PHARMACEUTICAL
PRODUCTIVITY NEXUS

UNDERSTANDING MALAYSIA'S PHARMACEUTICAL LANDSCAPE

Prepared by

PHARMACEUTICAL PRODUCTIVITY NEXUS
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FOREWORD

The pharmaceutical manufacturing sector plays a crucial role in Malaysia's economic and healthcare landscape, contributing significantly to national health security and industrial growth. As the Director General of the Malaysia Productivity Corporation (MPC), I emphasize the importance of driving productivity improvements to enhance the efficiency, competitiveness, and sustainability of pharmaceutical industry in Malaysia.

This Industry report provides a strategic landscape of the pharmaceutical sector, highlighting key productivity challenges and opportunities. To position Malaysia as a leading pharmaceutical hub, we must focus on strengthening production capabilities, improving regulatory efficiency, and accelerating digital adoption. Streamlining operational processes and fostering innovation in pharmaceutical are essential steps toward reducing production costs, enhancing quality standards, and meeting global market demands.

MPC remains committed to supporting industry players through initiatives aimed at enhancing productivity, optimising supply chains, and facilitating industry-wide digital transformation. By leveraging automation, Industry 4.0 technologies, and workforce upskilling, Malaysia's pharmaceutical manufacturers can achieve greater efficiency and long-term competitiveness in the global pharmaceutical landscape.

I extend my sincere appreciation to all contributors who have made this report possible. This collective effort underscores our commitment to fostering a high-performing pharmaceutical manufacturing sector that will drive economic growth and improve healthcare access for all Malaysians.

MR. CH'NG KIEN PENG

Champion
Pharmaceutical Productivity Nexus

President
Malaysian Organisation of
Pharmaceutical Industries

FOREWORD

It is truly rewarding to witness the successful completion of this Industry report, which represents a significant milestone in our efforts to strengthen Malaysia's pharmaceutical sector. As the Champion of the Pharmaceutical Productivity Nexus (PPN), I recognize the importance of addressing the challenges that have long affected the industry's growth and competitiveness.

The Pharmaceutical Productivity Nexus (PPN) was established to provide a platform for deliberation and collaboration among industry players, regulators, and stakeholders. Over time, we have identified key bottlenecks, particularly in regulatory complexities, investment attraction, and innovation adoption, that have hindered the sector's full potential.

This report serves as a valuable reference in bridging the gaps and aligning efforts toward sustainable growth. By streamlining regulatory processes, encouraging technological advancements, and fostering local pharmaceutical manufacturing, we can build a more robust and globally competitive industry. The insights gathered in this report will guide us in implementing effective strategies that will ultimately benefit both businesses and consumers.

A tremendous amount of effort has gone into making this report a reality, and I extend my deepest gratitude to all contributors—government agencies, pharmaceutical associations, research institutions, and the MPC team—for their unwavering dedication. The journey towards industry transformation continues, and I look forward to working together to achieve new milestones for Malaysia's pharmaceutical sector.

THE BACKGROUND OF
MALAYSIA'S PHARMACEUTICAL INDUSTRY

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1.1 Global Scenario

As the world economy slowly recovers from the detrimental effects of Covid-19 pandemic, all major industries across the globe are finding their way back to their pre-Covid-19 status. The pharmaceutical industry is one of the robust industries that has continued its growth momentum both before and after the Covid-19 pandemic. This sector is a multi-billion dollar industry with global sales estimated to be more than USD 1 trillion since 2018. Many areas of the pharmaceutical industry experienced rapid growth during 2020 and 2021 due to Covid-driven demand for vaccines and the need for personal protective equipment. With global inflation weakening consumer purchasing power, expenditure on healthcare is expected to impact personal hygiene and over-the-counter (OTC) medicines.

In terms of the market, the pharmaceutical industry was estimated to be worth more than USD 1.5 trillion by 2023 and is expected to grow stronger due to the high demand for healthcare, population growth, and the increasing number of elderly people. By 2032, the pharmaceutical market is projected to reach USD 2.8 trillion. In term of market share, North America is expected to remain the market leader with 45.33% of the global pharmaceutical market followed by the Asia-Pacific region with 24.07% and Europe with 20.24%. These three (3) regions are the main "battlefield" for top pharmaceutical companies to lead both product research and development and product supply. Among the three (3) regions, the Asia-Pacific region is projected to have the fastest-growing compound annual growth rate (CAGR) of more than 7% in pharmaceutical market for 2023 to 2032. The global key players in the pharmaceutical industry are giant corporations such as Pfizer Inc., Takeda Pharmaceutical Company Limited, Bayer AG, Merck and Co Inc., GlaxoSmithKline Inc., Novartis International Inc., Johnson and Johnson Inc., Astellas Pharma Inc., Sanofi SA., Aspen Holding and Catalent Inc. Some of these companies operate in Malaysia as manufacturers, importers or distributors.

Figure 1: Global Pharmaceutical Market 2023 (Navadhi Market Research [1])

NORTH AMERICA
North America (Canada & USA) is expected to retain its leadership position in global pharmaceutical market with 45.33% of global market share in 2023

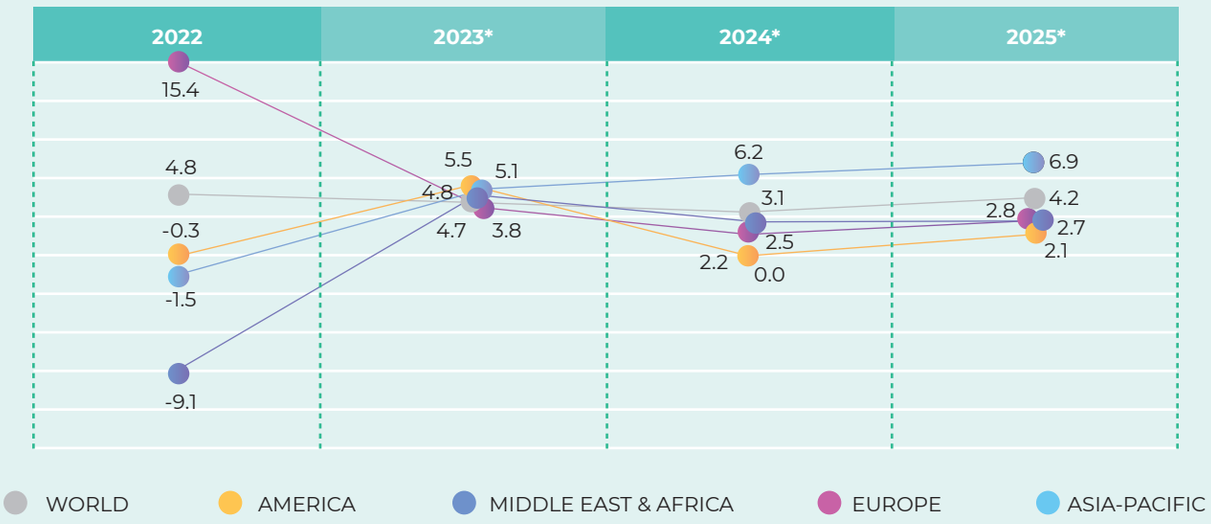
LATIN AMERICA
Latin America pharmaceutical market is expected to have 7.53% of global market share in 2023

MIDDLE EAST & AFRICA
Middle East & Africa pharmaceutical market is expected to have 2.96% of global market share in 2023

EUROPE
Europe pharmaceutical market will see a decline in its market share in 2023 which is expected to be 20.24% of global market share.

ASIA-PACIFIC
Asia-Pacific pharmaceutical market will retain its second position with 24.07% of global market share in 2023.

FIgure 2: Pharmaceutical Output Growth by Region [2]



The robust growth of the pharmaceutical market in recent years has been driven by various factors. One significant contributor to this growth is the increasing prevalence of chronic diseases as well as the aging global population. Longer life expectancy creates a higher demand for medication to treat conditions such as diabetes, cardiovascular disease, cancer and other chronic illnesses. In tandem with advances in technology, demand stemming from global health issues drives the development of innovative drugs and therapies, further expanding the pharmaceutical industry.

For the pharmaceutical market by prescription type, the over-the-counter (OTC) products segment is expected to show significant growth in the coming years compared to prescription drugs. The projection is driven by an increased inclination towards self-care and the empowerment of consumers in health management. Without the need for a prescription, the OTC products offer the convenience of addressing common ailments and health concerns independently. This ease of access has become a key factor in growing the sales of OTC products.

While the growth of the global pharmaceutical industry is expected to be fluctuating, the Asia-Pacific region is predicted to experience significant growth over the next three (3) years, rising from just over 5% in 2023 to 6.9% in 2025. The growth will be propelled by improvements in the healthcare system and the expansion of household income. Producers of generic medicines and over-the-counter medicines are likely to benefit from this growth.

1.2 Innovator Medicine

Innovator drugs refer to new drugs that are developed and released to the market by the original pharmaceutical company. These drugs represent a novel therapeutic approach or treatment and are patented, giving the company exclusive rights to market and sell them for 20 years. Innovator drugs are usually the result of significant research and development efforts and may be the first of their kind or provide a significant advancement over existing treatments. Once the patent expires, other companies can create generic versions of the drug, which are sold at lower prices. Innovator drugs can significantly impact public health by offering new treatment options, particularly for complex or rare diseases. Typically, innovator drug development involves huge R&D costs and a lengthy approval process before they can be marketed. The price of an innovator drug may be very high because there is no competition during the period of patent protection. Malaysia is a consumer of innovator drugs and is highly dependent on imported innovative medicines.

1.3 Generic Medicine

The generic drug industry plays an important role in providing affordable medicine for day-to-day healthcare needs. The rise in healthcare costs continues to challenge the sustainability of the national healthcare system. The Ministry of Health Malaysia (MOH) and healthcare industry players are always searching for options to supply affordable medicines to both government and private healthcare service providers. It is imperative that medicines remain affordable to ensure their accessibility for people across all income categories. The existence of high-quality generic medicines alongside innovator medicines is key to the country's progressive healthcare system. A generic drug refers to a type of chemically-derived drug produced after the patent protection on the original drug has expired. It contains the same active ingredients as the original branded drug and has equivalence in terms of dosage, quality, performance, characteristics, therapeutic effect and safety profile. The manufacturer of the generic drug must demonstrate the generic drug is bioequivalent to the original meaning the substance behaves the same way in the body as the original drug.

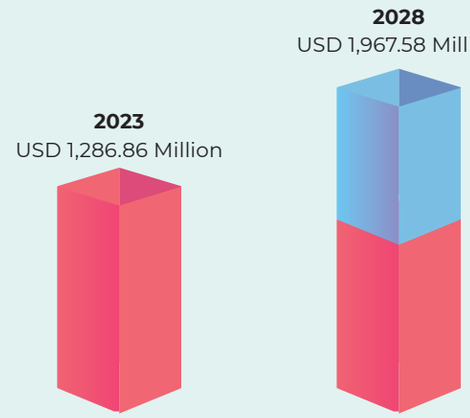
In Malaysia, the generic drug segment holds a significant market share in terms of volume and is expected to undergo significant growth due to the higher number of patent expirations of many well-known drugs. Patent expirations will drive generic pharmaceutical companies to produce and sell the drugs at lower prices, providing a more affordable option for patients and the healthcare system. The increased accessibility of generic drugs will lead to the expansion of the generic drug market. Furthermore, expenditure control by the government and healthcare providers is also a driving factor, making generic drugs the best choice for medical treatment and sustaining affordable medical services for society.

The Malaysian generic drug market is forecasted to achieve USD 1.97 Billion in year 2028 compared to USD 1.286 Billion in year 2023 with a CAGR of 7.3%. This implies positive growth for the industry which is driven by local and export demands.

Market forecast to grow at a CAGR of in year

2028

Figure 3: Forecast of Malaysia's Generic Metric to 2028 [3]



1.4 Biologics and Biosimilar

Biologics are a class of drugs consisting of large and complex heterogeneous molecules derived from living organisms using biotechnology methods involving cells or proteins, such as vaccines, insulin, growth hormones, monoclonal antibodies, blood factors, interferons and cytokines. Biologics are used to treat a wide range of diseases and conditions such as cancer, autoimmune diseases, infectious diseases and chronic illnesses.

Despite their important application, the high treatment cost of biologic has become a concern for healthcare budgets worldwide. Currently, Malaysia imports most biologics products to support healthcare service needs. Global supply chains disruptions can pose a serious threat to the national healthcare system. Therefore, there is a need for Malaysia to explore the potential of developing biologics manufacturing capabilities locally to combat the possible shortages in global biologics supply. However, the high R&D costs, significant capital requirements and the need for niche technical expertise have remained a barrier to making progress in this area.

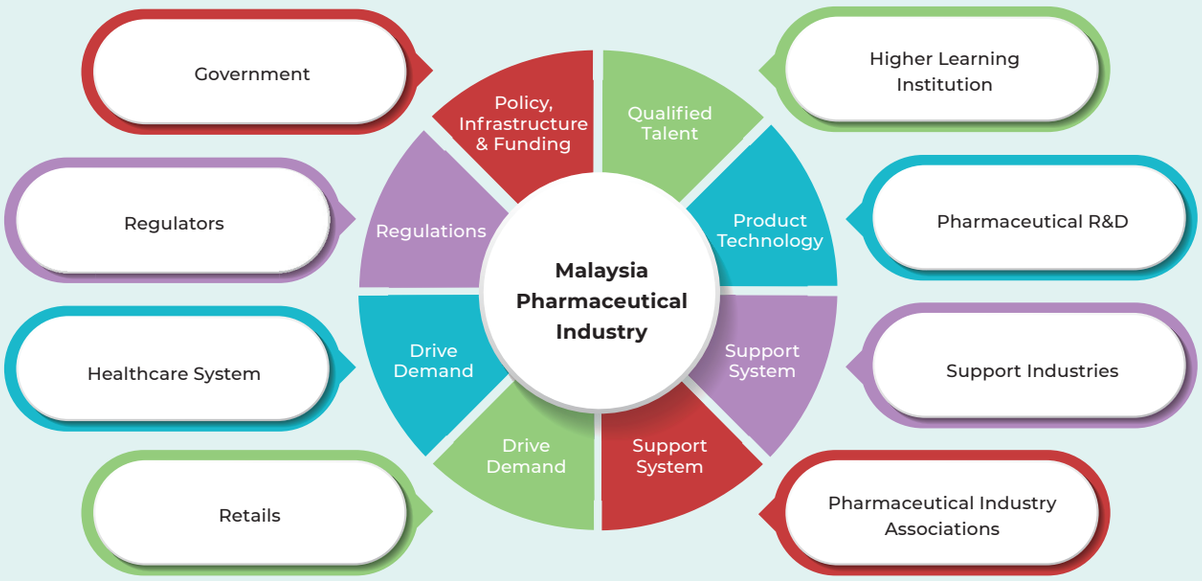
As the patent of innovator biologics has begun to expire, the development of follow-on biologics, called biosimilars, has grown to provide cost-saving alternatives to their respective reference products. In Malaysia, a biosimilar is defined as a new biologic product developed to be highly similar to the reference product, with no clinically meaningful difference in purity, safety or efficacy. Unlike generic medicines, a biosimilar is not identical to its reference product and cannot be regarded as a generic equivalent to the reference product due to its large and complex molecular structure (Ministry of Health Malaysia, 2022). In Malaysia, the biosimilar industry has been growing steadily. The increasing demand for cost-effective alternatives to expensive biologics is driving the growth of biosimilars. The rising prevalence of chronic diseases such as diabetes and cancer boosts the demand for biosimilars in Malaysia. Among the leading biosimilar manufacturers are Biocon Sdn Bhd, Pharmaniaga Berhad, and Duopharma Biotech Berhad.

1.5 Malaysia Pharmaceutical Sector Ecosystem Overview

The demand for healthcare continues to rise in Malaysia with increasing affluence and rising consumer awareness. The pharmaceutical industry is considered the backbone of the healthcare industry and requires a strong foundation to sustain an adequate supply of medicine for healthcare services. Malaysia continues to be committed to providing high-quality healthcare services for the country. Malaysia's Total Expenditure on Health (TEH) increased significantly from 3.9% of GDP in 2011 to 5.0% in 2021, with nominal health expenditure reaching RM78.95 billion and per capita expenditure amounting to RM2,414 (Ministry of Health Malaysia, 2023). Since the era of privatisation in the 1980's, Malaysia has maintained a dual healthcare system where the private healthcare sector co-exists with the public healthcare sector at the primary (rural and community clinics), secondary (general hospitals) and tertiary (hospitals with specialists) levels. The healthcare industry landscape has transformed the pharmaceutical sector to become more competitive and opened up opportunities for more innovative business models to cope with the demand and remain resilient in the challenging global economy. Economies of scale in Malaysia have driven the local pharmaceutical players to explore the global market to sustain growth and operations.

The pharmaceutical industry ecosystem in Malaysia encompasses a network of organisations involved in the delivery of pharmaceutical products through either competition or cooperation. The elements within the ecosystem include regulators, products, regulatory compliance, the market as well as the interconnected network of parties in the supply and demand of pharmaceutical products. Industry players must be knowledgeable and alert to the requirements necessary to operate a pharmaceutical business in the country. Whether as a manufacturer or distributor, there are typically eight (8) main elements in the pharmaceutical industry business ecosystem, as shown in Figure 4. The ripple effect of government commitment will pave the way for a strong business ecosystem for the pharmaceutical industry. In the New Industrial Master Plan 2030 (NIMP 2030), the government has included the pharmaceutical sector as a crucial sector to boost the national economy. By 2030, the government expects the gross domestic product (GDP) value of the pharmaceutical sector to reach RM2.5 billion. Specifically, NIMP 2030 identifies biologics, Active Pharmaceutical Ingredient (API), manufacturing of niche botanicals, and halal medicines as the key growth segment.

Figure 4: Ecosystem of Pharmaceutical Sector in Malaysia



1.6 Pharmaceutical Industry Associations in Malaysia

Pharmaceutical associations in Malaysia play an important role in promoting the interests and growth of the industry. As the backbone of the healthcare industry, the pharmaceutical sector in Malaysia is responsible for creating, manufacturing, and promoting drugs for various types of prevention, treatment, and therapy in healthcare. The supporting role from pharmaceutical associations complements the support system required by the industry to start, operate and grow in Malaysia.

Besides anchoring the demand for medicines in the country, the pharmaceutical sector is expected to propel socio-economic growth in Malaysia over the next 15 years along with the private healthcare sector. Pharmaceutical multinational companies are expected to contribute 2.3 billion USD to the national Gross Domestic Product (GDP) in 2024 and contribute more than 100 million USD of foreign direct investment along with annual investment in training and educational events for medical and pharmaceutical professionals. The existence of industry associations will indirectly strengthen this effort. There are four (4) main associations in the Malaysia's pharmaceutical industry namely the Malaysian Organisation of Pharmaceutical Industries (MOPI), Pharmaceutical Association of Malaysia (PhAMA), Malaysian Association of Pharmaceutical Suppliers (MAPS) and Malaysian Dietary Supplement Association (MADSA). Each association represents a different group of industry players within the local pharmaceutical industry.

Malaysian Organisation of Pharmaceutical Industry (MOPI)

The Malaysian Organisation of Pharmaceutical Industries (MOPI) was incorporated on 6 March 1981 with a diverse group of members consisting of local pharmaceutical manufacturers, API manufacturers, trading companies, packaging and printing companies. MOPI's membership has grown to 51 members as of the fourth quarter of 2024. MOPI members have also ventured into the high-tech industry and supply almost half of the prescription drugs in Malaysia. The members are also capable of producing a wide range of pharmaceutical products and providing training on Good Manufacturing Practice (GMP) and regulatory compliance to industry workers. MOPI plays an important role as an intermediary between the industry and policymakers.

Pharmaceutical Association of Malaysia (PhAMA)

PhAMA represents 41 of the largest names in pharmaceutical companies. Within that scope, its professional collective includes individuals from regulatory, research and development (R&D), medical expertise, finance, information technology, human resources, legal and compliance, as well as logistics and ethical marketing. More importantly, PhAMA brings together invaluable experience in coordinating with global and local authorities. With 50 years of service, PhAMA leads with a focus on industry support, strategic partnerships, advocacy, and capacity building to drive access to innovative medicines for Malaysia. The members consist of firms or companies engaged in pharmaceuticals as manufacturers, agents or representatives of distributors in Malaysia.

Malaysian Association of Pharmaceutical Suppliers (MAPS)

MAPS was formally registered with the Registrar of Societies on 17 November 2011. It was established to serve as a trade representative in the pharmaceutical industry. MAPS engages with the relevant government bodies such as the Pharmaceutical Services Programme (MOH), National Pharmaceutical Regulatory Agency (NPRA), Malaysia Competition Commission (MyCC), and other relevant bodies on issues related to the pharmaceutical trade, acting at the forefront of issues facing the industry. Members of MAPS are Malaysian companies that import pharmaceuticals into the country. They represent principals from Europe, North America, Asia, Oceania, and other regions. These principals may be R&D or generic manufacturers from these regions. As an association, MAPS is committed to building the industry in collaboration with the respective government authorities and the industry stakeholders. The country needs to have an industry that is conducive to attracting investments, supported by an ecosystem that promotes fairness, health, vibrancy, dynamism, accessibility, and affordable healthcare for Malaysians.

1.7 Pharmaceutical Products in Malaysia

In general, pharmaceutical products are a subset of healthcare products, which refer to goods or services concerned with human health. In technical terms, the World Health Organization (WHO) defines a healthcare product as "The result of the interaction of capital, labor and entrepreneurship in the production process which has the primary purpose of improving, maintaining or preventing the deterioration of health status or mitigating the consequences of ill-health". In the pharmaceutical industry, the discussion is narrowed down to healthcare products in the form of goods. Within this context, the Control of Drugs and Cosmetic Regulation (CDCR) 1984 defines product with: a) 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; and b) A drug to be used as an ingredient of a preparation for medicinal purpose.

The term "drug" technically means any substance, product or article intended to be used or capable of being used, or purported or claimed to be capable of being used, on humans or animals, whether internally or externally for a medicinal purpose as stipulated in Section 2 of the Sales of Drug Act 1952 (Sales of Drugs Act 1952 (Revised 1989)). In this context, "medicinal purpose" includes: a) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease; b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition; c) contraception; d) inducing anesthesia; e) maintaining, modifying, preventing, restoring, or interfering with the normal operation of a physiological function; f) controlling body weight; and g) general maintenance or promotion of health or well-being.

In Malaysia, the National Pharmaceutical Regulatory Agency (NPRA) has classified all drugs available in the market into six (6) categories, as outlined in its Drug Registration Guidance Documents (National Pharmaceutical Regulatory Authority), as summarised below:

- New Drug Products (NDP) – Any products that have not been previously registered in accordance with the provisions of the Control of Drugs and Cosmetic Regulation (CDCR) 1984.
- Generics (scheduled poisons and over-the counter) – A product essentially similar to a currently registered product in Malaysia.
- Biologics – Any pharmaceutical products made with active substances derived from living organisms such as plants, humans, animals and microorganisms. Every biologic is regulated as a new product and is considered high risk. The drug substance and drug product production must comply with Good Manufacturing Practice (GMP).
- Health Supplements – Any products used to supplement a diet and to maintain, enhance, and improve the health function of human body.
- Natural Products – Includes traditional medicines, herbal products, homeopathic medicines and natural products with therapeutic claims.
- Veterinary Products – Drugs used for animals.

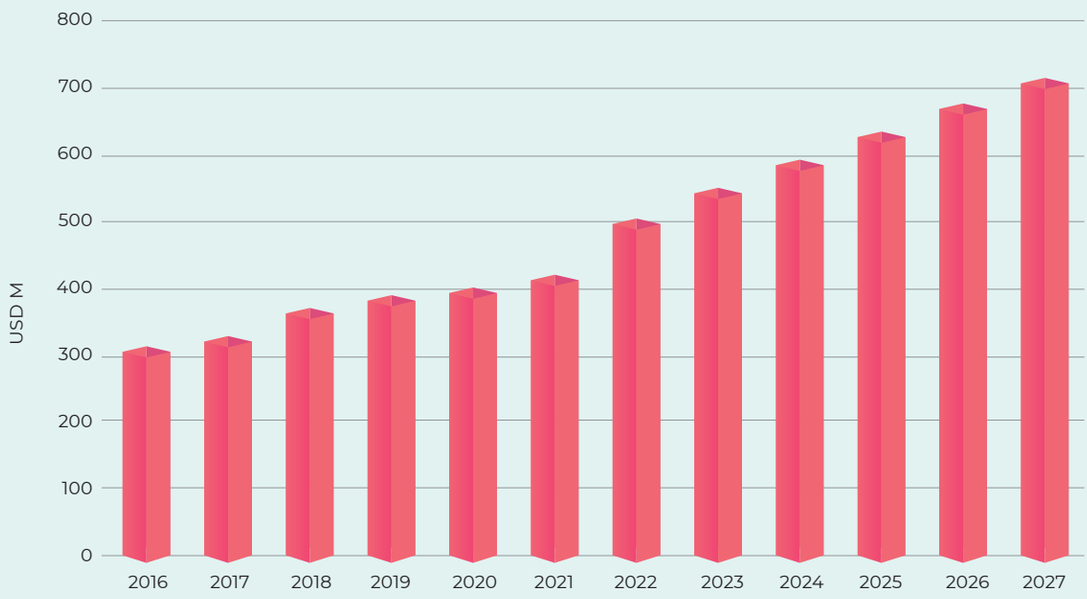
In the market, there are four (4) typical regulated pharmaceutical products manufactured by Malaysian pharmaceutical industry:

1) Over-The-Counter (OTC) Non-Poison Products: These are also called "non-prescription" products which can be purchased at most retail outlets without needing a prescription from registered medical practitioner. OTC products are generally safe and effective if consumed according to the manufacturer's recommendations. However, like any other medicine, there can also be side effects. There are two (2) categories of OTC products. Category A products refer to non-schedule poisons

which contain ingredients that are not listed in the First Schedule under the Poison Act 1952 (Act 366). Category B products refer to healthcare products such as vitamins, health supplements, natural products and non-prescription cosmetics. Examples include Vitamin C, multivitamins and minerals, Tongkat Ali, moisturizing cream, etc.

The OTC pharmaceutical market in Malaysia is forecasted to grow at a Compound Annual Growth Rate (CAGR) 6% to an estimated USD 715 million (approximately RM 3.2 billion) by 2027 (Kenanga Research, 2024) as consumers take a more proactive stance on their health and well-being, especially in the aftermath of the COVID-19 pandemic.

Figure 5: Forecast of OTC Market Value in Malaysia by 2027 (Kenanga Research [8])



2) Prescription Medicines (Ethical Products): Prescription medicines refer to the type of medicine that can only be made available to a patient on written instruction from registered medical practitioners due to their potential risks, need for safe administration, and potential for misuse. These medicines can only be purchased from licensed pharmacies, clinics, and hospitals with a prescription issued by a registered medical doctor. They are considered safe and effective when it is consumed according to the recommendation of the medical doctor, in tandem with the patient information leaflet, or under the guidance of a registered pharmacist. Generally, prescription medicines can be classified as innovator/original drugs and generic drugs. An original drug refers to a novel and inventive drug discovered for use as a new treatment for a disease. These drugs receive patent protection for 20 years from the date of filing the application in Intellectual Property Corporation of Malaysia (MyIPO). A generic enters the market after the patent expires (off-patent drug), offering an affordable price option for patients.

3) Traditional Medicines Product: WHO defines traditional medicines as "The sum total of knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness". Traditional medicine has a long history and is highly influenced by ancient practices, culture, norms, and religious beliefs. Generally, a traditional medicine product refers to the use of herbs as treatment for medicinal purposes. Under the Control of Drugs and Cosmetics Regulations 1984, a traditional product is defined as "Any product used in the practice of indigenous medicine in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude exact form, and a homeopathic medicine" (The Control of Drug and Cosmetics Regulation 1984). In Malaysia, traditional medicine products in the market comprise of Chinese traditional medicines, Malay traditional medicine, Western traditional medicines, Indian traditional medicine (Ayurverdic, Unani and Siddha) and homeopathic products. Nowadays, herbal products are available in tablets, capsules, syrup, cream, and plaster.

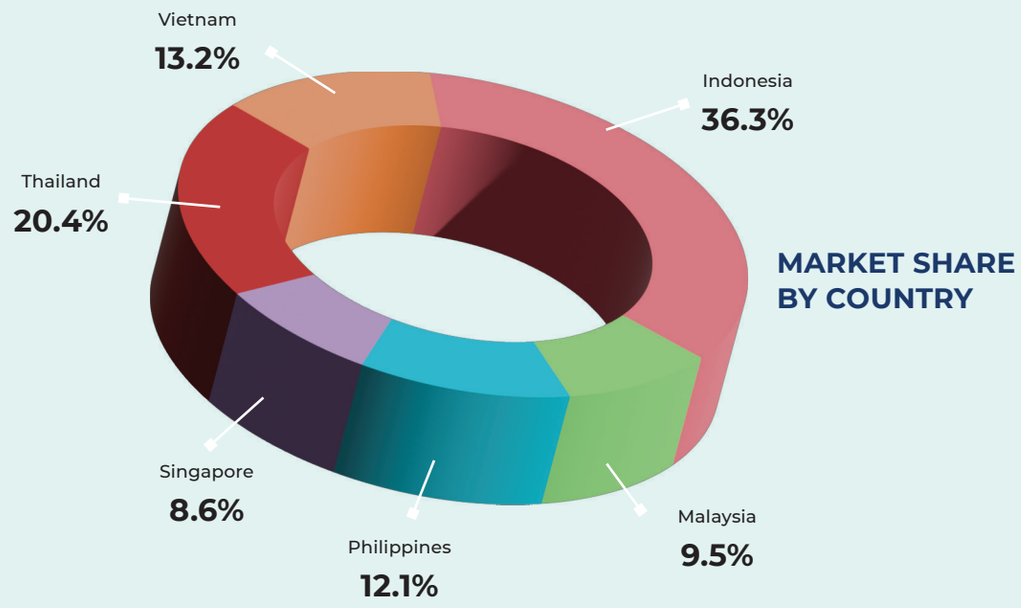
NPRA, as the secretariat of the Drug Control Authority (DCA), is responsible for ensuring safety and quality through the registration of traditional products. Traditional products from herbs can be contaminated with bacteria and fungi. Therefore, lab testing is performed to confirm that the heavy metal content does not exceed the allowable limit and to ensure the traditional products are not contaminated with pathogenic microorganisms or adulterated with scheduled poisons. Heavy metals, including arsenic, mercury, lead and cadmium, can cause serious health issues in humans, including cancer, and may affect the function of organs such as kidneys, lungs, nervous system, and cardiovascular system. Certified traditional medicines in Malaysia are issued a MAL number and a hologram logo.

4) Health Supplement: A health supplement refers to any products used to supplement the diet and to maintain, enhance and improve the health function of the human body. The product is consumed in small dosage forms such as capsules, powder, tablets and liquid. According to NPRA, a health supplement may contain one or more of the following ingredients:

- Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances;
- Substances derived from natural sources including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates and metabolites; and
- Synthetic sources of ingredients mentioned in above may only be used where the safety of these ingredients has been proven.

Since 1998, all health supplements sold in Malaysia have been required to be registered and approved by MOH, subject to renewal every five (5) years. In an effort to ensure safety and quality, the Control of Drugs and Cosmetics Regulation 1984 and the Drug Registration Guidance Document (DRGD) by NPRA stipulate that all health supplements in the Malaysian market are subject to post-marketing random sampling from time to time during the 5-year registration period. Every health supplement registered with the MOH will be issued a registration number (MAL) with an eight-digit number ending with the letter 'N' (code referring to a supplement). The second feature is the hologram sticker on the packaging. Health supplements may include vitamins and minerals, herbal supplements, Omega-3 fatty acids, probiotics, protein powders, antioxidants, weight management supplements, joint and bone health supplements, energy and immune boosters, as well as beauty supplements.

Figure 6: Market Research of Health Supplement Market in 6 Asian Countries [10]



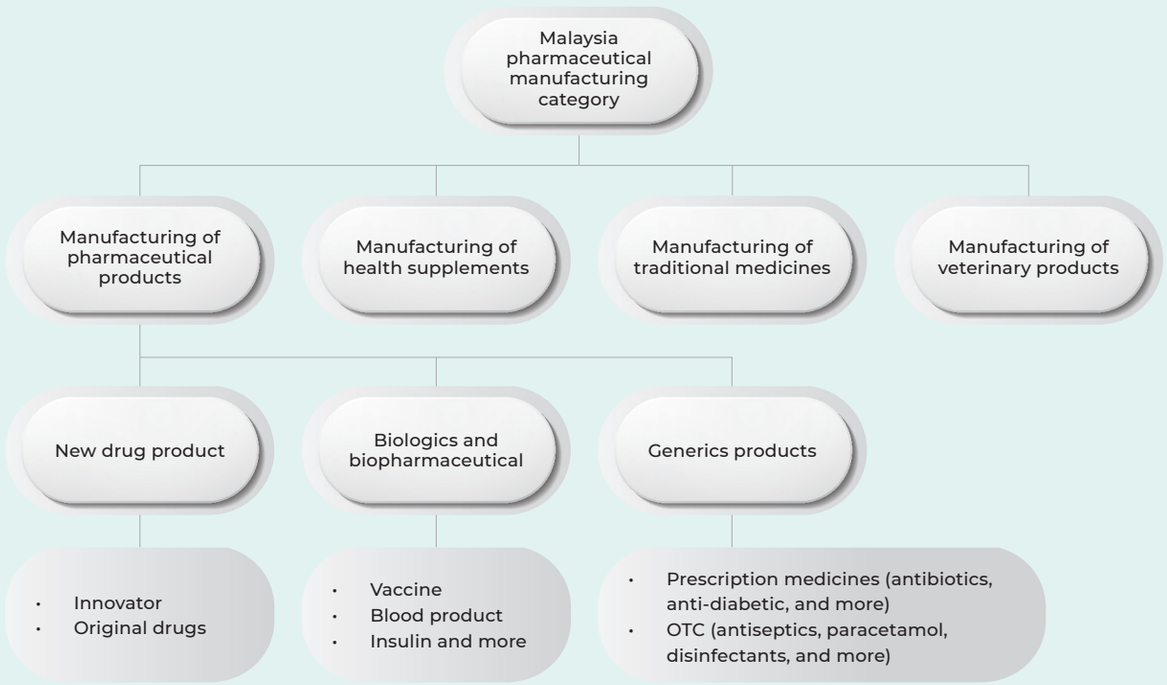
Health Supplement E-commerce Market Research by the TMO group highlighted that Malaysia holds a 9.5% market share out of six (6) Southeast Asian countries, with the largest market being Indonesia (36.3%), followed by Thailand, Vietnam, the Philippines and Singapore. The research also indicated that the highest number of products in the market are nutrition supplements and beauty supplements, followed by general health supplements, herbal and specialty supplements. In Malaysia and the other five (5) Southeast Asian countries, diet and weight loss supplement holds the biggest market share.

1.8 Pharmaceutical Manufacturing Sector in Malaysia

Malaysia pharmaceutical manufacturing industry consists of four (4) major subsectors, which manufacture four (4) types of medicinal products including pharmaceutical products, health supplements, traditional medicines and veterinary products. Pharmaceutical products comprise of New Drug Products (NDP), biologics generics, and biosimilars. New Drug Products are also known as innovator drugs, originator drugs or branded drugs, which are usually manufactured by large pharmaceutical corporations and are first authorized for marketing as patented products. A patent gives the inventor the right to a limited period of time to stop others from making, using, or selling the invention without permission. Generic products refer to products that contain the same ingredients as the original products and behave similarly to the original product in terms of safety, quality and efficacy. These typically originate from the originator products, whose patent have already expired after a 20 year period. In Malaysia, most of the manufacturers specialize in generic products.

Malaysia manufacturers are also gearing up towards manufacturing biologics and biopharmaceutical products, such as vaccines, blood products, and insulin. The Malaysian Vaccine Development Roadmap empowers this initiative and is expected to build local vaccine manufacturing capability and develop vaccine infrastructure by the year 2030. As a multicultural society, Malaysia is rich in cultural practices, which lead to demand for traditional medicines. The manufacturing of traditional medicines in Malaysia is mainly dominated by small and medium enterprises operating on a small to medium scale of manufacturing. Economics of scale require manufacturers in Malaysia to focus on export in order to upgrade to large-scale manufacturing.

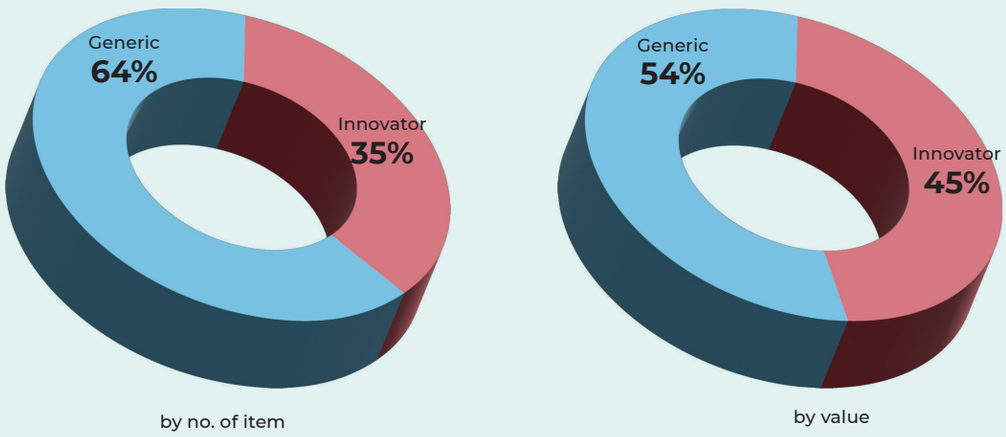
Figure 7: Malaysia Pharmaceutical Manufacturing Categories and Products



1.9 Consumption Trends and Market Projections for Generic and Innovator Medicines

Based on the data of medicine procurement by MOH, it is evident that Malaysia's market is dominated by generic drugs and imported medicines, where 64% of the total unit of medicine are generic drugs and the remaining 36% are innovator drugs. In terms of value, 54% comes from generic drugs and 46% from innovator drugs (Ministry of Health Malaysia, 2022). The difference in percentages is due to the high price of innovator drugs compared to generic drugs. Innovator drugs are more expensive due to the large amount of money invested in research by pharmaceutical companies for drug development, including activities such as clinical trials, marketing, and promotion of the drugs. The government tends to use more generic drugs due to their lower cost and relatively identical effects compared to original drugs. To ensure high quality medicine, the DCA has imposed stringent evaluation requirement for generic products, where the products are required to demonstrate bioequivalence (BE) studies to confirm that their therapeutic effects, safety and efficacy is equivalent to those of innovator drugs.

Figure 8: Medicine procurement by type of product for the year 2022 [11]



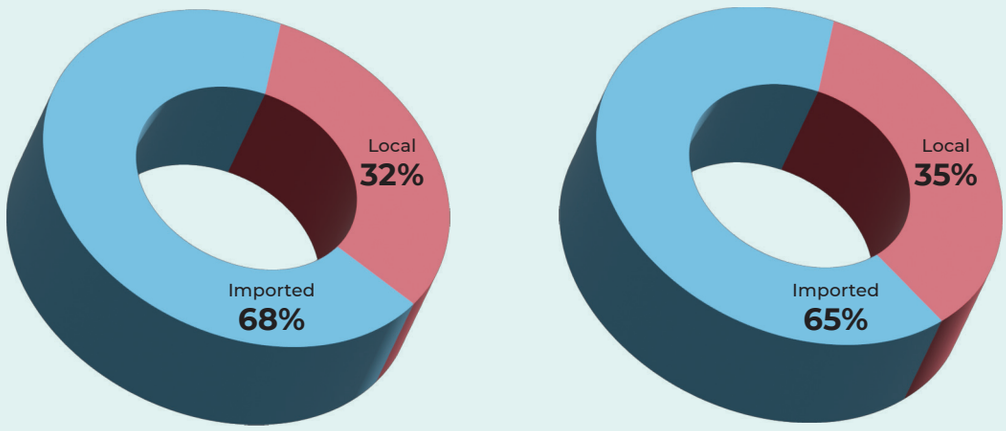
In terms of medicine origin, the data suggests that Malaysia's supply of medicine still heavily depends on imports for innovator products, with 98.91% of innovator products being imported at a value of more than RM 1.4 billion. This represents the highest expenditure of Malaysia government for medicine procurement relative to other type of products. The top 10 exporters of pharmaceutical products to Malaysia are Germany, USA, Switzerland, France, Australia, China, Ireland, Singapore, the United Kingdom, and India. Examples of innovator and generic products available in Malaysia are shown in Table 1 below:

Table 1: Example of Active Pharmaceutical Ingredient (API)

Active ingredient	Innovator	Generic	Medicine purpose
Ranitidine HCL	Zantac	X'tac	Heart burn, acid indigestion, GERD and gastric ulser
Piroxicam	Feldene	Apo-piroxicam	Osteoarthritis, rheumanoid arthritis
Mefenamic Acid	Ponstan	Mefetab	Pain relief, flu
Metformin hydrochloride	Glucophage	metformin	Type 2 diabetes

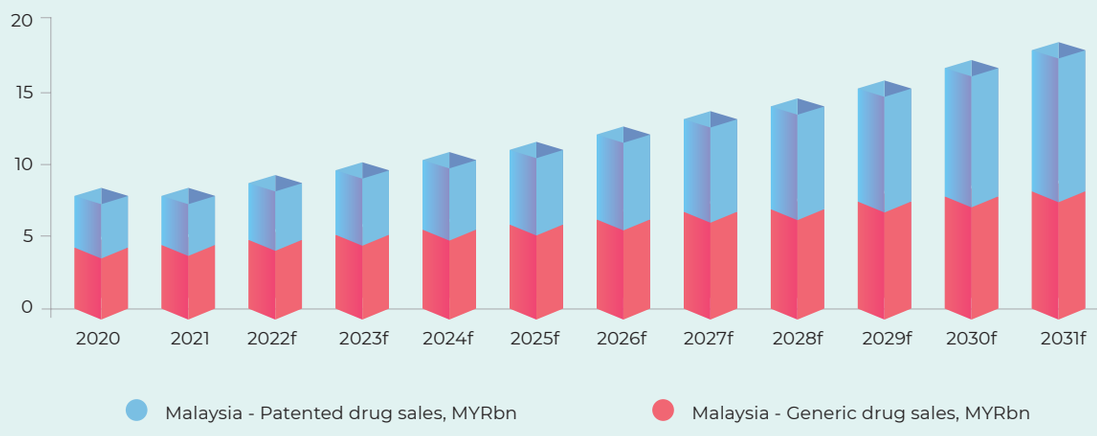
For imported medicines, the portion of innovator and generic medicines is relatively balanced, where out of the total 68% imported, slightly more than half (52.98%) are innovator products, and the balance comprises generic products. With the strong demand in generic products, the Malaysian government has the opportunity to reduce dependency on imports by empowering local manufacturers to produce more generic products.

Figure 9: Medicine Procurement by Origin of Product for the year 2022 [11]



Malaysia pharmaceutical market for generic and innovator drugs is projected by Fitch (BMI Fitch Solution, 2024) to increase steadily until the year 2031f as shown in the Figure 10 below. Despite challenging economic conditions, the demand for medicine is expected to grow to meet the needs of Malaysia's healthcare system. Sales of innovator drugs are expected to grow higher due to the rising need to treat cancer and other chronic diseases in Malaysia

Figure 10: Pharmaceutical Market Spending Projection 2020 - 2031 by Type of Product



Source: Fitch Solution [12]

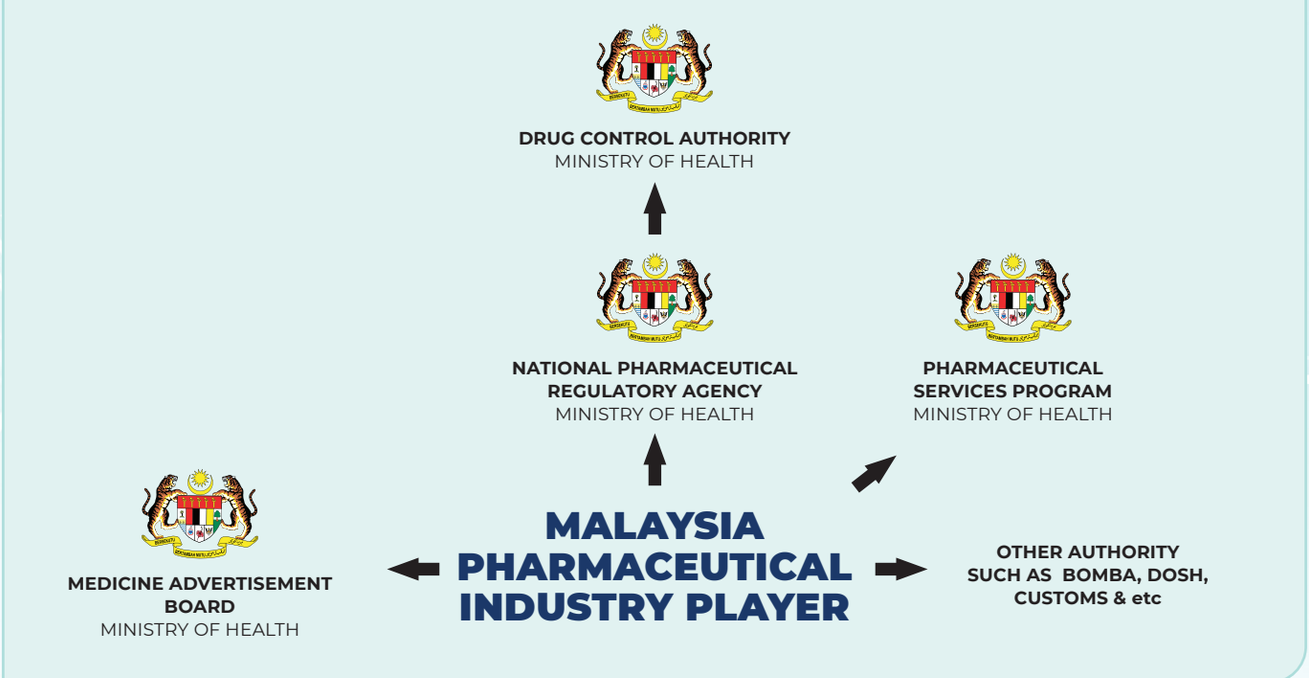
The market for generic drugs is expected to undergo steady growth with small increments yearly compared to innovator products, which are influenced by medicine price control by the government, the increase in chronic diseases and consumer behaviour. In Malaysia, the estimated volume and total expenditure of generic medicines are still considered low compared to advanced countries such as USA, Canada and Germany.

1.10 Regulatory Environment for Pharmaceutical Industry in Malaysia

In Malaysia, the National Pharmaceutical Regulatory Agency (NPRA) is the authority under MOH that is responsible for managing registration for drugs, pharmaceutical product licensing for manufacturing, import and wholesale, and licensing for clinical trials, as well as other functions pertaining to the pharmaceutical industry such as policy review, research, training, product recall, adverse drug effect management, and testing on drugs and cosmetic products for quality, efficacy, and safety. All drugs available in Malaysia must be registered. The agency has been accepted into the World Health Organization (WHO) program for international drug monitoring and designated as a WHO collaborating center for regulatory control of pharmaceuticals (Sani, et al., 2020). NPRA is also a member of the Pharmaceutical Inspection Cooperation Scheme PIC/S which is a leading organisation for international development, implementation and maintenance of harmonisation for Good Manufacturing Practices (GMP) standards and quality system based in Europe.

In terms of decision making, the Drug Control Authority (DCA) under MOH, chaired by the Director General of MOH, is responsible for approving the pharmaceutical product registration and policies regulating the industry. The NPRA acts as the secretariat to conduct meetings for the DCA. This body is established under the Control of Drug and Cosmetics Regulation 1984. The members consist of the Director General of Health as the chairperson, the Senior Director of Pharmaceutical Services Programme as the alternate chairperson, the Director of NPRA and eight (8) other members appointed by the Ministry from among the public service, local universities, medical practitioners, and veterinary practitioners. The main objective of DCA is to ensure that pharmaceutical, traditional medicines and personal care products marketed in Malaysia are safe, efficacious, and in good quality for consumption. The DCA meeting is usually conducted once a month.

Figure 11: Official Authority for Approval in Pharmaceutical Business Operation



Apart from that, ministries and government agencies offer various facilities and initiatives, including testing and certification, licensing, funding assistance, human capital development, consultancy, and tax incentives. The ministries and government agencies include:

Ministry of Health (MOH)

Ministry of Investment, Trade and Industry (MITI)

National Pharmaceutical Regulatory Agency (NPRA)

Drug Control Authority (DCA)

Clinical Research Malaysia (CRM)

Malaysian Investment Development Authority (MIDA)

Malaysia External Trade Development Corporation (MATRADE)

In terms of policies, the development of the pharmaceutical industry is guided by the Malaysian National Medicines Policy (MNMP) and the National Vaccine Development Roadmap (NVDR). For international recognition and cooperation, Malaysia is a member of Pharmaceutical Inspection Cooperation Scheme (PIC/S) which is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. Participation in PICS is open to any Authority having a comparable GMP inspection system. PIC/S presently comprises 56 Participating Authorities from all over the world (Europe, Africa, America, Asia, and Australasia). PIC/S aims to harmonise inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims to facilitate co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

Therefore, the codes and standards of Good Manufacturing Practice (GMP) in Malaysia are the same as those used by other PIC/s members such as Australia, Canada, United States and European countries.

1.11 Comparison with Benchmarking Countries

The benchmarking study focuses on constructive deliberation regarding advancements in Malaysia's pharmaceutical industry from two (2) perspectives:

Government policies and initiatives aimed at buildinga good ecosystem for the pharmaceutical industry	Good regulatory practices adopted by the pharmaceutical regulatory authority

Good Regulatory Practice (GRP) in the Pharmaceutical Industry

According to international practices, GRP in a pharmaceutical regulatory authority can be benchmarked using the World Health Organization Listed Authority (WLA) framework. WLA is an initiative by WHO to guide member states in developing a transparent and evidence-based pathway for regulatory authorities operating within their countries. It provides a structured, evidence-based process for regulatory authorities operating at an advanced level of performance to be globally recognized, previously referred to as "stringent regulatory authorities".

The implementation of the WLA framework is based on the WHO five (5)-step model for strengthening regulatory systems, also called the Regulatory Strengthening System (RSS). The system starts with the development of the benchmarking tool called the WHO Global Benchmarking Tool (GBT). The goal of the RSS is to assist the National Regulatory Authorities (NRAs) throughout the world in ensuring the availability of safe, effective, and quality medical products across countries. The deliverables of the assessment are expected to produce world-class NRAs that are stable and well-functioning organisations, equipped with an integrated regulatory system. The qualified NRA will be listed under the WLA. The GBT by WHO mainly focuses on nine (9) core functions as follows:

NATIONAL REGULATORY SYSTEMS

1

The national regulatory system provides the framework that supports the WHO recommended regulatory functions. The NRA is the institution in charge of ensuring quality, safety, efficacy, relevance, and accuracy of product information for medical products. It is expected that the NRA maintains a sustainable and well-functioning regulatory system to ensure independent and competent oversight of medical products.

REGISTRATION AND MARKETING AUTHORIZATION

2

Registration and marketing authorization focuses on the procedure for approval of a medical product for marketing after it has undergone a process of evaluation to determine the safety, quality, efficacy, and the appropriateness of the product information for the market. A systematic method is required to ensure that only products authorized by the NRA are allowed to be manufactured, imported, distributed, sold, and supplied to end-users. The process of marketing authorization includes the review of data on quality, safety, and efficacy of the product.

In the evaluation of well-established products, the NRA may elect to prepare its own report, rely on evaluation reports prepared by other national authorities, rely on decisions made by another NRA, or use a combination of these approaches. The Good Manufacturing Practices (GMP) inspections or certifications are expected to form part of the marketing authorization requirement. A legal provision should be in place to allow the NRA to grant marketing authorization for either an unlimited or a limited period of time

MEDICAL PRODUCT VIGILANCE

3

Medical products vigilance refers to science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other medical product-related problems. It is expected that vigilance activities will be established in a country based on risk management principles, where a reporting system must be established to monitor the safety of medical products. The monitoring and assessment of effects and other safety concerns such as adverse drug reactions (ADR) for medicines and adverse events following immunization for vaccines (AEFI), should be managed systematically for all types of patients.

A post-marketing vigilance system for medical products is essential to address side effects that occur after the marketing of medical products. In terms of harmonising practices, networking and information exchange with international bodies and regulators requires good facilitation by the NRA to ensure the vigilance system and safety reporting requirements are in accordance with internationally agreed standards.

MARKET SURVEILLANCE AND CONTROL

4

Market surveillance and control play a significant role in ensuring consumer safety. The surveillance and control mechanisms are designed to ensure compliance with the products available in the market with pre-set criteria for quality, safety and efficacy. The enforcement primarily focuses on four (4) themes as follows:

- Control of import activities;
- Prevention, detection, and response to substandard and counterfeit products;
- Market surveillance programmes to monitor the quality of medical products throughout the supply chain; and
- Control of promotional, marketing, and advertising activities.

LICENSING ESTABLISHMENTS

5

Licensing is an important regulatory approach to ensure the quality, safety, and efficacy of medical products used in a country. The NRA is expected to be responsible for coordinating licensing activities supported by published legal provisions, regulations and guidelines to ensure compliance with good practices within facilities or premises. All premises, facilities, establishments, or companies must obtain an operating licence issued by the NRA. In Malaysia, licensing is managed by NPRA. The issuance of license should be based on compliance with quality standards, including Good Practices such as Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

REGULATORY INSPECTION

6

Inspection of establishments across the medical product supply chain is extremely important in the pharmaceutical industry to ensure compliance with standards, guidelines, and practices in accordance with the national legislation and regulation, which should ideally be consistent with WHO recommendations and guidelines. Service providers include manufacturers, distributors, re-packers, re-labellers, importers, agents, traders, wholesalers, and retailers of medical products.

The NRAs are expected to have a legal mandate to inspect and enforce good practices such as GMP, GDP, or Good Clinical Practice (GCP) throughout the supply chain. They are responsible for making decisions concerning the issuance, suspension or withdrawal of establishment licenses, and issue authorizations or certifications for the activities conducted by the establishments. The NRAs are also expected to develop policies, regulatory actions, and procedures for the handling of medical products to control quality and prevent counterfeit products.

The inspection can include pre-licensing, post-licensing, pre-approval, post approval, unannounced inspection, and both domestic and overseas inspections. The credibility of the inspection depends on the transparency and clarity of the process along with the availability of clear regulations or guidelines supported by good quality management system.

LABORATORY TESTING

7

The laboratory testing element is in the context of regulatory function to ensure the ability of NRA to assess the quality of medical products by performing quality tests. These tests can be for the requirement to corroborate manufacturer's test results as part of the evaluation for marketing authorisation, a variation to a marketing authorisation, a requirement for lot release, or for reporting products that are under investigation due to an adverse effect on human health.

Laboratory testing is vital to ensure the safety of pharmaceutical products entering the market as well as detecting hazardous or falsified products which can potentially affect human health.

CLINICAL TRIAL OVERSIGHT

8

The clinical trials and oversight element in the Global Benchmarking Tools (GBT) evaluates the legal mandate of the NRA to authorise, regulate, and terminate clinical trials. The NRA is expected to have guidelines, procedures, and standardised forms in line with the national, regional, and international guidelines for clinical trials such as the Declaration of Helsinki, the Nuremberg Code, and the WHO's GCP guidelines. Clinical trial oversight aims to protect the safety and rights of human participants and to ensure that the procedures conducted are designed to meet scientifically sound objectives, free from potential fraud or falsification of data.

Generally, the NRA is responsible for two stages of critical evaluation of the documentation supporting clinical studies. The first stage is when the clinical trial is being proposed for authorisation. The second stage is when the results are submitted in an application for marketing authorization. In terms of quality and safety, a product is expected to be manufactured in compliance with GMP, while supporting preclinical studies should follow Good Laboratory Practices (GLP).

NRA LOT RELEASE (OFFICIAL AUTHORITY LOT RELEASE)

9

The NRA lot release refers to a specific system established for the regulatory release of specified biological products, such as vaccines, to ensure their quality, safety, and efficacy (QSE). Lot release is conducted on a lot-by-lot basis and considers the nature of the product as well as its inherent variability. The NRA is expected to have the legal mandate to perform independent lot release, develop and implement the required policies in accordance with the WHO and major international guidelines. For vaccines, the current practice uses three (3) methods for lot release:

- Review of the summary protocols only;
- Review protocols with independent testing; and
- Recognition and acceptance of lot release certificates from the responsible NRA or National Control Laboratory (NCL).

Each function consists of its own indicators and sub-indicators as specific measurement items to evaluate the overall performance of a regulatory system for a country. Each regulatory function is assessed through a set of sub-indicators that are clustered under nine (9) group of indicators, as listed below:

- Legal provisions, regulations and guidelines;
- Organisation and governance;
- Policy and strategic planning;
- Leadership and crisis management;
- Transparency, accountability, and communication;
- Quality and risk management system;
- Regulatory process;
- Resources (human, financial infrastructure, equipment, and information management system); and
- Monitoring progress and assessing impact.

The assessment also recommends maturity levels (ML) based on ISO 9004:2018 – Quality Management, which classifies maturity level of a regulatory system into four (4) levels:

MATURITY LEVELS 1

Some elements of regulatory systems exist according to "no formal approach"

MATURITY LEVELS 2

Evolving national regulatory systems that partially perform essential regulatory function according to the "reactive approach" level in ISO 9004:2018

MATURITY LEVELS 3

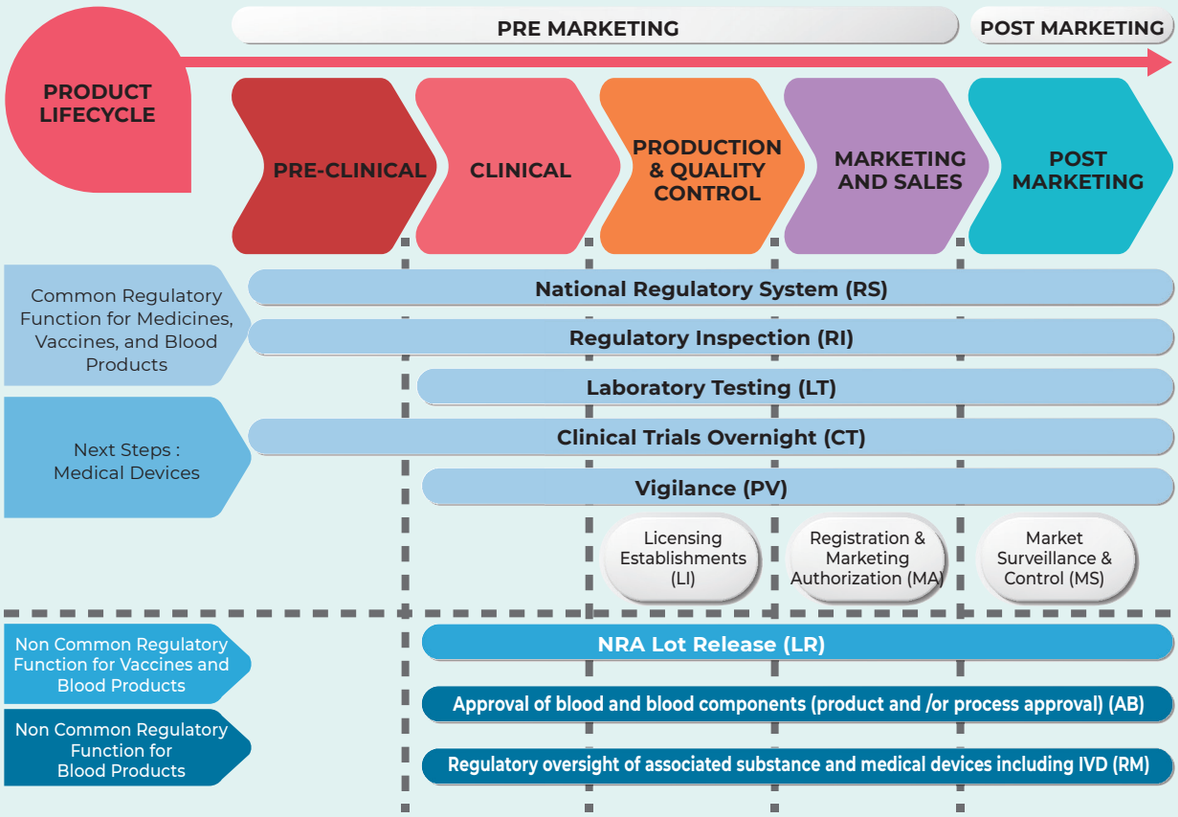
Stable, well-functioning and integrated regulatory systems that correspond to a "stable formal system approach" level in ISO 9004:2018

MATURITY LEVELS 4

Regulatory systems operating at advanced level of performance and continuous improvement corresponding to the "continual improvement emphasized" level in ISO 9004:2018

Based on the assessment, regulatory authorities that have attained Maturity Level 3 classification are eligible for consideration as a WHO-Listed Authority (WLA). Before being listed, a country can be listed under the Transitional WHO Listed Authorities (tWLA), a compilation of categories of authorities recognised by WHO as having achieved the levels of operation necessary for the regulation of medicines and/or vaccines. The tWLA list is valid for five (5) years from the date of publication. A regulatory authority will move from the WLA list to the permanent WLA list upon successful completion of the WLA evaluation process.

Figure 12: Regulatory Functions and Their Application Across the Medical Product Life Cycle



Source: World Health Organization (WHO)

As a developing country, Malaysia can benchmark good practices in pharmaceutical regulatory administration from the top-performing authorities listed under the WHO Listed Authority. Based on the WHO list of national Regulatory Authorities (NRAs) as of October 2023, the NRAs from 15 countries have been listed as operating under ML3 and ML4. Below is a list of selected countries identified for benchmarking purposes:

Table 2: Selected Regulatory Authority Classified as ML3 and ML4

Maturity Level (ML)	Regulatory authority	Country	Scope of product	Year of announcement
ML4	Ministry of Food and Drug Safety (MFDS)	Republic of Korea	1) Medicines 2) Vaccines (producing)	2022
ML4	Saudi Food and Drug Authority (SFDA)	Saudi Arabia	1) Medicines 2) Vaccines (producing)	2023
ML4	Health Science Authority (HSA)	Singapore	1) Medicines 2) Vaccines (non-producing)	2022
ML3	Food and Drug Administration (FDA)	Thailand	Vaccines (producing)	2021
ML3	National Agency of Drug and Food Control (BADAN POM)	Indonesia	Vaccines (producing)	2019
ML3	National Medical Product Administration (NMPA)	China	Vaccines (producing)	2022
ML3	Turkish Medicines and Medical Devices Agency (TITCK)	Turkiye	1) Medicines 2) Vaccines (producing)	2023

Source: WHO listed Authority [14]

Table 3: The WHO Listed Authority as of October 2023

Regulatory authority	Innovator	Listed product stream	Date of first listing
Ministry of Food and Drug Safety (MFDS)	Republic of Korea	1) Medicines 2) Vaccines	26 October 2023
Health Science Authority (HSA)	Singapore	Medicines	26 October 2023
Swissmedic	Switzerland	1) Medicines 2) Vaccines	26 October 2023

Source: WHO listed Authority [14]

Benchmark against the Top Country in the Pharmaceutical Industry

SWITZERLAND

The pharmaceutical sector has become the largest industry in Switzerland. Demand for medicinal products is hardly affected by any economic fluctuations due to the need for healthcare. Declines in prices have been compensated by increases in production volumes. Employment in the sector has grown significantly, and pharmaceutical products contribute substantially to Switzerland's goods trade. Top pharmaceutical companies in the world such as Roche, Novartis, and Lonza, originate from Switzerland. The industry accounts for more than a third of the country's GDP growth in the last decade, making it one of the main factors contributing to the economy of Switzerland.

The main factor behind the advancement of the industry in Switzerland is its strength in research and development (R&D) and innovation. The Swiss government's commitment to funding innovative ideas provides a significant advantage for innovation. For example, the registration process for obtaining a licence for a new pharmaceutical product is one of the fastest in the world.

From a broader perspective, Switzerland is not only an important production location but also a leading research hub. The availability of highly qualified scientists supports globally leading universities and excellent research-oriented pharmaceutical companies. One factor that differentiates Switzerland from other countries is its ability to commercialise discoveries. Prominent research institutions are located near to pharmaceutical companies, creating optimal conditions for drug development.

In terms of incentive policy, start-ups and newly established foreign companies in Switzerland are eligible for partial or full corporate and capital tax exemptions. Additionally, the government offers innovation-related tax incentives (such as R&D tax deductions), which serves as a driver for companies to excel in innovation. Switzerland also invests in strong international trade relations. It has free trade agreements with the European Union and many other countries, including major innovation leaders such as Japan and leading API manufacturers such as China, ensuring access to crucial export markets.

JAPAN

Japan is considered the world's third-largest pharmaceutical market after China and the United States of America. The market is expected to grow annually. The pharmaceutical industry growth in Japan has been marked by strategic partnerships, mergers, and collaborations with international pharmaceutical giants, fostering a culture of knowledge exchange and technological innovation. Japan has emerged as a global leader in pharmaceutical research and development, driven by a strong commitment to innovation and a robust regulatory framework.

Central to Japan's pharmaceutical industry is its stringent regulatory environment, overseen by the Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA ensures the safety, efficacy, and quality of pharmaceutical products through rigorous testing and evaluation processes. While these regulations uphold high standards, they can also present challenges for market entry and product approval, necessitating thorough compliance and extensive clinical trials.

It is well known that pharmaceutical companies require highly specialised knowledge and technology to produce a constant stream of innovative drugs. In Japan, R&D is powered by joint ventures between major pharmaceutical companies and universities to produce new drugs for the market. For example, the German pharmaceutical company Boehringer Ingelheim has started a research collaboration with the Inner Ear Research Group at Kyoto

University to develop drugs to combat hearing loss by finding a way to regenerate important cells in the human inner ear. The research is funded at an estimated 10 million yen a year. In another venture, the US-based company Eli Lilly partnered with the National Cancer Center Japan to conduct cancer research. Additionally, the German firm Bayer has opened a new innovation center in Osaka and a satellite office on Kyoto University's campus to establish an academic partnership with the university. Besides government agencies, collaborations within the private sector also pave the way for new innovative products. A joint venture between the US firm Amgen and Japan's Astellas Pharma led to the approval of Amgen's Repatha drug the for treatment of high cholesterol.

To boost the pharmaceutical industry, government policy plays a crucial role in providing a healthy business ecosystem for industry players. In Japan, the reform policies collectively known as "Abenomics" have pushed the progress of pharmaceutical products by easing biomedical regulations and expediting the approval of innovative drugs. Abenomics refers to a set of aggressive monetary and fiscal policies, combined with structural reforms, aimed at pulling Japan out of its deflationary slump. The approach includes a fiscal stimulus package worth 20.2 trillion yen focusing on building critical infrastructure projects such as bridges, tunnels, and earthquake-resistant roads.

The monetary policy reform in Japan involved quantitative easing, whereby the Bank of Japan injected liquidity into the economy, pushing some interest rates into negative values. Furthermore, structural reforms, such as deregulation of business activities, labour market liberalisation, corporate tax cuts and boosting workforce diversity, have improved the nation's competitiveness. All these measures have acted as catalysts for the advancement of Japan's pharmaceutical industry.

INDIA

The pharmaceutical industry in India is expected to reach USD 65 billion by 2024 and to $130 billion by 2030 (Invest India, n.d.). There are 500 API manufacturers in the country contributing approximately 8% to the global API industry. India is also the largest supplier of generic medicines, manufacturing 60,000 different generic brands across 60 therapeutic categories and accounting for 20% of the global supply of generics. Due to their low price and high quality, Indian medicines are preferred worldwide.

The Indian pharmaceuticals market is supported by Production Linked Incentive (PLI) schemes to boost domestic manufacturing capacity, including high-value products for global markets. The PLI Scheme for Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (PLI 1.0) aims to boost domestic production of critical bulk drugs in the country. Additionally, India has launched Ayushman Bharat Digital Mission to transform the healthcare industry digital transformation. E-pharmacy and E-lab platforms enable online medicine retailing and home collection services.

For a global pharmaceutical company seeking to enter the Indian pharmaceutical market, the opportunities are both exciting and attractive. There are six (6) important factors explaining why India attracts global pharmaceutical companies:

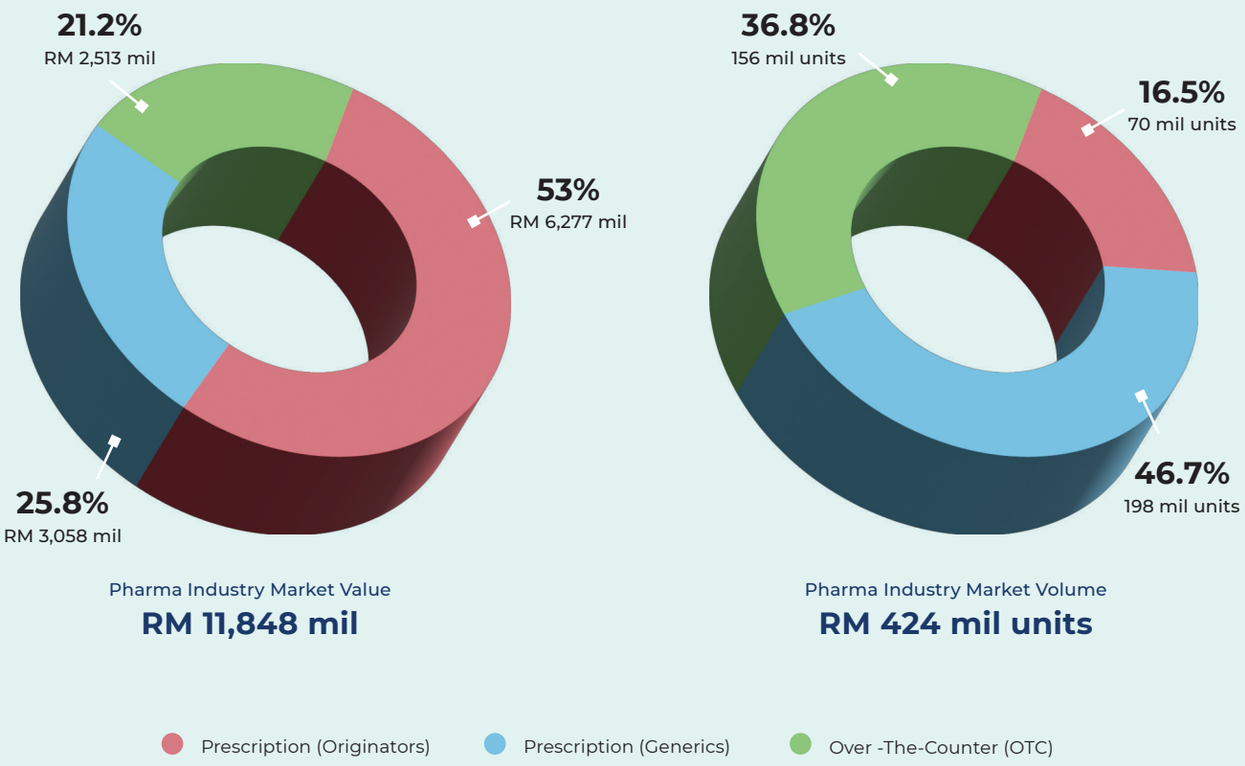
- Low production costs due to lower labour and raw material expenses;
- A diverse market catering not only to life-saving drugs, but also lifestyle medications;
- High potential for R&D activities, with 300 medical colleges and over 20,000 hospitals;
- Established manufacturing capabilities to produce active pharmaceutical ingredients (APIs) at lower costs while maintaining quality standards;
- The highest number of US FDA-approved manufacturing plants outside the United States; and
- Ease of conducting clinical trials, bioavailability, and bioequivalence studies due to India's ability to provide fast, cost-effective trials without compromising quality, and its vast patient pool.

1.12 Economic Contribution of Pharmaceutical Sector

The pharmaceutical segment has contributed over RM6 billion to Malaysia's gross domestic product (GDP) as an industry. By 2024, the industry is projected to contribute another RM10 billion toward Malaysia's GDP. The growth is empowered by Malaysia's New Industry Masterplan 2030 (NIMP 2030) which has identified pharmaceuticals as one of the priority sectors among 21 sectors expected to undergo a significant reform towards a high-value economy. The transformation from a market "user" to a market "producer" requires a synergistic effort and resources from the government and the private sector.

In terms of market contribution by value, prescription medicine (from originator) is the highest contributor in value which accounts for 53.0% of the total industry market value. In terms of volume, the highest contributor is prescription generics, followed by over-the-counter (OTC) products. Innovator medicines have a higher value but low volume due to their expensive prices in the market. The drugs are mainly used for chronic diseases, such as cancer which is well known for being an expensive medical treatment. The decline in Malaysia's currency is expected to have a significant effect on the price of imported medicines.

Figure 13: Malaysia Pharmaceutical Industry Value in year 2023



Source: MOPI & IQVIA

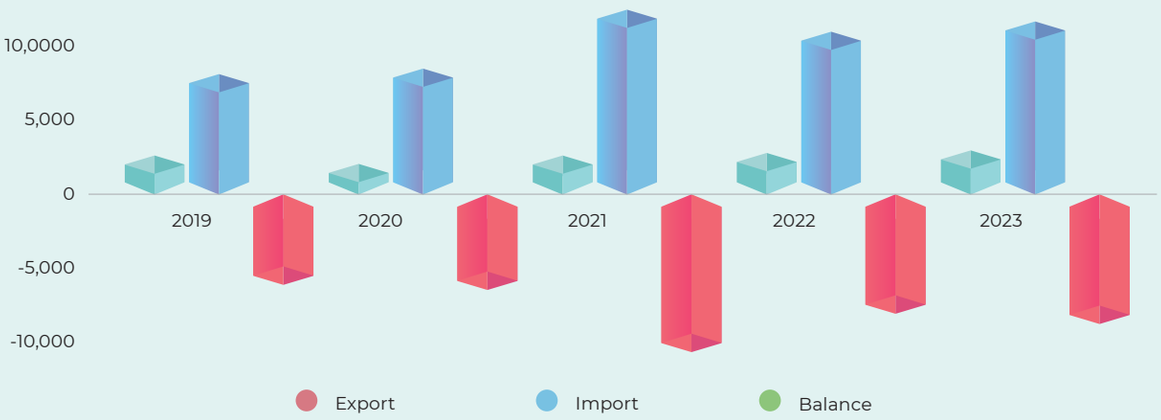
In terms of imports and exports, there was a significant imbalance in 2023 where the import values far exceed the export values. This indicates the industry's dependency on foreign medical supplies rather than locally manufactured products. This is also an indication of high risk to the national healthcare system if there are significant shortage of medicine from foreign medical suppliers.

Under NIMP 2030, Malaysia must begin paving the way towards producing key pharmaceutical products to achieve self-sufficiency and reduce heavy reliance on the global medicine supply chain in times of disruption.

As can be seen in the figure below, the imbalance between import and export has shown an increasing negative impact since 2018. Although exports have shown positive growth, import levels have risen sharply, peaking in 2021, possibly driven by the Covid-19 pandemic which began in early 2020.

In Malaysia, most imports consist of originator drugs. Besides growing capabilities for generic drugs, the pharmaceutical industry landscape in Malaysia must be driven towards high value activities such as R&D and developing a sustainable business model to start produce innovative drugs or API manufacturing.

Figure 14: Malaysia Pharmaceutical Import and Export until 2023



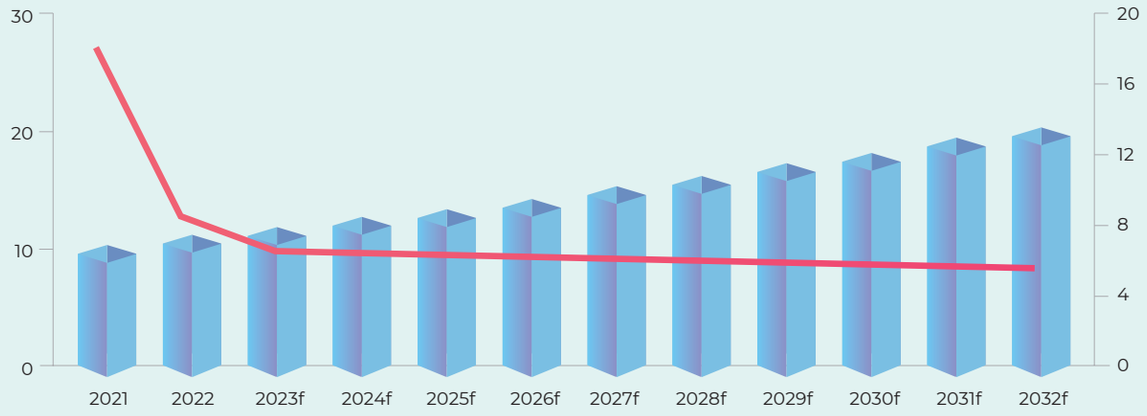
Category	2019	2020	2021	2022	2023
Export (RM million)	1,943.5	1,948.7	2,417.4	2,761.7	2,920.4
Import (RM million)	7,756.0	8,156.6	12,145.1	10,563.0	11,300.4
Balance (RM million)	-5,812.5	-6,207.9	-9,727.7	-7,801.3	-8,380.0

Source : MATRADE

As the economy continues to recover from 2019, Malaysia's pharmaceutical industry sales are expected to see a steady increase from RM 11 billion in 2023 to approximately RM 20 billion by 2032, driven by the strong domestic demand within the healthcare and retail industries.

Additionally, government incentives and national budget for healthcare are expected to provide steady support for the industry and build confidence among foreign investment. This includes the recently announced off-take agreements for pharmaceutical and medical device products for government procurement, as part of Malaysia's Budget 2025.

Figure 15: Malaysia Pharmaceutical Market Forecast until 2032



f : BMI forecast

Source: MOH National Health Account, BMI

1.13 Key Existing Laws and Regulations

The pharmaceutical sector is a highly regulated industry due to the highly technical and high-risk nature of products produced and distributed for human and animal consumption. In terms of legislation, this subsector is mainly regulated by nine (9) key laws as listed below:

- Registration of Pharmacists Act 1951 & Pharmacist Regulations 2004;
- Poison Act 1952 & Poison Regulations 1952;
- Dangerous Drugs Act 1952 & Dangerous Drugs Regulation 1952;
- Sale of Drugs Act 1952 & Sale of Drugs Regulation 1952;
- Control of Drugs & Cosmetics Regulation 1984;
- Poisons (Psychotropic substances) Regulations 1989;
- Medicines (Advertisement & Sales) Act 1956 & Medicine Advertisement Board Regulations 1976;
- Biosafety Act 2007 & Biosafety (Approval & Notification) Regulations 2010; and
- Patents Act 1983 & Patents Regulations 1986.

Table 4: Summary of Regulatory Requirements

PHARMACEUTICAL BUSINESS OPERATION REGULATORY REQUIREMENT

Licenses & permit to operate a pharmaceutical factory	Product registration (marketing authorization)	Sales of pharmaceutical product
›› Approval required from NPRA: • Factory layout and design approval. • GMP approval of the factory before commissioning. • Routine audits every 1 to 2 years. ›› Upon completion of the above approvals, the manufacturing license will be granted by NPRA. ›› Apart from the above approval, a pharmaceutical manufacturing factory will require approval from state authorities, local councils, DOSH, DOE, BOMBA, and other relevant regulators and/or agencies.	›› NPRA pharmaceutical product categories: • OTC medicines • OTC supplements and herbal products • Cosmetics • Traditional medicines • Prescription medicines (including biologics and biosimilars) ›› Companies wanting to commercialise pharmaceutical products must submit the product dossier via the online platform (Quest System) for registration review. ›› The level of dossier review will depend on the category of product registered. ›› Based on the completeness of the data provided in the dossier, NPRA will review the quality, safety, and efficacy of the pharmaceutical product. ›› Upon completion of the process, NPRA will issue a marketing authorization for the product.	›› In order to sell pharmaceutical products in Malaysia, a company must obtain the following licences: • Importer's license (if importing product) • Manufacturing license (if manufacturing locally) • Wholesale license to sell ›› The licences above must be held by a registered pharmacist of the company applying to sell the pharmaceutical products.

THE VALUE OF PHARMACEUTICAL SUBSECTOR IN MALAYSIA

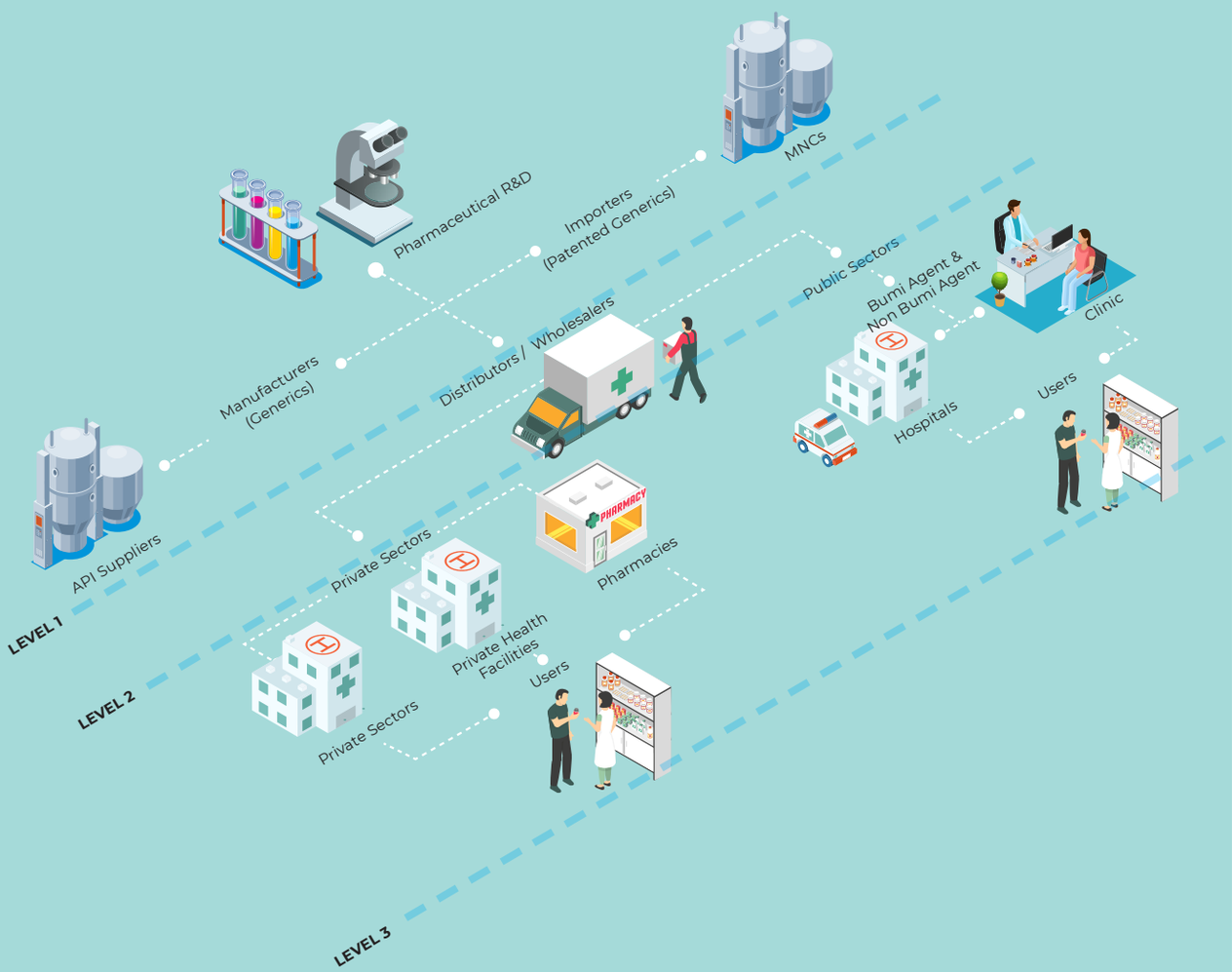
THE VALUE OF PHARMACEUTICAL
SUBSECTOR IN MALAYSIA

2.1 Market Structure and Supply Chain

Malaysia's pharmaceutical market structure generally is identified as oligopolistic in nature, characterised by a few dominant firms, interdependence among firms, collusive tendencies, and high entry and exit barriers (Zulfakar & Md Amin, 2023). The nature of the market is driven by a highly regulated industry with a high scientific knowledge requirement for innovative and generic products.

The supply chain of the pharmaceutical industry is divided into three (3) levels. Each level falls under the jurisdiction of different ministries and their respective agencies.

Figure 16: Overall Pharmaceutical Sector Supply Chain



Pharmaceutical Research and Development

Pharmaceutical research and development (R&D) is a complex, multi-phase process aimed at discovering, developing, and bringing new drugs to market. It involves several key stages:

- **Discovery and Preclinical Research**: This initial phase focuses on identifying potential drug targets and developing compounds to act against them. Researchers test these compounds in laboratory settings and on animal models to evaluate their efficacy, safety, and pharmacokinetics (how the drug is absorbed, distributed, metabolised, and excreted).

- **Clinical Trials**: If preclinical tests are successful, the drug moves to clinical trials involving human participants. This phase is typically divided into three (3) stages:

Phase 1	Tests the drug on a small group of healthy volunteers to determine safety, optimal dosage, and identify side effects.
Phase 2	Involves a larger group of patients to assess efficacy and further evaluate safety.
Phase 3	Conducted on a much larger scale, this phase compares the new drug to existing treatments and confirms its efficacy and safety in a diverse population.

- **Regulatory Review and Approval**: After successful clinical trials, the pharmaceutical company submits a New Drug Application (NDA) or a Biologics License Application (BLA) to regulatory authorities such as the FDA (U.S.) or EMA (Europe). The regulatory body reviews the data, assesses the drug's risk-benefit profile, and decides whether to approve it for public use.

- **Post-Marketing Surveillance**: Once the drug is approved and, on the market, ongoing monitoring is conducted to identify long-term effects, uncover rare side effects, and confirm sustained efficacy.

- **Market Access and Commercialisation**: In parallel with regulatory processes, companies develop strategies for commercialisation, covering pricing, market access, and distribution logistics. The entire R&D process is time-intensive, often spanning more than a decade, and requires substantial financial investment. It also requires collaboration among various stakeholders, including researchers, clinicians, regulatory agencies, and the pharmaceutical industry.

LEVEL 1
Pharmaceutical Licensed Manufacturer & Importer

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 owned and produce generic drugs, whereas the major importers are mainly MNCs that import patented drugs from their parent companies. There are also locally owned importers, which are mainly smaller companies that import generic drugs, accounting for only a minor portion of the market by value.

Licensed Manufacturers

Generally, most manufacturers of controlled medicines in Malaysia are locally owned. The major local companies listed on the Bursa Malaysia stock exchange are Pharmaniaga Berhad, Hovid Berhad, Duopharma Biotech Berhad, Y.S.P. Industries Sdn. Bhd., Kotra Pharma Sdn., Bhd and Xepa-Soul Pattison (Malaysia) Sdn. Bhd. (a subsidiary of Apex Healthcare Bhd). Pharmaniaga Berhad, is the largest locally owned pharmaceutical company, and Duopharma Biotech Berhad is are government-linked companies (GLCs). Malaysian pharmaceutical manufacturing companies are small compared to the MNCs that import drugs into Malaysia and are mainly producers of generic medicines. Most Malaysian pharmaceutical manufacturers are independent manufacturers that produce and market their own products. A small number of Malaysian manufacturers perform contract manufacturing, mostly for local distributors. Contract manufacturing refers to the production of goods by one firm under the label or brand of another company. It is important to highlight that currently, contract manufacturing is not a major business for Malaysian manufacturers.

Throughout the pharmaceutical supply chain, most of the major manufacturers participate at all levels of the supply chain where they import raw materials, process them, manufacture the medicines, store them in warehouse, and distribute the products directly to providers or to distributors such as Zuellig, DKSH or Apex Pharma. For sales in the public sector, transactions are usually conducted through Bumiputera agents. Usually, the APIs are imported for processing and manufactured into finished products. The main sources of API supply are China, India, and Europe. Some local manufacturers also import finished goods for distribution and sale.

Licensed Importers

To import controlled medicine, a company must obtain a license from NPRA. The importer can be divided into two (2) sub-categories – the MNCs and the local importers. In Malaysia, the major players for pharmaceutical imports are the MNCs which have registered their offices in the country to obtain product registration for sale. Most of the imported products are patented products. These MNCs act as principals importing finished products into Malaysia and selling them through distributors. The importer is the principal and retains ownership of the products while the distributor merely offers logistics services to the principals. Through their regional offices, all the foreign MNCs maintain marketing and sales teams that actively and directly market to providers in the private and public sectors.

In terms of market, the private hospitals and clinics together regularly purchase a large percentage of patented drugs. Therefore, most of the MNCs' marketing direction is set towards hospitals and clinics as the primary customers, with chain pharmacies as the secondary party to receive the supply. For public sector procurement, the MNCs use Bumiputera agents for bidding 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. On the other hand, local importers mainly focus on generic drugs and prefer collaboration with local distributors due to their lower supply volume.

LEVEL 2
Wholesaler / Distributors

The second level of the pharmaceutical supply chain consists of distributors and wholesalers. The NPRA grants wholesale licences to establishments for distributing and selling controlled medicines and other pharmaceutical products. In Malaysia, there are four (4) types of companies that possess wholesale licences listed by the NPRA. The first group consists of independent distributors. These are not the typical wholesaler or distributor who buy goods from suppliers and sell to retailers. They do not take ownership of the goods, or the risks associated with ownership. They are also not involved in marketing or determining prices. 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. The three (3) major players for pharmaceutical wholesalers in Malaysia are DKSH, Zuellig Pharma, and Pharmaniaga Logistics.

The second group of wholesalers/distributors consists of Bumiputera agents who act as intermediaries between public hospitals, on one side, and local non-Bumiputera and foreign pharmaceutical companies, on the other, 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 an exclusive concession to supply approximately 700 medical items, through the Approved Product Purchase List (APPL) programme, to government hospitals, institutions, and clinics. All tenders for APPL items must pass through Pharmaniaga Logistics. The company has extensive warehouse and logistics facilities for its own products, and these services are also offered to its clients. Other Bumiputera agents, such as Antah Healthcare Group and MS Ally Pharma Sdn Bhd, provide warehouse and distribution services. They started off as pharmaceutical wholesalers or retailers, and later added the role of tendering agents.

The third group of companies with wholesale licences comprises subsidiaries of local manufacturers with wholesale licences. Examples include Duopharma (M) Sdn. Bhd., which holds licences for manufacturing, importing, and distributing pharmaceutical products. Duopharma also owns subsidiaries like Sentosa Pharmacy and Unique Pharmacy, which 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.

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

LEVEL 3
Provider

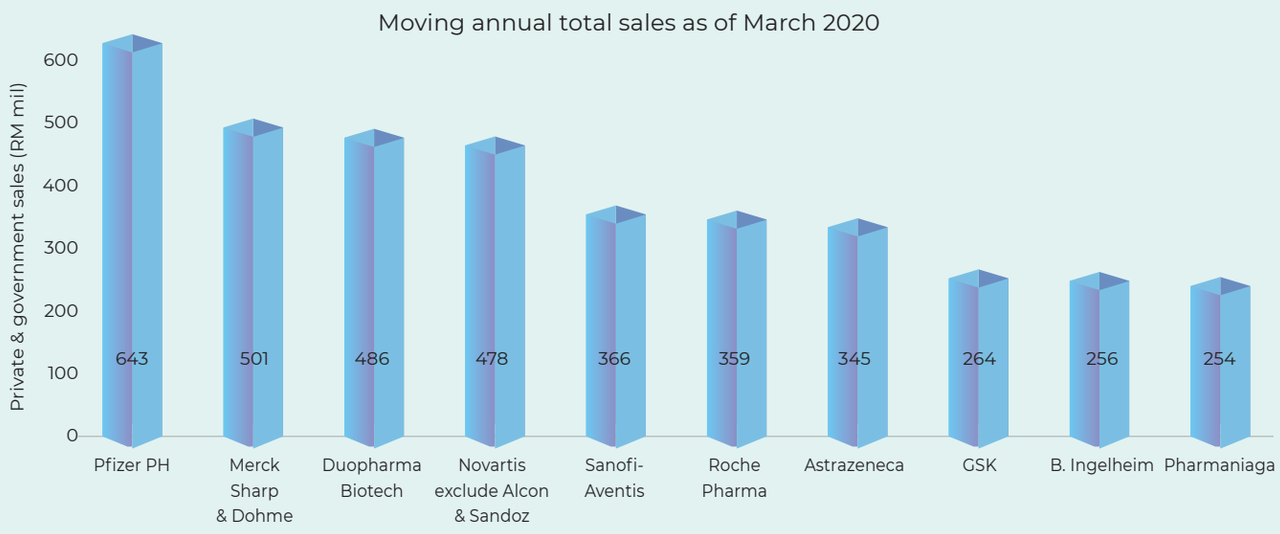
The third level in the supply chain comprises the providers, defined as institutions that dispense medicines to end users or patients, in both the public and private sectors. Providers in the private sector include specialists or GPs, private hospitals, and retail pharmacies, while providers in the public sector include government clinics, hospitals, and institutions. The recent database for the year 2022 shows that there are close to 9,830 private clinics owned and run by general practitioners and specialists; 1,077 government health clinics; 1,722 government rural clinics; 83 maternal and child health clinics; 239 government community clinics); 148 government hospitals; 207 private hospitals; and thousands of other healthcare facilities that require medical supplies to treat patients. The demand for medicine supply for these healthcare institutions are always critical and require a steady supply from the pharmaceutical sector.

Another important source of product demand in the private sector is the retail pharmacies. From a regulatory perspective, the NPRA issues licences to establishments, not to individuals, for the manufacture, import, and wholesale of controlled medicines and other products. On the other hand, the Pharmaceutical Service Programme under MOH issues Type A licences to individual pharmacists working in either wholesale-and-retail, wholesale-only, or retail-only types of establishments. Unlike traditional chain pharmacies that own and operate multiple outlets, there is another variant that does not directly operate or fully own the retail pharmacies that carry their names. 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 sell onward to their associated pharmacies. These chain pharmacies buy in large volume and are able to exercise significant market power to the extent that suppliers are obliged to pay listing and display fees for their products to be carried. Chain pharmacies have also been expanding through acquisitions of smaller retail pharmacies.

Leaders of Pharmaceutical Industry in Malaysia

In Malaysia's pharmaceutical industry, large multinational companies dominate the supply chain, especially in the upstream industry, due to their high financial and technical capacity. Companies such as Pfizer, Merck, Novartis, and Astrazeneca are well known for their R&D capabilities in producing innovative drugs as well as biologic products. The only local companies that can somewhat compete are Pharmaniaga and Duopharma. Pharmaniaga is owned by Boustead Holdings, a conglomerate owned by a military pension fund (Lembaga Tabung Angkatan Tentera) and controlled by government. Duopharma Biotech Berhad is a Malaysian-based investment holding company that is majority owned by Permodalan Nasional Berhad (PNB).

Figure 17: Top 10 Pharmaceutical Company in Malaysia 2020 by Value

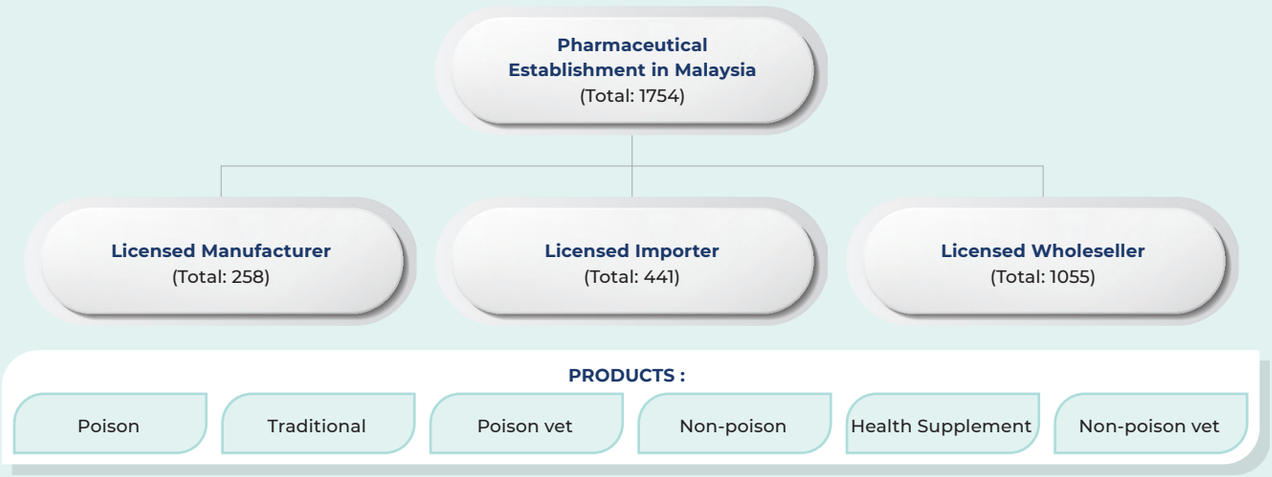


Source: The Star Articles

2.2 Number of Establishments and Its Composition Based on Business Activities

In general, there are 1,754 pharmaceutical establishments registered under the NPRA. It is evident that most of the establishments in Malaysia are licensed retailers of poison medicines (prescription medicines). As for manufacturers, most of the pharmaceutical factories in Malaysia are traditional or cosmetic manufacturers which reflects the scarcity of local manufacturing for important medicines such as prescription medicines.

Figure 18: Pharmaceutical Establishment Types and Product Categories



Source: NPRA Database as of Feb 2024

According to NPRA database as of February 2024, there are a total of 258 manufacturers registered under NPRA across six (6) categories of poison, non-poison, traditional medicines, health supplements, poison veterinary, and non-poison veterinary. The breakdown of the establishments indicates that the major players in medicine manufacturing are traditional medicines manufacturers (76.7%). Poison-type medicines (prescription medicines) are one of the crucial medicines for the modern healthcare industry. Besides the high demand for public consumption, only 16.67% (43) of the manufacturers are involved in producing prescription medicines. This situation indicates a high opportunity for local manufacturers to venture into producing prescription medicines (poison) to reduce reliance on imported medicines. Some of the top medicine manufacturers in Malaysia include Ranbaxy (Malaysia) Sdn. Bhd., Duopharma Biotech Group, Novo Nordisk Pharma (Malaysia) Sdn. Bhd, and AstraZeneca Sdn. Bhd.

In the current industry environment, Malaysian pharmaceutical manufacturers are mainly producers of generic medicines, rather than to originator medicines. The technological capacity to produce new medicines is very limited. In general, every patented medicine has at least two types of patents being a product patent and a process patent. When a product patent expires, other companies are allowed to produce generic versions of the originator medicine. However, if the process patent has not expired, generic manufacturers need to conduct research to develop their own method for formulating the medicine.

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

For medicine importers, there are 441 importers in total registered with the NPRA. The majority of importers deals with prescription medicines (poison). The major importers in the Malaysian pharmaceutical industry are the MNCs with registered regional offices for the purpose of registering their products for sale in Malaysia. The medicines imported are predominantly patented products. The top importers of pharmaceutical medicines include foreign MNCs such as Pfizer (Malaysia) Sdn. Bhd., Merck Sharp & Dohme (Malaysia) Sdn. Bhd., Bayer Co. (Malaysia) Sdn Bhd, Sanofi-Aventis (Malaysia) Sdn. Bhd., Novartis Corporation (Malaysia) Sdn. Bhd., GlaxoSmithKline Pharmaceutical Sdn. Bhd., Roche Malaysia Sdn. Bhd., Astrazeneca Sdn. Bhd., and Merck Sdn Bhd.

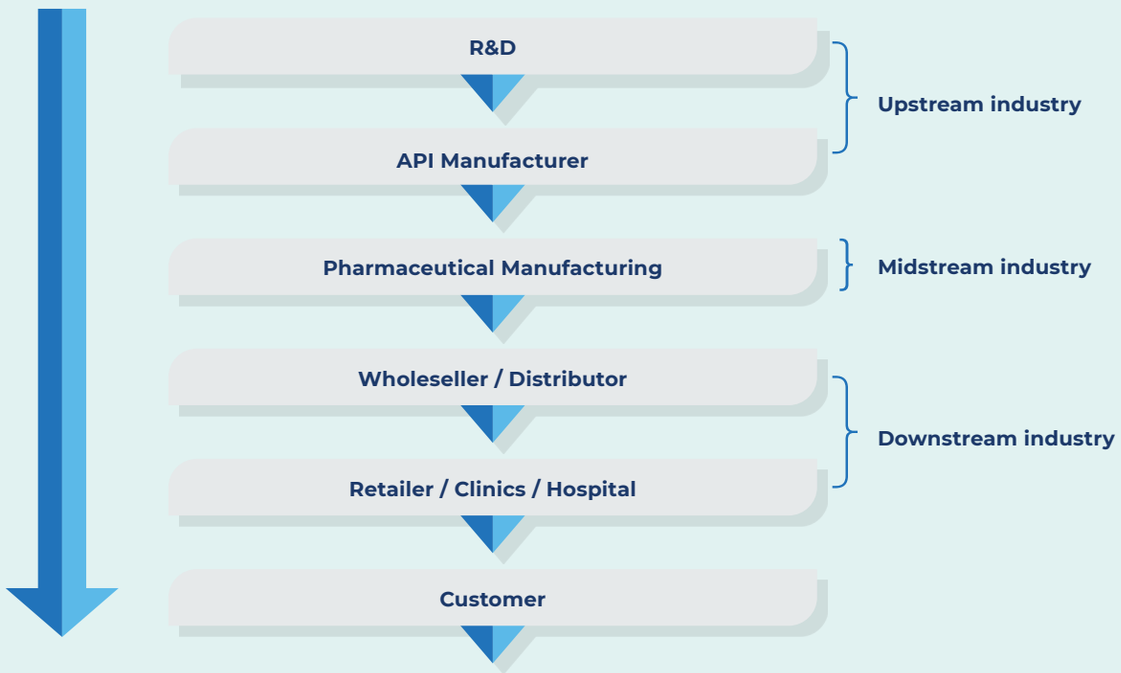
All these corporations are the principals, importing finished products into Malaysia and sell them through distributors, who mainly offer logistics services. Based on the registered importers' data, it is evident that Malaysia is still dependent on imports for crucial medicines, such as prescription medicine. With the challenging global economic condition, Malaysia needs to empower local manufacturers to reduce dependency on imported medicines.

In the context of regulation, all companies are required to hold an NPRA licence before they can manufacture, import, or sell pharmaceutical products in Malaysia. Licences are only available to a locally registered entity. This is why most importers establish registered offices in the country.

Local pharmaceutical importers are generally much smaller in size and mainly import generic drugs. Some major local importers includes Medispec (M) Sdn. Bhd., United Italian Trading (M) Sdn. Bhd., Healol Pharmaceuticals Sdn. Bhd., and Germax Sdn. Bhd. The main sources of imports are Canada, United States, Europe, Korea, and India. Larger importer such as Medispec (M) Sdn. Bhd. handles their own logistics, but the smaller local importer tends to use local distributors due to their relatively low volume. Large pharmaceutical distributors are driven by volume and value in operation and they do not give priority to low-value and low-volume business. Additionally, the generic medicines brought by local importers have the potential to compete with products owned by MNCs.

2.3 Upstream and Downstream Industry

Figure 19: Value Chain of Malaysia Pharmaceutical Industry



The value chain of the pharmaceutical industry includes:

- **Upstream activities**: the discovery and development process of pharmaceutical products through research and product development, as well as component manufacturing such as API manufacturing.
- **Midstream activities**: comprise dosage form selection, formulation, packaging, and labelling of products through manufacturing, assembly, and dosage activities.
- **Downstream activities**: logistics, sales, and distribution of pharmaceutical products.

There are various supporting services and infrastructure throughout the pharmaceutical industry supply chain including warehousing and distribution, clinical trials, extraction facilities, industrial electronics, machinery and equipment, maintenance services, sterilisation services, testing activities such as bioequivalence and bioavailability studies, and certification bodies, including NPRA. The stakeholders involved in the entire supply chain include manufacturers, importers, wholesalers, distributors, providers, ministries, government agencies, industry associations, and scholars from public research centers and the higher education sector.

In supply chain analysis, it is evident that pharmaceutical manufacturers are mainly focused on R&D, manufacturing and sales of generics. For R&D activities, there has been some development in generic medicines, health supplements, and traditional medicines, but not in innovator products and veterinary products. Malaysian manufacturers need to start strategising to have greater involvement in innovator products, biologics, and veterinary products for a sustainable supply of medicine in the country. Reliance on imported products poses a risk to the healthcare system of the country.

ISSUES AND CHALLENGES IN PHARMACEUTICAL INDUSTRY

ISSUES AND CHALLENGES IN PHARMACEUTICAL INDUSTRY

3.1 Market Competitiveness in the Pharmaceutical Industry: Dominance of MNCs and Major Corporations

In view of the market structure for Level 1, manufacturers and importers consist of MNCs and major local corporations, due to their advanced knowledge and capacity to absorb the high costs of R&D activities and production capabilities.

The local manufacturers obtain raw materials and undergo rigorous R&D work to produce generic pharmaceutical products. However complex regulatory requirements have become a barrier to entry for small enterprises attempting to break into the market. Moreover, anti-competitive behaviours, such as patent evergreening, unfair clauses, cartel price control, and mergers by large corporations have a significant impact on the downstream market, especially in terms of medicine price and stock availability.

For level 2, a similar issue can be observed, where the limited number of players at this level consist of manufacturer-owned subsidiary companies or independent companies. The categories of wholesalers and distributors are as follows:

- Large independent distributors;
- Bumiputra agents;
- Wholesalers and distributors that are subsidiaries of manufacturers; and
- Retail pharmacies that also operate as wholesalers.

Despite the large number of players, the market in level 2 of the pharmaceutical supply chain is highly concentrated, with dominant corporations controlling prices, setting high profit margins, and exercising oligopolistic power over the medicine supply.

Level 3 in the supply chain consists of providers supplying drugs to consumers and patients through healthcare facilities such as hospitals, clinics, and pharmacies, which procure their medicine supply from wholesalers and distributors. In situations where the large pharmaceutical manufacturers dominate the market, there is a possibility of vertical integration affecting the downstream players by large manufacturers (Zulfakar & Md Amin, 2023). All manufacturers import active pharmaceutical Ingredient (API) and other raw materials for production. Major pharmaceutical companies have their own warehousing and distribution subsidiaries and sell directly to providers.

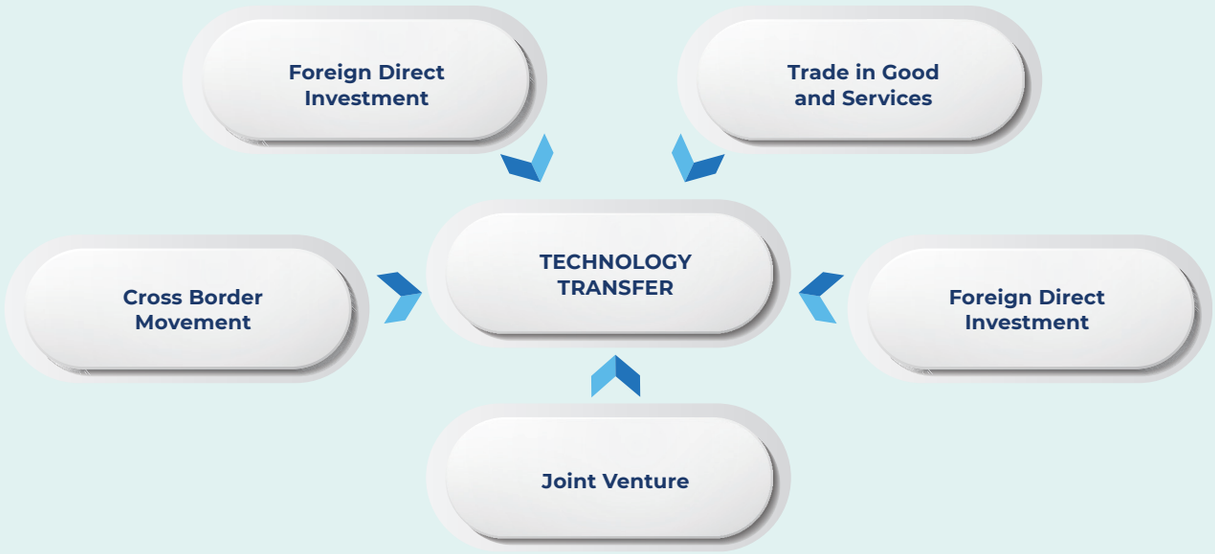
The market is highly competitive, but anti-competitive conduct can occur when companies sell to different providers at different prices. Collusion among market players can affect the quality of healthcare services, which can have a direct impact on society (patients). The act of bid rigging, for example, can reduce competition in the market, especially when it involves procurement contracts in the private and public sectors. In such a situation, the participating firms may agree to bid at almost the same prices that are higher than the reserve price, which can increase the tender costs and affect the overall expenditure to acquire the supply of products. Besides that, entry into the market for new companies becomes more difficult when the market is controlled by a cluster of companies (also called a cartel). This situation leads to infringement of Section 4(1) from the Competition Act 2010, which states that "A horizontal or Vertical agreement between enterprises is prohibited insofar as the agreement has the object or effect of significantly preventing, restricting or distorting competition in any market for goods or services".

Technology Transfer in the Pharmaceutical Manufacturing Industry in Malaysia

Technology transfer fundamentally refers to the process of moving technology from one entity to another. It is a key element in Malaysia's industrialisation and economic development. In highly technical field such as the pharmaceutical industry, a fast, effective and efficient technology transfer mechanism to enable industry players is essential to keep pace with the development of new drugs. Indeed, the transfer of manufacturing technology today has become a core element of the international business strategy for many firms. In general, there are five (5) pathways for technology transfer through market-mediated mechanism:

- Trade in goods and services;
- Foreign direct investment;
- Joint ventures;
- Cross-border movement of personnel; and
- Licensing [17]

Figure 20: Technology Transfer Modes to Enhance Malaysia's Pharmaceutical Manufacturing Technology



Since the technologies and innovator drugs originate from abroad, FDI is simply the fastest method for technology transfer. FDI can offer greater benefits to Malaysia if investors implement advanced technologies as opposed to less technologically intensive applications. To invest, investors look for locations advantageous for profitable operation as well as the option to internalise production instead of selling or licensing their intellectual assets to local entities in the country. This can be supported by strong Intellectual Property (IP) protection. Weak IP protection increases the probability of imitation and makes a country less attractive and profitable for FDI (PhAMA).

Through NIMP 2030, Malaysia has set direction to attract more local and foreign investment in the pharmaceutical and medical device sectors. The NIMP 2030 specifically identifies biologics, API manufacturing, and halal medicines as key growth segments for the pharmaceutical sector. The transition of Malaysia from a traditional manufacturing model of contract manufacturing to becoming an innovation-led manufacturing hub will require strong commitment from the government and private sector in implementing the NIMP 2030's strategies.

Figure 21: Transformation of Pharmaceutical Industry Towards R&D-Oriented Business

To increase value-added opportunities in the pharmaceutical industry, Malaysia needs to focus on six (6) enabling elements in transforming the pharmaceutical industry. The first element is investment in R&D capability for the development of innovative pharmaceuticals products to drive growth and attract more companies to establish research facilities in the country. The R&D funding from the government sector needs to be optimised and focused. Research institutions and research centers in higher learning institutions need to be empowered to drive innovation in pharmaceutical R&D. The quintuple helix model of innovation needs a synergistic effect from academia, industry, government, civil society, and the environment to drive sustainable and inclusive development.

Secondly, strengthening collaboration with international pharmaceutical companies, research institutions, and healthcare is a key strategy for Malaysia to facilitate knowledge transfer, technology sharing, and joint ventures, ultimately leading to the development of advanced solutions.

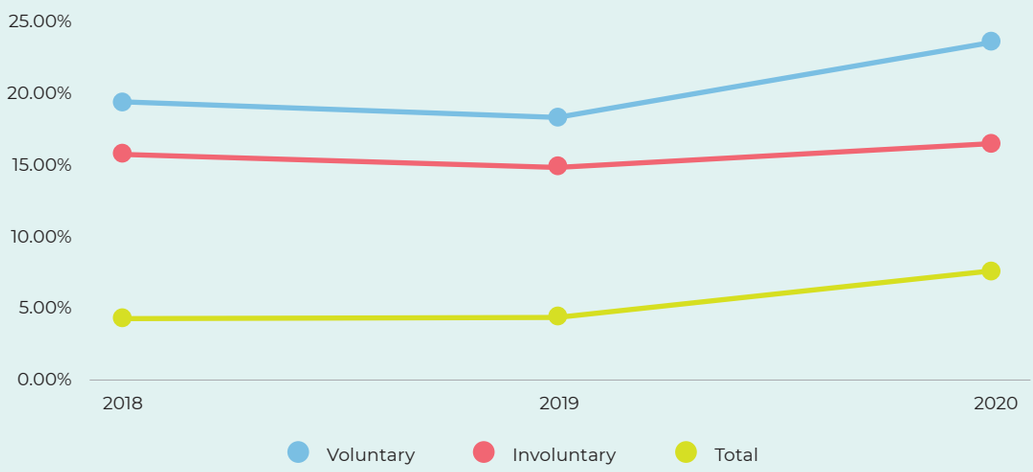
The third enabling element concerns the strength of the regulatory framework, which is vital to ensure compliance with international standards. The approval process and pharmacovigilance practices should also be streamlined with those of other benchmark countries and in accordance with international and regional standards. A strong regulatory framework will boost investor confidence and encourage further investment in the country. Besides that, the fourth enabling element focuses on investment in talent development.

Sustaining Qualified Talent in the Pharmaceutical Industry

Employee retention is becoming an important indicator in assessing the success of an organisation and the future of the industry. One of the most valuable aspect in an organisation is its sustainable human capital. In developing countries like Malaysia, employee turnover intention has become a serious problem across all industries, including the pharmaceutical industry. Several factors contribute to retaining qualified talents, such as effective communication, good reward programmes, clear career development, and performance-based bonuses. This indicates that compensation, training, and performance appraisal all have a favourable effect on employee retention. Some qualified talent in Malaysia choose to leave and serve abroad due to better financial offers, higher quality of life, and broader opportunities for international career advancement. A highly technical field such as the pharmaceutical industry must develop a proper strategy to retain qualified talent and encourage them to work in Malaysia.

The pharmaceutical industry is expected to experience significant changes in consumer behaviour, and greater demand for treatments due to several factors such as an ageing population, an increase in disposable income, lack of exercise leading to the rise of chronic diseases, and proactive behavior that favors prevention over cure. Human capital within the industry must be ready to meet the challenges. The industry must develop attractive packages to sustain, reskill, or upskill their workers to face the future challenges of the industry.

Figure 22: Voluntary and Involuntary Turnover in Pharmaceutical Companies in Malaysia



Source: Internal data from Towers Watson from 2018 to 2020 adapted [19]

Issue on Comprehensive and Progressive Agreement for the Trans-Pacific Partnership (CPTPP)

The CPTPP is a free trade agreement established by Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam to promote economic cooperation and reduce trade barriers. Historically, the CPTPP originated from the Trans-Pacific Partnership Agreement (TPPA), which was initially a trade agreement between 12 countries including the USA. However, in 2017, then-President Donald Trump signed an Executive Order to withdraw the USA from the TPPA. In light of the US withdrawal, the remaining 11 TPP countries reached an agreement, and the treaty was renamed as the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership (CPTPP).

In terms of economic impact, the CPTPP is expected to provide industry players in Malaysia with access to new markets and a broader range of high-quality raw materials at more competitive prices. The agreement also provides technical assistance and capacity building programmes to help improve local capabilities in areas such as automotive, chemicals, optical and scientific equipment, emergency and evacuation, and medical devices.

To reduce trade-related regulatory burden, the CPTPP is expected to eliminate most of the trade tariffs between its 11 member countries, providing Malaysian companies access to new markets that are not covered by any existing free trade agreement. Furthermore, the companies operating in other CPTPP economies would have improved access to the Malaysian market, granting them access to a more extensive selection of high-quality raw materials at competitive prices. The impact of the CPTPP for domestic pharmaceutical policy and regulation can be summarized into ten (10) provisions as outlined below (Gleeson, et.al, 2019):

- TRIPS-plus intellectual property protections;
- Investment protections, including investor-state dispute settlement;
- Procedural requirements for pharmaceutical pricing and reimbursement programs;
- Provisions with implications for regulation of pharmaceutical marketing;
- Regulatory requirements for assessment of safety, efficacy, and quality;
- Reduction/elimination of tariffs on medicines or their ingredients;
- Rules applying to government procurement of pharmaceuticals;
- Rules applying to state-owned enterprises and designated monopolies;
- Procedural requirements for customs administration and trade facilitation; and
- Rules applying to regulatory practices, cooperation and coherence.

For patent-related matters, the TRIPS-plus provisions in CPTPP include pathways that allow extended periods of exclusivity for patented medicines and obstacles to market entry for generic and biosimilar medicines. These provisions may reduce competition and result in governments and consumers paying monopoly prices for longer periods. Consequently, access to affordable medicines may be reduced. The IP provisions in the agreement may delay the market entry of less expensive generic and biosimilar medicines, thereby maintaining high prices for extended periods. The ripple effect of this is the potential increase of government expenditure on medicine procurement.

The Intellectual Property (IP) provisions in the Intellectual Property Chapter in CPTPP underwent suspensions, where a total of 12 provisions, including matters related to protection for biologics, data exclusivity, patent term adjustments, rights management information, copyright term of protection extension, and technological protection measures, have been suspended. Under Article 18.53 of the CPTPP, the provision states that if a member country allows a person other than the party who initially provided the safety and efficacy data to use information from a previously approved pharmaceutical product as a basis for marketing approval for their own pharmaceutical product, the country concerned must establish a patent linkage system. This patent linkage system requires notification to the patent holder or permits the patent holder to be notified of an application seeking market approval of a similar product during the existence of the patent term.

In addition, the patent holder must be provided with adequate time to seek remedies (such as judicial and administrative proceedings, and preliminary injunctions) prior to the marketing of an allegedly infringing product. To meet the obligations to set a patent linkage system under Article 18.53, Malaysia has been granted a transition period of 4.5 years from the date of the CPTPP came into force, i.e., from 29 November 2022 to implement the patent linkage system.

Protection of Pharmaceutical Innovation through Intellectual Property

Drug development in the pharmaceutical industry is characterised by unusually high research spending compared to other industries. Patents and related IP protections are critical considerations for decision-makers when evaluating investments in R&D. A strong and robust IP protection system must be in place for Malaysia to spur innovative behaviour among Malaysian and drive more investments in innovation from local and international MNCs. The role of Intellectual Property Corporation of Malaysia (MyIPO) and the Ministry of Domestic Trade and Costs of Living extends beyond providing administration and registration protection for IP rights. These institutions plays a more fundamental role, which is to stimulate investments in innovation that will lead to innovative activities beneficial to the country. In addressing the way forward to improve pharmaceutical IP protection in Malaysia, the Pharmaceutical Association of Malaysia (PhAMA) has identified six (6) gaps in Malaysia's IP system (PhAMA) to drive innovation in the Malaysian pharmaceutical industry:

PATENT TERM RESTORATION (PTR)

1

Innovative drugs originate from innovator companies, which depend heavily on the protection given by patents. Only during the patent term can an innovator company recover its investments to break even or make a profit, as there will be a significant decline in revenue when the patent expires. Although patents are typically granted for a term of 20 years from the date of application, the effective period of market exclusivity for a patented innovative drug is often significantly shorter than the full patent term due to the time taken to obtain marketing approval from the authorities. Drug regulatory approval is mandatory in almost all countries and is essential to safeguard consumer health and safety.

Innovator pharmaceutical companies must achieve significant revenue through sales and marketing of innovator drugs to break even and recover initial costs before they can hope to see profits. Failure to do so may result in financial losses, which if left unchecked, can threaten the company's survival. The longer the regulatory approval process takes, the shorter the remaining patent period available to market the innovator drug, thereby increasing the risk of failing to recover the significant costs and investments incurred.

In Malaysia, pharmaceutical products cannot be marketed without regulatory approval and prior clearance from the Drug Control Authority (DCA). The system of patent term restoration (PTR) was introduced to strike a balance between the need for a drug to undergo the approval process by the regulatory authority and the significantly shortened period during which a pharmaceutical patent can be commercially exploited, due to the prohibition on marketing prior to approval. Advanced countries such as the USA, Australia, Japan, Korea, and Singapore have implemented the PTR system, which allows the patent term to be restored up to a maximum of five (5) years to compensate for delays in marketing approvals by the regulatory authorities. Malaysia can consider the implementation of PTR to enhance the IP ecosystem in the country.

PATENT LINKAGES

2

The patent linkage is a form of legal ordering that ties patent protection for marketed pharmaceuticals to drug approval. The system of patent linkage establishes a relationship between the market approval process of generics and the patent status of the originator product. Marketing approval will not be granted to a generic manufacturer before the patent expires unless it can show that the patent is expired or demonstrates that the patent will not be infringed or is invalid. The national regulatory authority may not register or approve a generic drug if the drug for which approval is sought remains patented.

In addition, a patent linkage system that allows generic manufacturers to obtain information on existing patents has a beneficial role to play in helping them to plan their production schedules and to assess whether to wait for the patent to expire or to challenge its validity, if there is strong basis to do so. A patent linkage system will also prevent confusion in the marketplace, where infringing products are launched and subsequently withdrawn following infringement actions by the patent holder. Furthermore, it may also reduce the need for litigation over the amount of damages to be paid for the patentee's loss suffered due to the generic drug being marketed during the patent term.

The patent linkage system does not confer any presumption of patent validity other than what is already provided by the country's patent law. It also does not prevent or delay competition from the generics manufacturers. Competition during the patent term from not only the generics manufacturers but any other third party is prohibited by the Patents Act 1983, and not by any patent linkage system itself. With the global pharmaceutical market calculated to be worth trillions, there is a compelling reason for Malaysia to amend existing laws to align with best practices from other developing countries so that our country may optimally enjoy a share of this growing industry.

DATA EXCLUSIVITY

3

In the pharmaceutical industry, the public can only get the benefits of an innovative drug or a new or second indication of a drug once sufficient data has been generated to prove the drug's safety, quality, and efficacy to the satisfaction of regulatory requirements. As the generation of such data requires significant time and financial costs, the protection of such data from unfair commercial use is therefore necessary. Otherwise, there will be commercial and economic inequity caused to the innovator pharmaceutical companies that have generated the data in the first instance.

The Directive on Data Exclusivity (Directive No. 2 of 2011) (Directive) has been issued by the Director of Pharmaceutical Services of the MOH under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984, which mandates the protection of undisclosed, unpublished, and non-public domain pharmaceutical test data, the origination of which involves considerable effort, submitted to the MOH for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product containing a New Chemical Entity (NCE) or approval for a second indication of a registered drug product. Any person may apply for data exclusivity (DE) protection, and DE may be granted for:

- A new drug product containing NCE if an application is made in Malaysia within 18 months from the date the product is first registered or granted marketing authorization and is granted DE in the country of origin or any other country recognized by the Director of Pharmaceutical Services.
- A second indication of a registered drug product if an application is made in Malaysia within 12 months from the date the second indication is approved and is granted DE in the country of origin or any other country recognized by the Director of Pharmaceutical Services.

The Directive provides for the maximum period of DE protection, which shall not be more than five (5) years for a new drug containing an NCE and three (3) years for a second indication of a registered drug product (in respect of the data concerning the second indication only). The DE period is calculated as follows:

- New drug containing NCE – the period runs from the date the product is first registered or granted marketing authorization AND granted DE in the country of origin or in any country recognised by the Director of Pharmaceutical Services.
- Second indication of a registered drug product – the period runs from the date the second indication is first approved AND granted DE in the country of origin or any country recognized by the Director of Pharmaceutical Services.

SECOND MEDICAL USAGE/INDICATION AND DOSAGE REGIME

4

Drug repositioning, also known as drug reprofiling, refers to the process of finding new applications outside the existing indication for the drugs. Strong patent protection is available for second medical use in most developed and developing countries, including the USA, Australia, Canada, Japan, South Korea, New Zealand, Singapore, China, Indonesia, and many other countries. In Malaysia, the Patents Act 1983 similarly permits protection for second medical use. According to Section 13(1)(d) of the Patents Act, methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body are not patentable. However, the products used in any such methods remain patentable. The Patents Act has already placed Malaysia in line with international standards with regard to a new second or subsequent medical use.

In terms of the patentability of a new form or dosage of a known pharmaceutical product in Malaysia, there is no express prohibition in the Patents Act to disallow a patent for a novel, non-obvious dosage regime. Section 14(4) of the Patents Act would permit the patenting of any product, substance, or composition used in a novel, non-obvious dosage regime, in line with the current position adopted by an increasing number of developed and developing countries. The patent offices of many developed countries have granted protection for new dosage regimes, including the USA, Japan, Russia, Australia, and New Zealand.

As pharmaceutical products originating from R&D efforts by pharmaceutical companies represent a major part of the provision of health care, the discovery of drugs for new and existing diseases is critical to ensure advancement in healthcare. Despite the substantial R&D investments to discover new drugs, the number of new drugs being discovered has declined. Drug repositioning allows a reduction in the pharmaceutical R&D timeline. Development risks are also reduced as known drugs would typically have established safety and pharmacokinetic profiles. It is a research and production strategy that offers a shorter route to patients by bypassing several stages of traditional drug development. All-in-all, repositioning offers a better trade-off compared to other drug development strategies. Thus, research into further uses of known drugs has considerable health and economic importance.

COMPULSORY LICENSING

5

A compulsory license is a license granted by a competent national authority allowing the exploitation of a patent without the consent of the patentee. Broadly speaking, compulsory licenses are granted in the following situations:

- Non-working of a patent;
- Other, more broadly defined abuses; and
- Public interest.

In Malaysia, compulsory licensing is provided for under Section 84 of the Patents Act 1983, which mainly deals with instances when a patent is not utilized in Malaysia, or where a compulsory license is issued on the basis of interdependence of patents. Section 84 of the Patents Act 1983 provides for compulsory licensing pursuant to a national emergency, or where the public interest requires it, or where the patentee is found by a judicial or relevant authority to have exploited the patent in an anti-competitive manner.

For local working requirements and interdependence of patents in Malaysia, Section 49(1) of the Patents Act provides that an application for a compulsory licence may be made by any person at any time after the expiration of three (3) years from the grant of a patent, or four (4) years from the filing of a patent application, whichever is later, if:

- There is no production of the patented product or application of the patented process in Malaysia without any legitimate reason; or

- No production of the patented product in Malaysia for sale in any domestic market, or if there are some products but are sold at unreasonably high prices or do not meet the public demand without any legitimate reason.

5

Section 49A of the Patents Act deals with the situation when patents are inter-dependent and allows the grant of a compulsory license to the extent necessary to avoid infringement. This applies where the invention claimed in a later patent cannot be worked in Malaysia without infringing an earlier patent, and the invention of the later patent constitutes an important technical advance of considerable economic significance in relation to the invention of the earlier patent. Upon granting such a license, MyIPO will determine the scope and time period of the license, as well as the amount and conditions of royalty payments to the patentee. Additionally, Section 84(8), the exploitation of the patent by the Government agency or a person designated by the Government shall be predominantly for the supply of the market in Malaysia.

ADMINISTRATIVE ENFORCEMENT OF IP RIGHT

6

The counterfeiting of medicines can occur both in relation to branded and generic products. Counterfeit products may include products with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging. The counterfeiting of medicines is a lucrative business, with generally low production costs, high gross margins, and sales opportunities available at both local and export markets. Counterfeited medicines purportedly produced in Malaysia have been found not only in the local market but also in Hong Kong, Thailand, and Vietnam. An effective, robust, and well-functioning regulatory and legal enforcement framework is required if the problem of counterfeit medicines is to be kept controlled and curbed to a minimal level.

There is no single consolidated piece of legislation to govern the enforcement of IP rights concerning the pharmaceutical industry. Instead, provisions are found in a number of statutes. Section 58 of the Patents Act 1983 provides for the civil wrong of patent infringement and defines what constitutes infringing acts. Section 59 gives the patentee the right to sue in the High Court any person who has infringed, or is infringing, or who has performed acts likely to lead to imminent infringement of the patent. The exploitation of a patent without the patentee's licence is not classified as a criminal offence under the Patents Act. Hence, a patentee does not have the option to lodge complaints with the enforcement authority for criminal or administrative enforcement action to be taken against a person who exploits the patent without a licence. The patentee's rights in relation to their patent is enforceable primarily through an infringement action in the High Court. Other relevant statutes that may be used against counterfeit and unregistered medicines are as follows:

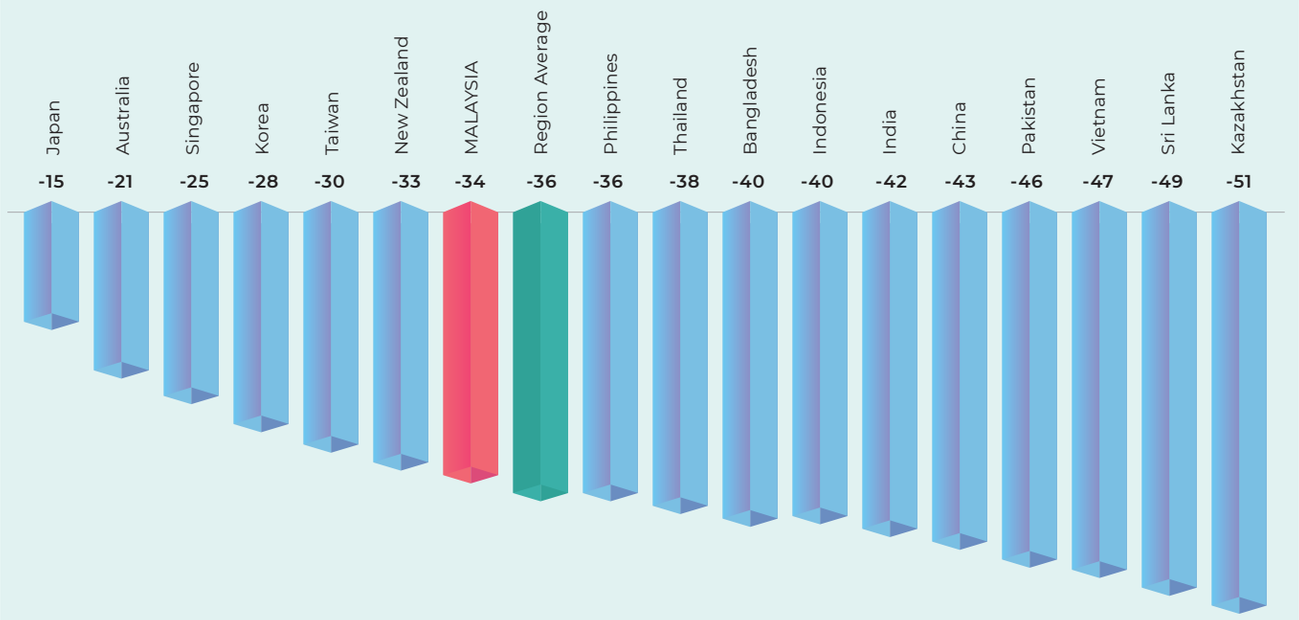
- Trade Descriptions Act 2011;
- Sale of Drugs Act 1952;
- Poisons Act 1952;
- Control of Drug and Cosmetic Regulations 1984; and
- Medicine (Advertisement and Sale) Act 1956.

In terms of penalty for offences relating to counterfeit medicine, there is no minimum penalty prescribed by any of the statutes governing offences relating to counterfeit medicines. Only the maximum penalties are prescribed. Judges thus have a wide discretion when it comes to sentencing. There is also no obligation to impose a jail term in the case of a repeat offender, although the maximum limit of the penalties for such cases is generally doubled.

Availability of new medicine in Malaysia

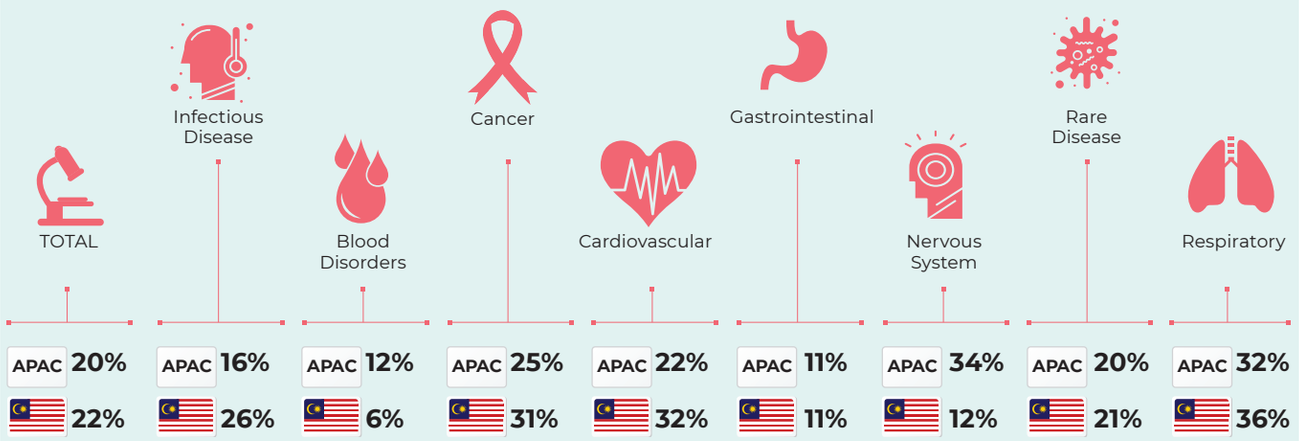
The availability of new medicines in Malaysia depends on whether innovator drug manufacturers choose to launch their products in the country. There are several driving factors which influence the time taken for the medicines to be launched. From a regulatory perspective, price control and market size are some of the key determinants in pharmaceutical business decision making. In the Asia-Pacific region, only 22 percent of new medicines were launched in Malaysia, based on data covering 460 new medicines launched from 2012 to 2021. This has led to an average delay of approximately three years for Malaysia to obtain new medicines.

Figure 23: Average Months from Global Launch to Local Launch by Asia-Pacific Market



According to therapy areas, the availability of new medicine is critical for gastrointestinal and blood disorders, with only 12% availability. On average, the availability of medicines across different therapy areas range from 32% to 11%, which is considerably low. This condition restricts patients' access to the best medicine to cure their disease.

Figure 24: Percentage of New Medicine Available in Malaysia by Therapy Area

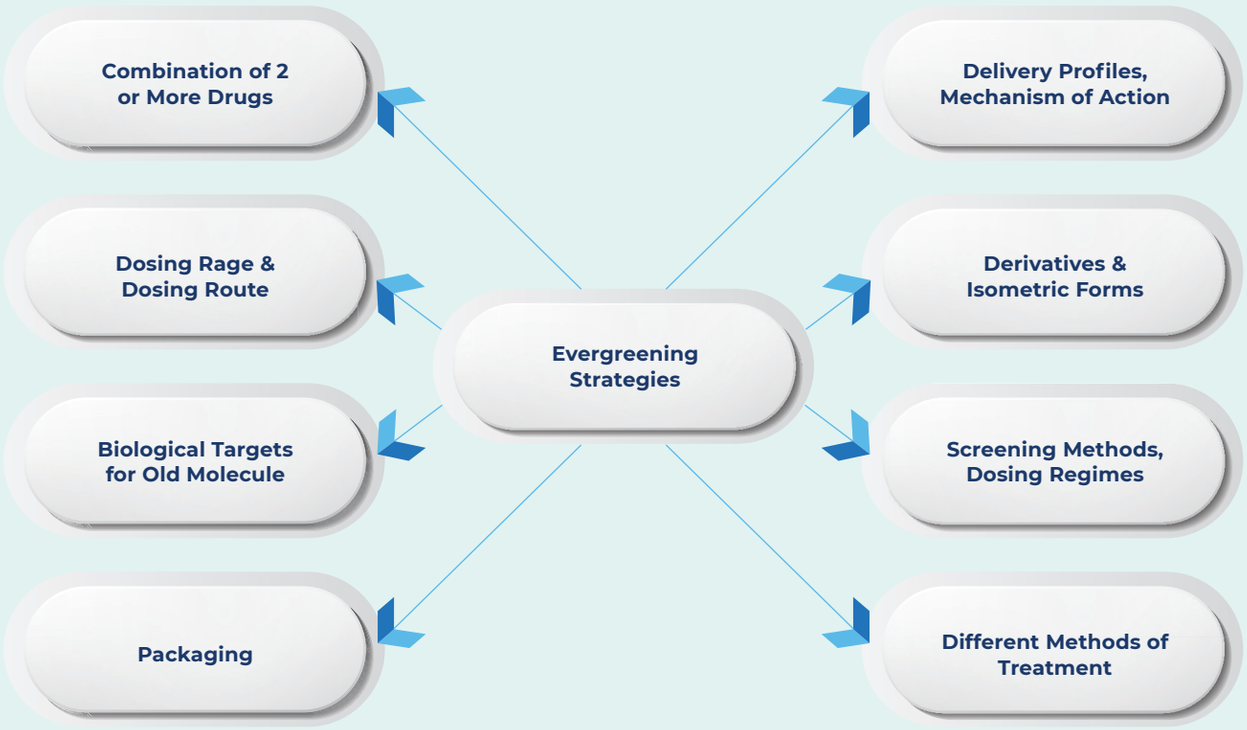


Whilst innovator drug R&D remains a long-term challenge in Malaysia, the government should re-evaluate its regulations, policies, and practices for regulating the pharmaceutical industry to improve the business ecosystem and enhance the country's attractiveness to foreign investment. Improving the healthcare system also requires reducing the time needed to obtain new medicines, especially for treating life-threatening diseases.

Evergreening

Evergreening refers to the strategies used by pharmaceutical product owners to use patent laws and minor drug modifications to extend their monopoly privileges over the drug (Alkhafaji, Trinquart, Baron, Desvarieux, & Ravaud, 2012). There are various ways in which the patent holder is capable of exploiting loopholes in patent laws and related regulatory processes in order to maximise their monopoly, especially over best-selling drugs by filing artful patents on previously patented inventions just before the end of the term of the parent patent. Once the drug goes off-patent, generic manufacturers are free to launch generic versions of the off-patented drug. The entry of generic versions will cause the price of the branded drug to inevitably fall. The huge differences in the price of generics and the branded drug encourage consumers to shift to the cheaper and widely available generic versions. To sustain the profitability of the company, the common strategies of evergreening among innovator drug companies are summarised:

Figure 25: Evergreening Strategies by Industry Players



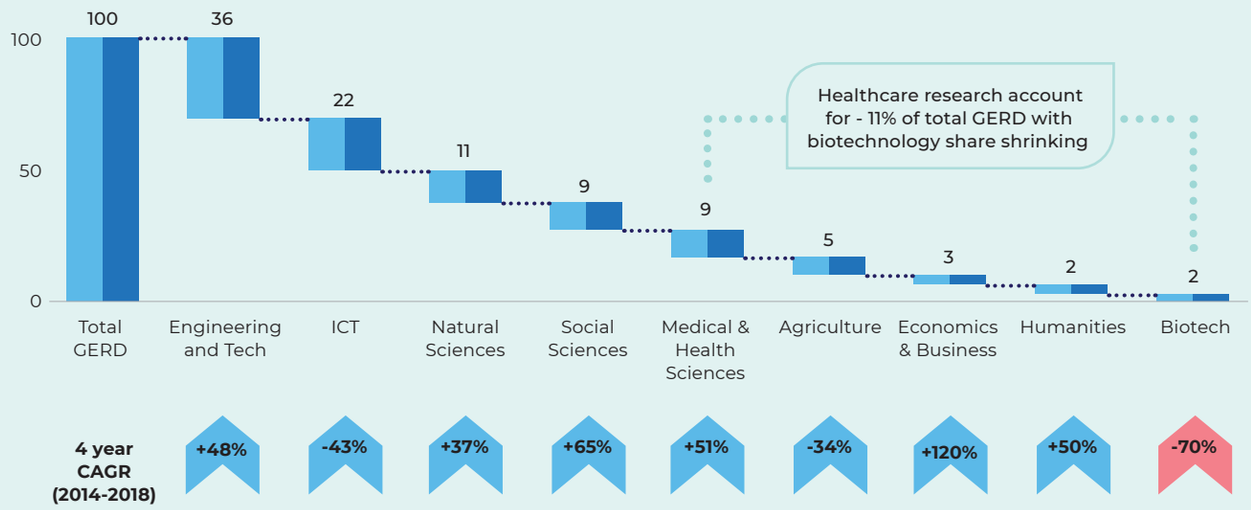
From a business perspective, evergreening is a strategy employed by innovator companies to recover the high costs incurred in R&D and to legally protect minor modifications intentionally made to the parent patent, allowing them to obtain multiple patents on the same drug. Consequently, it can extend the overall term of the patent protection, enabling the company to maintain a monopoly for an extended period.

To illustrate with a simple scenario: if a pharmaceutical company, AA Sdn. Bhd., launches a drug product and obtains patent protection for the product just before the term of that patent ends, the company files a new patent for a minor modification to the original molecule, this action extends the overall term of patent protection and contributes to their monopoly. This mechanism effectively extends the patent protection period and delays the entry of generic versions of the drug, which can affect the public health budget.

Boosting Pharmaceutical Research and Development in Malaysia: Transforming R&D Output to Industrial Product

R&D is a vital catalyst for locally manufactured drug innovation. In Malaysia, both private and public funding for R&D remains limited, according to national data on gross expenditure on R&D (GERD). From 2014 to 2018, GERD spending for healthcare research accounted for only 11% of the country's total GERD, as shown in the figure below. Investment in biotechnology is the key to new drug development. This decline shows regressive progress in R&D and requires a paradigm shift in government policy to drive innovation in high-value pharmaceutical products.

Figure 26: R&D Expenditure Values in Malaysia



Source: Malaysian Science and Technology Information Centre (MASTIC), PhAMA

Malaysia has the potential to become a champion in R&D activities due to its diverse genetic pool and the prevalence of chronic diseases, which facilitate research on rare and chronic diseases. Strategic fund allocation is needed to boost the upstream industry in pharmaceuticals, in tandem with strategic partnerships with international major pharmaceuticals companies. Talent development through interim attachment to world class R&D centers will further enhance human capital development. While novel drug development promises high returns, a high investment of time and resources is required. The need for investment over an extended gestation period and the high risk of failure acts as a barrier to progress. Thus, a strong innovation ecosystems and infrastructure are prerequisites to reform the industry. The key enablers for value-driven research and innovation in the pharmaceutical industry are illustrated in the figure below.

Figure 27: Research and Innovation Enablers to Move Pharmaceutical Industry to the Next Level [23]

30%

Need for robust innovation ecosystem:

- Industry-academia-government collaboration to advance research capabilities
- More alignment and collaboration between different academic and government research organisations

30%

Talent availability and development:

- Industry ready talent
- Development of advanced skill-set required for future of pharmaceutical industry
- Prevent brain drain
- Initiatives to bring back talented Indians

16%

IP and regulatory support:

- IP protection with robust enforcement
- Regulatory data protection

8%

Commercial viability :

- Create domestic market for innovative drugs
- Stability in policies to enable long-term decision making

8%

Incentives :

- Incentives to spur innovation and boost innovation network

16%

Mindset shift:

- Patient first mindset
- Incremental to transformative
- Long-term vision
- Willingness to take risks and embrace failure

Collaborative innovation ecosystem | Government enablers | Mindset shift

WAY FORWARD FOR
PHARMACEUTICAL SECTOR

WAY FORWARD FOR
PHARMACEUTICAL SECTOR

4.1 Insight and Strategic Recommendations

Malaysia has a strong pharmaceutical industry ecosystem in which the government and the industry have a close partnership to support the national healthcare system. Innovative healthcare solutions are required to ensure the sustainability of medicine supply to consumers. Industry players, such as local companies and MNCs in Malaysia, have their own interests, target markets, and business focuses. In general, local companies focus primarily on traditional medicines, vitamins, supplements, OTC drugs, and generics. Research-based MNCs (the innovators) are the main providers of new innovative drugs, which are internationally-tested and recognised with proven safety, quality, and efficacy. To move forward, emphasis needs to be given to the transformation of the generic drug industry, talent sustainability, preparation for high-value pharmaceutical products, strategic partnerships and sustainable business models for R&D-based products.

Figure 28: Proposed Strategic Plan to Improve Malaysia's Generic Drug Industry

Transformation of generics industry in Malaysia

Current state	Transition	Globally competitive
High import-export ratio	Create a new cluster of export-oriented manufacturing facilities to complement existing resources	Export generic version of recently expired blockbuster products (prioritize strong markets such as OIC countries)
Limited export due to cost competitiveness	Prioritise local manufacturer for domestic market	Move into bigger value-added products such as enhanced generics and biosimilars product
Large purchase of imported drug by government	Tap large market for generic version of drugs with newly-expired patents	
Focus on small molecules		

Generic drug companies worldwide play a significant role by providing cheaper generic versions of branded drugs, which, in some medical conditions, have become the only hope to save lives in under-developed and developing countries. Since generic companies spend less on R&D, they are able to provide drugs at prices significantly lower than branded drugs. In Malaysia, the generic drugs industry needs to undergo transformation to remain competitive. The current situation in Malaysia's pharmaceutical industry depicts high reliance on imported drugs, which is supported by significant purchases of imported medicine by the government. The ripple effect of this situation is a low value in pharmaceutical product export and low-capacity utilisation.

Malaysia generic drug industry players need to explore the global market and target high-end generic products for export. The production of blockbuster products, enhanced generics, and biosimilar products will improve the quality of medicine supply and provide access to a wider market around the world. In Malaysia's case, the initial target market can be focused on the OIC countries for export. To empower the local pharmaceutical industry, local manufacturers need to be prioritised to cater to the needs of the domestic market, and at the same time, create a new cluster of export-oriented manufacturing facilities to complement existing resources.

Strategy for Malaysian Generics Products

Malaysia's local generic players need to move forward by transforming their vision and business models to become global competitors. The production of generic products needs to be upgraded to super-generic products, such as enhanced generics, combination products, or new formulations. This goal can be achieved by promoting growth and improving the productivity of the companies to enable exports, substitute imported products, and set a direction to move to higher value product.

Figure 29: Transformation of Generic Product

A revised business model is extremely important to bring the business to the next level. Malaysia's generic players can adopt lean and focused approach by initially focusing on selected markets, such as Organization of Islamic Cooperation (OIC) countries to maintain cost competitiveness. This geographical expansion will create access to larger markets, and the resulting economics of scale will enable the companies to grow. The new portfolio of products must focus on blockbuster generics with recently expired patents and concentrate on high-value therapeutic areas. The value chain should be focused on manufacturing with both upstream and downstream partnerships.

Strategising for a Robust Talent Pool in the Pharmaceutical Industry

Effective reward (monetary or non-monetary) and recognition strategies can become determinants of the success of a pharmaceutical organisation because highly engaged and motivated employees are more productive and offer superior service compared to those who are disengaged. A good compensation package connects employees and organisational goals, and it serves as a bridge between the macro issue of retention in an organisation and the micro behaviour of individuals within the organisation.

Financial rewards are given to employees as part of an economic exchange when they display exceptional performance in their roles and responsibilities. Malaysia must move towards high-value business activities and prepare a strategic plan to provide attractive packages for top talent in the industry. In some cases, the high currency value in Singapore enables it to attract the best local talent in the pharmaceutical field to work in Singapore.

In pharmaceutical manufacturing and product supply, investment in employee development has a positive impact on employee retention, improves the working attitude of employees, and eventually increases the profitability of the company. Innovative career development strategies are needed as catalysts to produce more talented workers for the field. Therefore, a knowledge-based economy is one of the key elements to drive sustainable talent in the industry. A knowledge-based economy refers to an economic system that builds on intellectual capital based on workers knowledge and the intellectual properties of products. It capitalises scientific discoveries and applies research.

As one of the fast-growing sectors in Malaysia, the demand for well-trained human resources has been a challenge for the pharmaceutical industry players. The existing education programs in Malaysia's higher learning institutions can be improved by offering more courses designed specifically for pharmaceutical manufacturing. Currently, there are a few academic programmes from local institutions which offer a Pharmaceutical Technology Bachelor Program. As a highly technical industry, the pharmaceutical workforce requires high-value skills to cater to the technical demands of pharmaceutical manufacturing operations.

Figure 30: Strategic Move for Capacity Building in the Pharmaceutical Industry

Higher learning institutions, government agencies, or private training centers can look into developing more specialised courses to train future talent for pharmaceutical manufacturing. The knowledge and practical training in areas such as API and dosage manufacturing, product granulation, compression, coating, and packing are critical for pharmaceutical manufacturing operations. Some big pharmaceutical companies have a state-of-the-art training facilities, equipped with small-scale prototype equipment and simulation laboratories for talent development. To empower professionalism in the pharmaceutical manufacturing workforce, recognition for technologists, engineers, pharmacists, and other operational positions in pharmaceutical manufacturing can elevate the standard and quality of the workforce.

Venturing into World-Class R&D in Clinical Research, Biologics, and the Manufacturing of High-Demand Traditional Medicines

There is a need for Malaysia to develop its local biologics manufacturing capabilities in response to the global shortage of biologics products. However, entry into the market is challenging due to costs associated with R&D, significant capital requirements, and the limited available of specialised expertise. To overcome these barrier, leveraging existing manufacturing capabilities can accelerate capacity building and minimise investment risks. This includes manufacturing of biosimilars or contract manufacturing opportunities. Besides, it is important to improve the existing pharmaceutical-related educational structure to cater to the challenge of a limited supply of industrial pharmacists, who are in high demand to support the R&D of biologics.

The global pharmaceutical industry is characterised by significant investment in R&D and the new discovery of new products. Most of the R&D activities in the industry are carried out by large MNCs. The funding originates from the profits generated from the exclusive right granted to a patent holder during the patent's lifespan. The exclusive right creates substantial market power, which enables wide margins between price and cost. In Malaysia, R&D activities in high-value products are scarce. Research-based pharmaceutical companies operate in a high-risk, high-reward environment. A long period of marketing approval and the high cost of R&D are the two main barriers preventing local companies from entering the market.

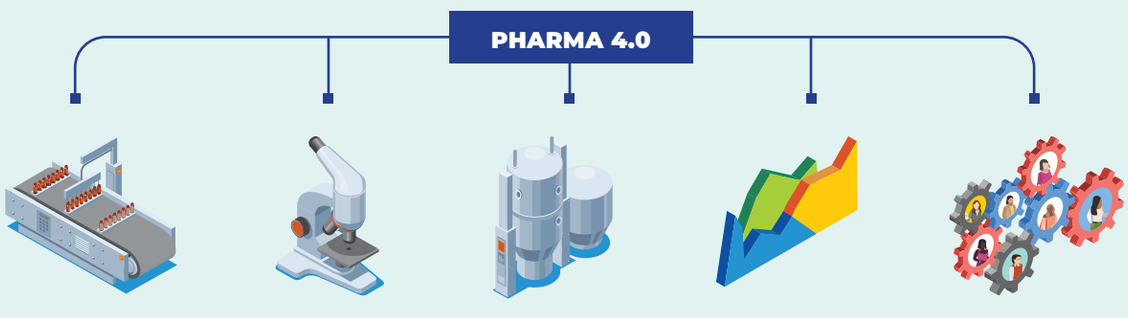
Malaysia has access to rich medicinal flora, with more than a thousand species of vascular plants, which creates opportunities for cost-effective extraction and manufacturing. The government needs to provide support through incentives and dedicated policy roadmaps to foster an ecosystem for innovation and growth. Driving investment in the botanical market will create opportunities for employment and enhance research capabilities. It is imperative for Malaysia to scale up operations by focusing on activities ranging from raw material extraction to the production of niche botanical materials. This will help develop traditional medicine products that are recognised globally such as traditional Chinese medicine and Ayuverda.

For a clinical research hub, Malaysia has the potential to become a leading early-stage clinical research hub due to its diverse genetic pool, which makes it easier for research on rare and chronic diseases. Developing Malaysia's early-stage clinical research can increase access to drugs for non-communicable diseases and improve treatment inclusivity for local communities. The development of clinical research in Malaysia contributes to the further development of skilled workers, which attracts more research projects to be funded by MNCs in Malaysia.

Industry 4.0 for the Pharmaceutical Industry

Industry 4.0 brings together emerging technologies such as artificial intelligence (AI), the internet of things (IoT), robotics, and advanced computing to change the landscape of manufacturing. In pharmaceutical manufacturing, the application includes supply chain-related data such as raw materials variability and global tracking of materials across facilities, manufacturing operation procedures, operator workflows, real-time operations monitoring by video, video-based training, and centralising quality event data for improved decision-making.

Figure 31: Digital Transformation in Pharmaceutical Industry



Pharma 4.0 is the adaptation of the Industry 4.0 concept in pharmaceutical manufacturing. The pharmaceutical industry needs to move from manufacturing drugs and vaccines in batches to optimised the manufacturing process with a continuous improvement focus. This will be critical for the pharmaceutical industry to increase its yields. Pharmaceutical manufacturers will need to invest in analytics to help develop digital twins of their operations to prepare their production lines for continuous manufacturing. Other adaptations of IR 4.0 in the pharmaceutical industry can be summarised as follows:

Blockchain

The disruptive impact of blockchain technology on the pharmaceutical sector is both significant and visible. The pharmaceutical business benefits greatly from blockchain technology at every stage of drug development and distribution. Due to the sensitive nature of the data, stakeholders in the pharmaceutical sector are discreet about their information. Blockchain is a viable tool for tracking and safeguarding the pharmaceutical transaction ecosystem, addressing global supply chain vulnerabilities, accelerating collaborations among companies, as well as reducing fraud and assuring product authenticity.

Real-time Data

Real-time data acts as a catalyst for innovation and transformation. The pharmaceutical sector is being reshaped by the availability of real-world data provided by the Internet of Things (IoT), sensors, and wearables. Real-time data contains information about a patient's health, treatment information, and health reports that are collected regularly. It can generate actionable evidence through professional services, data science and analytics on medicinal needs.

Artificial Intelligence

The pharmaceutical industry R&D has traditionally faced the slow rate of medication discovery and development. Pharmaceutical discovery can now be transformed and accelerated through sophisticated AI tools and approaches. Artificial intelligence is assisting industry players in accelerating R&D, lowering medicine prices, and increasing regulatory approval rates. In the discovery and development of drugs, particularly in clinical trials, patient identification is critical. To recruit patients for clinical trials, pharmaceutical corporations can use AI. While AI can be used to analyse clinical trial data, it can also be used in the pharmaceutical industry to find people who will participate in them. AI is a powerful tool for pharmacovigilance, such as improving drug safety, providing real-time monitoring of the drug manufacturing process, and determining drug efficacy.

Flexible Production

Pharmaceutical needs and challenges have evolved drastically over the last decade. The conventional pharmaceutical production methods are rigid and incapable of adapting to evolving demand. A flexible manufacturing system (FMS) enables industry players to increase or decrease production based on demand and need. To optimise manufacturing costs, it relies on computerised systems and merges multiple production models. Furthermore, flexible manufacturing reduce energy usage, boosts productivity, and reduces waste.

Digital Therapeutics

The growing demand for digital-therapeutic products and tools across the healthcare ecosystem has attracted significant investor interest. Digital therapeutics use software to deliver evidence-based treatment interventions aimed at preventing, managing, or treating a medical ailment or disease. While the term 'digital therapies' is often broadly defined to include millions of health and wellness wearables and mobile applications, the technologies used to demonstrate the effectiveness of pharmacological therapies and support drug research are significantly more advanced.

Big Data and Analysis

The pharmaceutical industry depends on high-performance technologies to extract insights from the huge volumes of data generated during the drug discovery and development process. Data management and security are critical areas of concern for pharmaceutical businesses because they need third parties to share data with collaborators. However, with big data and analytics solutions, historical and real-time data are now becoming valuable assets for pharmaceutical companies. Big data is transforming all key aspects of the business, including monitoring drug reaction, R&D costs, effective clinical trials, collaborations, and drug discovery.

Additive Manufacturing

For medical applications, additive manufacturing (AM) offers customisation based on unique patient data and needs. As it enables the production of personalised dosage forms and more sophisticated drug-release profiles, AM or commonly known as 3D printing, can be an innovative alternative approach for developing controlled release dosages. By depositing material according to computerized 3D design data, this technique creates parts layer by layer. Significant efforts are underway to develop powerful 3D printers capable of producing tissues or cells. The 3D printing of human tissues is beneficial to drug development, organ engineering, and regenerative medicine. This allows for the development of age-or physiology-dependent medicinal formulations. Aside from personalisation, additive processes can also eliminate the need to hand-produce multiple versions of a trial medicine.

Precision Medicine

Precision medicine is based on the concept of treating each patient as an individual. The ultimate goal, whether at the clinical level or during drug discovery and development, is to adapt treatment to the needs of the most appropriate group of patients. Advances in data analytics are providing new insights into how the human body responds to drugs. As a result of these and advanced manufacturing techniques, personalised medicine is becoming a reality. Drug exposure models are used to examine the pharmacokinetic and pharmacodynamic properties of drugs to determine the proper dosage based on age, sex, comorbidities, and other clinical information.

Extended Reality Technology

In medicine, extended reality (XR) is transforming medicine and patient care like never before. Mixed reality (MR), virtual reality (VR), and augmented reality (AR) technologies are being explored by pharmaceutical entrepreneurs in the areas of research and manufacturing. XR has a wide range of applications in the healthcare sector, including the development of surgical simulators for training medical providers, facilitating collaborations among multiple surgeons using an XR-based immersive interactive app solution, as well as exploring the acceleration of product development, testing, and delivery.

Exploring the Potential of Halal Pharmaceuticals

Malaysia's halal pharmaceutical industry has made significant progress and falls under the jurisdiction of the Department of Islamic Development Malaysia (JAKIM). The industry has expanded in recent years to meet the growing demand for halal-certified medicines among Muslim consumers.

The increasing global Muslim population and rising demand for halal products present substantial opportunities for the halal pharmaceutical sector. According to the State of the Global Islamic Economy Report 2022, the halal pharmaceutical market was valued at USD 100 billion in 2021, with an estimated growth of 6.7% in 2022 to reach USD 106 billion. It is projected to further increase to USD 129 billion by 2025, reflecting a four-year CAGR of 6.7% (Sullivan, 2022). In Malaysia, key players in the halal pharmaceutical industry include Duopharma Biotech Berhad, Ain Medicare Sdn. Bhd., and Pharmaniaga Berhad.

As a systematic mechanism for adhering to Islamic principles in the production and distribution of medicines, Malaysia has become a global leader in halal pharmaceuticals, supported by stringent certification processes, well-organised regulatory bodies, and growing industry collaboration. To achieve halal certification, pharmaceutical products must be registered with the National Pharmaceutical Regulatory Authority (NPRA) before undergoing a voluntary halal audit by JAKIM. Under current compliance practice, halal certification is considered a business-driven decision. JAKIM provides comprehensive halal audit guidelines, aligned with the requirements of the Halal Pharmaceuticals Standard MS2424:2012 (Halal Pharmaceutical Guideline), which is recognised as the first halal pharmaceutical standard in the world. The Halal Pharmaceutical Guidelines outlines the general guidelines for the manufacturing and handling of halal pharmaceuticals, ensuring halal principles are incorporated throughout the manufacturing process.

Strategically, Malaysia has positioned halal-certified pharmaceuticals as a major economic initiative for post-pandemic economic recovery. The government has implemented the Halal Industry Master Plan 2030 (HIMP 2030), a comprehensive framework aimed at leveraging Malaysia's capacity for the holistic development of its halal industry. Events such as the Malaysian International Halal Showcase (MIHAS) play a pivotal role in the industry, as they serve as platforms for local and global halal certification bodies to converge, fostering collaboration and promoting the growth of halal industries.

The challenges in the Halal pharmaceutical industry are summarised below:

- **Risk of Cross-Contamination**

One of the most challenging elements in pharmaceutical products' halal integrity is the risk of cross-contamination. Manufacturing facilities that produce both halal and non-halal products pose cross contamination risks. The development of unique halal pharmaceutical products requires proper research, production, and logistic facilities due to the need to identify halal alternatives for ingredients sourced from non-halal origins or containing potentially non-halal additives. Consequently, ecosystem-building and strategic collaboration with halal science experts must be seriously considered. Stringent measures involving distinct production lines, dedicated equipment, and strict cleaning protocols should be implemented throughout the manufacturing process to lower contamination risks. Such precautions can prevent unintentional contamination and uphold the halal integrity of end products.

- **Authentication of Pharmaceutical Products**

The specific Islamic attributes of the halal pharmaceutical products lead to challenges in complying with halal standards. Halal pharmaceutical product elements, such as the manufacturing process, certification procedures, and consumers' product perceptions, are important factors to ensure the sustainability of halal products. The authentication of pharmaceutical ingredients has been a continuous challenge in this industry.

Pharmaceutical formulations include a wide range of active and inactive components, some of which may originate from various animal sources, including animals which is classified as "non-halal". Thus, pharmaceuticals labelling their products as halal must perform extensive research, documentation, and compliance monitoring to ensure that all ingredients and manufacturing procedures comply with the necessary standards. The sourcing and manufacturing of each ingredient must be extensively examined and verified to ensure its halal compliance.

- **Halal Certification**

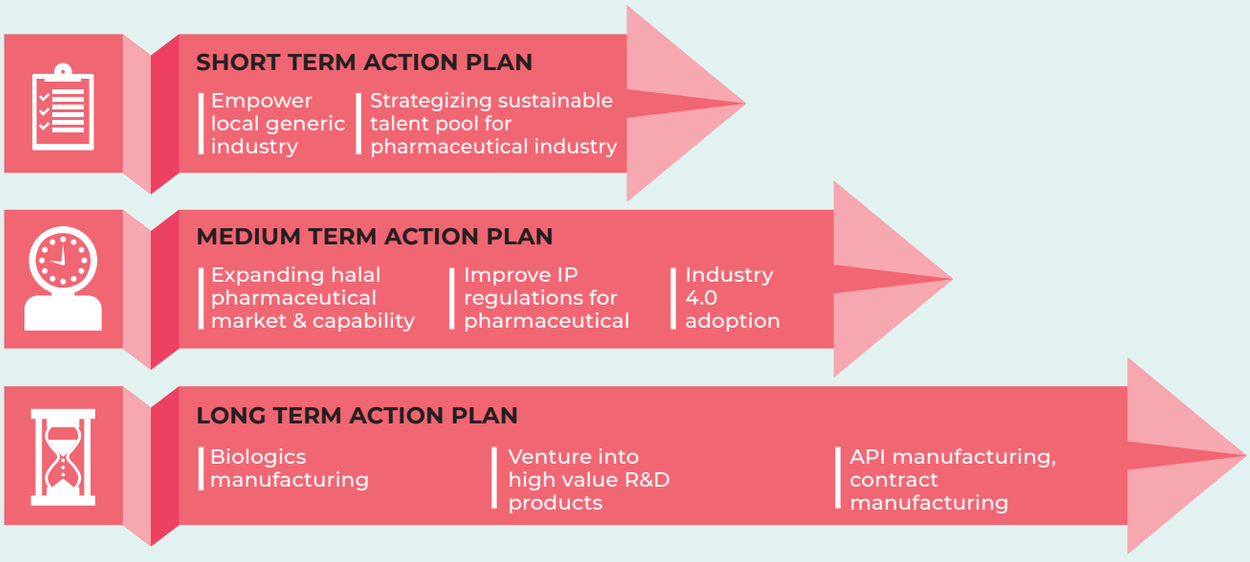
Certification requirements and the interpretation of halal requirements form the backbone of halal pharmaceuticals. However, it can be challenging for industry players due to the stringent and time-consuming processes required for compliance. In Malaysia, Halal labelling for pharmaceutical products must meet regulatory compliance under the purview of JAKIM. This regulatory body is responsible for halal certifications in Malaysia. Local pharmaceuticals must adhere to JAKIM regulations to obtain halal certification. Despite being complex and time-consuming, it is crucial to comply with specific nations' halal regulations and certification requirements by understanding and fulfilling the diverse regulatory frameworks and documentation requirements of different jurisdictions. The important elements for pharmaceutical manufacturing are stipulated in MS2424:12 and PIC/S GMP Guidelines as shown below:

Figure 32: MS2424:2012 Fundamental for Halal Pharmaceutical in GMP

4.2 Short-Term and Long-Term Recommendations

As a way forward, eight (8) key recommendations can be categorised into short-term, medium-term and long-term plans to elevate Malaysia's pharmaceutical industry to the next level. A synergistic effort between the government and the private sector is crucial to transform Malaysia to become globally competitive. The short-term action plan involves improvements expected to be achieved within one (1) to three (3) years, the medium-term plan covers a period of approximately five (5) years, and the long-term plan spans up to ten (10) years from now.

Figure 33: Eight (8) Recommendations to Drive Malaysia's Pharmaceutical Industry



The recommendations above are also aligned with the New Industry Master Plan (NIMP) 2030 for the pharmaceutical industry, which identifies biologics, active pharmaceutical ingredients (APIs), the manufacturing of niche botanicals, and halal medicines as key growth segments for the pharmaceutical sector. The NIMP is designed to drive Malaysia's trajectory as a global leader in industrial development, expand domestic linkages, generate national wealth, as well as strengthen the country's role in the global value chain.

In the Malaysian context, the buildup of the strategic planning for the pharmaceutical industry must focus on strengthening the pharmaceutical talent pool and empowering the generic medicine industry. These two (2) factors can serve as determinants of a strong foundation for the industry. The generic medicine industry is developing in Malaysia and is expected to grow stronger due to domestic demand and opportunities to explore the international market. The strengthening of human capital development will provide support for industry to grow. Local talent needs to be groomed systematically to ensure a sustainable supply of talent to the industry.

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