SURUHANJAYA PERSAINGAN MALAYSIA
MALAYSIA COMPETITION COMMISSION

MARKET REVIEW ON PRIORITY SECTOR UNDER COMPETITION ACT 2010

PHARMACEUTICAL SECTOR

Malaysia Competition Commission (MyCC)

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EXECUTIVE SUMMARY

The aims of Malaysia's National Medicines Policy are to promote equitable access to, and rational use of, safe, effective and affordable medicines by its population. In order to maximize social welfare, this policy is strengthened by Malaysia's Competition Act of 2010 and the establishment of the Malaysia Competition Commission (MyCC) to bring about allocation, production and innovation efficiencies.

The Malaysian healthcare system has changed from a predominantly public healthcare system to a dual or two-tiered system where public and private healthcare expenditure are almost equal today. The big rise in the incidence of non-communicable diseases and out-of-pocket expenses in the healthcare system has wielded significant financial impact on both the private and public sectors.

The pharmaceutical sector has grown by an average annual rate of 8% over the last decade, reaching RM8.6 billion or 16.5% of total healthcare expenditure (RM52 billion) in 2016. Imported medicines at RM5.4 billion still account for the largest part (63%) of the RM8.6 billion pharmaceutical market, while exports are only RM0.7 billion. Generic medicines now account for 55% of the controlled (prescription) medicines market by value.

The market structure of Malaysia's pharmaceutical sector is characterized by a three-level supply chain, starting with manufacturers of generic medicines and importers of originator and generic medicines at the first level, wholesalers and distributors at the second level, and providers at the third level who provide medicines to patients and end users.

The scope of this pharmaceutical sector Market Review is limited to controlled medicines. These are pharmaceutical products containing scheduled poisons as listed in the First Schedule under the Poisons Act 1952. They are commonly known as prescription medicines. The Review focuses primarily on manufacturers/importers at level 1 of the pharmaceutical supply chain, and the wholesalers/distributors at level 2. Due to time constraints, it was not possible to do a more in-depth study of the providers in level 3. A dedicated study should be carried out on the level 3 players as they represent an important link in the supply chain. That study will also need to examine the interactions between level 3 and levels 1 and 2.

Out of 28 companies manufacturing controlled medicines in Malaysia, 23 are locally owned and 5 are foreign-owned, with none from high-income countries. The total sales revenue of this market was RM1.7 billion in 2014/15. Though there are few players, the market is competitive, with a Concentration Ratio (CR) 5 of 54% and Herfindahl-Hirschman Index (HHI) of 824, with little evidence of price fixing. The companies produce generic drugs, facing price competition from imports from India and increasingly from other Southeast Asian and Eastern European countries.

Out of 54 importers in this study, 35 are foreign-owned, accounting for RM3.9 billion or 87% of market share, with 19 locally owned companies taking 13% of market share. This market's CR5 of 47% and HHI of 643 indicate a low degree of market concentration. However, market concentration measured in this traditional way does not capture market power. Importers are dominated by subsidiaries of multinational corporations (MNCs) from high-income countries that import patented (originator) medicines from their parent companies. The importers have market exclusivity over those products while pricing decisions lie with their parent companies.

At the second level of the supply chain, out of 709 companies holding wholesale licences issued by the National Pharmaceutical Regulatory Agency (NPRA) to distribute controlled medicines, 72 companies were studied. Four categories of wholesalers and distributors were identified: large independent distributors, Bumiputera agents, wholesalers and distributors that are subsidiaries of manufacturers, and retail pharmacies that also do wholesaling. Despite the large number of players, this market is highly concentrated, with a CR5 of 83% and HHI of 2,370. Whilst high market concentration should imply a high degree of market power over pricing, this is not the case here as the wholesalers and distributors do not own the products they distribute and hence have no power over pricing.

The third level of the supply chain is made up of the providers, which consist of general practitioners' and specialists' clinics (individual and group clinics), private hospitals (individual and group hospitals), retail pharmacies (single outlet and chain pharmacies) and public hospitals and clinics. In 2014, there were 6,978 private GP and specialist clinics, 184 private hospitals, 1,413 pharmacy companies with 2,098 outlets, 150 public hospitals and 2,871 public clinics. Owing to time limitations, no market concentration study was done at this level.

In the pharmaceutical sector, standard measures of market concentration using CR and HHI are inadequate to measure and understand market power at the companies' level. There is no strong correlation between market concentration (traditionally defined as sales revenue share), market power and anti-competitive behaviour. Other important factors such as entry barriers, supply conditions, and particularly patents may be more important factors in determining market power.

Unlike with other consumer goods, patients have little consumer choice in the frequency and type of medicines to take. This problem is compounded by information and knowledge asymmetry between patients and doctors, where those who prescribe have more power to decide than the consumers. As medicines are not easily substitutable, the definition of relevant market becomes critical. Functional similarities are insufficient to establish substitutability as the efficacy and side effects of taking a product can differ from one patient to another. Prescription medicines cannot be purchased at will and the prescribing doctor may not know the price-sensitivity of a particular patient, or may place a lesser priority on the patient's medical costs in a treatment.

For these reasons, in this sector, defining the market for anti-competition purposes is sometimes examined at a very detailed level, frequently down to the chemical substance level of Anatomical Therapeutic Chemical (ATC 5) where the originator company, through patent and other exclusive rights, has legal exclusive market rights, enjoys dominant market position and often unbridled power to determine prices.

With the lack of substitutability, competition is only enabled when generic medicines enter the market – prices often drop dramatically, by up to 90%, as seen in the case of HIV medicines. (Generic competition also often results in significant lowering of originator prices.) While patents are accepted as one form of incentive and reward for innovation, competition law is increasingly used to remedy misuse of the patent regime when such conduct adversely impacts on the fostering of competition in, and growth of, the domestic industry as well as consumer welfare and public health. In Malaysia, many medicines treating non-communicable diseases, such as cardiovascular illnesses and cancer, remain high even where patent rights in relation to these medicines have expired in other parts of the world. Experience shows that prolonged patent terms can be one reason for the continued high price of these medicines.

Patent and product life-cycle management strategies are employed by originator companies to extend the monopoly over blockbuster medicines in the form of patent clusters or thickets where multiple patents are filed on, for example, methods, formulations and salts. These lead to many secondary patents and follow-on products which do not necessarily have added therapeutic benefits. For this reason, the European Commission, upon completing its inquiry into competition in the pharmaceutical sector in 2009, now monitors patent settlement agreements on a regular basis as one major action.

Competition authorities can play a critical role in promoting greater access to medicines. Some countries have used competition law to improve the price, availability and transfer of health technologies. MyCC and the Malaysian Ministry of Health (MOH) have started to engage with United Nations agencies such as the UN Development Programme (UNDP) on the use of competition law to deal with abuse of patents and other intellectual property rights in order to increase availability and affordability of medicines.

This Review has elicited a wide range of feedback and concerns related to the current pharmaceutical product registration requirements. While respondents support Malaysia's imposition of high international standards, they point out that some of the requirements and standards pose significant challenges to the domestic generic drug industry. These challenges can delay the entry of generics into the market in addition to imposing high costs. One example is the retrospective requirement for bioequivalence test on products that have been registered and in use for many years, and that have not been associated with any complications or problems.

Data exclusivity is another aspect of product registration that is known to cause delay of generics and thus higher costs to consumers and public health budgets. The protection of clinical test data of an originator medicine for a number of years prevents drug regulatory authorities from registering a generic by relying on those test data. There is no international obligation to provide such market exclusivity. In adopting the Data Exclusivity Directive 2011, Malaysia has explicitly taken into account public health, and has achieved a balance between originator and generic companies whilst meeting requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) administered by the World Trade Organization (WTO).

An analysis of past studies and data from the MOH shows that availability has increased over the years. On-going studies are conducted by the MOH to monitor the public and private medicine prices using World Health Organization (WHO) methodology but these are not made publicly available. It is recommended that further studies be conducted to evaluate the availability, affordability and accessibility of the medicines concerned.

Public hospitals and clinics are providing most of the needed medicines at highly subsidized rates. The 10 most utilized medicines in the private sector are 1.4 times to 34 times higher than in the public sector. Due to budget constraints in the government, patients not covered by insurance or employer's provision who need to purchase medicines from the private sector will be severely affected by issues of affordability.

The price of medicines is largely determined by a country's public procurement system, the Australian system being a good example. Malaysia changed from a central government purchasing system to a privatization model where a private company is given exclusive concession to supply a large part of medical supplies to the government. A study in 2009 found that selected drug prices in the public sector increased post privatization, particularly between 2001 and 2003 when they rose by 64%.

In assessing whether there is anti-competitive conduct in the pharmaceutical sector, the definition of "relevant market" needs to fit the special characteristics of pharmaceutical products. A case-by-case approach is required, as seen in cases investigated by competition authorities in other countries. The WHO classification system of 5 ATC levels is commonly used to determine "interchangeability" or "substitutability" of products to establish dominant position in the pharmaceutical market. ATC 5 is generally favoured as the starting point.

Anti-competitive conduct of originator companies that has been investigated by the European Commission and several other countries was reviewed. The review identified anti-competitive conduct such as the use of patent strategies and product life-cycle management measures to maintain dominant position and delay entry of generic medicines; the interventions by originator companies before national authorities that determine marketing authorization, pricing and reimbursement of generic products; and price discrimination.

It is recommended that the Patents Act currently under review should be aligned with national competition and public health objectives; the scope of patentability be revisited in light of the characteristics of pharmaceuticals and updating of patentability criteria in other countries; linking patent status to product registration be treated with caution; patent transparency be enhanced; and all TRIPS flexibilities be included. There should be closer cooperation among the MOH, MyIPO, the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC) and the Ministry of International Trade and Industry (MITI) in dealing with patent and trade-related issues that impact on public health.

In terms of product registration, the requirement for retrospective bioequivalence for "grandfather" products should be reconsidered. Regulations on "biosimilars", a class of medicines that is growing in importance (e.g. for cancer, diabetes, etc.), also need to be attuned to the latest developments and experiences in other countries. The Guideline on Good Pharmaceutical Trade Practice is currently voluntary. The MyCC and MOH can continue the collaboration on this and other areas for potential guidance or regulation vis-à-vis industry players.

There is a need for a coherent price policy to be part of the National Medicines Policy. There should be price transparency at all levels of the supply chain. Malaysia should study examples from other countries like South Africa in regulating medicine prices and like the Philippines, which mandates that prescriptions to patients must include a choice of at least two generic medicines. Price regulation is a complex task and will need to balance between market forces and timely non-market intervention to ensure access to affordable medicines. There should be systematic price monitoring with better use of publicly available information from other countries; and the government should work towards sharing of government procurement prices.

Competition concerns related to marketing and promotional conduct were not covered in the Review and this merits study as it influences and shapes the prescription choices of doctors and dispensing by pharmacists. In Malaysia the dual role of doctors in prescribing and dispensing medicines also raises competition concerns. A comprehensive study of level 3 and its interactions with levels 1 and 2 is thus needed.

Although mergers and acquisitions are not within the scope of the Malaysian Competition Act, MyCC should cooperate with the Securities Commission that is responsible for this aspect, to monitor the sector's players.

In conclusion, although access to medicines and other health technologies has not traditionally been addressed through competition law, this is changing. Competition authorities in various jurisdictions are playing a larger role in using competition law to improve the price, availability and transfer of health technologies.

LIST OF ABBREVIATIONS

An entry with an asterisk in the list of abbreviations is defined in the glossary of terms that follows. The definitions in the glossary are not intended to be comprehensive and complete. The reader can often obtain more information by referring to the appropriate chapters in the Review.

ACTD*	ASEAN Common Technical Dossier
ACTR*	ASEAN Common Technical Requirements
API*	Active Pharmaceutical Ingredient
APPL*	Approved Product Purchase List
ARV*	Antiretroviral (medicine)
ASEAN	Association of Southeast Asian Nations
ATC*	Anatomical Therapeutic Chemical (classification system)
BE*	Bioequivalence
BMI	Business Monitor International
CDCR	Control of Drugs and Cosmetics Regulations
CMA	Competition and Markets Authority (UK)
CML	Chronic Myeloid Leukaemia
CR*	Concentration Ratio
DCA*	Drug Control Authority
DCGI*	Drug Controller General of India
DDD*	Defined Daily Dose
DRGD	Drug Registration Guidance Document
EC*	European Commission
ECJ*	European Court of Justice
EPP*	Entry Point Project
ETP*	Economic Transformation Programme
EU	European Union
FOMCA	Federation of Malaysian Consumers Associations
FTC*	Federal Trade Commission
FTPP*	Fair Trade Practices Policy
GDP	Gross Domestic Product
GLC	Government-linked Company
GMP*	Good Manufacturing Practice
GP	General Practitioner
HHI*	Herfindahl-Hirschman index
HIV*	Human Immunodeficiency Virus
HMT*	Hypothetical Monopolist Test
IB*	Innovator Brand
ICH*	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
INN*	International Non-Proprietary Name
IP*	Intellectual Property

IPR*	Intellectual Property Right
IRP*	International Reference Price or International Reference Pricing
KPDNKK	see MDTCC
LMIC	Low- or Middle-Income Country
LPO	Local Purchase Order
MAPS	Malaysian Association of Pharmaceutical Suppliers
MCPG	Malaysian Community Pharmacy Guild
MDA	Malaysian Dental Association
MDTCC	Ministry of Domestic Trade, Co-operatives and Consumerism
MIDA	Malaysian Investment Development Authority
MINDEF	Ministry of Defence
MITI	Ministry of International Trade and Industry
MNC	Multinational Corporation
MOH	Ministry of Health
MOPI	Malaysian Organization of Pharmaceutical Industries
MPP	Medicines Patents Pool
MPS	Malaysian Pharmaceutical Society
MyCC	Malaysia Competition Commission
MyIPO	Intellectual Property Corporation of Malaysia
NCD*	Non-Communicable Disease
NCE*	New Chemical Entity
NEML	National Essential Medicine List
NKEA	National Key Economic Area
NPRA*	National Pharmaceutical Regulatory Agency
OECD	Organization for Economic Cooperation and Development
OOP	Out of Pocket (expenses)
OTC*	Over-the-Counter
PEMANDU	Performance Management and Delivery Unit
PhAMA	Pharmaceutical Association of Malaysia
PIC/S*	Pharmaceutical Inspection Co-operation Scheme
PRH	Product Registration Holder
PSD*	Pharmaceutical Services Division
SDGs*	Sustainable Development Goals
SMEs	Small and Medium-sized Enterprises
SSM	Suruhanjaya Syarikat Malaysia (Companies Commission of Malaysia)
THCE	Total Healthcare Expenditure
TMHS	Traditional Medicines Health Supplements
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
WHO	World Health Organization
WHO-PAHO	World Health Organization-Pan American Health Organization
WHO-SEARO	WHO Regional Office for South East Asia
WHO-WPRO	WHO Regional Office for the Western Pacific
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

GLOSSARY

(This glossary has been developed with the assistance of multiple sources researched over the internet.)

"Active Pharmaceutical Ingredient (API)". Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical drug and that, when used, becomes an active ingredient of that pharmaceutical drug.

"Anatomical Therapeutic Chemical (ATC)" classification. An international standard of the World Health Organization for classifying medicines whereby the active substances in pharmaceutical drugs are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Drugs are classified in groups at five different levels. The drugs are divided into 14 main groups (1st level), with pharmacological/therapeutic subgroups (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance.

"Antiretroviral (ARV)". These are medications that treat HIV by preventing the growth of the virus.

"Approved Product Purchase List (APPL)". The list of items supplied by Pharmaniaga Logistics Sdn. Bhd. under its concession with the Ministry of Health (MOH).

"ASEAN Common Technical Dossier (ACTD)". The ASEAN Common Technical Dossier (ACTD) is a guideline of the common format agreed upon by members for the preparation of a well-structured Common Technical Dossier (CTD) for applications that will be submitted to ASEAN regulatory authorities relating to the registration of pharmaceuticals for human use.

"ASEAN Common Technical Requirements (ACTR)". It is a guidance document to provide supportive information on the requirements for submission of a variation application to implement a change to a pharmaceutical product. See also ACTD.

"Authorized (or Licensed) Generics". A generic which may be marketed by a company other than the originator company under a licence granted by that originator company.

"Bioequivalence (BE)". This means two drugs releasing their active ingredients into the bloodstream in the same amounts and at the same rate.

"Biologic". Also referred to as "biological medicine". A medicine that is made up of large, complex molecules grown in living cells rather than synthesized chemically, as in the case of small molecule drugs.

"Biosimilar". A medicine that is produced by a company other than the originator company and similar to the biological medicine of the originator company.

"Blockbuster Medicine". A medicine which achieves annual revenues of over US$1 billion at global level.

"Bumiputera Agent". In this Review, Bumiputera agents refer to Bumiputera entities that act as intermediaries between the Ministry of Health/public hospitals, on the one hand, and local non-Bumiputera and foreign pharmaceutical companies, on the other hand, bidding for government procurement of medical supplies.

"Community Pharmacies." Retail-only pharmacies that are publicly accessible pharmacies as opposed to hospital pharmacies. In this review, retail-only pharmacies that operate only one outlet are known as stand-alone community pharmacies. Pharmacies that own and operate more than one retail pharmacy outlet are defined as chain pharmacies.

"Concentration Ratio" measures how much of market share is accounted for by the top firms in the sector.

"Contract Manufacturer". Any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations (*as defined in Regulation 2, CDCR 1984*)

"Controlled Medicines" (commonly known as "Prescription Medicines"). Medicines that cannot be bought without a prescription by a physician. Technically these are known as pharmaceutical products containing scheduled poisons as listed in the First Schedule under the Poisons Act 1952 (or "controlled medicines").

"Defined Daily Dose (DDD)". The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.

"Differential Pricing". The strategy of selling the same product to different customers at different prices even though costs are the same. (Discriminatory pricing or tiered pricing is also used with the same meaning.)

"Dispensing Separation". The separation of prescribing of medicines (by doctors) from the dispensing of them (by pharmacists), in recognition of the respective specialisations of both professionals.

"Distributor". An entity that buys non-competing products or product lines, warehouses them, and resells them to retailers or direct to the end users or customers.

"Drug Control Authority (DCA)". The executive body established under the Control of Drugs and Cosmetics Regulations 1984. Its main task is to ensure the safety, quality

and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia.

“Drug Controller General of India (DCGI)”. The DCGI is responsible for approval of licenses of specified categories of drugs in India.

“Economic Transformation Programme (ETP)”. Launched on 25 September 2010, this was formulated as Malaysia’s Transformation Programme. Its goal is to elevate the country to developed-nation status by 2020, targeting GNI per capita of US$15,000. The ETP’s targets for 2020 will be achieved through the implementation of 12 National Key Economic Areas (NKEAs), representing economic sectors which account for significant contributions to GNI. There is a Healthcare NKEA. Each NKEA comprises Entry Point Projects (EPPs), which explore new growth areas, and Business Opportunities (BOs), which enable the sectors to move further up the value chain.

“Entry Point Project (EPP)”. See explanation for ETP.

“European Court of Justice (ECJ)”. This is the highest court in the European Union on matters of European Union law.

“European Union Commission (EU Commission)”. The EU’s executive body and represents the interests of Europe as a whole (as opposed to the interests of individual countries).

“Fair Trade Practices Policy (FTPP)”. FTPP was approved on 26 October 2005 to, among other things, promote consumer welfare and encourage socio-economic growth through promoting and protecting competition in the market economy.

“Federal Trade Commission (FTC)”. It is an independent agency of the United States government, established under the Federal Trade Commission Act. Its mission is to protect consumers and promote competition.

“Generic Medicine”. A medicinal product that is equivalent (in that it has the same qualitative and quantitative composition in active substances and the same pharmaceutical form) to a currently registered product (originator) in Malaysia. However, the term “biosimilar” is used for an equivalent biologic.

“Good Manufacturing Practice (GMP)”. A standard that should be followed by manufacturers of registered pharmaceutical products to ensure that the products manufactured are safe, efficacious and of quality. Compliance with GMP standards is a prerequisite for the application of a manufacturing licence as well as product registration.

“Herfindahl-Hirschman Index (HHI)” measures the size of firms in relation to the industry and is an indicator of the level of competition in that industry.

"Human Immunodeficiency Virus (HIV)" is a virus that attacks the immune system.

"Hypothetical Monopolist Test (HMT)" is a test used to define the relevant market. According to HMT, the relevant market is "The smallest group of products (in a geographical area) that a hypothetical monopolist controlling that product group (in that area) could probably sustain a price above the 'competitive' price i.e. a price that is at least a small but significant amount above the competitive price."

"IMS". Known as IMS Health or Quintiles, IMS is a private company that provides market research, business analysis, forecasting information, services and sales management services to the global healthcare industry.

"Innovator Brand". See "Originator".

"Intellectual Property (IP)" refers to creations of the mind such as inventions, literary and artistic works.

"Intellectual Property Corporation of Malaysia (MyIPO)" is the agency responsible for the development and administration of the intellectual property system.

"Intellectual Property Rights (IPR)" are rights given to individuals or legally constituted entities over creations or inventions. These include patents, copyright and trademarks. Such property rights allow the holder to exercise a monopoly over the use of the subject matter concerned for a specified period of time.

"International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)" brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH's stated mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

"International Non-proprietary Name (INN)" identifies pharmaceutical substances or active pharmaceutical ingredients.

"International Reference Pricing (IRP)". IRP is also known as external reference pricing. It refers to the practice of using the price of a pharmaceutical product (generally ex-manufacturer price, or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

"Licensed Importer". A person to whom an import licence has been issued under Regulation 12, CDCR 1984 (*as defined in Regulation 2, CDCR 1984*).

"Licensed Manufacturer". A person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer (*as defined in Regulation 2, CDCR 1984*).

"Licensed Wholesaler". A person to whom a wholesaler's licence has been issued Regulation 12, CDCR 1984 (*as defined in Regulation 2, CDCR 1984*).

"Loss of Patent Protection" refers to a situation where an invention no longer falls under the protection period provided by a patent.

"Manufacturer". A person or entity carrying out one or more of the steps specified in the definition of manufacture. Manufacture, in relation to any product, includes:

a) The making or assembling of the product;
b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container; and
c) The carrying out of any process in the course of any of the foregoing activities (*as defined in Regulation 2, CDCR 1984*).

"Market Concentration". This refers to the extent to which a small number of firms or enterprises account for a large proportion of economic activity such as total sales, assets or employment.

"Market Dominance". An enterprise has market dominance when it accounts for a significant share of a given market and has a significantly larger market share than its next largest rival.

"Market Power". This refers to the ability of a firm (or group of firms) to raise and maintain price above the level that would prevail under competition.

"Marketing Authorization". An official document issued by the NPRA for the purpose of marketing or free distribution of a pharmaceutical product after evaluation for safety, efficacy and quality.

"Medicinal Product". The term refers to "product" as stated in Regulation 2, CDCR 1984 which is applicable to pharmaceutical and natural products.

Medicines Patent Pool (MPP). The MPP negotiates licences to allow generic manufacturers to make medicines for HIV, tuberculosis and hepatitis C. It is a project under UNITAID, an international organization that invests in new ways to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, more cheaply and more effectively.

"Ministry of Health Medicines Formulary". The Ministry of Health Medicines Formulary (MOHMF) or *Formulari Ubat Kementerian Kesihatan Malaysia (FUKKM)* serves as a reference for medicines used in the Ministry of Health (MOH) facilities. Also known as "the Blue Book".

"National Essential Medicine List (NEML)". Medicines listed as National Essential Medicines are marked as NEML in the Medicines Formulary. WHO defines essential medicines as medicines that satisfy the priority healthcare needs of the population and

hence should be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. Not all medicines listed in the formulary are categorized as NEML.

“National Pharmaceutical Regulatory Agency (NPRA)”. The main regulatory agency is the Drug Control Authority, with its secretariat at the NPRA. The NPRA is responsible for pharmaceutical product registration and issues manufacturing, import and wholesale licences to pharmaceutical companies.

“New Chemical Entity” refers to a new chemical substance, not previously authorized for marketing for any pharmaceutical use in the country.

“Non-Communicable Disease (NCD)” is also known as chronic disease. These diseases tend to be of long duration and are the result of a combination of genetic, physiological, environmental and behavioural factors. The main types of NCDs are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma) and diabetes.

“Originator” is generally the product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization. The originator product always has a brand name which may vary between countries.

“Originator Company” is defined as a company that sells originators.

“OTC Medicines” refer to medicines that are sold over the counter, i.e., without prescription.

“Patent Cliff”. This refers to the situation when an enterprise’s revenues could “fall off a cliff” when one or more established products go off-patent, since these products can be replicated and sold at much cheaper prices by competitors.

“Patent Cooperation Treaty (PCT)”. The PCT is an international treaty with more than 150 Contracting States at the time of writing. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. A preliminary patent application examination is conducted by the World Intellectual Property Organization that administers the PCT. Substantive examination of an application remains the right of every PCT member, as the granting of patents is a national decision.

“Patent Linkage”. The practice of linking market approval for generic medicines to the patent status of the originator reference product.

"Patent Settlement Agreement" refers to any formal or informal agreement which settles an actual or potential patent issue, whether it was brought before a court or any other body or settled out of court without engaging in any formal adversarial procedure.

"Pharmaceutical Inspection Co-operation Scheme (PIC/S)". A non-binding, informal cooperative arrangement between regulatory authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any authority having a comparable GMP inspection system.

"Pharmaceutical Services Division (PSD)". A division of the Ministry of Health that has the responsibility of ensuring that the public gets access to safe, efficacious and quality pharmaceutical products, protecting their interest via enforcement of relevant legislations, and ensuring the rational use of medicines by both healthcare providers and patients. It carries out its responsibility through three main activities, namely pharmacy policy and management, pharmacy practice and development, and pharmacy enforcement.

"Prescription Medicines". See "Controlled Medicines".

"Primary patents". Patents covering active ingredients. Also referred to as "basic" or "compound" patents.

"Product" refers to an actually marketed product for which a marketing authorization has been granted (e.g. different dosages, administration forms).

"Providers". In this Review, the term "providers" refers to general practitioners' and specialists' clinics (individual and group clinics), private hospitals (individual and group hospitals), retail pharmacies (single outlet and chain pharmacies) and public hospitals and clinics.

"Secondary patents". Patents covering modified compounds, formulations, dosages, particular medical uses, etc.

"Small Molecule Drugs". Medicines derived from chemical synthesis molecules.

"Sustainable Development Goals (SDGs)". In 2015 Heads of States and Governments, including Malaysia, adopted the United Nations 2030 Agenda for Sustainable Development with 17 SDGs and 149 targets.

"Type A Licence". A Type A licence is issued to a pharmacist to import, store and deal generally by wholesale and retail or by wholesale only or by retail only.

INTRODUCTION

Pursuant to Section 11(1) of the Competition Act 2010, Third World Network Berhad (TWN) was appointed by the Malaysia Competition Commission (MyCC) to conduct a Market Review of the pharmaceutical sector in Peninsular Malaysia.

The objectives of this Review are to:
- Determine the sector's market profile, structure and supply chain;
- Determine the competition level among players at different levels of the supply chain;
- Identify whether anti-competitive practices exist; and
- Identify whether the government has to intervene or change any policies that facilitate anti-competitive conduct.

The scope of the Review is limited to controlled medicines. These are pharmaceutical products containing scheduled poisons as listed in the First Schedule under the Poisons Act 1952. They are commonly known as prescription medicines, i.e., prescription by a physician is required. This Review, which was conducted over a course of approximately 4 months, was focused primarily on the manufacturers/importers (level 1 of the pharmaceutical supply chain) and the wholesalers/distributors (level 2). Due to time constraints, it was not possible to do a more in-depth study of the providers in level 3. A dedicated study should be carried out on the players in level 3 as they represent an important link in the supply chain. That study will also need to examine the interactions between level 3 and levels 1 and 2.

This report contributes to MyCC's objectives of protecting the interests of consumers in this sector by providing them with safe, effective and affordable medicines while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry.

The Review is carried out in the policy context of the Generic Medicines Policy contained within the Malaysian National Medicines Policy, and the Fair Trade Practices Policy.

Against this backdrop, the sector Review considered the broader question that concerns us all today – the rising healthcare cost in this country and whether it is caused by any anti-competitive conduct within the sector. The Review considered whether there were any obstacles to entry for prescription medicines for human use. Further, it is acknowledged that the entry of generic medicines into the market can substantially lower prices of medicines and assist a country in better managing its healthcare budget while ensuring access to affordable medicines and treatments for its citizens. In line with that and our own national policy, the Review team specifically looked at the behaviour of the companies within this sector to determine if they impeded the entry of generics into the market.

The team would like to firstly thank all the participants who agreed to be interviewed for this Review and graciously shared their knowledge and time with the researchers. Secondly, the team appreciates the valuable feedback from members of the MyCC Steering Committee that helped sharpen the study. Thirdly, the team would like to thank the MyCC staff for their support and input, the Ministry of Health for their cooperation, and the Companies Commission of Malaysia (Suruhanjaya Syarikat Malaysia-SSM) for providing the financial data of companies for this study.

Research Team
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METHODOLOGY AND LIMITATIONS

Both qualitative and quantitative methods were used to gather information and data for this Review of Malaysia's pharmaceutical sector. The objectives and scope of reference for this study were provided by MyCC.

A literature review was made of academic articles, newspaper reports, business articles, reports of industry associations, government reports, publications from think-tanks and academic institutions available on the internet, United Nations agency websites such as the World Health Organization and United Nations Development Programme, as well as the Organization for Economic Cooperation and Development. This was to understand the issues and identify what is available in the public domain on this topic. The Ministry of Health (MOH) in particular provided valuable information and guidance.

Relevant publicly available materials from competition authorities in the European Union, the United States of America, South Africa and India were also reviewed. The Access Campaign of Médecins Sans Frontières (MSF) (Doctors Without Borders), the international medical humanitarian organization, provided pricing information of generic medicines that they procure globally. The local patent status of the medicines discussed in the Review was obtained from the database of the Intellectual Property Corporation of Malaysia (MyIPO). The database of the Geneva-based Medicines Patent Pool (MPP) also provided information on the patent status of key medicines for HIV treatment. The database includes the text of the licences signed between the MPP and multinational pharmaceutical companies that allow generic manufacturers to produce the patented products of those companies.

The literature review was followed up with initial discussions with academicians, pharmacists, doctors and industry players (management of hospitals and pharmaceutical manufacturing companies) to help frame the questions and issues for the study.

Time series quantitative data on the size and growth of the pharmaceutical sector were culled from various issues of the Business Monitor International (BMI) quarterly reports from years 2009 to 2017. Data on the lists of pharmaceutical manufacturers, importers, wholesalers and pharmacies were collected from the websites of the National Pharmaceutical Regulatory Agency (NPRA) and the Pharmaceutical Services Division (PSD). These data were used to identify the total population for these four sets of players in the pharmaceutical sector. Next, companies were filtered and selected for this study based on criteria explained in detail in subsequent chapters. Then financial information on the companies selected for study was collected from financial reports submitted to the Companies Commission of Malaysia (SSM) by these companies. Data on the number of doctors' and specialists' clinics, private hospitals, public hospitals and clinics were gathered from the Ministry of Health websites. No financial information was collected for these establishments.

The second part followed a qualitative approach to gather information on the market structure and supply chain, mode of operation of the companies, competition issues, procurement methods, interaction between industry actors within and between levels of the supply chain etc. This was done through semi-structured interviews based on a qualitative questionnaire with top management of companies at all levels of the industry (see Appendix 1 for the interview questions). A total of 37 organizations and 97 individuals were interviewed. The interviews were done from 28 June up to October 2017.[1]

Interviews were conducted at all 3 levels of the market supply chain in the pharmaceutical sector (manufacturers and importers; wholesalers/distributors; providers) though the focus was on the first 2 levels. Fewer interviews were done at the third level of the supply chain due to time constraints. Other players and stakeholders in this sector such as the regulatory agencies and industry organizations were also interviewed.

Table 1 shows a breakdown of the organizations and persons interviewed. Each interview lasted from 1.5 to 3.5 hours and was conducted by senior members of the research team (ranging from 1 to 4 members present). Notes were recorded at every interview and interviewees were assured of confidentiality and non-disclosure of source of information in the Review report unless they indicated otherwise.

Table 1: List of Organizations and Individuals Interviewed

	Number of Organizations Interviewed	Number of People Interviewed
Industry players		
Manufacturers	11	19
Importers	9	17
Wholesalers/Distributors	7	12
GPs, Specialists		5
Pharmacists		4
Private Hospitals	3	4
Industry associations		
Malaysian Organization of Pharmaceutical Industry (MOPI)	1	3
Pharmaceutical Association of Malaysia (PhAMA)	1	2
Malaysian Association of Pharmaceutical Suppliers (MAPS)	1	5
Malaysian Pharmaceutical Society (MPS)	1	3
Government agencies		
National Pharmaceutical Regulatory Agency (NPRA)	1	8
Pharmaceutical Services Division (PSD)	1	8
Ministry of Defence (MoD)	1	1
Academics		4
International experts (UNDP and South Centre)		2
TOTAL	37	97

[1] Pfizer sent in their written response to the questions on 1 November 2017.

The selection of interviewees was based on a purposive and non-random sampling approach, i.e., based on their key positions, professional expertise and knowledge of the industry, and their willingness to participate in the interview. The intention was to interview as many of the top companies as possible, within the limited time available, and a smaller selection of smaller companies. As many companies were initially reticent to be interviewed, personal introduction and references played a great part in obtaining consent for the interviews. The snowball method was also used where those interviewed were asked to help identify and refer prospective respondents.

Third World Network sent letters to companies requesting for interviews. These were accompanied by supporting letters from MyCC and the Malaysian Organization of Pharmaceutical Industries (MOPI). These were then followed up with telephone calls.

Of the 28 pharmaceutical manufacturers in Malaysia, a total of 17 companies in the Klang Valley, Penang, Kedah, Ipoh and Melaka were contacted for interviews; 6 of them declined. Thus 11 manufacturers were interviewed; 5 were publicly listed companies and 6 were non-listed, of which 5 were small and medium-sized enterprises (SMEs).

Of the 32 foreign-owned pharmaceutical importers, 13 in Klang Valley were approached for interviews and 8 turned down the request or were not available; 4 were interviewed and 1 replied by mail. Of the local importers, 4 were interviewed.

In the wholesale/distributors sector, since this market is highly concentrated, interviews were focused only on the large players in Klang Valley. Of the 72 wholesalers and distributors, 3 groups of companies were selected for interviews – the foreign companies, local non-Bumiputera companies, and Bumiputera companies. 3 foreign companies and 2 local non-Bumiputera companies were selected and all agreed to be interviewed; 6 Bumiputera companies were approached for interview and 2 agreed to the request. Thus, a total of 7 companies were interviewed.

At the level of providers, information on pharmaceutical companies was gathered mainly from interviews with 4 pharmacists. Interviews were conducted with 5 doctors and specialists practising in the Penang area and data on pricing was obtained from 3 private hospitals in the northern region.

Interviews were held with the following industry organizations – MOPI, Pharmaceutical Association of Malaysia (PhAMA), Malaysian Pharmaceutical Society (MPS) and Malaysian Association of Pharmaceutical Suppliers (MAPS).

Interviews were also held with 3 government agencies – the NPRA, PSD and Ministry of Defence.

Two international experts were interviewed: (i) Professor Carlos Correa, Senior Advisor at the South Centre (a think-tank for developing countries of which Malaysia is a founding

member). Professor Correa was the negotiator for the Government of Argentina during the negotiations of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement; and (ii) Professor Frederick Abbott, Professor of International Law at Florida State University College of Law and Senior Consultant to UNDP on competition law. He is Co-Chair of the Committee on Global Health Law of the International Law Association. He also regularly serves as a panellist for the WIPO Arbitration and Mediation Centre. Both the experts have served on various United Nations commissions and expert groups on intellectual property law and public health/access to medicines and innovation.

In addition to interviews, the Review team consulted with 2 pharmacists from Universiti Sains Malaysia and a hepatologist from Universiti Malaya Medical Centre.

The methods and data sources for analyzing competition concerns in the pharmaceutical sector included:

- Desktop research and analysis of government publications of selected legislation and regulations.

- Research on the recent trends and relevant case law in other countries (such as the European Union, the United States, India and South Africa) to analyse the type of conduct being investigated or found to be anti-competitive in this sector.

- Desktop research to determine if the originator companies of the medicines identified for case studies had been involved in any anti-competitive (or antitrust as it is known in the US) conduct or practices. The selection of the medicines was based on the following criteria: (i) the medicines are highly priced; (ii) the medicines are important for Malaysians' public health in light of the current disease burden in this country; and (iii) the increasing trend of non-communicable diseases. The medicines were selected after (i) review of literature on the medicines from internet searches, using their International Non-proprietary Names (INN). The literature included various MOH reports and studies; (ii) qualitative interviews with members of the industry including individual members of MOPI and PhAMA and the representatives of these organizations themselves. Interviews were also carried out with the MPS and MAPS; (iii) interview sessions held with the PSD and NPRA.

- Thereafter, comparisons were made with the local factual context, determined through searches on patent and marketing authorization status and price data on the websites of MyIPO, World Intellectual Property Organization (WIPO), IMS, NPRA and MOH. Patent details were compared (where possible) with the details of patents that were challenged and invalidated in other jurisdictions in the world. Searches were also done on legal databases concerning the medicines and companies in question.

- Analysis of Malaysia's obligations under the TRIPS Agreement administered by the World Trade Organization and the extent to which the available policy space and flexibilities allowed by the Agreement are made use of in Malaysia to achieve public health objectives.

Public consultations on the draft final report for market review on the pharmaceutical sector took place from 17 November to 7 December 2017. Two public consultation workshops were held in Kuala Lumpur (22 November) and Penang (24 November). On-line submissions were open throughout the period. The consultation workshops were well attended by government officials from the Ministry of Health (MOH), Ministry of Domestic Trade, Co-operatives and Consumerism (KPDNKK), Ministry of International Trade and Industry (MITI), Ministry of Defence (MINDEF), National Pharmaceutical Regulatory Agency (NPRA), Intellectual Property Corporation of Malaysia (MyIPO), Malaysian Investment Development Authority (MIDA), Companies Commission of Malaysia (SSM), SME Corp. Malaysia and Malaysia Productivity Corporation (MPC); members of the pharmaceutical industry including MNCs, local manufacturers, wholesalers and retailers, members of the various trade associations (MOPI, MAPs, MPS, PhAMA and MCPG); members of the medical profession and representatives of private hospitals, civil society groups, academicians (from USIM, UKM and USM) and members of the legal profession.

Limitations

There are two limitations in this Review. The first pertains to the sampling method of the subject under study and the second to the type of financial data available.

A purposive, non-random sample was adopted because within the overall objective of understanding market concentration, the primary focus of this study is on the big companies that account for disproportionate market share and the secondary focus is on smaller companies to get a more rounded perspective of the market. Due to time constraints and lack of response from some subjects, the sample size in this Review is limited and hence the study cannot claim that its observations from the exploratory phase can be generalized to the whole pharmaceutical sector.

A primary objective of this study was to determine the level of market concentration in the pharmaceutical sector. Two standard measures of market concentration, the Concentration Ratio and the Herfindahl-Hirschman Index, calculate the percentage of total market share (based on sales revenue) accounted for by the top companies in an industry. Sales revenue measures the sale of all products sold by a company. Pharmaceutical companies manufacture, import, distribute and sell different types of pharmaceutical products such as controlled (prescriptive) medicines, over-the-counter medicines, traditional medicines, health supplements, veterinary medication, medical devices etc. Whilst the focus of this Market Review is on controlled medicines, it was not possible to disaggregate the sales data by product. Hence the market concentration ratios apply at the company level and cover all products and not only controlled medicines. Interpretation on market concentration must therefore take account of this limitation.

In terms of determining if anti-competitive conduct exists among local industry players, much of the information required is of a sensitive nature, requiring disclosure of internal company documents and candidness on the part of the companies. A more thorough

examination needs to be done which should include the issuance of questionnaires for detailed information, including, for example, general market conditions, economic data, products (primary and follow-on from the particular chemical entity), details of patents, litigation files, if any, patent-related disputes and contacts, agreements and arrangements in the sector, stakeholders' experience with the legal and regulatory frameworks and market authorization details, if any.

POLICY CONTEXT FOR THE REVIEW

This Review is conducted within the context of key national policies related to health and competition.

The overriding objectives of the Malaysian National Medicine Policy, revised in 2012, are to promote equitable access to the use of safe, effective and affordable essential medicines of good quality to the population. There are 5 core areas in the Policy:

- Good governance in medicines;
- Provision of safe, quality and efficacious medicines;
- Access to medicines in terms of availability and affordability;
- Quality use of medicines; and
- Collaboration with the private healthcare industry.

The objective of the Generic Medicines Policy is to foster healthy competition in medicines pricing. This Policy that is part of the National Medicines Policy stipulates the following:

- Prescribing in generic International Non-proprietary Name (INN) shall be practised at all channels;
- Procurement of all medicines by generic INN shall be promoted;
- In selection for procurement, priority shall be given to domestically manufactured medicines;
- All dispensed medicines shall be labelled prominently with the generic INN of the medicine with or without the brand name;
- A list of interchangeable and non-interchangeable medicines shall be made available;
- Generic substitution shall be permitted and legislated for all interchangeable medicines; and
- Appropriate incentives to promote the use of generic medicines and their production in the country shall be introduced.

The Fair Trade Practices Policy[2] seeks to achieve the following policy objectives:

- Promote and protect competition in the market;
- Create dynamic and competitive entrepreneurs;
- Provide fair and competitive market opportunities for businesses;
- Prohibit anti-competitive practices including those originating from outside the Malaysian territory and affecting the domestic territory;
- Prohibit unfair trade practices in the economy;
- Promote rights of small and medium-sized enterprises (SMEs) to participate in the market place;
- Promote consumer welfare; and
- Encourage socio-economic growth, generate efficiency and equity.

[2] Approved on 26 October 2005.

These policies are consistent with Malaysia's most recent international commitments. In 2015 Malaysia was among more than 150 Heads of States and Governments that adopted the United Nations 2030 Agenda for Sustainable Development with 17 Sustainable Development Goals (SDG) and 149 targets. SDG 3 is to "Ensure healthy lives and promote well-being for all at all ages". Two relevant targets for the Review are:

- Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.

- Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

An important means to achieve these targets is to "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." (Paragraph 3.B)[3]

[3] https://sustainabledevelopment.un.org/SDG3

PART ONE

OVERVIEW OF MALAYSIA'S PHARMACEUTICAL SECTOR

CHAPTER 1: OVERALL GROWTH OF THE HEALTHCARE AND PHARMACEUTICAL SECTORS

1.1 Malaysia's Healthcare System in Brief

The development of Malaysia's pharmaceutical sector should be studied in the context of the growth of, and changes in, the country's healthcare system. Malaysia, at independence, inherited the British healthcare system where healthcare at the primary (rural and community clinics) and secondary (general hospitals) levels was provided predominantly by the government. Tertiary healthcare (hospitals with specialists) was still undeveloped. In 1960 there were only 10 public hospitals with specialists.[4] Private healthcare was concentrated only at the primary level where doctors, mainly general practitioners, ran their private clinics.[5] In 1970 there were 72 public hospitals compared with only 6 private hospitals. There were 1,563 doctors in the private sector who ran their own clinics, compared with 807 doctors in public hospitals. These doctors are either general practitioners or specialists.

This landscape, where the public healthcare system dominated over the private healthcare system, started to change in the 1980s. The government started to corporatize and privatize many of its public services and encouraged the setting up of private hospitals. As can be seen from Table 1.1, between 1970 and 1990 the number of public hospitals rose from 72 to 95, while the number of private hospitals increased tenfold from 6 to 63. This gained further momentum with the introduction of the Privatization Master Plan in 1991.[6] The number of private hospitals increased by more than threefold from 63 to 224 between 1990 and 2000, while the number of public hospitals increased by only 33% from 95 to 127. However, between 2010 and 2014, the number of private hospitals dropped to 184.[7]

This change in the public-private share was also reflected in the composition of private versus public healthcare expenditure. Private healthcare expenditure almost doubled from 24% of total healthcare expenditure in 1983[8] to 47% by 1997 (see Figure 1.2). The

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[4] Safurah Jaafar et al. (2013). *Malaysia Health System Review*. Health Systems in Transition, Vol. 3, No. 1, World Health Organization (on behalf of the Asia Pacific Observatory on Health Systems and Policies), at page 18. http://www.wpro.who.int/asia_pacific_observatory/hits/series/Malaysia_Health_Systems_Review2013.pdf

[5] *Ibid.*, at page 58.

[6] Hameed, Latifa M. and Fadilah Mat Nor (2014). "Public and Private Shares in the Distribution of Doctors in Malaysia", in E-proceedings of the Conference on Management and Muamalah (CoMM 2014), 26-27 May 2014, at page 58. http://www.kuis.edu.my/comm2014/eproceedings/C006%20PUBLIC%20AND%20PRIVATE%20SHARES%20IN%20THE%20DISTRIBUTION%20OF%20DOCTORS%20IN%20MALAYSIA.pdf

[7] The decline in the number of private hospitals between 2000 and 2010 is because the 2010 number excludes maternity and nursing homes. Such disaggregated numbers were not available for the year 2000 and prior to 2000.

[8] Chee, H.L. and P.H. Hong (2014). "1Care and the politics of healthcare in Malaysia", in Meredith L. Weiss, editor, Routledge Handbook of Contemporary Malaysia, 312-323. Routledge, New York, at page 313.

picture of healthcare in the private sector is complicated by the fact that in recent years the government, both at the federal and state levels, has invested substantially in private hospitals through government-linked companies, most notably Khazanah, the major shareholder of IHH Healthcare Bhd. that owns the Gleneagles and Pantai hospitals. The other big player is KPJ Healthcare Bhd., owned by the Johor Corporation Group (part of the Johor state government). The total number of such government-linked hospitals was 47 (26%) out of 184 private hospitals in 2014.

Thus, Malaysia has a dual or mixed healthcare system: a private healthcare sector co-existing with the public healthcare sector at primary, secondary and tertiary levels. At the primary level, there were two and a half times more private clinics (6,978) than clinics run by the Ministry of Health (2,871) in 2014.[9] However, public clinics serviced more patients and at lower costs; they accounted for 60% of outpatient care but 35% of primary healthcare expenditure, with the private sector taking up the balance.[10] At the secondary level, there are twice as many private hospitals as public hospitals. However, public hospitals carry the main burden; they had three times more hospital beds than private hospitals (43,822 versus 13,038) in 2014 (see Table 1.1).

Table 1.1: Malaysia Selected Healthcare Indicators, 1970 to 2014

	1970	1980	1990	2000	2010	2014
Public MOH clinics	1,167	2,234	258	2,871	2,886	2,871
Private clinics	n/a	n/a	n/a	n/a	6,442	6,978
Total	1,167	2,234	258	2,871	9,328	9,849
Public hospitals	72	88	95	127	145	150
Private hospitals	6	14	63	224	217	184
Total	78	102	158	351	362	334
Public hospital beds	17,063	33,901	33,400	37,519	41,483	43,822
Private hospital beds	n/a	n/a	4,675	9,547	13,186	13,038
Total	17,063	33,901	38,075	47,066	54,669	56,860
Doctors in public sector	2,370	3,514	3,021	8,410	22,429	33,275
Doctors in private sector	n/a	n/a	3,991	7,209	10,550	12,290
Doctors per 1,000 population	0.22	0.25	0.39	0.66	1.15	1.47
Pharmacists in public sector	n/a	n/a	n/a	434	4,610	6,752
Pharmacists in private sector	n/a	n/a	n/a	1,899	3,149	3,325
Total	n/a	n/a	n/a	2,333	7,759	10,077
Pharmacists per 1,000 population	n/a	n/a	n/a	0.10	0.27	0.33
Population	10,881,535	13,879,237	18,102,362	23,494,900	28,588,600	30,979,000

Source: Chan, T.H. (2016). *Malaysia Health Systems Research*. Vol. 1. Harvard School of Public Health, Table 5, p. 116; Hameed, Latifa M. and Fadilah Mat Nor (2014). "Public and Private Shares in the Distribution of Doctors in Malaysia", in E-proceedings of the Conference on Management and Muamalah (CoMM 2014), 26-27 May 2014, Table 1, p. 59; Health Facts, Malaysia 2000, 2010, 2015
Note: The number of private hospitals in years 2010 and 2014 excludes maternity and nursing homes. This partially explains the decline in the number of private hospitals after 2000. Such disaggregated numbers were not available for the year 2000 and prior years.

[9] At the primary level, the government runs public healthcare clinics, rural community clinics, maternal and child care clinics, mobile clinics and 1Malaysia clinics.

[10] Chan, T.H. (2016). *Malaysia Health Systems Research*. Vol. 1. Harvard School of Public Health, at page 116.

There have been changes in the public-private share in healthcare. The percentage of hospital beds accounted for by private hospitals has risen from 8% to 25% from 2000 to 2011, while the percentage of medical practitioners in the private sector declined from 65% to 29% over the same period.[11]

Public sector health services in Malaysia are centrally administered by the Ministry of Health (MOH) through its federal, state and district offices. In addition, the Ministry of Higher Education runs the university teaching hospitals, the Ministry of Defence has several military hospitals and medical centres, and the Department of Orang Asli Affairs provides health services to the Orang Asli population in collaboration with the MOH. The Department of Social Welfare provides nursing homes for the elderly, the Ministry of Home Affairs manages the drug rehabilitation centres, and the Ministry of Housing and Local Government provides environmental health services and limited health services, such as in the Kuala Lumpur Federal Territory.[12] The National Heart Institute (Institut Jantung Negara) and National Cancer Institute provide specialist care.

A peculiar feature of Malaysian healthcare is that general practitioners (GPs) can also dispense medicines. This dual role of prescribing and dispensing medicines is a matter of longstanding debate between pharmacists and consumer groups who advocate for dispensing separation and doctors who are against it.[13] This issue has significant implications for the price of medicines in Malaysia.

Total Healthcare Expenditure

Malaysia's total healthcare expenditure (THCE) in 2014 was RM49.7 billion or 4.5% of GDP, a share that has risen from 2.9% in 1997 (see Figure 1.1). While this is not high by comparison with other upper-middle-income countries,[14] it is in line with the World Health Organization (WHO)'s recommendation that health spending in the Asia-Pacific region should hover between 4% and 5% of GDP.[15] In 2016, THCE reached RM54.6 billion and market analysts BMI estimates it would more than double over the next 10 years to RM125 billion by 2026.[16] From 1997 to 2014, real per capita spending on health increased 153%

[11] MOH (2012). Health Facts 2012.

[12] Safurah Jaafar et al. (2013). *Malaysia Health System Review*. Health Systems in Transition, Vol. 3, No. 1, World Health Organization (on behalf of the Asia Pacific Observatory on Health Systems and Policies), at page 18.

[13] Haggan, Megan (2016). "Malaysian Pharmacists Fight for Dispensing Separation", https://ajp.com.au/news/malaysian-pharmacists-fight-dispensing-separation/, accessed 30 September 2017; Idris, S.M. Mohamad (2017). "The Proposed Pharmacy Bill is Unjustified", https://www.malaysiakini.com/letters/, accessed 30 September 2017.

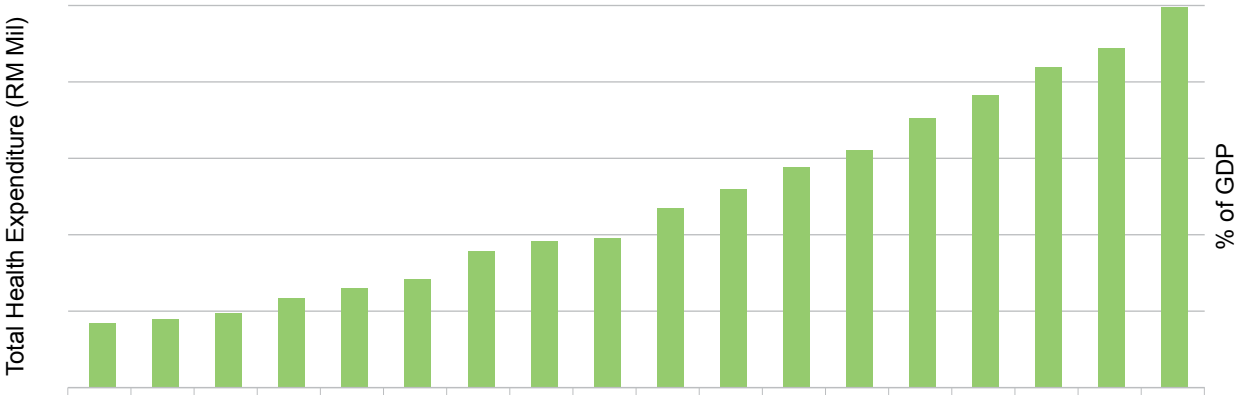
[14] China (5.6%), Thailand (4.1%), Brazil (8.3%), South Africa (8.8%): WHO, Global Health Observatory data on health financing: http://www.who.int/gho/health_financing/total_expenditure/en/. Lower-middle-income countries: India (4.7%), Philippines (4.7%).

[15] Cited in Rachagan, Sothi, Abida Haq Syed M. Haq and Shankari Sothirachagan (2016). "Affordable Medication with a Dose of Competition", paper presented at the 15th Session of the Intergovernmental Group of Experts (IGE) on Competition Law and Policy Round Table on Examining the Interface between Objectives of Competition Policy and Intellectual Property held in Geneva, Switzerland, 19-21 October, at page 4.

[16] BMI (2017). Malaysia: Pharmaceuticals & Healthcare Report, Q3, 2017, at page 15.

from RM642 to RM1,625[17] although it is still low by international comparison.[18] The factors driving higher healthcare expenditure are economic, demographic, epidemiological, social and technological.[19]

Figure 1.1: Malaysia's Total Healthcare Expenditure from 1997 to 2014



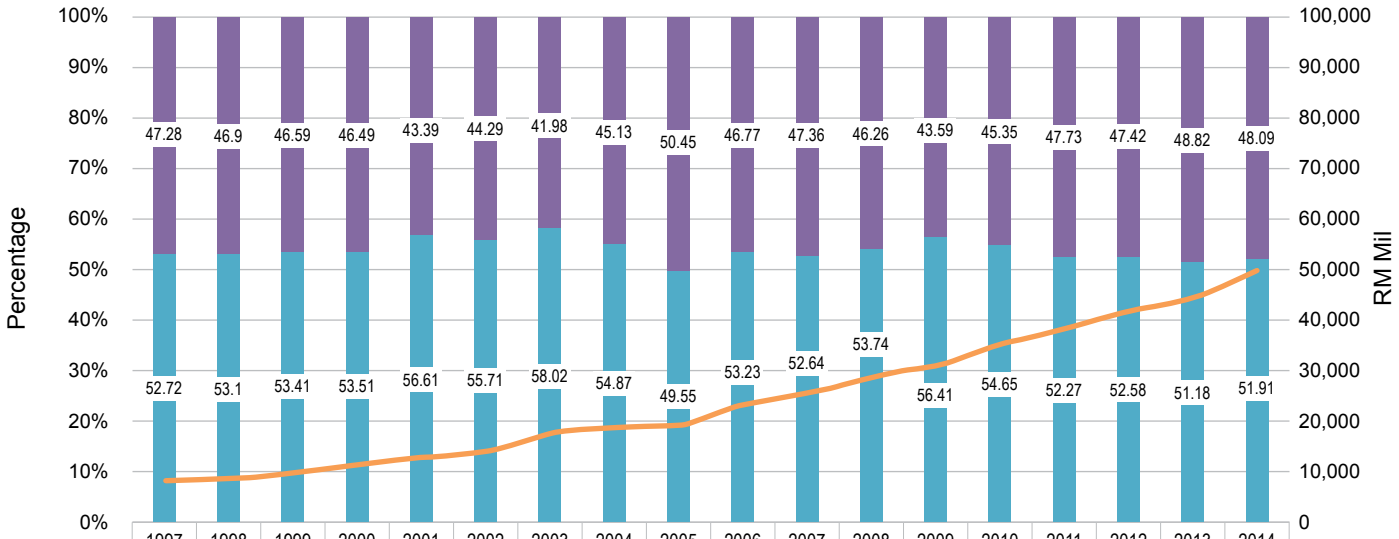
	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Total Health Expenditure, Nominal (RM Million)	8,190	8,844	9,703	11,578	12,841	14,022	17,753	19,037	19,314	23,376	25,921	28,843	31,060	35,231	38,206	41,913	44,346	49,731
Total Health Expenditure as %GDP	2.91	3.12	3.23	3.25	3.64	3.66	4.24	4.02	3.55	3.92	3.9	3.75	4.36	4.29	4.19	4.32	4.35	4.49

Source: MOH-Malaysian National Health Accounts (MNHA), 2016, Table 4.1

As stated earlier, Malaysia has moved from a predominantly public sector healthcare system to a dual sector healthcare system. This transformation started in the 1980s, accelerated in the 1990s and took a breather with the Asian Financial Crisis of 1997/98. But by 2005, private healthcare expenditure slightly exceeded the public component and the ratio has since fluctuated around the 50-50 level (see Figure 1.2). In 2014, public healthcare spending was RM25.8 billion compared with private spending at RM23.9 billion.

[17] MOH (2016). Malaysian National Health Accounts, Health Expenditure Report 1997-2004, at page 10.
[18] Chan, T.H. (2016). *Malaysia Health Systems Research*. Vol. 1. Harvard School of Public Health, at page 134.
[19] For a fuller discussion, see Chan, T.H. (2016). *Malaysia Health Systems Research*. Vol. 1. Harvard School of Public Health, from page 93.

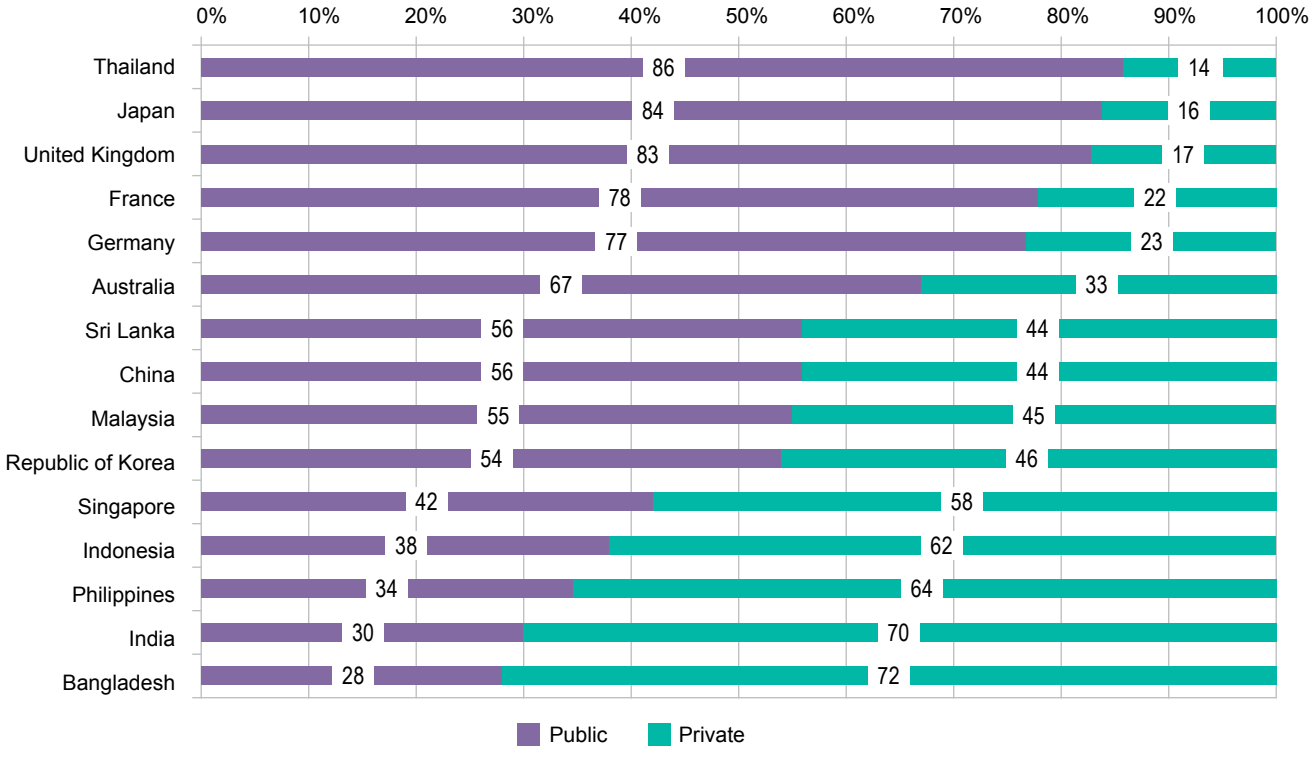
Figure 1.2: Malaysia Health Expenditure: Private versus Public Sector Spending



	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Private Health (%)	47.28	46.9	46.59	46.49	43.39	44.29	41.98	45.13	50.45	46.77	47.36	46.26	43.59	45.35	47.73	47.42	48.82	48.09
Govt Health (%)	52.72	53.1	53.41	53.51	56.61	55.71	58.02	54.87	49.55	53.23	52.64	53.74	56.41	54.65	52.27	52.58	51.18	51.91
Total Health Spending (RM Mllion)	8190	8844	9703	11578	12841	14022	17753	19037	19314	23376	25921	28843	31060	35231	38206	41913	44346	49731

Source: MOH-Malaysian National Health Accounts (MNHA), 2016, Table 5.1

Figure 1.3: Public versus Private Healthcare Expenditure: Selected International Comparison

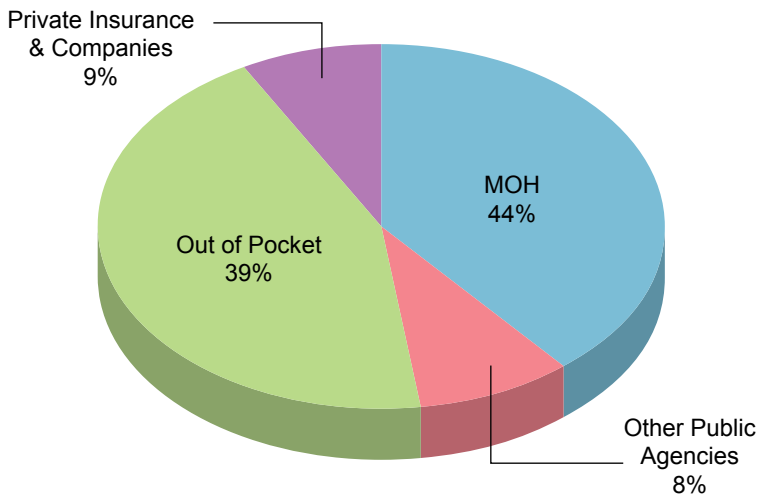


Source: Global Health Expenditure Database (GHED) WHO NHA on 15 September 2016

Compared with other countries in Figure 1.3, Malaysia fell in the middle in terms of public healthcare spending as a percentage of THCE. Countries that proportionately spent more on public healthcare include Thailand, Japan, the United Kingdom, France, Germany, Australia, Sri Lanka and China. Among the ASEAN countries in that list, Malaysia led in public spending after Thailand with 86%.

Figure 1.4 shows the sources of healthcare financing in Malaysia. The largest source is the MOH and other government agencies, which together account for 52% of THCE. The public health system is funded primarily from taxation that finances the MOH budget. Out-of-pocket expenses (OOP) by members of the public are the second largest source of financing (39% of THCE), followed by private insurance (9%). One of WHO's recommendations is that OOP spending should be below 40% of THCE; Malaysia's OOP fluctuated between 31% and 39% of THCE between 1997 and 2014. While OOP accounts for 39% of THCE, it constitutes 82% of health expenditure in the private sector in 2014. [20]

Figure 1.4: Sources of Funding for Malaysia's Healthcare Expenditure, 2014



Source: MOH-Malaysian National Health Accounts (MNHA), 2016, Table 5.2c, p.20

In nominal ringgit terms, OOP expenses rose from RM3 billion to RM20 billion between 1997 and 2014. The MOH Report calculates OOP "through the integrative method whereby the gross level of direct spending from consumption, provision and financing perspective is collated followed by a deduction of third party financial reimbursements by various agencies to avoid double counting".[21] OOP therefore covers consultations at public and private hospitals and clinics, medicine costs in such health institutions as well as in pharmacies, medical appliances, as well as spending on traditional and complementary medicine, and health-related education and training.

[20] MOH (2016). Malaysian National Health Accounts, Health Expenditure Report 1997-2004, at page 73.
[21] MOH (2016). Malaysian National Health Accounts, Health Expenditure Report 1997-2004, at page 72.

The large jump in OOP expenses is a cause for concern as it places a huge financial burden on people and in many cases has led to financial catastrophe for those who have to borrow to pay for hospital expenses, as is attested to by the frequent appeals in the media for public donations. In- and outpatient services formed the largest component (54%) of OOP expenses, followed by medical appliances and non-durable goods (13%) and pharmaceuticals (12%), in 2014.

The Malaysian consumer bears a significant portion of healthcare expenditure compared with Australia (19%) and Thailand (12%),[22] both of which have universal health coverage through regulated national reimbursement schemes.

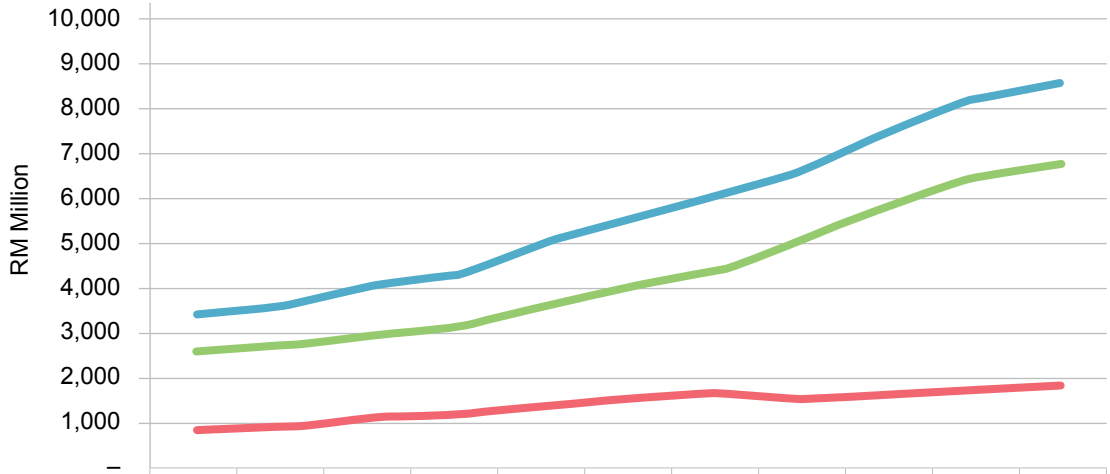
The cost of medicines (pharmaceuticals) borne by members of the public through OOP (i.e., not including medicine costs in the public sector, and in the private sector paid for by insurance and employers) has risen 700% from RM325 million to RM2.4 billion between 1997 and 2014.[23] Medicines dispensed by the private sector, especially private hospitals, are usually priced higher than the medicines dispensed by public hospitals and clinics.[24] With a policy of universal access to medicines, the government strives to provide subsidized healthcare with free or minimal charges for medicines.

1.2 Overall Growth of the Pharmaceutical Sector in Malaysia

From 2006 to 2016, the pharmaceutical market (prescription and over-the-counter (OTC) drugs) grew at an average annual rate of 8.3% from RM3.4 billion to RM8.6 billion (see Figure 1.5). Pharmaceutical sales (medicine costs) represented 16% of THCE in 2016. This growth has been driven by rising income, demographic changes and changes in lifestyle resulting in much higher incidence of non-communicable diseases (NCDs). Sales of prescription drugs[25] are rising faster than those of OTC drugs. In percentage terms, prescription drug sales rose from 75% of the pharmaceutical market (in value terms) in 2006 to 79% in 2016, while OTC drug sales fell from 25% to 21% for the same period.

[22] MOH (2016). Malaysian National Health Accounts, Health Expenditure Report 1997-2004, Figure 10.5 at page 85.
[23] MOH (2016). Malaysian National Health Accounts, Health Expenditure Report 1997-2004, Table 9.2a at page 80.
[24] See Chapter 4.
[25] This report uses the term “controlled medicines”, which is the legal term for prescription medicines under the Poisons Act 1952. This figure is based on the BMI report in which the term “prescription drugs” is used and thus accordingly retained here.

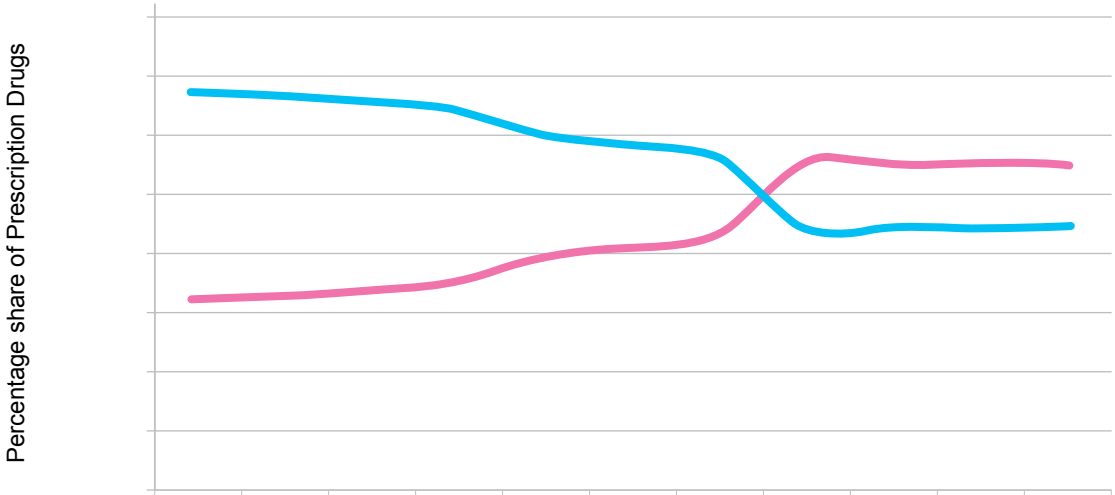
Figure 1.5: Pharmaceutical Sales (Prescription and OTC Drugs), 2006 to 2016



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Pharmaceutical Sales	3420	3645	4069	4293	5000	5550	6060	6597	7510	8223	8600
OTC Drugs	844	922	1094	1168	1400	1540	1670	1531	1650	1770	1806
Prescription Drugs	2576	2723	2975	3125	3600	4010	4390	5066	5860	6472	6794

Source: BMI (2011). Malaysia: Pharmaceuticals & Healthcare Report, Q1, 2011; BMI (2013). Malaysia: Pharmaceuticals & Healthcare Report, Q4, 2013; BMI (2017). Malaysia: Pharmaceuticals & Healthcare Report, Q3, 2017.

Figure 1.6: Sales of Patented versus Generic Medicines as Percentage of Prescription Drugs, 2006-2016



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Patented Drugs	67%	67%	66%	64%	60%	59%	56%	44%	45%	44%	45%
Generic Drugs	33%	33%	34%	36%	40%	41%	44%	56%	55%	56%	55%

Source: BMI (2011). Malaysia: Pharmaceuticals & Healthcare Report, Q1, 2011; BMI (2013). Malaysia: Pharmaceuticals & Healthcare Report, Q4, 2013; BMI (2017). Malaysia: Pharmaceuticals & Healthcare Report, Q3, 2017.

Of the prescription drugs, patented drugs, which used to have a strong foothold accounting for over 67% of the prescription drug market share (by value) in 2006, have steadily declined to 45% of market share by 2016 (see Figure 1.6).[26] On the other hand, generic drug sales have risen significantly from 33% to 55% for the same period, with the largest jump occurring between 2012 and 2013.[27] In 2016, generic drug sales were RM3.74 billion against patented drugs at RM3.05 billion. However, BMI has forecast that the market share of patented drugs will hold steady or improve slightly over the next 5 years.[28]

As healthcare expenditure is 4.5% of Malaysia's GDP, the government has identified healthcare as one of the National Key Economic Areas under the Economic Transformation Programme (ETP) to steer Malaysia to high-income status by 2020. It plans to expand the healthcare market through investments in healthcare infrastructure, clinical research, promotion of medical tourism, promotion of the domestic use of generic drugs, and also production for export.

Six Entry Point Projects (EPPs) were proposed for the healthcare sector to grow during the Healthcare Lab in 2010.[29] These were EPP1 – mandatory health insurance for foreign workers, EPP2 – create ecosystem to grow 1,000 clinical trials by 2020, EPP3 – leverage off patent cliff [30] and encourage production of generic medicines, EPP4 – promote healthcare tourism, EPP5 – create diagnostic services nexus, and EPP6 – establish health metropolis to encompass clinical care, research and education in one campus.

Under EPP3, priority is given to the use of generic medicines domestically (through prescription, dispensing, generic substitution and government procurement) and to promoting production for export. As was noted earlier, the generic medicines market as a percentage of the prescription drug market has risen steadily over the years to 55%. Nevertheless, because the domestic medicines market is limited, exports are the only route for the domestic generic industry to grow. Under this programme, pharmaceutical manufacturers are given off-take agreements to supply the MOH for 3 years, with another 2 years' extension if they are able to penetrate the export market.[31]

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[26] Possible explanations could include certain medicines going off-patent with subsequent entry of generics in the market, and increased consumption of generics in public health institutions as well as private hospitals.

[27] This could be due to the surge in production of generic medicines following patent expiration for a large number of originator medicines in 2011 and 2012; and the increased consumption of generic medicines in hospitals as part of the government's national medicines policy.

[28] BMI (2017). Malaysia: Pharmaceuticals & Healthcare Report, Q3, 2017, at page 21.

[29] Pemandu (2013). National Key Economic Area (NKEA) Healthcare. LINK Healthcare Event, http://etp.pemandu.gov.my/upload/LINK_Healthcare_Event.pdf

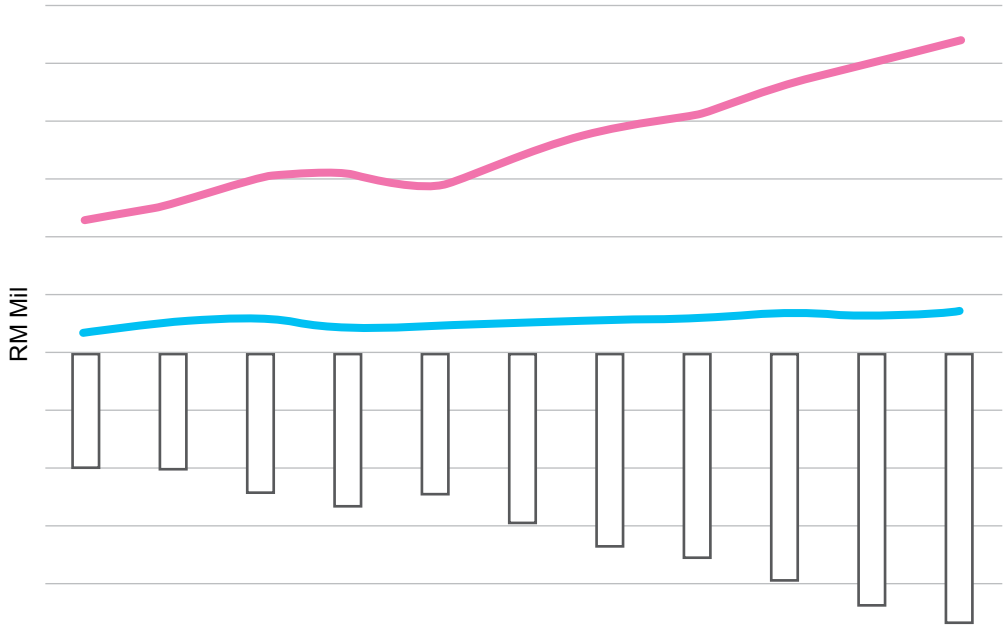
[30] A patent cliff refers to a situation when one or more of a company's products' patent protections expire. The expiration exposes the company's product to external competition and potential significant loss of revenue: MarketRealist.com (2016). "Why the patent cliff is a key driver of generic drug growth", http://marketrealist.com/2016/03/patent-cliff-driver-generic-drugs-growth/; PharmTech.com (2013). "Responding to the patent cliff", http://www.pharmtech.com/responding-patent-cliff?id=&sk=&date=&pageID=3

[31] Pemandu (2013). National Key Economic Area (NKEA) Healthcare. LINK Healthcare Event, http://etp.pemandu.gov.my/upload/LINK_Healthcare_Event.pdf

1.3 Import, Export and Trade Balance

Imported medicines (both patented and generics, with the former accounting for a larger share) account for the largest part of the pharmaceutical market, though the percentage has been slowly declining.[32] In 2006, RM2.3 billion of pharmaceutical products were imported, accounting for 68% of pharmaceutical sales. Imports rose to RM5.4 billion by 2016, but percentage wise it marked a decline to 63%. (This is calculated from data in Figure 1.5 on pharmaceutical sales, and Figure 1.7 on imports and exports.)

Figure 1.7: Import and Export of Pharmaceuticals in Malaysia, 2006-2016



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Trade Balance	-1,972	-2,021	-2,412	-2,643	-2,434	-2,934	-3,331	-3,524	-3,945	-4,362	-4,665
Exports	343	542	597	424	466	493	571	590	700	642	718
Imports	2,315	2,564	3,008	3,067	2,900	3,427	3,902	4,114	4,644	5,005	5,383

Source: BMI Reports (2009-2017); Third World Network's calculation for 2006-2008.
Note: RM-USD conversion is based on Bank Negara's annual average exchange rate.

Most imports of originator medicines are from the developed markets of the United States, Europe and Japan, while imports of generic medicines are largely from India and increasingly from Eastern European and even other Southeast Asian countries. Several large pharmaceutical multinational corporations (MNCs) have set up companies in Malaysia operating mainly as importers of their own products.[33] The few exceptions

[32] It should be noted that import numbers include veterinary medicaments and medical supplies. To the extent these items cannot be disaggregated, the import of medicines is overstated.
[33] This is in contrast to local Malaysian companies that import generics.

of MNCs with manufacturing plants in Malaysia include Ranbaxy, Biocon and Sterling Drug.[34] A few MNCs like Servier appoint local manufacturers (e.g., Kotra Pharma) to produce some of their products.

The sales of the top 10 importers accounted for RM3.3 billion or 72% of the RM4.6 billion pharmaceutical imports in 2014 (see Figure 1.7 and Table 2.4). Of the 10 largest importers, only one, CCM Pharmaceuticals, is a local company (government-linked company (GLC)). The rest are all MNCs from developed countries. The largest importer is Pfizer, with sales of RM453 million or 10% of market share (see Table 2.4).

Manufacturers of pharmaceuticals in Malaysia are mostly locally owned and all produce only generic medicines and mainly for the domestic market. The research and development capabilities of these companies are limited to formulating the processes of manufacturing generic medicines and not inventing original medicines. Only 5 manufacturers are foreign-owned, hailing from India, Singapore and Hong Kong (see Table 2.2).

Production of generic medicines is mainly for domestic consumption although the larger companies are increasingly turning to exports. These include Duopharma (CCM) and Pharmaniaga (both GLCs), Hovid, Kotra and Y.S.P. Several factors contribute to the focus on the export market. Firstly, the size of the domestic market is small. Hence, the two large GLC pharmaceutical manufacturers are casting their nets abroad. Exports account for 25% of Pharmaniaga's and 11% of CCM's sales revenues respectively.

Secondly, given the small domestic market and the less-than-level playing field in securing government procurement contracts, where priority is given to Bumiputera companies to nurture Bumiputera entrepreneurship, the larger local non-Bumiputera manufacturers are turning to export markets to expand their business. About 60% of Hovid's and 45% of Kotra's sales now come from exports.[35]

Thirdly, the government has introduced programmes such as EPP3 to promote exports. Kotra, which has participated in this programme, was incentivized to invest in a new manufacturing facility under EPP3. Similarly, Biocon was awarded a RM300 million off-take contract to supply insulin to the MOH under a programme to boost production of medicines for local and export markets.[36] The government is also promoting halal pharmaceuticals and hopes to penetrate the Middle East and other Muslim countries. Other factors like Malaysia being a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and having high regulatory standards are advantageous for moving into the export market. The major markets for Malaysia's pharmaceuticals are the smaller ASEAN economies like Myanmar, Cambodia and Brunei, as well as some African countries like Nigeria.

[34] Sterling Drug is a subsidiary of GSK and manufactures mainly consumer products and OTC medicines.

[35] Interviews conducted with several local manufacturers.

[36] Biocon (2017). "Biocon Wins RM300 Million Contract for Insulin from MOH, Malaysia", Press Release, https://www.biocon.com/docs/PR_Malaysia_OTA_JanF3.pdf

Despite the policies to promote exports, local manufacturers interviewed raised a concern that Malaysia's zero tariff on import of medicines disadvantages them when compared with other ASEAN countries (Indonesia and Thailand) which maintain such tariffs.

Further, the export policies have shown a lack of effectiveness, as reflected in the slow progress in pharmaceuticals exports. Figure 1.7 shows that over 11 years, between 2006 and 2016, pharmaceuticals exports rose at an annual average of 7% from RM343 million (USD 97 million) to RM718 million (USD 173 million), compared with imports that grew at 8% annually from RM2,315 million (USD 656 million) to RM5,383 million (USD 1,299 million). Malaysia suffers from persistent and large current account deficits in the pharmaceuticals trade – USD 1.1 billion or RM4.7 billion in 2016. This is not expected to be reversed for a long time.

Local manufacturers and importers suggested patents as a major barrier to the entry of generics. Malaysia's EPP3 was designed to leverage off a 'patent cliff', such as the one in 2014 to 2016 when the patents of some blockbuster medicines in the US expired. However, secondary patents[37] granted in Malaysia posed challenges.[38] In contrast, the success of India's generic industry can be attributed in large part to the fact that India did not have to grant pharmaceutical product patents until 2005, enabling the domestic industry to grow to become globally competitive.[39] However, among the objectives of Malaysia's National Intellectual Property Policy (2007) is to "develop an efficient and effective IP protection system to ensure fast and easy acquisition of protection and rights." (See Chapter 5 for a discussion on the Policy.)

1.4 Conclusion

Malaysia's total healthcare expenditure has grown from 2.9% of GDP to 4.5% of GDP from 1997 to 2014, in line with WHO's recommended 4%. It has moved away from a predominantly public healthcare system to a mixed system where today private and public healthcare expenditures are almost equal. The public healthcare system is funded through taxation and heavily subsidized, making healthcare affordable to a great majority of the population. But the privatization effort of the government has led to a large private healthcare sector. A major concern is that out-of-pocket expenses have become a big part (39%) of total healthcare expenditure and 82% of private healthcare expenditure, placing a financial burden on those who use private healthcare.[40]

[37] A patent on the base compound of a medicine is usually called a primary patent. Patents on salts, polymers, dosages, formulations, combinations, etc. are referred to as secondary patents. See Chapters 5 and 6 for more discussion.

[38] Interviews conducted with several local manufacturers and importers.

[39] This transition period till 2005 was part of the negotiated outcome of the Trade-Related Aspects of Intellectual Property Rights Agreement, administered by the World Trade Organization. See: Ali, Feroz (2016). *The Access Regime: Patent Law Reforms for Affordable Medicines*, Oxford University Press.

[40] MOH (2016). Malaysian National Health Accounts, at page 73.

Pharmaceutical sales have grown in tandem with the increase in healthcare expenditure, accounting for roughly 15% of the latter. There has been a shift in usage of medicines. Patented medicines that accounted for close to 70% of sales have declined to 45% over the last decade. This is partly due to government policies that encourage production and use of generic medicines and the patent cliffs in 2011 and 2012 that boosted production of generics. However, most pharmaceuticals are still imported, with imports accounting for 63% of total pharmaceutical sales in 2016, while exports are only 13% of the value of imports. Thus, Malaysia suffers from persistent trade deficits in the pharmaceutical sector.

CHAPTER 2:
MARKET STRUCTURE AND SUPPLY CHAIN

This chapter describes the market structure and supply chain of the pharmaceutical sector in Malaysia. How is the market organized and regulated? Who are the major players? How do the players interact with one another? How do controlled medicines flow from the point of manufacture or import down to the ultimate users or patients?

Medicines, unlike most ordinary commodities, are essential goods; they can be either life-saving or life-threatening depending on how well they are regulated. As noted earlier, Malaysia has high standards in regulating the production, storage and distribution of drugs. The main regulatory agency is the Drug Control Authority, with its secretariat at the National Pharmaceutical Regulatory Agency (NPRA). The NPRA is responsible for product[41] registration and issues manufacturing, import and wholesale licences to pharmaceutical companies. The Pharmaceutical Services Division (PSD) issues Type A licences to pharmacists. Both agencies are under the MOH.

Using data from these agencies, a market profile of Malaysia's pharmaceutical sector was developed.

Figure 2.1 gives a simplified overview of the market structure and supply chain of the pharmaceutical sector in Malaysia. There are three levels in the market structure. Level 1 consists of manufacturers[42] and importers of drugs. Level 2 is where wholesalers operate, including distributors who operate under a wholesale licence. Level 3 is made up of providers who supply the drugs to the consumers. These levels are analytical constructs. In reality, many of the players, especially large companies that are vertically integrated, occupy positions at two or even all the three levels, i.e., they hold manufacturing, importing and wholesale licences from the NPRA.

Although the term "distributor" is not used in the law regulating the pharmaceutical sector, it is widely used by players in the industry and as such shall be used in this report. Business Dictionary defines "wholesaler" as a "person or firm that buys large quantity of goods from various producers or vendors, warehouses them, and resells to retailers." The same source defines "distributor" as "An entity that buys noncompeting products or product lines, warehouses them, and resells them to retailers or direct to the end users or

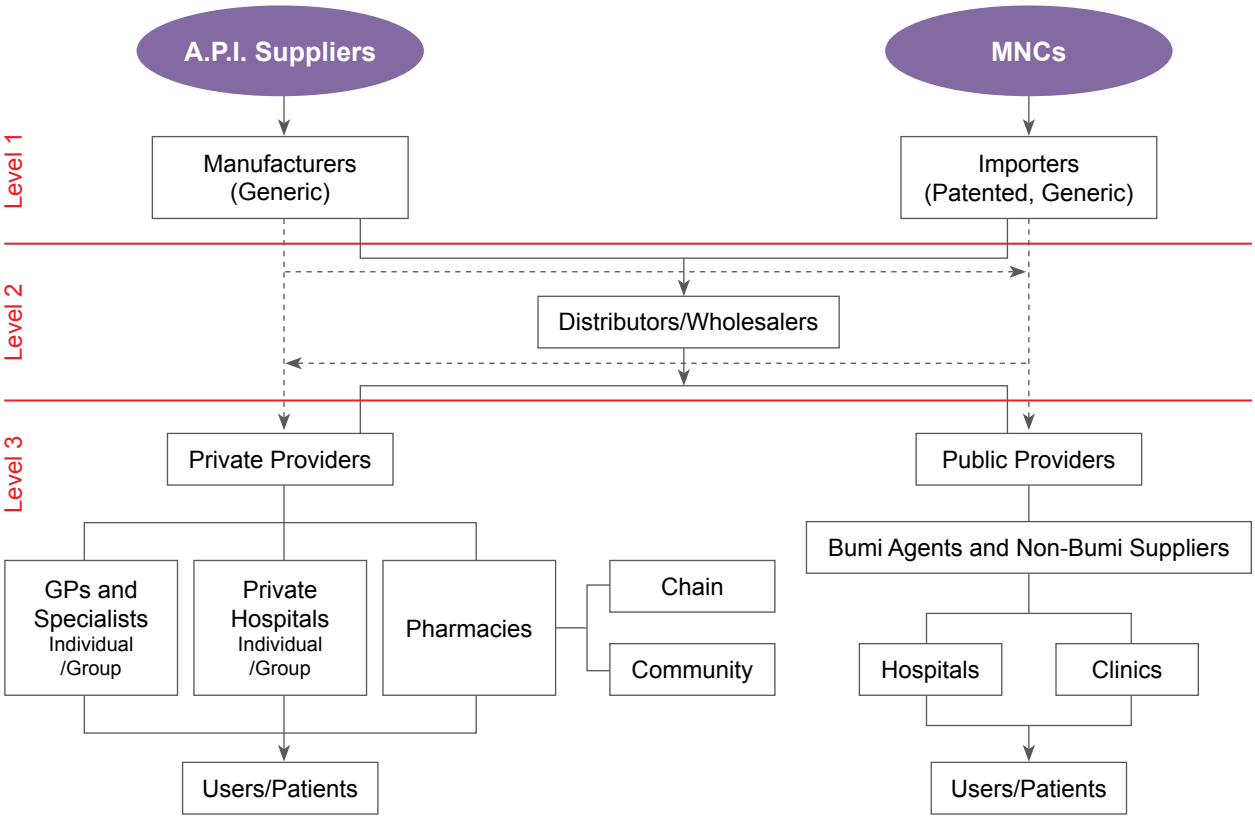
[41] Under the Control of Drugs and Cosmetics Regulations 1984, "product" means a "drug" in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or a drug to be used as an ingredient of a preparation for a medicinal purpose (Regulation 2).

[42] Under the Control of Drugs and Cosmetics Regulations 1984, "manufacture", in relation to any product, includes: (a) the making or assembling of the product; (b) the enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container; and (c) the carrying out of any process in the course of any or the foregoing activities. These manufacturing licences are given by the NPRA.

customers. Most distributors provide strong manpower and cash support to the supplier or manufacturer's promotional efforts. They usually also provide a range of services (such as product information, estimates, technical support, after-sales services, credit) to their customers." [43]

"Providers" refer to establishments that sell (provide) medicines to final users or patients. These providers include doctors' and specialists' clinics, private and public hospitals, and pharmacies. No distinction is made here between providers that solely dispense medicines (pharmacies) and providers who diagnose and dispense medicines (doctors' clinics).

Figure 2.1: Market Structure and Supply Chain



2.1 Level 1 – Pharmaceutical Manufacturers

There are two major sets of players in Level 1 – manufacturers of drugs and importers of finished drugs. These two parties have different characteristics. While both are locally incorporated to do business in Malaysia, the manufacturers are mostly locally incorporated and owned and produce generic drugs, whereas the big importers are mainly MNCs that import mostly patented drugs from their parent companies. There are also locally owned importers which are mainly smaller companies that import mostly generic drugs; they account for only a minor portion of the market by value.

[43] For more details see http://www.businessdictionary.com/definition/distributor.html

According to the NPRA database (accessed 17 July 2017), there are 244 companies holding manufacturing licences for drugs: 37 hold licences for producing controlled medicines, 45 for OTC drugs, 136 for traditional drugs, and 26 for other drugs (supplements, traditional medicines health supplements, veterinary) (see Table 2.1). This study focuses on companies manufacturing controlled medicines.

Table 2.1: Companies Holding Pharmaceutical Manufacturing Licences in Malaysia, July 2017

Manufacturing licences issued by the NPRA as of July 2017	
Controlled medicines	37
OTC	45
Traditional	136
Others	26
TOTAL	**244**

Source: NPRA website

The NPRA listed 37 companies that hold licences to manufacture controlled medicines.[44] Table 2.2 lists the names of 28 companies whose core business is manufacturing controlled medicines. Nine companies whose core business is not manufacturing controlled medicines are excluded from the analysis in this section. These companies are: B Braun, whose main business is manufacturing medical devices; DKSH and Zuellig, which are distributors operating under wholesale licences; Seutic Pack, which is a packaging firm; Sterling Drug and Steripack, which both manufacture pharmaceutical consumables, OTC medicines and medical devices; Beacon International Specialist Centre, which is a hospital; Fasiliti Penyediaan Radiofarmaseutikal, which is a government institution; and Kuehne + Nagel, which is a logistics provider.

[44] The term "*racun*" (poison) refers to controlled medicines that are listed under Group B Poison and Group C Poison under the Poisons Act 1952. The approximate commercial equivalent would be prescription medicines. Most of the pharmaceutical manufacturers are members of the Malaysian Organization of Pharmaceutical Industries (MOPI), which is the trade body that represents locally incorporated manufacturers of pharmaceutical products. See Appendix 2 for the list of MOPI members.

Table 2.2: Selected List of Controlled Medicines Manufacturers in Malaysia*					
No.	**Company**	**Ownership**	**Revenue (RM '000)**	**Net Profit (Loss) After Tax (RM '000)**	**Net Profit (Loss) Margin**
1	Pharmaniaga Manufacturing Bhd.	Local	206,260	54,256	26.3%
2	Hovid Berhad	Local	188,406	18,567	9.9%
3	Duopharma (M) Sdn. Bhd.	Local	176,961	34,992	19.8%
4	Y.S.P. Industries (M) Sdn. Bhd.	Local**	175,117	17,335	9.9%
5	Ain Medicare Sdn. Bhd.	Local	152,638	17,924	11.7%
6	Kotra Pharma (M) Sdn. Bhd.	Local	145,174	1,059	0.7%
7	Upha Pharmaceutical Manufacturing (M) Sdn. Bhd.	Local	109,048	5,038	4.6%
8	Hoe Pharmaceuticals Sdn. Bhd.	Local	105,979	35,138	33.2%
9	Xepa-Soul Pattinson (M) Sdn. Bhd.	Local	94,794	17,534	18.5%
10	Ranbaxy (Malaysia) Sdn. Bhd.	Foreign	76,378	(22,906)	(30.0%)
11	Royce Pharma Manufacturing Sdn. Bhd.	Local	44,923	7,000	15.6%
12	Sunward Pharmaceutical Sdn. Bhd.	Foreign	39,371	4,121	10.5%
13	Noripharma Sdn. Bhd.	Local	28,785	4,373	15.2%
14	SM Pharmaceuticals Sdn. Bhd.	Foreign	28,512	216	0.8%
15	Dynapharm (M) Sdn. Bhd.	Local	27,340	n/a	n/a
16	Winwa Medical Sdn. Bhd.	Local	26,982	1,682	6.2%
17	Malaysian Pharmaceutical Industries S/B.	Local	13,073	1,200	9.2%
18	KCK Pharmaceutical Industries Sdn. Bhd.	Local	10,731	768	7.2%
19	AV Manufacturing Sdn. Bhd.	Local	9,293	2,654	28.6%
20	Bio Molecular Industries Sdn. Bhd.	Local	3,485	n/a	n/a
21	Teraputics Sdn. Bhd.	Local	2,983	(29)	(1.0%)
22	Xorix Sdn. Bhd.	Local	2,212	n/a	n/a
23	Idaman Pharma Manufacturing Sdn. Bhd.	Local	147	38	25.5%
	TOTAL		**1,668,592**	**200,960**	**12.0%**
24	Biocon Sdn. Bhd.	Foreign	n/a	n/a	n/a
25	Pharmaniaga Lifescience Sdn. Bhd.	Local	0	(13,895)	n/a
26	Prime Pharmaceuticals Sdn. Bhd.	Local	n/a	n/a	n/a
27	Goodscience Sdn. Bhd. (formerly Scanlab)	Foreign	n/a	n/a	n/a
28	Chulia Pharma Sdn. Bhd.	Local	n/a	n/a	n/a

Source: Companies Commission of Malaysia (SSM)
Notes: n/a = not available
* The list is based on the 2017 NPRA list published on its website. However, financial data are based on financial years 2014 or 2015 depending on availability of data from SSM.
** Y.S.P. is 35% owned by Taiwanese.

(A) OWNERSHIP AND SIZE

Most manufacturers of controlled medicines in Malaysia are locally owned. Of the 28 companies, only 5 are foreign-owned: Ranbaxy (India), Biocon (India), SM Pharmaceuticals (India), Sunward (Singapore) and Goodscience (formerly Scanlab) (Hong Kong).

The remaining 23 are locally owned companies. Of these, 6 are listed on the Bursa Malaysia stock exchange. Ranked by sales revenue,[45] they are Pharmaniaga, Hovid, Duopharma (subsidiary of CCM), Y.S.P. Industries, Kotra Pharma and Xepa-Soul Pattinson (subsidiary of Apex Healthcare Bhd). (For profiles of these companies, see Appendix 3.) The remainder are privately owned companies. The Pharmaniaga group, the largest locally owned pharmaceutical company, has three companies on this list: Idaman Pharma Manufacturing, Pharmaniaga Lifescience and Pharmaniaga Manufacturing. Chemical Company of Malaysia (CCM) has two subsidiaries listed here, namely Duopharma and Upha Pharmaceutical. Both Pharmaniaga and CCM are GLCs.

Malaysian pharmaceutical manufacturing companies are small compared with the MNCs that import drugs into Malaysia. Only 8 companies had sales revenues exceeding RM100 million in 2014/2015, with Pharmaniaga Manufacturing leading at RM206 million (see Table 2.2). Five companies had sales of under RM10 million. By comparison, the sales revenues of the top four importers are over RM400 million each, twice the revenues of Pharmaniaga Manufacturing, the largest manufacturer (see Tables 2.2 and 2.4).

(B) GENERIC MANUFACTURERS

Malaysian pharmaceutical manufacturers are producers of generic medicines, as opposed to originator medicines. They do not yet have the technological capacity to produce new medicines. Every patented medicine has at least two types of patents – product patent and process patent. When a product patent expires, other companies are allowed to produce generic versions of the originator medicine. If the process patent has not expired, generic manufacturers need to conduct research to arrive at their own process of formulating the medicine.

Malaysian manufacturers import most of the raw materials and inputs, such as active pharmaceutical ingredients (APIs), excipients (the inert substance) and even some packaging materials, to formulate medicines. After the products are formulated, the manufacturers need to perform both quantitative and qualitative tests of the products to meet regulatory standards. In recent years, the NPRA's regulations require bioequivalence (BE) tests for dosage in the form of tablets and capsules to ensure the efficacy and specification of the product are equivalent to those of the originator medicines.

[45] While the major business of these 28 companies is the manufacture of controlled medicines, the sales revenue data provided by SSM are not disaggregated by product line and hence could include non-pharmaceutical products. This is a limitation with using company-level sales data rather than product sales data, which are not available.

Generic medicines account for 55% of the Malaysian pharmaceuticals market (in terms of sales revenue), while originator medicines (patented medicines) account for the remaining 45% in 2016 (Figure 1.6). While no exact data are available on sales by volume, several interviewees indicated that generic medicines could account for 70% of market share by volume.

(C) INDEPENDENT VERSUS CONTRACT MANUFACTURING

Contract manufacturing refers to the production of goods by one firm under the label or brand of another firm, as opposed to the firm manufacturing its own goods for sale. The latter is known as independent manufacturing. Most Malaysian pharmaceutical manufacturers are independent manufacturers producing and marketing their own medicines. Some perform contract manufacturing mostly for local distributors either on a regular basis or on an ad hoc basis, like KCK. A few engage in contract manufacturing for MNCs, like Kotra for Servier. In general, contract manufacturing is not a major business of Malaysian pharmaceutical manufacturers.[46] Of the companies interviewed for this Review, all have less than 10% of their business in contract manufacturing.[47]

(D) STRADDLING THE SUPPLY CHAIN

Most of the major manufacturers straddle all levels of the supply chain, i.e., they import the raw materials, process and manufacture the medicines, and warehouse and distribute the products, some directly to the providers (in both the private and public sectors) and others through distributors like Zuellig, DKSH and Apex Pharma. In the case of sales to the public sector, sales are through Bumiputera agents, while marketing is undertaken by the principals; logistics and distribution are through distributors (refer to Figure 2.1). Big companies like Pharmaniaga, Duopharma and Hovid own subsidiaries that specialize in manufacturing, importing, distribution and even retailing (see Appendix 3 on the profiles of the top 6 companies).

APIs are imported for processing and for manufacturing into finished products. The biggest sources of supply of APIs are from China and India, followed by Europe.[48] Some local manufacturers also import finished products for distribution and sale, although this is a smaller component of their business.

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[46] This stands in contrast to the Philippines where toll (contract) manufacturing is a large part of the pharmaceutical industry. See Reyes, Celia M. et al. (2011). "A Profile of the Philippine Pharmaceutical Sector", PIDS Discussion Paper Series, 2011-11.

[47] A total of 11 pharmaceutical manufacturers were interviewed. These comprised the 6 public listed companies and 5 privately owned companies that are smaller in size.

[48] From interviews with generics manufacturers. See also API Industry Guide "*The API Industry as a Glance*" http://www.mdtvalliance.org/the-api-industry-at-a-glance/: "… the greatest concentrations of API manufacturers are located around Asia, specifically in India and China"

2.2 Level 1 – Pharmaceutical Importers

The NPRA issues licences to establishments for importing controlled medicines. According to the NPRA website (accessed on 17 July 2017), 424 establishments hold licences to import controlled medicines and other products: 126 are licensed to import controlled medicines, 102 OTC drugs, 124 traditional drugs, and 72 other drugs (supplements, traditional medicines health supplements (TMHS), veterinary medicines) (see Table 2.3). This study focuses only on controlled medicines, commonly known as prescription medicines.

Table 2.3: Companies Holding Licences for Pharmaceutical Import, July 2017

Import licences issued by the NPRA as of July 2017	
Controlled medicines	126
OTC	102
Traditional	124
Others	72
TOTAL	**424**

Source: NPRA website, accessed 17 July 2017.

Many of these 424 companies with import licences also hold manufacturing and wholesale licences from the NPRA. This study identifies and focuses on companies whose core business is the importing of controlled medicines for distribution and sale in Malaysia. The criteria and process for selecting these companies are as follows. The first step is to determine their core business (i.e., business that accounts for a major part of sales revenue). Only those whose core business is importing controlled medicines for sale in Malaysia are retained; the remainder are left out. Second, manufacturing companies that hold import licences but have already been included in the list of 28 manufacturers above are omitted. What is left are 61 companies identified as importers of controlled medicines (see Table 2.4).

These companies constitute the second set of players at Level 1 of the supply chain. These importers can be divided into two sub-categories – the MNCs[49] and the local importers.[50]

[49] Most of the pharmaceutical MNCs are members of PhAMA. Membership is open to companies engaged in the pharmaceuticals sector as manufacturers, agents, representatives or distributors in Malaysia. There are 42 members in PhAMA. See Appendix 4.

[50] Most of them are members of the Malaysian Association of Pharmaceutical Suppliers (MAPS). See Appendix 5.

Table 2.4: Selected Importers of Controlled Medicines in Malaysia as of 2017*					
No.	**Company**	**Ownership**	**Revenue (RM '000)**	**Net Profit (Loss) After Tax (RM '000)**	**Net Profit (Loss) Margin**
1	Pfizer (Malaysia) Sdn. Bhd.	Foreign	452,584	10,826	2.4
2	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	Foreign	425,446	1,568	0.4
3	Bayer Co. (Malaysia) Sdn. Bhd.	Foreign	408,665	15,730	3.8
4	Sanofi-Aventis (Malaysia) Sdn. Bhd.	Foreign	404,825	6,981	1.7
5	Novartis Corporation (Malaysia) Sdn. Bhd.	Foreign	370,162	9,702	2.6
6	GlaxoSmithKline Pharmaceutical Sdn. Bhd.	Foreign	349,387	18,959	5.4
7	Roche (Malaysia) Sdn. Bhd.	Foreign	299,327	9,999	3.3
8	AstraZeneca Sdn. Bhd.	Foreign	286,211	20,823	7.3
9	Merck Sdn. Bhd.	Foreign	185,462	2,988	1.6
10	CCM Pharmaceuticals Sdn. Bhd.	Local	146,541	607	0.4
11	Servier Malaysia Sdn. Bhd.	Foreign	117,975	9,467	8.0
12	Eli Lilly (Malaysia) Sdn. Bhd.	Foreign	101,634	9,523	9.4
13	AbbVie Sdn. Bhd.	Foreign	78,315	1,514	1.9
14	Medispec (M) Sdn Bhd	Local	60,852	7,321	12.0
15	Fresenius Kabi Malaysia Sdn. Bhd.	Foreign	55,254	5,409	9.8
16	Healol Pharmaceuticals Sdn. Bhd.	Foreign	53,326	4,577	8.6
17	Takeda Malaysia Sdn. Bhd.	Foreign	42,755	134	0.3
18	United Italian Trading (M) Sdn. Bhd.	Local	40,122	697	1.7
19	Germax Sdn. Bhd.	Local	37,052	1,060	2.9
20	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.	Foreign	37,013	606	1.6
21	A. Menarini Singapore Pte. Ltd.	Foreign	33,824	(23,475)	(69.4)
22	Orient Europharma (M) Sdn. Bhd.	Foreign	32,953	1,239	3.8
23	Unimed Sdn. Bhd.	Local	32,754	704	2.1
24	Medidata Sdn. Bhd.	Local	31,821	3,307	10.4
25	Aspen Medical Products Malaysia Sdn. Bhd.	Foreign	31,603	19	0.1
26	Eisai (Malaysia) Sdn. Bhd.	Foreign	31,477	6,920	22.0
27	Idaman Pharma Sdn. Bhd.	Local	26,695	(1,182)	(4.4)
28	Grifols Malaysia Sdn. Bhd.	Foreign	24,875	997	4.0
29	Jetpharma Sdn. Bhd.	Local	22,812	2,124	9.3
30	Winthrop Pharmaceuticals (Malaysia) Sdn. Bhd.	Foreign	18,306	682	3.7
31	Somedico Sdn. Bhd.	Local	17,348	456	2.6
32	Unam Pharmaceutical (M) Sdn. Bhd.	Foreign	17,135	1,299	7.6
33	Biocare Pharmaceutical (M) Sdn. Bhd.	Local	16,757	2,307	13.8

No.	Company	Ownership	Revenue (RM '000)	Net Profit (Loss) After Tax (RM '000)	Net Profit (Loss) Margin
34	Averroes Pharmaceuticals Sdn. Bhd.	Local	16,680	3,498	21.0
35	Mundipharma Pharmaceuticals Sdn. Bhd.	Foreign	16,618	(12,271)	(73.8)
36	Komedic Sdn. Bhd.	Local	15,234	226	1.5
37	Ferring Sdn. Bhd.	Foreign	12,835	(797)	(6.2)
38	Mepharm (Malaysia) Sdn. Bhd.	Local	12,051	92	0.8
39	First Pharmaceutical Sdn. Bhd.	Local	10,690	631	5.9
40	Mansa Pharma (M) Sdn. Bhd.	Local	8,427	185	2.2
41	Hyphens Pharma Sdn. Bhd.	Foreign	8,295	544	6.6
42	Ziwell Medical Sdn. Bhd. - distribution	Local	7,239	1,855	25.6
43	TRB Chemedica Malaysia Sdn. Bhd.	Foreign	6,955	772	11.1
44	Stadpharm Sdn. Bhd.	Local	6,724	144	2.1
45	Nano Medic Care Sdn. Bhd.	Local	5,214	174	3.3
46	Kireen Pharmaceutical Sdn. Bhd.	Foreign	3,069	432	14.1
47	Cipla Malaysia Sdn. Bhd.	Foreign	2,074	69	3.3
48	Atlantic Laboratories (M) Sdn. Bhd.	Foreign	2,019	137	6.8
49	Ubisson Sdn. Bhd.	Local	1,504	(209)	(13.9)
50	Eucogen Sdn. Bhd.	Local	1,300	190	14.6
51	Exeltis Pharma Sdn. Bhd.	Foreign	914	(1,017)	(111.3)
52	SPG Pharma (Malaysia) Sdn. Bhd.	Foreign	303	(969)	(319.7)
53	UCB Trading (Malaysia) Sdn. Bhd.	Foreign	290	(49)	(17.0)
54	Zest Pharma Sdn. Bhd.	Foreign	156	(164)	(104.8)
	TOTAL		**4,429,857**	**127,362**	**2.9**
55	Baxalta Malaysia Sdn. Bhd.	Foreign	n/a	n/a	n/a
56	Imeks Pharma Sdn. Bhd.	Local	n/a	n/a	n/a
57	Milrin Pharmaceutical Co (M) Sdn. Bhd.	Local	n/a	n/a	n/a
58	Accord Healthcare Sdn. Bhd.	Foreign	n/a	n/a	n/a
59	AJ Biologics Sdn. Bhd.	Foreign	n/a	n/a	n/a
60	Meta Pharma Sdn. Bhd	Local	n/a	n/a	n/a
61	Pharmaforte (M) Sdn. Bhd.	Local	n/a	n/a	n/a

Note: * This list is based on the 2017 NPRA list of companies with import licences. However, financial data from SSM are for years 2014 or 2015 depending on availability.

(A) MULTINATIONAL IMPORTERS AND METHOD OF OPERATION

The big importers are MNCs with registered offices in Malaysia for the purpose of registering their products for sale in Malaysia. The medicines imported are predominantly patented products. No MNC from high-income countries has established manufacturing facilities in Malaysia to produce controlled medicines. All their products are imported.

The top 10 importers of pharmaceutical medicines are foreign MNCs except for CCM Pharmaceuticals. Ranked by sales revenue, they are: Pfizer, Merck Sharp & Dohme, Bayer, Sanofi-Aventis, Novartis, GSK, Roche, AstraZeneca, Merck and CCM Pharmaceuticals. They had combined sales revenue of RM3.3 billion and accounted for 74% of the total sales revenue of the importers. (See Table 2.4.)

These MNCs act as principals importing finished products into Malaysia and sell them through distributors.[51] The importer is the principal and retains ownership of the products while the distributor merely offers logistics services to the principals.

All companies are required to hold an NPRA licence before they can manufacture, import or sell by wholesale pharmaceutical products. Such licences can only be held by a locally registered entity. Hence most importers establish registered offices in the country. They maintain marketing and sales teams who actively and directly market to providers in the private and public sectors. Distributors do not get involved in pricing and marketing decisions; they simply provide logistics services like warehousing, transportation, distribution, invoicing and collection of money. As principals, importers are responsible for demand creation, marketing and pricing. For smaller MNCs that do not have a registered office in Malaysia, they appoint their distributor to register and market their products.

Private hospitals and clinics together purchase 40% of patented drugs.[52] Consequently, most of the MNCs' marketing efforts are directed at them, and to a lesser extent at chain pharmacies. The marketing strategies of these MNCs are well known. With considerable resources and support from headquarters, these companies are able to, for example, organize conferences and workshops for their potential clients, particularly for doctors and specialists in private hospitals as well as GPs.[53]

With regard to public sector procurement, the MNCs bid for contracts through Bumiputera agents when tenders are called. However, the price of the product is determined by the head office of the MNC with input from its local office. In cases of direct price negotiations, MNCs or their authorized agents deal directly with the MOH, but prices are set by the MNC principals. In most cases, MNCs appoint their own distributors to handle logistics services.

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[51] A distributor can hold wholesale and import licences.

[52] PhAMA (2016). Industry Overview, at page 3, accessed 17 August 2017.

[53] Local manufacturers and importers also occasionally give talks at hospitals but with much less frequency given resource constraints. Source: interviews with 3 private hospitals, 5 GPs, 5 manufacturers and 4 pharmacists.

(B) LOCAL IMPORTERS AND METHOD OF OPERATION

Local pharmaceutical importers, though numerous, are much smaller in size; they import mainly generic drugs. Most local importers are members of the Malaysian Association of Pharmaceutical Suppliers (MAPS). The sales revenues of local importers range from a few million ringgit to RM60 million; the one exception is CCM Pharmaceuticals,[54] which had sales of over RM145 million in 2014. (See Table 2.4.) The combined total value of imports of members of MAPS is about RM200 million,[55] out of an import bill of RM5.4 billion in 2014.

The major local importers are CCM Pharmaceuticals, Medispec, United Italian Trading, Healol Pharmaceuticals and Germax. About 90% of pharmaceuticals imported by local importers are generic medicines, of which 10% are originator generics. The important sources of imports are Canada, the US, Europe, Korea and India. While some local importers like CCM Pharmaceuticals and Medispec have the capacity to handle their own logistics including warehousing and transportation, most of other local importers tend to use local distributors rather than foreign distributors like Zuellig and DKSH for several reasons. Firstly, the business of pharmaceutical distributors is volume- and value-driven. Big foreign distributors do not give priority to servicing local importers that do not have high-value or -volume business. Secondly, given the low value and volume, local importers end up paying higher margins. Thirdly, major independent distributors whose bulk of business is from MNCs routinely do not accept local importers' generic products as these compete with patented products.[56] Given these constraints, local importers tend to organize their own distribution channel or hire local distributors. Local importers are less able to procure products on consignment basis due to lacking in market power. Most have to purchase and take ownership of the products, thereby increasing their financing costs.

While local importers also deploy sales teams to call on providers, they are focused on sales rather than marketing and promotional activities that require more financial resources. If they undertake marketing activities, these are usually done on behalf of and paid for by suppliers.

[54] CCM Pharmaceuticals has import and wholesale/distribution activities. Within the group, manufacturing is carried out by Duopharma and Upha.

[55] Data courtesy of MAPS.

[56] From interviews with 4 importers as well as other industry experts who are not importers.

2.3 Level 2 – Wholesalers cum Distributors

The second level of the supply chain comprises distributors and wholesalers. The NPRA issues wholesale licences to establishments for distributing and selling controlled medicines and other products. A total of 1,257 such licences were issued to establishments: 709 are for controlled medicines, 327 for OTC, 137 for traditional medicines and 84 for other drugs (see Table 2.5). This study focuses only on controlled medicine licences.

Table 2.5: Companies Holding Wholesale Licences for Pharmaceuticals, July 2017

Wholesale licences issued by the NPRA as of July 2017	
Controlled medicines	709
OTC	327
Traditional	137
Others	84
TOTAL	**1,257**

Source: NPRA website

From the 709 companies holding wholesale licences for controlled medicines, 72 were selected based on the following criteria and process. The first step was to identify the companies whose core business is wholesaling. Next, the NPRA list was checked against the PSD list. Only establishments with pharmacists holding a PSD Type A licence and listed in the wholesale-only category were included. The following types of establishments were excluded: (i) all companies that had appeared in the NPRA list of manufacturers and importers; (ii) all establishments with pharmacists carrying PSD Type A licences engaged in both wholesale and retail trade; (iii) all establishments with pharmacists carrying PSD Type A licences engaged in only retail trade; (iv) all public hospitals and clinics; (v) all private hospitals and clinics; (vi) all establishments dealing predominantly in veterinary medicaments, medical devices/equipment, dental products or traditional medicines. Establishments with the same name and same address, or same name but different addresses were consolidated and counted as a single establishment. As a result, 72 wholesale establishments were selected for this study. (See Table 2.6.)

There are four types of companies that possess wholesale licences in the NPRA list. First are the independent distributors. These are not the typical wholesaler or distributor who buys goods from suppliers and sells to retailers. They do not take ownership of the goods or the risks associated with ownership; they are not involved in marketing or determining price. These companies only provide logistical services, such as warehousing, storage, transport, distribution, packaging, redressing, and other ancillary services like invoicing, provision of credit and collection of payment on behalf of their clients. Where principals do not have registered offices in Malaysia, the distributors take on additional functions such

as registering the products in their name and marketing the products for their principals. Though there are 709 establishments holding NPRA wholesale licences to distribute controlled medicines, the number of independent distributors is small and the industry is highly concentrated. The two largest distributors, DKSH and Zuellig, with combined sales revenue of RM9.4 billion, account for 65% of market share.[57]

Table 2.6: Selected Companies Holding Wholesale Licences for Controlled Medicines in Malaysia as of 2017*

No.	Company	Revenue (RM '000)	Net Profit (Loss) After Tax (RM '000)	Net Profit Margin
1	DKSH Malaysia Sdn. Bhd.	5,479,889	25,192	0.5%
2	Zuellig Pharma Sdn. Bhd.	3,937,480	12,472	0.3%
3	Pharmaniaga Logistics Sdn. Bhd.	1,697,269	29,731	1.8%
4	Primabumi Sdn. Bhd.	488,538	2,451	0.5%
5	Summit Company (Malaysia) Sdn. Bhd.	361,919	17,577	4.9%
6	Pharmaserv Alliances Sdn. Bhd.	349,695	401	0.1%
7	Apex Pharmacy Marketing Sdn Bhd	322,924	14,475	4.5%
8	M.S. Ally Pharma Sdn. Bhd	318,752	3,757	1.2%
9	Quality Reputation Sdn. Bhd.	253,226	2,325	0.9%
10	Mutiara Murni Sdn. Bhd.	188,458	2,316	1.2%
11	Antah Pharma Sdn. Bhd.	137,108	3,307	2.4%
12	LF Asia Sebor (Sarawak) Sdn.Bhd.	95,833	(5,279)	-5.5%
13	Geliga Sistem Sdn. Bhd.	94,045	94	0.1%
14	Hovid Pharmacy Sdn. Bhd.	85,218	915	1.1%
15	Tamasetia Resources Sdn. Bhd.	78,118	294	0.4%
16	LF Asia (Malaysia) Sdn. Bhd.	73,278	(5,983)	-8.2%
17	Teraju Farma Sdn. Bhd.	54,878	1,508	2.7%
18	Pharmex Sdn. Bhd.	39,093	1,447	3.7%
19	Prestige Pharma Sdn. Bhd.	32,057	2,501	7.8%
20	Bioscenergy International Sdn. Bhd.	31,710	3,318	10.5%
21	Propharm (M) Sdn. Bhd.	30,329	1,659	5.5%
22	Oratis Pharmaceuticals Sdn. Bhd.	28,579	3,209	11.2%
23	Uni Drug House Sdn. Bhd.	26,327	819	3.1%
24	Dynapharm Marketing (M) Sdn. Bhd.	25,883	1,901	7.3%
25	Advance Pharma Sdn. Bhd.	22,085	4,576	20.7%
26	Pharm-D Sdn. Bhd.	21,726	1,767	8.1%

[57] As noted in the "Methodology and Limitations" section of this Review, the sales revenue data at company level are not disaggregated by product. They include pharmaceuticals and non-pharmaceutical products. Consequently, the sales figures here exceed the pharmaceutical market size quoted from the BMI report in Figure 1.5.

No.	Company	Revenue (RM '000)	Net Profit (Loss) After Tax (RM '000)	Net Profit Margin
27	Baroko Sdn. Bhd.	19,025	423	2.2%
28	Kuala Lumpur Pharmacy (W.O) Sdn. Bhd.	12,911	(532)	-4.1%
29	Antah Bumimedic Sdn. Bhd.	11,458	(100)	-0.9%
30	Yin Woh Tong Medical Supplies Sdn. Bhd.	9,580	613	6.4%
31	Pharmex Pharma (Sarawak) Sdn. Bhd.	9,120	274	3.0%
32	Ecopharm Sdn. Bhd.	8,464	15	0.2%
33	Zulat Pharmacy Sdn. Bhd.	8,185	372	4.5%
34	Medical Supplies (Sarawak) Sdn. Bhd.	6,823	39	0.6%
35	Farmasi Utama Wholesales Sdn. Bhd.	6,563	101	1.5%
36	Almedico Sdn. Bhd.	5,693	188	3.3%
37	Healthcare Solution Sdn. Bhd.	5,636	(104)	-1.8%
38	Zontron Pharmaceuticals Sdn. Bhd.	5,220	(27)	-0.5%
39	J.Bio Medic Marketing Sdn. Bhd.	4,765	317	6.7%
40	Medical Supplies (Labuan) Sdn. Bhd.	3,574	658	18.4%
41	LF Mercu Sdn. Bhd.	2,906	(136)	-4.7%
42	Subang Chemist Sdn Bhd	2,702	4	0.2%
43	Penta Healthcare Sdn. Bhd.	2,507	21	0.9%
44	Pharmaexpress Sdn. Bhd.	2,478	(225)	-9.1%
45	J S Pharma Concept Sdn. Bhd.	1,931	129	6.7%
46	Medical Supplies (Sabah) Sdn. Bhd.	1,776	(698)	-39.3%
47	Bemed Pharma Sdn. Bhd.	1,644	94	5.7%
48	SC Pharmacare Sdn. Bhd.	1,539	4	0.3%
49	Alpha Bio Medic (M) Sdn. Bhd.	947	(116)	-12.3%
50	Pharmserve Pharma Sdn. Bhd.	687	84	12.2%
51	AJ Research & Pharma Sdn. Bhd.	539	(4,919)	-911.8%
52	IPH Pharmaceuticals Sdn. Bhd.	496	(153)	-30.8%
53	Alpharme PLC Sdn. Bhd.	288	(50)	-17.5%
54	Bumimedic (Malaysia) Sdn. Bhd.	267	11	4.0%
55	Suaut Enterprise Sdn. Bhd.	183	8	4.2%
56	Pharmarise Sdn. Bhd.	155	(227)	-146.5%
57	Jinaun Pharma Sdn. Bhd.	5	(13)	-253.0%
	TOTAL	**14,412,485**	**122,808**	**0.9%**
58	Be-P Pharmacy Sdn. Bhd.	n/a	n/a	
59	Fidin Universal Sdn. Bhd.	n/a	n/a	
60	Mediearth Bumi Medical Supplies Sdn.Bhd.	n/a	n/a	
61	Oralix Sdn. Bhd.	n/a	n/a	

No.	Company	Revenue (RM '000)	Net Profit (Loss) After Tax (RM '000)	Net Profit Margin
62	Cahaya Mekar Jaya Sdn. Bhd.	n/a	n/a	
63	Invespharma Sdn. Bhd.	n/a	n/a	
64	K.F.N Pharma Trading Company	n/a	n/a	
65	Mayflax Sdn. Bhd.	n/a	n/a	
66	S & M Healthcare Supply Sdn. Bhd.	n/a	n/a	
67	Sirius Care Malaysia Sdn. Bhd.	n/a	n/a	
68	Tydeal Global Sdn. Bhd.	n/a	n/a	
69	The Zyfas Medical Co	n/a	n/a	
70	Medik Pharma Trading	n/a	n/a	
71	Luen Wah Medical Co. Sdn. Bhd.	n/a	n/a	
72	Borneo Pharmacy Supplies Sdn. Bhd.	n/a	n/a	

Source: NPRA website (accessed 17 July 2017)
* Note: This list is based on the 2017 NPRA list of companies holding wholesale licences. However, financial data is based on financial year 2014 or 2015 depending on availability from SSM.

The second group of wholesalers/distributors consists of Bumiputera agents who act as intermediaries between public hospitals, on the one hand, and local non-Bumiputera and foreign pharmaceutical companies, on the other hand, bidding for government procurement of medical supplies. Within the Bumiputera agents group, a further distinction can be made between those that act purely as tendering agents and those that provide additional services such as warehousing and distribution. Pharmaniaga is the largest Bumiputera agent with exclusive concession to supply approximately 700 medical items, under the Approved Product Purchase List (APPL) programme, to government hospitals, institutions and clinics. All tenders for APPL items must pass through Pharmaniaga Logistics.[58] The company has extensive warehouse and logistics facilities for its own products; these services are also offered to its clients. Other Bumiputera agents, like Antah and MS Ally, that provide warehouse and distribution services started off as pharmaceutical wholesalers or retailers, subsequently adding on the function of tendering agents.

[58] If Pharmaniaga seeks to make a bid itself, that bid has to be submitted 2 weeks before the bidding by other companies.

What is the modus operandi of a Bumiputera tendering agent? When the MOH puts out a procurement tender (outside the APPL programme), Bumiputera agents will source for potential suppliers (holders of registered medicines) to negotiate with the latter to supply the medicines according to the MOH's specifications.[59] The supplier (also known as the principal) will either offer an exclusive contract to a Bumiputera agent or provide quotations to several Bumiputera agents. If negotiations with the principal are successful, the Bumiputera agent will sign a contract to mirror the terms of the MOH. The tender with pricing and other technical specifications are submitted to the MOH for evaluation and approval.[60] Bumiputera agents handle all administrative dealings with the government; for example, purchase orders are made to the agents and payments are made to the agents. The agents are responsible for sourcing and supplying the products in a timely manner, with a penalty imposed for delays. The agents are required to post performance bonds equal to between 2.5% and 5.0% of the transaction value. Acting as tender agents, they do not take ownership of the products supplied; pricing is determined by the principals and logistics are provided by other independent distributors. Most MNCs use DKSH or Zuellig to handle their logistics. Bumiputera agents charge a fee of between 2% and 3% for their services.[61]

The third group of companies with wholesale licences comprises subsidiaries of local manufacturers with wholesale licences. Examples are Duopharma (M) Sdn. Bhd., a subsidiary of CCM that holds licences for manufacturing, importing and distributing pharmaceutical products. Duopharma also owns subsidiaries like Sentosa Pharmacy and Unique Pharmacy that are retail pharmacies. Other companies such as Pharmaniaga own distribution subsidiaries like Pharmaniaga Logistics Sdn. Bhd., one of the largest local distributors of pharmaceutical products. Another large local company involved in manufacturing and distribution is the Apex Pharma Group which owns Apex Pharmacy Marketing. This company, with its large warehousing and distribution capacity, is able to provide logistical services not only for its related company, Xepa-Soul Pattinson, but also for other companies.

The fourth group comprises retail pharmacies that also hold wholesale licences. They form the majority of the 709 companies with wholesale licences in the NPRA list but account for the smallest market share in terms of value. These pharmacies buy in bulk from suppliers in order to get lower prices, and in turn sell them to smaller community pharmacies. Examples are chain pharmacies like AM PM Pharmacy, Aeon Pharmacy and even some single independent community pharmacy outlets.

[59] For the purpose of this discussion, we refer only to the MOH; the process is the same with other government hospitals under the Ministry of Defence and the Ministry of Education.

[60] A detailed discussion on the public procurement method is provided at the end of this chapter.

[61] From interviews with a Bumiputera agent and several principals.

2.4 Level 3 – Providers

The third level in the supply chain comprises the providers, defined as institutions that dispense medicines to end users or patients, in both the public and private sectors (refer to Figure 2.1). Providers in the private sector are specialists or GPs, private hospitals and retail pharmacies; while providers in the public sector are government clinics, hospitals and institutions. According to a PhAMA industry overview (2016), at the providers' level, retail pharmacies account for 30% of all pharmaceutical sales, private hospitals 22%, doctors' (GPs) clinics 18%, public hospitals and clinics 25%, and others 5%.

(A) GENERAL PRACTITIONERS' AND SPECIALISTS' CLINICS

As seen from Table 1.1, there were close to 7,000 private clinics owned and run by GPs and specialists in 2014 operating mostly as independent standalone clinics. Group clinics, where a doctor or group of doctors own and manage several clinics, have also become quite prevalent. In Penang, for example, there are more than a dozen group clinics whose size ranges from 2 clinics to more than 10 clinics. Larger and well-known group clinics in Malaysia include Qualitas and Mediviron that own and manage about 200 clinics in urban centres.

(B) PRIVATE HOSPITALS

There were 184 private hospitals in Malaysia in 2014. There are different types of private hospitals: some are community hospitals like Columbia Asia in Petaling Jaya, others are specialist hospitals like Island Hospital in Penang. Some private hospitals are owned and run independently with only one hospital, like Loh Guan Lye Specialists Centre in Penang. Others are chain hospitals with many hospitals under a single ownership and management structure. The big chain hospitals include 10 Pantai hospitals and 4 Gleneagles hospitals owned by IHH Healthcare Bhd, which is in turn owned and controlled by Khazanah, a GLC; and 25 KPJ hospitals owned by KPJ Healthcare Bhd, which is owned by the Johor state government. Private hospitals are the major employers of specialist doctors; 44% of clinical specialists worked in private hospitals in 2013.[62] Private hospitals accounted for about 30% of in-patient care in 2016.[63] Private hospitals as a group account for 22% of pharmaceutical sales[64] and are significant buyers of originator medicines.

(C) RETAIL PHARMACIES

The third set of providers in the private sector is the retail pharmacies, which account for a 30% market share of pharmaceutical sales. The NPRA issues licences to establishments, not to individuals, for manufacture, import and wholesale of controlled

[62] MOH (2015). Pharmaceutical Services Division Annual Report, https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/annual-report-2015.pdf, at page 22.
[63] MOH (2016). Health Facts 2016, http://www.moh.gov.my/images/gallery/publications/KKM%20HEALTH%20FACTS%202016.pdf
[64] PhAMA (2016). Industry Overview, accessed 17 August 2017.

medicines and other products. On the other hand, the PSD issues Type A licences to individual pharmacists working in either wholesale-and-retail, wholesale-only or retail-only types of establishments.

A total of 2,903 Type A licences were issued to pharmacists, according to the PSD website accessed on 14 July 2017 (see Table 2.7). A total of 2,181 licences were issued to pharmacists working in retail-only establishments, 366 to pharmacists working in wholesale-only establishments, and 356 to those working in wholesale and retail establishments.[65]

Table 2.7: Number of Type A Licences Issued to Pharmacists in Malaysia By Type of Establishment as of 2017

Type of Establishment	Number of Type A Licences	Percentage
Retail only	2,181	75%
Wholesale only	366	13%
Wholesale and retail	356	12%
TOTAL	**2,903**	**100%**

Source: MOH PSD website

To determine the number of retail pharmacy outlets in Malaysia, the selection process is as follows: Firstly, establishments in categories 1 and 3 in Table 2.7, listed as retail-only, and wholesale and retail, were chosen. Next, if more than one Type A licence was issued to several pharmacists working in one location (i.e., having the same address), these pharmacists were counted as working in a single outlet. Thirdly, pharmacies bearing the same name operating in different locations (i.e., having different addresses) were counted as different outlets. Fourthly, government hospitals and clinics were left out. Using these criteria, there were 1,413 pharmacy companies with 2,098 retail outlets in Malaysia in 2017 (see Table 2.8).

A total of 1,216 (84.3%) retail-only pharmacies operate only one outlet. These are known as standalone community pharmacies. On the other hand, pharmacies that own and operate more than one retail pharmacy outlet are defined as chain pharmacies. The majority of these chain pharmacies (182) are small and operate only between 2 and 10 outlets. The larger ones (12) own and operate between 11 and 28 outlets, and 3 have between 48 and 72 outlets.

[65] The MOH/PSD regularly updates the Type A licences issued to pharmacists that need to be renewed yearly. As this list was accessed on the PSD website in July, the total number of Type A licences issued or renewed was 2,903. On 8 September 2017, the total has been updated to 4,485.

Table 2.8: Number of Retail Pharmacy Outlets in Malaysia as of September 2017				
Number of Outlets Per Company	**Number of Pharmacy Companies**	**Total Number of Outlets**	**Percentage of Companies**	**Percentage of Outlets**
Single outlet per company	1,216	1,216	86.1%	58.0%
Between 2 and 5 per company	172	421	12.2%	20.1%
Between 6 and 10 per company	10	78	0.7%	3.7%
Between 11 and 28 per company	12	206	0.8%	9.8%
Between 48 and 72 per company	3	177	0.2%	8.4%
TOTAL	**1,413**	**2,098**	**100.0%**	**100.0%**

Source: Calculated from MOH/PSD Website

Unlike traditional chain pharmacies that own and operate multiple outlets, there is another variant that do not operate or fully own the retail pharmacies that carry their names. Examples of pharmacies which fall under this category are AA Pharmacy, Georgetown Pharmacy and Big Pharmacy. These companies sell their products to retail pharmacies that are owned and operated by independent third parties. Sometimes they may have joint ownership with the third party. The primary objective of these companies is to purchase in large quantities in order to get the best price and onward sell to their associated pharmacies.

Table 2.9 shows the names of the 15 chain pharmacies with more than 10 outlets. These chain pharmacies buy in big volume and are able to exercise much market power to the extent that suppliers are obliged to pay listing and display fees for their products to be carried.[66] Chain pharmacies have also been expanding through acquisitions of smaller retail pharmacies. For example, Alpro Pharmacy bought over its competitor Farmasi PD in the Port Dickson area, and Farmasi Lim in Melaka. Cosway Pharmacy acquired Farmasi Alpha and Farmasi Vichem, and IJ Pharmacy bought Farmasi Rasah Jaya and Farmasi NS both in Seremban.

[66] Obtained from interviews with several pharmacists.

Table 2.9: Chain Pharmacies with More than 10 Outlets		
	11 to 28 Outlets	**Number of Outlets**
1	Aeon Co (M) Bhd (Farmasi Aeon Wellness)	15
2	Alpro Alliance Sdn Bhd	28
3	AM PM Pharmacy Sdn Bhd	18
4	Cosway (M) Sdn Bhd	11
5	Health Lane Family Pharmacy Sdn Bhd	26
6	IJ Pharmacy (M) Sdn Bhd	19
7	Kumpulan Farmasi Vitacare Sdn Bhd	13
8	Multicare Pharmacy Sdn Bhd	16
9	My Pharmacy Sdn Bhd	15
10	Otto Pharma Sdn Bhd	12
11	RedCap Pharmacy Sdn Bhd	21
12	Sunlight Pharmacy Sdn Bhd	12
	Total	**206**
	48 to 72 Outlets	**Number of Outlets**
13	Caring Pharmacy Sdn Bhd	57
14	Guardian Health & Beauty Sdn Bhd	72
15	Watson's Personal Care Stores Sdn Bhd	48
	Total	**177**

Source: Authors' calculation from MOH/PSD website

(D) PUBLIC HOSPITALS AND CLINICS

Providers in the public sector are the government clinics, hospitals and institutions. They account for 25% of the pharmaceutical market.[67] Government healthcare institutions are the largest providers of healthcare in Malaysia, accounting for 55% of the country's total healthcare expenditure. The government provides healthcare services at all three levels – primary (rural and community clinics), secondary (hospitals) and tertiary (specialist centres). There were 2,871 government clinics and 150 public hospitals and specialist centres in 2014 (refer to Table 1.1).

2.5 Procurement of Medicines

(A) PROCUREMENT IN THE PRIVATE SECTOR

A procurement system defines the relationship between providers and their suppliers who may be manufacturers, importers or wholesalers/distributors. How do providers procure their supply of medicines? Do providers purchase directly from principals or from wholesalers/distributors?

[67] PhAMA (2016). Industry Overview, accessed 17 August 2017.

(i) Private Hospitals

Private hospitals are major purchasers of pharmaceuticals, accounting for 22% of market share by sales value.[68] Pharmaceutical companies market directly to hospitals. These companies employ marketing and sales teams who approach medical consultants (doctors and specialists) in private hospitals and provide them with the technical information and literature on their products.

Medical consultants who need the medicines will initiate the procurement process and submit their recommendation for purchase supported by relevant clinical literature. These applications are reviewed by a special committee that makes the final decision. Typically, such a committee is composed of senior pharmacists, medical specialists and senior management. In some hospitals, the identity of members of these committees is not revealed to the medical consultants to minimize undue influence. Factors to consider in procurement are maintaining the right level of inventory and medical safety. Hospitals usually do not keep too many medicines of the same kind to minimize occurrence of human error in handling them. Individual hospitals negotiate prices directly with the principals. In some chain hospitals, prices are negotiated centrally by the head office and procurement is done by individual hospitals.

Private hospitals are significant buyers of originator medicines. Most prefer to use originator medicines.[69] Issues of safety and efficacy are ranked higher than price and affordability in their procurement decisions. Medical consultants believe that patients who come to private hospitals expect to pay more and hence expect the "best medicines". In one of the hospitals where we conducted interviews for this study, only 1% to 2% of its medicines carried were generic. Even then, "branded generics", i.e., generics made by big foreign pharmaceutical companies, were preferred to non-branded generics. In another hospital, the percentage of generic medicines carried was higher, at about 20%. Yet another hospital indicated that generic substitutes would be purchased if the originator medicines were not available.

(ii) General Practitioners' and Specialists' Clinics

These private clinics buy from two sources, mainly from principals (importers or manufacturers of the drugs) or their distributors, and sometimes from pharmacies. If the purchase orders are small and need to be met quickly, the doctors buy from their regular retail pharmacies and usually enjoy a 10% to 15% discount.[70] If the orders are large, they purchase from the principals or distributors.[71] Sales representatives of pharmaceutical companies do marketing and sales calls on GPs. According to a survey in Penang, GPs

[68] PhAMA (2016). Industry Overview, accessed 17 August 2017.
[69] From interviews with 3 private hospitals in Penang.
[70] From interviews with GPs in Penang.
[71] From interviews with 5 GPs and specialists in the Penang area.

are given better prices and higher discounts by pharmaceutical companies.[72] The system of giving discounts and bonuses according to the volume of purchase is widely practised.

GPs use mainly generic medicines because, unlike private hospitals, the fees they can charge are limited. Currently there is a schedule for GP consultation fees of between RM10 and RM35 per visit.[73] Given this low budget, GPs are more inclined to use generic rather than originator medicines unless there are compelling medical reasons to use the latter.

(iii) Retail Pharmacies

Pharmacies purchase between 70% and 80% of their medicines from independent distributors like Zuellig and DKSH.[74] The remaining 20% to 30% are purchased directly from local manufacturers and importers (referred to as principals) and wholesalers. As with the other providers, principals send their marketing and sales staff to generate demand. The price is negotiated between principals and pharmacies; distributors merely provide logistical services.

Given the large number of retail pharmacies, principals focus their marketing effort on chain pharmacies that purchase in large quantities. Chain pharmacies carry mostly originator medicines while community pharmacies carry more generic than originator medicines.[75] Because of their market power, chain pharmacies are able to negotiate with and secure better deals from pharmaceutical companies compared with community pharmacies.[76] For example, chain pharmacies are able to earn revenue even before any sales take place. Pharmaceutical companies selling to chain pharmacies pay multiple fees such as listing fees, display fees, window fees, and sometimes incentives to the staff of the pharmacies to promote their products to customers. Although these additional fees apply to cosmetics and consumable products rather than controlled medicines, they nevertheless give leverage to the chains since the fees collected augment their profit and give them operating cost advantage.[77] All these incentives and fees can add up to 20% to 30% of chain pharmacies' revenue. Hence chain pharmacies are able to sell at competitive prices to the extent that community pharmacies end up buying drugs from the chain pharmacies, like retail shops purchasing goods from Tesco.

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[72] Hassali, M.A., S.T. Tan, F. Saleem and A. Alradsheedy (2014). "Assessment of Medicine Prices Among Community Pharmacies and General Practitioners in the State of Penang, Malaysia", School of Pharmaceutical Sciences, Universiti Sains Malaysia.

[73] Seventh Schedule of Private Healthcare Facilities and Services (Private Medical Clinics or Private Dental Clinics) Regulations 2006.

[74] From interviews with 2 senior pharmacists.

[75] From interviews with 2 senior pharmacists.

[76] Hassali, M.A., S.T. Tan, F. Saleem and A. Alradsheedy (2014). "Assessment of Medicine Prices Among Community Pharmacies and General Practitioners in the State of Penang, Malaysia", School of Pharmaceutical Sciences, Universiti Sains Malaysia.

[77] From interviews with 3 senior pharmacists.

When principals sell to pharmacies, volume is not the only consideration. Principals pick pharmacies that they think are sales leaders and supply them at higher discounts. Principals will sell and give special price to pharmacists who are well known and thought to exercise influence over consumers. Other marketing channels are through sponsorship of medical campaigns (e.g., an anti-dengue event), medical classes and conferences conducted by pharmacists and doctors. In return, these providers are given all types of incentives.

Finally, some pharmacies are able to purchase their supply illegally through unofficial channels known as the "runner" system, through which runners without a valid wholesale licence supply drugs to community pharmacies. Runners normally get their stock from different sources such as doctors or through illegal means (stolen products), parallel import or even counterfeit products. The runner system has worsened price competition among community pharmacies.[78] According to 3 pharmacists interviewed, this practice, while not totally absent, is less prevalent now after the introduction of the Goods and Services Tax (GST) and the Guidelines on Good Pharmaceutical Trade Practice (GPTP).

(B) PROCUREMENT IN THE PUBLIC SECTOR

The MOH Medicines Formulary or *Formulari Ubat Kementerian Kesihatan Malaysia* serves as a guide for doctors with regard to medicines that can be prescribed for patients seeking treatment in MOH facilities. This is also referred to as "the Blue Book". Since 2016, companies can submit dossier for listing into the formulary. The MOH Medicines Formulary list as of July 2017 contains 1,689 medicines. A medicine must first be registered by the NPRA to be considered for inclusion in the formulary. The company responsible for marketing a medicine can apply for it to be considered for listing.

Medicines listed as National Essential Medicines are marked as NEML in the Medicines Formulary. WHO defines essential medicines as medicines that satisfy the priority healthcare needs of the population and hence should be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. Not all medicines listed in the formulary are categorized as NEML.

The Ministry of Finance is responsible for setting the procurement procedures for all government ministries and departments. All tender decisions are posted online.[79] All companies that want to participate in the tender process must be registered with the Government Procurement Division of the Ministry of Finance.

[78] Hassali, M.A., S.T. Tan, F. Saleem and A. Alradsheedy (2014). "Assessment of Medicine Prices Among Community Pharmacies and General Practitioners in the State of Penang, Malaysia", School of Pharmaceutical Sciences, Universiti Sains Malaysia, at pages 23 and 35.

[79] http://myprocurement.treasury.gov.my

Two government committees are responsible for the procurement process: the Technical Evaluation Committee that reviews the technical specifications, and the Financial Evaluation Committee for financial review. The evaluation of both committees will result in the ranking of tenders received and this evaluation report will be submitted to the Procurement Board of the Ministry for consideration and decision.

One of the procurement policies of the government is to "encourage and support the evolvement of Bumiputera entrepreneurs in line with the nation's aspirations to create Bumiputera Commercial and Industrial Community".[80] Accordingly, a government-linked company was granted a sole concession to supply items in the Approved Product Purchase List (APPL) determined by the MOH. Pharmaniaga Logistics Sdn. Bhd. is the current concessionaire.

From 1964 to 1994, the MOH purchased medicines centrally through a general medical store which then distributed the medicines to all hospitals and clinics. In 1994, the government privatized the procurement system. A 15-year sole concession was awarded to Southern Task Sdn. Bhd. (which later became known as Remedi Pharmaceuticals Sdn. Bhd., which in turn became known as Pharmaniaga Logistics Sdn. Bhd.) to procure, store and distribute pharmaceutical products and medical devices listed on the APPL to government hospitals and clinics. After the initial expiry of the concession, it was extended for 10 years to 2019. The intention of the privatization exercise is to reduce Malaysia's reliance on imported pharmaceuticals.

There are three pathways or channels by which the MOH procures pharmaceutical products. In this study, the focus is on purchase of controlled medicines that are prescribed by doctors. The first pathway is through Pharmaniaga under the APPL, the second is through direct tender by the MOH, and the third is through a Local Purchase Order (LPO) at the institutional level (see Table 2.10).

Table 2.10: Public Procurement System for Pharmaceutical Products (MOH)

Mode of Procurement	Approved Product Purchase List (APPL)	MOH National Tender	Local Purchase Order (LPO)
Tenderer	Concession given to Pharmaniaga (PN) to supply medicines to MOH	MOH	This can be by way of quotation or direct purchase Procurement is done by individual hospitals/ institutions or health centres
Number of items	38.5% of medicines purchased by MOH by value in 2015. About 700 items in the APPL list (medicines are part of the list that also includes other medical items)	About 300 items	Purchases identified by the local government hospitals and health centres that are not in the APPL and MOH tender channels

[80] Ministry of Finance. "Malaysia's Government Procurement Regime", http://www.treasury.gov.my/pdf/lain-lain/msia_regime.pdf, accessed 17 August 2017.

Mode of Procurement	Approved Product Purchase List (APPL)	MOH National Tender	Local Purchase Order (LPO)
Procurement method	MOH provides procurement list to PN every 3 years. PN advertises the full list for tender for 30 days. Upon close of tender, PN passes tender list to MOH. Technical and Financial Evaluation Committees submit recommendations to Procurement Board who decides on successful bidders. PN has no role in decision-making. Contract valid for 3 years. Last tender call was January 2017 for the supply period of 2017 to 2019.	Open tender Technical and Financial Evaluation Committees submit recommendations to Procurement Board who decides on successful bidders Contract valid for 2 to 3 years All parties must be registered with Ministry of Finance to participate in tenders	Direct purchase for orders less than RM50,000 Quotation from minimum of 5 bidders for orders between RM50,000 and RM500,000 Price valid for 1 to 2 years
Eligible participants	All companies intending to participate in local tenders must be registered with the government.[81] Any registered party, local or foreign, can submit bid directly through E-tender system. First preference given to Bumiputera manufacturers with production facilities and registered products. PN can also participate in tender but must submit bids 2 weeks before other companies submit their bids. If only one Bumiputera supplier, it becomes "*anak angkat*" and price is directly negotiated. If more than one Bumiputera supplier, contract is shared.	All companies intending to participate in local tenders must be registered with the government. Preference given to Bumiputera companies Non-Bumiputera companies typically submit bids through Bumiputera agents International tenders will be invited for supplies and services if there are no locally produced supplies or services available[82]	For direct purchase, the requirement for registration of the vendor is exempted For direct quotation, all suppliers wishing to take part must be registered with the government

Sources: Hassali, M.A. et al. (2014). "Pharmaceutical Pricing in Malaysia", in Z. Babar, ed., *Pharmaceutical Prices in the 21st Century*, Springer Cham, Heidelberg, Table 10.3; Ministry of Finance website; interviews conducted by the authors.

[81] In the case of foreign companies, this would mean the establishment of a local subsidiary in order that they may participate in the tender process via a Bumiputera agent.

[82] *Ibid*.

Under the APPL channel, Pharmaniaga as the sole concession holder supplied 38.5% of the total cost of medicines procured for all MOH hospitals, institutions and clinics in 2015. The concession is for Pharmaniaga to provide all logistics and distribution services for all products procured under the APPL channel. The total expenditure was RM2,323.12 million.[83] Every 3 years, the MOH submits its procurement list to Pharmaniaga, which will call for open tenders to supply these items. Contracts are awarded for a period of 3 years. Pharmaniaga will advertise to invite tenders for a period of 30 days. The Procurement Board, under the advice of the Technical Evaluation and Financial Evaluation Committees, decides on who are awarded the contracts.

Any registered company, local or foreign, holding a licence for the registered products can participate in the tender and submit its bids directly through the E-tender system. The E-tender is open to registered holders of a manufacturing or importation licence.

First preference is given to Bumiputera manufacturers that qualify, i.e., those that own a factory or facilities and have registered the products that are tendered. Pharmaniaga, having its own manufacturing companies, can also participate in the tender exercise. But it must submit its bids ahead of others – at least 2 weeks before the other companies submit their bids. In cases where only one Bumiputera company qualifies for the items tendered, that company is adopted as the "anak angkat" and the price is negotiated on a direct basis. If there is more than one Bumiputera company that qualifies, the procurement contract is shared among them, though not necessarily on an equal basis.

Under the second channel, the MOH will conduct an open tender for the items not covered under the APPL tender. Contracts for these tenders are valid for 2 years and are for a value of over RM500,000. Under this channel, theoretically any company registered with the Ministry of Finance can bid to supply the items tendered. In accordance with Bumiputera preference under the government's procurement policy, suppliers typically employ a Bumiputera agent to assist in the submission of documents for the tender process. In 2015 the value of medicines purchased by the MOH under this channel was 42.6% of total expenditure.

Foreign as well as local pharmaceutical companies which are the product licence holders (the principals) bid for the projects through Bumiputera agents, who are paid a commission of between 2% and 3% by the principals. The Bumiputera agents will bid for the projects under their name and will liaise directly with the MOH. The principals are responsible for supplying and providing all logistics services. Contractually the Bumiputera agents hold performance risks, i.e., to deliver the supplies on time and according to specifications. But in practice, they usually negotiate for reimbursements from the principals. Among the large and well-known Bumiputera agents are Primabumi, MS Ally, Mutiara Murni and Quality Reputation.

[83] MOH (2015). Pharmaceutical Services Division Annual Report, https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/annual-report-2015.pdf

The third channel is the LPO, through which 19% of the MOH medicine purchases for 2015 were made. Local government hospitals and health centres are allowed to procure drugs on their own for medicines that are not in the APPL and MOH tender lists, and if the orders are RM500,000 or less. There are two types of local purchase, namely, direct purchase if orders are below RM50,000, and quotation if orders are between RM50,000 and RM500,000. Under the second type of local purchase, there must be a minimum of 5 quotations. All prices under LPOs are valid for 1 to 2 years. Bumiputera agents are also required for this channel.

Public procurement for medicines also takes place in the Ministry of Defence (MINDEF) that operates 5 hospitals and 72 medical clinics serving the armed forces. MINDEF procures its own pharmaceutical products, including supplies for peacekeeping operations outside the country, and has a Division of Pharmacy. It has its own formulary, known as "the Maroon Book", which contains more than 1,400 items. The Ministry has a syariah-compliant policy for pharmaceuticals and has taken the lead in promoting the local manufacturing of halal products. The procurement rules of the Ministry of Finance are applicable.[84]

In such situations of public procurement, aligning national development objectives and competition objectives requires special attention. The United Nations Conference on Trade and Development (UNCTAD) Intergovernmental Group of Experts on Competition Law and Policy has been discussing this issue; the following summary of a paper prepared for a 2012 meeting of the Group raised salient points:

"There is increased awareness of the power of public procurement to shape supply and to thereby influence a whole array of economic factors. Yet for States to get good value for money and hence make good use of scarce public resources, competition is paramount. This background paper emphasizes the role of competition in public procurement. Substantive and institutional aspects of public procurement systems are discussed, including strategies to broaden the circle of potential bidders, to incentivize competitive behaviours and to fight bid rigging. The paper also aims at initiating and provoking further discussion on applied issues, on bid rigging prevention, detection and enforcement as well as to share learnt lessons on policy frameworks and procuring practices that effectively promote competition in procurement markets."

[84] Interview with Brigadier-General Dato Dr. Halim bin Hj Basari, Head of Pharmacy, Armed Forces Health Services (Perkhidmatan Kesihatan Angkatan Tentera).

[85] UNCTAD (2012). "Competition Policy and Public Procurement", note on consultations and discussions regarding peer reviews on competition law and policy, review of the Model Law, and studies related to the provisions of the Set of Principles and Rules. Trade and Development Commission Intergovernmental Group of Experts on Competition Law and Policy.

2.6 Conclusion

This chapter has described the market structure and supply chain of Malaysia's pharmaceutical sector from point of manufacture/import to sale to end-users. There are three levels in the supply chain. The first level consists of manufacturers and importers of medicines. There is a significant division between these two sets of players. Manufacturers of controlled medicines are mostly locally owned companies (23 out of 28) that produce generic drugs mainly for the domestic market although the bigger companies are orientating towards export markets. Contract manufacturing is a tiny part of their business accounting for less than 5%.

Importers of controlled medicines, on the other hand, are dominated by MNCs from high-income countries that import patented medicines from their parent companies. Out of 54 importers in this study, 35 are foreign-owned, accounting for RM3.9 billion of total revenue or 87% of market share in 2014/2015. MNC importers maintain strong marketing teams that focus on demand creation and market directly to all providers (doctors, specialists, pharmacies, private and public hospitals). Local importers much smaller in size import generic medicines; their combined revenue was RM553 million or 13% of market share.

The second level of the supply chain comprises companies with an NPRA wholesale licence. Four categories of such companies were identified – independent distributors, Bumiputera agents, subsidiaries of manufacturers that own wholesale and distribution companies, and retail pharmacies that also engage in wholesaling. The last category is the largest in terms of numbers but accounts for only a small part of the market share. This market is dominated instead by two independent MNC distributors (Zuellig and DKSH) that provide logistics services to most of the MNC importers. Most of the time, these distributors do not take ownership of the products; they simply distribute on behalf of the principals. Then there are the Bumiputera agents that act as tender agents for non-Bumiputera local and foreign pharmaceutical companies bidding for government contracts. In between are subsidiaries of local pharmaceutical manufacturers that distribute their own products as well as those of unrelated companies.

Providers, establishments that provide medicines directly to patients and end users, form the third and final level of the supply chain. These are the some 6,978 private clinics run by general practitioners and specialists, 184 private hospitals, and 1,413 pharmacy companies in the private sector, and the 150 public hospitals and 2,871 MOH clinics in Malaysia. In the private sector, procurement of medicines is done directly with the manufacturers or importers or through wholesalers/distributors. In the public sector, procurement is carried out through three channels: the first is through Pharmaniaga, a government-linked company that has the exclusive right to supply about 39% of the MOH's formulary by value; the second is through open tender called by the MOH; and the third is through local purchase orders for value of below RM500,000. In most of these cases foreign MNCs and non-Bumiputera local companies bid for government tenders through Bumiputera agents who act as intermediaries between the MOH and the suppliers.

CHAPTER 3: MARKET SHARE AND MARKET CONCENTRATION

The previous chapters examined how the pharmaceutical sector is structured, who the major players are at each level of the supply chain, and the nature of relationships among these players.

This chapter will focus on one aspect of market structure, i.e., market concentration. How concentrated is the market among the pharmaceutical manufacturers, importers, distributors and providers in Malaysia? How many players are there in each of these sectors and how much of the market share is accounted for by the top players? How is market concentration measured? What is the level of market concentration in Malaysia compared with some other Asian countries? What is the relationship between market concentration and market behaviour? Does high market concentration naturally result in anti-competitive behaviour by firms in the market? What other factors determine or affect market behaviour? What is the relationship between market concentration and pricing, entry barriers to the industry, and costs of medicines?

This study measures market concentration at the level of company rather than of product. At company level, total sales revenue is not disaggregated by product line. Hence the market concentration ratio measures company concentration and not product concentration. The limitations of this approach are discussed in later sections.

3.1 Market Share and Concentration Among Manufacturers

As noted in Table 2.2, there are 28 manufacturers of controlled medicines in Malaysia. Financial data, available for only 23 of these manufacturers, showed they had combined sales revenue of RM1.7 billion and net profit of RM200 million in 2014.[86] Their combined sales represented 24% of the pharmaceutical market (RM7.2 billion) in Malaysia in 2014. This shows that manufacture of pharmaceuticals is still underdeveloped, with imports accounting for an overwhelming share of the Malaysian market, making the country a net importer of pharmaceuticals.

What are the salient characteristics of the pharmaceutical manufacturers? In terms of ownership, 23 are locally owned companies (one of these companies is partly foreign-owned) and 5 are foreign-owned. No MNC from developed countries has manufacturing plants in Malaysia. The 5 foreign-owned manufacturers are from India (3), Singapore (1) and Hong Kong (1). Y.S.P. is a Taiwanese-Malaysian joint venture.

[86] The financial data are for either financial year 2014 or 2015 depending on SSM data availability.

The locally owned Malaysian pharmaceutical manufacturers can be divided into two groups, namely the large ones with sales of over RM100 million, and the small and medium-sized enterprises. Among the large domestic pharmaceutical manufacturers, 6 are publicly listed (see Table 3.1). These are Pharmaniaga Berhad, Hovid Berhad, CCM DuoPharma Biotech Berhad, Kotra Industries Berhad, APEX Healthcare Berhad (parent of Xepa-Soul Pattinson) and Y.S.P. Southeast Asia Holding Berhad.[87] These companies are vertically integrated. They own subsidiaries that are involved at different levels of the supply chain – manufacturing, import, distribution/logistics (under wholesale licences), sales/marketing, retailing as well as research and development (R&D) that consists of discovering new processes to formulate off-patent drugs (as opposed to discovery of new originator medicines). Of these 6 listed companies, further distinction can be made between two that are government-linked companies, Pharmaniaga and CCM Duopharma, and the other four that are publicly owned without government ownership. The two GLCs, being majority owned and controlled by government, enjoy advantages in securing government business. In particular, Pharmaniaga, since its inception, has exclusive rights through a concession to supply pharmaceutical products to the Ministry of Health for an initial period of 15 years (1994 to 2009) that was extended for another 10 years till 2019.[88] All these advantages give the company considerable market power over others, that is not captured by simply looking at its concentration ratio.

Table 3.1: Six Public Listed Pharmaceutical Manufacturing Companies

	Public Listed Parent Company/Group	Manufacturers
1	Pharmaniaga Bhd.	Pharmaniaga Manufacturing, Idaman Pharma Manufacturing, Pharmaniaga Lifescience
2	Hovid Bhd.	Hovid Bhd.
3	CCM DuoPharma Biotech Bhd.	Duopharma (M) Sdn. Bhd., Upha Pharmaceutical
4	Kotra Industries Bhd.	Kotra Pharma (M) Sdn. Bhd.
5	APEX Healthcare Bhd.	Xepa-Soul Pattinson (M) Sdn. Bhd.
6	Y.S.P. Southeast Asia Holding Bhd.	Y.S.P. Industries (M) Sdn. Bhd.

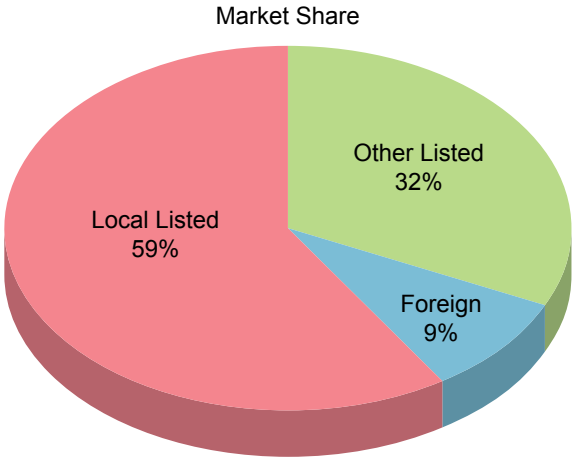
Source: Company annual reports

The 6 listed companies account for 59% of market share, while the remaining 14 locally owned SME pharmaceutical manufacturers take up 32% of market share. Foreign-owned manufacturing companies account for the remaining 9% of market share. (See Figure 3.1.)

[87] Y.S.P. is 35% Taiwanese-owned.

[88] Pharmaniaga is confident the concession will be extended for a further 10 years. Source: CIMB (2017). "Pharmaniaga Bhd. The Worst Is Over", Company Note, http://www.investing.com.my/clients/inveszcom/Downloads/Pharmaniaga_Bhd-The_worst_is_over_(CIMB)_17042017417201792547AM1.pdf. Accessed 23 September 2017.

Figure 3.1: Market Share of Manufacturers, 2014/5 (Market Size: RM1.7 billion)



Source: Calculated from Table 2.2 based on SSM data

To capture the level of market competition, two estimates are used: the concentration ratio (CR) and the Herfindahl-Hirschman index (HHI).[89] The CR measures how much of market share is accounted for by the top firms (for example, the top 3, 5, 10 or 20 firms), while the HHI measures the size of firms in relation to the industry and is an indicator of the level of competition in that industry. Both measurements indicate the level of market fragmentation and market power. An HHI of close to zero indicates perfect competition where no firm has any influence over market price, while an HHI of 10,000 indicates monopoly. An HHI of less than 1,500 denotes an unconcentrated (competitive) market; between 1,500 and 2,500 denotes a moderate level of concentration; and over 2,500 denotes a highly concentrated market.[90]

Market power is the ability of a firm in a particular market to determine or affect the price, supply of and even demand for the goods or services in that industry. In terms of pricing power, a firm with market power is able to raise the price above its marginal and long run average cost without significant loss to competitors. It is often believed that the higher the market share and concentration, the stronger the market power of the firms; and that such powers can result in certain types of market behaviour, normally anti-competitive in nature, and even influence market performance. However, size is not the sole determinant of market power. Other factors like barriers to entry or expansion into

[89] The Herfindahl-Hirschman index is a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in a market, and then summing the resulting numbers. The HHI figure can range from close to zero to 10,000. Empirical evidence suggests that, other things being equal, the concentration of firms in a market is an important element of market structure and a determinant of competition. The higher the HHI, the higher is the market's concentration and the closer the market is to being a monopoly.

[90] Hays, F.H. and S. Ward (2011). "Understanding Market Concentration: Internet based Applications from the Banking Industry", *Journal of Instructional Pedagogies*, http://files.eric.ed.gov/fulltext/EJ1096952.pdf, accessed 30 September 2017.

an industry and the patent system can enhance market power. On the other hand, there exist countervailing forces such as government policies to protect local industry, and the presence of monopsonistic buyers in the form of state authorities or insurance funds that influence market share and power.

In this report, market concentration can refer to a situation where a single firm has a dominant share of the market or where a small group of firms dominate the market. However, such market power should not be assumed to necessarily result in anti-competitive conduct; the latter has to be established on a case-by-case basis. It will also be argued that the standard measurements of market concentration, using CR and HHI based on company sales, are not adequate to understand market power and behaviour in the pharmaceutical sector due to issues with substitutability and lack of consumer sovereignty.

Based on sales revenue data for 2014/2015 for the 23 pharmaceutical manufacturers identified in Chapter 2, the concentration ratios and HHI for the market were estimated.[91] Table 3.2 shows that the top 3 companies enjoy a combined revenue share of 34.3%, and the top 5 and top 10 companies account for 53.9% and 85.7% of the total market share respectively in 2014/2015. Moreover, the HHI is reported at 824, which implies a relatively competitive market for pharmaceutical manufacturers in Malaysia.

Compared with the pharmaceutical sector in other Asian countries, the HHI for Malaysian pharmaceutical manufacturers is lower than the average normalized HHI for 350 Asian pharmaceutical firms that had an HHI of 1,990 in 2009, according to the Economist Intelligence Unit.[92] Interestingly, the same report also finds that the biggest pharmaceutical firms have less dominance than their counterparts in other industries such as the information technology services sector (HHI of 5,700) and the precision engineering sector (HHI of 9,300).

According to the research team of Torreya Partners, the global HHI for the world's pharmaceutical market was 2,100 (or 0.021) in 2016, which indicates a relatively high concentration among the major players.[93] A report by research and consulting firm ECORYS,[94] however, showed that the HHI for the European pharmaceutical market

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[91] One limitation of the HHI in this study is that it is based on aggregated sales revenue at the company level, which includes all products (pharmaceuticals and non-pharmaceutical products). It was not possible to obtain disaggregated sales revenue by product. In fact, studies of market concentration of medicines should be conducted at an even more detailed level of ATC 4 or 5 under the Anatomical Therapeutic Chemical (ATC) classification system. This issue is addressed in later parts of this chapter.

[92] Economist Intelligence Unit (EIU) (2012). Asia Competition Barometer, Pharmaceuticals, Statista, https://www.statista.com/statistics/314648/leading-global-pharmaceutical-companies-by-net-margin/, accessed 28 August 2017.

[93] Torreya Partners (2016). *Generic Pharmaceutical Industry Yearbook*, GPhA Conference Edition, February 2016.

[94] ECORYS (2009). "Competitiveness of the EU Market and Industry for Pharmaceuticals – Vol. II: Markets, Innovation and Regulation", http://www.pedz.uni-mannheim.de/daten/edz-h/gdb/09/vol_2_markets_innovation_regulation_en.pdf, accessed 28 August 2017.

ranged from 915 to 1,221, which is considered as unconcentrated. In comparison, the HHI for the Indian pharmaceutical sector was relatively low, ranging between 291-434 during 1996-2008, with profit ratios mostly recorded above 20%.[95]

In other words, even though the number of pharmaceutical manufacturers in Malaysia is small, market concentration among the manufacturers is considerably low and prices are highly competitive. Local pharmaceutical manufacturers in Malaysia produce only generic medicines where price competition among themselves as well as from Indian imports is intense.[96] Without patent protection, anyone with the technology can produce the medicines, and the main way to compete is through pricing and marketing strategy.[97] The local manufacturers' marketing expenditure is modest compared with that of manufacturers of originator medicines, which invest heavily in branding and marketing, creating another type of advantage for their products. Questioning the quality and efficacy of generics is also a strategy that has been identified in some anti-competition cases, as discussed in Chapter 6.

Table 3.2: Market Concentration for 23 Pharmaceutical Manufacturers

	Company	Ownership	Revenue (RM '000)*	Market Share	Concentration Ratios
1	Pharmaniaga Manufacturing Bhd	Local	206,260	12.4	CR3=34.3
2	Hovid Berhad	Local	188,406	11.3	CR5=53.9
3	Duopharma (M) Sdn. Bhd.	Local	176,961	10.6	CR10=85.7
4	Y.S.P. Industries (M) Sdn. Bhd.	Local	175,117	10.5	CR15=95.9
5	Ain Medicare Sdn. Bhd.	Local	152,638	9.1	
6	Kotra Pharma (M) Sdn. Bhd	Local	145,174	8.7	HHI=824
7	Upha Pharmaceutical Manufacturing (M) Sdn Bhd.	Local	109,048	6.5	
8	Hoe Pharmaceuticals Sdn. Bhd.	Local	105,979	6.4	
9	Xepa-Soul Pattinson (M) Sdn. Bhd.	Local	94,794	5.7	
10	Ranbaxy (Malaysia) Sdn. Bhd.	Foreign	76,378	4.6	
11	Royce Pharma Manufacturing Sdn. Bhd.	Local	44,923	2.7	
12	Sunward Pharmaceutical Sdn. Bhd.	Foreign	39,371	2.4	
13	Noripharma Sdn. Bhd.	Local	28,785	1.7	
14	SM Pharmaceuticals Sdn. Bhd.	Foreign	28,512	1.7	
15	Dynapharm (M) Sdn. Bhd.	Local	27,340	1.6	
16	Winwa Medical Sdn. Bhd.	Local	26,982	1.6	

[95] Available at http://shodhganga.inflibnet.ac.in/bitstream/10603/32697/13/13_chapter_5.pdf

[96] Other sources of generic imports, though in less significant amounts, are countries like Eastern European countries, Thailand and Indonesia.

[97] A survey was done by a generic manufacturer, who was interviewed for this Review, on retail pharmacies and private hospitals regarding factors that influence their purchasing decisions. For retail pharmacies, price, sales service and quality were ranked in that order of importance; for private hospitals it was quality, service and price.

	Company	Ownership	Revenue (RM '000)*	Market Share	Concentration Ratios
17	Malaysian Pharmaceutical Industries S/B.	Local	13,073	0.8	
18	KCK Pharmaceutical Industries Sdn. Bhd.	Local	10,731	0.6	
19	AV Manufacturing Sdn. Bhd.	Local	9,293	0.6	
20	Bio Molecular Industries Sdn. Bhd.	Local	3,485	0.2	
21	Teraputics Sdn. Bhd.	Local	2,983	0.2	
22	Xorix Sdn. Bhd.	Local	2,212	0.1	
23	Idaman Pharma Manufacturing Sdn Bhd	Local	147	0.0	
	TOTAL		**1,668,592**	**100.0**	

Note: * Financial data from SSM for financial year 2014 or 2015 depending on availability
Source: Calculated from Table 2.2, based on SSM data

In addition to competing among themselves, local manufacturers are exposed to price competition from generic imports of two types. First are generic medicines produced by established MNCs from high-income countries that enjoy brand recognition and loyalty. Many manufacturers of originator medicines also produce their own generic medicines.[98] Secondly, local generics face price competition mainly from Indian generic manufacturers but also increasingly from other countries like South Korea, Taiwan, Thailand and Eastern European countries. It was repeatedly stated in the interviews conducted for this study that it was very difficult to compete with Indian generics that are often much cheaper. For all these reasons, local pharmaceutical manufacturers are facing intense price pressure.

The tough competition and lack of market power are reflected in their financial performance data. The 2014/2015 average net profit margin for 20 manufacturers for which data were available was 12%. The average profit margin for the big 6 public listed companies was slightly better at 14% (see Table 3.3). But upon closer examination, of these 6 companies, the 2 with the highest profit margins of 20% or more are Pharmaniaga (26%) and CCM Duopharma (20%); both are GLCs that enjoy market advantage over the non-government-linked companies. Hovid's and Y.S.P.'s profit margins were in the low teens while that of Xepa-Soul Pattinson was higher at 19% and Kotra Pharma was an outlier with a 0.7% profit margin.[99] (See Table 2.2.)

The profit squeeze is even more intense for small local producers like Winwa Medical, Malaysian Pharmaceuticals and KCK Pharmaceutical, with profit margins of below 10% (refer to Table 2.2).

[98] In interviews with specialists and doctors in two private hospitals in Penang, and a pharmacist in a Kuala Lumpur specialist hospital, preference was expressed for "branded" generics, i.e., those produced by well-known MNCs rather than generic manufacturers.

[99] Kotra's profit margin of 0.7% in 2015 was unusual. In 2014 it was 3.8% and in 2016 it was 4.8%. Kotra's low margin is probably due to the high capital expenditure of its newly built plant.

Table 3.3: Net Profit Margin of Pharmaceutical Manufacturers, 2014/15	
Company	**Net Profit Margin**
6 public listed companies	14.2%
Listed companies excluding Kotra	16.9%
Local non-listed companies	14.2%
Foreign companies	-6.2%*
Average	12.0%

* Net profit margins of the 3 foreign companies were: Ranbaxy -30.0%, Sunward 10.5%, SM Pharmaceuticals 0.8%.
Source: Calculated from Table 2.2 based on SSM data

There is some degree of vertical integration, all downstream, among the large pharmaceutical manufacturers. None have any upstream integration. All of the manufacturers import their active pharmaceutical ingredients and other raw materials. The big companies have their own warehousing and distribution companies and market and sell directly to pharmaceutical providers. A few companies like Pharmaniaga, CCM Duopharma, Hovid and Apex Pharmacy Group own and operate retail pharmacies.

Some horizontal integration has occurred in the pharmaceutical manufacturing industry. For example, CCM entered into the pharmaceutical business through acquisition of Upha Corporation in 1995 and then further expanded through acquisitions of Duopharma in 2005 and Malayan Pharmaceuticals in 2007. In another case, in 2011, Boustead Holdings Berhad (owned by Lembaga Tabung Angkatan Tentera) acquired Pharmaniaga Berhad – Malaysia's largest integrated local healthcare company and generic pharmaceuticals manufacturer. In 2014, Pharmaniaga acquired Errita Pharma (Indonesia).

In general, while some large companies have expanded through vertical and horizontal integration with a corresponding rise in their market share, this has not increased market concentration in the industry noticeably; the pharmaceutical manufacturing sector remains highly competitive in terms of pricing and there is not much evidence of anti-competitive conduct in terms of price or quantity fixing.

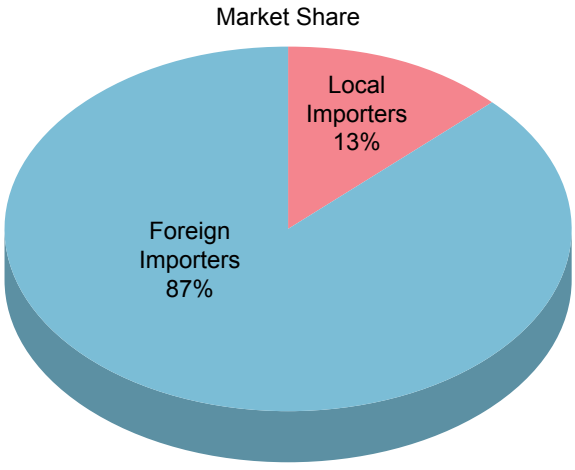
Despite the lack of market dominance and concentration, there are barriers to entry into the pharmaceutical manufacturing sector. These come mainly in the form of high capital costs in starting new manufacturing facilities, a strict regulatory regime, and the implementation of compulsory bioequivalence (BE) tests, including on a retrospective basis, for all controlled medicines by 2019. All these regulatory requirements will increase the manufacturers' costs of production. This may explain the fact that Kotra was the last locally owned company to enter the generic producer market, back in 1985.

3.2 Market Share and Concentration Among Importers

As noted in Table 2.3, there are 126 companies holding NPRA licences for the import of controlled medicines. However, in this study only 61 of these 126 companies are selected for the examination of market concentration. The criteria and process for selecting these companies were explained in Chapter 2. Financial data were available for 54 of the 61 companies. These 54 companies had combined sales revenue of RM4.4 billion and net profit of RM127 million in 2014/15.[100] (Refer to Table 2.4.) Their combined sales represented 61% of the Malaysian pharmaceuticals market (RM7.2 billion) in 2014. By contrast, the combined sales of 23 pharmaceutical manufacturers in Malaysia were only RM1.7 billion for the same period. This shows that Malaysia is still highly dependent on imports for pharmaceuticals.

What are the salient characteristics of these 54 pharmaceutical importers? There are clear differences between foreign importers that are mainly large MNCs and local importers in terms of market share and types of products. In 2014/2015, 33 foreign importers accounted for 87% of total revenue (RM3.9 billion) and 77% of total profit (RM98 million) in this sector. In contrast, 21 local importers took 13% of revenue (RM571 million) and 23% of profit (RM29 million). (See Figures 3.2 and 3.3.) Among foreign importers, the large MNCs dominate the market, as will be shown later. In terms of product type, MNCs import patented medicines from their parent companies while local importers handle mainly generic medicines.

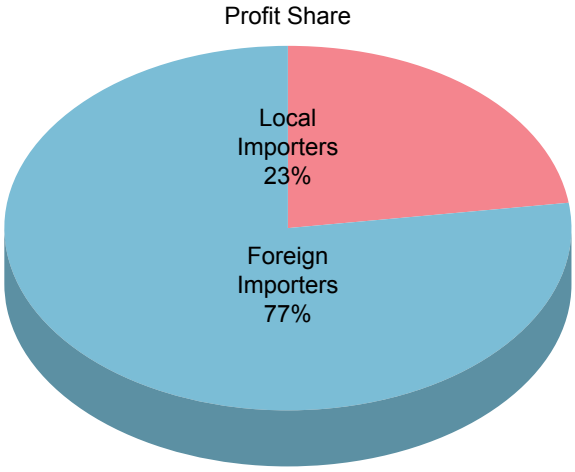
Figure 3.2: Market (Revenue) Share of 54 Pharmaceutical Importers in Malaysia by Ownership (2014/2015) (Market Size RM4.4 billion)



Source: Calculated from Table 2.4 based on SSM data

[100] The financial data were for either financial year 2014 or 2015 depending on SSM data availability. As with the pharmaceutical manufacturers, the sales revenue of these importers includes revenue not only from pharmaceuticals but from all products sold. It is not possible to disaggregate the sales revenue by type of product. Hence, the market concentration ratios measure company concentration and not product concentration. This is a limitation imposed by lack of detailed data. Another limitation is that no financial data were available for 7 of the 61 companies.

Figure 3.3: Profit Share of 54 Pharmaceutical Importers in Malaysia by Ownership (2014/2015)



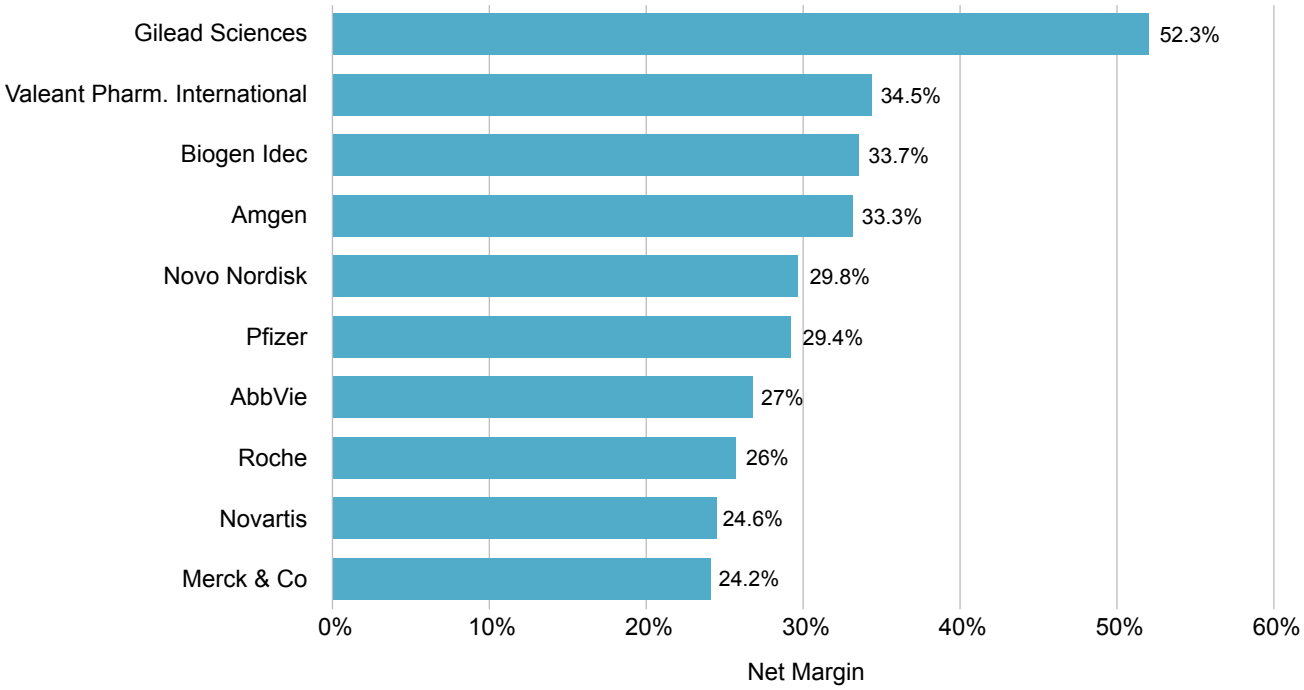
Source: Calculated from Table 2.4 based on SSM data

Many of the world's multinational pharmaceutical companies operate in Malaysia and are among the importers in this study. The top 10 importers (except CCM Pharmaceuticals) are well-known MNCs. The top 5 importers are Pfizer, Merck Sharp & Dohme, Bayer, Sanofi-Aventis and Novartis, each with annual sales exceeding RM370 million. The next 5 are GlaxoSmithKline (GSK), Roche, AstraZeneca, Merck and CCM Pharmaceuticals, with sales ranging from RM146 million to RM350 million. Major multinational pharmaceutical companies from developed countries do not produce drugs in Malaysia. All of them import patented drugs from their parent companies for sale in the country.

Despite the high sales revenue of MNC importers, the average profit margin (net profit after tax/sales revenue) of the 33 foreign importers is only 2.6%. Correspondingly, the amount of taxes paid is small (RM54 million) compared with sales revenue of RM3.8 billion. Taxes paid by local importers were RM13 million on sales of RM571 million. The profit margin of the top 10 importers in Malaysia ranged from 0.4% for Merck Sharp & Dohme to 7.3% for AstraZeneca (refer to Table 2.4). The average profit margin of the top 10 companies was 3.7%.

Figure 3.4 shows the profitability of the 10 most profitable pharmaceutical companies in the world. Their average profit margin was 26%, with Gilead leading at 52%.

Figure 3.4: Global Top Pharmaceutical Companies Based on Net Income Margin in 2014



Source: Statistica, 2014

Five of these companies – Pfizer, Novartis, Merck, Roche and AbbVie – have subsidiaries in Malaysia. The low profit margin (average of 2.4%) of their Malaysian subsidiaries stands in sharp contrast to the high margin (average of 26.2%) of their parent companies. (See Table 3.4.) As these companies import directly from their parent companies, such intra-company transactions may involve transfer pricing.[101] Such practices are common with MNCs. When transfer pricing occurs, companies can book profits in a country that may have a lower tax rate and this would affect the profitability of subsidiaries that originate the transfer pricing.

Table 3.4: Net Profit Margins of Parent versus Malaysian Subsidiaries, 2014

Company	Parent Company	Malaysian Subsidiary
Pfizer	29.4%	2.4%
AbbVie	27.0%	1.9%
Roche	26.0%	3.4%
Novartis	24.6%	2.6%
Merck	24.2%	1.6%
Average	**26.2%**	**2.4%**

Source: Calculated from Figure 3.4 and Table 2.4

[101] Transfer pricing is the setting of price at which one related company in a group sells or buys its goods or services to or from another related entity (e.g., between a parent and its subsidiary companies). The cost of goods or services sold to or bought from the other entity is the transfer price.

Locally owned pharmaceutical importers are much smaller in size. There were only 5 local companies among the top 20 importers. The largest is CCM Pharmaceuticals with sales of RM146 million, followed by Medispec (RM61 million), Healol Pharmaceuticals (RM53 million), United Italian Trading (RM40 million) and Germax (RM37 million).[102] The rest are small companies with sales of below RM35 million. Most local importers are members of MAPS. While foreign MNCs import patented medicines from their parent companies, local companies import generic medicines.

Based on 2014/2015 sales revenue data of the 54 pharmaceutical importers whose financial data were available, the concentration ratios and HHI of the market were estimated. Table 3.5 shows that the top 3 companies enjoy a combined revenue share of 29.0%, and the top 5 and top 10 companies account for 46.5% and 75.2% of the total market share respectively. The HHI is reported at 643, which implies a competitive market for pharmaceutical importers in Malaysia.

Table 3.5: Market Share and Market Concentration Ratios of 54 Pharmaceutical Importers

No	Company Name	Ownership	Revenue (RM '000)*	Market Share	Concentration Ratios
1	Pfizer (Malaysia) Sdn. Bhd.	Foreign	452,584	10.2%	CR3=29.0
2	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	Foreign	425,446	9.6%	CR5=46.5
3	Bayer Co. (Malaysia) Sdn. Bhd.	Foreign	408,665	9.2%	CR10=75.2
4	Sanofi-Aventis (Malaysia) Sdn. Bhd.	Foreign	404,825	9.1%	CR15=84.5
5	Novartis Corporation (Malaysia) Sdn. Bhd.	Foreign	370,162	8.4%	
6	GlaxoSmithKline Pharmaceutical Sdn. Bhd.	Foreign	349,387	7.9%	HHI= 642.9
7	Roche (Malaysia) Sdn. Bhd.	Foreign	299,327	6.8%	
8	AstraZeneca Sdn. Bhd.	Foreign	286,211	6.5%	
9	Merck Sdn. Bhd.	Foreign	185,462	4.2%	
10	CCM Pharmaceuticals Sdn. Bhd.	Local	146,541	3.3%	
11	Servier Malaysia Sdn. Bhd.	Foreign	117,975	2.7%	
12	Eli Lilly (Malaysia) Sdn. Bhd.	Foreign	101,634	2.3%	
13	AbbVie Sdn. Bhd.	Foreign	78,315	1.8%	
14	Medispec (M) Sdn. Bhd.	Local	60,852	1.4%	
15	Fresenius Kabi Malaysia Sdn. Bhd.	Foreign	55,254	1.2%	
16	Healol Pharmaceuticals Sdn. Bhd.	Local	53,326	1.2%	
17	Takeda Malaysia Sdn. Bhd.	Foreign	42,755	1.0%	
18	United Italian Trading (M) Sdn. Bhd.	Local	40,122	0.9%	
19	Germax Sdn. Bhd.	Local	37,052	0.8%	
20	Glenmark Pharmaceuticals (Malaysia) Sdn. Bhd.	Foreign	37,013	0.8%	

[102] Some large local importers such as Pharmaforte are left out due to absence of financial data as it is an exempt private company.

No	Company Name	Ownership	Revenue (RM '000)*	Market Share	Concentration Ratios
21	A. Menarini Singapore Pte. Ltd.	Foreign	33,824	0.8%	
22	Orient Europharma (M) Sdn. Bhd.	Foreign	32,953	0.7%	
23	Unimed Sdn. Bhd.	Local	32,754	0.7%	
24	Medidata Sdn. Bhd.	Local	31,821	0.7%	
25	Aspen Medical Products Malaysia Sdn. Bhd.	Foreign	31,603	0.7%	
26	Eisai (Malaysia) Sdn. Bhd.	Foreign	31,477	0.7%	
27	Idaman Pharma Sdn. Bhd.	Local	26,695	0.6%	
28	Grifols Malaysia Sdn. Bhd.	Foreign	24,875	0.6%	
29	Jetpharma Sdn. Bhd.	Local	22,812	0.5%	
30	Winthrop Pharmaceuticals (Malaysia) Sdn. Bhd.	Foreign	18,306	0.4%	
31	Somedico Sdn. Bhd.	Local	17,348	0.4%	
32	Unam Pharmaceutical (M) Sdn. Bhd.	Foreign	17,135	0.4%	
33	Biocare Pharmaceutical (M) Sdn. Bhd.	Local	16,757	0.4%	
34	Averroes Pharmaceuticals Sdn. Bhd.	Local	16,680	0.4%	
35	Mundipharma Pharmaceuticals Sdn. Bhd.	Foreign	16,618	0.4%	
36	Komedic Sdn. Bhd.	Local	15,234	0.3%	
37	Ferring Sdn. Bhd.	Foreign	12,835	0.3%	
38	Mepharm (Malaysia) Sdn. Bhd.	Local	12,051	0.3%	
39	First Pharmaceutical Sdn. Bhd.	Local	10,690	0.2%	
40	Mansa Pharma (M) Sdn. Bhd.	Local	8,427	0.2%	
41	Hyphens Pharma Sdn. Bhd.	Foreign	8,295	0.2%	
42	Ziwell Medical Sdn. Bhd.	Local	7,239	0.2%	
43	TRB Chemedica Malaysia Sdn. Bhd.	Foreign	6,955	0.2%	
44	Stadpharm Sdn. Bhd.	Local	6,724	0.2%	
45	Nano Medic Care Sdn. Bhd.	Local	5,214	0.1%	
46	Kireen Pharmaceutical Sdn. Bhd.	Foreign	3,069	0.1%	
47	Cipla Malaysia Sdn. Bhd.	Foreign	2,074	0.0%	
48	Atlantic Laboratories (M) Sdn. Bhd.	Foreign	2,019	0.0%	
49	Ubisson Sdn. Bhd.	Local	1,504	0.0%	
50	Eucogen Sdn. Bhd.	Local	1,300	0.0%	
51	Exeltis Pharma Sdn. Bhd.	Foreign	914	0.0%	
52	SPG Pharma (Malaysia) Sdn. Bhd.	Foreign	303	0.0%	
53	UCB Trading (Malaysia) Sdn. Bhd.	Foreign	290	0.0%	
54	Zest Pharma Sdn. Bhd.	Foreign	156	0.0%	
	TOTAL		**4,429,857**	**100.0**	

Source: Calculated from Table 2.4 based on SSM data

Of the 54 importers, 12 have sales of over RM100 million and these are the large MNCs (with the exception of CCM Pharmaceuticals). Among the 33 MNCs, there is also a division between the large MNCs and the smaller ones, of which 13 have sales of less than RM20 million.

Does low market concentration, as measured by the HHI, translate into lack of market power over pricing, low product prices, low profit and absence of anti-competitive behaviour?

As mentioned above, this study measures market concentration at the level of company rather than of product. At company level, based on total sales revenue not disaggregated by product line, the market is not concentrated. But all the large MNCs sell patented products over which, by definition, they enjoy exclusive rights. Medicines, unlike other consumer goods, are less likely to be substitutable. Hence the holder of the patent on a particular medicine has considerable power over the price and supply of that product during the patent protection period if there is no competition.

Indeed, many jurisdictions are beginning to recognize that in the case of pharmaceutical products, the classic Hypothetical Monopolist test (HMT)[103] for defining the market is merely a starting point in any competition inquiry. As market definition is essentially about substitutability, the special nature of pharmaceutical products must be recognized. As stated above, pharmaceuticals are not like other commodities.

As Jonathan Berger explains: "Pharmaceutical technologies are unlike soft drinks or cell phones. A particular increase in the price of Coca Cola may see consumers switching either to Pepsi Cola or other soft drinks; similarly, an increase in the cost of the iPhone 5 (over the previous model) may result in consumers willing to give the BlackBerry Z10 a chance. But even a substantial increase in the price of a drug to treat breast cancer will not see patients switching to antifungal medication, or even to another drug that targets a different cancer. In the health technologies field, substitutability takes on a very particular flavour."[104]

Since the pharmaceutical market is a differentiated product market,[105] the intensity of competition and substitution between products is a more important indicator of market

[103] For an explanation of the test, see MyCC Guidelines on Market Definition: http://www.mycc.gov.my/sites/default/files/handbook/MYCC-4-Guidelines-Booklet-BOOK4-10-FA-copy_market-defination.pdf

[104] Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP, at page 98: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2439416

[105] In its decision on the AstraZeneca case, the European Commission stated: "[A] properly defined market does not need to include all functionally interchangeable products, as such interchangeability between products normally only defines the outer boundaries of a product market but may not be a decisive criterion. When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may compete in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure." Commission Decision, 15 June 2005, para 370, page 88: http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf

power than market shares. The assessment of market dominance then is more product-specific. The pharmaceutical market should not be studied as a single market but as a sum total of a large number of individual sub-markets. This is because medicines used in the treatment of a particular health condition cannot be substituted with medicines used in the treatment of another health condition.[106] (See further discussion in Chapter 6.)

In addition, it is not the customer who decides when and whether to switch from one product to another but the doctor. Product attributes are the major factor in the prescribing decision and non-price competition is more important and price competition less so. Branded drug manufacturers focus marketing efforts on physicians: their sales representatives discuss product claims and clinical evidence, and often distribute samples.[107]

Given the above, how do we identify products that are sufficiently close substitutes in demand to the product being considered? Originator companies and the European Commission's Competition Directorate have adopted the practice of defining the relevant product market according to the therapeutic classes set out in the Anatomical Therapeutic Chemical (ATC) classification system of the WHO.

Most originator companies submitted that the market coincides with the ATC 3 therapeutic classes in the ATC system.[108] This would, however, only be the starting point. In the Servier case discussed in Chapter 7, the European Commission went on to consider the prescribing patterns of physicians. The relevant portion of the Commission's decision is as follows: "Starting from the product that is the subject of the practices under review, a relevant product market comprises all those products which are regarded as sufficiently substitutable by the consumer by reason of the products' characteristics, their prices and their intended use. Perindopril aims at lowering blood pressure. There were many other medicines with the same therapeutic use ... Therefore, at first sight, it may not seem completely intuitive that a medicine such as perindopril may constitute a market in its own right, where many other similar medicines were available. However, certain functional similarities are not sufficient to establish that those other medicines represented sufficiently close substitutes to constrain Servier's behaviour given the circumstances of the case."[109]

The Commission then considered the side effects that anti-hypertensive medicines can cause from one patient to another. It considered that a doctor would be unlikely to risk provoking side-effects by switching a patient from one medicine to another, for a few

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[106] Mehta A., H. Hasan Farooqui and S. Selvaraj (2016). "A Critical Analysis of Concentration and Competition in the Indian Pharmaceutical Market", *PLoS ONE*, 11(2): e0148951. doi:10.1371/journal. pone.0148951; see Competition and Regulation Issues in the Pharmaceutical Industry 2001, OECD, DAFFE/CLP (2000) 29.

[107] Competition and Regulation Issues in the Pharmaceutical Society 2000, OECD Policy Roundtables, DAFFE/CLP(2000)29, 6 February 2001, para 4.6, page 45: https://www.oecd.org/competition/sectors/1920540.pdf

[108] *Ibid.* page 11; see also Market Definition and the Characteristics of Pharmaceutical Markets, Canadian Bar Association 2009 Competition Law Fall Conference, Andrew Tepperman, Charles River Associates: http://www.cba.org/cba/cle/PDF/COMP09_Tepperman_paper.pdf

[109] Case AT.39612 - Perindopril (Servier), European Commission, 30 September 2016, paragraphs 1230-1238, http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12422_3.pdf

euros of savings in monthly treatment. This well-known phenomenon is often referred to as “the doctors’ inertia”.

The Commission went on to state: “… the degree of substitutability of a given molecule with other molecules will therefore depend, among other things, on the degree of doctors’ inertia and on the relative proportion of continued-use patients out of all patients treated with a given medicine. These may differ over time and depend on the type of pathology. These are empirical questions which require due consideration on a case-by-case basis ... With respect to perindopril, it is established that perindopril could benefit from both effects. Already prior to the investigated period the medicine had accumulated a large base of continued-use patients. Those patients were expected to continue the treatment for a significant period, while the existing group of loyal prescribers continuously provided for an inflow of new patients ... The combination of the aforementioned factors, the ex ante uncertain effects of treatments and the doctors’ personal experience, effectively restricted the substitutability between available therapies.”

The Commission found that in the case of perindopril, decreases in the prices of other medicines intended for the same use did not negatively affect the sales of perindopril, in contrast with generic perindopril that could challenge all the existing sales of originator perindopril.

As observed in the OECD Competition Committee: “An increasing number of jurisdictions are reconsidering the role of market definition and embracing new approaches to overcome its limitations in particular cases. Some jurisdictions have emphasised that market definition is not an end in itself, does not need to be a first step in any competition analysis nor has to be employed in all cases. Rather than abandoning market definition, most jurisdictions complement it with additional approaches ... [For example, the] 2010 US Horizontal Merger Guidelines state that market definition is only one of many available tools to assess harm ... and outline that the analysis of competitive effects need not begin with market definition ... In the United Kingdom, the revised merger assessment guidelines also reflect the shift from defining the relevant market to analysing the intensity of competition ... A number of other competition authorities are also increasingly considering new approaches, such as in Ireland, where merger guidelines are currently undergoing review.”[110]

Further, for monopolization or abuse-of-dominance cases, evidence relating to the direct effects of anti-competitive practices or other conclusive evidence of abuse has also been proposed. In cases of monopolization and abuse of dominance, instead of establishing dominance by looking at market share thresholds, it has been suggested to bypass the definition of the relevant market and establish dominance by considering the direct effects of the impugned conduct.[111]

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[110] Market Definition 2012, OECD Policy Roundtables, DAF/COMP(2012)19, 11 October 2012, para 5, page 13: http://www.oecd.org/daf/competition/Marketdefinition2012.pdf

[111] *Ibid.*, para 3, page 13.

Patent holders lose market power over pricing once a patent expires, and prices can subsequently plunge dramatically. As discussed in Chapter 6, certain patent strategies may be used to maintain market exclusivity.

In short, market power among pharmaceutical importers is largely derived from the patents granted on a product that create market dominance or monopoly, and not from market concentration per se at companies' level. In Malaysia, this dominance is confined to the large MNCs that import patented medicines from their parent companies. Local importers of generic medicines do not enjoy such privileges: the level of competition among them is intense, prices are highly competitive, and profit margins are low.

Establishing an import business does not require high levels of capital or technology. The primary requirements are good connections with suppliers of pharmaceuticals and a registered office. In the case of MNCs, they import from their parent companies. All logistical services are available and provided by specialized distributors. Therefore, MNC importers bring in little capital investment, as shown in Table 3.6. The Companies Commission of Malaysia (SSM) data show that the average capital investment of foreign importers is RM2.1 million per company, which is one-third that of local importers (RM6.1 million).

A final point is that it is often expected that market power conferred on a patent holder should translate to high profit. Yet, we do not see this happening in Malaysia. What we find is that the profit margins of the large MNCs operating in Malaysia are very low. This unexpected phenomenon and the possible causes have been addressed in preceding paragraphs.

Table 3.6: Capital Investments of Importers by Ownership, 2014/2015

	Capital Investment	Capital Investment per Company
Foreign importers	69,449,479	2,104,530
Local importers	128,296,926	6,109,377

Note: Capital Investment = Fixed Assets + Investments
Source: Calculated from SSM data

3.3 Market Share and Concentration Among Wholesalers

Unlike the manufacturing and import sectors of the pharmaceutical sector which have fewer players, the wholesale sector (which is predominantly about distribution services) is more crowded with both big and small players. This sector is highly skewed, with a few large companies dominating the market.

Table 2.5 shows 1,257 companies holding NPRA wholesale licences to distribute and sell pharmaceutical products, of which 709 are licensed to distribute controlled medicines. This study focuses on these 709 companies. Sixty-nine of these companies were selected for the purpose of estimating market concentration. The criteria for and process of selecting these companies were explained in Chapter 2.

Of the 69 companies with wholesale licences, financial data were available for only 57 companies. These 57 will represent the population used for calculating market share and concentration in the pharmaceutical wholesale sector. These 57 wholesalers had combined sales of RM14.4 billion and combined net profit of RM123 million in 2014/2015 (see Table 2.6).[112]

Table 3.7: Market Share and Concentration Ratios of Pharmaceutical Wholesale Sector, 2014/2015

No	Company Name	Revenue (RM '000)*	Market Share	Concentration Ratios
1	DKSH Malaysia Sdn. Bhd.	5,479,889	38.0%	CR3=77.1
2	Zuellig Pharma Sdn. Bhd.	3,937,480	27.3%	CR5=83.0
3	Pharmaniaga Logistics Sdn. Bhd.	1,697,269	11.8%	CR10=92.9
4	Primabumi Sdn. Bhd.	488,538	3.4%	CR15=96.4
5	Summit Company (Malaysia) Sdn. Bhd.	361,919	2.5%	
6	Pharmaserv Alliances Sdn. Bhd.	349,695	2.4%	HHI=2370.2
7	Apex Pharmacy Marketing Sdn Bhd	322,924	2.2%	
8	M.S. Ally Pharma Sdn. Bhd	318,752	2.2%	
9	Quality Reputation Sdn. Bhd.	253,226	1.8%	
10	Mutiara Murni Sdn. Bhd.	188,458	1.3%	
11	Antah Pharma Sdn. Bhd.	137,108	1.0%	
12	LF Asia Sebor (Sarawak) Sdn.Bhd.	95,833	0.7%	
13	Geliga Sistem Sdn. Bhd.	94,045	0.7%	
14	Hovid Pharmacy Sdn. Bhd.	85,218	0.6%	
15	Tamasetia Resources Sdn. Bhd.	78,118	0.5%	
16	LF Asia (Malaysia) Sdn. Bhd.	73,278	0.5%	
17	Teraju Farma Sdn. Bhd.	54,878	0.4%	

[112] Again we face the problem of not being able to disaggregate the sales revenue data. This is particularly acute in the wholesale sector as the combined sales of the 57 pharmaceutical wholesale companies (RM14.4 billion) are twice the sales value of the pharmaceutical market (RM7.2 billion).

No	Company Name	Revenue (RM '000)*	Market Share	Concentration Ratios
18	Pharmex Sdn. Bhd.	39,093	0.3%	
19	Prestige Pharma Sdn. Bhd.	32,057	0.2%	
20	Bioscenergy International Sdn. Bhd.	31,710	0.2%	
21	Propharm (M) Sdn. Bhd.	30,329	0.2%	
22	Oratis Pharmaceuticals Sdn. Bhd.	28,579	0.2%	
23	Uni Drug House Sdn. Bhd.	26,327	0.2%	
24	Dynapharm Marketing (M) Sdn. Bhd.	25,883	0.2%	
25	Advance Pharma Sdn. Bhd.	22,085	0.2%	
26	Pharm-D Sdn. Bhd.	21,726	0.2%	
27	Baroko Sdn. Bhd.	19,025	0.1%	
28	Kuala Lumpur Pharmacy (W.O) Sdn. Bhd.	12,911	0.1%	
29	Antah Bumimedic Sdn. Bhd.	11,458	0.1%	
30	Yin Woh Tong Medical Supplies Sdn. Bhd.	9,580	0.1%	
31	Pharmex Pharma (Sarawak) Sdn. Bhd.	9,120	0.1%	
32	Ecopharm Sdn. Bhd.	8,464	0.1%	
33	Zulat Pharmacy Sdn. Bhd.	8,185	0.1%	
34	Medical Supplies (Sarawak) Sdn. Bhd.	6,823	0.0%	
35	Farmasi Utama Wholesales Sdn. Bhd.	6,563	0.0%	
36	Almedico Sdn. Bhd.	5,693	0.0%	
37	Healthcare Solution Sdn. Bhd.	5,636	0.0%	
38	Zontron Pharmaceuticals Sdn. Bhd.	5,220	0.0%	
39	J.Bio Medic Marketing Sdn. Bhd.	4,765	0.0%	
40	Medical Supplies (Labuan) Sdn. Bhd.	3,574	0.0%	
41	LF Mercu Sdn. Bhd.	2,906	0.0%	
42	Subang Chemist Sdn Bhd	2,702	0.0%	
43	Penta Healthcare Sdn. Bhd.	2,507	0.0%	
44	Pharmaexpress Sdn. Bhd.	2,478	0.0%	
45	J S Pharma Concept Sdn. Bhd.	1,931	0.0%	
46	Medical Supplies (Sabah) Sdn. Bhd.	1,776	0.0%	
47	Bemed Pharma Sdn. Bhd.	1,644	0.0%	
48	SC Pharmacare Sdn. Bhd.	1,539	0.0%	
49	Alpha Bio Medic (M) Sdn. Bhd.	947	0.0%	
50	Pharmserve Pharma Sdn. Bhd.	687	0.0%	
51	AJ Research & Pharma Sdn. Bhd.	539	0.0%	
52	IPH Pharmaceuticals Sdn. Bhd.	496	0.0%	
53	Alpharme PLC Sdn. Bhd.	288	0.0%	
54	Bumimedic (Malaysia) Sdn. Bhd.	267	0.0%	
55	Suaut Enterprise Sdn. Bhd.	183	0.0%	
56	Pharmarise Sdn. Bhd.	155	0.0%	
57	Jinaun Pharma Sdn. Bhd.	5	0.0%	
	TOTAL	**14,412,484**	**100.0**	

Source: Calculated from SSM data

The pharmaceutical wholesale sector is marked by a high degree of market concentration. The top 3 companies accounted for 77% of the market share, the top 5 accounted for 83% and the top 10 accounted for 93% of market share. The HHI at 2,370 suggests a relatively high degree of market concentration. (See Table 3.7.)

There are only three companies with sales of over RM1 billion. Top of the league is DKSH with RM5.5 billion in sales, followed by Zuellig (RM3.9 billion) and Pharmaniaga (RM1.7 billion). DKSH and Zuellig are MNCs while Pharmaniaga is a local GLC. Pharmaniaga has an exclusive concession to supply the MOH's procurement of pharmaceuticals. Hence it owns and runs huge warehouse and delivery facilities. DKSH, Zuellig and Pharmaniaga Logistics are independent distributors that provide logistics services to their clients, as described in Chapter 2. However, DKSH is much more diversified and its healthcare division also undertakes marketing and sales.

In the next tier are 8 locally owned companies with sales of between RM100 million and RM500 million (see Table 2.6). These can be divided into two groups. One group consists of 6 Bumiputera companies – Primabumi, Pharmaserve Alliance, M.S. Ally, Quality Reputation, Mutiara Murni and Antah Pharma – with combined sales of RM1.7 billion or 12% of market share. Bumiputera agents stand as intermediaries between their principals (non-Bumiputera pharmaceutical companies that bid for government procurement contracts) and public hospitals. If the sales of Pharmaniaga Logistics are added to the other big 6 Bumiputera agents, the total sales come to RM3.4 billion or 24% of market share. The second group, such as Apex Pharmacy Marketing and Summit, are local wholesalers/distributors that provide traditional logistical services. Apex is a large vertically integrated company with manufacturing, import, distribution and retailing arms. While Apex distributes the products of its related companies, a major part of its business is offering logistics services to unrelated companies.

With the top 10 companies taking 93% of the market, the remaining 7% is shared between 47 companies, most of which are small wholesalers with sales of a few million. The bottom 29 companies all have sales of below RM10 million. A few exceptions in this group are some foreign companies, the most prominent of which is LF Asia. LF Asia offers traditional distribution services; it also does marketing for some large MNCs, in particular Gilead Sciences, that do not have physical presence in Malaysia. As seen in Table 3.7, there are two LF Asia companies in the group with combined revenue that equals 1.2% of market share.

Of the three sets of players in the pharmaceutical sector examined above, i.e., manufacturers, importers and wholesalers/distributors, the sector with the highest market concentration (based on the HHI) is the wholesale sector. Here we find the top three companies taking 77% of market share. Based on the HHI, one is inclined to conclude that these companies enjoy oligopolistic power, exercise a high degree of control over prices, reap high profit margins and are disposed to engage in anti-competitive conduct. However,

interviews conducted for this study – with wholesalers as well as the manufacturers and importers which are their paying clients (principals), and with providers like pharmacies, private hospitals and GPs – provided little evidence that wholesalers have market power.

As discussed in Chapter 2, the big pharmaceutical distributors like DKSH and Zuellig are not like the traditional wholesalers who buy and sell. Most of the time they do not take ownership of the products they distribute. They offer specialized logistics and financial services to their principals; they have no control over pricing. All marketing and pricing are done by their principals.

Market concentration also does not translate into high profit margins because the distribution industry is a high-volume business with thin margins. The average net profit margin for the selected 57 wholesale/distributor companies was 0.9% in 2014/2015. The profit margins for the three largest distributors were 0.5% for DKSH, 0.3% for Zuellig and 1.8% for Pharmaniaga. (See Table 2.6.)

The pharmaceutical wholesale industry is a two-tier system. Two to three players make up the top tier in this industry. Here entry barriers are high due to high capital investments and loyal relationships that are difficult to penetrate. Considerable capital investments are required to establish modern and state-of-the-art storage and distribution systems. For example, the total fixed assets of Zuellig and Zuellig Pharma Properties (a related company that owns the plant) amounted to RM78 million, Pharmaniaga RM172 million and DKSH RM37 million. Furthermore, DKSH and Zuellig have established longstanding relationships with pharmaceutical MNCs that are difficult to penetrate.

The second-tier companies in this market are small and highly competitive. Fixed capital investments are modest. Most of these companies serve local importers whose volume and value of business are low. While entry barriers into the second-tier market are weak, they remain very high for the first tier and it is difficult for local importers to break into the tier-one market.

3.4 Market Concentration at the Level of Providers

This study did not calculate market share and concentration among providers due to the large number of players at this level and time constraints in collecting financial data on these thousands of establishments. Nevertheless, some preliminary observations can be made.

There are close to 7,000 GP and specialist clinics in Malaysia, most of which are single clinics owned and operated by a doctor. While several group clinics have been established over the years, none is so large as to dominate the market. The largest group clinics like Qualitas and Mediviron each owns and operates about 200 clinics. In short, it is a highly competitive market.

With 184 private hospitals in Malaysia, this market is also saturated and competitive. Although there are a few large hospital chains like Pantai Hospitals and KPJ, there exist enough smaller private hospitals that have carved a niche market for themselves to maintain a competitive market in this sector.

This study estimated there are 1,413 retail pharmacy companies with 2,098 outlets in Malaysia, of which 86% are single-outlet pharmacies owned and run by individual pharmacists. While chain pharmacies are few in number, the large ones with between 10 and 30 outlets, and 3 with over 40 outlets wield considerable market power. Information obtained from interviews with pharmacists revealed that chain pharmacies commanding large sales volume exert much market power over their suppliers. Suppliers have to pay listing fees, display fees and other types of incentives to chain pharmacies for selling their products.

Malaysia does not regulate the price of medicines. It is left to providers to charge what they feel the market can bear. While providers do not have power to determine the overall market price, they have considerable control over the price they charge their clients. This is due to the unequal nature of the relationship between doctors and their clients – patients do not choose their medicines, which are instead prescribed by doctors. This inherent information asymmetry, accentuated by doctors not providing detailed costing of their services and medicines to patients, gives clinics and private hospitals power to determine the product dispensed and the price charged. In this regard, GPs and private hospitals have an advantage over pharmacies in their pricing policies. Several studies show that the price of drugs tends to be higher in private clinics and hospitals compared with pharmacies.[113]

Several cases of alleged anti-competitive conduct were shared in our interviews. The most prevalent type of practice is selling to different providers at different prices. This can be in the form of price, i.e., discount given, or more often in the form of quantity, i.e., bonus given for larger quantity bought. This is sought to be justified in the name of bulk buying. Depending on one's view, it is termed as either differential pricing or discriminatory pricing. Irrespective of terminology, however, the community pharmacies are the ones disadvantaged. With the introduction of the Good Pharmaceutical Trade Practice, the situation has improved.

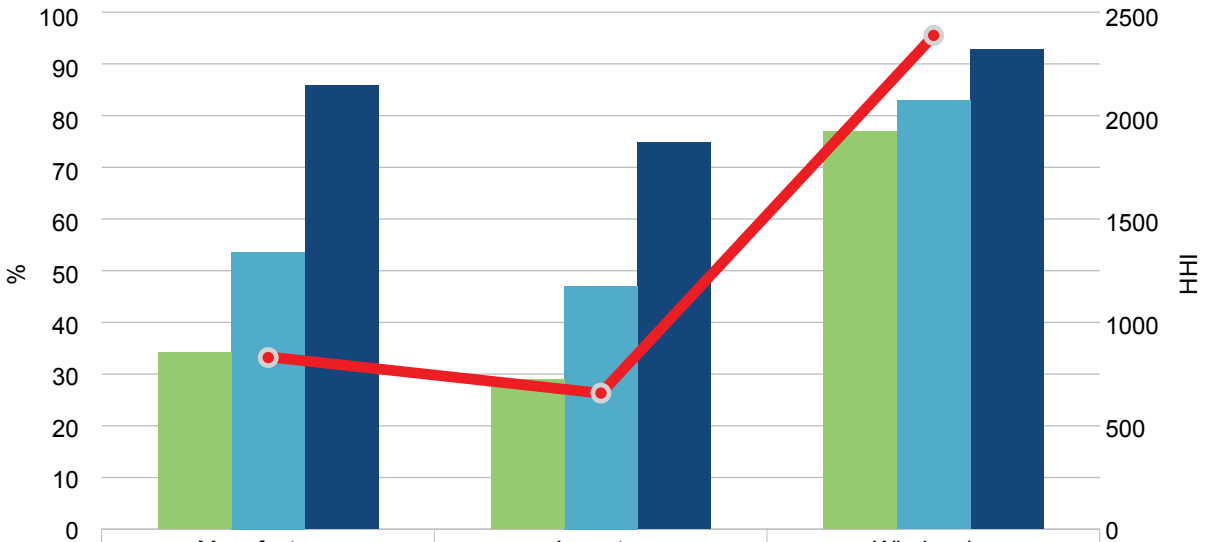
[113] Hassali, M.A. et al. (2014). "Assessment of Medicine Prices among Community Pharmacies and General Practitioners in the State of Penang, Malaysia", School of Pharmaceutical Sciences, Universiti Sains Malaysia. Babar, Z. et al. (2005). "A survey of medicine prices availability, affordability and price components in Malaysia using the WHO/HAI methodology", a research report from University College Sedaya International and Universiti Sains Malaysia in collaboration with World Health Organization and Health Action International.

3.5 Conclusion

Figure 3.5 provides a summary of market concentration in the Malaysian pharmaceutical sector. The pharmaceutical market is competitive at the level of generic manufacturers and importers. In fact, the concentration ratios for the top 3 companies (CR3) in both these sectors are very similar, in the region of 30%, though the HHI is slightly higher for manufacturers (824) than for importers (643). In contrast, the wholesalers and distributors market is highly concentrated, with an HHI of 2,370 and CR3 of 77%.

However, market concentration does not necessarily translate into market power. Other factors influence the ability of companies to determine market price, such as patents, supply conditions, entry barriers and prevalence of anti-competitive conduct. In other words, there is no strong correlation between market concentration (traditionally defined as sales revenue share), market power and anti-competitive behaviour.

Figure 3.5: Market Concentration in the Malaysian Pharmaceutical Sector



	Manufacturer	Importer	Wholesaler
CR3	34	29	77
CR5	54	47	83
CR10	86	75	93
HHI	824	643	2370

Source: Compiled from Tables 3.2, 3.5 and 3.7

There are two reasons for this. The first is due to data limitations. Measuring market concentration using aggregated sales data at company level is inaccurate as the data include products other than the ones studied. Second, the assessment of substitutability in defining market and market power in the pharmaceutical sector is unique by reason of the characteristics of the products in question. Functional similarities are insufficient to establish substitutability as the effectiveness and side effects of taking a product can differ from one patient to another. In addition, there is asymmetry of knowledge between consumers and providers, and the fact that prescribing doctors may not know the price sensitivity of a particular patient; or in treatment, a patient's medical costs may be of a lesser priority. For these reasons, market concentration and price-setting power in relation to pharmaceuticals are often examined at a very detailed level, frequently down to ATC 5.

In the manufacturing sector, the market is competitive because these companies are producing generic drugs on which there are no exclusive rights. While it may not be easy for new players to enter the market due to high capital outlay, there are enough existing players in the market to make for a competitive environment. There is price competition particularly from cheaper generic drugs imported from India and, to a lesser extent, from other countries (Eastern European countries and Southeast Asian countries such as Indonesia and Thailand).[114] There is also little evidence of anti-competitive conduct in terms of collusion or price fixing.

In the importers' sector, while market concentration is low, there is a high degree of market power concentrated among the major MNC importers. Market concentration in terms of sales revenue does not capture this market power because it is measured at company level and not at product level. The high degree of market power comes from importing patented products which grant these MNCs pricing power. MNCs tend to further extend their market exclusivity through secondary patents (after expiry of molecule patents) and other methods.[115] For example, there are two cases where MNCs initiated patent infringement claims against local manufacturers and importers, with one case successfully defended (Hovid) and one settled (Pharmaforte).[116] In contrast, local importers of generic drugs face a high level of competition and have to contend with both MNC importers and local manufacturers of generics.

The high degree of market concentration in the wholesale and distributors sector does not translate into market power because these companies do not take ownership of the goods they distribute. They primarily provide logistics services and have no market power in terms of control over pricing. They do not seem to enjoy high profit margins. The average

[114] Information from interviews with 3 generic drug manufacturers.

[115] See Chapter 6 for a discussion on patents and competition. Other methods for extending market power include life-cycle management, e.g., selling a medicine as an immediate-release product during the patent period and then switching to a modified-release version just before the patent expiry. A generic product waiting to enter the market would have been prepared as an immediate-release product.

[116] Interviews with the 2 companies concerned. See also the patent infringement case of KLHC (Commercial Division) Civil Suit No. 22IP-72-12/2014), http://kl.kehakiman.gov.my/sites/kl.kehakiman.gov.my/attachments/merck_sharp_v_hovid_(4).pdf

net profit margin for the industry is around 0.9%. Their profits arise from handling high volumes of sales. It should be noted, however, that the big players are in a better position to diversify within the pharmaceutical sector and beyond, DKSH being an example.

Finally, at the providers' level, the market is highly competitive among the GPs. One of the doctors interviewed for this study said that many GPs are shutting down their clinics due to poor business. This is corroborated by a news report based on a study of 1,800 GPs which stated that as many as 500 GP clinics closed down between 2014 and 2016 due to poor business.[117]

The private hospital market is saturated and competitive although private hospitals still manage to charge higher prices for medicines than GPs and pharmacies. The retail pharmacy market is also highly competitive. A study by Hassali et al. shows that there is a severe price war going on among the pharmacies and their profit margins have declined significantly over the years.[118] This sector is facing the pressure of consolidation as chain pharmacies begin to take over smaller community pharmacies.

[117] Loh, F.F. and M. Kumar (2017). "Clinics closed due to poor business", The Star Online, 22 June 2017, http://www.thestar.com.my/news/nation/2017/06/22/clinics-closed-due-to-poor-business-gps-seeing-fewer-patients-amid-rising-operating-costs/

[118] Hassali, M.A., S.T. Tan, F. Saleem and A. Alradsheedy (2014). "Assessment of Medicine Prices Among Community Pharmacies and General Practitioners in the State of Penang, Malaysia", School of Pharmaceutical Sciences, Universiti Sains Malaysia.

CHAPTER 4: MARKET DOMINANCE AND IMPACT ON AVAILABILITY, AFFORDABILITY AND ACCESSIBILITY OF MEDICINES

The objectives of the Malaysian National Medicines Policy are to promote equitable access to the use of safe, effective and affordable essential medicines[119] of good quality to the population. This chapter examines the issues of availability, affordability and accessibility of medicines in Malaysia and their relationship to market dominance where possible.

Although there are few published studies that provide current data, the literature that is reviewed in this chapter does raise issues that are pertinent for new research and analysis.

However, the MOH systematically monitors the public sector medicine needs and use and there is up-to-date price and related information for MOH procurement and delivery of treatment in public health facilities. Every few years, the MOH publicly releases Malaysian Statistics on Medicines that include private sector expenditures. This is the product of the National Medicines Use Survey that collects information on the supply, procurement, prescription, dispensing and use of medicines. The Survey is designed to support implementation of the National Medicines Policy. This is a challenging task and the latest report of 2017 provides data and analysis for the period 2011-2014.[120]

4.1 Availability of Medicines in Malaysia

As discussed in Chapter 2, the MOH Medicines Formulary is a reference for doctors' medicines prescriptions in MOH facilities. The company responsible for marketing a medicine, after the product has been registered by the NPRA, can apply for it to be listed in the formulary.

Medicines listed as National Essential Medicines are marked as NEML in the MOH Medicines Formulary. WHO defined essential medicines as medicines that satisfy the healthcare needs of the population and hence should be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford in the public and private sectors. MOH Medicines Formulary contains more medicines in comparison with NEML to cater for the current needs of patients in MOH.

[119] The terms "medicines" and "drugs" are used interchangeably.
[120] https://www.pharmacy.gov.my/v2/en/documents/malaysian-statistics-medicines.html

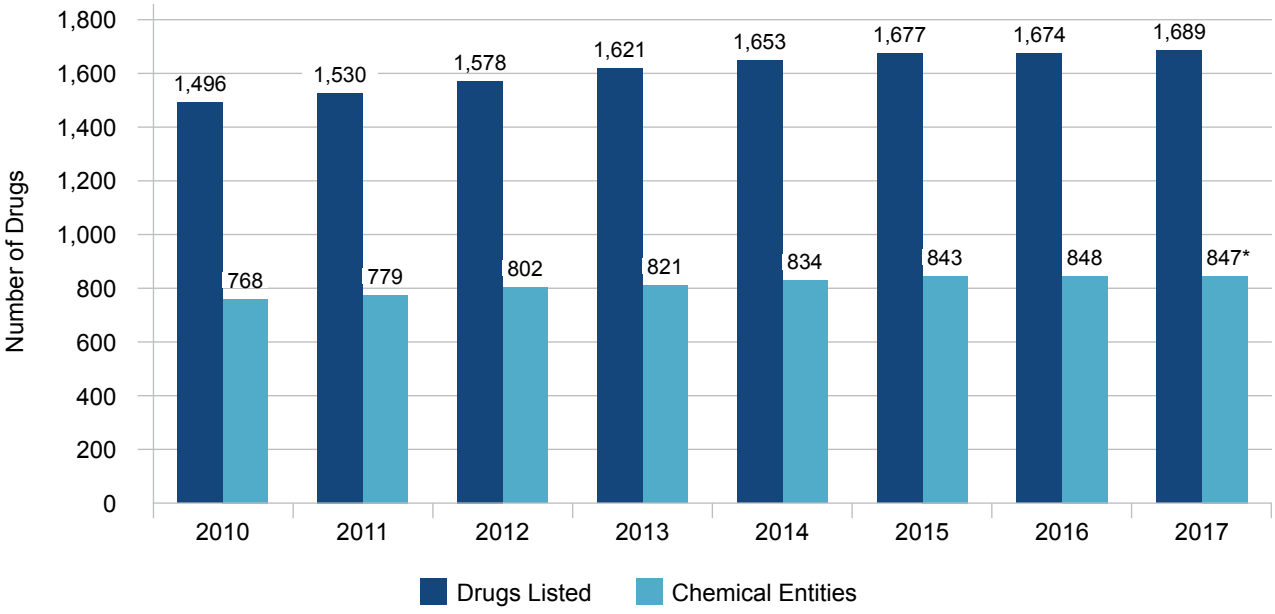
The evaluation for such listing is based on criteria such as proof of superior effectiveness compared with standard therapy, a positive cost-benefit ratio and an acceptable safety profile. The listing of medicines in the MOH Medicines Formulary is decided by a panel appointed by MOH.

However, not all medicines get listed in the formulary if there is a very high budget impact, for example, newer targeted cancer therapies. Nevertheless, if a patient needs these therapies, access to the medicines is still possible. This is done through a case-by-case approval by the MOH of the use of non-formulary medicines.

All medicines listed in the formulary are provided to patients without any charges – patients pay only RM1 to RM5 when seeking outpatient treatment. For in-patient services, they pay only for ward charges and certain investigations while medicines are provided for free. For cancer treatment there is co-payment by the patient.

The number of medicines listed in the MOH Medicines Formulary has been on the increase, from 1,496 in 2010 to 1,689 as of March 2017 (see Figure 4.1). The MOH allocated and spent increasingly more resources on medicines in absolute RM value except in 2015 (see Table 4.1), but it was still at about 10% of total MOH actual expenditure. Given that in recent years the MOH continues to face expenditure or budget constraints, while the public demand for services is increasing year-on-year, the MOH has set priorities for drug purchases that heavily favour generic drugs.

Figure 4.1: Number of Items in the MOH Medicines Formulary, 2010-2017



Source: Pharmacy Programme MOH Annual Report 2015 and MOH/PSD (* data as of August 2017)

Table 4.1: MOH Medicines Expenditure, 2011-2015		
Year	**Total expenditure (RM million)**	**Percentage increment over the previous year (%)**
2011	1,767.61	10.09
2012	1,983.51	12.21
2013	2,200.43	10.94
2014	2,384.64	8.37
2015	2,323.12	-2.58

Source: Pharmacy Programme MOH Annual Report 2015

However, there are certain treatments that can only rely on one or more available patented originator drugs in the market. This raises the possibility of how a drug price set by the manufacturer could affect its inclusion in the MOH Medicines Formulary and its actual availability in public hospitals. This is a part of pharmacoeconomics that the MOH is considering, and in that context healthy and fair competition among manufacturers and suppliers has to be in place for the best outcome.

A survey by Babar and colleagues in 2003 compared the availability of 28 types of medicines on the NEML between 3 types of healthcare institutions – public hospitals and centres, private retail pharmacies and private dispensing doctors.[121] Table 4.2 shows the percentage of healthcare institutions that carry at least 14 (50%) of the 28 selected medicines (defined as median availability). The public sector has the weakest coverage in all three categories of medicines – innovator brand (IB), most sold generics (MSG) and lowest-priced generics (LPG). Only 25% of public healthcare institutions have median availability for LPG; none appeared in the IB and MSG categories. Availability was better, though still low, among private retail pharmacies. The median availability was 43% for LPG, 18% for MSG and 39% for IB. For dispensing doctors, the median availability was 45% for LPG, 15% for MSG and 10% for IB. In short, availability of 28 selected medicines in the NEML was an issue in 2003.

Table 4.2: Median Availability of Medicines by Type of Healthcare Institution			
Healthcare Institutions	**Innovator Brand (IB)**	**Most Sold Generics (MSG)**	**Lowest-Priced Generics (LPG)**
Public hospitals	0	0	25%
Private retail pharmacies	39%	18%	43%
Dispensing doctors	10%	15%	45%

Source: Babar et al., 2007

[121] Babar, Z., Mohamed Izham Mohamed Ibrahim, Harpal Singh and Nadeem Irfan Bukhari (2005). "A survey of medicine prices availability, affordability and price components in Malaysia using the WHO/HAI methodology", a research report from University College Sedaya International and Universiti Sains Malaysia in collaboration with the World Health Organization and Health Action International.

A later study by Saleh and Ibrahim (2005) of 20 public health clinics, 20 public district drug stores and 20 private retail pharmacies on the availability of 13 key medicines showed higher levels of availability.[122] The average availability of these medicines in the public health clinics in the country was 95.4% and the average stock-out days were 6.5 days. In the public medicines stores the respective figures were 89.2% and 32.4 days.[123] They concluded that the majority of the population had access to essential affordable medicines in the country although accessibility was lower in the state of Sabah.

According to MOH, there are on-going studies on price monitoring in the public and private sectors using the WHO methodology. However, these studies are not publicly available. A study by IMS commissioned by PhAMA using IMS MIDAS data in the first quarter of 2014 on two particular diseases, namely diabetes mellitus (DM) and rheumatoid arthritis (RA), found that only 0.4% and 0.21% of patients respectively were treated with listed therapies, as compared with Taiwan (10.8% and 9.2%) and South Korea (9.8% and 4.92%).[124]

The listed therapies in the study were DPPIV Inhibitors for Type-2 DM and biological therapies for RA, selected because at that time these were relatively new medicines that had been in local clinical use for a number of years. The study took 2014 volume sales data of each listed DPPIV inhibitor for DM and biological therapy for RA and divided these sales figures by the corresponding annual dosage estimated using the daily defined dose by WHO, to estimate the number of patients treated with these medicines. These numbers were then divided by the estimated total number of patients with Type-2 DM and RA using the reported prevalence rates of these two conditions in the 3 countries.

According to the study, these medicines were covered by the public payers of the countries concerned. It concluded that the low access findings suggested that there might be more patients in need of DPPIV inhibitors and biological therapy for Type-2 DM and RA, respectively, than were being treated at the time of the study. There was no explanation provided for the lower access in Malaysia.

Official data reporting on drug availability to the public is scarce. In recent years, media reports[125] have highlighted the issue of poor availability of certain critical (e.g., cancer) drugs despite their inclusion in the formulary.

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[122] Saleh, K. and Mohamed I.M. Ibrahim (2005). "Are essential medicines in Malaysia accessible, affordable and available?", *Pharm World Sci.*, 27, 442-446.

[123] Availability was not done for private retail pharmacies because many of these key medicines are dispensed in private general practitioners' clinics and therefore not carried in pharmacies.

[124] PhAMA (Pharmaceutical Association of Malaysia) (2014). "Building greater access to innovative medicines – What is next for Malaysia?", report prepared by IMS Health Singapore, pages 12-13.

[125] Boo, Su-Lyn (2016). "Why new cancer drugs are unavailable in Malaysian public hospitals", *The Malay Mail Online*, 5 December 2016. Also Lim,Teck Onn (2016). "Cancer and other under-funded therapies deserve better", *The Malay Mail Online*, 7 December 2016.

The Case of Atazanavir for Second-line HIV Treatment

Atazanavir (ATV) is an antiretroviral medicine used for second-line treatment of HIV. It is recommended by WHO for adolescents and adults, including pregnant and breastfeeding women. Second-line treatment is needed when a person develops resistance to the first line of medicines. ATV is boosted with ritonavir (RTV/r) or cobicistat for treatment.

The originator company is Bristol-Myers Squibb (BMS), which markets ATV under the brand name Reyataz. BMS manufactures ATV under a licence from Novartis, which holds patents on atazanavir.

The product was first approved by the US Food and Drug Administration (FDA) in June 2003. World sales in 2015 were US$1.139, billion up from US$81 million when the product was first launched in the US market (see Table 4.3).

Table 4.3: World Sales of Originator Product of Atazanavir, 2003 to 2015

Year	World Sales (US$)
2015	1.139 billion
2014	1.362 billion
2013	1.551 billion
2012	1.5 billion
2010	1.5 billion
2009	1.4 billion
2008	1.3 billion
2007	1.1 billion
2006	931 million
2005	696 million
2004	369 million
2003	81 million

Source: MSF, Untangling the Web of Antiretroviral Price Reductions, 18th Edition, 2016
(Originally compiled from BMS data)

The product's profitability is due in large part to the market exclusivity conferred by patents. Novartis had filed for the primary patent on the ATV compound in April 1997 through the Patent Cooperation Treaty system administered by the World Intellectual Property Organization. This primary patent expired in most countries in April 2017.

Novartis and BMS have obtained several ATV-related patents in countries with the capacity to manufacture generic medicines such as Brazil and China. In India, generic producers and civil society organizations have initiated a number of pre-grant oppositions. Novartis abandoned its primary patent application in a challenge on the ground of lack of novelty. This has enabled the manufacture of generic atazanavir, thereby creating some competition in countries where there is no patent barrier.

Although the originator Reyataz was first registered in Malaysia in 2008, the medicine is not included in the National Formulary and thus is not available in MOH hospitals. The cost could be a factor; inclusion of a medicine in the Formulary was a MOH decision until 2016 when a company can apply for inclusion of a medicine.

The primary patent on the ATV compound family expired on 31 October 2017. However, there is a patent on the ATV bisulfate salt that will expire only in May 2019.

In July 2017 Malaysia was one of 12 countries included in the geographical scope of the BMS licence with the Medicines Patent Pool (MPP) for adult dosages of atazanavir.[126] This licence was granted in December 2013 and Malaysia and a number of other middle-income countries were excluded at that time. As noted above, the patent on the atazanavir compound was already due to expire on 31 October 2017.[127] This raises two concerns: a patent and the decision of an originator company to restrict the geographical scope of a voluntary licence can have anti-competitive effects (as discussed in Chapter 6).

In conclusion, atazanavir had not been available for the 14 years since the originator product entered the global market due to cost. Generic products were also not available due to patent barriers. However, in 2015 a local company, Medispec, had registered a product (Atazor-300, a 300mg atazanavir capsule) manufactured by Emcure Pharmaceuticals Limited of India. Emcure, an MPP licence holder, supplies dosages of 100mg (US$0.267 per capsule), 150mg (US$0.283 per capsule), 200mg (US$0.433 per capsule) and 300mg (US$0.60 per capsule). The discounted price of the originator 150mg capsule offered to developing countries included in the MPP licence is US$0.564.[128] This translates to US$207 per person per year (2 capsules a day) for the Emcure generic capsule and US$412 per person per year for the discounted originator capsule. There is also a second medicine that needs to be taken with atazanavir. HIV medication is for life.

With the inclusion of Malaysia in the MPP licence, Medispec will now be able to import the medicine. This case does illustrate that without generics, there was a delay of more than a decade.

It is noteworthy that in the US, where there is no generic atazanavir available during the patent term (first patent expiry in June 2017), the lowest available price for the originator was almost US$49 per 300mg capsule[129] (Emcure's generic price is US$0.60). In 2009

[126] http://www.medicinespatentpool.org/bristol-myers-squibb-medicines-patent-pool-extend-licence-for-atazanavir-to-122-developing-countries/

[127] The exclusion of most middle-income countries from several voluntary licences of originator MNCs has been widely criticized. Interestingly, the timing of the BMS announcement and also of Gilead's inclusion of Malaysia, Thailand, Ukraine and Belarus (Twitter announcement on 24 August) coincided with the Malaysian government's move to use its Rights of Government under Section 84(1) of the Patents Act to authorize a compulsory licence for sofosbuvir, a Hepatitis C medicine.

[128] MSF (2016). "Untangling the Web of ARV Prices", at page 55. www.msfaccess.org/utw2016

[129] https://www.lowestmed.com/reyataz-price-patent-expiration-dates/

Teva Pharmaceuticals USA Inc. tried to introduce a generic version before the various patents (compound, method, etc.) expired. Teva filed for registration of different dosages, claiming that the proposed generic would not infringe a BMS patent (expiry December 2018) and a Novartis patent (expiry June 2017). Alternatively, Teva argued, the patents were invalid or unenforceable. BMS and Novartis filed lawsuits against Teva to defend their patents.[130] In October 2011 a settlement was reached over this patent dispute. Under the terms of the settlement, Teva agreed not to launch its generic until at least July 2017. Other terms of the settlement were confidential.[131]

4.2 Affordability and Prices

The issue of affordability is intrinsically linked to that of pricing and public provision. This will be examined from four angles. First, how affordable are drugs in relation to the purchasing power and standard of living in the country? Secondly, how affordable are they when compared with other countries? Thirdly, how does the patent system affect pricing and affordability? Fourthly, how does the public procurement system affect prices?

(A) AFFORDABILITY WITHIN THE COUNTRY

Affordability is related to purchasing power in a country. So how affordable medicines are in Malaysia can be measured in terms of the cost of drugs and healthcare in relation to the earnings of ordinary labour and in comparison with other countries. Malaysia's healthcare system, as described in Chapter 1, is a dual system where medical costs in the public sector are heavily paid for by the government and drug prices are much cheaper, while medicine prices are unregulated in the private sector. For patients using the private healthcare system, for various reasons, including the non-availability of medicines, Babar et al. found that patented drugs such as glibenclamide (for treating diabetes) and amlodipine (for treating hypertension) would cost 2.1 and 4.9 days of wages respectively for the lowest-paid government workers. The drug for depression (fluoxetine) would take 26.6 days of wages.[132] The study by Saleh and Ibrahim also found that while affordability was better in the public healthcare sector (average of 1.5 weeks' wages) for the 13 key medicines studied, it was high in the private sector (average of close to 1 month's wages).[133]

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[130] *Bristol-Myers Squibb Co. et al. v. Teva Pharmaceuticals USA Inc.*, case number 1:09-cv-00919 (US District Court for the District of Delaware).

[131] Birbrair, L. (2011). "Bristol-Myers, Novartis Settle With Teva Over HIV Drug IP", 24 October 2011, https://www.law360.com/articles/280037/bristol-myers-novartis-settle-with-teva-over-hiv-drug-ip

[132] Babar, Z., Mohamed Izham Mohamed Ibrahim, Harpal Singh and Nadeem Irfan Bukhari (2005). "A survey of medicine prices availability, affordability and price components in Malaysia using the WHO/HAI methodology", a research report from University College Sedaya International and Universiti Sains Malaysia in collaboration with the World Health Organization and Health Action International.

[133] Saleh, K. and Mohamed I.M. Ibrahim (2005). "Are essential medicines in Malaysia accessible, affordable and available?", *Pharm World Sci.*, 27, 442-446, at page 442.

This is not a dedicated study on prices of drugs. Nevertheless, the prices of selected drugs from two categories of drugs based on disease burden (cardiovascular illnesses and cancer) in Malaysia were collected from private hospitals and compared with those in the MOH. Table 4.4 shows the difference in the price of 5 drugs (3 for treating cardiovascular illnesses and 2 for treating cancer) between 3 private hospitals and the MOH. The price in private hospitals refers to selling price which includes a mark-up margin while the price in public hospitals refers to the procurement price. The objective of this comparison is to better understand the issue of affordability of medicines, i.e., at what price is an equivalent medicine available to a patient in a public hospital versus a private hospital, bearing in mind that the patient does not pay for the medicine in a public hospital.

All the 3 private hospitals carry mainly originator medicines. The price differential in the drug prices between the MOH and private hospitals for treating cardiovascular illnesses is on the average 33 times higher in the private hospitals. This is due to the fact that the private hospitals tend to carry originator medicines. In 1 of the 3 hospitals that carried a generic version of atorvastatin, the price was still 13 times that of the MOH. In the case of cancer treatment drugs, where both the MOH and private hospitals dispense originator medicines, the price differential is much less – 1.4 times higher for trastuzumab in private hospitals but lower for imatinib in private hospitals (0.98 times). (See Table 4.4.)

In terms of affordability, patients who use public hospitals get free or highly subsidized treatment, although availability might be an issue given the serious budget constraints facing the MOH. Patients who are unable to get the medicines from public hospitals have to purchase them from the private sector. For trastuzumab one month's treatment at an average of RM8,600 is clearly unaffordable for most Malaysians, unless they have private health insurance, considering Malaysia's median household income was only RM5,228 per month in 2016.

With the increase of cancer patients, the burden on the public budget is already evident. For the period 2007 to 2011, cancer was the fourth most common cause of death in MOH facilities (13%) and the second in private hospitals (25.5%).[134] The use of trastuzumab increased by more than 200% in public hospitals compared with 72% for private hospitals from 2011 to 2014. In 2014 the public sector spending was RM14 million. The current MOH procurement price (2017 to 2019) is RM6,170 per vial of 440mg (see Table 4.4).

[134] National Cancer Institute, MOH (2015). Malaysian National Cancer Registry Report 2007-2011: www.nci.moh.gov.my. The MOH is currently updating the data for 2012 to 2014.

Table 4.4: Difference in Prices of 5 Selected Drugs in 3 Private Hospitals and the MOH, 2017				
Types of drug	**MOH (RM)**	**Average price of 3 private hospitals (RM)**	**Difference between MOH and private hospitals**	**Private hospitals' price range (RM)**
Cardiovascular				
Atorvastatin (40mg/tablet)	0.20 (GM)	6.50 (OM)	32.5x	4.90 - 7.60
Perindopril*	0.08 (GM)	3.00 (OM)	37.5x	3.0 - 3.1
Clopidogrel (75mg/tablet)	0.30 (GM)	9.43 (OM)	31.4x	9.00 - 10.30
Cancer				
Trastuzumab (440mg per vial)	6,170 (OM)	8,658 (OM)	1.4x	8,000 - 9,426
Imatinib (400mg/tablet)	276 (OM)	272 (OM)	0.98x	153 - 352
Treatment for 30 days**	8,280 (OM)	8,183 (OM)		4,600 -10,560

Source: From MOH and interviews and survey of 3 private hospitals in Northern Malaysia
Note: For private hospitals the prices are selling price, and for the MOH they are purchase prices.
GM=generic medicine; OM=originator medicine

* Perindopril comes in 2 salt forms – erbumine and arginine. Perindopril arginine is a follow-on product from perindopril erbumine. Perindopril erbumine comes in dosages of 2, 4 and 8mg and perindopril arginine comes in dosages of 2.5, 5 and 10mg. In Malaysia, the MOH procures generic perindopril erbumine 4mg whilst the private hospitals interviewed procure originator perindopril arginine 5mg. Perindopril arginine 5mg is bioequivalent to perindopril erbumine 4mg.[135]

** 30 days for the imatinib is used for comparison purposes and does not reflect any treatment guideline.

The MOH publishes data on utilization and expenditure of the top 40 to 50 drugs in the country, and these data could be found in the Malaysian Statistics on Medicines reports. Table 4.5 shows the most utilized drugs (in ranked order) in Malaysia in 2014, the number of persons using the drugs, as well as the total expenditure in the public and private healthcare sectors.

The most utilized drug was amlodipine for treating hypertension. A total of 1.54 million people used it at a cost of RM50.6 million (public and private sector combined). Eighty-eight percent of the amlodipine used in 2014 was by the public sector (more than 80% of all hypertension drugs for the year were used by the public sector). According to the MOH, the high use of amlodipine was due to a change in prescribing category from A (specialist only) to B (medical officer or above) in the MOH formulary and the introduction of generic amlodipine in the public sector. It is also used in combination with other drugs.

[135] National Health Service, UK (2014). NHSPrescQIPP, Bulletin 59, Switching from Coversyl Arginine Products (perindopril arginine) to perindopril erbumine tablets: https://www.prescqipp.info/-perindopril-arginine/send/89-perindopril-arginine/1009-bulletin-59-perindopril-arginine

The total number of persons using the top 10 drugs amounted to 5.5 million or 18% of the population at a cost of RM413 million in 2014. What stands out is that 6.7 times more people accessed the drugs in the public sector but at only 1.3 times the cost when compared with the private sector.[136]

Table 4.5: Top 10 Most Utilized Drugs in Malaysia, 2014					
	Top 10 Drugs Used	**Public**	**Private**	**Public**	**Private**
		No. of Persons ('000)	**No. of Persons ('000)**	**RM '000**	**RM '000**
1	Amlodipine	1,355	184	8,951	41,657
2	Gliclazide	1,138	122	44,172	34,383
3	Perindopril	755	43	24,974	10,751
4	Metformin	535	99	65,798	26,173
5	Simvastatin	426	73	32,934	15,964
6	Hydrochlorothiazide	361	21	N/A	N/A
7	Atenolol	245	91	9,385	9,597
8	Acetylsalicylic acid	276	43	N/A	N/A
9	Metoprolol	275	15	26,754	2,459
10	Paracetamol	127	125	24,344	35,135
	TOTAL	**5,492**	**817**	**237,312**	**176,119**

Source: MOH, Malaysian Statistics on Medicines 2011-2014 (published in 2017)

Table 4.6 compares the cost of defined daily dosage (DDD) per person in the public versus private sector for each of the top 10 drugs. For amlodipine, which is the most utilized drug, the DDD cost per person was RM0.02 in the public sector versus RM0.62 in the private sector – a difference of 31 times. The differential for the other drugs is less but still ranging from 1.5 times for paracetamol (a most commonly used drug for mild to moderate pain and fever) to 7.6 times for perindopril (used for treating high blood pressure).

The MOH macro data and the micro data from our survey of 3 private hospitals yield similar conclusions, i.e., price of medicines in the private sector is many times more than that in the public sector. This is a result of two major factors. First, private healthcare institutions especially private hospitals are more inclined to use originator medicines that are expensive. Secondly, with the dual-sector healthcare system in Malaysia, drug prices in the private sector are non-regulated and it is left to private parties to charge

[136] Data on the quantity used in the private sector is not available.

whatever the market can bear. On the other hand, the public sector prioritizes generics that are competitively priced. For example, there are currently 106 companies in India manufacturing 201 generic brands of amlodipine.[137] MOH thus has the option to source from a competitive generics market.

In 2014, pharmaceuticals accounted for RM2.3 billion (12%) of the RM 20 billion out-of-pocket (OOP) expenses in the private sector.[138] Given that OOP accounts for 39% and private health insurance only 6% of total healthcare expenditure, affordability is a major concern that must be addressed.[139]

Table 4.6: Comparison of Cost of Defined Daily Dosage per Person Between Public and Private Sector

	Top 10 Drugs Utilized	Public Sector	Private Sector	
		Cost/person (RM)	Cost/person (RM)	Difference
1	Amlodipine	0.02	0.62	31x
2	Gliclazide	0.11	0.77	7x
3	Perindopril	0.09	0.69	7.6x
4	Metformin	0.34	0.73	2.2x
5	Simvastatin	0.21	0.60	2.8x
6	Hydrochlorothiazide	N/A	N/A	N/A
7	Atenolol	0.11	0.29	2.7x
8	Acetylsalicylic acid	N/A	N/A	N/A
9	Metoprolol	0.27	0.43	1.6x
10	Paracetamol	0.53	0.77	1.5x

Source: MOH, Malaysian Statistics on Medicines 2011-2014 (published in 2017)

(B) AFFORDABILITY COMPARED WITH OTHER COUNTRIES

How do drug prices in Malaysia compare with those in other countries? Three studies have been done on this issue – one by PhAMA (the pharmaceutical industry organization, consisting mainly of MNC pharmaceutical importers), and the other two by academicians. The choice of medicines could be one reason for the different conclusions. PhAMA's

[137] http://www.medindia.net/drug-price/amlodipine-combination.htm. In the US the average generic amlodipine price falls between US$7-12 for 30 tablets of 5mg each from retailer stores such as Walmart, Kmart and Walgreens (www.truemedcost.com/amlodipine-price/). On the other hand, the cost for the originator (brand Norvasc by Pfizer) is from US$150 for 30 tablets of 5mg each, depending on the pharmacy (https://www.drugs.com/price-guide/norvasc).

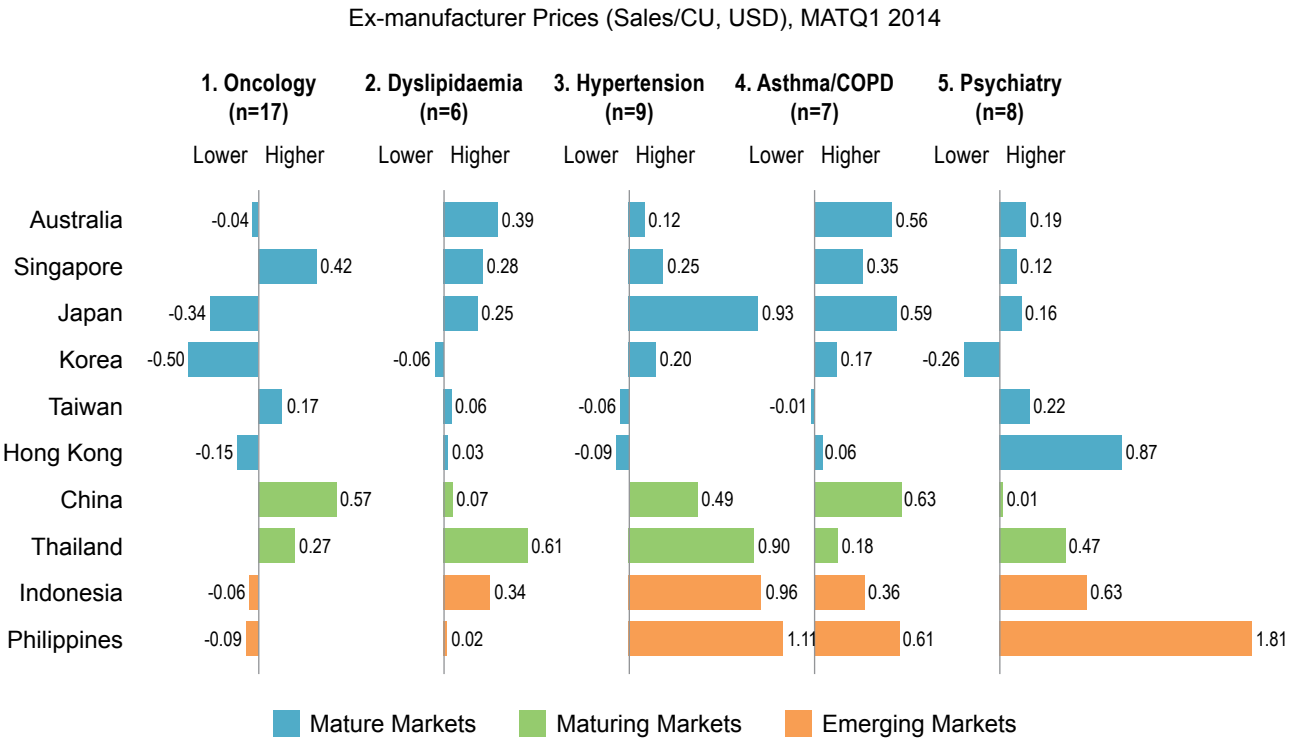
[138] MOH, 2016. Malaysian National Health Accounts, at page 80. The pharmaceutical costs are probably underestimated because medicines costs are included in the outpatient bills charged by GPs.

[139] The cost of medicines is only one component of the OOP. The other charges include professional fees of doctors and other personnel, hospital procedures, hospital facilities, etc.

study chose 47 branded originator medicines in the top 5 therapeutic areas, Babar's study covered 28 core list medicines suggested by WHO/HAI based on disease burden, supplemented by 20 other medicines, and Hassali's study surveyed the 10 most utilized medicines in Malaysia.

PhAMA has conducted a comparative pricing analysis in 2014 (ex-manufacturer prices) for the top 5 therapy areas (oncology, dyslipidaemia, hypertension, asthma/COPD and psychiatry) across 10 Asia-Pacific countries (Australia, Singapore, Japan, South Korea, Taiwan, Hong Kong, China, Thailand, Indonesia and the Philippines) (see Figure 4.2). The study concluded that prices across the studied therapy areas in Malaysia are, on average, not higher than many countries listed in the analysis. Only prices in South Korea were 9% lower; even Taiwan was found to be 8% higher than Malaysia. China, for example, a maturing market like Malaysia, had prices that were approximately 30% higher than Malaysia despite having lower GDP per capita.

Figure 4.2: Comparative Pricing Analysis of Top 5 Therapy Areas Across Asia-Pacific Countries



Source: Adapted from PhAMA (2014). "Is reference pricing right for Malaysia?", report prepared by IMS Health Singapore

However, two academic studies, one by Babar et al. (2005) and the other by Hassali et al. (2012),[140] found that prices for the selected drugs studied are higher in Malaysia compared with the International Reference Price (IRP) and when compared with prices in Australia. (See Section 4.4 below for a short discussion on IRP.)

Table 4.7 summarizes the findings of Babar et al. For all types of healthcare institutions, prices were higher in Malaysia compared with the IRP for all 3 categories of medicines, ranging from 1.1 times to 16 times.

Table 4.7: Comparison of Median Price Ratio for Selected Medicines in Malaysia with International Reference Price

Healthcare Institutions	Innovator Brand	Most Sold Generics	Lowest-Priced Generics
Government Procurement	2.4x	1.6x	1.1x
Private Retail Pharmacies	16.0x	6.9x	6.6x
Private Dispensing Doctors	15.0x	7.5x *	

Source: Babar, Z., Mohamed Izham Mohamed Ibrahim, Harpal Singh and Nadeem Irfan Bukhari (2005). "A survey of medicine prices availability, affordability and price components in Malaysia using the WHO/ HAI methodology", a research report from University College Sedaya International and Universiti Sains Malaysia in collaboration with the World Health Organization and Health Action International, V-VI

Note: Comparison is between median price ratio and international reference price
*No distinction was made for generics in the Private Dispensing Doctors category.

For example, for originator drugs, prices were on average 2.4 times higher in the public sector, 16 times higher in private retail pharmacies, and 15 times higher in doctor dispensaries compared with the IRP. For most sold generic drugs, they were 1.6 times higher in the public sector, 6.9 times higher in private retail pharmacies and 7.5 times higher in doctors' dispensaries compared with the IRP.[141]

The study by Hassali et al. showed that, for 10 selected retail prescription branded drugs, all are found to be more expensive than their counterparts in Australia, ranging from 30.3% to 148.3% in excess, with a total median difference of 58%. The variation in Malaysian retail drug prices is also rather significant; 3 out of 10 drugs have registered a standard deviation of more than 1 (see Table 4.8).

[140] Hassali, M.A., A.A. Shafie, Z. Babar and T.M. Khan (2012). "A study comparing the retail drug prices between Northern Malaysia and Australia", *Journal of Pharmaceutical Health Services Research*, 3, 103-107.

[141] The WHO accepts a maximum level of 3 times of a world market reference price for public procurement prices for selected medicines in comparison to IRP: WHO (2012). Regional Framework for Action on Access to Essential Medicines in the Western Pacific (2011-2016) at page 30.

Table 4.8: Comparison of 10 Selected Originator Drug Retail Prices Between Northern Malaysia and Australia	
Originator Branded	**Median Difference**
Norvasc	+53.9%
Lipitor	+62.5%
Glucovance	+107.9%
Diamicron	+89.6%
Noten	+30.3%
Ventolin	+88.2%
Voltaren	+44.8%
Adalat LA	+42.4%
Zocor	+42.3%
Betaloc	+148.3%
MEDIAN DIFFERENCE	**+58.2%**

Source: Babar, Z., Mohamed Izham Mohamed Ibrahim, Harpal Singh and Nadeem Irfan Bukhari (2005). "A survey of medicine prices availability, affordability and price components in Malaysia using the WHO/ HAI methodology", a research report from University College Sedaya International and Universiti Sains Malaysia in collaboration with the World Health Organization and Health Action International, V-VI

Note: Comparison is between median price ratio and international reference price
*No distinction was made for generics in the Private Dispensing Doctors category.

Affordability is related to purchasing power in a country. If drug prices are lower in Australia with a per capita income (US$51,885 at constant 2010 US$) 5 times that of Malaysia (US$9,071), one can conclude that the affordability index of medicines for Malaysians is low, notwithstanding the fact that the two health systems are different. This raises the question of why there are such significant price differences and the market conditions that allow for the high cost of medicines.

The different systems may raise questions on the validity of such price comparisons as akin to comparing apples and oranges. However, this is the crux of the matter. Australia has a "central purchasing" scheme where the Australian Pharmaceutical Benefits Scheme,[142] managed by a public authority, is the single largest purchaser of prescription medicines, thereby endowing it with substantial bargaining clout in negotiating the best prices for the public. This demonstrates the central and crucial role of government in managing affordability of medicines in a country.

[142] The Scheme was set up under the Pharmaceutical Benefits Act 1947 as part of a wider plan to create a system like the UK's National Health Service. It provides subsidies for prescription medicines.

In sharp contrast, in Malaysia's dual healthcare system, medicine prices in the public healthcare system are managed by the MOH through a public procurement system as described in Chapter 2. In the private healthcare system, they are unregulated, with all the attendant problems.

(C) EUROPEAN COMMISSION STUDY ON DRUG PRICING (2016):[143] EXTERNAL PRICE REFERENCING, DISCOUNTS AND DIFFERENTIAL PRICING

International price referencing is also known as **external price referencing**. It refers to the practice of using the price of a pharmaceutical product (generally ex-manufacturer price, or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

According to a European Commission study on drug pricing (2016), "The complicated world of drug pricing presents an array of challenges for keeping costs low in the US and EU, though European countries are increasingly employing new policies to keep price gouging in check."[144]

The 260-page report examined two policy options: external price referencing (EPR) and differential pricing.

EPR is defined in the study "as the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of a medicine in a given country."

EPR is used in 29 countries in the EU, as well as in Iceland, Norway, Switzerland and Turkey, though different approaches are applied in Germany, Sweden and the UK, which employ various forms of EPR, value-based pricing and other pricing regulation schemes. Twenty of the 29 countries that apply EPR use this policy as their sole or main pricing policy. Countries most frequently referenced to are France, Belgium, Denmark and Spain, followed by Italy, the UK and to a lesser extent, Austria, Germany and Slovakia.

However, the report notes that the details of how an EPR scheme is designed differ between countries. Twenty-one countries compare medicine prices at the level of ex-factory prices, while 8 countries do so at the pharmacy purchasing price (wholesale price) level.[145]

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[143] European Commission (2016). Study on enhanced cross-country coordination in the area of pharmaceutical product pricing, https://ec.europa.eu/health//sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf

[144] http://www.raps.org/Regulatory-Focus/News/2016/02/25/24409/European-Drug-Prices-New-Commission-Report-on-What-Policies-Work-and-What-Could-Work/

[145] Others, such as Sweden, use an entirely unique system for determining drug prices through value-based pricing using 3 principles: (i) societal perspective, based on the principles of human value, need and solidarity and cost effectiveness, (ii) threshold value, based on the individuals' maximum willingness-to-pay for a quality-adjusted life year (QALY) gained, and (iii) marginal decreasing utility of treatments, which considers that the benefits of a treatment vary by indication or by degree of severity.

The study discusses limitations of EPR,[146] concluding that, "In practical terms, EPR is a cost- and time-intensive exercise and would benefit from tools and mechanisms to ease the work load."

One of the main limitations highlighted is that price comparisons are often not done at the level of real prices paid by payers (i.e. discounted prices). In that regard, higher savings might be generated if prices actually paid by public payers are referenced to, i.e. considering also confidential discounts, rebates, and similar financial arrangements in the other countries. Such lack of transparency could lead to risks of overpaying for medicines.

A second limitation identified in the study is that EPR has the potential to contribute to accessibility problems. Though EPR does not necessarily restrict access, it incentivizes the marketing authorization holders to first launch drugs in high-priced countries in order to have the list prices of these countries become the reference for others, and to delay, or not market at all, products in lower-priced countries so as not to negatively impact the reference price. It may in addition inhibit manufacturers from offering medicines at lower prices in lower priced countries.

A separate study by the OECD considered EPR as a policy that is "readily gameable by the pharmaceutical industry and – by reducing firms' willingness to price to market – contributes to access and affordability problems".[147]

Other limitations are that EPR does not reflect a country's willingness to pay or ability to pay (compared for example, to value-based pricing), and that it is exposed to exchange rate volatility when referenced prices are in local currencies.

Therefore, while the EPR policy has become more commonly applied in the EU, the limitations of EPR have increasingly been discussed in recent years. Despite methodological issues, questions about the underpinning philosophy have also arisen, as EPR tends to import relative value judgments. Decisions about pricing and reimbursement reflect a country's social preferences in the health system. Differences in national health settings also raise questions about comparability of prices.

The report provides four ways to improve EPR, including through the use of a medicine price database;[148] comparing real prices paid in EPR, rather than official prices, which would lead to price reductions; performing regular (i.e. bi-annual or annual) price re-evaluations; and further coordinating the use of EPR, for instance by extending the current formula to include some measures of countries' economic situations."[149]

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[146] European Commission (2016) at pages 36 to 40.

[147] Ibid. at page 39 citing OECD (2008). Pharmaceutical Pricing Policies in a Global Market.

[148] As of mid-2015 the restricted Europid database includes data from 27 European countries: http://www.euripid.eu

[149] For instance, countries could adjust prices by reference countries' purchasing power parities, rather than merely by nominal exchange rates, when performing EPR.

The study also notes that in response to these limitations many EU Member States have increasingly considered value-based pricing elements in their pricing and reimbursement decisions.

On the issue of **discounts**, the study states that the practice of lowering list prices through discounts, rebates and similar financial arrangements between public payers and marketing authorization holders is widespread, with 22 countries reporting that discounts, rebates or similar financial arrangements either based on a law or confidential (based on agreements) are in place. However, the use of discounts provides financial benefits to the country using them, but other countries do not benefit from the lower prices since they refer to undiscounted higher prices.[150]

The report shows that price confidentiality eliminates, or at least reduces, accountability since decision-makers involved in activities such as procurement and medicine regulation are less able to exercise institutional and democratic control, thus increasing opportunities for discrimination and corruption.

The European Commission study also examines **differential pricing**, which is defined as "the strategy of selling the same product to different customers at different prices" even though costs are the same.[151]

The rationale of differential pricing is that while manufacturers continue to receive high prices in high-income countries to cover all cost elements, medicines are provided to poorer countries at or slightly above their marginal costs. Since this would grant manufacturers additional markets where low profit margins might be outweighed by high unit sales, this would not be a loss for them.

However, the Commission found that overall, "differential pricing is not a panacea" for ensuring access and it often "heavily relies on the willingness of the pharmaceutical industry," meaning it does not encourage sustainability or autonomy in low and middle-income countries.

The study states:
"It is generally known and acknowledged that the costs of manufacturing of most medicines are not prohibitive but high prices mainly result from the need to provide adequate return on investment, to fund R&D and to pay high promotion costs in the highly competitive markets. Manufacturers should be rewarded for innovation, so prices are seen as a financial incentive to fund R&D. However, costs of R&D are difficult to assess, and some authors demythologized the high cost of research." [152]

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[150] European Commission (2016) at page 36. See also WHO Guideline on Country Pharmaceutical Pricing Policies (2013) referenced in the study: http://apps.who.int/medicinedocs/en/d/Js21016en/

[151] *Ibid.*, at pages 60 to 70.

[152] *Ibid.*, at page 64. WHO estimates that at the beginning of the 21st century most originator medicines were sold at 20 to 100 times their marginal costs.

It goes on to note that the 'secondary costs' of "rewarding industry for research and compensating management and marketing costs are mainly borne by high income countries, typically with universal coverage, since considering these price elements in low and middle income countries would make most medicines unaffordable in these countries."

The study notes that the use of differential pricing has apparently improved access to medicines in low-income countries especially Least Developed Countries, particularly to specific therapeutic groups such as vaccines, contraceptives and antiretroviral medicines. But differential pricing has not proved to be successful in middle-income countries. It appears to be useful in those cases when markets are small and highly uncertain, production capacity is limited, rapid access is required and/or a time delay in overcoming barriers to competition, and small quantities of medicines are required.[153]

The Commission also called for more countries to work on price monitoring, as this is included in the legislation of 25 European countries, but it is only done on a regular basis in 17 countries. Similarly, in the case of Malaysia better price monitoring is much needed.

(D) AFFORDABILITY AND THE CASE OF LOPINAVIR/RITONAVIR FOR HIV TREATMENT

The fixed dose combination antiretroviral medicine of lopinavir/ritonavir is one of the most important HIV treatment options. The originator company is AbbVie and the brand name is Kaletra. The US FDA approved ritonavir in 1996 (brand name Norvir) and lopinavir/ritonavir in 2000. Lopinavir has never been approved as a single entity product in the US.[155]

The MOH's formulary contains the following:

- Lopinavir 100mg/ritonavir 25mg tablet and lopinavir 200mg/ritonavir 50mg tablet: to be used as a second-line medicine if a patient is intolerant to a combination of indinavir/ritonavir as part of what is known as "highly active antitretroviral therapy" (HAART) regimen.

- Lopinavir 80mg/ritonavir 20mg (per ml) oral solution: Management of patients with early or advanced HIV Infection according to MOH indicators.

[153] *Ibid.*, at pages 62-63.

[154] The patents were granted to Abbott Laboratories. Since then a restructuring of the company resulted in AbbVie, the entity that manufactures prescription medicines.

[155] Amin, T. and A.S. Kesselheim (2012). "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades", Health Affairs, 31(10), 2286-2294.

These products are registered in Malaysia by AbbVie[156] (the originator company) and Cipla[157] (generic manufacturer from India).

However, there are 3 patents granted in relation to lopinavir/ritonavir: 2 related to ritonavir crystalline polymorphs (expiry in 2021 and 2027) and one on lopinavir/ritonavir heat-stable formulations (expiry in 2026). With these patents, the originator has market exclusivity over different formulations and dosages (see Table 4.9). The primary patent on the ritonavir compound expired in 2014 and the one on the lopinavir compound in 2016 in the US where these were first granted. The existing patents granted in Malaysia are all secondary patents.

Table 4.9: Patents Granted that Affect Different Formulations of Lopinavir/Ritonavir (2017)

Formulation/Dosage	Description	Status	Application No.	Expected Expiry Date
Lopinavir/Ritonavir 100/25 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 100/25 mg tablet	Lopinavir crystal forms	Filed	MYPI20011034	03/07/2021 (if granted)
Lopinavir/Ritonavir 100/25 mg tablet	Lopinavir/Ritonavir heat-stable formulations[158]	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 100/25 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027
Lopinavir/Ritonavir 200/50 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 200/50 mg tablet	Lopinavir crystal forms	Filed	MYPI20011034	07/03/2021 (if granted)
Lopinavir/Ritonavir 200/50 mg tablet	Lopinavir/Ritonavir heat-stable formulations	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 200/50 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Lopinavir/Ritonavir liquid compositions & capsules	Granted	MY199902107	27/05/2019
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Lopinavir crystal forms	Filed	MYPI20011034	03/07/2021 (if granted)
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027

Source: Medicines Patent Pool (www.medspal.org)

[156] Kaletra 100mg/25mg Film-Coated Tablet; 200mg/50mg Film-Coated Tablet (lopinavir/ritonavir); Kaletra 160ml oral solution.

[157] Lopimune tablet (lopinavir and ritonavir 200/50 mg tablet) and Lopimune soft gelatine capsules.

[158] Heat-stable means that there is no need for refrigeration for the medicine concerned.

Malaysia is not included in the LPV/r and RTV licence agreement between AbbVie and the MPP (treatment for adults) and so the generic version is not available in this country.

Therefore the MOH and the private sector are buying the originator product. As seen from Table 4.10, if the MOH could buy the generic product from Cipla of India (US$268 per patient per year) instead of sourcing from the originator company (US$1,489.20 per patient per year), there would be a savings of about US$1,221 per patient per year. This is about 82% savings. Compared to the MOH procurement price, the private pharmacy price is 48.9% higher.[159] However, the purchase price paid by the pharmacy and the originator's price for Malaysia are not available.

Table 4.10: Developing Country Prices for Lopinavir/Ritonavir in US$ per Patient per Year Compared with Malaysian Prices (2016 prices)

Antiretroviral for HIV treatment	Daily dose	Originator company	Generics companies				Malaysia	
Lopinavir 200mg/ ritonavir 50mg tablet	4	AbbVie	Aurobindo	Cipla	Hetero	Macleods	**MOH**	**Private pharmacy in Kuala Lumpur**
		Category 1 countries: 231 (0.158) Category 2 countries: 740 (0.507)	243 (0.167)	268 (0.183)	280 (0.192)	293 (0.201)	**1489.2 (1.02)**	**2219.3 (1.52)**

Source: MSF, Untangling the Web (2016), page 19:
Developing country prices in US$ per patient per year, as quoted by companies:
http://www.msf.org/sites/msf.org/files/msf_access_utw.pdf; MOH; private pharmacy in Kuala Lumpur.

Notes:
(i) MSF compiled the prices for other developing countries: these are 2016 prices in US$ per person per year based on WHO dosing recommendations, as quoted by companies. Prices per tablet are in brackets. Currency conversions were made when the pricing information was received, using the currency converter from www.oanda.com.
(ii) The originator company applies its own eligibility criteria for discounting. Usually, companies create two groups of discount-eligible countries, often called "Category 1" (countries that are eligible for the deepest discounts) and "Category 2" (countries that are offered a lesser discount).
(iii) Malaysian MOH data added courtesy of MOH: tender contract for 2017-2019 at RM4.31 (US$1.02) per tablet (RM517 per 120 tablets). The authors obtained the price on cash terms of a private pharmacy in Kuala Lumpur: RM6.42 per tablet (RM770 per 120 tablets).

[159] In the US, the originator price for the lopinavir 200mg/ritonavir 50mg tablet is between US$8.48 to US$9.81 per tablet, meaning US$12,380.80 to US$14,322.60 per patient per year: https://www.drugs.com/price-guide/kaletra#oral-tablet-200-mg-50-mg (accessed 1 October 2017).

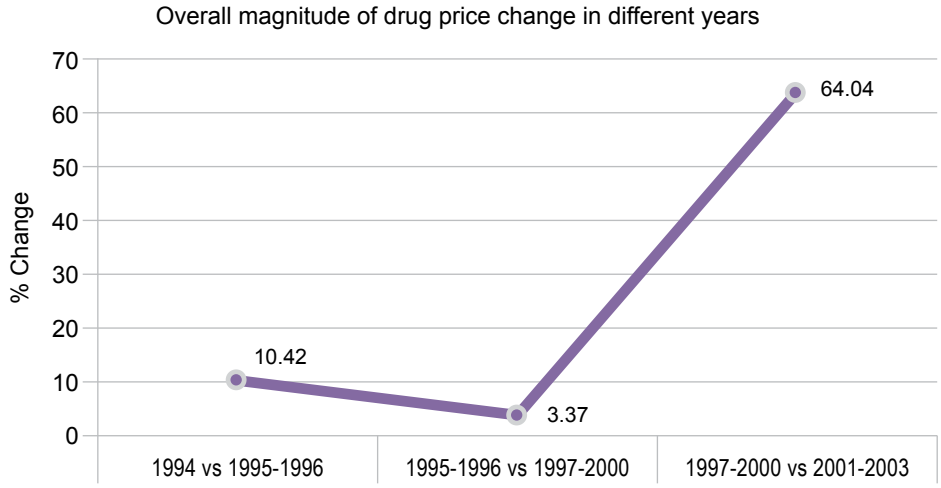
(E) PUBLIC PROCUREMENT OF MEDICINES AND PRICES

Governments play a central role in managing drug prices in a country. Many countries such as Australia, Canada and Japan have centralized or semi-centralized systems of public purchases. As noted in Chapter 2, Malaysia's public procurement of medicines changed from a central purchasing and distribution system managed by the MOH to a system where an exclusive concession was given to a company to supply a specified number of medicines. What is the impact of this on price?

Few published studies have been done on this important question. The 2009 Babar and Izham study[160] was one of the few, if not the only, that analyzed the price of 564 drugs in 15 categories in the pre- and post-privatization periods. In 1994, the MOH privatized the public procurement of essential medicines. Prices were compared over three periods: 1994 versus 1995-1996; 1995-96 versus 1997-2000; and 1997-2000 versus 2001-2003.

The result shows that there was an increase of 10.42% in drug prices within just 2 years after privatization (Figure 4.3). The study also found that the increase in drug prices was steeper in 2001-2003 compared to the 4 preceding years, registering an average increase of 64.04%.[161] Some specific drugs and drug categories were affected more than others. The study pointed to privatization of drug distribution as having a major effect on drug prices in the mid-1990s and the beginning of the 2000s. However, the privatization largely affected the procurement and distribution of medicines to the government hospitals and clinics only.

Figure 4.3: Overall Drug Price Change in 3 Different Periods



Source: Babar, Z. and M.I. Izham (2009). "Effect of privatization of the drug distribution system on drug prices in Malaysia", Public Health, 123(8), 523-533.

[160] Babar, Z. and M.I. Izham (2009). "Effect of privatization of the drug distribution system on drug prices in Malaysia", Public Health, 123(8), 523-533.

[161] One reason given is that this coincided with the time when Malaysia became a member of the PIC/S in 2002 and Pharmaniaga had to upgrade its plants: interview with Pharmaniaga. According to MOPI, significant changes as a result of the step up in regulatory regime play a role in impacting production cost and consequently the price of medicines.

4.3 Accessibility

The demand for medicines, unlike other consumer goods, is outside the control of consumers. The decision of whether and what to purchase is most likely decided by doctors who prescribe the medicines. This information and knowledge asymmetry between doctors and patients fundamentally determines whether, and what type of drugs (the issue of availability), are prescribed to end-users. A particular drug may be available, but it may not be accessible to the consumer if those who prescribe and dispense do not make it available. Hence, making information available as well as pricing transparency are important to address the issue of accessibility.

There is little transparency over prices of drugs charged and the choice of drugs that can be interchangeable or substituted. In other countries like the Philippines, it is now mandatory for doctors and dispensers of drugs to offer choices to their patients. For any originator drug dispensed, the dispenser is required to offer a choice of at least two other generics, if available. Such a system allows the user to choose according to her financial ability.

In terms of increasing transparency in pricing, MOH has initiated discussions and consultations to mandate price disclosure by companies to obtain price information of a product when it is required to establish and update the drug prices database in Malaysia and for sharing the price information with the public at the web portal (www.pharmacy.gov.my) as the Consumer Reference Price.

One of the proposed amendments is to entrust clearer authority to the Senior Director of Pharmaceutical Services to obtain price information of a product when it is required to establish and update the drug prices database in Malaysia and for sharing the price information with the public on the Pharmaceutical Services Division's web portal[162] as the Consumer Reference Price.

Decision-making and planning would require the best available and accurate information. Once the information imbalance between the supplier and the buyer is addressed, it would be advantageous to the government and public to get the best value out of medicine purchases. Transparency in pricing would be the first very crucial step to achieve it.

Another aspect of accessibility is linked to availability and affordability as discussed above. When medicines are not available or affordable, access is naturally denied or restricted.

[162] https://www.pharmacy.gov.my

4.4 Price regulation

Many competition agencies in principle do not support the regulatory control of prices, preferring that market forces determine prices. However, experts have recognised that among others, uncertainties of the "incidence of disease and in the efficacy of treatment"[163] in the healthcare market can lead to market failure and inefficient allocation of resources, calling for intervention by non-market institutions. Nevertheless, price regulation is a complex task. It must be carried out with careful consideration of the characteristics of the market and the different levels of the supply chain, with proper impact assessments to ensure that the desired outcomes of regulatory measures are achieved. The WHO Guideline on Country Pharmaceutical Pricing Policies 2015 provides a useful tool for consideration by MOH and other relevant agencies.

4.5 Conclusion

From available data, it can be generally observed that the availability of controlled medicines in Malaysia has increased over the years. There are on-going studies conducted by the MOH to monitor process of medicines in the public and private sectors. However, these are not made publicly available.

In view of the increasing trend of non-communicable diseases in the country, and the high cost of the new medicines for these classes of diseases, it is recommended that further studies be conducted to evaluate the availability, affordability and accessible of the medicines concerned. There should also be a systematic monitoring of the patent status of essential medicines and the time it takes for generics and biosimilars to enter the Malaysian market. Generic industry players, especially the bigger ones, do undertake such monitoring but for the majority of players the cost and expertise required for such an exercise pose challenges.

On affordability, the Review found that with the Malaysian dual healthcare system, public hospitals and clinics are providing most of the medicines needed at highly subsidized rates and therefore affordable. However, the federal government budget allocation since 2015 has shown a downward trend for medicines. Patients who have to purchase medicines from the private sector will face severe issues of affordability for some drugs. Of the 10 most utilized medicines, private sector prices are 1.4 times to 34 times higher than those in the public sector. At the same time, OOP expenses are increasing. Meanwhile the private sector prices are unregulated and many times more than public prices, especially for treatment of cancer and other non-communicable diseases whose incidence is increasing among the Malaysian population.

[163] K.J. Arrow, 'Uncertainty and the Welfare Economics of Medical Care', The American Economic Review, Vol LIII, No. 5, December 1963, as referred to in Savedoff, William D., WHO, 'Kenneth Arrow and the Birth of Health Economics' https://www.scielosp.org/article/bwho/2004.v82n2/139-140/en/

With increasing OOP expenses and the overall rise in cost of living, the declining purchasing power of many Malaysians is leading to more use of public health facilities. This in turn drives medicines expenditure up, as seen in several categories of medicines use in the 2011-2014 MOH survey.

Independent updated studies on pricing as it relates to availability and affordability should be undertaken. In this respect, the MOH has valuable data for public sector analysis. Private sector data will need to be obtained through IMS and directly from the entities concerned, an exercise that would be more challenging.

International price referencing (or external price referencing) is widely used as a tool for public and private sector procurement of medicines. As discussed above, its limitations are also acknowledged and procurement agencies responsible for public health delivery, as in Malaysia, often work with a basket of different tools, and share experiences across countries in relation to health technology assessment and pharmacoeconomics approaches. The MOH in Malaysia is in the same position.

The Review found that available studies generally show that prices in Malaysia tend to be higher compared with other countries. Price strategies are therefore needed, and various options and experiences in other countries can be explored. In this regard, price transparency within the country, and sharing of price information among countries is gaining increasing interest and cooperation among procurement agencies in Europe and members of the WHO-PAHO region. There is potential for similar regional cooperation through ASEAN and the WHO regional offices where initial steps are already starting (WHO WPRO, WHO SEARO).

In considering price regulation as a tool to ensure that medicines are affordable, there is need to conduct a thorough study given the complexities and challenges in this area.

The type of public procurement system in a country determines to a large extent the price of medicines, the Australian system being a good example. Malaysia changed from a central government purchasing system to a privatization model where a private company is given exclusive concession to supply a large part of medical supplies to public facilities. A study in 2009 found that selected drug prices in the public sector increased post-privatization, particularly between 2001 and 2003 when they rose by 64%. It would be useful to do a more up-to-date study on this important issue, taking into account the increased cost of compliance with increased drug regulatory requirements in recent years.

PART TWO

COMPETITION CONCERNS IN THE PHARMACEUTICAL SECTOR

CHAPTER 5: KEY EXISTING LAWS AND REGULATIONS AND AN ASSESSMENT OF IMPACTS

This chapter provides a general overview of the key laws that govern and regulate the pharmaceutical sector in Malaysia.[164] It also considers the impacts of the regulatory framework on the availability and accessibility of medicines in the country.

The government has various policies on healthcare and these provide the framework within which the pharmaceutical sector operates. The key policies for the purposes of this Review are the National Medicines Policy (which includes the Generic Medicines Policy), the Economic Transformation Programme (ETP) and the Competition Policy. In 2015, a guideline on "Good Pharmaceutical Trade Practice (GPTP) for Private Sector" was issued towards ensuring best trade practices across the pharmaceutical distribution chains.[165]

The main laws for the regulation of the pharmaceutical sector include the following:
- Poisons Act 1952 and regulations;
- Sale of Drugs Act 1952;
- Control of Drugs and Cosmetics Regulations (CDCR) 1984 under the Sale of Drugs Act;
- Directive on Data Exclusivity 2011 under the CDCR;
- Registration of Pharmacists Act 1951 and regulations; and
- Medicines (Advertisement and Sale) Act 1956 and regulations.

These laws with their respective regulations, orders, guidelines and directives together define pharmaceutical products and govern licensing, as well as related issues on the production, import, wholesaling/distribution, prescribing, dispensing and the overall use of medicines in Malaysia.

The Patents Act 1983 plays a major role in determining the scope and period of patent protection resulting in market exclusivity that is given for originator medicines. The National Intellectual Property Policy of 2007 is also reviewed.

The Financial Procedure Act 1957 and the Government Contracts Act 1947 and circulars issued thereunder in relation to public procurement policy define the procurement of medicines for the public sector.

[164] Laws governing the establishment of companies are not included in this Review.
[165] Guideline on Good Pharmaceutical Trade Practice (2015), https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/good-pharmaceutical-trade-practice_0.pdf

This chapter discusses the CDCR, the Data Exclusivity Directive 2011 and the Patents Act as they relate to the objective of ensuring a robust and competitive pharmaceutical sector. The relationship between competition law and patent law is also highlighted.

Malaysia is a party or member to various international instruments that set international standards related to the pharmaceutical sector and these form the basis for national laws and practices. Some of these international instruments are legally binding, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement administered by the World Trade Organization (WTO), and the treaties administered by the World Intellectual Property Organization (WIPO). Others are non-legally binding, such as the various WHO technical guidelines and the guides of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The Malaysian government also refers to the laws, standards and practices of other countries, including the European Union and its member states, the United States, Australia and Japan, for adaptation and adoption domestically. At the ASEAN level, there is longstanding on-going work to cooperate on exchange and harmonization of standards for safety, quality and efficacy of pharmaceutical products.

5.1 Control of Drugs and Cosmetics Regulations 1984

The Drug Control Authority (DCA) is the regulatory authority established under the CDCR for its purposes. The NPRA acts as its secretariat. The DCA is responsible for: (a) registration of pharmaceutical products; (b) licensing of manufacturers, importers and wholesalers; (c) monitoring the quality of registered products; and (d) monitoring and surveillance activities (e.g., adverse drug reaction monitoring).

Any person seeking to manufacture, sell, supply, import, possess or administer any "product"[166] must register the product and hold the appropriate licence required and issued under the CDCR (Regulation 7).[167] Upon registration, each drug is given a registration number, which must be printed on its label or package. This Review focuses on what is commonly called "prescription medicines". These are technically known as pharmaceutical products containing scheduled poisons as listed in the First Schedule under the Poisons Act (or "controlled medicines").

The NPRA uses a further categorization of products as follows: poisons, over-the-counter (OTC) medicines, traditional medicines health supplements (TMHS), veterinary products, health supplements, and traditional medicines.

[166] "Product" means a "drug" in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or a drug to be used as an ingredient of a preparation for a medicinal purpose (Regulation 2).

[167] See Chapter 2 for the discussion on the licences.

The applicant for product registration shall be known as the Product Registration Holder (PRH) and must be a locally incorporated company, corporate or legal entity, with permanent address and registered with the Companies Commission of Malaysia (with the scope of business related to the health/pharmaceutical product).[168]

(A) PRODUCT REGISTRATION

Malaysia joined the PIC/S in January 2002, and is one of the few developing countries in that inspection scheme. PIC/S and the ASEAN Common Technical Dossier/Requirements (ACTD/ACTR)[169] inform the process of pharmaceutical product registration in this country. Being a member of the PIC/S, the country's exports of pharmaceutical products have shown an upward trend, especially to fellow member countries, which include the EU, Australia and Canada. Since then, the NPRA has been actively involved in Good Manufacturing Practice (GMP) and Quality Assurance programmes.

The industry has the capacity to produce medicines in different forms, e.g., tablets (coated and non-coated), capsules (hard and soft gelatine), liquids, creams, ointments, sterile eye drops, small volume injectables (ampoules and vials), large volume infusions and dry powders for reconstitution, as well as active pharmaceutical ingredients. Manufacturers in Malaysia are also moving into the biosimilars market.[170] In June 2017, an agency under the Ministry of Science, Technology and Innovation (MOSTI), Inno Bio Ventures Sdn. Bhd. (Inno Bio), signed a joint venture agreement with Aryogen Pharmed Co. (Aryogen) of Iran. Under the collaboration, Inno Bio will be developing and producing biosimilars for non-communicable diseases such as breast cancer, leukaemia, blood disorders and rheumatoid arthritis. For now, the partnership is focusing on four products, namely, factor vii, rituximab, trastuzumab and etanercept.[171]

Malaysia has also been growing as a producer of halal pharmaceuticals, which are increasing in global demand, and has gained increasing recognition of its expertise in this area of the industry.

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[168] Hence, in the case of a foreign company wanting to bring a pharmaceutical product into Malaysia, it can do so either through its own local office where it has incorporated a subsidiary in Malaysia or through an appointed local agent. The local agent who is the PRH should be authorized in writing by the product owner to be the holder of the product registration, and will be responsible for all matters pertaining to quality, safety and efficacy of the product. This shall include updating any information relevant to the product/application.

[169] These are adapted from standards set by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), http://www.ich.org/home.html. See also Khirul Falisa Mustafa (2015). "Regulatory Control of Generic Medicines in Malaysia", 11 March 2015, 1st Malaysia-Japan Symposium on Pharmaceutical Regulatory System, Kuala Lumpur, https://www.pmda.go.jp/files/000204339.pdf

[170] See, for example, CCM Berhad's 2014 Annual Report on the acquisition of PanGen Biotech Inc., http://www.ccmberhad.com/documents/54282/496464/2014_CCMB_Annual_Report.pdf/db55916f-6777-4431-9b42-61553f566eac. Also, The Star Online (2017). "CCM DBio, PanGen set to launch biosimilars for kidney dialysis", 15 February, https://www.thestar.com.my/business/business-news/2017/02/15/ccmdbio-pangen-set-to-launch-biosimilars-for-kidney-dialysis/

[171] June 2017, http://innobioventures.com/v1/2017/06/14/inno-bio-all-geared-up-for-the-development-and-production-of-biosimilar-products/

The main document guiding the process of drug registration in Malaysia is the Drug Registration Guidance Document (DRGD), now into its second edition (September 2016, revised in March 2017).[172] (See Appendix 6 for more details of the product registration process.)

Thus, the NPRA has in place a well-structured and comprehensive regulatory system. It is well established and respected.

The process for marketing authorization of generic drugs is different from the assessment of originator drugs containing new chemical entities. As part of the approval process, generic drugs must be shown to be similar in quality, efficacy and safety to the originator drugs and this is done through bioequivalence (BE) studies. Pharmaceutically equivalent drugs are products with the same active ingredients, dosage form, strength and route of administration.[173]

The sum total of the above is that generic medicines in this country are manufactured according to international standards to ensure their quality, safety and efficacy.[174]

There is no question that industry players agree with the need to maintain standards and ensure the need for proven safety, quality and efficacy of pharmaceuticals that reach the market. However, before proceeding with specific comments from industry players (importers and manufacturers) about the regulatory requirements, it is important to recognize that the international standards which are adopted impact different countries differently due to the particular characteristics of the local industry.[175]

To begin with, the need for more cohesiveness in the industry was recognized by the government's Performance Management and Delivery Unit (PEMANDU) and it sought to address the asymmetry with the Healthcare NKEA (National Key Economic Area) that was part of the ETP launched in October 2010: "While numerous efforts are already underway to stem the expenditure trajectory, there is no coordinated effort to grow healthcare revenues. The Healthcare NKEA intends to address this asymmetry of focus and identify private sector opportunities to reframe health as an economic commodity as well as a social right."[176]

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[172] The review of regulatory policies takes into account the global regulatory environment to allow for timely and pertinent changes (NPRA).

[173] NPRA. "Bioequivalence", http://npra.moh.gov.my/index.php/regulatory-information/bioequivalence-be

[174] Wong, Z.Y., Mohamed A. Hassali, Alian A. Alrasheedy, Fahad Saleem, Abdul H.M. Yahaya and Hisham Aljadhey (2014). "Malaysian Generic Pharmaceutical Industries: Perspective from Healthcare Stakeholders", *Journal of Pharmaceutical Health Services Research*, http://www.haiasiapacific.org/wp-content/uploads/2014/11/Malaysian-generic-pharmaceutical-industries.pdf, at page 8.

[175] See also Fatokun, O. et al. (2016). "Generic medicines entry into the Malaysian pharmaceutical market", *Generics and Biosimilars Initiative Journal*, 5(4), http://gabi-journal.net/generic-medicines-entry-into-the-malaysian-pharmaceutical-market.html

[176] NKEA Penjagaan Kesihatan, Chapter 16 Heathcare, at page 553, http://www.moh.gov.my/images/gallery/ETP/NKEA%20Penjagaan%20Kesihatan.pdf

From the interviews conducted for this study, however, it seemed an assessment of the implementation of the NKEA with all stakeholders and all governmental departments and ministries involved would be timely, to consider if goals and objectives have been met in the effort to steer this industry forward.

In implementing policies and regulations, the current state of development of the pharmaceutical industry as a whole must be borne in mind. As said earlier, most companies in Malaysia are small to medium-sized. Local manufacturing companies are small compared with other generic producers within the region and are at the nascent stage of research and development. At the moment, most input materials such as APIs, additives and packaging materials are still imported, resulting in higher costs. Further, there is a lack of human skills and knowledge within this sector. An interviewee commented that in Malaysia there was still a lack of emphasis in university courses towards research and development in this sector. Pharmacy studies were still geared towards patient care, with pharmacists who graduate locally still mainly serving the retail sector. Universities can support the pharmaceutical sector by introducing studies along the lines of research and development, manufacturing and regulatory issues in pharmaceuticals, in order that the knowledge gained by graduates might have greater industrial application.

While Malaysia has a zero-tariff policy for imported pharmaceuticals, other countries in ASEAN retain tariffs. Some regulatory barriers to entry[177] still exist in these countries although there is a move towards greater harmonization.

Among the 10 ASEAN countries in a comparative study on generic drug registration requirements, Malaysia and Singapore are viewed as having well-established regulations and being stricter on quality and safety of drugs.[178] As discussed below and in Chapter 6, this has implications for SMEs as the cost of compliance is high.

At present there is still a heavy reliance on imported generics, which is inherently volatile in that suppliers can negotiate for freedom to terminate a supply contract at any time at their own discretion. In particular, the market faces fierce competition from Indian imports, which generally enter the market earlier and are lower in price.

Against such a backdrop, it can be said that the demands of the current regulatory environment are felt more keenly.

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[177] Previously, Thailand's Food and Drug Administration (FDA) made it a requirement for BE studies to be conducted locally in the country for acceptance of BE data. However, in 2016, ASEAN countries signed the BE Mutual Recognition Agreement, thereby standardizing requirements in this area – with BEs conducted in Malaysia being acceptable in Thailand. See Eisah A. Rahman (2016). "Current Updates on ASEAN Harmonization", April 2016, http://apac-asia.com/images/achievements/pdf/5th/ATIM_06_Dato'AISAH.pdf. To obtain access into the Indonesian pharmaceutical market, overseas manufacturers need to have their own plant in the country or partner with a local manufacturer.

[178] Nagaraju, P. et al. (2015). "Comparison of Generic Drug Registration Requirements in ASEAN Countries", *International Journal of Research in Pharmacy and Chemistry*, 5(1), 145-149, http://www.ijrpc.com/files/13-01-15/15-520.pdf. The study compared administrative, technical, clinical and non-clinical documentation requirements.

(B) COST

The implementation of regulations has cost implications. According to the local manufacturers and importers interviewed, the costs of conducting safety, quality and efficacy testing can add up and in some cases become prohibitive, given that generics enter the market at a low price point. Specific examples of high costs raised were those involved in BE studies and BE Centre Accreditation Inspections, stability testing and GMP inspections.[179] GMP requirements entail major investments in upgrading manufacturing facilities and this has implications for local manufacturers. Smaller companies that cannot afford to upgrade can be pushed out of the market.[180]

Most of the BE studies and thus BE Centre Accreditation Inspections are carried out in India.[181] These can cost up to RM100,000 each. Malaysia has 6 local BE centres.[182] However, local manufacturers state that the cost of conducting BE studies at these centres is greater. This is an area for consideration by the government. Incentives and tax relief could be put in place which would encourage BE studies to be done locally. It was further pointed out that the current 6 centres would not be able to cope with demand, should local manufactures utilize them fully for conducting BE studies.

Product re-registration is required every 5 years, upon which fresh BE studies will have to be conducted. This means that BE studies will also have to be carried out for the re-registration of "grandfather" products – products which have been in the market for a long time and accepted. As the pricing for generic products can and does get lower with time, this additional cost can lead to a situation where suppliers withdraw a drug from the market when it becomes unprofitable to manufacture. In comparison, there are other countries like Singapore that do not require re-registration. This is an area that is not without difficulties, with constant monitoring and on-going discussions continuing.

Such "retrospective" BE requirements can also work against innovation. Any innovation that leads to a medicine with better absorption than an old originator product, for example, may not meet the BE test. If it is then treated as a new chemical entity, the generic manufacturer will be required to conduct clinical trials, thereby incurring more costs. This has the unintentional effect of discouraging innovation, and the manufacturer may have

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[179] Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP covers all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff: ISPE. "GMP Resources", https://www.ispe.org/initiatives/regulatory-resources/gmp

[180] "Good Manufacturing Practice in the Pharmaceutical Industry", Working Paper 3, prepared for Workshop on "Tracing Pharmaceuticals in South Asia", 2-3 July 2007, University of Edinburgh, The Center for International Public Health Policy, http://www.csas.ed.ac.uk/__data/assets/pdf_file/0011/38828/GMPinPharmaIndustry.pdf

[181] Information obtained through interviews with local industry and the NPRA.

[182] These are Bioxis Sdn. Bhd.; Borneo Kinetics Sdn. Bhd.; Clinical Research Ward, Clinical Trial Unit, Clinical Research Centre; Info Kinetics Sdn. Bhd.; Pusat Kajian Bioekuivalens, Pharmacy-Attest Research Sdn. Bhd. (ARSB) BA/BE Centre, Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia (USM); and Pusat Pengajian Sains Farmasi, Universiti Sains Malaysia (USM). Source: http://npra.moh.gov.my/en/index.php/regulatory-information/bioequivalence-be

to “work down” its product to satisfy BE tests to compare with the old originator product or, as stated above, decide to discontinue manufacture of the product.

It is noteworthy that the Malaysian Productivity Commission recognizes that regulations can impose significant compliance costs: “Direct compliance costs can include the time taken to comply with regulations, the need for additional staffing, the development and implementation of new information technology and reporting systems, external advice, education, advertising, accommodation and travel costs. As well as having a direct impact on regulated businesses, compliance costs also impact indirectly on the community, by changing pricing and distorting resource allocation, impacting on international trade and delaying the introduction of new products or services. There remain concerns that such costs are excessive.”[183]

The Commission also states: “Malaysia has traditionally followed the prescriptive approach in regulation, more so in areas where safety and health is concern [sic]. However, there is now interest in pursuing the performance-based rules as is being done in other benchmarked countries like Australia. Performance-based rules are most suited to areas for which the desired outcome is easily quantifiable. In specifying the desired outcome, individuals and firms can seek out the optimum cost for achieving it.”[184]

Indeed, while enforcement of international standards has increased the competitiveness of Malaysian pharmaceuticals in the international arena, caution needs to be exercised in implementing such standards to ensure that it does not stifle local industry. A study done by Dr. Peter Folb and Dr. Piero Olliaro for WHO highlights the concerns:

“The establishment of the International Conference on Harmonization (ICH) presents a challenge to international public health objectives. The declared structure and purpose of ICH – which is made up of representatives of drug regulatory authorities of the European Union, Japan and USA and the pharmaceutical industry – does not take particular account of the special needs of the developing world. Standards have been set through ICH guidelines which, although excellent and helpful in developing innovative new medicinal products, have been interpreted as rules. Beyond an observer status, WHO and countries not included in the ICH are effectively excluded. In a sense, ICH is counterproductive to approaches for development of critically required new drugs by groups such as WHO and the non-ICH countries…

“It is a further challenge to this new public health perspective that national drug regulatory authorities must also foster the development of local industry in a manner that promotes public confidence, supports excellent essential standards and is free of special arrangements between government and industry.”[185]

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[183] “RURB Logistics Draft Full Report, Regulatory Burdens: Core Concepts”, Chapter 3, Malaysian Productivity Commission, http://www.mpc.gov.my/wp-content/uploads/2016/04/CHAPTER-3-1.pdf

[184] *Ibid*.

[185] Folb, Peter and Piero Olliaro (2000). “Pharmaceutical policies and regulatory control”, *WHO Drug Information*, 14(2), http://apps.who.int/medicinedocs/en/d/Jh1463e/3.html#Jh1463e.3.1

The originator companies in fact echo some of the concerns above. The feedback received was that the ASEAN region should have a harmonized system so that standard regulations apply across member countries.

(C) DELAY

Upon submission of the full dossier for marketing approval, the approval process is estimated by the NPRA to take 210 days.[186] However, according to many MNCs and local companies interviewed, the time period taken for approval can be longer (up to a year). Nevertheless, this is already shorter than the time frame taken by some other countries within the region.

With regard to generic entry into the market, delay in the approval of generics can impact competition and be expensive for a nation. The European Commission in its competition inquiry into the pharmaceutical sector (for the years 2000-2007) found that had there not been a delay of roughly 7 months from the expiry of patents of originator products to the introduction of generics, savings from generic entry could have been 3 billion euros more. The US Federal Trade Commission (FTC), on its part, estimates that pay-for-delay settlements cost taxpayers, insurance companies and consumers US$3.5 billion per year.[187] Although the European Commission was referring to delays caused by strategies of originator companies, the fact is that delay is costly for public health budgets and consumers.

Further, the US Food and Drug Administration (FDA) in a study found that "On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower."[188]

In June 2017 the Commissioner of the US FDA recognized the need for a more dynamic environment in favour of generic suppliers, stating that the current regime for market authorization is causing delay in the entry of generic medicines into the American market:

"Over the last decade alone, competition from safe and effective generic drugs has saved the health care system about $1.67 trillion. When generics are dispensed at the pharmacy, the immediate savings to each of us are clear. We could see even greater cost savings if we helped more safe and effective generic drugs get to market sooner, after

[186] DRGD, para 8.4.4, http://npra.moh.gov.my/images/Guidelines_Central/guideline-DRGD/Complete_DRGD_with_appendices_MARCH_2017.pdf

[187] Blood, Michael H., Michael A. Carrier, Richard T. Silver and Hagop Kantajian (2016). "Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States", 27 January 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/

[188] US FDA (2015). "Generic Competition and Drug Prices", https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm

patent and statutory exclusivity periods have lapsed, by addressing some of the scientific and regulatory obstacles to generic competition across the full range of FDA-approved drugs. These barriers may delay and, in some cases, ultimately deny patient access to more affordable drugs. That's why we're working on a Drug Competition Action Plan. As part of this effort, today, we're announcing in the Federal Register our intent to hold a public meeting on July 18, 2017, to solicit input on places where FDA's rules – including the standards and procedures related to generic drug approvals – are being used in ways that may create obstacles to generic access, instead of ensuring the vigorous competition Congress intended."[189]

5.2 Registration of Biological and Biosimilar Medicines in Malaysia

Biological medicines or biologics are becoming increasingly important for the treatment of major diseases.[190] These are made up of large, complex molecules grown in living cells rather than synthesized chemically, as in the case of small molecule drugs.[191] The vast majority of biologics are derived from living sources: humans, animals, microorganisms;[192] i.e., they are naturally occurring or synthetic versions of naturally occurring products. Biologics are now available for treatment of cancer, high cholesterol, rheumatoid arthritis and asthma.

Biologics that are produced by companies other than the originator company are called biosimilar medicines (often referred to as biosimilars). Biosimilars are manufactured from large-scale cultures of living cells that are *similar* – but not structurally identical – to the originator's biological entity or reference product.[193] Since biosimilars are not exactly identical to biologics, the registration requirements for biosimilars are much more stringent than for generic medicines which are based on chemical molecules.

The regulatory pathway for biologics and biosimilars is also different in different countries. Generic manufacturers establish quality with GMP standards and in some cases, they are asked to do stability and bioequivalence studies to register a generic version of a small molecule, as described above in Section 5.1. In contrast, biosimilar manufacturers have a higher threshold to meet to register their medicines. They must demonstrate that

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[189] Gottlieb, Scott (Commissioner of the US FDA) (2017). "FDA Working to Lift Barriers to Generic Drug Competition", FDA Voice, 21 June 2017, https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/

[190] In 2008, 28% of sales from the pharmaceutical industry's top 100 products came from biologics; by 2014, that share was expected to rise to 50%: http://www.fda.gov/downloads/BiologicsBloodVaccines/InternationalActivities/UCM273181.pdf. In 2010, biologics already made up 25% of the new products approved by the US Food and Drug Administration: http://www.nytimes.com/2010/03/08/opinion/08so.html?_r=1&

[191] Morrow, Thomas (2004). "Defining the difference: What makes biologics unique", https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/

[192] http://www.fda.gov/downloads/BiologicsBloodVaccines/InternationalActivities/UCM273181.pdf

[193] Gabowski, H., R. Guha and M. Salgado (2014). "Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future", *Health Affairs*, 33(6), 1048-1057.

their product is *similar* to a biologic medicine in terms of quality, safety and efficacy. To do this, companies seeking registration must submit clinical trial data for phases 1, 2 and 3 as well as comparative studies to demonstrate safety and clinical comparability with the originator product.

Biologics are priced very high and the availability of biosimilars in the market is crucial for competition and ensuring access to affordable treatments. In the US, various economic impact studies pin the projected savings at between US$42 billion and as high as US$108 billion over the first 10 years of biosimilar market formation.[194] A recent study by Express Scripts found that in California alone, patients and payers could save US$27.6 billion over the next 10 years from the introduction of biosimilars on 11 biologics whose patents expire in the near future.[195]

However, there are formidable challenges facing biosimilar manufacturers in entering the market and generating competition to bring down prices. A 2014 study[196] stated:

"Because bringing biosimilars to the market currently requires large investments of money, fewer biosimilars are expected to enter the biologics market than has been the case with generic drugs entering the small-molecule drug market. Additionally, given the high regulatory hurdles to obtaining interchangeability – which would allow pharmacists to substitute a biosimilar for its reference product, subject to evolving state substitution laws – most biosimilars will likely compete as therapeutic alternatives instead of as therapeutic equivalents. In other words, biosimilars will need to compete with their reference product on the basis of quality, price, and manufacturer's reputation with physicians, insurers, and patient groups. Biosimilars also will face dynamic competition from new biologics in the same therapeutic class – including 'biobetters,' which offer incremental improvements on reference products, such as extended duration of action."

In Malaysia, the Biotechnology Section of the Centre for Product Registration of the NPRA is responsible for registration of biologics/biopharmaceuticals and biosimilars in accordance with the Sale of Drugs Act, the Control of Drugs and Cosmetics Regulations and the DRGD, as described above. In addition, Appendix 3 of the DRGD sets out the Guidelines on Registration of Biologics, which is "a living document that will be updated/ revised further in line with the progress in scientific knowledge and experience".

The document states that requirements for registration of biologics/biopharmaceuticals are "aligned with the scientific guidelines and recommendations for quality, clinical efficacy and safety and non-clinical [sic] of the World Health Organization (WHO), European Medicines Agency (EMA) and International Conference of Harmonization (ICH). Where appropriate, the relevant WHO, EMA and ICH guidelines on biologics/biopharmaceuticals shall be consulted".

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[194] http://www.gphaonline.org/issues/biosimilars

[195] http://www.gphaonline.org/media/cms/Lttr_to_FDA_on_biosimilars_INN_June_2014.FINAL.pdf

[196] Gabowski, H., R. Guha and M. Salgado (2014). "Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future", *Health Affairs*, 33(6), 1048-1057.

The NPRA regulates every biologic as a new product and considers it "high risk", stressing strict compliance with GMP.

Since biosimilars are follow-on products of the original biopharmaceutical products, the biologics registration guideline is also applicable to biosimilars. In addition, there is a separate Guidance Document and Guidelines for Registration of Biosimilars in Malaysia (2008).[197]

For the purpose of this document, a "biosimilar" medicinal product (a short designation for "similar biological medicinal product") is considered as a new biological medicinal product developed to be similar in terms of quality, safety and efficacy to an already registered, well-established medicinal product.

The information in the NPRA guidance is adopted from the EMA guidelines, in particular the guidelines on similar biological medicinal products containing biotechnology-derived proteins as active substances, with some adaptations for Malaysian application.[198]

The purpose of the Guidance Document is:
- To introduce the concept of biosimilars;
- To outline the basic principles to be applied;
- To provide applicants with a "user guide" for the relevant scientific information, in order to substantiate the claim of similarity.

As stated above, the regulatory pathway for biosimilars is much more complex and costly than that for bioequivalence of generic medicines based on chemical molecules.

Between 2012 and September 2017, the NPRA had received 195 applications for registration of biologics and biosimilars. Of these, 165 have been registered. There are 20 registered biosimilar products and all the product registration holders are local entities.[199]

The Malaysian domestic pharmaceutical industry is at a nascent stage where biosimilars are concerned, although there are at least two companies[200] that are investing in this field, especially for oncology biosimilars. Therefore the design of Malaysia's regulatory framework for biosimilars needs to be carefully calibrated.

[197] http://npra.moh.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/GUIDELINES%20FOR%20REGISTRATION%20OF%20BIOSIMILAR%20(1).pdf
[198] *Ibid.*, page iv.
[199] Communication from NPRA dated 20 September 2017.
[200] CCM Duopharma and Kotra.

On the issue of interchangeability and substitution, the NPRA Guidance Document states:[201]

> *"Biosimilars are not generic products and cannot be identical to their reference products. Further, the formulations may be different and these can have profound effect on their clinical behaviour. In addition, biosimilars do not necessarily have the same indications or clinical use as the reference products.* ***Therefore, given current science, they cannot be considered interchangeable with the reference product or products of the same class. Automatic substitution (i.e. the practice by which a different product to that specified on the prescription is dispensed to the patient without the prior informed consent of the treating physician) and active substance-based prescription cannot apply to biologicals, including biosimilars.*** *Such an approach ensures that treating physicians can make informed decisions about treatments in the interest of patient safety."* (Emphasis added.)

The EMA guidelines, one of the sources for the NPRA guidance document, focus on the requirement of similarity. This approach has raised concerns among scholars. The main argument presented by the pharmaceutical industry is that "it is impossible to make an identical replica of a biological medicine since biological substances, such as proteins, cannot be reproduced exactly." That being so, the EMA guidelines (and also WHO's 2009 Guidelines on Evaluation of Similar Biotherapeutic Products) require that comparative clinical trials are carried out to demonstrate that a drug is similar but not identical to the reference product. This approach may have implications for competition in terms of relevant market definition and substitutability and is discussed in Chapters 6 and 7.

German Velasquez, former Director of WHO's Department of Technical Cooperation for Essential Drugs and Traditional Medicine, points out that the focus should not be on making an *identical* product but rather one that has an *equivalent therapeutic effect*. "If the product has the desired effect, there is no need for it to be identical. The patients who take the medicine are not identical either." The requirement for clinical trials for biosimilars is in fact an extension of the principle of data exclusivity (see discussion below). Authorities must bear in mind the distinction between "measures designed to ensure patient safety" and "barriers intended to boost monopolies".[202]

In 2014 the World Health Assembly adopted a resolution that stated:

"Conscious that similar biotherapeutic products could be more affordable and offer better access to treatments of biological origin, while ensuring quality, safety and efficacy, …

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[201] http://npra.moh.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/GUIDELINES%20FOR%20REGISTRATION%20OF%20BIOSIMILAR%20(1).pdf, page 17, section 5.

[202] Velasquez, German, November 2017. *The International Debate on Generic Medicines of Biological Origin, South Centre*; https://www.southcentre.int/wp-content/uploads/2017/11/RP82_The-International-Debate-on-Generic-Medecines-of-Biological-Origin_EN.pdf

"URGES Member States: … to work to ensure that the introduction of new national regulations, where appropriate, does not constitute a barrier to access to quality, safe, efficacious and affordable biotherapeutic products, including similar biotherapeutic products."[203]

The regulatory regime adopted by Colombia can be considered as a starting point for revision of Malaysia's guidelines.[204]

5.3 Data Protection and Data Exclusivity

An applicant (the originator company) seeking to register a medicine with a new chemical entity has to submit test and clinical data to a country's regulatory authority for assessment of safety, efficacy and quality. When a generic company subsequently applies for registration of its generic version of the medicine, there is no international rule that requires clinical trials to be repeated although there are still requirements for the generic company to conduct certain tests. The regulatory authority can rely on the originator's test and clinical data for the registration of a bioequivalent generic medicine. This is a very important factor for timely market entry of generic pharmaceutical products, and hence competition and price reductions.

The logic is that the market exclusivity conferred by a patent for a minimum of 20 years is balanced by generic manufacturers entering the market much later but not having to repeat all the clinical trials and other tests for medicines that are proven to be bioequivalent.[205] Bioequivalence is a standard that is accepted for molecule-based generic medicines. This balance promotes access to affordable medicines.

However, originator companies have been advocating for such data to be given legal exclusivity, and not be used by regulatory authorities when they assess generic medicines applications during the period of exclusivity. Nevertheless, there is no international legal obligation to confer such regulatory exclusivity for test and clinical data. "Data exclusivity" (DE) was in fact rejected by developing countries during the negotiations of the TRIPS Agreement. This was due to concerns that it would prevent drug registration authorities from relying on test and other data from originator companies to register generic versions of the same medicine, causing delay to the entry of competition.[206] There was also no

[203] WHA67.21, 24.5.2014. Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy; http://apps.who.int/medicinedocs/documents/s21459en/s21459en.pdf

[204] Velasquez, German, February 2015. *The Registration of Biosimilar Medicines: lessons from Colombia's Experience*; https://www.southcentre.int/south-bulletin-83-12-february-2015/

[205] There are also ethical issues related to the repeat of an efficacy trial with a compound for which efficacy has already been established. See Declaration of Helsinki – Ethical principles for medical research involving human subjects 1964 (latest amendment in October 2013), section on Risks, Burdens and Benefits. The Declaration has been incorporated into the Malaysian Guideline for Good Clinical Practice (3rd edition, 2011), page v: http://www.crc.gov.my/wp-content/uploads/2016/07/07_GCP3.pdf

[206] Correa, C. (2016). *Public Health Perspective on Intellectual Property and Access to Medicines: A compilation of studies prepared for WHO*, South Centre, pages 90-91. Generic manufacturers would also be obliged to seek the consent of the originator company to use its data for the registration of the generic product.

consensus on the meaning of the term as jurisdictions that confer this regulatory exclusivity were largely limited to the European Union and the United States at that time.[207]

The compromise is a provision on data protection and not data exclusivity, in Article 39.3 of the TRIPS Agreement.[208] There are three conditions under Article 39.3 for a party to obtain data protection in the drug marketing approval process:

- The pharmaceutical product utilizes new chemical entities;
- The data is undisclosed test or other data; and
- The data was obtained with considerable effort.

When those three conditions are satisfied, the WTO Member concerned has to protect the data submitted for marketing approval against unfair commercial use and against disclosure by the authorities to third parties. However, disclosure is permitted under two circumstances, i.e., to protect the public or after steps have been taken to protect the data against unfair commercial use.

Most developing countries comply with their TRIPS obligation through existing laws related to trade secrets. In the case of Malaysia, such protection would be conferred through the Official Secrets Act 1972.

In recent years, some developing countries have usually adopted national DE regulations or guidelines as part of their WTO accession commitments (e.g., China) or as a requirement under bilateral free trade agreements with the United States (e.g., Chile, Colombia, Peru, Singapore). DE was a contentious issue in the US-Malaysia FTA negotiations (June 2005 to 2008) that, for several reasons, were eventually not concluded.

In India there was intensive national debate on the scope of data protection as required under the TRIPS Agreement, during the 2005 amendment of the Indian Patents Act. The conclusion was to reject DE as this would have a negative impact on the country's thriving generic pharmaceutical industry. Brazil, which also has a substantial domestic generics industry, has rejected DE as well.

On the other hand, originator companies argue that there is considerable time and financial investment involved in generating data to prove the safety, quality and efficacy of an innovative drug or second indication of a drug. Reliance by drug regulatory authorities on such data to register a generic product is interpreted as "unfair commercial use" and so data exclusivity along the model of the Hatch-Waxman Act[209] in the US is seen as

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[207] Interview in May 2017 by authors with Prof. Carlos Correa, TRIPS Agreement negotiator for Argentina during the Uruguay Round of trade negotiations.

[208] Article 39.3 reads: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

[209] Drug Price Competition and Patent Term Restoration Act of 1984. Other country examples proposed include Australia, Canada, China, the EU, Japan, Singapore and Taiwan.

preferable. Otherwise, according to originator companies, there will be commercial and economic inequity.[210]

Thus, the ultimate decision on whether to provide such regulatory exclusivity, and its terms and conditions, is a national policy choice and dependent on the development objectives (including public health) of a country. DE as a concept and term does not have a common definition, meaning or even understanding.

Data Exclusivity Directive 2011

In Malaysia, on 28 February 2011 the Director of Pharmaceutical Services issued the Directive on Data Exclusivity under Regulation 29 of the Control of Drugs and Cosmetics Regulations.[211] This entered into force on 1 March 2011 and applies to new drug products containing a new chemical entity (NCE), and second indications of a registered drug product. Biologics are not included.

The objective is "to protect the undisclosed, unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort", that is submitted for scientific assessment of the quality, safety and efficacy of any new drug product containing an NCE. Similar protection is available for such test data related to the safety and efficacy for a second indication of a registered drug product.

An application for DE is made during the submission of documents for product registration to the Director of Pharmaceutical Services of the MOH. An application that relates to a new drug product containing an NCE must be made within 18 months from the date the product is first registered or granted marketing authorization AND granted DE/test data protection in the country of origin or any country recognized by the MOH. If the application relates to a second indication of a registered drug product, it must be made within 12 months from the date the second indication is approved AND granted DE/test data protection in the country of origin or in any country recognized by the MOH.

This avoids the situation where an applicant waits till a product patent in Malaysia is almost expiring before seeking product registration for marketing purposes, thereby extending exclusivity beyond the life of the patent. For example, a product patent is due to expire in January 2018 and the originator company submits a DE application only in 2017. If this is granted for 5 years and the duration starts from the approval date in Malaysia, the originator product will have its market exclusivity extended until 2022.

The exclusivity period shall not be more than 5 years for a new drug product containing an NCE, and not more than 3 years for a second indication of a registered drug product. The protection period is for the data concerning the second indication only, i.e., the applicant cannot claim an additional period for the product itself.

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[210] Pharmaceutical Association of Malaysia. PhAMA Position Papers on Intellectual Property, http://www.phama.org.my/index.cfm?&menuid=95&parentid=6

[211] http://npra.moh.gov.my/images/Circulars_Directive/Regulatory_Information/page-10/DIREKTIF_DE-1.pdf

Calculation of the exclusivity period starts from the date the product is first registered or granted marketing authorization AND granted DE/test data protection in the country of origin or in any country recognized by the MOH. For a second indication of a registered product, the duration is from the date that indication is approved AND granted DE/test data protection in the country of origin or in any country recognized by the MOH.

Concerns have been raised about the fact that a DE system would delay the entry of more affordably priced generic versions of essential medicines, and developing countries have been cautioned against introducing such a regime.[212] In the European Union the 8-year DE rule and other market exclusivity measures that aim to promote investment in medical product development have also caused concerns with regard to their impacts on availability of medicines. These include supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high-priced essential medicinal products for conditions that pose a high burden for patients and health systems, as well as availability of generic medicinal products.[213]

Thus, data or market exclusivity can have anti-competitive effects.

However, Malaysia's Data Exclusivity Directive incorporates several safeguards to achieve a balance. For example, the Director of Pharmaceutical Services, who is responsible for DE applications, has discretion on whether DE will be granted. The DE period is decided on a case-to-case basis, which provides flexibility. This means that the period can be different for each case, subject to the ceiling of 5 and 3 years respectively of the 2 types of applications.

The balance with public health and access to medicines is reflected in the provision that DE shall not apply to situations where compulsory licences have been issued or where there is implementation of any other measures consistent with the need to protect public health and ensure access to medicines for all. DE is also not applicable when the government needs to take necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the government.

Since the Directive was implemented, DE has been approved for a total of 53 products (for 26 NCEs).[214] For second indications of a registered drug product, DE has been approved for 5 products (for 3 active ingredients).[215]

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[212] See, for example, WHO (2006). "Public Health, Innovation and Intellectual Property Rights", Report of the Commission on Intellectual Property, Innovation and Public Health. For discussion in the EU, see 't Hoen, E., P. Boulet and B. Baker (2017). "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation", *Journal of Pharmaceutical Policy and Practice*, 10:19, https://joppp.biomedcentral.com/articles/10.1186/s40545-017-0107-9

[213] Council of the European Union (2016). "Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States", http://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/, at paragraphs 47(a) and 9(b).

[214] http://npra.moh.gov.my/images/reg-info/DataEx/2017/DETableUpdateforPPO18092017.pdf. The number of applications that were rejected is not available.

[215] http://npra.moh.gov.my/images/reg-info/DataEx/Register-of-DE-for-AI-04-02-2014.pdf. The number of applications that were rejected is not available.

The Directive exceeds Malaysia's obligation under the TRIPS Agreement to provide data protection but is more flexible (like Chile) than the laws in countries such as the US, the EU, China and Singapore. While there can be competition concerns from implementing DE, such flexibility provides a degree of mitigation. If the scope of the Directive were to be expanded to biologics and possibly for a period longer than 5 years, the impact on competition from biosimilars will be more serious.

5.4 Patents and Competition

Research and development activities of pharmaceutical companies can be broadly categorized into two phases. The first is the innovation of new medicines that contain novel pharmaceutically active substances. Secondly, there can be incremental innovation related to existing medicines. This could include finding new therapeutic uses for existing medicines, the development of a new formulation or mode of delivery, the combination of previously disclosed active substances, or the use of a new salt or derivative of the original product.

A useful summary of the challenge and current trend in thinking about innovation in medical technologies is provided by a 2013 trilateral study conducted by WHO, WIPO and WTO on this point:[216]

"Innovation in medical technologies requires a complex mix of private and public sector inputs; it differs from innovation in general due to the ethical dimension of medical research, a rigorous regulatory framework, liability questions, and the high cost and high risk of failure. Economic, commercial, technological and regulatory factors have precipitated rapid change in the current landscape for R&D, involving more diverse innovation models and a wider range of active players.

"Providing specific incentives to absorb the high cost and associated risks and liabilities is a central policy challenge; this has been the historic role of the patent system in particular as applied to pharmaceuticals. While estimates vary of the actual cost of medical research and product development, innovation is undoubtedly costly and time consuming. The risk and uncertainty of innovation increases R&D costs in this sector, as the cost of products that fail to clear regulatory hurdles to become commercialized products has to be added...

"Rising expenditure for medical research has not been matched by a proportionate increase in new products entering the market, sparking a debate about research productivity and a quest for new models of innovation and for financing R&D. Many initiatives are exploring new strategies for product development, thus informing a rich debate about how to improve and diversify innovation structures to address unmet health needs. Current policy discussions have reviewed possibilities for open innovation structures, and a range

[216] WHO, WIPO, WTO (2012). *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (trilateral study), http://www.who.int/phi/promoting_access_medical_innovation/en/

of push and pull incentives, including schemes such as prize funds that would delink the price of products from the cost of R&D."

So far, patents have been considered to be a major incentive for innovation. Patents on the active molecules themselves are usually known as "primary patents". Further applications can be filed for "secondary patents", including for different dosage forms (e.g., tablets, capsules or solutions for injection) or for particular pharmaceutical formulations (mixtures of active agents and other substances which promote the activity of the medicine by, for example, enhancing absorption in the body) or to cover compositions/combinations, esters and ethers, polymorphs, analogy processes, active metabolites etc. The "evergreening" effect of secondary patents is increasingly the subject of competition investigations (see Chapters 6 and 7) and national patent regulations in some countries are setting more rigorous standards for what can be "new" or an "inventive step" for a medicine to qualify for a patent.

According to the WHO Commission on Intellectual Property Rights, Innovation and Public Health, "evergreening" is "a term popularly used to describe patenting strategies when, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term". Secondary patents often extend exclusivity when a primary patent expires, and consequently delay or limit entry of generics and competition. A study of the 1,304 patents on new molecular entities listed in the US Food and Drug Administration's Orange Book between 1988 and 2005 showed that secondary patent claims extended patent protection by an average of 6.3 to 7.4 years.[217]

At the same time the number of patent challenges has increased rapidly since the late 1990s. In this regard, over 80% of the new molecular entities (NMEs) experiencing first generic entry in 2011-12 experienced a patent challenge, compared with an average of less than 20% prior to 1998.[218]

A patent gives its owner the right to prevent others from making, using, selling, offering for sale or importing for these purposes the patented invention, which may include a medicine. The basic function of the patent is anti-competitive in that it prevents identical (or equivalent in a patent sense) versions of the same product from being made and placed on the market. However, patents are thought to induce innovation and new products, and this innovation-inducing function is seen as promoting competition by promoting new entrants into a market (or creating new markets). In theory, this provides an adequate social offset to the anti-competitive function.[219]

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[217] Kapczynski, A., P. Chan and B. Sampat (2012). "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents", *PLOS Journal*, http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470

[218] Gabowski, H., R. Guha and M. Salgado (2014). "Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future", *Health Affairs*, 33(6), 1048-1057.

[219] Abbott, Frederick M., Sean Flynn, Carlos Correa, Jonathan Berger and Natasha Nyak (2014). *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries, UNDP*, at page 75.

Patented health technologies present complex issues in respect to monopoly and/or dominant position. The patent by its nature confers on its owner the right to exclude third parties from introducing an identical or equivalent (i.e., infringing) product into the market. When it adopts patent protection for health technologies, a national government elects to confer monopolies on particular innovators. Each patent owner (assuming a drug is introduced into the market) possesses a monopoly for that specific product but does not necessarily enjoy monopoly in a therapeutic class. That is, there may be acceptable substitutes.[220]

The fact that a patent owner enjoys a legislated monopoly does not mean that this monopoly position may not be abused. For example, the owner might require purchasers of its patented medicine to purchase a full product line as a condition of purchasing the patented medicine. Such a condition will substantially leverage the power of the patent owner. The patent owner may be unlawfully extending the power of the patent to foreclose competitors from pursuing the same customers.[221]

In 2013 the US Supreme Court observed in *FTC v.* Actavis that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' – and consequently antitrust law immunity – that is conferred by a patent."[222]

The WHO, WIPO and WTO trilateral study also covered this topic, stating that:
"Competition policy is relevant to all stages in the process of supplying medical technology to patients, from their development to their sale and delivery. The creation of sound competitive market structures through competition law and enforcement has thus an important role to play in enhancing both access to medical technology and fostering innovation in the pharmaceutical sector. It can serve as a corrective tool if and when IP rights hinder competition and thus constitute a potential barrier to innovation and access. Competition authorities in several jurisdictions have taken action to address anticompetitive practices in the pharmaceutical sector, including some patent settlements, certain licensing practices and pricing policies. Competition policy also has an important role to play in preventing collusion among suppliers of medical technology participating in procurement processes."

The TRIPS Agreement came into effect in Malaysia in January 1995. This agreement sets international minimum standards for the regulation of intellectual property for its Members, but leaves considerable policy space for national laws to determine the level of intellectual property protection. In the case of patents, a minimum patent term of 20 years[223] is to be provided for all technological products and processes that satisfy the

[220] *Ibid*.
[221] *Ibid*.
[222] US Supreme Court, *Federal Trade Commission (FTC) v. Actavis*, Sup. Ct., 526 U.S. 756, US Supreme Court, Washington, DC, 2013.
[223] The duration of a granted patent starts from the date of filing of the patent application.

criteria of novelty, inventive step and industrial applicability. These 3 patentability criteria are determined under a country's national law. This is an important aspect of national sovereignty in law-making because rigorous patentability criteria can filter out "weak" patents from being granted on medicines that are not really new when compared with everything that has already been done in the world or on medicines incorporating small changes without additional therapeutic value. In this way, generic competition can be increased in the pharmaceutical sector.

The TRIPS Agreement has two parts that are directly related to competition. The first is Article 31 that deals with the right of Members to use compulsory licensing on grounds to be determined in national patent law. Article 31(k) permits such licensing to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration to be paid to the patent holder in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.

The anti-competition ground for a compulsory licence is significant because the conditions that apply to third-party compulsory licences can be waived: prior negotiations with the patent holder; limits on scope and duration; non-exclusivity; prohibition of assignment; export restrictions. In such a situation, therefore, a generic company would be able to enter the domestic market as well as export to other countries.

The second part of the TRIPS Agreement that is directly related to competition deals with control of anti-competitive practices in contractual licences. Article 40.1 states, "Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology." As such, the national law of countries can specify licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.

Patents Act 1983, Patent Regulations 1986 and Guidelines for Patent Examination 2011

The Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC) is responsible for intellectual property in Malaysia, and the administration of the Patents Act. The examination and granting of applications for patents and other intellectual property claims lies with the Intellectual Property Corporation of Malaysia (MyIPO).

The government can also control or prevent certain licensing practices that are anti-competitive when a patent holder grants a voluntary licence to another party. For example, a voluntary licence may be granted by an originator company to a generic company on anti-competitive terms such as exclusive grantback conditions, conditions preventing challenges to patent validity or coercive package licensing.

In situations of anti-competitive conduct, the government (through MDTCC) can grant a compulsory license to allow someone else to manufacture the patented product or use the patented process without the consent of the patent owner. The use of compulsory license requires payment to the patent owner. This is one of the flexibilities on patent protection included in the TRIPS Agreement and contained in the Patents Act.

(A) SCOPE OF PATENTS AND PATENTABILITY CRITERIA

As stated above, the TRIPS Agreement does not directly restrict Members' right to define what constitutes patentable subject matter, and Members do have considerable flexibility in defining patentable subject matter.[224]

The scope of what can be patented, and the criteria for what is patentable, impact on the level of competition in the pharmaceutical sector. Some countries exclude from patentability, subject matter that would fail to meet rigorous patentability criteria of novelty, inventive step and industrial applicability.[225] Malaysia's Patents Act and Patent Examination Guidelines allow for a broad range of secondary patents for pharmaceuticals that have been excluded in some countries because these have an "evergreening effect" which can have anti-competitive impact on entry of generics.

Although the TRIPS Agreement does not require patents to be granted on new uses of an old medicine (in fact Article 27.2 thereof specifically excludes patenting of methods of treatment), the Patents Act allows patents on new uses in a number of ways, including methods of treatment.[226] So, for example, zidovudine (AZT) was originally developed as a medicine to treat cancer, but it was later found to be effective in treating HIV.[227] Using AZT to treat HIV did not constitute a new medicine or a new manufacturing process, but it could be characterized as a new "method of treatment" and so could be patentable.

From a health perspective, the standard for "inventive step" should be high. The Patents Act defines "inventive step" as something that is not obvious to someone with ordinary skill in the art. A higher standard would be something that is not obvious to someone who is highly skilled in the art because an experienced professional in the given field will find more things obvious and so fewer medicines which are simple innovations or variations would be patentable with this higher standard.

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[224] Article 27 of the TRIPS Agreement, which contains the provisions as to patentable subject matter, leaves the definition of the relevant terms therein such as "invention" or "fields of technology" to the discretion of each Member country.

[225] Examples include Argentina, Ecuador and India. South Africa is in the process of developing patentability criteria that take into account pharmaceutical characteristics: https://pharmaintelligence.informa.com/resources/product-content/tighten-up-on-patenting

[226] Section 11 states that an invention is patentable if it is new, involves an inventive step and is industrially applicable. Section 12 then goes on to define "invention" and states that "an invention may be or may relate to a product or process." The wording "may relate to" by itself broadens the scope of what is an invention to include methods of treatment, which is one way of allowing patents on new uses of a known medicine. The qualification to Section 13(1)(d) allows patenting of a product used for a method of treatment and thus opens the door for patents on new uses of a known medicine. Section 14(4) ensures that old medicines which are used in a new method of treatment will still be patentable by making sure they do not lose their novelty.

[227] See for example http://vrc.nih.gov/publications/discovery/thiv.htm and http://aidshistory.nih.gov/transcripts/bios/Samuel_Broder.html.

Further, if there is evidence that an invention is already known at the time when a patent is applied for (known as "prior art"), then the application will be rejected. A wider definition for what constitutes prior art would result in fewer patents being granted. In the Patents Act, the definition of prior art under the inventive step requirement is narrow.[228] This narrower definition means that more medicines could be deemed inventive and so be granted a patent.

Argentina's experience is revealing. New guidelines for the examination of patentability of chemical-pharmaceutical inventions were jointly developed by the Ministry of Health, Ministry of Industry and the National Institute of Industrial Property and issued in May 2012. This was in response to growing concerns over high medicine prices linked to the high number of pharmaceutical patents granted in the country. When the new guidelines were applied (including on pending applications) in 2012 itself, the number of patents granted in Argentina was 54, while in Mexico, a similar-sized market to Argentina, the number of patents granted was 2,500.[229] The reason for the difference was that Argentina's guidelines do not allow patenting of compositions, doses, ethers, polymorphs, etc. because these do not satisfy the requirements of "novelty" and "inventive step".

(B) EXAMINATION OF PATENT APPLICATIONS

Under Malaysia's Patents Act, the person applying for the patent has to request that their application be substantively examined.[230] This substantive examination can be the full "substantive examination" or a "modified substantive examination". If a patent has already been granted for essentially the same invention in certain countries or under certain treaties, then only a modified substantive examination needs to be done.[231]

Substantive examination: This requirement for applications to be substantively examined can be waived for any reason as long as the intention to waive it is published in the Gazette.[232] Although no pre-grant opposition is currently allowed in Malaysia, a person who would be aggrieved by the decision to not substantively examine the patent application can be heard by the patent office.[233]

Modified substantive examination: If a patent has already been granted to the applicant in Australia, Japan, the Republic of Korea, the United Kingdom or the US or under the Patent Cooperation Treaty (PCT) administered by the World Intellectual Property Organization or European Patent Convention for substantially the same invention, then a modified substantive examination can be carried out.[234]

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[228] It has been narrowed for inventive step compared with the definition of prior art used for novelty. Section 15 excludes unpublished patent applications from being part of the prior art for the purposes of inventive step.

[229] Velasquez, G. (2015). "Guidelines on Patentability and Access to Medicines", Research Paper No. 61, South Centre, March 2015, https://www.southcentre.int/wp-content/uploads/2015/03/RP61_Guidelines-on-Patentability-and-A2M_rev_EN.pdf

[230] Section 29A.

[231] Section 29A(2).

[232] Section 30(7).

[233] Section 30(7).

[234] Section 29A(2).

This means that the only substantive requirements that are checked are novelty and whether it is a patentable invention. However, novelty is only checked in special circumstances and even then, it is a very limited novelty search. In effect, this means that a patent that has been granted in the countries listed above and all those granted under the PCT will automatically be granted if an application is made in Malaysia.

Malaysia is a PCT member, which usually leads to more applications received, all of which are more likely to be approved if they have been granted overseas. As Malaysia does not require patent holders to automatically provide information if their patents are later revoked or invalidated in other countries, this approach means significantly more medicines in Malaysia can receive patents and remain patented.

The special character of medicines, as discussed in Chapters 6 and 7, means that pharmaceutical patents can have a major impact on competition and access to affordable medicines. Substantive examination of these patent applications should always take place, rather than a waiver or modified examination.

Another issue related to pharmaceutical patent examination is the technical and scientific knowledge that is needed to assess prior art. Some patent offices have in-house technical expertise in pharmaceuticals and chemistry (e.g., China). In Malaysia, there is an agreement between the MOH and MyIPO to establish a mechanism for the MOH to provide inputs in pharmaceutical patent examination. At the time of writing this is not in place yet.

(C) COMPULSORY LICENCE/"RIGHTS OF GOVERNMENT"

Where a patent has been granted but there is anti-competitive conduct by the patent holder, the Patents Act provides for compulsory licences on application of a third party (in this case, it would normally be a generic company).[235]

The government can also invoke the "Rights of Government" for itself or a third party, to use a patent without the consent of the patent holder. This is a form of compulsory licence as well.

The Act sets out the circumstances and conditions for the issuance of a compulsory licence and Rights of Government authorization. The Minister of Domestic Trade, Cooperatives and Consumerism[236] is responsible for issuing the two types of authorization.

(i) Compulsory licences for third parties are covered in Part X of the Patents Act. There is a prescribed form under the Act for applications for a compulsory licence, which is simple to use.

[235] Section 84(1)(b).

[236] In Malaysia, the Ministry of Domestic Trade, Co-operatives and Consumerism is responsible for intellectual property. MyIPO is a statutory body responsible for patent examination.

Compulsory licences can be given if the patented invention is not being produced in Malaysia without any legitimate reason[237] (failure to do "local working"); or if the product made in Malaysia is sold at unreasonably high prices or does not meet the public demand without any legitimate reason;[238] or if certain inventions in later patents cannot be worked in Malaysia without infringing on earlier patents ("interdependent patents").[239]

The TRIPS Agreement allows compulsory licences to be issued in any situation,[240] but the Malaysian law significantly restricts the situations in which a compulsory licence can be issued. The lack of national emergency/extreme urgency grounds for issuing compulsory licences in Malaysian legislation also means that a compulsory licence cannot be issued in Malaysia without prior negotiations with the patent holder as allowed by the TRIPS Agreement.[241]

Anyone can apply for a compulsory licence in Malaysia[242] (except for interdependent and lapsed patents), which means generic manufacturers/importers or patient groups, for example, are eligible to apply. Recipients of a compulsory licence are permitted in Malaysia to exercise any of the rights of the patent holder (except assigning/transmitting/licensing the patent).[243] The TRIPS Agreement requires countries that are WTO Members to allow a compulsory licence to be terminated if the circumstances which led to it cease to exist and are unlikely to recur.[244] This is in the Patents Act.

There is an amendment to the TRIPS Agreement to allow generic medicines manufactured under a compulsory licence to also be exported to countries with insufficient manufacturing capacity. The original TRIPS provision had a restriction whereby such medicines must be predominantly for supply to the domestic market of the country that issued the licence. The Patents Act has not been accordingly amended yet, so for the time being a compulsory licence in Malaysia is still predominantly for supplying Malaysia.[245]

Including this TRIPS Agreement amendment in the Patents Act would open up opportunities for Malaysian companies authorized to manufacture under a compulsory licence in the country to also export the medicines concerned.

Section 49(2) of the Patents Act requires anyone applying for a compulsory licence to first attempt to negotiate a voluntary licence with the patent holder. A compulsory licence holder has to pay a royalty to the patent holder. There appears to be no maximum level

[237] Section 49(1)(a).
[238] Section 49(1)(b).
[239] Section 49A.
[240] Reaffirmed by paragraph 5(b) of the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"), 14 November 2001, WT/MIN(01)/DEC/2.
[241] Article 31(b), TRIPS Agreement.
[242] Section 49(1).
[243] Section 48.
[244] Article 31(g), TRIPS Agreement.
[245] Section 53(1)(b).

of remuneration set in the legislation or regulations. The decision to grant a compulsory licence can be appealed to the courts.

(ii) "Rights of Government"

Section 84(1) of the Patents Act titled "Rights of Government" provides an important remedy for the government when a patent owner or his licensee (e.g., a company that holds a voluntary licence to manufacture or sell a patented medicine) behaves in an anti-competitive manner. In such a situation, if a judicial or relevant authority (i.e., MyCC) determines that there is anti-competitive conduct, the Minister of Domestic Trade, Cooperatives and Consumerism can, without the agreement of the patent owner, designate a government agency to work the patent. Alternatively, a third party can be designated by the Minister to do so.

The Minister can also exercise this right "where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires".

These provisions implement what is known as "public non-commercial use" under the TRIPS Agreement, whereby under defined circumstances a patent can be worked by a government (or a third party) without the consent of the patent holder.

As allowed in the TRIPS Agreement for "public non-commercial use", Malaysia's government use provision does not require the government to try and negotiate with the patent owner for a voluntary licence before issuing the "government use" order.

The patent owner shall be notified of the Minister's decision "as soon as is reasonably practicable". Section 84(3) provides for "the payment to the owner of the patent of an adequate remuneration". This provision mirrors the TRIPS Agreement.

The Rights of Government provision is limited to predominantly supplying the market in Malaysia.[246] This means that if MyCC or a court decides that there is anti-competitive conduct by a patent owner, and another company is authorized to manufacture the patented medicine, it must be "predominantly" for the Malaysian market and the quantity allowed for export will be restricted. It is to be noted that the TRIPS Agreement does not require government use orders or compulsory licences issued to remedy anti-competitive conduct to be limited to predominantly supplying the domestic market.[247] This limitation in the Patents Act can thus be considered for amendment.

The patent owner can appeal to the courts the Minister's decision to issue a Rights of Government order.[248]

[246] Section 84(8).
[247] Article 31(k), TRIPS Agreement.
[248] Section 84(12).

If such an order proceeds, "adequate remuneration" shall be paid to the patent owner, and the amount is to be decided "after hearing the patent owner and any other interested person if they wished to be heard". This is consistent with the TRIPS Agreement.

In 2003, Malaysia became the first country following the adoption of the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health to issue a "government use" type of compulsory licence.[249] This was for the import of generic versions of selected patented antiretroviral (ARV) medicines from the Indian company Cipla for HIV treatment in government hospitals and clinics.

As a result of growing concerns over high prices of patented and non-patented ARVs in Malaysia, the MOH started in 2001 to seek price reductions from pharmaceutical companies. In July 2001 some reductions were obtained as a result of these negotiations but these were not satisfactory; prices remained too high, especially with the MOH's limited budget.

Thus in 2003 the MOH initiated the process for a Rights of Government order. With the use of the generic ARVs, the average cost of MOH treatment per month per patient dropped from US$315 to US$58, equivalent to about an 81% reduction. There was thus a considerable reduction in cost for the first- and second-line ARV regimen for use in government hospitals and clinics. The number of patients who could be treated in government hospitals and clinics increased from 1,500 to 4,000. However, the import authorization was only for 2 years and currently the new ARVs that are patented are once again unaffordable. (See Chapter 4.)

In September 2017, Malaysia invoked Section 84(1) again, this time for sofosbuvir for hepatitis C treatment – a medicine that actually cures hepatitis C patients. The decision was made after more than 2 years of unsuccessful negotiations to reach a price that is affordable to the MOH for scaling up treatment.

In both instances, the Cabinet made the decision after considering the facts and public health need.

(D) CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Section 8 of the TRIPS Agreement contains a set of rules aimed at the control of "anti-competitive practices" in voluntary licences granted by a patent owner. Article 40.1 recognizes that some licensing practices pertaining to intellectual property rights which restrain competition "may have adverse effects on trade and impede the transfer and dissemination of technology". Article 40.2 expressly allows Member countries to adopt measures to control or prevent certain licensing practices. The test to assess the practices to be prevented should be based on a case-by-case analysis of whether the practices

[249] The Doha Declaration adopted by the WTO Ministerial Conference reaffirmed the rights, flexibilities and safeguards vested in WTO Members by the TRIPS Agreement. One of these is the use of compulsory licences on grounds to be determined by national law.

constitute an “abuse” of intellectual property rights with an “adverse effect on competition in the relevant market”.

Article 40.2 also provides a few examples of practices that may be deemed restrictive, but this list is not exhaustive. The examples listed are exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing. In some cases, where a practice (e.g., no-challenge clause) will always constitute an abuse with adverse effects on competition, it may be defined as restrictive per se (UNCTAD, 1996:52).

The Patents Act currently has Section 45 on invalid clauses in licence contracts but this could be reviewed and further expanded in light of current jurisprudence and state practice in other countries regarding anti-competitive licensing practices that constitute an abuse of intellectual property rights.

(E) OTHER ISSUES

A patent can be challenged only through a patent invalidation process at the High Court. There is no provision in the Patents Act for pre-grant opposition (as in India) or pre-grant third-party observation (as in China). The TRIPS Agreement leaves patent challenge procedures to a country to determine in its national patent law – such procedures can be administrative (as in most countries) or judicial (as in the US). As seen in India, an established pre-grant opposition system when used well can assist patent examiners in gathering more information, e.g., on prior art, that is available in other parts of the world.

In contrast, judicial challenges are more expensive and can go on for many years. From the interviews with generic manufacturers and importers conducted for this Review, there is a “chilling effect” which results in a high degree of reluctance to challenge patents even though there may be legitimate and strong grounds to do so.

The Patents Act review can also consider these issues.

5.5 National Intellectual Property Policy (NIPP)

This section assesses Malaysia’s NIPP that was adopted in July 2007 in the context of the National Medicines Policy and Competition Act. A comparison is made with China’s National IP Strategy that was released in June 2008 after more than 2 years of research and consultations. The World Intellectual Property Organization (WIPO) provided considerable technical assistance to developing countries to formulate national intellectual property (IP) policies and laws so there are some basic similarities in the 2 policies.

The NIPP is a short, generally worded document compared with the National Medicines Policy. One of the aims is to “Strengthen the long-term competitiveness of the nation, by developing the IP industry into a mature and highly developed industry that generates, manages and commercializes IP effectively.”

At that time the rationale was centred on the government's ambition for the Multimedia Super Corridor focusing on the information technology and biotechnology sectors and these are mentioned in the document. Health and the pharmaceutical sector are not mentioned. The policy regards IP as an industry and an asset with economic potential that can be exploited. There is no differentiation in terms of how IP will affect different sectors, and there is no differentiation on the types of IP (patents, trademarks, copyright, industrial design, geographical indication).

The NIPP has 8 objectives with the overarching goal of using IP as a driver for Malaysia's innovation and domestic industry development.[250] The first, on "Highest Standard of IP Protection System", seeks to "Develop an efficient and effective IP protection system to ensure fast and easy acquisition of protection and rights". The reasoning is that "In today's world where technology changes rapidly, a quick and easy protection of IP gives owners better competitive advantage and longer period to exploit the IP created and acquire from their efforts and investment ..."

The assumption of this objective does not seem to align with the domestic pharmaceutical sector. Firstly, technology does not change rapidly where medicines are concerned. Secondly, pharmaceutical patents are complex and the claims require careful examination and technical prior art search as opposed to "quick and easy protection". Thirdly, as this Review shows, there are anti-competitive effects resulting from pharmaceutical patents in terms of availability, affordability and accessibility of medicines.

Another objective is to "Encourage greater foreign investment and technology transfer by guaranteeing the highest standard of IP protection for IP brought into Malaysia, the opportunity to acquire returns from their investment and the availability of legal channels to seek redress and solution in cases of infringement. With the availability of foreign technology, the transfer of the needed technology into local industry can be encouraged through acquisition, licensing, franchising and etc."

As seen in Part One of this Review, foreign investment in manufacturing in the pharmaceutical sector is small, with local companies investing much more. There are multiple factors that determine foreign investment flows. Several major anti-competitive conduct cases as discussed in Chapters 6 and 7 show that patent strategies have been used for market monopoly rather than facilitate technology transfer.

Overall, the NIPP does not take into account the different interests in the Malaysian economic sectors and the balance of private and public interests.

[250] NIPP objectives: (1) Highest Standard of IP Protection System, (2) Promotion of IP-generated Activities, (3) Promotion of Commercial Exploitation of IP, (4) Development of IP Management Capabilities, (5) Development of Infrastructure of IP Transaction, (6) Protection of National IP Interest, (7) Human Resource Development and Public Awareness, (8) Promotion of Foreign Investment and Technological Transfer.

In contrast, the National IP Strategy of China[251] was based on a series of research studies, extensive national consultations with different industry and social sectors as well as inputs from experts from other countries.[252]

Paragraph 2 states:

> *"Intellectual property system is a basic system for developing and utilizing knowledge-based resources.* ***By reasonably determining people's rights to certain knowledge and other information, the intellectual property system adjusts the interests among different groups of persons in the process of creating and utilizing knowledge and information, encourages innovation and promotes economic and social progress.*** *In the world today, with the development of the knowledge-based economy and economic globalization, intellectual property is becoming increasingly a strategic resource in national development and a core element in international competitiveness ...* ***Developed countries take innovation as the main impetus driving economic development, and make full use of the intellectual property system to maintain their competitive advantages. Developing countries actively adopt intellectual property policies and measures suitable for their respective national conditions to promote development****"* (emphasis added).

There is recognition of the need to prevent abuses of IP, maintain fair market competition and safeguard the public lawful rights and interests in paragraph 14.

Paragraph 20 talks about balancing "the need for patent protection and the need to protect public interest properly. While strengthening patent right protection … we need to improve the compulsory licensing system and make good use of exception provisions. We need to work out relevant policies that are rational to ensure that the public is able to obtain necessary products and services in a timely and sufficient manner whenever a public crisis happens."

Since Malaysia's NIPP was formulated in 2007, it would be timely to develop a new policy that harmonizes with the public health and competition policies and laws in the country. This would also be consistent with the Patents Act review which requires clear policy direction and context.

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[251] http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn021en.pdf

[252] The Director of the Pharmaceutical Services Division (MOH) at that time was a speaker at an international consultation seminar (23-24 February 2006) organized by the State Intellectual Property Office of China that was the secretariat for the formulation of the country's national IP strategy. The MOH was invited to share Malaysia's experience in using a government use compulsory licence for HIV medicines.

5.6 Conclusion

The review of laws, regulations and technical requirements in this chapter is within the context of Malaysia's National Medicines Policy, promotion of the domestic pharmaceutical industry and Fair Trade Practices Policy.

Patents were identified by domestic manufacturers and importers as one of the barriers to generic medicines entering the Malaysian market and generating competition and growth of the domestic industry. The Patents Act is currently under review, which provides an opportunity for making maximum use of the rights and flexibilities that Malaysia has under the TRIPS Agreement. For example, MyCC and the Ministry of Domestic Trade, Co-operatives and Consumerism (MDTCC)/MyIPO can collaborate to expand Section 45 of the Patents Act on invalid clauses in licence contracts to include more anti-competitive licensing practices that constitute an abuse of intellectual property rights.

The Patent Examination Guidelines also need to be reviewed to be more rigorous for the examination of pharmaceutical patent applications. The technical work that has been undertaken by international experts in the field of patents and pharmaceuticals as well as the recent national experiences in other countries can benefit Malaysia. MyIPO's scientific and technical capacity for the examination of pharmaceutical patent applications can be enhanced, while the role for the MOH in this regard should be clearly established in a joint mechanism.

In addition, the NIPP is not aligned with the abovementioned policies with regard to access to affordable medicines. A review and updating of the NIPP would be useful.

The current pharmaceutical product registration requirements are in compliance with international standards, and comparable to those in high-income countries. These are important to create confidence in the quality, safety and efficacy of products manufactured in Malaysia, both for domestic consumers and for export markets. Nevertheless, some of the requirements and standards pose significant challenges to the domestic generic industry. The main concern is delay in generics entering the market and high costs to the local manufacturers and importers. Thus there should be attention on such regulatory requirements becoming regulatory barriers without adding value to quality, safety and efficacy considerations (see Chapter 6).

The Data Exclusivity Directive explicitly takes account of public health, and more than meets the international requirements of data protection related to clinical tests under the TRIPS Agreement.

MyCC and the MOH have started engaging with the United Nations Development Programme (UNDP) on the use of competition law to deal with abuse of patents and other intellectual property rights in order to increase access to affordable medicines and ensure robust competition in the pharmaceutical sector. The potential to develop rules and practices in this area is promising, at both the national and regional levels (e.g., through ASEAN and WHO regional offices).

CHAPTER 6: COMPETITION CONCERNS AMONG INDUSTRY PLAYERS

As seen from Part One, the government is the largest pharmaceuticals purchaser and generic medicines make up almost 60% of its procurement. These are mostly supplied by local manufacturers, with the rest sourced from generic imports. While some domestic manufacturers are investing in research and development to produce higher-value-added generic medicines such as oncology medicines and biosimilars, the majority of high-end medicines are still imported and these are originator medicines of MNCs.

A 2014 industry market review notes that Malaysia's changing disease burden and demographic profile provide good opportunities for foreign pharmaceutical companies that have already developed drugs to treat these "Western type diseases" (i.e., non-communicable or "lifestyle" diseases). It further noted the rapid growth of the Malaysian pharmaceutical market.[253]

While innovation is key to the continued availability of medicines to treat the diseases of this century, the high cost of originator medicines often renders them unaffordable to most of the population. It is recognized that generics play a crucial role in cost containment for public health budgets and in making safe, effective and affordable medicines available to all. While innovation should be rewarded (for example, by way of intellectual property rights), balance is needed to ensure a competitive business environment that will not harm public budgets and ultimately consumers. In this regard, a new study shows that the cost of development of 10 new cancer medicines (the most expensive of new drugs) is not as high as previously estimated.[254] The median cost was found to be US$757 million per drug; half of the drugs cost less and the other half cost more. This is far less than the oft-quoted figure of US$2.7 billion per drug (in 2017 dollars) previously estimated by the Tufts Centre for the Study of Drug Development.

This chapter seeks to indicate the type of conduct of level 1 and 2 players (predominantly level 1) that is considered in anti-competition investigations. As stated earlier, the Review team was not able to look at issues concerning level 3 players in detail due to time constraints. Note is however made of the issues relating to dispensing separation and price discrimination towards the end of the chapter.

[253] "Malaysia pharmaceutical market update", Pharmaphorum, https://pharmaphorum.com/views-and-analysis/malaysia-pharmaceutical-market-update-2014/

[254] Prasad, V. and S. Mailankody (2017). "Research and development spending to bring a single cancer drug to market and revenues after approval" , *JAMA Intern Med.*, published online 11 September 2017, 10.1001/jamainternmed.2017.3601Google Scholar

Chapters 6 and 7 do not suggest any wrongdoing or make any finding of liability concerning any player in the industry in Malaysia. Such matters can only be evaluated and concluded on a full consideration of the facts on the basis of the statutory criteria set out in Chapters 1 (Section 4) and/or 2 (Section 10) of the Competition Act 2010. This is not within the purview of this Market Review which is carried out under Section 11 of the Act.

This chapter highlights the provisions of Chapters 1 and 2 of the Competition Act. The discussion on abuse of dominance focuses on the definition of "relevant market" for the pharmaceutical sector, identifies possible anti-competition issues at levels 1 and 2 in relation to the medicines selected for this Review, and suggests preventive or remedial measures. Dispensing separation and price discrimination as well as regulatory barriers are also discussed.

6.1 The Competition Act and the Role of the Competition Authority

Increasingly, competition law is being used to promote access to medicines and other health technologies as an additional tool to complement other areas of the law.[255]

In Malaysia, the Competition Act 2010 (CA) came into effect on 1 January 2012. The Act is administered by the Malaysia Competition Commission (MyCC).

The long title to the Act states as follows: "An Act to promote economic development by promoting and protecting the process of competition, thereby protecting the interests of consumers and to provide for matters connected therewith.

"WHEREAS the process of competition encourages efficiency, innovation and entrepreneurship, which promotes competitive prices, improvement in the quality of products and services and wider choices for consumers:

"AND WHEREAS in order to achieve these benefits, it is the purpose of this legislation to prohibit anti-competitive conduct:"

Clearly then, the Act is primarily concerned with the protection of the process of competition and the interests of consumers, as opposed to the protection of competitors within the industry.[256] With that focus, it can be a tool to ensure the efficient use of public resources.[257]

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[255] UNDP (2017). "Using Competition Law to Promote Access to Medicines and Related Health Technologies in Low-and-Middle-Income Countries", Issue Brief, August 2017, http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicines-and-related.html

[256] See the discussion on the difference in Safinaz Mohd Hussein, Nazura Abdul Manap and Mahmud Zuhdi Mohd Nor (2012). "Market Definition and Market Power as Tools for the Assessment of Competition", *International Journal of Business and Society*, 13(2), 163-182.

[257] *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP.

The Act seeks to achieve its ends by governing horizontal and vertical anti-competitive agreements (Chapter 1)[258] and ensuring that a dominant position is not abused (Chapter 2).[259] It differs from competition law in many other jurisdictions in that it does not regulate mergers and acquisitions.

Its scope extends to all "commercial activity" within Malaysia, and that outside Malaysia which has an effect on competition in any market in Malaysia. For the purposes of the Act, "commercial activity" does not include "any activity, directly or indirectly in the exercise of governmental authority".[260]

In the short course of this study, the team did not come across instances of horizontal collusive behaviour by originator or generic firms. At level 1 of the supply chain, a frequently raised concern (by local manufacturers) is the legal monopoly granted on originator medicines by the patent regime. For that reason, Chapter 6 concentrates on the manner in which the dominant position granted by the patent regime can be abused. This is done by looking at anti-competitive conduct arising under Chapter 2 of the Competition Act.

However, level 3 players have complaints of monopolistic behaviour and price discrimination by originator drug companies and/or distributors, and the possibility of vertical anti-competitive agreements and abuse of dominance impacting on level 3 players need to be the subject of further study.

On abuse of dominance, the Competition Act does not prohibit monopolies. The issue here is that an enterprise which is in a position of dominance is prohibited from engaging (whether independently or collectively with other enterprises) in any conduct which amounts to an abuse of its dominant position.[261]

Danzon's 2014 study in the US[262] clarifies: "Monopolies that result from patents are generally regarded as necessary to encourage innovation. However, attempts by originator companies to extend the effective patent life of their drugs by filing patents for additional features or purified forms may overstep the intent of patents and constitute monopolization." Here, the issues include the use of patent strategies, product life-cycle management of medicines as patents for "blockbuster" drugs begin to expire, patent settlements to delay generic entry, and other practices affecting generic entry.

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[258] Examples of Chapter 1 prohibitions are cartel practices, bid rigging or price-fixing agreements. See MyCC (2012). Guidelines on Anti-competitive Agreements, http://www.mycc.gov.my/sites/default/files/handbook/MYCC-4-Guidelines-Booklet-BOOK1-10-FA-copy_chapter-1-prohibition.pdf

[259] Chapter 2 prohibitions are the main focus of this chapter. See also MyCC (2012). Guidelines on Abuse of Dominant Position, http://www.mycc.gov.my/sites/default/files/handbook/MYCC%204%20Guidelines%20Booklet%20BOOK2-6%20FA%20copy.pdf

[260] Section 3, Competition Act.

[261] MyCC (2012). Guidelines on Abuse of Dominant Position, http://www.mycc.gov.my/sites/default/files/handbook/MYCC%204%20Guidelines%20Booklet%20BOOK2-6%20FA%20copy.pdf. Chapter 2 prohibitions are essentially activities that may force competitors out of the market and include imposition of unfair practices or trading terms, predatory behaviour, refusal to supply, the application of different conditions and controlling production.

[262] Danzon, Patricia M. (2014). "Competition and Antitrust Issues in the Pharmaceutical Industry", The Wharton School, University of Pennsylvania, https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf

Regulatory issues also have a role in determining robustness of competition in the pharmaceutical sector and these have been discussed in Chapter 5.

Danzon summarizes the situation in this sector as follows: "The pharmaceutical industry is characterized by atypical economics and an unusual intersection of regulation, patent and antitrust law … The anti-trust issues that have emerged in the pharmaceutical industry reflect the intersection of the industry's underlying economic characteristics with the patent, regulatory and insurance institutions."[263] The Malaysian pharmaceutical sector review shows the same conclusion.

The use of competition law in the pharmaceutical sector in this country is in its early stages. There is thus much to be gleaned from more established jurisdictions. This chapter discusses competition concerns based on issues that have arisen from market research, inquiries and investigations in the European Union, the United States, South Africa and India, as they are relevant to Malaysia. The European Commission's competition inquiry into the pharmaceutical sector (covering 2000 to 2007), in particular, provides useful insights into how the patent regime and life-cycle management strategies can lead to abuse of dominance.[264]

Further, under the Competition Act, an "enterprise" means any entity carrying on commercial activities relating to goods or services, and a parent and subsidiary company shall be regarded as a single enterprise if, despite their separate legal entity, they form a single economic unit where the subsidiaries do not enjoy real autonomy in decision making.[265] Representatives of originator companies interviewed for this Review confirmed that substantial decisions for these companies are made globally. That then necessitates a consideration of the actions of the parent company in the wider context.[266]

Table 6.1 contains some examples of anti-competitive cases.

Table 6.1: Some Selected Cases of Anti-competitive Conduct

Allegation (anti-competitive conduct)	Countries	Example
Kickback	US	Novartis (Exjade, an iron chelation drug; and Myfortic, an anti-rejection drug for kidney transplant patients) (Court settlement reached – admission of liability, 2015) [267]

[263] This Review does not consider the role and impact of insurance institutions in this sector. A further study in this area is required.

[264] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

[265] MyCC (2012). Guidelines on Anti-competitive Agreements, http://www.mycc.gov.my/sites/default/files/handbook/MYCC-4-Guidelines-Booklet-BOOK1-10-FA-copy_chapter-1-prohibition.pdf, paragraph 2.6.

[266] Further, the Malaysian court does refer to the decisions of other authorities where the legal provisions in question are substantially similar. See the patent infringement case of KLHC (Commercial Division) Civil Suit No. 22IP-72-12/2014), http://kl.kehakiman.gov.my/sites/kl.kehakiman.gov.my/attachments/merck_sharp_v_hovid_(4).pdf

[267] US Attorney's Office, Department of Justice (November 20, 2015). Manhattan US Attorney Announces $370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals for Kickback Scheme Involving High-Priced Prescription Drugs, Along with $20 million Forfeiture of Proceeds From the Scheme: https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis

Allegation (anti-competitive conduct)	Countries	Example
Excessive pricing	South Africa	Roche, Pfizer and Aspen in South Africa (high-priced cancer drugs – Trastuzumab (Herceptin), Xalkori Crizotinib, Leukeran, Alkeran and Myleran) (Ongoing investigation at the time of writing) [268]
	EU	Aspen in the EU for high-priced cancer drugs (On-going investigation at the time of writing) [269]
	UK	Pfizer (phenytoin sodium capsules, anti-epilepsy drug) (fined £84.2 million by UK Competition and Markets Authority, 2016) [270]
Vexatious litigation/ denigration of generics	India	Roche (Trastuzumab, cancer drug) (On-going investigation at the time of writing) [271]
Anti-competitive discount scheme	UK	MSD (Remicade, a biological medicine called infliximab for treatment of patients with gastroenterology and rheumatology conditions) (UK's Competition and Market Authority's provisional decision, 2017) [272]
Pay-for-delay	EU	Lundbeck (Citalopram, used to treat depression) (EU Commission finding upheld by the General Court, 2016) [273]
		Servier (Perindopril, cardiovascular drug) (2014, EU Commission fined Servier 427.7 million euros) (see case study in Chapter 7)
	US	Pfizer and Ranbaxy (Lipitor, atorvastatin, reduces "bad" cholesterol) (Federal Appeals Court revived cases against companies, 21 August 2017) [274]
	UK	GSK (Paxil, antidepressant) (Fined US$54.5 million by UK regulators, on appeal at the time of writing) [275]
Refusal to supply	Spain	Aspen Pharma Ireland Ltd, Aspen Pharmacare Holdings Limited and Aspen Pharma Trading Limited (Aspen) (cancer therapies) (investigation on-going by Spain's National Authority for Markets and Competition at the time of writing) [276]

[268] International pharmaceutical companies investigated for cancer medicine prices: http://www.compcom.co.za/wp-content/uploads/2017/01/International-pharmaceutical-companies-investigated-for-cancer-medicine-prices.pdf

[269] Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines: http://europa.eu/rapid/press-release_IP-17-1323_en.htm

[270] Competition and Markets Authority (UK) (2016). "CMA fines Pfizer and Flynn £90 million for drug price hike to NHS", Press Release, 7 December 2016, https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs

[271] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.*, Competition Commission of India, Case No. 68 of 2016, http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf

[272] Hirschler, Ben (2017). "UK Competition Watchdog Accuses Merck of Obstructing Biosimilars", https://www.reuters.com/article/us-merck-co-britain-remicade/uk-competition-watchdog-accuses-merck-of-obstructing-biosimilars-idUSKBN18J12Z

[273] EU Commission (8 September 2016). Antitrust: Commission welcomes General Court judgments upholding its Lundbeck decision in first pharma pay-for-delay case, http://europa.eu/rapid/press-release_MEMO-16-2994_en.htm

[274] Pfizer, Teva, Ranbaxy must litigate Revived Anti-trust Claims: https://www.bna.com/pfizer-teva-ranbaxy-n73014463423

[275] Silverman, Ed (2016). "Glaxo, other drugs makers appeal UK fines for pay-to-delay deals", 20 April 2016, https://www.statnews.com/pharmalot/2016/04/20/glaxo-generics-antitrust-gsk/

[276] FDA News (2017). "Spanish anti-trust authority investigates prices of Aspen Pharma's cancer drugs", 13 February 2017, http://www.fdanews.com/articles/180431-spanish-antitrust-authority-investigates-prices-of-aspen-pharmas-cancer-drugs

Allegation (anti-competitive conduct)	Countries	Example
Bid rigging, price fixing, customer allocation	US	First charges brought by anti-trust division involving generic drugs against Jeffrey Glazer, former CEO, and Jason Malek, former president of generic drug company (antibiotic, doxycycline hyclate) (ongoing at the time of writing)[277]

6.2 Competition Act Chapter 2 Prohibitions: Abuse of Dominance

(A) DEFINING THE RELEVANT MARKET

In assessing a competition case, the relevant market in which the competition takes place must first be defined. This involves determining both the relevant product and geographical market. As explained by Mark Lemley and Mark McKenna in their work "Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP":

"[Competition law] is about market relationships. It is designed to promote competition. Competition doesn't occur in a vacuum; a company must compete with others in some market. As a result, the first step in virtually any [competition] case is the definition of the market in which the competitive harm is alleged."[278]

Defining the market accurately is crucial, as the breadth or narrowness of the definition may be determinative of the issue: the broader the definition, the more difficult it is to establish dominance. Hence in practice, complainants will seek to define the market narrowly, whilst the companies under investigation will seek to define it as broadly as is reasonably possible.[279]

The issue in pharmaceutical cases is establishing the relevant product market with accuracy. Traditionally, dominance is looked at from the viewpoint of market share, translating into market power, of a particular product. However, in pharmaceuticals, market share figures do not necessarily provide a good guide to market power. This is due to the high level of product differentiation within this market – the market should in fact be studied as a sum total of a large number of individual sub-markets and not as a single market.[280]

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[277] Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer

[278] Lemley, Mark A. and Mark P. McKenna (2012). "Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP", Georgetown Law Journal, 100(2055). Quoted by Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP.

[279] Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP.

[280] See Section 3.2 above.

As the European Court of Justice puts it: "The definition of the market is essentially a matter of interchangeability."[281] In pharmaceutical products, the industry turns to the Anatomical Therapeutic Chemical (ATC) classification system to determine interchangeability (or substitutability, as it is otherwise known).[282] There are 5 levels of ATCs, with ATC 1 being the widest and ATC 5 being the most specific.[283]

Take the example of cardiovascular drugs.[284] ATC 1 indicates the cardiovascular system. ATC 2 indicates the therapeutic main group: an example of this would be anti-hypertensive medicines which are used to treat high blood pressure (other examples would include diuretics, beta-blocking agents, calcium channel blockers and agents acting on the renin-angiotensin system). ATC 3 indicates the therapeutic /pharmacological subgroup, for example, plain ACE inhibitors (such as benazepril, enalapril, ramipril, lisinopril and perindopril) as opposed to other anti-hypertensives such as beta blockers, diuretics, calcium channel blockers and angiotensin-II receptor blockers, which form their own individual subgroups. For ACE inhibitors, there is an overlap between ATC 3 and 4.[285] At ATC 5, which indicates the chemical substance, an example would be perindopril alone. At this level, the only substitute for the drug would be its bioequivalent generic.

Price sensitivity is limited in this sector. A substantial factor defining substitutability is the doctor's prescribing pattern, influenced by the science underpinning the prevention, treatment and cure of the specific condition or illness and the safety, efficacy and side effects of the medicines under consideration.[286] Again, as stated in Chapter 3, how a particular drug affects a patient is a crucial consideration. "It is recognized that the spectrum of disease and their symptoms are unique for each patient. Disease management too is personalized to suit the individuals' requirements through the selection of specific formulations, their dosage form and strengths so as to achieve maximum therapeutic benefit. In addition, the pharmacodynamic response of a patient's body to a medicine varies due to genetic variability, co-morbidities and co-medication. Hence, the treating physician chooses the appropriate medicine in the suitable dosage form and strength, taking into account all the possible variability depending among other things on patient history…

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[281] For a more detailed discussion of interchangeability, see Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP, pages 118-119; see also definition of "market" under Section 2 of the CA.

[282] ATC is an internationally accepted classification system for drug utilization: WHO Collaborating Centre for Drug Statistics Methodology ATC/DDD Metholodgy/ History, http://www.who.int/medicines/regulation/medicines-safety/toolkit_methodology_history/en/

[283] Level 1 indicates the anatomical main group; level 2 indicates the therapeutic main group; level 3 indicates the therapeutic/pharmacological subgroup; level 4 indicates the chemical/therapeutic/pharmacological subgroup; level 5 indicates the chemical substance.

[284] See WHO ATC/DDD index https://www.whocc.no/atc_ddd_index/?showdescription=yes&code=C02

[285] See WHO ATC/DDD index, https://www.whocc.no/atc_ddd_index/?code=C09AA&showdescription=no. Also explained in the decision of the European Commission in the Perindopril (Servier) case (http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12422_3.pdf).

[286] Competition Commission of India. *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.*, Case No. 68 of 2016, para. 43, page 20.

Owing to these factors, the likelihood of substitution between formulations by patients is negligible. This argument is further strengthened by the fact that the standard treatment guidelines and consensus statements released by professional bodies for specific diseases explicitly mention treatment of choice (i.e. formulations, which are preferred over other formulations within the same group and are theoretically substitutable). For example, the treatment of choice for hypertension for young patients, pregnant women and elderly differs significantly." [287]

Evidence of substitution in the recent past is normally fundamental for market definition[288] and the market is defined on the basis of practical substitutability between formulations and not just theoretical substitutability.[289]

The relevant market thus has to be looked at on a case-by-case basis. Frequently, however, the relevant authority finds that the only substitute to the originator drug is its bioequivalent generic, and not the other alternatives in its therapeutic class (which prove to have no significant constraints on the price of the product under investigation).[290] The ATC 5 "standard" has been applied to both small molecule drugs (e.g., perindopril) and biologics (e.g., trastuzumab).[291] Both cases are discussed in Chapter 7. The medicines selected for this Review for treatment of cardiovascular diseases, cancer and HIV cover these 2 categories.

In some cases, Jonathan Berger points out, it might even be necessary to be more specific than ATC 5, by considering the galenic form (i.e., the pharmaceutical dosage form) of the drug. This might be necessary if the authority were dealing, for example, with a drug used to treat young children.[292] Again, the caveat would be that at the end of the day every case, or product, has to be looked at on its own facts.

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[287] Mehta A, Hasan Farooqui H, Selvaraj S (2016) A Critical Analysis of Concentration and Competition in the Indian Pharmaceutical Market. PLoS ONE 11(2): e0148951. doi:10.1371/journal. pone.0148951

[288] Case COMP/A. 37.507/F3 AstraZeneca, 15 June 2005, http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf

[289] Mehta A., H. Hasan Farooqui and S. Selvaraj (2016). "A Critical Analysis of Concentration and Competition in the Indian Pharmaceutical Market", PLoS ONE, 11(2): e0148951. doi:10.1371/journal. pone.0148951

[290] It was also observed by Jonathan Berger that US antitrust authorities almost always defined markets as consisting of a single product (ATC 5): Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP, page 114.

[291] See the decision of the European Commission in the Perindopril (Servier) case (http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12422_3.pdf), the decision of the Competition Commission of India in the Trastuzumab (Roche) case (http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf), the letter of chronic myeloid leukaemia (CML) experts in relation to the CML drug imatinib (http://www.bloodjournal.org/content/bloodjournal/121/22/4439.full.pdf) and the expert testimony of Professor Robin Wood in the South African Hazel Tau case in relation to antiretrovirals (see https://www.keionline.org/node/2074 and Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP, pages 119-122).

[292] Model 2, "Defining the relevant product market in access to health technologies cases: Using the ATC system as a starting point", *Using Competition Law to Promote Access to Health Technologies: A Guidebook for low-and middle-income countries*, UNDP, May 2014, pages 143-144.

The United Nations Development Programme (UNDP) also recommends adopting a more access-friendly approach in determining the issue of relevant market, i.e., the starting point for market determination should be ATC 5, with the company under investigation bearing the burden of showing why the relevant product market should be defined more broadly.[293]

(B) SELECTION OF MEDICINES FOR SPECIFIC CASE STUDIES

As explained earlier, any study of anti-competitive behaviour in the pharmaceutical market will necessarily have to be product-specific. For this reason, the Review identified specific medicines for consideration. The criteria for selection of the medicines were:

(i) The impact on Malaysians' public health according to the disease burden in the country (especially the rising trend of NCDs);
(ii) The high prices of the medicines;
(iii) The treatment efficacy of the medicines;
(iv) In relation to HIV/AIDS medicines that were chosen, it is part of the UN Sustainable Development Goal (SDG) 3 to reduce or end AIDS. Malaysia is committed to the SDGs and does in fact have in place an AIDS eradication programme whereby first-line treatment is provided for free. It will be seen, however, that the cost of medicines for second- and third-line treatments as well as patented medicines for some first-line treatments remains high and needs to be addressed in order that realization of the country's goal is not jeopardized.

The following are the medicines chosen:

(i) Cardiovascular drugs such as atorvastatin, perindopril and clopidogrel;
(ii) Cancer drugs such as trastuzumab and imatinib; and
(iii) Several second- and third-line treatments for HIV.

From the general list, research was done to determine if any anti-competition complaints had been made or investigations initiated against the manufacturers of the medicines in other countries. Chapter 7 sets out some of the results.

The European Commission's pharmaceutical sector inquiry is also relevant. The inquiry report looks at the utilization of patents and life-cycle management strategies by originator companies to prolong the monopoly of blockbuster originator drugs. These measures delay the entry of much-needed generics into the industry.

[293] Berger, J. (2014). "Market Definition", in F. Abbott et al., *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, UNDP, page 103.

(C) EUROPEAN COMMISSION PHARMACEUTICAL SECTOR INQUIRY: RELEVANCE FOR MALAYSIA

In January 2008 the European Commission launched a sector inquiry into EU pharmaceuticals markets under the EU competition rules (Articles 81 and 82 of the Treaty Establishing the European Community). Chapters 1 and 2 of the Malaysian Competition Act 2010 are similar in many respects to Articles 81 and 82 (renumbered as Articles 101 and 102 in an amendment of the Treaty).

The Commission's Pharmaceutical Sector Inquiry Report was adopted on 8 July 2009. It concluded that market entry of generic drugs was delayed and there was a decline in the number of novel medicines reaching the market. As more and more medicines, especially blockbuster drugs, went off-patent, originator firms were using different strategies to maintain profits. The sector inquiry suggested that company practices were among the causes of delay in generic entry, but did not exclude other factors such as shortcomings in the regulatory framework. As a follow-up, the Commission expressed the intention to intensify its scrutiny of the pharmaceutical sector under EU antitrust law, including continued monitoring of patent settlements between originator and generic drug companies.

On the basis of a sample of medicines that faced loss of exclusivity in the period from 2000 to 2007 in 17 EU Member States, the inquiry found that citizens waited more than 7 months after patent expiry for cheaper generic medicines, costing them 20% in extra spending.

The report noted that generic delays matter, as generic products are on average 40% cheaper 2 years after market entry compared with the originator drugs. Competition from generic products thus results in substantially lower prices for consumers. The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible. Among the conclusions was that defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts would remain under scrutiny. The methodology used in the inquiry is instructive and the findings are of assistance when considering the behaviour of originator companies that have global operations.

In the 8 years examined, due to the rising costs of healthcare, the European Commission had been vigilant in its monitoring of the European pharmaceutical sector for anti-competitive conduct. Following the final report, the Commission instituted a monitoring of the sector to ensure that patent settlements are not delaying entry of generics into the market or do not contain other restrictions that would be problematic under EU competition law. Annual reports have been published for the period mid-2008 to December 2015.[294]

[294] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

In particular, the Commission found that practically all originator companies subject to the inquiry had developed a tool-box – a term used by the industry – of instruments and measures for how to prepare for and react to generic entry.[295] Issues that are addressed in more detail in this chapter include:

(i) Patenting activities of originators;
(ii) Contracts, disputes and litigations between originator and generic companies;
(iii) Opposition procedures and appeals before patent offices;
(iv) Patent settlements and other agreements between originator and generic companies;
(v) Interventions of originator companies before national authorities deciding on marketing authorization, pricing and reimbursement of generic products;
(vi) Promotional activities; and
(vii) Second-generation products.

In a number of interviews conducted for this Review, generic manufacturers and importers highlighted patent barriers and the "chilling factor" of potential patent infringement proceedings when a medicine is covered by multiple patents. There is no provision for pre-grant opposition in the patent application process in Malaysia, and a patent can be challenged only through an invalidation process at the High Court. This is costly and time-consuming.

Several specific complaints of unfair or unreasonable treatment by suppliers in relation to procurement of medicines by providers were also raised.[296]

6.3 Anti-Competition Issues: Practices that Create a Barrier to Entry for Generic Medicines

(A) PATENT STRATEGIES

(i) Secondary Patents with "Evergreening" Effect

National patent systems that allow for secondary patents claim that it is important for patent holders to maintain the freedom to operate, to ensure that their research options remain as open as possible, in particular with regard to further development of their own inventions. Broad primary patents and secondary patents are considered instrumental to achieving this goal.

[295] European Commission (2009). *Executive Summary of the Pharmaceutical Sector Inquiry Report*, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

[296] At the same time, some suppliers also pointed to demands from providers for additional discounts and "bonus" packages.

However, the number of newly developed chemical entities has dramatically fallen[297] over the past years, but the number of patents over simple changes in chemistry/formulation of existing pharmaceutical products has continuously increased. Thousands of patents are granted per year on these incremental innovations, often trivial for a person skilled in pharmaceutical research and production.[298] There are concerns that secondary patents prolong the period of patent coverage for originator drugs and delay the entry of generics. The "evergreening" effect was discussed briefly in Chapter 5.

In Malaysia, a 2013 study lists the main obstacles to local generic entry as: pre-patent expiration market value of the innovator product; early entry of imported generics; patent clusters by innovators; cost of generics development; and compatibility of the new generic medicine with firms' existing product range.[299] Although this study was conducted several years ago, the interviews carried out for this Review confirm the same concerns regarding multiple secondary patents.

A case in point is that of a critical HIV medicine (brand name Kaletra) which is a combination of two antiretroviral agents: ritonavir and lopinavir. The basic patents for the underlying compounds were set to expire in 2014 and 2016, respectively, meaning that theoretically generic suppliers should have been able to supply the generic product beginning in 2016. However, the patent holder Abbott Laboratories filed a number of follow-on secondary patents (see Figure 6.1) that could delay generic competition in certain markets until at least 2028, i.e., 12 years after the basic compound patents expired and 39 years after the first patents for ritonavir were filed.[300]

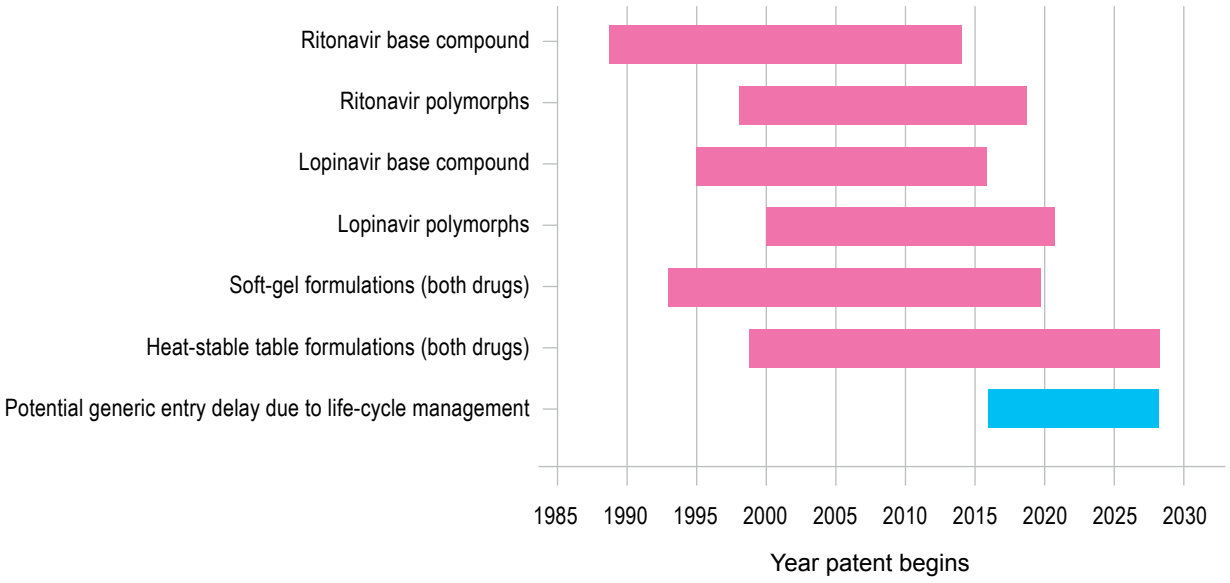
[297] Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO, 2006; Correa, C. (2011). "Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing", Research Paper 41, South Centre.

[298] Correa, C. (2011). "Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing", Research Paper 41, South Centre.

[299] Fatokun, Omotayo, Mohamed Izham Mohamed Ibrahim and Mohamed Azmi Ahmad Hassali (2013a). "Factors determining the post-patent entry of generic medicines in Malaysia: A survey of the Malaysian generic pharmaceutical industry".

[300] Amin, T. and A.S. Kesselheim (2012). "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades", *Health Affairs*, 31(10), 2286-2294.

Figure 6.1: Duration of Patents Covering Ritonavir and Lopinavir/Ritonavir



Source: Amin and Kesselheim (2012)

Note: (1) Timeline represents patents and patent clusters held by Abbott Laboratories. Dates shown are subject to future patent extensions and re-examination of patents at the request of parties who may have evidence of lack of inventiveness. The blue bar represents potential delay in generic entry as a result of life-cycle management, and not a patent duration.

(2) Polymorphs are alternate crystalline forms or amorphous solid forms of a base compound. Polymorphs may affect the drug's physical properties and pharmacokinetic characteristics, such as its stability, solubility, dissolution rate and absorption.

Table 6.2: Ritonavir and Ritonavir/Lopinavir Patents Granted

Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date
Lopinavir/Ritonavir 100/25 mg	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 100/25 mg	LPV crystal forms	Filed	MYPI20011034	03/07/2021
Lopinavir/Ritonavir 100/25 mg	LPV/r heat-stable formulations	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 100/25 mg	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027
Lopinavir/Ritonavir 200/50 mg	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 200/50 mg	LPV crystal forms	Filed	MYPI20011034	03/07/2021
Lopinavir/Ritonavir 200/50 mg	LPV/r heat-stable formulations	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 200/50 mg	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027

Product Name	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date
Lopinavir/Ritonavir 80/20 mg/ml	Lopinavir/RTV liquid compositions & capsules	Granted	MY199902107	27/05/2019
Lopinavir/Ritonavir 80/20 mg/ml	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 80/20 mg/ml	LPV crystal forms	Filed	MYPI20011034	03/07/2021
Lopinavir/Ritonavir 80/20 mg/ml	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027

In Malaysia, no patent application was filed for the lopinavir base compound. However, several secondary patents have been granted such as for lopinavir/ritonavir (LPV/r) liquid compositions and capsules (expires 27 May 2019), the ritonavir crystalline polymorph (expires 28 February 2021) and the LPV/r heat-stable formulation (expires 22 February 2026). In India, pre-grant oppositions led to the withdrawal of the patent applications for the ritonavir crystalline polymorph and LPV/r heat-stable formulation. These applications have also been rejected in Brazil and Argentina.[301]

A study by the European Commission in relation to 219 drugs found: "... nearly 40,000 patents had been granted or patent applications ... were still pending ... Of the nearly 40,000 cases, some 87 percent were classified by the companies as involving secondary patents, giving a primary: secondary ratio of approximately 1:7." The most common types of secondary patents filed in relation to the drugs included formulations (57%), combinations (7%), polymorphs (5%) and salts (4%). The European Commission also estimated a loss of around 3 billion euros due to delays in the entry of generic products caused by such patents.[302]

In 2011, the World Intellectual Property Organization (WIPO) released its patent landscape report for ritonavir, which is considered a critical part of HIV treatment and which acts as a booster in combination with key antiretroviral (ARVs). The report found that since the first specific patent filing on this essential medicine in 1994, around 800 patent families have been filed (with Abbott Laboratories as the primary assignee).

Another example is the case brought against pharmaceutical MNC Servier in Europe for its conduct in relation to its blockbuster drug perindopril (see below).

The European Commission in its pharmaceutical sector inquiry found that in general, blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product, also after product launch. Occasionally they show

[301] http://www.medspal.org/?product_standardized_name=Atazanavir/Ritonavir%20300/100%20mg

[302] European Commission (2009). Pharmaceutical Sector Inquiry, Final Report, paras 426 and 427; http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

an even steeper increase at the end of the protection period conferred by the first patent, in anticipation of imminent generic entry. In patent litigation cases, originator companies often rely on patents that were not yet filed when the product in question was launched.

The creation of the web of patents would mean that any attempt to develop a generic version of the medicine in a salt, crystalline or amorphous form would inevitably infringe a patent. To quote the originator companies:

- *"We were recently successful in asserting the crystalline form patent in [name of country], where we obtained an injunction against several generic companies based on these patents by 'trapping' the generics: they either infringe our crystalline form patent, or they infringe our amorphous form process patent when they convert the crystalline form to the amorphous form. […] The availability of 'trapping' strategy will be evaluated on an on-going basis".*[303]

- *"Our intelligence reveals that [generic company name] is developing a [salt form] of [patented pharmaceutical]. […] Fortunately we had anticipated the possibility of such a threat and last year filed several applications to alternative salts, including two for the [salt form]".*[304]

(ii) Disputes Between Originator and Generic Companies and Patent Settlement Agreements[305]

Originator and generic companies have different reasons for entering into settlement agreements when patent disputes arise. In its sector inquiry, the European Commission found that for originator companies, the fundamental factor considered is the strength of their position in a patent litigation (the expected likelihood of winning). When companies assess their position as strong, they do not consider entering into a settlement agreement. However, if their chances of winning are assessed as less strong and there is a great deal at risk, they give careful consideration to the possibility of settling with the other party.

For local generic manufacturers and importers interviewed for this Review, the main consideration is cost. Patent litigation is viewed as an extremely costly and lengthy affair which the companies cannot afford.

(iii) "Pay-for-Delay" Agreements

Although enforcing patent rights in court is a legitimate right of the patent holder, patent litigation can have a strong dissuasive effect on generic companies. The threat of such litigation can in itself create obstacles to market entry, namely, by increasing costs. Interim injunctions can further be used to prevent the sale of the generic product. The European Commission reports that patent holders do bring actions even where the chances of

[303] -ibid- para 493.

[304] -ibid- para 495.

[305] Observations in this section are from interviews with domestic companies and findings from the European Commission inquiry.

success are uncertain. This is reflected in the internal communication of one originator company: “Our strategy is clear. We want to send a signal (by applying for interim injunctions well knowing that we will not be granted a ban) that we do not accept early [generic] entry and then later we withdraw everything”.[306]

Not all patent settlements raise anti-competition concerns because in any jurisdiction, settlement agreements are accepted as a legitimate way to end legal disputes. However, as highlighted by the US Federal Trade Commission, settlements may contain arrangements that could fall within the scope of competition rules.[307] For example, the settlement agreement might lead to a delay in a generic product’s entry in a specific market in return for a payment by the originator company to the generic company. The types of settlement agreements that can be caught by anti-competition law are those where there is:

- A restriction on the ability to market; and
- A reverse payment from the innovator company to the generic one (direct transfer of money, distribution agreements, side deals or a licence).

There is a difference, however, between US and EU positions in assessing whether pay-for-delay agreements are anti-competitive.

The European Commission took the view that the sort of patent settlement agreement mentioned above constitutes a “by object” violation of competition law. According to the Commission, pay-for-delay agreements between an innovator and a generic company that restrict the ability of the generic company to enter the market in exchange for a transfer of value raise competition issues. This is because, in the view of the Commission, they induce the sharing of profits to the detriment of patients and public health budgets.

In comparison, the US Supreme Court held, in the Actavis case, that pay-for-delay agreements must be reviewed under the full rule of reason. The rule of reason consists of a case-by-case analysis which requires weighing the pro-competitive and anti-competitive effects of a particular agreement. Although the Court reasoned that “large” and “unjustified” payments might violate the antitrust laws, it left the task of developing the rule of reason analysis more fully to the lower courts.

In this Review, it is observed that in relation to Gleevec/Glivec (Novartis’ blockbuster cancer drug, imatinib mesylate), Ranbaxy did file for a patent for its generic on 15 February 2013 but did not proceed with the process, whilst Cipla received market authorization for its generic on 28 March 2013 but has not proceeded with supply of the medicine in Malaysia. It is further noted that both these companies were involved in disputes and subsequent settlement agreements with Novartis around about the same period.[308]

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[306] European Commission (2009). Pharmaceutical Sector Inquiry, Final Report, para 546; http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[307] -ibid -, at page 255.

[308] See *United Food and Commercial Workers Unions v Novartis*, US District Court, Massachusetts, Civil Action No. 15-cv-12732, at page 14.

(B) PRODUCT LIFE-CYCLE MANAGEMENT

The Indian Competition Commission in the trastuzumab case observed as follows: "… in the pharmaceutical industry, apart from pricing strategies, firms also indulge in non-price strategies to unlawfully raise their rivals' costs or exclude them from the market. Some of these practices, which have gained a reasonable degree of acceptance by other competition authorities as being abusive when adopted by dominant entities, are as follows:

(a) Rendering rivals' products incompatible without adding any technical improvement to the replaced product;
(b) Indulging in vexatious litigation purely aimed at harassing rivals;
(c) Influencing government or regulatory procedures; and
(d) Impeding entry of generics/biosimilars by denigrating or disparaging rivals' products." [309]

(i) "Authorized Generic Drugs"

This is where the originator company gives a licence to a generic company to manufacture and distribute a generic version of its product. The drug is manufactured according to the originator product specifications. As the generic company is bound by the terms of the licence, the generic entry is thus subject to licensing terms and conditions, leading to the term "authorized generic drugs". Competition authorities should monitor conduct in this area for potential anti-competitive arrangements and effects.[310]

(ii) "Second-Generation" Products

An illustration of how follow-on or second-generation products can be used to deter the entry of generics can be found in the perindopril case discussed more fully in Chapter 7. A second-generation product is essentially a product with the same active ingredient but in different formulation or dosages. In the perindopril case, Servier released perindopril arginine after it released perindopril erbumine in European markets. These two products are bioequivalent to each other but perindopril erbumine comes in dosages of 2mg, 4mg and 8mg whilst perindopril arginine comes in dosages of 2.5mg, 5mg and 10mg. It was found that perindopril erbumine and perindopril arginine are therapeutically the same and there is no increased efficacy.

Secondary products can be used to make generic entry difficult when the second-generation product is launched shortly before the expiry of the period of exclusivity of the initial product, accompanied by intensive marketing efforts to encourage the switch of patients to the new product. In the case of a successful switch, the precursor will be pulled from the market, patients will be transferred to the follow-on product, and generic sales of the precursor will not happen as most private hospitals will only use originators and prescriptions will be written for the new dosage form.

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[309] Biocon Limited and Anor v F. Hoffman -La Roche AG and 2 Ors., Competition Comission of India, Case No. 68 of 2016, para 60.

[310] For example, the US Federal Trade Commission has conducted a study on the competitive effects of authorized generic drugs. Source: FTC (2011). "Authorized Generic Drugs: Short Term Effects and Long Term Impact", https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf

Another example of follow-on products is the case of trastuzumab in India. The Roche Group had introduced trastuzumab, a breast cancer drug, under the brand name Herceptin in 2002. In 2012, it withdrew Herceptin from the Indian market and introduced cheaper versions of trastuzumab, viz., Biceltis and Herclon.[311]

(C) ACQUISITIONS OF, AND MERGERS WITH, GENERIC COMPANIES

The European Commission inquiry report also observed that a growing number of originator companies have acquired or are in the process of acquiring generic companies. They do so with a view to diversifying their product and risk portfolios as well as extending their geographical reach. Acquisition is seen by companies as an alternative strategy to launching their own generic products or licensing them out. The acquisition of potential generic competitors could pursue the objective of avoiding or limiting generic competition. However, mergers are carefully scrutinized under EU or national merger control rules. Furthermore, a trend to concentration among large originator companies or to the acquisition of biotechnology companies has been observed in recent times.[312]

In Malaysia, mergers and acquisitions are excluded from the scope of the Competition Act and regulated by the Securities Commission instead. Therefore this Review did not specifically investigate the issue of mergers and acquisitions. From the research of the general market, there did not seem to be cases of MNCs purchasing local generic companies. There have been purchases of local generic manufacturers by CCM and Pharmaniaga over the years to expand their operations. This *per se* does not appear to have anti-competition effects although monitoring of the growth of companies in this sector would be advisable.

(D) QUESTIONING THE EFFICACY OR QUALITY OF GENERIC MEDICINES

The Competition Commission of India, in deciding to initiate an investigation into trastuzumab against Roche India for alleged abuse of its dominant position in the market, considered conduct that raised doubts about biosimilars. Roche India had sent out letters to various regulatory authorities such as the Drug Controller General of India (DCGI) and to doctors and hospitals on safety issues pertaining to biosimilars of Roche's trastuzumab produced by its rivals Biocon and Mylan. Essentially, Roche "raised concerns regarding the clinical trials undertaken by the Informants for biosimilars and has tried to influence DCGI and other authorities. It has also tried to create a perception that biosimilar versions of the Informants' drugs may 'pose potential unknown risks to patients'."[313]

The Commission ruled that on the face of it, such efforts appeared to be an attempt by Roche to influence regulatory authorities against Biocon and Mylan's biosimilars. In so finding, the Commission cautioned: "The Commission is conscious that competitors, in normal business parlance, indulge in tactics to belittle competitors' products. However,

[311] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.*, Competition Commission of India, Case No. 68 of 2016, para 8, page 5.

[312] European Commission (2009), at pages 34-35.

[313] -ibid-, at para 67, page 29.

there is difference between puffery aimed at promoting one's own product and adopting practices which disparage or malign the image of competitors, thereby causing competitive disadvantages to them. This is even more harmful in the pharmaceutical sector, where such disparagement is made to the doctors who are treating the patients of cancer. The line of difference between these two business strategies is very thin, however, when crossed by a dominant enterprise to its own illegal advantage, it warrants intervention by the competition authority."[314]

Considering only the prescription medicines segment, on the global level, originator companies spent more money on marketing and promotion than on R&D (on average 23% of global turnover in the period 2000-2007). During the latter part of this period, the increase in the R&D budget was higher than that for marketing. From 2000 to 2007, absolute R&D expenditures constantly increased (with the exception of 2003) from 34 billion euros to 49 billion euros (for the sample of companies that provided complete data). However, in the same time period, marketing and promotion expenditures rose from 52 billion euros to 57 billion euros.[315]

In contrast, the generic industry does not have matching resources for marketing and promotion of its products. Therefore, educating the public about generic medicines is important to begin to overcome the information imbalance between consumers and doctors. For example, the US FDA's website provides dedicated information on generic medicines: "A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics … A generic medicine works in the same way and provides the same clinical benefit as its brand-name version. This standard applies to all FDA-approved generic medicines. A generic medicine is the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as in the way it is taken and should be used."[316]

Several studies have been conducted to address concerns over marketing strategies and the quality of information provided by pharmaceutical representatives. A comparative study covering Australia and Malaysia was carried out by Noordin Othman et al. in 2015[317] regarding primary care doctors' perceptions of claims made by pharmaceutical representatives. It concluded that doctors believed in the accuracy of the claims made by the representatives despite classifying most of those claims as vague. The majority of doctors further reported that presentations are likely to change their prescribing habits. In a previous study carried out in 2010, Othman found that although information on indications

[314] -ibid-, para 73, page 32.

[315] European Commission (2009). Pharmaceutical Sector Inquiry, Final Report, para 74; http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[316] US FDA. "Generic Facts", https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/UCM167991.htm

[317] Othman, Noordin et al. (2015). "Doctors' views on the quality of claims provided by pharmaceutical representatives: A comparative study in Malaysia and Australia", *Journal of Taibah University Medical Sciences*, 10(4), 471-480, http://www.sciencedirect.com/science/article/pii/S1658361215000499

and dosages was usually provided by pharmaceutical representatives, risk and harmful effects of medicines were often missing in their presentations.[318]

In both countries, pharmaceutical promotion of prescription medicines is self-regulated by pharmaceutical companies. In Malaysia, PhAMA's code of conduct for prescription (ethical) products complements government regulation and guidelines.

The research further observed that doctors are susceptible to misinterpreting the accuracy of information provided by pharmaceutical representatives and may lack the skills needed to critically assess the quality of information provided by pharmaceutical companies. There are initiatives by WHO, Health Action International and the US FDA[319] to build the capacity of doctors to assess promotional techniques of pharmaceutical companies.

6.4 Providers' Level (Level 3)

(A) SEPARATION OF DISPENSING FROM PRESCRIBING

In 2012, Henry and Searles provided a country study statement of the supply chain mark-ups in Malaysia. The country study found that despite the expectation that the prices of medicines in the public sector would be relatively low, in some cases, public sector prices were higher than the international reference price. The study also found that the post-manufacture margins charged in the supply chain were significantly driving prices upward in both the public and private sectors. The authors concluded that the lack of a coherent government policy to regulate medicine prices allowed excessive profits and reduced medicine affordability. The survey also found substantial price differences within the private sector between dispensing doctors and pharmacies. Compared with pharmacies, brand-name medicines tended to be cheaper when purchased from a dispensing doctor, but generic medicines were more expensive. Overall, the study found the dispensing doctors had excessive profit margins, particularly on some lower-priced generic medicines.[320]

This Review did not cover this issue due to time constraints. However, the qualitative interviews conducted by the team confirm that the above concerns prevail. The main causes are:

- Lack of enforceable price control mechanisms in Malaysia;
- Price discrimination between pharmacists and physicians in terms of the prices charged by originators for patented drugs supplied;

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[318] Othman, N., A. Vitry, E. Roughead, S. Ismail and K. Omar (2010). "Medicines information provided by pharmaceutical representatives: a comparative study in Australia and Malaysia", *BMC Public Health*, 10(1), 743.

[319] Health Action International (2010). "Understanding and responding to pharmaceutical promotion – a practical guide", http://www.haiweb.org/11062009/drug-promotion-manual-CAP-3-090610.pdf; US FDA (2010). "'Bad Ad Program' to help health care providers detect, report misleading drug ads", http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm211611.htm

[320] Cited in Rachagan, Sothi, Abida Haq Syed M. Haq and Shankari Sothirachagan (2016). "Affordable Medication with a Dose of Competition", paper presented at the 15th Session of the Intergovernmental Group of Experts (IGE) on Competition Law and Policy Round Table on Examining the Interface between Objectives of Competition Policy and Intellectual Property held in Geneva, Switzerland, 19-21 October, page 8.

- The practice of physicians dispensing in Malaysia; and
- Lack of transparency in prices charged by hospitals and physicians to consumers.

Currently in Malaysia, physicians are allowed to both prescribe and supply (dispense) medicines. Physician dispensing is defined as "physician control over revenues from drug dispensing" so that there is "financial integration of diagnosis and dispensing functions", as compared with "strict enforcement of patients' property rights to a prescription, so that the patient may have a prescription filled at any pharmacy and the provider does not receive dispensing revenues ('separation of prescribing and dispensing')". Dispensing by physicians encompasses the following:

- A physician preparing drugs for patients in a back counter of the office;
- Any arrangements in which physicians and outpatient clinics "buy" drugs on the open market at one price and "sell" them to patients and their insurers at a higher price (common in Japan, South Korea before 2000, and also true of US oncologists);
- A physician hiring a pharmacist for on-site dispensing or owning a free-standing pharmacy (a common arrangement in Taiwan); or
- Hospital-based physicians earning substantial income from hospital outpatient pharmacy revenues often linked to individual prescribing (this was typical in China as a way for hospitals to also generate revenue but this practice is now prohibited).[321]

The issue of dispensing separation has long been debated in Malaysia. The concerns over physician dispensing are that prescriptions would be on the basis of the profits to be made from the drug prescribed rather than the interest of the patient concerned, and the rising costs of healthcare.

In terms of physician-induced demand for medicines, UNCTAD warned that the practices of bribe and rebate – not price and quality – might determine which drugs are chosen. Proponents of dispensing separation push for the clear demarcation of dispensing/ prescribing functions, citing the need to ensure neutrality and prioritize patients' well being. In fact, the South Korean government introduced dispensing separation through the Korean Health Care System Reform Act of 2000, primarily in an effort to reduce the use of antibiotics and injections. South Korean doctors and pharmacists were widely known for prescribing excessive doses of antibiotics to boost their profits and respond to patients' expectations. Kim and Ruger report that the rate of antibiotic resistance among South Koreans was among the world's highest before the reform.[322]

An audit study by Currie, Lin and Zhang (2010)[323] found that when facing patients who not only report symptoms that do not warrant antibiotics but also state reluctance to take

[321] Eggleston, K.N. (2011). "Prescribing Institutions: Explaining the Evolution of Physician Dispensing", Working Paper Series on Health and Demographic Change, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University, https://aparc.fsi.stanford.edu/sites/default/files/AHPPwp_24.pdf

[322] Kim, H.J. and J.P. Ruger (2008). "Pharmaceutical Reform in South Korea and the Lessons It Provides", *Health Affairs*, 27(4).

[323] Currie, Janet, Wanchuan Lin and Wei Zhang (2010). "Patient knowledge and antibiotic abuse: Evidence from an audit study in China", National Bureau of Economic Research Working Paper 16602, https://www.ncbi.nlm.nih.gov/pubmed/21733587

antibiotics, Chinese dispensing physicians nevertheless prescribe antibiotics to more than a third of such patients. Chen, Gertler and Yang (2011)[324] found that Taiwanese physicians, when no longer paid a profit margin for dispensing, reduced prescriptions (measured by expenditures) by almost 30%.

Further, Eggleston[325] also points out, referring to Iizuka (2007),[326] that physician dispensing in Japan led to 15% higher expenditures for hypertension drugs than would be the case if the physician mark-up were eliminated.

As for increasing medicine prices, doctors in private practice do not issue a prescription to patients, nor do they give itemized bills after consultation and dispensation of the drugs. Such practice removes price competition in the pharmaceutical retail sector, as the patient has no basis to compare the price paid with the price of the same medicine at any other source.[327]

Many countries have moved towards separation of the functions of prescription and dispensing of medicines, a move consistently sought by pharmacists. In rural parts of some countries, exemption from separation of these "powers" is granted. In Asia, reference is frequently made to Japan and South Korea. However, as pointed out by Rachagan et al.,[328] from a competition point of view this will not in itself address the concern that the choice of drug to be dispensed would be that which is more profitable for the dispenser, be it the doctor or the pharmacist.

In South Korea, the government argues that the abovementioned reforms have been a success as use of antibiotics and injections has decreased. However, Kim and Ruger reported in 2008 that in spite of the reforms, government health spending had increased. Even though cost containment measures were also introduced, these did not halt discounting, which was driven under the table instead, and it did little to encourage price competition because hospitals had no incentive to choose lower-priced drugs. In addition, foreign pharmaceutical companies were giving sizable non-cash benefits to doctors in hospitals and clinics as advertising, affecting doctors' prescribing practices. Due to

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[324] Chen, Brian K., Paul J. Gertler and Chun-Yuh Yang (2011). "Physician ownership of non-physician medical services", working paper, 21 February 2011. See also Chen, Brian K., Paul J. Gertler and Chun-Yuh Yang (2016). "Physician Ownership of Complementary Medical Services", http://www.paulgertler.com/uploads/4/7/5/1/47512443/physician_ownership_09_1_2016.pdf

[325] Eggleston, K.N. (2011). "Prescribing Institutions: Explaining the Evolution of Physician Dispensing", Working Paper Series on Health and Demographic Change, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University, https://aparc.fsi.stanford.edu/sites/default/files/AHPPwp_24.pdf

[326] Iizuka, Toshiaki (2007). "Experts' agency problems: Evidence from the prescription drug market in Japan", *RAND Journal of Economics*, 38(3), 844-862, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=949668

[327] Lee, K.S. et al. (2016). "The fate of the new Pharmacy Bill, going backwards or forwards", *Journal of Pharmaceutical Policy and Practice*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5034454/pdf/40545_2016_Article_81.pdf

[328] Rachagan, Sothi, Abida Haq Syed M. Haq and Shankari Sothirachagan (2016). "Affordable Medication with a Dose of Competition", paper presented at the 15th Session of the Intergovernmental Group of Experts (IGE) on Competition Law and Policy Round Table on Examining the Interface between Objectives of Competition Policy and Intellectual Property held in Geneva, Switzerland, 19-21 October.

doctors' preferences, the use of multinational and domestic brand-name products had soared, causing a shift away from cheaper generics.[329]

A study carried out by Kamal and Priya[330] shows that the public still have mixed views about dispensing rights. The public believe in the capability of the pharmacists in dispensing medication but they lack the confidence to make a change from the existing system. There is a preference for the current physician dispensing system generally, with visits to the pharmacy when their conditions are not severe. This preference is embedded in culture. "In the West, prescribing and dispensing of medications has often been ancillary to the primary expected outcomes of a physician visit, diagnosis and explanation. In herbal medical traditions as dominated in East Asia, however, the prescription and preparation of medications was central to the entire enterprise, and the dispensing of medicine came to be seen as the central outcome of the physician-patient interaction," observes Eggleston in explaining the evolution of physician dispensing.[331]

Other concerns raised in the study by Kamal and Priya were the "inconvenience of having to go to two places, increased costs in terms of petrol, parking and time costs, privacy of a doctor's consultation; in the event of medication error or prolonged illness, consumers were unsure who to consult, inconvenient for those who have to take public transportation to go to two places, no community pharmacies in rural areas." Human resource managers interviewed stated that they would have to address company standard operating procedures on employees seeking medical treatment during work hours to prevent abuse of the leeway given.[332]

The public need to understand the benefits of reform, including the improvement with regard to patients' rights to information (for example, as to the type, quantity, treatment period and side-effects of drugs, which are commonly not explained by the doctors). Measures to address their concerns must also be made clear.

Although suggested reforms are lauded by many groups in Malaysia, community physicians do not agree. In South Korea physicians blocked separation reforms for a long time, and constituted a more powerful interest group in the 2000 reforms than the pharmaceutical industry, pharmacists, patients or other affected parties. It was only after the health ministry authorized a 72% increase in consultation fees for seeing outpatients and a fivefold increase in prescribing fees for the year 2000 in response to doctors'

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[329] Kim, H.J. and J.P. Ruger (2008). "Pharmaceutical Reform in South Korea and the Lessons It Provides", *Health Affairs*, 27(4).

[330] Kamal Kenny and Priya Madhavan (2016). "Dispensing Separation: Perceptions of Public Visiting Primary Care Clinics in Malaysia", http://web.usm.my/mjps/mjps14012016/MJPS%2014-1-2-EV.pdf

[331] Eggleston, K.N. (2011). "Prescribing Institutions: Explaining the Evolution of Physician Dispensing", Working Paper Series on Health and Demographic Change, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University, https://aparc.fsi.stanford.edu/sites/default/files/AHPPwp_24.pdf

[332] Kamal Kenny and Priya Madhavan (2016). "Dispensing Separation: Perceptions of Public Visiting Primary Care Clinics in Malaysia", http://web.usm.my/mjps/mjps14012016/MJPS%2014-1-2-EV.pdf

demands that the issue was resolved.[333] The fear of losing their rice bowl is real and this issue needs to be addressed. Governmental investment is required in order that the total cost of seeing a doctor and getting medicines does not become prohibitive. However, physicians profiting from dispensing is an issue which must be addressed.[334]

Eggleston points out that "[r]eforms that led to the separation of prescribing and dispensing in most countries – especially those from our part of the world – took decades to become law and to be implemented. The outcomes were (of course) never as rosy as painted by supporters of separation, but not as apocalyptic as suggested by their opponents either. And sometimes social practices developed that were unanticipated and outside of policy intentions. In the case of Taiwan for example, health expenditure did not decrease, and the elderly appeared more inclined to visit physicians who had hired on-site pharmacists." [335]

The Malaysian government is moving in the direction of dispensing separation. It is likely that the MOH will make this mandatory in Malaysia, especially since such a move has been supported by the Federation of Malaysian Consumers Association (FOMCA), the Malaysian Medical Association (MMA), the Malaysian Dental Association (MDA) and the Malaysian Pharmaceutical Society (MPS) in the Malaysian Patients Charter agreed to by the parties as early as 21 August 1995.[336]

However, the government is proceeding with caution. "We feel that the current system should be allowed to continue but we are liberalizing it a bit, giving patients a choice of where to get their medicine," Health Minister Datuk Seri Dr S. Subramaniam told reporters when asked for updates on the Pharmacy Bill.[337]

The proposed Pharmacy Bill, which would see doctors being restricted to only diagnosing and prescribing medicines, and pharmacies dispensing them, has been debated for years, but has yet to be tabled.

Although an advisory has already been issued by the Director-General of Health Malaysia to all medical practitioners in November 2015 specifying that a prescription stating the generic name (INN) of the drug and the indication for its use should be given to all patients (this would then allow them to choose whether to purchase the drug from the

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[333] Kim, H.J. and J.P. Ruger (2008). "Pharmaceutical Reform in South Korea and the Lessons It Provides", *Health Affairs*, 27(4).

[334] Promoting rational prescribing, Chapter 29, Management Sciences for Health 2012: http://apps.who.int/medicinedocs/documents/s19606en/s19606en.pdf

[335] Eggleston, K.N. (2011). "Prescribing Institutions: Explaining the Evolution of Physician Dispensing", Working Paper Series on Health and Demographic Change, Walter H. Shorenstein Asia-Pacific Research Center, Stanford University, https://aparc.fsi.stanford.edu/sites/default/files/AHPPwp_24.pdf

[336] Rachagan, Sothi, Abida Haq Syed M. Haq and Shankari Sothirachagan (2016). "Affordable Medication with a Dose of Competition", paper presented at the 15th Session of the Intergovernmental Group of Experts (IGE) on Competition Law and Policy Round Table on Examining the Interface between Objectives of Competition Policy and Intellectual Property held in Geneva, Switzerland, 19-21 October.

[337] Kaur, Minderjeet (2017). "Pharmacy Bill to be tabled soon, says Subra", FMT News, 26 September 2017, http://www.freemalaysiatoday.com/category/nation/2017/09/26/pharmacy-bill-to-be-tabled-soon-says-subra/

medical practitioner or from a retail pharmacy), the advisory has no legal effect and is not generally followed by private medical practitioners.

As in Malaysia, Singapore also permits doctors to prescribe and dispense medication. Private hospitals and clinics are required by law to provide information to the patient before and after treatment and this includes an itemized bill stating the drug supplied and the associated price.

(B) PRICE DISCRIMINATION

Lack of dispensing separation can give rise to price discrimination issues at level 3 of the pharmaceutical supply chain (providers).

A common complaint among community pharmacists interviewed for this Review was that they were being charged more for a particular drug than the pricing given to clinics and/or private hospitals. There were cases where pharmacists were at risk of losing customers because of the higher prices they charged for medicines due to higher procurement prices. There were also some cases of refusal by the originator company to supply medicines to the community pharmacist.

In the Competition Act, price discrimination and refusal to supply are dealt with under Section 10(2) along with other instances of abuse of dominant position. Further, the guidelines issued by the MOH on good pharmaceutical trade practice stipulate that pharmaceutical companies should encourage and extend a similar bonus scheme to all distributing channels.

Price discrimination occurs where the same product is sold at different prices and such price difference is unrelated to the cost of supplying the products. This includes selling the same product to different customers at different prices and selling the product to the same customer at different prices. Discrimination can be commercially justified. For example, volume discounts can reflect savings and economies of scale and better prices may be offered for early payment.

MyCC will examine price discrimination complaints on a case-by-case basis. The difficulty that may be faced by complainants in price discrimination cases is in establishing that such discrimination is unjustified or in bringing forward concrete evidence of negative impacts or injury to their businesses as a fact.

An interesting case which illustrates how price discrimination at level 3 was actually a by-product of anti-competitive conduct at the suppliers' level (level 1) is the case of Napp in the UK.[338]

[338] Napp Pharmaceutical Holdings Limited and Subsidiaries (NAPP), 30 March 2001, Decision of the Director General of Fair Trading No. CA98/2/2001, https://assets.publishing.service.gov.uk/media/555de4bf40f0b669c4000169/napp.pdf

In March 2001, the Director General of Fair Trading (DGFT) found that Napp had abused its dominant position in the UK market for the supply of sustained release morphine tablets and capsules (MST), an analgesic commonly used in the treatment of cancer-related pain, and imposed a penalty of £3.21 million. Napp had charged excessive prices to customers in the community segment of the market while practising heavy discounting, often in excess of 90% of the list price, to hospitals in order to drive out competitors. A smaller portion of MST was sold via the hospital segment compared with the community segment. Napp however considered the former segment to be an indispensable gateway to community sales. The DGFT directed Napp to reduce the price of MST tablets in the community and limit the extent to which discounts are offered to hospitals.

As such, when allegations of price discrimination are raised, some factors to consider from the competition standpoint would be:

- Percentage of differentiation between prices charged to pharmacies as opposed to hospitals and doctors;
- Reasons for such differentiation;
- Impacts of the price differentiation on the business of the particular complainant;
- Whether there is market dominance by the product in question at public or private procurement level;
- Whether there are in fact competitors within the market (at the ATC 3 level);
- Factors affecting substitution;
- Whether generics of the product in question are available.

6.5 Regulatory Barriers

Generic competition is only possible if generic medicines are available in the first place.

Regulatory approval to market a generic medicine has a direct impact on competition within the pharmaceutical market. The regulatory requirements and the length of time for processing and approving product registration applications will determine the timing of market entry of generics. (See the discussion in Chapter 5.)

Malaysia has incorporated the “Bolar exemption” into domestic law under Section 37(1A) of the Patents Act 1983, which allows the manufacture, use or sale of a patented drug without first obtaining the owner’s permission for the purposes of researching, developing and submitting information to relevant regulatory authorities.

This rule is the result of a judicial decision in Canada that is now an international rule in the TRIPS Agreement and it facilitates the preparations for entry of generics as soon as patents on originator medicines expire. Regulatory barriers could however negate the operation of the Bolar exemption and delay generic entry.

Thus a trilateral study by WHO, WIPO and WTO states that “Regulation of medical technologies addresses essential health policy objectives: products must be safe,

efficacious and of adequate quality. Yet, regulation also shapes the landscape for access and innovation: higher safety standards require the generation of more data and thus increase the cost of innovation. Unjustified regulatory barriers and lengthy marketing authorization processes delay access to needed medical technologies".[339]

6.6 Government Policy on Pharmaceutical Procurement

In 1994 the government changed its procurement system for medicines from a central purchasing system to one where a sole concession was given to a private Bumiputera company to supply medical products to government hospitals and clinics in order to increase efficiency of the procurement system and to promote Bumiputera entrepreneurship. To what extent have these two objectives been realized? Has the public benefited in terms of lower drug prices in the public sector? The only study done on this, by Babar and Izham,[340] showed that prices of the drugs studied had increased post-privatization of the procurement process.

Also, on the face of it, this sole concession system in Malaysia's pharmaceutical products procurement reduces competition in the sector. In this situation, competition concerns can partially be addressed through transparency in the procurement rules and practice. This is a matter that is being recommended in the UNCTAD work on public procurement and competition policy. Some interviewees for this Review expressed expectations for enhanced transparency and timeliness in government tenders.

From an investment point of view, Malaysia is a relatively small market and this arrangement could be a disincentive for companies to invest in the pharmaceutical sector.

6.7 Conclusion

The definition of relevant market, for purposes of assessing the level of competition and potential anti-competitive conduct, needs to fit the special characteristics of pharmaceutical products. A case-by-case approach is required, guided by the WHO ATC classification system that is commonly used to determine interchangeability or substitutability. From the experiences of several competition authorities and the recommendation of UNDP, ATC 5 should be the starting point as a general rule. The behaviour of suppliers (manufacturers and wholesalers/distributors) in influencing and shaping doctors' prescription choices and patterns needs to be monitored and scrutinized.

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[339] WHO, WIPO, WTO (2012). Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade. http://www.who.int/phi/promoting_access_medical_innovation/en/ (see Chapter II, Section A.6)

[340] Babar, Z. and M.I. Izham (2009). "Effect of privatization of the drug distribution system on drug prices in Malaysia", Public Health, 123(8), 523-533.

Anti-competitive conduct of originator companies that has been investigated in other countries includes a range of patent strategies and product life-cycle management measures as well as interventions before national authorities that decide on marketing authorization, pricing and reimbursement of generic products. The European Commission's pharmaceutical sector inquiry is illuminating on these types of conduct which industry itself labels a "tool-box" to deal with generic entry.

Patent laws and standards as discussed in Chapter 5 can have anti-competitive effects, and this chapter highlights that there can be anti-competitive patent strategies employed by originator companies. Regulations for product registration and market authorization can also promote or hinder competition.

Competition concerns related to marketing and promotional conduct were also highlighted by the European Commission inquiry, an issue that is not covered by this Review but merits study.

In level 3 of the supply chain in Malaysia, the role of doctors in prescribing and dispensing medicines raises competition concerns. Linked to this are complaints of price discrimination by suppliers, especially the originator companies. There are also price discrimination complaints related to private hospitals and chain pharmacies getting better terms and prices than community pharmacies. A comprehensive study of level 3 and its interactions with levels 1 and 2 is needed.

Mergers and acquisitions are not within the scope of the Malaysian Competition Act, but in the pharmaceutical sector this is an area of considerable competition concern, as is the case in other countries. There should therefore be monitoring of the sector's players in Malaysia, in cooperation with the Securities Commission.

Finally, although issues of access to health have not traditionally been addressed through competition law, in recent years, competition and antitrust authorities in various jurisdictions have been playing a larger role in ensuring that nations' objectives of universal health coverage are met.

As shown above and in Chapter 7 with some case discussions, competition law has been used successfully to improve the price, availability and transfer of health technologies. Greater use of competition law is recommended by the United Nations Secretary General's High-Level Panel on Access to Medicines, as well as by the Global Commission on HIV and the Law.[341]

[341] UNDP (2017). "Using Competition Law to Promote Access to Medicines and Related Health Technologies in Low-and-Middle-Income Countries", Issue Brief, August 2017, http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicines-and-related.html

To quote UNDP: “In principle, competition law is designed to protect consumer welfare and promote industrial and economic development through restricting or regulating unfair business practices, abuse of market dominance and excessive concentration of economic power. While competition law does not in itself provide the financial resources necessary to procure and supply health technologies, by promoting greater competition and reduction of corrupt practices it may constrain prices and ensure efficient use of public resources. Competition law can also help stimulate the quicker introduction of new and improved health technologies. These positive effects of competition law will in turn advance the human rights, health, and development objectives enshrined in the SDGs [Sustainable Development Goals].”[342]

[342] -ibid-, at page 2.

CHAPTER 7: SELECTED CASE STUDIES ON ANTI-COMPETITIVE CONDUCT

This chapter discusses some cases relating to the question of market dominance in the pharmaceutical industry and of anti-competitive conduct that have been investigated or are under investigation in other countries that have competition law provisions similar to Malaysia's Competition Act. The cases also involve medicines that are marketed in Malaysia at high prices or where generic competition is not available or limited (see Table 7.1 for a summary of the cases).[343]

Table 7.1: Summary of Cases with Anti-competition Concerns

Country	Party Involved	Facts	Decision/Importance
EU India EU	Servier Roche Astra AB/ AstraZeneca Plc (AZ)	**Defining the Market** **ATC Level 5** See below See below **ATC Level 4** Product: Omeprazole (Losec), anti-ulcer medication in the area of gastrointestinal treatment	Establishing the issue of market dominance for the particular drug in question
EU	Servier	**Pay for Delay/Life-cycle Management Strategies** Product: Perindopril, an angiotensin converting enzyme (ACE) inhibitor that is used for treating cardiovascular diseases. **Market Defined at ATC 5 level**	Fine of 427.7 million euros
India	Roche	**Vexatious Litigation/ Denigration of Generics** Product: Trastuzumab (Herceptin), a biologic drug used to treat breast cancer **Market Defined at ATC 5 level**	Detailed investigation warranted (decision of competition authority)

[343] It is reiterated that Chapters 6 and 7 do not suggest any form of wrongdoing or make any finding of liability concerning any player in the industry. It is also noted that the global policies of such companies could have changed over time. At the end of the day, any complaint of anti-competitive conduct has to be decided on the basis of its own facts. However, a consideration of these past or ongoing cases is instructive as to the type of conduct which will be scrutinized and the manner in which an investigation may be carried out.

Country	Party Involved	Facts	Decision/Importance
US	Novartis	**High Price of Cancer Drugs** Product: Imatinib (Gleevec or Glivec), treatment of chronic myeloid leukaemia	US experts publicly stated that the pricing of crucial originator drugs (including imatinib) is unjustifiable, requiring policy and regulatory responses. Similar situation in Malaysia. Also, patent settlements between originator and generic companies in other parts of the world can have impacts on the Malaysian market.
UK	Napp	**Anti-competitive Heavy Discounting** Product: Sustained release morphine (SRM) used to treat moderate and severe pain	Fine of £2.2 million Reduction of National Health Service (NHS) list price of drug by at least 15% Drug to be sold hospitals in the UK at a price of not less than 20% of the (reduced) NHS list price
UK	GSK	**Pay for Delay** Product: Paroxetine, an anti-depressant	Fine of more than 48 million euros
Spain	Aspen	**Refusal to Supply and Excessive Pricing** Product: Cancer drugs	Investigation on-going at the time of writing

7.1 Defining the Market

Cases included under this section are for the purpose of illustrating the manner in which the relevant market for a given drug is determined. As stated in Chapters 3 and 6 of this Review, reference is made to the ATC system when defining the market for the pharmaceutical industry. For cases where the market has been defined at ATC 5, see the Servier (perindopril) and Roche (trastuzumab) cases below.

AN ILLUSTRATION OF MARKET DEFINITION AND ABUSE OF MARKET DOMINANCE: THE CASE OF AZ PHARMACEUTICAL CO LTD AND OMEPRAZOLE

Summary

The European Commission fined AZ 60 million euros for blocking the entry of generic versions of its blockbuster drug Losec, which contained the active ingredient omeprazole. Omeprazole is used in gastrointestinal anti-ulcer treatment. The EC's decision was upheld by the European Court of Justice (ECJ) in December 2012, although the Court reduced the fine to 52.5 million euros. In determining market dominance, the EU concluded that the relevant market was the group of products known as PPIs (proton pump inhibitors), corresponding with ATC 4 level of classifying products (chemical/therapeutic/pharmacological subgroup).[344]

[344] Case COMP/A. 37.507/F3 AstraZeneca, 15 June 2005, http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf

Facts

Losec was AZ's blockbuster gastrointestinal treatment, containing omeprazole, an anti-ulcer drug. In 2003, the EC initiated proceedings against AZ on complaints lodged by generic companies that AZ sought to block/delay the entry of generic versions and parallel imports of its drug through:

(i) Patent strategy: Here AZ was alleged to have deliberately given misleading information to several national patent agencies over the dates when it originally filed patents on Losec. It then obtained extensions of its exclusivity longer than those to which it was entitled under EU rules on "supplementary protection certificates"; and

(ii) AZ's strategy in relation to a switch (mainly in 1998) from capsule to tablet formulations of Losec and withdrawing its registration of the original drug with regulators in a number of European countries. This made it more difficult for generic companies to launch their versions of omeprazole as they had to prepare full regulatory dossiers for approval, as if for a new drug. The usual procedure would have been for the generic companies to show bioequivalence to Losec had AZ not withdrawn the original registration.

Findings

The EC, whose decision was upheld by the ECJ, found that AZ had infringed Article 82 on abuse of market dominance by reason of their conduct above and fined AZ 60 million euros. This fine was reduced to 52.5 million euros by the ECJ.

In coming to its decision, the EC had to define the market relevant to Losec in order to determine if AZ was in fact dominant within that market. AZ's argument was that the relevant market consisted of H2 blockers (histamine receptor antagonists) and PPIs (proton pump inhibitors) – classes of medicines which proactively inhibit the acid secretion into the stomach. The EC did not agree, adopting a narrower definition of market as encompassing PPIs alone. It found that:

(i) PPIs have a mode of action which is fundamentally distinct from (and therapeutically superior to) that of the H2 blockers;
(ii) PPIs cure more patients and cure them more quickly;
(iii) The Commission has conducted a classic market definition exercise basing itself on an overall assessment of particular product characteristics, product uses, demand and price factors. It found that doctors increasingly (across the entire disease spectrum) considered that PPIs constituted the most effective and appropriate remedy. Evidence showed that PPIs were superior in cost effectiveness compared with H2 blockers and that there was a gradual shift towards PPIs at the expense of H2 blockers;
(iv) Prescription PPIs faced no significant competitive constraints from H2 blockers or other products used for the treatment of acid-related gastro-intestinal diseases;
(v) Only prices of other PPI products were capable of constraining, to some extent, demand for AZ's omeprazole and the price of generic versions of omeprazole had the strongest impact on demand for AZ's omeprazole (and other PPIs).

Its conclusion thus corresponded to the ATC 4 level and AZ's dominance was to be assessed on national markets for oral formulations of prescription PPIs.

The Commission also stated that the type of evidence relevant to assess whether two products are demand substitutes includes evidence of substitution (in this case in the form of IMS data) in the recent past. Such evidence would normally be fundamental for market definition.

The Malaysian Situation

The case above is instructive of the practical considerations to be taken into account when defining market in the pharmaceutical industry. It can supplement the general guidelines on market definition issued by MyCC.[345]

7.2 Patent Litigation/Life-cycle Management Strategies

(A) AN ILLUSTRATION OF LIFE-CYCLE MANAGEMENT TOOLS: THE CASE OF LABORATOIRES SERVIER'S PERINDOPRIL

Summary

The European Commission investigated a case involving Servier and its product, perindopril, an angiotensin converting enzyme (ACE) inhibitor that is used for treating cardiovascular diseases. As a result, in 2014, Servier and 5 companies that manufacture generics were fined 427.7 million euros for delaying generic versions of the medicine through "pay-for-delay" settlements. In coming to its conclusion, the European Commission considered the life-cycle management tools that were part of Servier's "anti-generic strategy". The information below, unless otherwise stated, was extracted from the decision of the Commission, which ran to more than 800 pages.

Facts

Perindopril was originally produced by Servier, and in the EU it is marketed under the brand name Coversyl. In 2006 to 2007, perindopril was Servier's blockbuster product, accounting for approximately 30% of the company's total turnover with annual global sales of more than US$1 billion. Numerous strategy documents regarding perindopril present this product as the guarantee of Servier's positive forecasts in the short, medium and long term. For example, according to Servier's Strategic Plan for the period 2002/2003 until 2011/2012: "Coversyl remains the guarantee of our long-term development and, as such, will remain one of the top priorities throughout the duration of the Plan."

[345] MyCC Guidelines on Market Definition, http://www.mycc.gov.my/sites/default/files/handbook/MYCC-4-Guidelines-Booklet-BOOK4-10-FA-copy_market-defination.pdf

Of the three uses of perindopril (hypertension, congestive heart failure, stable coronary artery disease), Servier's internal documents confirm that hypertension is the most important indication for the medicine. Available guidelines suggest that most patients treated with hypertension medicines continue to use them for the rest of their lives. Perindopril, like other long-term treatments, is taken by a patient over a number of years. Once confirmed a successful treatment for a patient, the patient is likely to take the medicine for a long period and is unlikely to switch to an alternative even when one is available at significantly lower prices.

The European Commission found that Servier had an anti-generic strategy, some elements of which flouted the EU anti-competition rules (specifically Articles 101 and 102 of the Treaty on the Functioning of the European Union, similar to Chapters 1 and 2 of Malaysia's Competition Act).

It is widely accepted that when generics of a product are made available, there are:
- Substantial volume shifts from the originator drug to generic versions; and
- Substantial reductions in drug prices.

The compound patent for perindopril expired around 2003/2005 (in different EU member states), upon which generic perindopril should have entered the market. However, it was only around 2007 that the UK became the first country in Western Europe where entry was made possible. This delay, the European Commission found, was because of Servier's conduct as part of the anti-generic strategy documented in Servier's internal documents. The strategy included:[346]

i. "Blocking patents": In 2000 and 2005, Servier applied for and obtained patents on a number of process and crystalline forms. According to Servier's own assessment, some of them involved "zero inventive activity". In a strategy described as seeking protection through a "maze of patents", Servier was found to have filed as many blocking patents as possible, to create a patent cluster of process patents around perindopril. In addition thereto, the broadest protection resulted from the EP 1 296 947 patent (known as "the 947 patent") for the "alpha crystalline form" of erbumine. This was one of Servier's most controversial patents, challenged by many generic companies and finally annulled by the European Commission. Apotex brought a case against this patent in the UK, and the courts found that the patent was baseless as the alpha crystalline form of erbumine did not meet the principles of novelty or inventiveness. It is actually the stable form of perindopril and, in the absence of special circumstances, it follows that any process for producing perindopril from ethyl acetate will produce this form.

[346] All of Servier's strategies are described in the Commission's decision in the following order, including: (1) filing a patent cluster (section 4.1.2.1); (2) publication of perindopril monograph in the European Pharmacopoeia (section 4.1.2.2); (3) acquisition of alternative technologies and accompanying intellectual property rights (IPRs) (section 4.1.2.3); (4) patent disputes and patent settlements (section 4.1.2.4); (5) distribution agreements with friendly generics (section 4.1.2.5); and (6) selective switch to the arginine salt (section 4.1.2.7).

ii. Servier further acquired active pharmaceutical ingredients (API) technologies and removed them as a competitive source from the market. Through these acquisitions, Servier eliminated direct competition from the patent holders themselves and also removed them as a source of potential inputs for other would-be generic entrants.

iii. Between 2003 and 2008, Servier engaged in patent disputes with the generic competitors. The European Commission found that as a result, there was no single generic producer that could enter the market without being challenged in one way or another. These challenges led to patent settlement agreements with the (most) advanced generic contenders, save one, covering all EU member states. In total, Servier's payments to the generic companies exceeded 120 million euros.

iv. Distribution agreements with "friendly generics": Servier concluded 10 distribution agreements in total with generic companies, including Teva, Docpharma and Orifarm. All of the agreements concerned the commercialization of perindopril in the contractual territory with exclusive supply by Servier. The agreements generally granted the generic companies the right to distribute a so-called "authorized generic". These arrangements can lead to a controlled generic entry as the generic company, in return, normally promises not to sell other generic versions, while the originator may retain a degree of control over certain commercial parameters (for example, date of launch, quantities, prices etc.).

v. Further, Servier developed a second-generation product, which was based on a new salt, arginine instead of erbumine, and for which Servier had obtained patent protection until 2023. The European Commission found that the second-generation product is a bioequivalent, generic version of the first-generation product, without additional therapeutic advances. However, due to the different molecular weight of the new salt, the second-generation product is sold in different dosages (arginine: 2.5, 5 and 10mg; erbumine: 2, 4 and 8mg). The Commission found that Servier's strategy was to switch patients to the second-generation product and withdraw its first-generation product before generic versions of the first could enter the market. Depending on the national regulatory regime, generic substitution was made impossible or limited.

Findings

i. Anti-competitive conduct

At the conclusion of the case, the Commission found that the practices of patent acquisition and reverse payment settlements were considered to be violations of EU competition law. The reverse payment settlements amounted to anti-competitive agreements pursuant to Article 101 of the Treaty. For that reason, the Commission's decision was addressed to Servier as well as its contractual partners in the settlement agreements. The combination of the patent acquisition and the reverse payment settlements also amounted, in the Commission's assessment set out in the decision, to an abuse of a dominant position by Servier pursuant to Article 102 of the Treaty.

ii. Definition of market (determining market dominance)

In terms of defining the market, Servier claimed in the investigation to be in competition with other cardiovascular drugs, specifically those produced by Pfizer (amlodipine), SanofiAventis (ramipril and irbesartan), Bristol-Myers Squibb (irbesartan), Merck Sharp & Dohme (enalapril, lisinopril and losartan), AstraZeneca (lisinopril) and Novartis (valsartan, valsartan+hctz).

However, the European Commission, after undertaking an extensive investigation, found that perindopril was unrivalled in the market except for the generic version; there were no other potential competitors except the generics of perindopril that would be capable of constraining Servier's perindopril in the same way with respect to the core of its patient base. The Commission stated: "A particularity of perindopril, like many other long-term treatments, is that it is taken over a number of years. Once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the drug over many years and is unlikely to switch to an alternative, even when the purported alternative becomes available at significantly lower prices. In economic terms this corresponds to the low price-elasticity of demand. In the absence of a loss of efficacy, the occurrence of new side effects or the launch of a truly superior treatment (which was not the case during the period investigated), the patients will continue to take the same medicine, as doctors and patients are reluctant to go through a new trial period with an uncertain outcome. This was also confirmed by the extensive market survey carried out by the Commission."

In coming to that conclusion, the Commission considered the following: "The Commission's analysis relies among others on a series of natural events. The events relate to several products which were the closest potential competitors to Servier's perindopril and were subject to multi-fold price decreases in the course of the investigated period. None of the observed events, apart from the entry of generic perindopril, harmed the sales of Servier's perindopril" (paragraph 2405, page 607).

"The Commission's analysis shows not only that the natural events did not harm Servier's sales but also it explains for what reasons perindopril was that resistant. Among the relevant reasons, the analysis points at: (a) active product differentiation, (b) perindopril being an experience good, (c) presence of the lock-in effects with respect to the bulk of perindopril prescriptions [perindopril had a relatively stable patient base, with renewals and low negative switches of medication – section 6.4.5.5, page 598], (d) presence of loyal prescribers, (e) general price insensitivity observed with respect to both the prescribers and the patients, and (f) the regulatory frameworks that shielded Servier's perindopril from price constraints from other molecules. Cumulatively all those elements enabled Servier to operate on the market for perindopril in a largely unconstrained manner" (paragraph 2405, page 607).

The European Commission's illumination of the law on defining the market is relevant in the Malaysian context as there are similarities between the EU and Malaysian competition laws.

It is important to note that, "functional interchangeability or similarity of characteristics may not, in themselves, provide sufficient criteria, because the responsiveness of customers to relative price changes may be determined by other considerations as well" (paragraph 2414, page 609). "When products such as pharmaceutical products can be broadly used for the same purpose but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated" (paragraph 2417, page 610).

The Malaysian Situation

In Malaysia, perindopril is an important medicine listed as No. 3 in the top 10 most utilized drugs by expenditure in the public and private sectors combined in 2014 (see Table 4.5). In the public sector, as at 2013, the MOH purchases perindopril erbumine in 4mg and 8mg dosages.[347]

According to the MIMS drug directory, perindopril is available in Malaysia in both originator and generic forms from several companies in different dosages (see Table 7.2).

Table 7.2: Originator and Generic Perindopril Available in Malaysia

International Non-Proprietary Name (INN) and Dosage	Brand The originator brand is Coversyl and Coversyl FC. The rest are generics
Perindopril erbumine 4mg	Covapril (CCM Duopharma) Covinace (Pharmaniaga Manufacturing Berhad) Provinace (Xepa-Soul Pattinson) Perinace (CCM Pharmaceuticals)
Perindopril arginine 5mg	Coversyl (brand name) Coversyl FC tab 5mg (Servier)
Perindopril arginine 10mg	Coversyl (brand name) Coversyl FC tab 10mg (Servier)

Source: MIMS

Some preliminary research showed the following:

i. The perindopril API takes the form of a salt. There are two main salts of perindopril that are registered and marketed: tert-butylamine (erbumine) and arginine. Erbumine comes in dosages of 2mg, 4mg and 8mg, while arginine comes in dosages of 2.5mg, 5mg and 10mg. There is essentially no therapeutic difference between the two. However, Servier has introduced both into the Malaysian market.

ii. As shown in Table 7.2, perindopril is available in the Malaysian market in erbumine form at 4mg dosage (generic) and arginine form in 5mg and 10mg (originator). Although perindopril erbumine in its originator form does not seem to be available in

[347] See MOH Medicines Formulary (March 2017) and Kontrak Ubat-ubatan KKM (as at 31 May 2013): https://www.scribd.com/doc/234844647/Malaysia-drug-medicine-price-list-Kontrak-Pusat-Ubat-ubatan-KKM-31-05-13

the Malaysian market, it is being supplied to the MOH. This original form of perindopril erbumine is manufactured by Kotra in the 8mg dosage. In "Kontrak Ubat-ubatan KKM [MOH] (Kemaskini pada 25.09.13)", the following are listed:

- **Perindopril 4mg tablet:** Covapril Tablet 4mg; Manufacturer: Duopharma (M) Sdn. Bhd.; Quantity: 3,361,061; Unit: box of 100s; Cost per unit: RM9.00; Contract value: RM30,249,549.00
- **Perindopril (Tert-Butylamine) 8mg tablet:** Coversyl 8mg; Manufacturer: Kotra Pharma (M) Sdn Bhd; Quantity: 1,595,220; Unit: box of 30s; Cost per unit: RM8.60; Contract value: RM13,718,892.00

iii. Further, in relation to the availability of perindopril in the arginine form, it is noted from conversations with pharmacists that this can hamper dispensation of the product by pharmacists. In Malaysia, dispensation is done against the specific details of the prescription. Hence, if a particular prescription states perindopril 5mg or 10mg, arguably the pharmacist will not be able to dispense the generic form of perindopril to the customer (as generics only come in the 4mg dose).

iv. There were 32 patents filed and granted on perindopril (relating to both perindopril arginine and erbumine) (MyIPO database).

v. On the face of it, the patents above are described similarly to the blocking or paper patents in the EU case. Servier did make an application to patent the alpha crystalline form of perindopril erbumine (the 947 patent which was annulled in Europe) in Malaysia but was "deemed refused" by MyIPO. The notation on MyIPO's website on December 13th, 2017 states as follows:

PI 20051025	NEWa *(sic)* CRYSTALLINE FORM OF PERINDOPRIL TERT-BUTYLAMINE SALT, A PROCESS FOR ITS PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING ITS. *(sic)*	11/03/2005	Deemed Refused

In light of the European Commission's findings, the above facts within the Malaysian scenario raise the following questions:

i. There are many patents surrounding perindopril, on the face of it similar to patents in the EU case. Some of these were found by the European Commission to be invalid or required "zero inventive step" in Servier's own words. Is this evidence of a patent thicket or evergreening? (A caveat is made here that an expert's opinion is required to determine whether these patents were in fact the same.)

ii. What is the rationale for producing two drugs that are therapeutically similar in all respects, that are bioequivalent and rival each other in the market? Why supply originator perindopril erbumine (Coversyl 8mg) to the MOH but originator perindopril arginine (Coversyl 5mg and 10mg) to the market?

iii. Why is generic perindopril only available in the 4mg dosage and not in 8mg? And why only in perindopril erbumine and not arginine form?

It is suggested that the facts above, read in the light of the decision of the European Commission, raise issues for which clarification should be sought.

(B) VEXATIOUS LITIGATION/DENIGRATION OF GENERICS: THE CASE OF ROCHE'S TRASTUZUMAB

Summary

In July 2016, Mylan Pharmaceuticals and Biocon Limited lodged a complaint with the Competition Commission of India against Roche. They alleged that Roche had acted in abuse of its dominant position in the manner in which it sought to protect and maintain its monopoly on the biologic drug trastuzumab.

Trastuzumab is used in the treatment of HER2-positive breast cancer. Roche is said to have blocked the entry of more affordable biosimilars by activities such as influencing regulatory standards, raising unwarranted concerns regarding the safety and efficacy of biosimilars, influencing tender conditions and abusing the legal process to stall approval and marketing of the biosimilar.

In December 2016 the Competition Commission of India[348] ruled that the complaint had merit and warranted a detailed investigation. It also ruled that a pending Civil Suit in the Honourable Delhi High Court does not impede the Commission's jurisdiction to look into the matter.

Further, in a separate latest reported case, the Competition Commission of South Africa on 13 June 2017 issued a press release announcing that it had initiated an investigation against Roche and 2 other companies, Pfizer Inc. and Aspen Pharmacare Holding Ltd, for cancer medicine prices. The investigation against Roche is related to trastuzumab. The Commission stated that it had reason to believe that Roche and Genentech have and continue to engage in excessive pricing, price discrimination and/or exclusionary conduct in the provision of breast cancer medicine in South Africa.[349]

[348] Case No. 68 of 2016: http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf

[349] "International Pharmaceutical Companies investigated for cancer medicine prices", Competition Commission South Africa, Media Release, 13 June 2017: http://www.compcom.co.za/wp-content/uploads/2017/01/International-pharmaceutical-companies-investigated-for-cancer-medicine-prices.pdf

Facts

Trastuzumab is a cancer drug that was added to WHO's Essential Medicines List in 2015 and is primarily used for the treatment of breast and gastric cancer.[350] It is a biologic. The Roche parent company, F. Hoffmann-La Roche AG, has worldwide exclusive marketing rights from Genentech Inc. US.

In terms of patent status, the primary patent on Herceptin (Roche's brand name for trastuzumab) expired on 28 July 2014 in Europe while it will expire in the US in 2019. In 2014 too, as a result of a patent challenge by Hospira, two additional protections that relate to the dosages and composition of the drug were invalidated, which allowed Hospira to start selling its own biosimilar Celltrion.[351] Other than Hospira, there are several other pharmaceutical companies manufacturing biosimilar trastuzumab.[352]

As mentioned above, in India, Biocon and Mylan filed a complaint with the Competition Commission of India (CCI) against F. Hoffmann-La Roche AG, Genentech Inc. and Roche Products (India) Private Limited for using anti-competitive practices to prevent Biocon's and Mylan's biosimilars from reaching patients.

It was alleged, among other things, that:

(i) The Roche Group filed vexatious litigation against Biocon and Mylan; and

(ii) The Roche Group wrote to doctors, hospitals and regulatory authorities to create an impression about the propriety of the approvals granted, the safety and efficacy of biosimilars, the risk associated and the outcome of the on-going court proceedings in the medical fraternity.

The Roche competition investigation in India was preceded by a history of patent dispute in the period 2011 to 2014.

Trastuzumab had been sold by Roche in India under the international brand name Herceptin and a second brand called Herclon. Herceptin was priced at approximately Rs.110,000 per 440mg vial. When there was a concern about very high pricing, Roche launched the drug under another brand name (around September 2012) Herclon, priced at approximately Rs.75,000 per 440mg vial.

Roche also entered into a marketing agreement with an Indian manufacturer, Emcure Pharmaceuticals, in early 2012 to market another rebranded version of trastuzumab

[350] http://www.herceptin.com/hcp/

[351] "2 patents down, 1 to expire: herceptin biosimilar coming to EU", Biosimilar News, 11 April 2014, http://www.biosimilarnews.com/2014/04/2-patents-down-1-to-expire-herceptin-biosimilar-coming-to-eu/, accessed 19 January 2016.

[352] Biosimilars of trastuzumab, 19.9.2014, updated 29.9.2017, GaBI Online, http://www.gabionline.net/Biosimilars/General/Biosimilars-of-trastuzumab

known as Biceltis which was launched in August 2012. Through the deal, Roche shipped trastuzumab manufactured in its foreign plants to Emcure for repackaging. Biceltis is priced similarly to Herclon at Rs.75,000.

In 2012, the Campaign for Affordable Trastuzumab was formed, triggered by one woman using a public hospital whose doctor was reluctant to prescribe trastuzumab as the price was too high. The Campaign started to challenge the patent in a number of ways. In 2013, the Campaign called for the rejection/dismissal of Roche's multiple divisional patent applications on the grounds that Roche's application was filed incorrectly. The patent barrier which was preventing the sale of biosimilar trastuzumab in India by competitor companies was removed following the recommendation of an inter-ministerial committee to issue a compulsory licence and Roche announced that it would not pursue further patents on the medicine in India. Those familiar with the case reported that this was to prevent further action on the recommendation for a compulsory licence.[353]

In November 2013, India's medicines regulatory authority approved the first biosimilar version of trastuzumab in the country. The biosimilar, which is marketed by Biocon as Cancab and Mylan as Hertraz, was launched in India in February 2014. Seeking to prevent the sale of the Biocon-Mylan biosimilar, Roche filed a court case against Biocon and the Indian medicines regulatory authority. Roche requested an injunction on various grounds including claiming copyright infringement of its package insert and trying to extend proprietary rights to a non-proprietary term "trastuzumab" which is a chemical name without any intellectual property protection.[354]

With biosimilars in the Indian market, there has been a dramatic decrease in prices of 68-70% from Rs.110,000 a vial in 2012 to Rs.32,100-35,000 a vial in October 2017 (dosage of 440mg).

Findings

In deciding that a detailed investigation into the matter was warranted (December 2016), the CCI found that "when seen collectively in the background of surrounding facts and circumstances, they [the letters/communications by the Roche Group] only appear to be a part of the bigger plan/strategy of Roche Group to eliminate competition posed by biosimilars to Roche's products in the relevant market".[355]

The CCI applied the ATC 5 standard in defining the relevant product market for trastuzumab, a biologic. Below are relevant excerpts from the Commission's decision:

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[353] See Trastuzumab Factsheet: https://donttradeourlivesaway.files.wordpress.com/2013/08/trastuzumab-factsheet_final.pdf. Also: http://www.ipwatchdog.com/2013/08/21/compulsory-licenses-and-statements-of-working-in-india-2/id=44761/ and http://www.reuters.com/article/2013/08/16/us-roche-herceptin-india-idUSBRE97F08220130816#E3BRr4sFUfsThidi.97

[354] http://infojustice.org/archives/32146

[355] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.* Competition Commission of India, Case No. 68 of 2016, para 75, page 33.

"A relevant market, as defined under Section 2(r) of the [Indian Competition] Act, means a market comprising of a relevant product market or relevant geographic market or both. A relevant product market, as defined under Section 2(t) of the Act, means a market comprising all those products or services which are regarded as interchangeable or substitutable by the consumer, by reason of characteristics of the products or services, their prices and intended use. Although the definition provided under the Act plays a vital role in guiding the delineation of the relevant market, the same cannot be done by overlooking the peculiarities of the sector under consideration. The pharmaceutical sector is characterised by a structure where the ultimate consumer, i.e. patient, is not the decision maker. The doctor determines treatment of a particular disease, thus inducing the demand for a drugs/medicines/therapy prescription. The words of the doctor are generally considered as sacrosanct by the patients. Price sensitivity is, therefore, limited in this sector. Since the health of a patient is of paramount importance, the intended use of a drug gains more relevance which, for the purposes of substitutability, is governed by its 'quality', 'safety' and 'efficacy'." [355]

The Commission then went on to determine the relevant market for trastuzumab at the ATC 5 level. "As per the information, Trastuzumab falls at the fifth level of Anatomical Therapeutic Chemical (ATC) Classification System, which denotes chemical substances. In case of biological drugs, Trastuzumab appears to be equivalent to the molecular level. Thus, going by the analogy, drugs based on Trastuzumab, i.e., the reference biological drug as well as its biosimilars, would be considered part of the same relevant product market … In the present case, the relevant product market, thus, would be the market for biological drugs based on Trastuzumab, including its biosimilars."

In the case at hand, the CCI took the following factors into account:
- Market share, size and resources of the Roche Group;
- Dependence of the consumers (e.g., existing patients undergoing treatment would not switch to substitutes);
- Absence of countervailing buying power;
- High entry barriers (e.g., there is significant cost, time and expertise involved in the development of biosimilar trastuzumab and significant regulatory approvals to be obtained);
- The nature and extent of patent protection.

In terms of the relevant geographic market, the Commission found that "the conditions of competition are homogenous across India for pharmaceutical products" and assessed the geographical market on a national level.

After considering these factors, "it *prima facie* appears that Roche Group is dominant in the relevant market and can operate independently of the market forces".[357]

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[356] Competition Commission of India. *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.*, Case No. 68 of 2016, para 43, page 20.

[357] *Ibid.*, para 58, page 25.

On the allegations themselves, the decision of the CCI on allegation (i) above is instructive: "[The] mere fact that litigation was ultimately unsuccessful does not render it vexatious. However, in exceptional cases, the legal processes can be pursued by a dominant enterprise as a tactic to exhaust smaller rivals' resources and delay or prevent their entry in the relevant market. Where anticompetitive litigation of this kind by a dominant enterprise is identified, it amounts to an abuse within the meaning of the [Indian Competition] Act. Though there cannot be any straightjacket formula for identifying such exceptional circumstances, there can be certain guiding factors which may help in examining a case. First, it needs to be established that the impugned legal action, on an objective view, is baseless and appears to be an instrument to harass the defendant/respondent. Secondly, the legal action appears to be conceived with an anti-competitive intent/plan to eliminate competition." [358]

On allegation (ii), the CCI's words of caution are important: "We are dealing with a case which involves a highly sensitive sector, where the safety of the patient is of paramount importance. Thus, creating any iota of doubt in the minds of doctors can adversely affect the market for biosimilars, which is prescription induced, beyond repair. Such disparagement may also have ripple effects within the medical community. In this scenario, those biosimilar manufacturers who do not have strong marketing channels amongst doctors may be forced out of the market because of abusive denigration by a dominant player." [359]

Also, specifically in the case of biosimilars: "Each such letter/communication to the medical fraternity may have a cumulative effect of foreclosing the market for biosimilars. Further, Roche Group has admitted that biosimilars are different from generics, which are identical copies of the branded drugs. Being developed from plant/animal cells, biosimilars can never have identical characteristics even if they are equally efficacious and safe, as compared to a reference biological drug. In such a scenario, any denigration of a biosimilar drug may have far reaching ramifications." [360]

The Malaysian Situation

In Malaysia the originator brand Herceptin is marketed by Roche (Malaysia) Sdn. Bhd. and distributed by DKSH. It is very expensive and can add significantly to the cost of a patient's treatment regime.[361] (See Table 7.3 for prices of trastuzumab in several countries.)

[358] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.* Competition Commission of India, Case No. 68 of 2016, para 62, page 26.

[359] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.* Competition Commission of India, Case No. 68 of 2016, para 78, page 34.

[360] *Biocon Limited and anor v F. Hoffmann-La Roche AG and 2 ors.* Competition Commission of India, Case No. 68 of 2016, para 76, page 33.

[361] Nelson, Roxanne (2015). "WHO Adds 16 New Cancer Drugs to the Essential Medicines List", 16 June 2015, http://www.medscape.com/viewarticle/846561

The ASEAN Costs in Oncology (ACTION) study by the George Institute for Global Health reported that:[362]

- About half (45%) of Malaysian cancer patients suffer from "financial catastrophe" a year after they were diagnosed;
- Around 51% will be pushed into "economic hardship", with 49% of them already using up all their personal savings while 39% of all respondents could not pay for their medication;
- Of the respondents, 35% could not pay for medical consultation fees, 22% could no longer pay for their rents and mortgages, while 19% of them quit treatments altogether.

Table 7.3: Comparison of Average Price of Trastuzumab (2013)

	Average trade price in US$ per unit
Biosimilar ("generic")	
India (total sales)	941.58
Innovator (originator)	
South Africa	2,115.61
UK hospital	317.73
UK retail	631.25
US clinic	2,907.49

Source: IMS (2013), cited in 't Hoen, Ellen (2014). "Access to cancer treatment: A study of medicine pricing issues with recommendations for improving access to cancer medication", a report prepared for OXFAM

In Malaysia, the MOH is procuring the 440mg vial of Herceptin at a cost of RM6,170 (about US$1,456) per vial. The relevant contract is for the period 2017 to 2019.[363] The price which Malaysia pays is clearly on the higher end. An option is to try to create savings through price negotiations at procurement. However, access to biosimilars is key as this can significantly reduce the price of trastuzumab. This is evident from the prices offered to Médecins Sans Frontières/Doctors Without Borders (MSF) by Mylan and Biocon in India at US$535 (Rs.35,000) and US$491 (Rs.32,100) respectively for a vial of 440mg (as of October 2017).[364]

[362] Policy Roundtable on South East Asia Countries Readiness in Cancer Control, Turning Action Results into Policy Actions, The George Institute for Global Health, Bali, Indonesia, 20 August 2015, Meeting Report; "Close to 50% of Cancer Patients in Malaysia Experience Financial Catastrophe", AIA, Media Release, Kuala Lumpur, 28 October 2015, https://www.aia.com.my/content/dam/my/en/docs/press-releases/2015/28%20October%202015%20-%20Press%20Release_Cancer's%20Hidden%20Price%20Tag_ENG_Final.pdf

[363] Price obtained from MOH.

[364] Courtesy of MSF Access Campaign (5 October 2017).

In Malaysia, in June 2017, Inno Bio Ventures Sdn. Bhd. entered into a joint venture with Aryogen Pharmed Co. of Iran to develop and produce biosimilars for life-threatening diseases such as breast cancer, leukaemia, blood disorders and rheumatoid arthritis. For now, the partnership is focusing on four products, including trastuzumab.[365] These products will be distributed locally and in the region. This is a positive move, as the entry of a biosimilar will reduce very significantly the treatment cost in this country.

However, in Malaysia there are 2 patents already granted for trastuzumab, while 5 other applications are under examination by MyIPO. (See Table 7.4.)

Table 7.4: Patent Status of Trastuzumab in Malaysia

No.	Application No.	Title	Filing Date	Expiry Date (if patent is granted)	Legal Status	Applicant
1	PI 2016703899	Methods of treating early breast cancer with trastuzumab-mcc-dm1 and pertuzumab	23/04/2015	23/04/2035	Clear preliminary examination	Genentech Inc. US
2	PI 2013700947	Treatment of her2-positive cancer with paclitaxel and trastuzumab-mcc-dm1	06/06/2013	N/A	Deemed withdrawn	Genentech Inc. US
3	PI 2010004352	Combinations of an anti-her2 antibody-drug conjugate and chemotherapeutic agents, and methods of use	10/03/2009	10/03/2029	Substantive examination in progress	Genentech Inc. US
4	PI 20084949	Treatment of metastatic breast cancer	05/12/2008	05/12/2028	Granted	Genentech Inc. US F. Hoffmann-La Roche AG, CH
5	PI 2014001021	Combinations of an anti-her2 antibody-drug conjugate and chemotherapeutic agents, and methods of use	10/03/2009	10/03/2029	Clear full substantive examination	Genentech Inc. US
6	PI 2014001022	Combinations of an anti-her2 antibody-drug conjugate and chemotherapeutic agents, and methods of use	10/03/2009	10/03/2029	Clear full substantive examination	Genentech Inc. US

[365] "Inno Bio all geared up for the development and production of biosimilar products", 14 June 2017, http://innobioventures.com/v1/2017/06/14/inno-bio-all-geared-up-for-the-development-and-production-of-biosimilar-products/

No.	Application No.	Title	Filing Date	Expiry Date (if patent is granted)	Legal Status	Applicant
7	PI 20030358	Use of tyrosine kinase inhibitors for the treatment of inflammatory processes	31/01/2003	10/03/2029	Deemed withdrawn	Boehringer Ingelheim Pharma GMBH & CO. KG, DE
8	PI 2012000396	Subcutaneous anti-her2 antibody formulation	28/07/2010	28/07/2030	Granted	F. Hoffmann-La Roche AG
9	PI 2014002480	Subcutaneous anti-her2 antibody formulation	28/07/2010	28/07/2030	Substantive examination in progress	F. Hoffmann-La Roche AG

Source: MyIPO, http://onlineip.myipo.gov.my/index.cfm/search/pt/index, accessed 3 October 2017

From a competition standpoint, when other jurisdictions have invalidated patents of a drug under consideration, an assessment of whether those invalidated patents bear any similarities to any of the patents filed or granted in Malaysia should be carried out. As earlier stated, in the Malaysian case of Hovid, the court acknowledges that decisions of the European Patent Office (for example), although not binding, are persuasive.

In that regard, it is important to note that Hospira UK Limited brought several actions in the UK against Genentech Inc. (a subsidiary of Roche). Hospira did not challenge the basic patent for the amino acid sequence of Herceptin (known as patent EP 0 590 058). Table 7.5 presents the patent challenges by Hospira and the outcome of the cases.

Table 7.5: Cases by Hospira UK Limited Against Genentech Inc.

	Details of Legal Action	Patent In Issue	Decision
1	Hospira UK Limited v Genentech Inc. [2014] EWHC 1094 (Pat)	EP 1 210 115 entitled "Dosages for treatment with Anti-ErbB2 antibodies" EP 1 308 455 entitled "A composition comprising anti-HER2 antibodies"	Patents invalidated for obviousness. Upheld by the Court of Appeal [2015] EWCA Civ 57
2	Hospira UK Limited v Genentech Inc. [2014] EWCH 3857	EP (UK) 1 516 628 and EP (UK) 2 275 119 entitled "Stable Isotonic lyophilized protein formulation". The patents related to the lyophilized (i.e., freeze-dried) formulation of antibodies. Two antibodies were referred to in the specification. One was trastuzumab. It was called huMAb4D5-8 in the specification. The other antibody in the patents was rhuMabE25. The patents explained that rhuMabE25 might have a role to play in treating allergy.	Patents invalidated by the High Court, Genentech appeal pending.

	Details of Legal Action	Patent In Issue	Decision
3	Hospira UK Limited v Genentech Inc. [2015] EWHC 1796 (Pat)	European Patent (UK) No. 1 037 926. The patent related to the use of trastuzumab in combination with a taxane for the treatment of HER2-positive breast cancer. The taxanes (also referred to as "taxoids") in this case were a class of chemotherapeutic agents which included paclitaxel (marketed by Bristol Myers-Squibb under the trade mark Taxol) and docetaxel (marketed by Sanofi-Aventis under the trade mark Taxotere).	Patent invalidated on the basis of obviousness in light of a review article entitled "HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications" ("Baselga 97"). Genentech's appeal dismissed in Hospira v Genentech [2016] EWCA Civ 1185

Analysis should be done on the patents granted and pending on trastuzumab in Malaysia to see if they are similar to the patents which were invalidated in the Hospira challenges. This can then inform MyIPO in its decision-making process. Given that there is intention and ability to introduce a Malaysian biosimilar in the market, efforts should be made to ensure that there are no unnecessary barriers to entry of the same.

(C) PATENT SETTLEMENT AGREEMENTS: THE CASE OF NOVARTIS' IMATINIB

Summary

Imatinib is a very important medicine for treatment of chronic myeloid leukaemia (CML). It is sold under the brand name Gleevec and Glivec, among others. Its development involved a team of scientists from Ciba-Geigy that patented the compound, while its use to treat CML was largely due to oncologist Brian Druker of Oregon Health and Science University who led the clinical trials confirming imatinib's efficacy in CML. Major contributions were also made by scientists and physicians from University of Milano Bicocca (Italy), Hammersmith Hospital (UK) and Memorial Sloan-Kettering Cancer Center (US).[366] Ciba-Geigy merged with Sandoz to become Novartis in 1996.

The US FDA subsequently approved Imatinib for treatment of 10 types of cancer. The high prices of imatinib soon raised widespread concern. In 2013 more than 100 health experts in the US publicly stated that the pricing of crucial originator drugs (imatinib being one example) is unjustifiable and called for policy and regulatory responses in the country. A similar situation is found in Malaysia.

This case also shows the possibility that patent settlements between originator and generic companies in other parts of the world can have impacts on the Malaysian market.

[366] Gambacorti-Passerini, C. (2008). "Part I: Milestones in personalised medicine – imatinib", *Lancet Oncology*, 9(600): 600. PMID 18510992. doi:10.1016/S1470-2045(08)70152-9. See also Claudia Dreifus' interview with Dr. Brian J. Druker, *New York Times*, 2 November 2009: http://www.nytimes.com/2009/11/03/science/03conv.html?pagewanted=all

Facts

In 2009, the Lasker-DeBakey Clinical Medical Research Award, often called the "American Nobel Prize", was awarded to Dr. Brian J. Druker, an oncologist at Oregon Health and Sciences University and a Howard Hughes Medical Investigator, Nicholas B. Lydon, a former researcher for Novartis, and Charles L. Sawyers of Memorial Sloan-Kettering Cancer Center "for the development of molecularly targeted treatments for chronic myeloid leukemia, converting a fatal cancer into a manageable chronic condition." [367]

A drug discovery group in Ciba-Geigy (that through a merger with Sandoz in 1996 became Novartis) led by Lydon developed imatinib, a tyrosine kinase inhibitor (TKI). In 1988 Lydon had consulted with Druker who pointed him to CML to develop targeted chemotherapies. The Lydon team screened for agents that worked on CML and Lydon sent Druker his best compounds, from which Druker found one that was better than the others (STI571). By 1995 this was a lead compound set for clinical development. However, most researchers thought it would not work. Then, in 1996, before they were about to go to trials, the corporate merger took place and Lydon left the company. According to Druker, "Gleevec was now caught in the changeover. I lobbied with the new executives. After some ambivalence, they agreed to go forward with Phase 1 trials. I think they felt it wouldn't work and they could get rid of us afterwards. But during clinical trials we saw this miracle: Once the patients were up to effective doses, we got a 100 percent response rate." [368]

Novartis then had to make another decision. "They had not made enough drugs for a large-scale Phase 2 trial. But patients knew about Gleevec, and many more wanted to be included in the trials. Through the Internet, they generated a petition that landed on the C.E.O.'s desk, asking for greater access. That's how Phase 2 was rapidly expanded." [369]

When interviewed on whether he received any commercial benefits, Druker replied: "I don't see a penny, though that never was an issue for me. When I obtained the compound, it was already patented. I wasn't going to get to test it if I tried to put my mark on it. I wanted to work on it because I thought it was going to be the way to treat CML.

"You know, my patients were people who'd been told 'to get their affairs in order' because they were going to die soon. And now some of them play with grandchildren they'd thought they'd never live to see. That's worth more than money." [370]

On 30 May 2013, a group of more than 100 experts in CML presented an article in *Blood* journal on the high prices of cancer medicines, especially those used to treat CML, one of which is imatinib.[371] The experts agreed that "[i]nnovation and discoveries must be

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[367] *Ibid.*, New York Times, 2 November 2009.

[368] *Ibid.*

[369] *Ibid.*

[370] *Ibid.*

[371] Experts in Chronic Myeloid Leukemia (2013). "The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts", Blood, 30 May 2013, 121(22), 4439-4442.

rewarded. Pharmaceutical companies that invest in research and development and discover new lifesaving drugs should benefit from healthy revenues."

However, "[a]s physicians, we follow the Hippocratic Oath of '*Primum non nocere*,' first (or above all) do no harm. We believe the unsustainable drug prices in CML and cancer may be causing harm to patients. Advocating for lower drug prices is a necessity to save the lives of patients who cannot afford them. Pricing of cancer and other drugs involves complex societal and political issues which (1) demand immediate attention and (2) will need to consider many factors and involve many constituencies including FDA and governmental regulators; legislation changes; patent laws; multitudes of US and international regulatory agencies; offices of human research protection; impediments by lawyers and contract research organizations, which increase the cost of clinical research; patient advocacy groups; excessive regulation and bureaucracy; profits of physicians and hospitals/pharmacies; insurance companies; pharmaceutical companies; etc.''

In the case of Gleevec, its list price when it was launched in the US in 2001 was US$26,400 a year.[372] Although similar drugs have come into the market since then, the price keeps going up, with the US wholesale list price for a year's supply of Gleevec in 2016 reported to be US$120,000.[373] This is despite the fact that (1) all research costs were accounted for in the original proposed price and it is reported that Novartis would have already recouped its cost of development within the first two years of sales;[374] (2) new indications were developed and approved by the US Food and Drug Administration (FDA); and (3) the prevalence of CML population continuing to take imatinib was dramatically increasing. To put things in perspective, a year's worth of imatinib, made into tablets and bottled, with a 50% profit factored in, would cost no more than US$216.[375] The increase in the price of Gleevec not only seems unjustifiable, but is said to be a "failure of the competitive pricing process."[376]

As noted above, imatinib was a revolutionary treatment when it first hit the market in 2001, transforming the lives of people with CML. Before imatinib, the lifespan of those with CML was about 5 to 6 years. Now it approaches normal with lifelong medication. Gleevec is Novartis' blockbuster drug. In 2015, it generated US$4.7 billion in worldwide revenue.[377]

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[372] Johnson, Carolyn Y. (2016). "This drug is defying a rare form of leukemia - and it keeps getting pricier", *The Washington Post*, 9 March, https://www.washingtonpost.com/business/this-drug-is-defying-a-rare-form-of-leukemia--and-it-keeps-getting-pricier/2016/03/09/4fff8102-c571-11e5-a4aa-f25866ba0dc6_story.html?utm_term=.5a689eb44160

[373] *Ibid.*

[374] Experts in Chronic Myeloid Leukemia (2013). "The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts", Blood, 30 May 2013, 121(22), 4439-4442.

[375] Johnson, Carolyn Y. (2016). "This drug is defying a rare form of leukemia - and it keeps getting pricier", *The Washington Post*, 9 March, https://www.washingtonpost.com/business/this-drug-is-defying-a-rare-form-of-leukemia--and-it-keeps-getting-pricier/2016/03/09/4fff8102-c571-11e5-a4aa-f25866ba0dc6_story.html?utm_term=.5a689eb44160

[376] *Ibid.*

[377] *Ibid.*

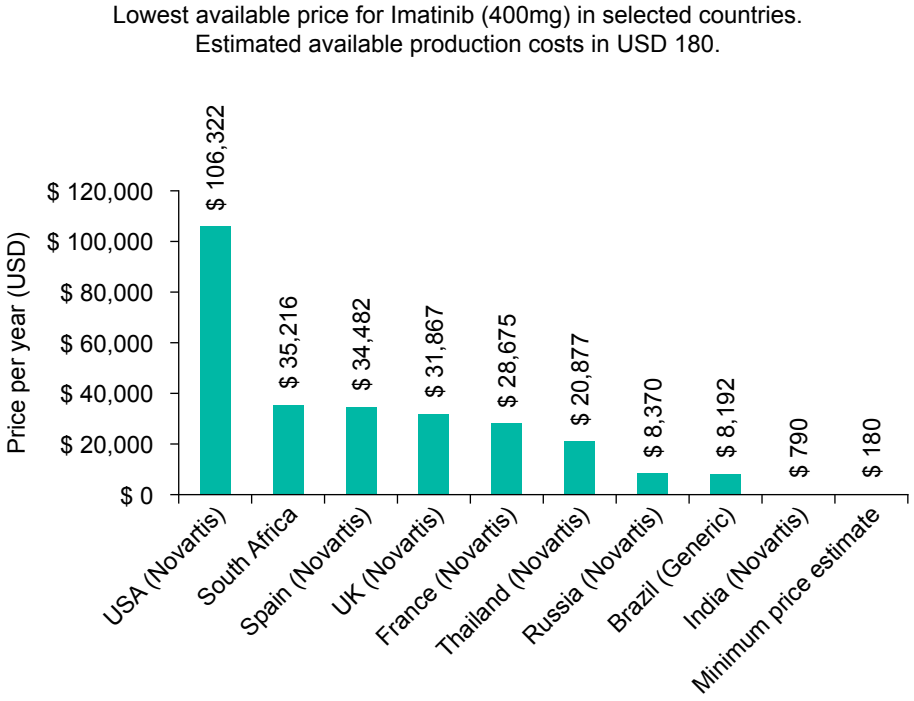
Despite its proven efficacy, imatinib was not included in WHO's essential medicines list until recently.[378] Non-governmental organizations (NGOs) point out that a potential reason for this is the high price of drugs in the category.[379]

The Malaysian Situation

Imatinib is marketed by its patent holder, Novartis, as Glivec in Malaysia.

The MOH has not included it in Malaysia's National Essential Medicines List, although it does procure the medicine.[380] The standard dose for imatinib is 400mg daily.[381] For the period 2016 to 2018, the MOH is paying RM74.87 per 100mg tablet and RM276.33 per 400mg tablet.[382] Figure 7.1 presents price comparisons for imatinib in 2016 in other countries as well as one cost of production.

Figure 7.1: Price Comparison of Originator and Generic Prices of Imatinib in Selected Countries, 2016



Source: Hill, Andrew et al. (2016). "Target prices of mass production of tyrosine kinase inhibitors for global cancer treatment for global cancer treatment", BMJ Open 2016, Figure 3.

[378] World Health Organization. 19th WHO Model List of Essential Medicines. 2015. http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf?ua=1 (accessed 8 May 2015).

[379] Hill, Andrew et al. (2016). "Target prices of mass production of tyrosine kinase inhibitors for global cancer treatment for global cancer treatment", *BMJ Open* 2016, 1-9.

[380] See National Essential Medicines List (NEML), 4th Edition, https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/national-essential-medicines-list-fourth-edition-upload-update-preparations-321-2.pdf

[381] Hill, Andrew et al. (2016). "Target prices of mass production of tyrosine kinase inhibitors for global cancer treatment for global cancer treatment", *BMJ Open* 2016, 1-9.

[382] Prices obtained from MOH.

According to MyIPO's website, Ranbaxy filed a patent application for "stable dosage forms of imatinib mesylate" in 2013. However, as the status of that application is reported as "deemed withdrawn", it would seem that Ranbaxy did not pursue substantive examination of its application. At present, Ranbaxy does produce and market generic imatinib, although not in Malaysia.[383]

In that regard, the following facts may be relevant:

i. Ranbaxy Laboratories Limited was acquired by Sun Pharmaceutical Industries Limited in March 2015.[384]
ii. About a year before that, on 14 May 2014, it was reported that Novartis had settled its litigation with a subsidiary of Sun Pharmaceutical Industries Limited (Sun Pharma Global FZE) relating to Novartis' patents covering the use of certain polymorphic forms of Gleevec which expire in 2019. The basic compound patent for Gleevec expired in the US on 4 July 2015 (and in the EU in 2016). As a result of the settlement, Novartis permitted the subsidiary to market generic Gleevec in the US on 1 February 2016.[385]
iii. In or around 2014, several other generic manufacturers filed ANDAs (applications for approvals of generic drugs) for generic Gleevec. Novartis filed infringement suits against each of these generics, which resulted in 30-month stays of FDA approval as to those ANDAs. Two of these cases, one involving Dr. Reddy's Lab and the other involving Ranbaxy, were settled.[386]
iv. Currently 2 generics have been granted market approval in Malaysia. NPRA granted marketing approval for generic imatinib in 2013 to Cipla Malaysia Sdn. Bhd.[387] and to Dr. Reddy's Laboratories in August 2017.[388] However, at the moment the MOH still purchases Glivec.

The fact that there are patent settlement agreements between Novartis and Ranbaxy and Novartis and Sun Pharma, which acquired Ranbaxy, is relevant as these settlement agreements could have a global reach.

Essentially, for a company to have a monopoly is not in itself illegal. However, where a company utilizes unreasonable methods to acquire or maintain its monopoly, then there would be cause for investigation of possible anti-competitive conduct. To this end, it has been recognized in various jurisdictions around the world (as can be seen in the analyses above) that originator companies do utilize patent litigation threats and/or actions to deter the entry of generics. In light of that, the European Commission conducted a pharmaceutical

[383] https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=225482&agid=(PrintDetailsPublic)&actionid=1
[384] http://www.sunpharma.com/investors/archives/sunpharma-ranbaxy-merger
[385] https://www.novartis.com.eg/en/news/media-releases/novartis-settles-patent-litigation-gleevec-imatinib-mesylate-sun-pharma
[386] United Food and Commercial Workers case against Novartis, page 14.
[387] Senarai Kelulusan Mesyuarat PBKD 268 (Produk Quest 2), 30 September 2013.
[388] "Senarai produk-produk yang telah diluluskan oleh Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat PBKD kali ke-314, tarikh mesyuarat 3.8.2017".

sector inquiry from January 2008 to July 2009 upon observing that there was a delay in the entry of generics into the European market. Where generics could normally enter the pharmaceutical market immediately upon expiry of a patent, the Commission found there was an average of 7 months' delay.[389] The Commission further concluded that savings from generic entry "could have been about €3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay".[390] Following from the sector inquiry, the Commission increased scrutiny of the sector and has since then conducted regular monitoring of patent settlements.[391]

7.3 Price Discrimination

THE CASE OF NAPP PHARMACEUTICALS AND SUSTAINED RELEASE MORPHINE TABLETS[392]

Summary
This was the United Kingdom's Office of Fair Trading's (OFT) first abuse of dominance case under the Competition Act 1998 (which entered into force on 1 March 2000). The OFT investigated the case following a complaint. At its conclusion, the OFT found that "Napp had used heavy discounting, often in excess of 90 per cent of the list price, when bidding for hospital contracts to supply SRM (sustained release morphine) against other competitors. This type of exclusionary behaviour in the hospital segment enabled Napp to charge excessive prices in the larger community segment and retain a very significant share of the market (well over 90 per cent). A smaller proportion of SRM tablets were sold via the hospital segment (10-14 per cent) than the community segment. However, this segment was considered 'an important, or even indispensable, "gateway" to community sales'. Any new entrant had to establish itself in the hospital segment before it could penetrate the much larger and profitable community segment, with doctors in primary care preferring patients to remain under the same drug regime once they leave the hospital."

Facts
Morphine is a strong opioid analgesic used to treat moderate and severe pain (particularly in cancer patients).

[389] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf, para 219.
[390] *Ibid.*
[391] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/citizens_summary.pdf; http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/
[392] OFT (Office of Fair Trading) (2011). Evaluating the Impact of OFT's 2001 abuse of dominance case against Napp Pharmaceuticals. Excerpts from the report are used in this case discussion. https://assets.publishing.service.gov.uk/media/555de4bfe5274a708400015a/OFT1332.pdf

As at 1 March 2000 there were four suppliers of sustained release morphine in the UK: (i) Napp, which supplied MST and MXL; (ii) Boehringer Ingelheim Limited, which supplied Oramorph SR; (iii) Link Pharmaceuticals Limited (Link), which supplied Zomorph; and (iv) Sanofi-Winthrop, which supplied Morcap SR. Boehringer Ingelheim had stopped supplying sustained release morphine in the UK. Sustained release morphine is supplied in many different presentations (i.e., tablets, capsules, suspension and different pack sizes). The brands are also sold in different strengths. Napp's MST is offered in seven different strengths and is the only product to offer tablets in 5mg and 15mg packs. Napp's MXL and Sanofi Winthrop's Morcap SR are the only once-daily (24 hour) sustained release products. The others all need to be administered twice daily.

Napp offered high discounts in the hospital segment. Napp offered highest discounts on those products for which it faced a directly competing product from Boehringer Ingelheim.

In the community segment, Napp charged excessive prices by exploiting the lack of competition.

Findings

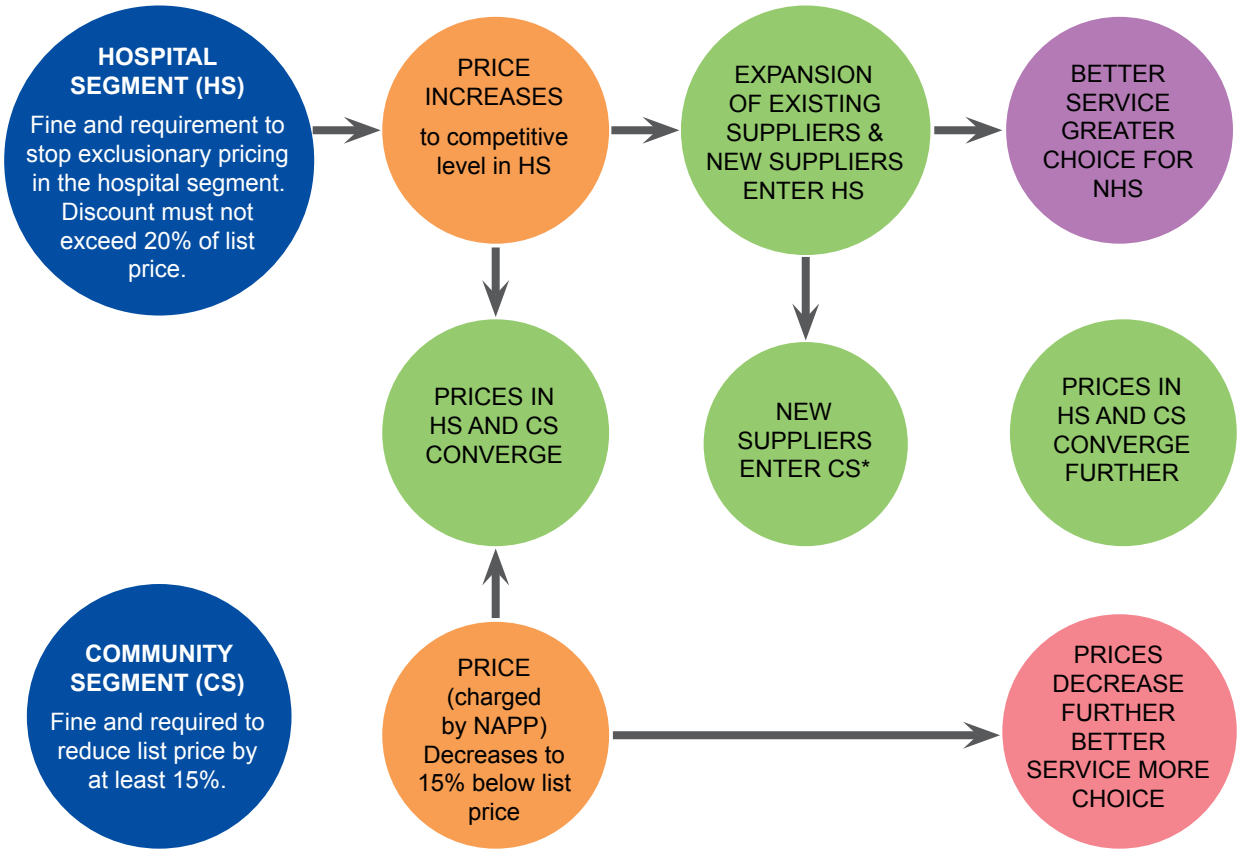
The OFT found that Napp had abused its position of dominance for the supply of sustained release morphine in the UK in the following manner:

Hospital segment (10-14%)	Napp's conduct in this sector created strategic barriers to entry (that is, exclusionary pricing), preventing other suppliers from getting a foothold in this market.
Community segment (86-90%)	Competition was weak in this segment due to demand-side barriers to entry such as the strength of the Napp brand in this segment, risk aversion to using substitute drugs alongside price insensitivity of GPs (spending on this drug represented a small proportion of their overall budget). The price of sustained release morphine charged in the community segment at the time of the decision was described as "significantly higher than the price charged to hospitals, in the case of some higher strength tablets the community wholesale price being in excess of 1,000 per cent higher than the average hospital price".

The OFT found that there are three factors that interact with each other to influence the procurement of specialized drugs such as sustained release morphine: procurement regulations, prescribing decisions made by clinicians and dispensing decisions made by pharmacists (in particular, the risk of side-effects on switching to other brands), and branding.

At the end of the case, the OFT imposed a fine of £3.21 million (this was later amended to £2.2 million by the Competition Commission Appeal Tribunal which affirmed all the other aspects of the OFT's decision). Additionally, Napp was required, inter alia, to reduce the National Health Service (NHS) list price of MST tablets by at least 15% and to sell MST tablets to hospitals in the UK at a price of not less than 20% of the (reduced) NHS list price.

Figure 7.2: Intervention Logic Model



Source: OFT decision

As a consequence of the OFT's decision, new suppliers in the hospital segment were able to build up their reputation, spilling over into the community segment. GPs were more willing to consider prescribing sustained release morphine supplied by manufacturers other than Napp.

However, the OFT also found that "despite the fact that Napp's prices in the hospital segment are higher than those of its competitors … it is still the biggest supplier in the hospital segment. This would confirm that price is not the only determinant of drug choice, and whilst hospitals tend to be price sensitive, they do also attach a clinical risk to switching from one product to another. This 'inertia' may be limiting, or delaying the immediacy of the impact of price restrictions such as those imposed by the OFT in 2001."

The Malaysian Situation

As stated in Chapter 6, in the course of this Review, a common complaint among community pharmacists was that they were being charged more for a particular drug than the pricing given to clinics and/or private hospitals. Again, the recommendation is for a thorough study to be conducted on the issues raised by level 3 providers. However, the Napp case is interesting as it illustrates how price discrimination at level 3 was actually a by-product of anti-competitive conduct at the suppliers' level (level 1).

As such, as stated in Chapter 6, when allegations of price discrimination are raised, some factors to be considered from the competition standpoint would be:

- Percentage of differentiation between prices charged to pharmacies as opposed to hospitals and doctors;
- Reasons for such differentiation;
- Impacts of the price differentiation on the business of the particular complainant;
- Whether there is market dominance by the product in question at public or private procurement level;
- Whether there are in fact competitors within the market (at the ATC 3 level);
- Factors affecting substitution; and
- Whether generics of the product in question are available.

7.4 "Pay-to-Delay" Agreements

THE CASE OF GLAXOSMITHKLINE AND PAROXETINE

In February 2016 the Competition and Markets Authority of the United Kingdom (CMA) fined GlaxoSmithKline and generics manufacturers more than 48 million euros over the sale of paroxetine, an antidepressant.

The conduct was found to be in violation of the UK Competition Act 1998: Chapter I that prohibits agreements with the object or effect of preventing, restricting or distorting competition within the UK, and Chapter II on prohibition on abuse of a dominant position in the UK. The CMA also considered the EU counterpart of the Chapter I prohibition in Article 101 of the Treaty on the Functioning of the European Union (equivalent agreements which may affect trade between EU member states).

The agreements among the companies concerned and their conduct had been brought to the OFT's attention by the European Commission in 2010. In August 2011 the OFT opened an investigation into certain patent dispute settlement agreements relating to paroxetine. Responsibility for the investigation then passed to the CMA in April 2014.

The infringement decision[393] was addressed to the following companies, which the CMA considers were either directly involved in the infringement(s) and/or were liable as parent

[393] Decision of the CMA (Case CE-9531/11): https://assets.publishing.service.gov.uk/media/57aaf65be5274a0f6c000054/ce9531-11-paroxetine-decision.pdf

companies of the companies directly involved, or as successors to these companies:

- GSK: Beecham Group plc (GSK), GlaxoSmithKline UK Limited, GlaxoSmithKline plc and SmithKline Beecham Limited (formerly SmithKline Beecham plc).
- Generics (UK) Limited (GUK) and Merck KGaA.
- Actavis UK Limited (formerly Alpharma Limited), Xellia Pharmaceuticals ApS (formerly Alpharma ApS) and Alpharma LLC (formerly Zoetis Products LLC, Alpharma LLC and Alpharma Inc.).

The total fines imposed were as follows:

- The total penalty for GSK was £37,606,275, for which each entity comprising GSK was jointly and severally liable.
- The total penalty in respect of GUK was £5,841,286, for which Merck KGaA was liable for £5,841,286; and of that amount Generics (UK) Limited was jointly and severally liable, with Merck KGaA, for £2,732,765.
- The total penalty in respect of Alpharma was £1,542,860, for which each of Actavis UK Limited, Xellia Pharmaceuticals ApS and Alpharma LLC was jointly and severally liable.

Below are excerpts from the CMA website:[394]

"The CMA's decision relates to conduct and agreements between 2001 and 2004 in which GSK, the supplier of branded paroxetine (an anti-depressant medicine), agreed to make payments and other value transfers totalling over £50 million to suppliers of generic versions of paroxetine. The CMA has found that these payments and other value transfers were aimed at delaying the potential entry of generic competitors into the UK market for paroxetine.

"In 2001, a number of pharmaceutical companies – including GUK and Alpharma Limited (Alpharma) – were taking steps to enter the UK market for paroxetine with a generic version. GSK's own branded version of paroxetine, Seroxat, was a 'blockbuster' product: In the UK, 4.2 million prescriptions were issued for Seroxat in 2000 and Seroxat sales exceeded £90 million in 2001. At the time GSK held certain patents in relation to paroxetine.

"GSK challenged these pharmaceutical companies, alleging that their generic products would infringe its patents, and commenced litigation proceedings against GUK and Alpharma. Before that litigation went to trial, GUK and Alpharma each entered into agreements with GSK, which included terms prohibiting their independent entry into the UK paroxetine market.

"These 'pay-for-delay' agreements deferred the competition that the threat of independent generic entry could offer, and potentially deprived the National Health Service of the significant price falls that generally result from generic competition. In this case, when

[394] https://www.gov.uk/government/news/cma-fines-pharma-companies-45-million. For full details see: https://www.gov.uk/cma-cases/investigation-into-agreements-in-the-pharmaceutical-sector

independent generic entry eventually took place at the end of 2003, average paroxetine prices dropped by over 70% in 2 years.

"The CMA has found that GSK's agreements with each of GUK and Alpharma infringed the competition law prohibition on anti-competitive agreements. The CMA has also found that GSK's conduct, in making payments to GUK, Alpharma and one further company, Norton Healthcare Limited (IVAX), to induce them to delay their efforts to enter the UK paroxetine market independently of GSK, infringed the competition law prohibition on abuse of a dominant position."

Michael Grenfell, the CMA's Executive Director for Enforcement, said in a public statement: "Today's decision sends out a strong message that we will tackle illegal behaviour that is designed to stifle competition at the expense of customers – in this case, the NHS and, ultimately, taxpayers.

"This investigation shows our determination to take enforcement action against illegal anti-competitive practices in sectors big and small. Cracking down on these practices is essential to protect consumers, to encourage legitimate business activity that such practices stifle, and to stimulate innovation and growth." [395]

7.5 Refusal to Supply and Excessive Prices

This is an on-going investigation at the time of writing. On 3 February 2017 the Spanish Markets and Competition Commission (Comision Nacional De Los Mercados y la Competencia or CNMC) initiated anti-competition proceedings against Aspen Pharma Ireland Ltd, Aspen Pharmacare Holdings Limited and Aspen Pharma Trading Limited (Aspen) for possible abusive practices centred on a refusal to supply certain pharmaceuticals and for excessive prices.

The actions mentioned would be in violation of the country's Competition Defence Law, as well as the Treaty on the Functioning of the European Union, by causing deliberate shortages of certain products in the national market in order to avoid the price guidelines set by the Spanish market, importing said products from other countries and allowing Aspen to set its own prices.

The CNMC's probe was kick-started after information on these possible uncompetitive practices was notified by the competition authority of Italy. Some of the medications involved had been imported from Italy.[396]

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[395] *Ibid*.

[396] https://www.competitionpolicyinternational.com/spain-cnmc-strikes-at-aspen-pharmaceutical-group-over-market-power-abuse/

7.6 Conclusion

It is generally accepted that the granting of quality patents for novel and innovative ideas is an incentive for industry. At the same time the role of anti-competition law as embedded in the Competition Act, is to protect the consumer and the process of competition, by considering the conduct of players within the sector. It is recognised that the entry of generic drugs into the pharmaceutical market is essential to reduce the cost of medicines, and healthcare cost containment. Generic competition also brings down originator product prices, again contributing to public health.

Therefore the Review is an analysis of substantial issues that exist which delay the entry of generic medicines. There is no judgment of the legality or the validity of any patents or product life management strategies mentioned. Many of the terms used such as patent clusters, follow-on or second-generation products, as well as secondary patents, are to be found in internal documents of the originator companies themselves that were obtained in the cases included in the report and are not intended to bear any pejorative connotations.

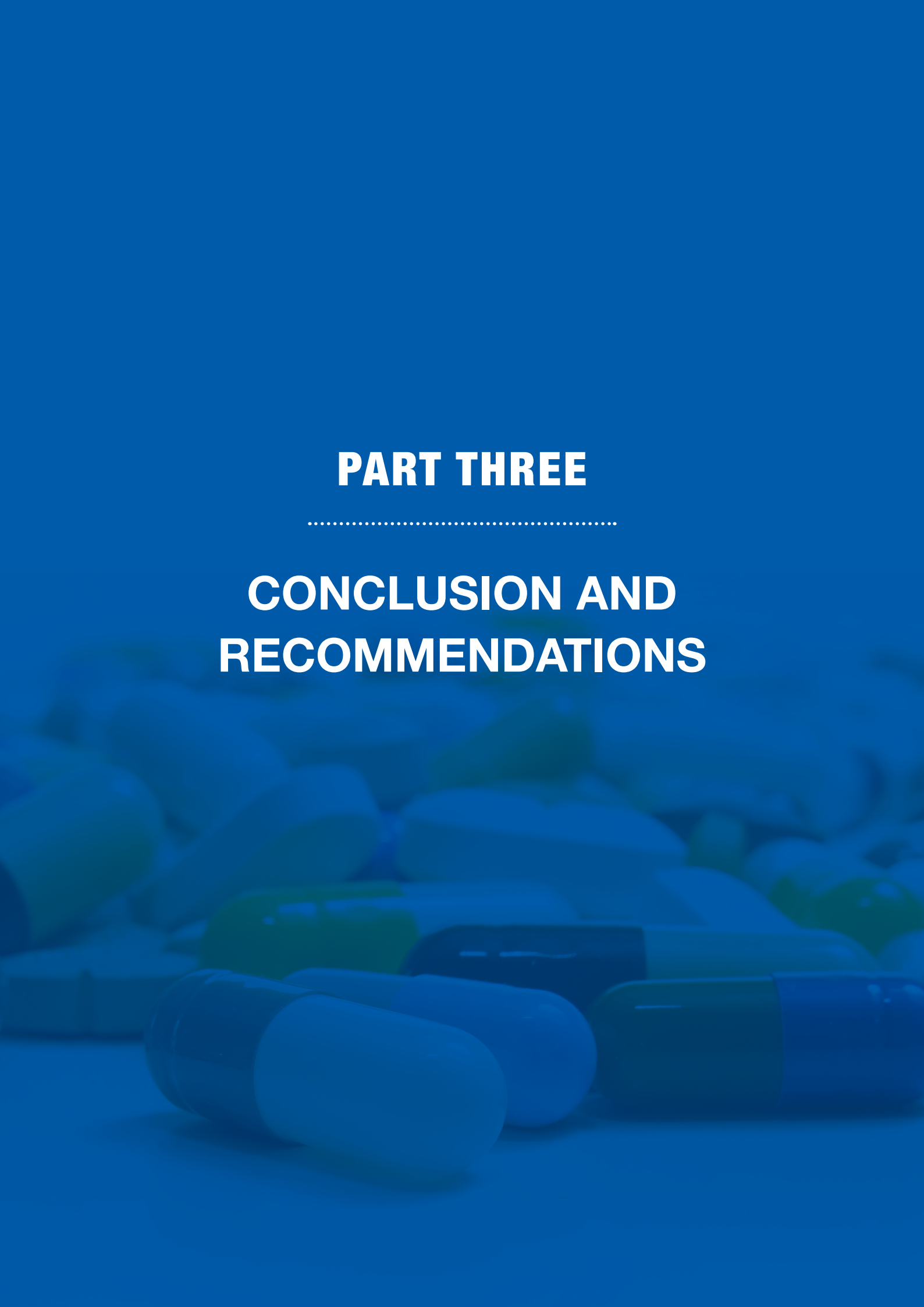
In studying the conduct of industry players at level 1, competition cases that have emerged in various countries can inform MyCC and other relevant government agencies in Malaysia. Certainly, every case must be decided on its own facts. However, it is agreed by the representatives of originator companies that substantially, subsidiaries of originator companies in Malaysia have little autonomy in decision making related to pricing, acting instead on the instructions of their parent companies. Such being the case, the subsidiaries and their parent companies are looked at as a whole. Under Section 2 of the Competition Act 2010, "enterprise" that can be the subject of scrutiny under the Act has been defined as "any entity carrying on commercial activities relating to goods or services, and for the purposes of this Act, a parent and subsidiary company shall be regarded as a single enterprise if, despite their separate legal entity, they form a single economic unit within which the subsidiaries do not enjoy real autonomy in determining their actions on the market".

As pointed out by the EU Commission in its pharmaceutical sector inquiry, "These are real multinational companies acting in a global environment. Typically, strategic business decisions with regard to R&D projects are made at a global level while marketing and distribution decisions are rather taken at local level."[397] As such, scrutiny of the policies of parent companies and their conduct on a global level is the starting point of the analysis. However, it is noted that some of the originator companies have modified their policy and business model due to the case development in other countries.

[397] European Commission (2009). "Pharmaceutical Sector Inquiry Report", DG Competition Staff Working Paper, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/, para 54.

PART THREE

CONCLUSION AND RECOMMENDATIONS



CHAPTER 8: CONCLUSION AND RECOMMENDATIONS

8.1 Conclusion

This Pharmaceutical Market Review was conducted within the context of Malaysia's National Medicines Policy, which aims to promote equitable access to and rational use of safe, effective and affordable medicines by its population, and the Competition Act of 2010 to promote competition in industry. The government's "generics first" policy contributes to accessibility and affordability of medicines, while the entry of generics in the market often brings prices of originator medicines down as well.

The study begins by looking at the growth of and changes in Malaysia's healthcare system as well as the pharmaceutical sector. Malaysia's healthcare system changed from a predominantly public healthcare system to a dual or two-tier system where private healthcare expenditure now almost equals that of the public sector (48:52 split). Public healthcare is heavily subsidized and funded through taxation, while private healthcare is mostly paid for from out-of-pocket expenses (OOP). The figures provided under the Malaysian National Health Accounts (2016) show that total healthcare expenditure in Malaysia reached RM50 billion or 4.5% of GDP in 2014. OOP has risen from 32% of total healthcare expenditure in 2001 to 39% in 2014 and accounts for 82% of private healthcare expenditure. In 2014, pharmaceuticals comprised 12% of OOP.

Pharmaceutical (prescription and OTC medicines) sales grew by an annual average of 8% over the last decade and reached RM8.6 billion or 16.5% of total healthcare expenditure in 2016. Imported medicines at RM5.4 billion accounted for the largest part (63%) of the pharmaceutical market in 2016. Exports of pharmaceuticals are only 13% of imports; thus Malaysia suffers from a RM4.6 billion-trade deficit in this sector. There are opportunities for Malaysia's export sector to grow with the right policies and government support. However, competition from a well-established generic sector in India and China's emerging export capacity pose challenges for Malaysian manufacturers and exporters.

(A) MARKET STRUCTURE AND CONCENTRATION: UNIQUE CHARACTER OF THE PHARMACEUTICAL SECTOR

The market structure of Malaysia's pharmaceutical sector comprises three levels in the supply chain: manufacturers of generic medicines and importers of originator and generic medicines at level 1; wholesalers and distributors at level 2; and providers at level 3 who provide the medicines to patients and end users.

In this Review, the market profile of the pharmaceutical sector was developed using data from the licences issued by the NPRA and Pharmaceutical Services Division of the MOH

to manufacturers, importers, wholesalers and pharmacists, and financial data for 2014 or 2015 from the Companies Commission of Malaysia. The study focused on companies whose core business is the manufacture, import and/or distribution of controlled medicines ("prescription medicines"), as opposed to all types of pharmaceutical products.

Based on criteria explained in earlier parts of the report, 28 companies were identified as manufacturers of controlled medicines, most of which are locally owned. Only 5 of these companies are foreign-owned and none are from high-income countries. Production is mainly for the domestic market although the bigger companies are orientating towards export markets. Contract manufacturing is only a small part of their business, accounting for less than 5%.

Though there are few players in the pharmaceutical manufacturing sector, the market is not concentrated, with a Concentration Ratio (CR) 5 of 54%, and Herfindahl-Hirschman Index (HHI) of 824. This market is competitive because the companies are producing generic drugs on which there are no exclusive rights. There is heavy price competition particularly from imported generic drugs from India and increasingly from other countries, and there is little evidence of price fixing.

Importers, on the other hand, are dominated by multinational corporations (MNCs) from high-income countries that import patented (originator) medicines from their parent companies. Of the 54 importers selected for review, 35 are foreign-owned with total sales revenue of RM3.9 billion or 87% of market share in 2014. MNC importers maintain strong marketing teams focused on demand creation, marketing directly to all providers (doctors, private hospitals, pharmacies and public hospitals). Local importers are small in size and import mainly generic medicines with combined revenue of RM553 million.

This market's CR5 of 47% and HHI of 643 indicate a low degree of market concentration. However, market concentration measured by aggregated sales revenue at the company level does not capture market power. The high degree of market power of MNCs comes largely from importing patented products over which they enjoy market exclusivity and, consequently, pricing power. MNCs further tend to extend their market exclusivity through various methods like broad patent claims on molecules and filing for secondary patents (in addition to molecule patents) that create an "evergreening" effect.

At the second level of the supply chain, there are many more players: 709 companies hold NPRA wholesale licences to distribute controlled medicines, from which 69 companies were selected for this review. Four types of wholesalers/distributors were identified – large independent distributors, Bumiputera agents, subsidiaries of pharmaceutical manufacturers that own wholesale and distribution companies, and retail pharmacies that also do wholesale business. Despite the large numbers, the market is highly concentrated, with 2 large foreign distributors – DKSH and Zuellig – accounting for 65% of market share in 2014. Seven Bumiputera agents as a group accounted for 24% of market share; the remaining 11% is shared among the smaller wholesalers and distributors.

Standard economic theory would suggest that high market concentration should translate into a high degree of market power by the big players. However, this is not the case here because the large distributors mainly provide warehousing, distribution and other logistics services without taking ownership of the goods; hence, they have no power over pricing. The relationship between these large distributors and the different groups of level 3 providers was not studied in this review though complaints have been made by pharmacies to MyCC.

The third and final level of the supply chain comprises the providers, which consist of general practitioners' and specialists' clinics (individual and group clinics), private hospitals (individual and group hospitals), retail pharmacies (single outlet and chain pharmacies) as well as public hospitals and clinics. There were 6,978 private GP and specialist clinics, 184 private hospitals, 1,413 pharmacy companies with 2,098 outlets, 150 public hospitals and 2,871 public clinics in 2014. Owing to time limitations, no market concentration study was done for this level.

Using standard measures of market concentration, the pharmaceutical market in Malaysia is found to be competitive among the manufacturers, importers and providers. The only level of the supply chain that has high market concentration is among wholesalers and distributors. However, it was found that market concentration does not necessarily translate into market power especially in terms of ability to influence or determine market prices, and vice versa a low degree of market concentration does not imply lack of power to determine market prices. Other important factors such as entry barriers, supply condition and particularly the patent system determine market power. In other words, there is no strong correlation between market concentration (traditionally defined as sales revenue share), market power and anti-competitive behaviour.

This limitation is due to the unique character of the pharmaceutical market. Unlike other consumer goods, such as cars or electronics, where consumers have the choice and final say of whether to purchase or not a particular brand in the market, patients who require medication are in no position to decide on the type of medicines to consume. The problem is compounded by information and knowledge asymmetry between patients and the doctors and health professionals who prescribe the medicines. In many cases, those who prescribe have more power to decide on the product than the consumer.

(B) GENERICS OFTEN THE ONLY SUBSTITUTE: IMPLICATIONS OF PATENTS FOR INNOVATION AND ACCESS TO MEDICINES

A vexing question is the substitutability of the product. In the pharmaceutical market, where medicines are not easily substitutable, the definition of relevant market becomes critical. Functional similarities are insufficient to establish substitutability as the effectiveness and side effects of taking a product can differ from one patient to another.

In addition to the asymmetry of knowledge between consumers and providers, price may not be a priority in the treatment of patients by prescribing doctors. For these reasons, market concentration in relation to pharmaceuticals are often examined at a very detailed

level, frequently down to the chemical substance level (ATC 5), where the seller through patent and other statutory rights has legal exclusive market rights and enjoys a dominant market position and often the power to determine prices. With the lack of substitutability, the only time when there is competition is when generic medicines enter the market and prices then drop dramatically, often up to 90% as seen in the case of antiretroviral drugs (ARVs) for HIV.

Accordingly, domestic manufacturers and importers identified patents as one of the barriers to generic medicines entering the market and the fostering of competition and growth of the domestic industry, and as one of the major factors behind the continued high price of drugs.

For this Review, an extensive legal analysis was done on issues surrounding the patent system as it relates to high prices of several drugs in treating non-communicable diseases, in particular cardiovascular disease and cancer whose incidence has been rising in this country.

For that reason, several key medicines relevant to the treatment of these diseases were chosen as the subjects of case studies to determine the reasons behind the high costs of these medicines in this country. In the case of ARVs for HIV, the government has established a treatment programme made possible by using generics. However, as patients develop resistance, second- and even third-line ARVs are needed. These being newer drugs, patents make them unaffordable. As a result, some of these medicines continue to be out of reach for treatment in Malaysia even when the monopoly granted by patents on them had expired elsewhere and generics were available in other parts of the world.

Among others, substantial reasons for the prolonged high prices in Malaysia include the following factors that emerged from the Review:

- Patent clusters – on some of the medicines, multiple patents had been filed, for example, on methods, formulations and salts, leading to many secondary patents and the situation of a patent cluster. This situation is caused by generous patenting criteria within our patent system and also a lack of monitoring of the substance of the patents which have been filed and approved. It is possible that some of these patents had in fact been invalidated in other jurisdictions or the patent applications had been rejected. Patents form a barrier to entry to generics, as they are undoubtedly a chilling factor. The lack of pre-grant opposition procedures in Malaysia results in patent validity challenges being a drawn-out and expensive affair in the courts. In addition, Malaysia has not incorporated all of the policy space and flexibilities under the TRIPS Agreement in order that we may have a patent system that supports the generic industry and competition while rewarding innovation in research and development;

- Follow-on products – this is where an originator company develops a further product with the same active chemical base by using different salts or formulations, in anticipation of generic competition to the original product. Intensive marketing then takes place to switch patients over to the new product before the generic version enters the market. An issue arises when the follow-on product does not necessarily have added therapeutic benefit and is actually bioequivalent to the original medicine;

- In some cases where patents had already expired, there was still a delay in entry of generics and medicine prices remained high. This calls for further study and investigation.

The Review raises a basic challenge: balancing the role of patents as incentives and reward for innovation on the one hand, and ensuring that patents are used for the public good and serve development objectives on the other hand, requires appropriate policy and law. The relationship between patents and innovation is not linear. Literature and experience show that a more complex web of factors determines innovation at the company and country level. The special nature of medical innovation adds even more complexity. As pointed out in the 2013 trilateral study by WHO, WIPO and WTO mentioned earlier, it differs from innovation in general due to the ethical dimension of medical research, a rigorous regulatory framework, liability questions, and the high cost and high risk of failure. Since rising expenditure for medical research has not been matched by a proportionate increase in new products entering the market, many initiatives are exploring new strategies for product development, thus informing a rich debate about how to improve and diversify innovation structures to address unmet health needs. Possibilities include open innovation structures, and a range of push and pull incentives, including schemes such as prize funds that would delink the price of products from the cost of R&D.

(C) COMPETITION LAW

Although traditionally, public health and access to medicines issues have not been addressed through competition law, competition authorities in a number of countries are now taking on a bigger role in ensuring that national objectives of universal health coverage are met through a competitively robust pharmaceutical market. The authorities of the European Commission and member states of the European Union as well as the US have been proactive as seen from cases highlighted in this Review. The establishment of competition laws in developing countries, including Malaysia, over the past 10 years is contributing to this trend.

In several cases competition law has been used successfully to improve the price, availability and transfer of health technologies. The United Nations Secretary-General's High-Level Panel on Access to Medicines, the Global Commission on HIV and the Law and UNDP recommend the greater use of competition law.

In enforcing competition law, the government can initiate the necessary actions, in contrast to intellectual property law that creates private rights and thus requires a private party to take action.

MyCC and the MOH have started engaging with UNDP on the use of competition law to deal with abuse of patents and other intellectual property rights in order to increase access to affordable medicines and ensure robust competition in the pharmaceutical sector. The potential to develop rules and practices in this area is promising, at both the national and regional levels (e.g., through ASEAN and WHO regional offices).

(D) REGULATORY REQUIREMENTS AND CHALLENGES

The Review also elicited a wide range of feedback and concerns related to the current pharmaceutical product registration requirements. These requirements are in compliance with international standards and comparable to those in high-income countries, and create confidence in the quality, safety and efficacy of products manufactured in Malaysia, both for domestic consumers and for export markets. Without compromising on safety, efficacy and quality, care should be taken that there are no unjustified regulatory requirements that could become a barrier to the manufacturing of generics and innovation in the country. This is particularly the case for development of biosimilars. The main concern is that the requirements can lead to a delay in generics entering the market in addition to incurring high costs for the local manufacturers and importers. Compliance requires major investments in the upgrading of manufacturing facilities. Smaller enterprises that cannot afford the cost of upgrading will be pushed out of the market. In that way, barriers to entry are created which can hamper the growth of the domestic industry.

Another aspect of product registration that is known to cause delay of generics and thus higher costs to consumers and public health budgets is data exclusivity related to clinical test data, as discussed in Chapter 5. There is no international obligation to provide such market exclusivity. However, in adopting the Data Exclusivity Directive 2011, Malaysia does explicitly take account of public health and has achieved a balance between the originator and generic companies whilst going beyond the requirements of the TRIPS Agreement.

(E) AVAILABILITY, AFFORDABILITY AND ACCESSIBILITY

Finally, an analysis was done on the issues of availability, affordability and accessibility of essential medicines in Malaysia based on review of past studies and data from the MOH. It can be generally observed that the availability has increased over the years. However, there has been no detailed direct study since 2005. It is recommended that further studies be conducted to evaluate the availability, affordability and accessibility of the medicines concerned.

On affordability, public hospitals and clinics are providing most of the medicines needed at highly subsidized and therefore affordable rates. However, low-income patients who have to purchase medicines from the private sector would face severe issues of affordability as the prices of the 10 most utilized medicines in the private sector are 1.4 times to 34 times higher than in the public sector.

International or external reference pricing is a common tool for setting prices of medicines, but has limitations. One element is the need for actual versus negotiated or concealed prices (e.g., discounts). In addition, as shown in the European Commission study (2016), differential pricing does not seem to work to improve access to medicines for middle-income countries.

The type of public procurement system in a country determines to a large extent the price of medicines, the Australian system being a good example. Malaysia changed from a central government purchasing system to a privatization model where a private company is given exclusive concession to supply a large part of medical supplies to the government. A study in 2009 found that selected drug prices in the public sector increased post privatization, particularly between 2001 and 2003 when they rose by 64%.

8.2 Recommendations

From the Review, there are several policies and related laws that may have the potential of impeding competition. Government action is needed to remedy this. Additional measures can also be taken to increase competition in the pharmaceutical sector.

A process of stakeholder and public consultation and education of the public on suggested reforms would be important, as would a thorough consideration of the various types of reforms and the possible impacts within the local context.

(A) STRENGTHENING THE DOMESTIC PHARMACEUTICAL INDUSTRY AND EXPANDING EXPORT MARKETS

While the market share of generics has grown, the Review shows that the prices are very high for many key medicines needed to treat diseases that are of high burden or increasing in prevalence. These are predominantly imported originator medicines. To reduce this reliance on imports, the following could be considered:

(i) A long-term strategy to strengthen domestic manufacturing capacity, and to increase support for research and development so that the generic players can graduate to higher levels of innovation.

(ii) An integrated approach with clear responsibilities for the designated agencies is needed so that there is a comprehensive policy with institutional and financial support.

(iii) Support for access to markets outside Malaysia because the domestic players will not enjoy economies of scale if they are restricted to the Malaysian market.

(iv) There should be an assessment of whether the goals and objectives of the Healthcare National Key Economic Area are sufficient and whether they are being met. This assessment should be carried out with all stakeholders and government departments and ministries involved in the effort to steer this industry forward.

(B) REGULATORY ISSUES FOR PRODUCT REGISTRATION AND MARKET AUTHORIZATION

Malaysia has a strict regulatory regime that is demanding both on the regulators and on the industry players. At present, Malaysian manufacturers have the potential for export, due to the country's high regulatory standards of pharmaceutical quality, efficacy and safety.

(i) The MOH should hold discussions with industry players to determine a more tailored approach for local manufacturers that maintains standards while addressing legitimate concerns. Some questions to be considered would be:
- What is the level of quality assurance actually required at each stage of the process, and what are the costs of implementation?
- How are these costs then reflected in the price of the pharmaceutical products which are sold?
- How do domestic players perceive the standards set and their implementation?

(ii) As biologics become a bigger part of the innovation stream and market, the ability of domestic players to succeed in developing biosimilars will depend on their R&D and manufacturing capacity as well as the regulatory framework for biosimilars. The trilateral study of WHO, WIPO and WTO cautions against unjustified regulatory barriers and lengthy marketing authorization procedures that may delay access to much needed medical technologies. The design of Malaysia's regulations and standards needs to be carefully and skilfully calibrated. In that regard, expanding the Data Exclusivity Directive to include biologics would have impacts that need careful study first.

(iii) There should be support for NPRA and all relevant government agencies to ensure the necessary technical capacity to assess and evaluate bioequivalence studies for molecules, biosimilars dossiers and new chemical entities.

(iv) The requirement for retrospective bioequivalence for "grandfather" products should be reconsidered.

(v) The issue of insufficient local BE accreditation centres and the high cost of conducting BE studies locally, which was raised in Chapter 5, needs to be addressed.

(vi) The NPRA can develop further the criteria for expedited product registration.

(vii) The Guidelines on Good Pharmaceutical Trade Practice are currently voluntary. The MOH and MyCC can continue their collaboration on this and other areas for potential guidance or regulation vis-à-vis industry players.

(viii) The current practice of defining the relevant market at ATC 3 level when looking at competition issues within the pharmaceutical sector should be reconsidered. UNDP suggests starting at ATC 5, with the onus on the company concerned to show why the market should be wider.

(C) ADDRESSING THE PATENT SYSTEM

MyCC can play a vital role in coordinating with other relevant agencies to address issues that interface between competition law, intellectual property law and health regulations.

(i) The MOH, MDTCC/MyIPO and MyCC should collaborate to:
- Collectively increase their knowledge and understanding of the interface between intellectual property and competition laws, and its impact on access to medicines;
- Develop a new national intellectual property policy that integrates the public health and competition dimensions;
- Align the Patents Act, its regulations and guidelines with the national competition and public health objectives, laws and policies as part of the review of the Act;
- Monitor the working and use of patents; and
- Remedy anti-competitive conduct of industry players.

(ii) The scope of patentability and the criteria for "novelty", "inventive step" and "industrial applicability" (patentability criteria) should be made more rigorous to ensure a system that properly balances the promotion of innovation and industrial development with prioritizing public health and improving access to affordable medicines.

(iii) Patent transparency should be established by:

- Requiring originator companies to disclose in their patent applications to MyIPO, patent information in other jurisdictions related to the product in the application, such as the rejection or withdrawal of patent applications or invalidation of granted patents; and

- MyIPO setting up its website to disclose the information above. In this regard, the level of transparency in the Indian patent office website, to the point of disclosing communications between the patent applicant and the patent office, is a good model to consider.

(iv) To ensure that applications for pharmaceutical patents are properly evaluated, there must be an allocation of resources to enhance the expertise of MyIPO officers in technical evaluation of such applications.

(v) There is agreement between the MOH and MyIPO on a mechanism for collaboration on the examination of pharmaceutical patent applications, tapping on the pharmaceutical knowledge of the MOH. Related to this, there should be capacity building on patent and prior art search and analysis for MOH officers.

(vi) Since the Patents Act allows for parallel importation, and its appropriate use for medicines will have to be aligned with the drug regulatory system, MOH can consider measures to facilitate this option.

(vii) To amend the Patents Act to take into account the amendment to TRIPS which allows for generic medicines manufactured under a compulsory license to also be exported to countries with insufficient manufacturing capacity.

Several of the proposals in this section are under consideration by MyIPO but the information is not publicly available at the time of writing.

(D) PRICING

(i) Given the various studies mentioned in Chapter 4 above that have shown Malaysian drug prices are high by international standards and significant price variations exist between providers, there is a need for a coherent price policy that should be part of the National Medicines Policy. A consultation process with the participation of relevant stakeholders can be a start.

(ii) In the private sector, the issue of regulation of chain mark-ups should be studied, taking into the consideration the variables that determine medicines prices and the characteristics of each level of the supply chain. Countries use different models and Malaysia could learn from these as appropriate. As an example, South Africa has introduced a single factory price with a maximum mark-up of 28% and regressive mark-up margins, i.e., higher-value products have lower mark-up margins. Other measures apart from such price control can be explored, taking into account the balance between market forces and the need for non-market intervention to address market failures.

(iii) There should be price transparency at all levels starting from manufacturer/importer exit price to the level of providers, taking into account acceptable business practices that are compatible with competition and public interest. The price at level 3 in particular should be made transparent to consumers. Reference can be made to the WHO Guideline on Country Pharmaceutical Pricing Policies 2015.

(iv) There are on-going studies conducted by the MOH to monitor public and private medicine prices using WHO methodology. This can be supplemented with more and better use of publicly available information on originator and generic prices in other countries. The Philippine and Indonesian health ministries publish medicine prices on their websites and the MOH can consider this too.

(v) As recommended by WHO, international or external reference pricing should be part of an overall strategy, in combination with other methods, for setting the price of a medicine. In developing such a system, countries should define transparent methods and processes to be used. Countries should select comparator countries to use for ERP based on economic status, pharmaceutical pricing systems in place, the publication of actual versus negotiated or concealed prices, exact comparator products supplied, and similar burden of disease.

(vi) The government is committed to the Price Information Exchange for Essential Medicines (PIEmeds) initiative of WHO WPRO to share government procurement prices to know if it is getting good prices. This is an important start and efforts can also be made for potential joint price negotiations among countries for affordable prices.

(E) PRESCRIBING PATTERNS

The following could be considered:

(i) At the very least, it should be mandated that:
- Prescriptions with International Non-proprietary Names (INN) be given by doctors to patients automatically (and not upon request);
- Patients then be given the choice to purchase drugs from doctors or pharmacies (if there is no dispensing separation); and
- Itemized receipts be given for all medicines purchased.

(ii) A thorough study should be carried out on the various cost-containment methods available at this level that can then be tailored to address the issue of rising healthcare costs in Malaysia, in particular in the private sector. Level 3 providers can have a significant impact on the cost of treating certain diseases. Both physicians and pharmacists can assist in cost reduction if they substitute originators with generics where possible. In various jurisdictions it has been recommended that they be incentivized to do so.

(iii) Any reform which is implemented at level 3 should include public consultation procedures and the education of the public on the suggested reforms.

(F) PUBLIC PROCUREMENT

The type of public procurement system adopted by a country determines to a large degree the prices of drugs in that country. This is because the government not only has the power to regulate prices but in cases where it provides public healthcare and is the single largest purchaser of medicines, it has considerable negotiating power. Australia is one example that demonstrates the central and crucial role of government in managing affordability of medicines in a country.

Has the privatization of public procurement of medical products in Malaysia affected prices? Several studies found that the median price ratio for the public sector ranges from 1.1 to 2.4 times higher than the international reference price, and the MOH Medicine Price Monitoring Survey of 2008 showed it was 1.3 times higher than the IRP. Furthermore, the study by Babar and Izham showed that drug prices rose after the privatization of the public procurement system. It is necessary to do independent, comprehensive and more up-to-date studies on these important issues as to whether, and if so why, drug prices in the public sector are higher than the IRP, bearing in mind the limitations of the IRP as discussed in Chapter 4. The cost of compliance with new sets of drug regulatory requirements implemented over the past few years should also be considered.

A measure that could improve competition in the market is to split large procurement tenders, where there are multiple suppliers of the medicine in question, in order that multiple firms may compete for the same. It is also noted that there have been instances whereby tenders have been requested for 2 dosages of a medicine as one item (or tender price). This practice can prevent competition as manufacturers do not always produce all available doses of a particular medicine and those who have one but not the other dosage will be precluded from tendering.

(G) GENERIC MEDICINES POLICY

Generics provide huge savings to consumers and the public health budget, as they are lower in cost. A necessary condition for encouraging substitution is that consumers, doctors and payers have confidence that generics are of comparable quality to originator drugs. Malaysia meets these requirements by having high standards of safety, efficacy and quality for the approval of generics.

However, there is a need to educate the Malaysian public and the providers on generic medicines as negative perceptions about generics still prevail. For example, efforts can be made to publish the results of regulatory testing and to create awareness of pricing and the safety, efficacy and quality of generics. Authorities should also be vigilant against bad publicity/propaganda denigrating generics.

The experiences of other countries promoting generic medicines and providing more choices to consumers should be studied. For example, the Philippines mandates that prescriptions to patients must include a choice of at least two generic medicines.

(H) FREE TRADE AGREEMENTS

The Review did not cover bilateral, regional and plurilateral (more than 2 countries across different regions) free trade agreements outside of the WTO, but these have increasing relevance for access issues. As jointly described by WHO, WIPO and WTO in their trilateral study, the recent growth of trade and intellectual property agreements negotiated outside the established multilateral reforms, has made the international policy and legal framework more complex. The study pointed out that policy debate has focused on intellectual property and pharmaceutical regulation measures in these agreements, and their impact on access to medicines. Measures such as patent term extensions, data exclusivity and patent linkage contained in certain free trade agreements which are designed to incentivize innovation, also have the potential to affect access to medicines by delaying the market entry of generic products.

These agreements also set standards in other policy areas with implications for access, notably standards established on government procurement and competition policy, as well as preferential tariffs on pharmaceuticals, inputs and other health products. The overall impact of this trend for the international system is yet to be systematically analysed, in particular the full implications of the entire range of such agreements for access to medical technologies.

In negotiating trade agreements such as the Regional Comprehensive Economic Partnership, a primary consideration is the safeguarding of national policy and regulatory space.

The MDTCC/MyIPO, MOH and MyCC should undertake a comprehensive assessment of the implications of trade agreements on access to medicines and the domestic industry.

(I) AWARENESS RAISING ON THE COMPETITION ACT AND THE ROLE OF MYCC

The Competition Act has been in force since 2011 but public awareness of the law and its objectives is still low. Programmes should be undertaken to disseminate information and generate knowledge on the use of the Act by, for example, consumer groups and patient groups, while general awareness building can also target students from primary to tertiary levels. This would be in line with the function of MyCC to inform and educate the public regarding the ways in which competition may benefit consumers in, and the economy of, Malaysia.

Players in the pharmaceutical sector, especially industry associations, have been engaging with MyCC and the MOH in relation to awareness of the Guideline on Good Pharmaceutical Trade Practice. These associations to varying degrees are educating their members on competition issues and the law. More concerted efforts can be made to increase the knowledge and awareness among the pharmaceutical sector players – the most informed about the conduct of players in the industry are those players themselves. Building practice in competition law implementation and enforcement requires active industry players. Since competition law is still relatively new to Malaysians, including to many industry players, there is also lack of awareness that certain conduct is anti-competitive and thus violates the law. With more awareness, compliance with the Competition Act would also be enhanced.

(J) INTER-AGENCY COLLABORATION

Awareness among other government ministries and agencies is also required for the Competition Act to be effective. There is already collaboration between MyCC and its secretariat with counterparts in the MOH which can be further deepened. Collaboration can be expanded to other relevant agencies, including MyIPO, MIDA/MITI and the Securities Commission. Collaboration can include development of guidelines and regulations in relation to the implementation and enforcement of the Act.

(K) FUTURE STUDY ON PHARMACEUTICAL MARKET

This Review did not focus on the pharmaceutical industry players at level 3 of the supply chain. MyCC has received complaints regarding conduct at this level, several of which indicate anti-competitive conduct that merits investigation. Therefore, level 3 private sector providers, in particular, require a dedicated review.

A future study should also include the following:

- The relationship between players of levels 1 and 2 on the one hand, and level 3 on the other (especially the independent or community pharmacies).

- The role and impact of third-party payers (e.g., private insurance and employers) in the Malaysian healthcare market.

- Marketing strategies of pharmaceutical players in the sector, including incentives and inducements.

This is in addition to several other studies identified above.

(L) EVALUATION OF MYCC MEASURES

MyCC should consider yearly evaluation of measures and/or interventions taken on its part. Through these evaluations, assessments can be made as to whether projects achieved the desired impact or whether the outcomes could be further improved. The findings on such assessments can inform further steps to be taken.

APPENDICES

APPENDIX 1: GUIDING QUESTIONS FOR INTERVIEWS WITH INDUSTRY PLAYERS

A. General interview questions*

1. What are the major products imported and sold and rough percentages – prescriptive, OTC, innovator products, generic?
2. Who are the major suppliers and from where?
3. Who are the major buyers?
4. How do you market your products – direct to providers or through distributors (who); percentage?
5. Describe in more detail the nature of relationship with distributors, what they do and don't do etc.
6. What is the relationship with the providers – GPs, pharmacies (chain vs. independent), private hospitals?
7. What is the relationship with public hospitals?
8. Do you have a uniform pricing policy or differential pricing?
9. What factors determine prices?
10. How do you get tenders from public health institutions?
11. Do you think the registration process for medicines is about right or too onerous in Malaysia? Do they aid or impede? Do they contribute to high costs of medicines?
12. What other regulatory requirements do you face?
13. What obstacles and challenges do you face in doing business and what do you suggest to address them?
14. What suggestions do you have to improve business in the pharmaceutical sector in Malaysia?

*These were the guiding questions sent to interviewees when requested. The interviews conducted were qualitative and involved information which was sensitive to interviewees. In order for the interviewees to speak openly, the research team agreed to hold confidential the identity of the interviewees and in some cases, even the precise details of what were shared, for purposes of the Review report that will be a public document.

B. Questionnaire (guide for open-ended interview) used by the consulting team during the interviews, where relevant

Company Name:

Address and Phone:

Contact Person:

(1) OBJECTIVE: COLLECT DATA ON COMPANY PROFILE, ITS CORE BUSINESS, DIVISION OF SALES REVENUE BY TYPE OF BUSINESS, EXPORT

Type of company	Mark where applicable	% of sales revenue	% of revenue from export
Manufacturer			
• contract manufacture			
• independent manufacture			
• other			
Importer			
Wholesaler/distributor			
• warehouse			
• stock only			
• other			
Retailer			
• chain			
• independent			

Total Number Employees:

Year Business Started:

Brief History of Company:

Name of subsidiary	Type of business	Total assets	Sales revenue	Profit before tax	Profit after tax

For manufacturing company
- What percentage of medicines made are prescription, OTC, others?
- What percentage of medicines manufactured are generic?
- What percentage of medicines produced are exported? Where?
- Do you sell to wholesalers or to providers (retailers) directly?
- What is the selling price? Is it uniform?
- What factors determine the selling price?

For importing company
- What percentage of medicines imported are prescription, OTC, others?
- What percentage of medicines are generic, innovator brand?
- What percentage of medicines imported are exported? Where?
- Do you sell to wholesalers or to providers (retailers) directly?
- What is the selling price? Is it uniform?
- What factors determine the selling price?

For wholesaling company
- What percentage of medicines sold are prescription, OTC, others?
- What percentage of medicines are generic, innovator brand?
- What are the top 5 medicines (not API) that you sell, percentage of sales revenue, and selling price?
- Which types of providers do you sell to?
- Which types of providers do you give special discounts to, and why?

(2) PROCUREMENT PROCESS

Objective: To understand the procurement process in the market structure

For manufacturer
- Who are the major suppliers of your API and other raw materials?
- What are the main considerations for purchasing your inputs?
- How do you get tender for your manufacturing jobs?

For importer
- Who are the major suppliers of your API and other raw materials?
- Are there special or restrictive conditions for purchase and sale of the medicines?
- What are the main considerations for purchasing your inputs?
- How do you get tender for your manufacturing jobs?

For wholesaler/distributor
- Who are the major suppliers of your prescriptive medicines?
- What are the main considerations for purchasing your medicines?
- Are there special or restrictive conditions for purchase and sale of the medicines?
- How do you get tender for your sales order?
- Please explain your mode of operation.

(3) PRICING AND MARK-UP MARGIN

Objective: To understand what are the major factors accounting for high prices, and at which level of the supply chain this occurs

Several studies (e.g., Babar (2005), Hassali (2011)) have shown that the prices of drugs in Malaysia are many times the international reference price (IRF), especially in the private sector. Also, there is significant price differential among providers for the same type of drugs, e.g., GPs vs. retail pharmacies vs private hospitals.

What are the major factors accounting for higher prices compared to the IRF?

- Patents
- Oligopolistic power
- High mark-up margins
- Too restrictive registration conditions, e.g., bioequivalence, clinical testing
- Other regulatory restrictions – please identify
- Discriminatory pricing
- Presence of medical insurance
- Available alternatives or competitors
- Distribution costs
- Tax
- Any others – please specify

(4) ADDITIONAL QUESTIONS

For manufacturers

- What is the nature of your manufacturing business – independent, contract (%)?
- How much do you export?
- Do you also have import and wholesale licences?
- Total number of employees
- How many products registered; to be registered?
- Percentage of products – prescription drugs, OTC drugs
- Your views on bioequivalence tests, registration process etc.
- Do you sell your products through distributors or directly to providers?
- Percentage of business with GPs, pharmacies, private hospitals, public hospitals
- Your views on the public procurement system
- What are the major challenges facing this industry for smaller manufacturers and how to address them?
- What suggestions for improvement in the industry?

For doctors and hospitals

- Explain how purchasing is done
- Who approaches you to sell medicines? Manufacturer, importers, distributors?
- If all, which categories most often?
- What bonus/discount do you get? Describe
- How aggressive are the marketers? MNCs vs. local generics
- Do you buy only for your own use or also wholesale?
- What percentage of the medicines you buy are generic, originator?
- What are your main considerations for drug purchase – efficacy, price, others (rank)?
- Who recommends what medicines to buy?
- Who has the final decision?
- Do you call for tender or quotation, or just buy?

APPENDIX 2: MALAYSIAN ORGANIZATION OF PHARMACEUTICAL INDUSTRIES (MOPI) MEMBERS

1. Ain Medicare Sdn Bhd
2. AJ Research & Pharma Sdn Bhd (Associate Member)
3. B. Braun Medical Industries Sdn Bhd
4. Biocon Sdn Bhd
5. CCM Pharmaceuticals Sdn Bhd
6. Chulia Pharma Sdn Bhd
7. Duopharma (M) Sdn Bhd
8. Dynapharm (M) Sdn Bhd
9. Fortune Laboratories Sdn. Bhd.
10. Goodscience Sdn Bhd
11. Herbal Revival Sdn Bhd
12. Herbal Science Sdn Bhd
13. The Himalaya Drug Company Pte. Ltd. (Associate Member)
14. HOE Pharmaceuticals Sdn Bhd
15. Hovid Bhd
16. Idaman Pharma Sdn Bhd
17. IDS Manufacturing Sdn Bhd
18. KCK Pharmaceutical Industries Sdn Bhd
19. Kotra Pharma (M) Sdn Bhd
20. Leung Kai Fook Medical Sdn Bhd
21. Lonnix (M) Sdn Bhd
22. Malaysian Pharmaceutical Industries
23. MRT Sdn Bhd
24. Natural Wellness Industries Sdn Bhd
25. Pahang Pharmacy Sdn Bhd
26. Pharmaniaga Manufacturing Berhad
27. Ranbaxy (M) Sdn Bhd
28. Royce Pharma Manufacturing Sdn Bhd
29. SG Global Biotech Sdn Bhd
30. SM Pharmaceuticals Sdn Bhd
31. Sunward Pharmaceutical Sdn Bhd
32. Symbiotica Speciality Ingredients Sdn Bhd
33. Teck Aun Medical Factory Sdn Bhd
34. Teraputics Sdn Bhd
35. Tiger Balm (M) Sdn Bhd
36. Unison Nutraceuticals Sdn Bhd
37. White Heron Pharmaceutical Sdn Bhd
38. Winwa Medical Sdn Bhd
39. Xepa-Soul Pattinson (M) Sdn Bhd
40. Yanling Natural Hygiene Sdn Bhd
41. Y.S.P. Industries (M) Sdn Bhd
42. Thunder Print Sdn. Bhd. (Associate Member)

APPENDIX 3: BRIEF PROFILES OF TOP 6 MALAYSIAN LOCAL/JOINT VENTURE PHARMACEUTICAL COMPANIES

	Pharmaniaga Manufacturing Bhd	Duopharma (M) Sdn Bhd (CCM Group)	Hovid Bhd
Ownership	Government-linked company (GLC)	Government-linked company (GLC)	Local
Parent Company	Pharmaniaga Bhd	CCM Bhd	Hovid Bhd
Brief History	Started 1994 as Remedi. Became Pharmaniaga in 1998. Boustead is major shareholder.	CCM was part of ICI, a British MNC. Management buyout of CCM in 1994. PNB acquired 52% of CCM in 2005. Became a GLC.	Started as herbal tea company. Branched into pharmaceutical manufacturing in 1980s.
Product Portfolio	> 430	> 700 generic drugs	> 400
Contract Manufacturing	Small percentage	N/A	N/A
Export Share of Revenue	> 25%	Target 40%	60% in 2012 to > 50 countries
Related Companies (i) Manufacture	• Idaman Pharmaniaga Manufacturing Sdn Bhd • Pharmaniaga LifeScience Sdn Bhd	Upha Pharmaceutical Manufacturing (M) Sdn Bhd	Hovid Bhd
(ii) Import	Pharmaniaga Logistics Sdn Bhd	CCM Pharmaceuticals Sdn Bhd	Hovid Bhd
(iii) Wholesale/ Distribution	Pharmaniaga Logistics Sdn Bhd	CCM Pharmaceuticals Sdn Bhd	Hovid Pharmacy Sdn Bhd
(iv) Retail		• Sentosa Pharmacy Sdn Bhd • Unique Pharmacy Sdn Bhd	Hovid Pharmacy Sdn Bhd
Business Strategy & Challenges	• Control 75% of public procurement • Moving towards export and JV with foreign cos. • Heavy investment in capital expenditure, R&D, upgrading warehouse and production plant	• Biggest OTC producer. • Moved into biosimilar. Bought 11% equity in PanGen Biotech, a Korean co., and teamed up with Biocon, Indian manufacturer in Malaysia	• Concentrate on export markets. Production plants in India, Vietnam. • First and only pharmaceutical manufacturer with bioequivalence studies laboratory • Emphasize R&D
Financials 2014/2015	In RM million	In RM million	In RM million
Revenue	206.3	176.9	188.4
Net Profit	54.3	35.0	18.7
Fixed Assets	59.5	112.6	132.2
Equity	116.3	130.6	183.7
Net Profit/Sales	26.3%	19.8%	9.9%

	Y.S.P. Industries (M) Sdn Bhd	Kotra Pharma (M) Sdn Bhd	Xepa-Soul Pattinson (Apex Group)
Ownership	Joint venture	Local	Joint venture
Parent Company	Y.S.P. Bhd	Kotra Industries Bhd	Apex Healthcare Bhd
Brief History	Started 1976 as pharmaceutical distributor. Branched into manufacture of medicines, veterinary medicines, herbal medicines (with Taiwanese).	Started 1982 as Chinese medicine shop. Moved into manufacture of generics in 1991.	Apex started in 1962 as retail pharmaceutical. Started Xepa in 1967 to manufacture pharmaceuticals. 1973 – Xepa joint venture with Soul-Pattinson of Australia.
Product Portfolio	> 350	> 200	> 100
Contract Manufacturing	< 5% upon request for local companies	< 3% mainly for Servier	3%
Export Share of Revenue	About 15%	45% (2016) Export to 35 countries	35% (2016) Export to about 16 countries
Related Companies (i) Manufacture	Y.S.P. Industries (M) Sdn Bhd	Kotra Pharma (M) Sdn Bhd	Xepa-Soul Pattinson
(ii) Import	Y.S.P. Industries (M) Sdn Bhd		Apex Pharmacy Marketing Sdn Bhd
(iii) Wholesale/ Distribution	Y.S.P. Industries (M) Sdn Bhd	Kotra Pharma (M) Sdn Bhd	Apex Pharmacy Marketing Sdn Bhd
(iv) Retail		Appeton Healthcare	Apex Retail Sdn Bhd
Business Strategy & Challenges	• Strong sales and marketing team, penetrate even rural areas • Also focus on export market. Set up JV manufacturing plant in Indonesia	• Built strong base in OTC then moved into generics. • Invested US$160 million in state-of-art plant • Growth strategy based on export markets	• Strong in both manufacturing and marketing cum distribution with 50:50 share in revenue. • Emphasize R&D (5% of revenue). • Aim to expand export market to > 50% of revenue
Financials 2014/2015	In RM million	In RM million	In RM million
Revenue	175.1	145.2	94.7
Net Profit	17.3	1.1	17.5
Fixed Assets	98.0	120.2	48.7
Equity	157.9	120.2	48.7
Net Profit/Sales	9.9%	0.7%	18.5%

APPENDIX 4: PHARMACEUTICAL ASSOCIATION OF MALAYSIA (PHAMA) MEMBERS

1. 1.A. Menarini Singapore Pte Ltd
2. Abbott Laboratories (M) Sdn Bhd (Pharmaceuticals)
3. Abbvie Sdn Bhd
4. Allergan Malaysia Sdn Bhd
5. Antah Pharma Sdn Bhd
6. Aspen Medical Products Malaysia Sdn Bhd
7. AstraZeneca Sdn Bhd
8. Balxata Malaysia Sdn Bhd (now part of Shire)
9. Bayer Co. (M) Sdn Bhd
10. Boehringer Ingelheim (Malaysia) Sdn Bhd
11. Delfi Marketing Sdn Bhd
12. DKSH Malaysia Sdn Bhd
13. Eisai (M) Sdn Bhd
14. Eli Lilly (M) Sdn Bhd
15. EP Plus Group Sdn Bhd
16. Ferring Sdn Bhd
17. Geliga Sistem Sdn Bhd
18. GlaxoSmithKline Consumer Healthcare S/B
19. GlaxoSmithKline Pharmaceutical S/B
20. IMS Health (M) Sdn Bhd
21. Inova Pharmaceuticals (S) Pte Ltd (A Valeant Company)
22. Johnson & Johnson Sdn Bhd
23. LF Asia (Malaysia) Sdn Bhd
24. LNS Integration Sdn Bhd
25. Lundbeck Malaysia
26. Meda Healthcare Sdn Bhd
27. Merck Sdn Bhd
28. Merck Sharp & Dohme (M) Sdn Bhd
29. MIMS MEDICA Sdn Bhd
30. Mundipharma Pharmaceuticals Sdn Bhd
31. Novartis Corporation (M) S/B
32. Novo Nordisk Pharma (M) S/B
33. Pfizer (M) Sdn Bhd
34. Primabumi Sdn Bhd
35. Reckitt Benckiser (M) Sdn Bhd
36. Roche (Malaysia) Sdn Bhd
37. Sanofi Aventis (M) Sdn Bhd
38. Servier (M) Sdn Bhd
39. Summit Co (M) Sdn Bhd
40. Sun Pharmaceutical (M) S/B
41. Takeda Malaysia Sdn Bhd
42. Zuellig Pharma Sdn Bhd

APPENDIX 5: MALAYSIAN ASSOCIATION OF PHARMACEUTICAL SUPPLIERS (MAPS) MEMBERS

ORDINARY MEMBERS

1. Accord Healthcare Sdn Bhd
2. Apex Pharmacy Marketing Sdn Bhd
3. Averroes Pharmaceuticals Sdn Bhd
4. BioCare Pharmaceutical (M) Sdn Bhd
5. Cipla Malaysia Sdn Bhd
6. Evertrade Sdn Bhd
7. First Pharmaceutical
8. Germax Sdn Bhd
9. Glenmark Pharmaceuticals (M) Sdn Bhd
10. Healol Pharmaceuticals Sdn Bhd
11. Hyphens Pharma Sdn Bhd
12. IMEKS Pharma Sdn Bhd
13. Jetpharma Sdn Bhd
14. Komedic Sdn Bhd
15. Medispec (M) Sdn Bhd
16. Mepharm (Malaysia) Sdn Bhd
17. Nano Medic Care Sdn Bhd
18. Parvus Sdn Bhd
19. Pharmaforte (Malaysia) Sdn Bhd
20. Pharm-D Sdn Bhd
21. Propharm (M) Sdn Bhd
22. Rigel Pharma Sdn Bhd
23. Sandoz Division, Novartis Corp (M) Sdn Bhd
24. Schmidt Biomedtech Sdn Bhd
25. Somedico Sdn Bhd
26. Stadpharm Sdn Bhd
27. Syarikat Wellchem Sdn Bhd
28. The Zyfas Pharma Sdn Bhd
29. Unimed Sdn Bhd
30. Zulat Pharmacy Sdn Bhd

ASSOCIATE MEMBER

1. Choe Tong Seng

APPENDIX 6: DRUG REGISTRATION PROCESS[398]

The table below sets out key requirements for the registration of pharmaceutical products containing scheduled poisons in immediate release, oral and solid dosage form.

No.	Requirement	Date of Coming into Force
1	Patient dispensing pack size for pharmaceutical product with tablet/capsule dosage form, including oral liquid preparation and dermatological preparation[399]	2008
2	Bioequivalence study report for all generic products containing scheduled poison with immediate release, oral, solid dosage form (for the renewal of registered products, the effective date is on 1 January 2013)[400]	1 January 2012
3	Valid GMP document/certificate (and for imported product[401] 1 January 2014)	2012
4	Long-term stability study report under the Zone IVb conditions (30°C ± 2°C / 75% RH ± 5% RH) for pharmaceutical products containing scheduled poison and non-scheduled poison (but excluding cold chain product) which were submitted for registration before the year 2009, unless exempted by the Authority	1 January 2016
5	Regulatory control of active pharmaceutical ingredient for all dosage forms of registered pharmaceutical products containing scheduled poison	Comes into force for product registration which is expiring starting from 1 January 2020

Source: NPRA

In addition, manufacturers, importers and wholesalers are required to comply with the principles of Good Distribution Practice. Applications are done online via the QUEST system.[402]

[398] For full details, please refer to the Drug Registration Guidance Document, 2nd Edition, September 2016, revised March 2017: http://npra.moh.gov.my/images/Guidelines_Central/guideline-DRGD/Complete_DRGD_with_appendices_MARCH_2017.pdf

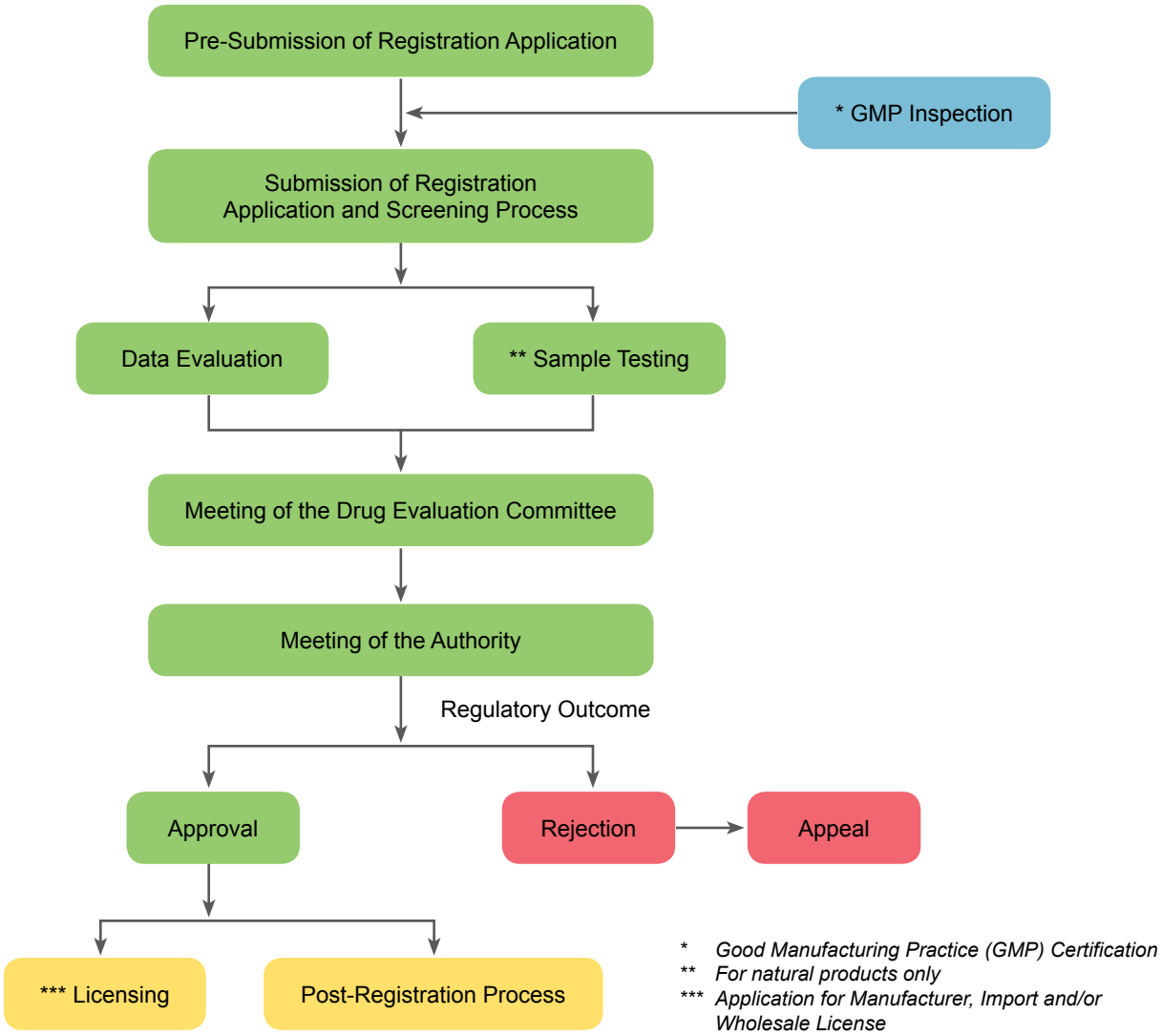
[399] See Appendix 10: Guideline on Patient Dispensing Pack for Pharmaceutical Products in Malaysia, page 535, Drug Registration Guidance Document, 2nd Edition, September 2016, revised March 2017: http://npra.moh.gov.my/images/Guidelines_Central/guideline-DRGD/Complete_DRGD_with_appendices_MARCH_2017.pdf

[400] Directive Arahan di Bawah Peraturan 29, Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 Bil. 1 Tahun 2011, 2 March 2011 Bil (10) dlm BPFK/PPP/01/03 Jld 1.

[401] All manufacturers, whether local or foreign, must meet GMP-certification requirements for their products to be registrable in Malaysia.

[402] http://npra.moh.gov.my/q3plus/index.php

The figure below shows a simple flow chart of the registration process.[403]



Source: NPRA

[403] Drug Registration Guidance Document, 2nd Edition, September 2016, revised March 2017, at page 34: http://npra.moh.gov.my/images/Guidelines_Central/guideline-DRGD/Complete_DRGD_with_appendices_MARCH_2017.pdf

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