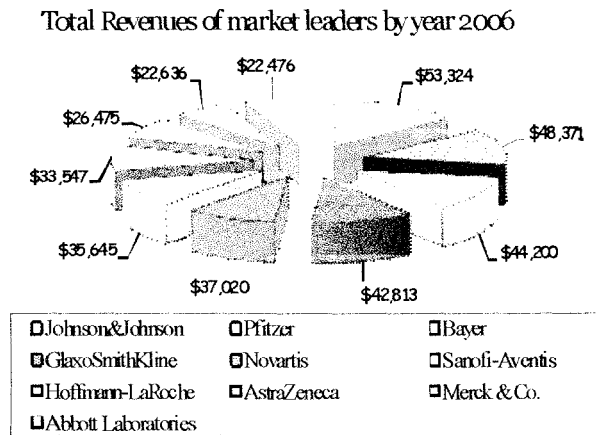
| Revenue Rank 2006 | Company | Country | Total Revenues | Healthcare R&D 2006 | Net income/ loss 2006 | Employees 2006 |
|-------------------|---------------------------|----------------|----------------|---------------------|-----------------------|----------------|
| 1 | Johnson and Johnson (J&J) | USA | \$53,324 | \$7,125 | \$11,053 | \$138,00 |
| 2 | Pfizer | USA | 48,371 | 7,599 | 19,337 | 122,200 |
| 3 | Bayer | Germany | 44,200 | 1,791 | 6,450 | 106,200 |
| 4 | GlaxoSmithKline | United Kingdom | 42,813 | 6,373 | 10,135 | 106,000 |
| 5 | Novartis | Switzerland | 37,020 | 5,349 | 7,202 | 102,695 |
| 6 | Sanofi-Aventis | France | 35,645 | 5,565 | 5,033 | 100,735 |
| 7 | Hoffman-La | Switzerland | 33,547 | 5,258 | 7,318 | 100,289 |

| | | | | | | |
|----|---------------------|-----------|--------|-------|-------|--------|
| | Roche | | | | | |
| 8 | AstraZeneca | UK/Sweden | 26,475 | 3,902 | 6,063 | 98,000 |
| 9 | Merck & Co. | USA | 22,636 | 4,783 | 4,434 | 74,372 |
| 10 | Abbott Laboratories | USA | 22,476 | 2,255 | 1,717 | 66,800 |

Source: Wikipedia encyclopedia – Pharmaceutical industry

Figure 2.1

Total Revenues of market leaders (USD Million) year 2006



Source: Wikipedia encyclopedia – Pharmaceutical industry

2.4.2 Global Market Leaders in Terms of Sales

Below has shown table of the lists of top ten pharmaceutical companies by 2006 sales in USD Million.

Table 2.2

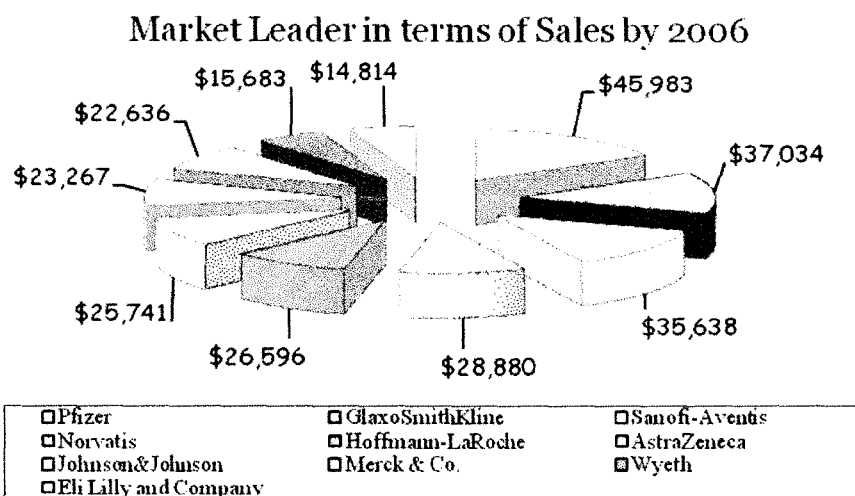
Market Leader in Terms of Sales (USD Million) Year 2006

| Rank | Company | Sales (\$m) | Growth (%) | Market Share (%) | Based/Headquartered in |
|------|-----------------------|-------------|------------|------------------|------------------------|
| 1 | Pfizer | 45,983 | 2.1 | 7.3 | US |
| 2 | GlaxoSmithKline | 37,034 | 9.7 | 5.9 | UK |
| 3 | Sanofi-Aventis | 35,638 | 5.0 | 5.7 | France |
| 4 | Novartis | 28,880 | 18.0 | 4.6 | Switzerland |
| 5 | Hoffmann-LaRoche | 26,596 | 21.8 | 4.2 | Switzerland |
| 6 | AstraZeneca | 25,741 | 10.5 | 4.1 | UK/Sweden |
| 7 | Johnson & Johnson | 23,267 | 4.2 | 3.7 | US |
| 8 | Merck & Co. | 22,636 | 2.8 | 3.6 | US |
| 9 | Wyeth | 15,683 | 2.4 | 2.5 | US |
| 10 | Eli Lilly and company | 14,814 | 7.5 | 2.4 | US |

Source: Wikipedia encyclopedia – Pharmaceutical industry

Figure 2.2

Market Leaders in Terms of Sales (USD Million) 2006

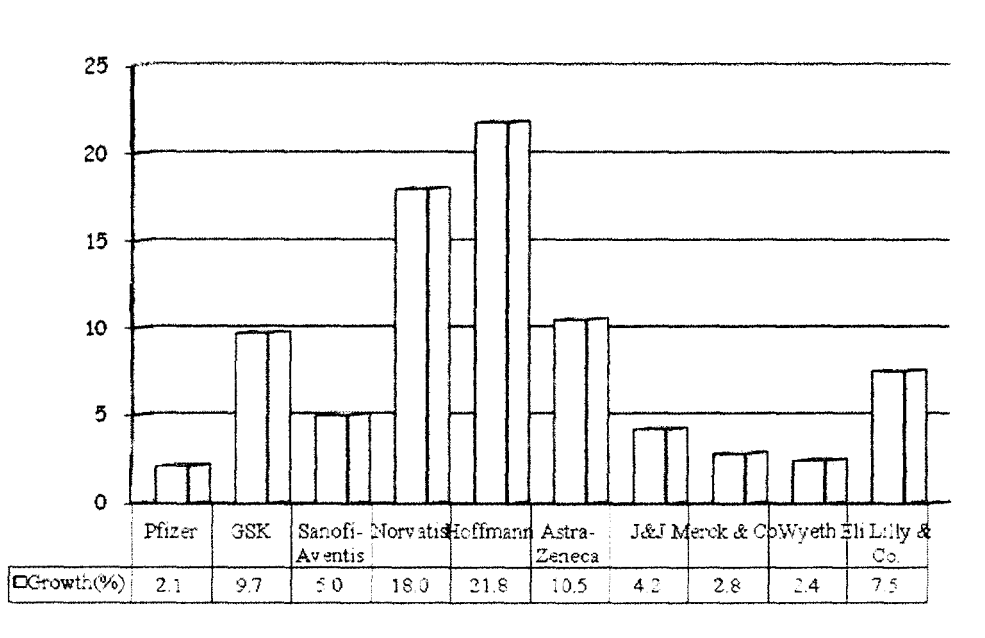


Source: Wikipedia encyclopedia – Pharmaceutical industry

2.4.3 Market Leader Growth (%) Year 2006

Figure 2.3

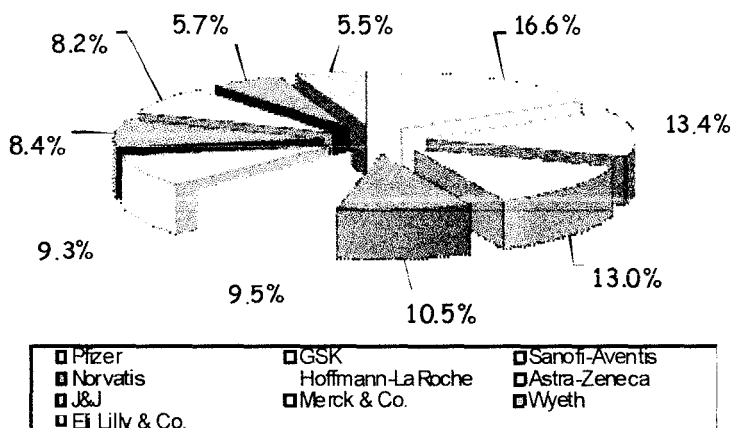
Market leader's growth (%) in percentage by year 2006



Source: Wikipedia encyclopedia – Pharmaceutical industry

Figure 2.4

Market Leaders in term of Market Share (%) 2006



Source: Wikipedia encyclopedia – Pharmaceutical industry

2.5 Malaysia Pharmaceutical Industry

Referring to Malaysia Industrial Development Authority (MIDA), Malaysian pharmaceutical manufacturers have produced medicines in dosages of all forms e.g. tablets (coated & non-coated), capsules (hard and soft gelatin), liquids, creams, ointments, small volume injectables, dry powders and active pharmaceutical ingredients. The local industry is producing about 30 per cent of the domestic demand, as well as exporting to the Asia-Pacific countries, the Middle East, Latin America and Europe. Total exports in 2008 amounted to RM513 million (USD\$142 million). Currently, a total of 234 pharmaceutical companies with Good Manufacturing Practice (GMP) certification have registered with Drug Control Authority (DCA). A total of 67 companies are involved in the production of modern medicines and 167 companies are local traditional and herbal medicine manufacturers. Source from ()

The prominent market research firm estimates that the Malaysia pharmaceutical industry, which is valued at \$1.03 billion (RM3.23 billion) in 2007, will record a compound annual growth rate of 10.5% and reach the \$1.8 billion mark by 2013. Main growth is expected to be seen in generic medication, therapy, over-the-counter (OTC) and traditional & herbal supplements. The generic products and medication will continue to be major source of medication with the government set to become the main purchaser from the pharmaceutical companies. More general hospitals are also being built and it is only natural that the demand for the generic medications increases for public consumption.

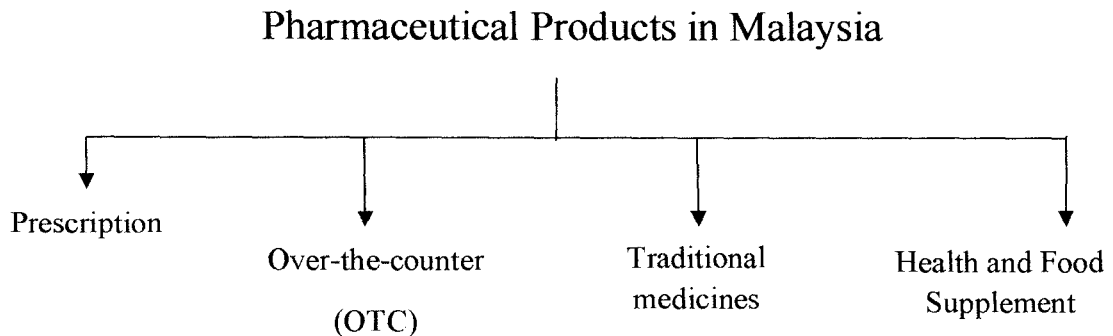
Source from: (

)

On the other hand, the potential of the domestic pharmaceutical industry has been recognized by the Malaysian government who has identified it as a strategic industry which should be promoted. In Malaysia pharmaceuticals industry, Malaysia Organization of Pharmaceutical (MOPI) plays an important role to their memberships that are from manufacture pharmaceuticals. MOPI's membership is restricted to manufacturers with factories in Malaysia that are licensed by the DCA, Ministry of Health, to manufacture pharmaceuticals. MOPI's functions are to co-operate with the government and other bodies, represent the interests of the pharmaceutical industry, promotion and development of the industry, facilitate and encourage the development, exchange and transfer of information and technology, domestically and internationally and promote and facilitate orderly trade in life science products. According to Malaysia organization of pharmaceutical (MOPI) pharmaceutical products can be broadly categorized as a below:

Figure 2.5

Categories of Pharmaceutical Products in Malaysia



Source: Malaysia Organization of Pharmaceutical Industries –

The industry can now produce almost 80% of the various categories in the Malaysian Essential Drugs List. In 1998, the government registered 7,416 prescription medicines and 8,873 OTC medicines while about 20,000 applications for traditional medicines were received. Source from: (Malaysia Organisation Pharmaceutical Industry

)

A prescription drug is a licensed medicine that is regulated by legislation to require a prescription before it can be obtained. The term is used to distinguish it from over-the-counter drugs which can be obtained without a prescription. Different jurisdictions have different definitions of what constitutes a prescription drug. Dispensation of prescription drugs often includes a package inserted (a Patient Information Leaflet or PIL) with detailed information about the drug. The prescription medicines comprise patented and generic drugs, the sale and transaction of which are confined to doctors and pharmacists.

Over-the-counter (OTC) products are these which can be obtained without a prescription. The OTC, traditional medicines and health/food supplements may be sold by non-professional outlets and to members of the public. They are used to treat conditions not necessarily requiring care from a health care professional and have been proven to meet higher safety standards for self-medication by patients. OTC products are products such as Adult mouth care; Allergy care; Analgesics; Calming and sleeping products; Child-specific OTC healthcare; Cough; cold and allergy (hay fever) remedies; Digestive remedies; Ear care; Emergency contraception; Eye care; Medicated skin care; NRT Smoking cessation aids; OTC obesity; OTC statins; OTC triptans; and Vitamins and dietary supplements.

Traditional medicines refer to health practices, approaches, knowledge and beliefs incorporating plants, animals and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being. Traditional medicines are also known as Complementary or Alternative Medicines (CAM). Traditional medicines are allowed to be sold as over the counter medicines without any restrictions. Limited health claims may be made. Malaysia does not have any national pharmacopoeia. However, international pharmacopoeia such as The Chinese pharmacopoeia and the Pharmacopoeia of India are used as references but are not considered legally binding. Health and food supplement is a preparation intended to supply nutrients, such as vitamins, minerals, fatty acids or amino acids, that are missing or are not consumed in sufficient quantity in a person's diet.

Pharmaceutical Practice and law in Malaysia are regulated by the Drug Control Authority (DCA) in Malaysia, under the *Control of Drugs and Cosmetics Regulations*

1984. The DCA is managed by the Director General of Health, Director of Pharmaceutical Services, Director of the National Pharmaceutical Control Laboratory, and seven other appointed members. The main responsibility of the DCA is to ensure the safety, quality and efficacy of pharmaceuticals in Malaysia. Some of the DCA's duties include:

- (1) Reviewing registration applications for drugs and cosmetics;
- (2) Licensing importers, manufacturers and wholesalers;
- (3) Post-marketing safety surveillance and
- (4) Adverse drug reaction (ADR) monitoring.

According to the DCA, any drug in a pharmaceutical dosage form, intended to be used, or capable or purported or claimed to be capable of being used on humans or animals, whether internally or externally, for a medicinal purpose is required to be registered with the DCA. This includes products which alleviate, treat or cure diseases, products that diagnose a disease, anesthetics, and products that maintain, modify, prevent, restore or interfere with normal physiological functions. Source from: Pharmaceutical Service Division of the Malaysia Ministry of Health. Source from

2.6 Pharmaceutical Industry in term of Market Share

The Malaysian pharmaceutical industry is expanding at a high rate and has amounted to USD652.8 million by the end of 2007. In 2000 and 2005, the pharmaceutical

industry was only at USD315.8 and 539.5 million respectively. Today there are around 300 registered pharmaceutical companies in Malaysia, of which 100 are local. The top 40 pharmaceutical companies hold some 30% of the market share. Large local manufacturers, which fall within the top 40 include UPHA, a wholly owned subsidiary of listed entity Chemical Co. of Malaysia Bhd., and Raza Manufacturing, 100% owned by Pharmaniaga Bhd. Other significantly large local pharmaceutical companies include YSP Industries, Duo Pharma and Xepa-Soul Pattison. The Malaysian pharmaceutical industry is expanding at an average of 10% annually. The market share held by Malaysian companies is growing and they now hold between 20 and 30% of the market compared to ten years ago, where they only held some 10 to 15% of the market. Multinational corporations (MNCs) control about 70% of the pharmaceutical market. Source from

2.7 Drug Application Process

There are three types of applications for drug approval in Malaysia: **(1)** application for an innovator product, **(2)** application for a generic drug, and **(3)** abridged application. An application for an innovator drug includes drugs containing a new chemical or biological entity, or a new combination of existing chemicals/biological. Changes in product composition or characteristics (such as color, shade, flavor, fragrance or shape) will also require a new registration application. Conversely, a change in product name, specifications, packaging, indications, labeling, package insert, product literature,

or excipients only requires an abridged application, which must be submitted to the DCA prior to making the change(s).

Product registration for imported products will require additional documents and information, including:

- Certificate of Pharmaceutical Product (CPP) from the pharmaceutical authority in the country of origin. (If a CPP is not available, a GMP certificate or manufacturing license is generally acceptable along with either a (1) CPP from the country of the product owner or (2) CPP from country of release.)
- Alternatively, traditional medicines, dietary supplements, and external personal care products require a Free Sale Certificate and Good Manufacturing Practice (GMP) certificate.

A separate application is required for each product to be registered. Products with the same ingredients but different specifications, such as the amount of ingredient(s), dosage forms, descriptions, manufacturer, etc., will require a separate application for each product registration. Products differing only in their packaging materials or pack sizes can be registered in a single product application. Source from:

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2.8 Halal Industry

In the Ninth Malaysia Plan (RMK-9), 2006-2010 Malaysia will be developed as a centre for the certification of Halal products and the JAKIM certification will be promoted worldwide. Halal is significantly related with Muslim population. Statistics have shown how the huge Muslim population in the world will provide big opportunities for companies or business entities involved with Halal industry to grab the profit from Muslim population. The statistics in the year 2008, have shown that the Muslim population is (1 billion) out of the world population of the population of (6.7 billion). In percentage it is 24.31% and the Muslim population estimated for year 2009 will be increasing at 1.84% or (1657.6 million). For Malaysia specifically (Asia Pacific), the total population is 25,715,819 million (July 2009 est). The Malay population is (50.4%) and Muslim is (60.4%). Based on the Muslim population figures the opportunities are there for the Halal industry. Source from:

Malaysia is not in the forefront in Halal industry and also it is not the only country that participates in the halal food industry or generally Halal industry. Others competitors like India, Australia, New Zealand and Brazil have already created names in the Halal food industry. For example Australia is the largest exporter of Halal red meat, India the largest exporter of Halal chicken and New Zealand the largest exporter of Halal lamb. The difference between these countries and Malaysia are (1) these countries just have a small Muslim population except India but yet they can be the largest exporters in halal

food (2) among the countries/competitors none of them has a government which gives full support to the development of the Halal sector.

Many agencies and institutions are involved in the development of the Halal industry. To promote the development of the Halal industry, coordination among the ministries and agencies will be further enhanced. The main agency that is responsible is Ministry of International Trade and Industry (MITI). MITI is responsible in bringing-out the Halal industry to international / global market. MITI had set-up strategies and policies towards global Halal hub. Its means Malaysia will be the base of operations for the industry. In the near future MITI aims, to make Malaysia the centre for the production, Halal service providers, reference on the Halal standard and R&D on Halal matters. MITI had set up eleven strategies purposely for the development and promotion of Malaysia as 'Global Halal Hub'.

1. Enhancing the awareness on Malaysia as the centre for Halal products and services
2. Managing the increasing competition from countries in the region
3. Leveraging upon outward investments to gain access to raw materials and enhance competitiveness
4. Enhancing R&D in product and process developments and leveraging upon latest technological developments to expand the product range
5. Developing Halal-compliant services
6. Utilizing and leveraging upon Malaysian Halal Standard to differentiate Malaysia's Halal products

7. Undertaking systematic development of halal parks
8. Ensuring product quality and food safety
9. Harmonizing the Halal certification process
10. Enhancing the coordination and of organization among agencies involved in the development and promotion of the industry
11. Strengthening the institutional capacity of organization involved in the development and promotion of Halal products and services.

To achieve the above strategies MITI has made collaboration with other government and private agencies. Malaysia External Trade Development Corporation (MATRADE) is responsible for enhancing MATRADE'S capabilities in gathering market intelligence for new and emerging markets and encouraging. Malaysian food and non-food companies acquire marketing capabilities, to expand their operations in identified markets including the establishment of Malaysia food outlets overseas. Tourism Malaysia and MATREDE also collaborate to develop specific programmes to promote Malaysia Halal food products and encourage Malaysian Halal food and non-food companies to foreign countries.

Research and development is needed to growing Halal market, so the industry will be encouraged to achieve a higher level of innovation in product and process developments in both the food and non-food industries. SMEs assisting involved in Halal food and non-food production, in acquiring the necessary technological capabilities to upgrade their manufacturing processes, enhance product development and improvements. Small and Medium Industries Development Corporation (SMIDEC) are also responsible

for the development and capacity building of SME's and the Department of Standards Malaysia will coordinate the development of the Malaysia Halal Standards.

Before the RMK-9, JAKIM was the agency that fully was responsible for the Halal standard and certification. Before HDC was established, the objective of JAKIM was to upgrade and to enable it to provide more efficient services to the industry, both at the domestic and international level. To enhance the abilities and emphasize Halal industry HDC was establish on 18 September 2006 with objective to coordinate the overall development of the industry. Source from: MITI

2.9 CCM Pharmaceuticals Sdn Bhd Analysis

CCM Pharmaceuticals is under the CCM Berhad Company. It's one of CCM Berhad major subsidiaries. CCM Pharmaceuticals was a leader company in pharmaceuticals industry. In Malaysia, the OTC healthcare and health wellness industry is still growing and remained as the review period. The presences of few domestic and multinational competitors have made some impact to cause their stability in the market. In 2007, CCM Pharmaceuticals ranked 24 with only a 1 percent value share. The company has increased its stake in the OTC healthcare and health wellness healthcare industry. During the year 2006, the company was acquired Malayan Pharmaceuticals by its parent company the Chemical Company of Malaysia. The acquisition was a success