AUSSENWIRTSCHAFT AUSTRIA

AUSSEN WIRTSCHAFT BRANCHENREPORT MALAYSIA

HEALTHCARE - LIFE SCIENCE
(PHARMACEUTICALS, BIOTECHNOLOGY, CLINICAL RESEARCH, MEDICAL EDUCATION, VETERINARY SCIENCE)

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1. INTRODUCTION TO MALAYSIA: SOCIETY, ECONOMY, POLITICS

A federal constitutional monarchy, Malaysia consists of 13 states and 3 federal territories. Its landmass is separated into Peninsular (where the country's capitals Kuala Lumpur and Putrajaya can be found) and East Malaysia on Borneo by the South China Sea.

The population of Malaysia is estimated at 34.1 million in Q3 of 2024 (+1.6 % y-o-y growth), consisting of 30.7 million (90 %) Malaysian citizens and 3.4 million (10 %) non-citizens. This reflects a return to status quo from the COVID-era when restrictions in international travel led to a sharp decrease in non-citizens. The Malaysian population is made up of a wide variety of ethnic groups, with the majority (70.1 %) being Bumiputras ("Son of the Soil"). 22.6 % of the Malaysian population is under the age of 15 and 70 % are between the ages of 15 and 64, making the average population relatively young, though with 7.34 % of the population being over 65, Malaysia is already considered an aging society, further expected to reach "aged" status (over 14 %) in 2030. Due to the country's multicultural demographic, the majority of its residents grow up multilingual and speak at least two languages fluently. In large cities this generally includes English, which is the language of business throughout the country.

Malaysia ranked 59th out of 173 countries according to the World Bank's Human Capital Index. In order to realize the full potential of its population, it will greatly need to make further progress in education, health, and nutrition, as well as in the outcomes of social protection. Improving the quality of school education, rethinking nutritional interventions, and providing adequate social protection are therefore among the main priority areas.

Malaysia is one of the leading nations in the Southeast Asian economic area: the gross domestic product (GDP) per capita was USD 13,140 in 2024 and is expected to continue its upward trajectory to reach USD 14,420 in 2025. Today Malaysia can be seen as a stable emerging country with a diversified economy. In addition to a traditionally strong agricultural sector, the production and service sectors also make a large contribution to the economy. Meanwhile, the country has become a leading exporter of electrical appliances, electronic parts, and components.

According to the World Bank, Malaysia is one of the most investment-friendly economies in the world. This has been a major contributor to job creation and income growth. After the global financial crisis in 2019, the Malaysian economy recorded average growth rates of around 6 %. However, this growth slowly flattened out over the years and was 4.4 % in 2019. According to Bank Negara (Malaysia's central bank), this was the lowest economic growth since the Great Financial Crisis and was mainly due to lower production of palm oil, crude oil and natural gas, as well as a decline in exports amid the trade war between the US and China. Due to the unstable political situation and the effects of the COVID-19 virus, the economy shrank by -5.5 % in 2020.

Post-COVID-19, 2021's year-end saw a modest recovery of +3.3 %, and it strengthened further in 2022 with +8.7 %, due to the border reopening in April 2022, allowing a fairly strong economic recovery, as the trade and tourism sectors are among the strongest contributors to GDP. In 2023 this moderated to +3.7 % but strengthened to +4.8 % in 2024. The IMF's prediction for 2025 (as of February 2025) is +4.4 %.

The current economic indicators per the Economist Intelligence Unit (EIU) forecasts (as of Jan 2025) are as follows:

Key Indicators	2025	2026	2027	2028	2029
Real GDP growth (%)	4.7	4.5	4.8	4.9	4.9
Consumer price inflation (%)	2.2	2.3	2.2	2.3	2.0
Government balance (% of GDP)	-3.7	-3.6	-3.5	-3.2	-2.9
Current-account balance (% of GDP)	2.3	1.2	1.6	2.3	2.3
Short-term interest rate (%)	3.5	3.6	3.6	3.5	3.4
Unemployment rate (%)	3.4	3.7	3.6	3.4	3.5
Exchange rate (USD:MYR)	4.44	4.54	4.54	4.46	4.33

[a] Actual [b] EIU forecasts [c] EIU estimates

A detailed statistical analysis can be found in the Country profile Malaysia.

In the medium term, it is expected that Malaysia will successfully transition from an "upper middle-income economy" to a "high income economy" between 2024-2026. According to the World Bank, Malaysia's economy will depend heavily on government measures to strengthen the private sector in the short term. Currently, the external environment makes export-oriented growth difficult, while local or investment-based expansion remains limited as the country recovers from the pandemic. Other factors impeding growth are higher-than-reported inflation rates, and a weak currency.

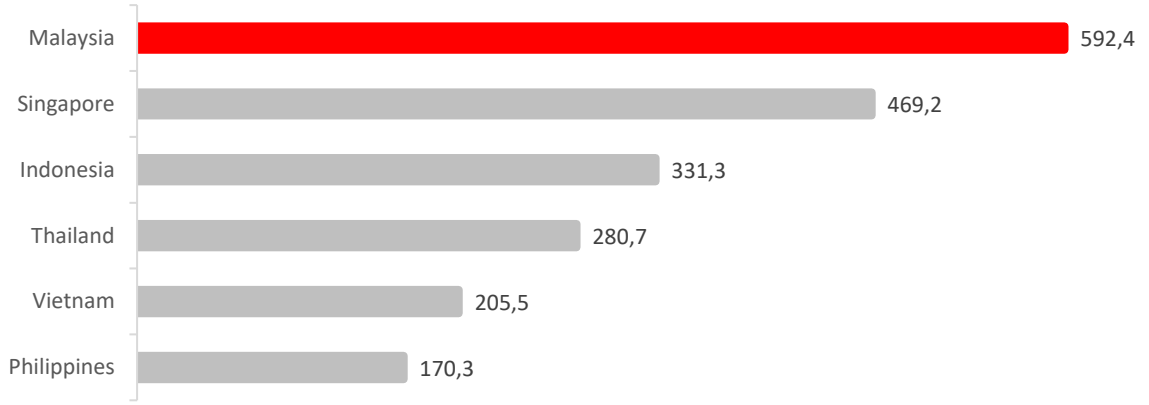
In the long run, economic growth will depend on increasing productivity levels. Although the productivity level in Malaysia has risen sharply over the past 25 years, it is still below that of several regional countries by comparison. Ongoing reform efforts are crucial.

At the political level, Malaysia is also far from stable. In 2018 the ruling coalition Barisan Nasional, which had been the dominant party, was defeated by the opposition for the first time since Malaysia's independence. This gave the country a strong, if temporary, upturn in sentiment. However, the resignation of the Prime Minister two years later, in February 2020, and that of his successor in August 2021, showed that the country still appears to be at a political impasse even after a change of government. The 15th General Election was held November 19th 2022. You can find more about the current political situation in our Economic report Malaysia, as well as our Malaysia country report.

2. STATUS QUO

Malaysia's Economic Relations with Austria

The importance of Malaysia for Austrian foreign trade is often underestimated and lesser known compared to other countries in the ASEAN community. In reality, however, the situation is very different, as the following graphic illustrates.



Foreign trade - Austria's exports in 2023 to the most important ASEAN countries in EUR million (source: Statistics Austria, 2024)

With EUR 402.7 million in Austrian exports in 2020, EUR 469.2 million in 2021, EUR 561.4 million in 2022, and 592.4 million in 2023 **Malaysia has ranked first among the ASEAN buyer countries for three consecutive years**. Singapore was in second place with EUR 496.2 million, followed by Indonesia and Thailand.

Exports to Malaysia have seen an especially strong growth in recent years (+23.4 % in 2020-2021, and +13 % in 2021-2022). This eased in the 2022-2023 term to +5.5 %, but the continued growth reaffirms Malaysia's position as the most important buyer of Austrian goods and services in the ASEAN region. While Singapore also enjoys a strong position, in terms of export volume relative to population size, it is important to note that some of the export goods reported for Singapore have their final destination in Malaysia. This positions Malaysia as the biggest and one of the most promising future markets for Austrian companies in the region.

Austria also imported EUR 584.7 million worth of goods from Malaysia in 2023 – a 8.9 % decline from 2022's EUR 640.1 million. The majority of imports comes from HS codes 85 (Electrical Machinery, Equipment and parts thereof) and 84 (Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof): with values of EUR 304.5 million and 93.1 million respectively.

Regarding to pharmaceutical products (HS 3001 – 3006), Austria exported a total of EUR 10.597.378 worth of merchandise to Malaysia in 2023, with a breakdown of the export values in EUR below:

Code	Description	2022	2023
3001	Drüsen und andere Organe - Glands and other organs	0	0
3002	Menschliches und tierisches Blut Antisera udgl - Human and animal blood Antisera etc.	1.138.363	3.447.477
3003	Arzneiwaren nicht für den Kleinverkauf - Medicinal products not for retail sale	0	0
3004	Arzneiwaren für den Kleinverkauf - Medicinal products for retail sale	6.218.540	6.063.199
3005	Watte Gaze Binden Heftpflaster udgl - Cotton wool Gauze Bandages Adhesive plasters etc.	77	170
3006	Andere pharmazeutische Waren - Other pharmaceutical goods	753.591	1.086.532

(source: Statistics Austria 2024; *last available data up to 2024 Q3)

Malaysia's Healthcare System

The Malaysian healthcare system is a two-tier system, divided into public and private. All Malaysians have access to universal healthcare via government facilities with only a nominal charge for consultations and most treatments, while procedures and inpatient boarding are heavily subsidised. However, due to crowds, long queues, and the lesser availability of facilities, many citizens (if able) opt instead to go to private clinics or hospitals, which are faster and have a perceived better service. Therefore, despite approximately 52.7 % of total healthcare expenditure coming from the public sector (latest data reporting for 2023), private hospitals outnumber public ones, with 60 % of the existing structures (207 vs 137). While the government also encourages private investment to reduce the financial burden of its public health sector, the majority of hospitalisations and outpatient treatment still leans towards public healthcare, especially outside city centres.

In 2020, despite a sharp growth in health expenditure of +6.9 % YoY, with a value of RM 63.8 billion, the public sector contribution to GDP was only 2.6 % and total health expenditure remained only 4.7 % of GDP, far from the World Health Organisation's recommended 7 %. The impact of COVID-19 in 2020 led to an increase of RM652 million for the recruitment of new contract health personnel, for a total allocation of RM 1.9 billion. In 2021, this continued to increase as the country spent approximately RM 72.7 billion on its total health expenditure, but only marginally: approximately 5 % of GDP. For the 2021 national budget, the allocation to healthcare was focused on funding for development, maintenance and upgrades of facilities and medical equipment. Key sectors of development included improving access to healthcare, especially for rural areas; tele- and e-medicine; health tourism; and the management of Non-Communicable Diseases (NCDs). These themes remained important in Budget 2022, as 13.5 % of a RM 32.4 billion budget was earmarked for development expenditure. However, government contribution to health expenditure remained low: 2.58 % of GDP.

For Budget 2023, amidst a period of public health service crisis, the Ministry of Health (MoH) received a RM36.3 billion allocation (a 12 % increase), with RM3 billion earmarked for staff hiring. Other main components include procurement of medicines, reagents, vaccines, and consumables, while RM4.8 billion was allocated for development expenditure. At the end of 2023, government contribution was only at 2.4 % of GDP, and total health expenditure was at 4.6 % of GDP, still short of WHO's recommendation. The Madani Health Scheme was presented in Budget 2024 with the aim of increasing access to primary healthcare, especially for those from low-income backgrounds. The MoH received a RM41.2 billion allocation (a 13.7 % increase), of which a total of RM5.5 billion was allocated is for procuring medicines, consumables, reagents and vaccines.

For Budget 2025 (as presented in October 2024), the Ministry of Health received the second-highest funding allocation, totalling RM45.3 billion, a 10 % increase from the previous year. This trend is expected to continue as Malaysia prioritises its healthcare infrastructure, and health expenditure is now expected to increase at a CAGR of 8.7 % over the 2023-2038 period. Aside from the RM1.35 billion earmarked for the maintenance of public health infrastructure, with a further RM300 million allocated to the repair of dilapidated hospital toilets and patient wards in rural areas, private hospitals are also expected to strengthen their collaborations with the public sector, leading to increased demand for their services.

Malaysia's COVID-19 response was a testament to the capacity of its healthcare system and proved that the country is able to manage and contain a pandemic – Malaysia was initially one of the best countries in bringing its case numbers down to zero and had one of the fastest vaccination rollouts in Southeast Asia, remaining one of the highest fully vaccinated countries in the world. Post-pandemic, the country also began looking seriously at its capacity to develop its own vaccines.

A brief summary of key metrics in 2023 (latest available data):

Hospitals	214 **private**: 149 **public** (138 hospitals, 11 special institutions)		
Medical Clinics	10,495 **private** : 3,114 **public**		
Healthcare Provider to Patient Ratios	**Doctors** 1:406	**Nurses** 1:282	
	Dentists 1:2,343	**Pharmacists** 1:1,626	
Life Expectancy	**M** 71.8 years	**F** 76.6 years	
Childhood Immunisation Coverage	**BCG** 98.65 %	**DPT-HIB** 107.71 %	
	Hepatitis B 107.68 %	**MMR** 100.56 %	**Polio** 107.71 %

Source: MOH Health Facts 2024

Health Concerns in Malaysia

Non-communicable diseases (NCDs) represent a significant challenge within the Malaysian healthcare system, with pneumonia emerging as the principal cause of death in 2023, accounting for 18,181 deaths (15.2 %), surpassing ischaemic heart disease for the first time in two decades, with the exception of the impact of the pandemic in 2021. Ischaemic heart disease ranked as the second leading cause of death, accounting for 15.1 % of all fatalities, followed by cerebrovascular diseases (7.2 %) and transport accidents (3.5 %).

Pneumonia emerged as the predominant cause of death among Chinese and other Bumiputera communities, as well as among the population aged 60 years and above. The population aged 41-59 years recorded ischaemic heart disease as the primary cause of death, a condition that was also identified as the leading cause of death for Malay and Indian individuals. For the population below the age of 40, transport accidents were identified as the principal cause of death.

Diabetes is one of the top causes of death in Malaysia (15.6 %). The country also has an adult overweight and obesity rate of 54.4 %. The prevalence of childhood obesity is also increasing at an alarming rate in Malaysia, with over 30 % of children in the 5-17 years age range being overweight or obese in 2022.

Almost 2.3 million of the adult population in Malaysia live with three NCDs. Approximately 7.6 million adults have high cholesterol with a 33.3 % prevalence rate, and one in three adults in Malaysia is currently suffering from hypertension.

On the other end of the spectrum, malnutrition is also a concern, as the prevalence of childhood stunting in children aged below five years in Malaysia was 21.2 % in 2022. Furthermore, one out of five Malaysians (21.3 %) was estimated to have anaemia, representing 4.6 million people. The majority of them are women, with an estimated 30.4 % of women of reproductive age (15-49 years) reported to have anaemia; an MOH survey in 2019 noted that among Malaysian women of reproductive age group, the prevalence of mild anaemia was 15.9 %, while moderate and severe anaemia made up 14 %.

The COVID-19 pandemic has highlighted the above issues, as those with pre-existing issues were most susceptible and had more adverse or severe reactions. As with other countries, there are also new worries about the long-term impact of Covid-19, including respiratory, cardiac, and neurological issues. A MOH press statement in February 2022 also stated that 10 %-15 % of those infected with Covid-19 have Long Covid (although the worldwide prevalence is expected to be as high as 43 %). There is also emerging data that up to 20 %-30 % of asymptomatic infections may also result in persistent symptoms.

For Communicable Diseases, the most common concerns are Vector-borne (usually transmitted by mosquitoes) diseases such as Dengue and Malaria, food/water borne diseases like food poisoning (notably in rural states) and other Infectious Diseases like Hepatitis B & C, Hand Foot Mouth Disease, Tuberculosis.

VIEW OF THE FUTURE

According to a 2018 report by Fitch Solutions, the total market size for healthcare in Malaysia is expected to rise to RM 127.9 billion (USD 30.5 billion) by 2027, a growth of 127 % over ten years. This remains in line with their updated report dated 10 November 2021 that expects Malaysia to spend RM 69.2 billion (USD 16.6 billion) on healthcare in 2021, a +9.6 % YoY growth. They also forecast a five-year CAGR (compound annual growth rate) of +8.9 % to reach RM 91.1 billion (USD 23.0 billion) by 2025.

Per MIDA's 2021 report, health services brought in RM 741 million of investment in 2021, creating almost 900 new jobs. Seven projects with investments of RM 419.5 million were for pharmaceutical products. This trend is expected to continue in the coming years: the private healthcare services market in Malaysia is anticipated to grow steadily at a CAGR of +9.6 % from 2022 to 2026, underpinned by overall population growth, an ageing population (14.3 % over 60 by 2030 and increased life expectancy), increasing incidence of non-communicable diseases, and the emergence of new and recurring pathologies.

For 2022, MIDA notes RM 2.14 billion of investment in health services, of which the pharmaceutical sub-sector saw an FDI contribution of RM180.9 million. Per the 2022 Investment Performance report, Malaysia's healthcare sector is supported by a growing and vibrant scientific and measuring equipment industry through the production of laboratory diagnostics platforms and measuring instruments and apparatus. While the industry's main driver is the medical devices sub-sector, there is also a focus on funding domestic research facilities for diseases and vaccines.

According to the 2023 Investment Performance Report, the service sector continued dominating Malaysia's economic growth, being accountable for 51.1 % of total approved investments in 2023. In health services, MIDA noted approved investments worth RM 727.4 million. Out of these, a total of RM 347.5 million (47.8 %) were domestic and RM 379.9 million (52.2 %) were foreign investments. There were four approved projects in the health service sector and a total of 710 job opportunities.

Malaysia's healthcare sector also continues to see strong growth, with the medical tourism industry playing a pivotal role. Tourists are attracted by lower costs, shorter waiting times, and access to specialized medical expertise. As of 2023, the number of individuals travelling to Malaysia for medical purposes exceeded one million, contributing to a total revenue from medical tourism estimated at RM1.7 billion.

As stated during the International Health Care Week 2025 in October 2024, Malaysia's private healthcare and medical tourism sector is expected to generate RM2.2 billion in revenue in 2024.

Pharma

The global pharmaceuticals industry is expected to grow by a CAGR of 3-6 % to USD1.6 trillion in 2025, with Asia Pacific being the second-largest market in the world, accounting for approximately 26 % of the market share. In Malaysia, the pharmaceuticals industry is capable of producing a wide range of products such as sterile preparations, injectables and infusions, capsules and tablets, and time-release and liquid medications.

In Malaysia, the pharmaceuticals market has been experiencing growth due to various factors, including increasingly health-conscious consumers and an ageing population, leading to a higher demand for pharmaceutical products or medication for chronic diseases. According to the Pharmaceutical Association of Malaysia (PhAMA), the pharmaceutical segment is expected to contribute MYR10 billion to the nation's GDP in 2024. The association notes that over 445 pharmaceutical companies with a total market value of MYR7.5 billion (2018) have invested in products spanning across the healthcare supply chain in Malaysia.
One unique aspect of the Malaysian pharmaceutical market is the dominance of local companies, which have a strong presence in the market and are able to compete with multinational corporations, especially when it comes to manufacturing: most MNCs in Malaysia act as sales and distribution hubs only. Additionally, the government plays a significant role in regulating the industry, with strict requirements for product registration and pricing. In line with the government's efforts to control pricing, they have also been promoting the use of generic drugs to reduce healthcare costs.

In recent years, the domestic industry has increasingly focused on COVID-19-related activities, seizing opportunities by leveraging the worldwide scarcity in specific products related to the pandemic. It is worth noting that the industry's ecosystem remained resilient despite the movement restrictions and border closures. Recognizing the pharmaceutical industry's great potential, the government continues to encourage investments involving cutting-edge innovations and technologies to spur the local pharmaceutical ecosystem towards producing high-value-added products.

Given Malaysia's established pharmaceutical ecosystem, R&D capabilities, available incentives and abundance of natural raw materials, the government is pushing the industry to grow beyond the production of generic drugs and fill-and-finish vaccines towards undertaking clinical trials and drug development. COVID-19 has also jumpstarted the country's drive to develop its own vaccinations, as well as infectious disease control, with government plans for new R&D centres to be established, and the planned Vaccine Development Roadmap that envisions Malaysia as a powerhouse for vaccine manufacturing in Asia. This presents ample opportunities for Austrian companies in the sector who might be interested in cooperation.

Biotechnology
The global biotechnology market was worth USD627.63 billion in 2020 and is projected to grow at a CAGR of 8.57 % until 2026 driven by new developments in drug discovery for various diseases, for example the R&D for COVID-19 vaccines and treatments greatly stimulated growth in the biotech industry.

In Malaysia, investors can consider the various opportunities to develop biopharmaceutical and biomedical solutions that enhance the quality of healthcare provision for the domestic and global markets. An example of such a solution is the advent of personalised or precision medicines. Rather than having drugs and medicines created on a 'one-size-fits-all' basis, which has traditionally been the case, modern genomics makes it possible to tailor specific medications for individuals depending on the makeup of their DNA.

In the healthcare sphere, biotechnology research is also important for bioinformatics, proprietary tech, biosimilar, biobetters, new entities, vaccines, IVD, stem cell, or cellular medicines.

Other important sectors include agricultural biotechnology – notably solutions to help the nation achieve self-sufficiency in food, agricultural upscaling, or sustainable farming. Key Agri-Food focuses include ingredients for pharmaceuticals, nutraceuticals, cosmetics, and fragrances. Technology to aid in livestock and aquaculture development, animal health & nutrition, or crop health are also important targets.

With Malaysia pursuing its Net Zero goals, bioindustry as it pertains to the circular economy or ESG also has strong potential. This includes bio-based materials (e.g. bioplastics, bioadhesives, biofibres) that reduce environmental pollution, as well as biogas or biohydrogen as energy sources.

12th Malaysia Plan (12MP, 2021-2025)
The Malaysian government regularly sets its strategic goals and formulates fundamental commitments to economic policy pursued in 5-year plans. The medical and healthcare sector has always played a role in Malaysian economic planning, from the formation of the Rural Health Service back in the First Malaysia Plan (1MP, 1966-1970), which succeeded in reducing the gap in quality of healthcare between rural and urban areas, to developments in the 9th Malaysian Plan (9MP, 2006-2010) which allowed for the setting up of national institutions such as the National Institute of Cancer, National Institute of Forensic Medicine and National Institute for Oral Health (under the Oral Health Program by the Ministry of Health).

Under the auspices of the 11th Malaysia Plan, the T&CM Blueprint 2018-2027 and a preliminary Regulatory Framework and Guidelines for T&CM Private Health Care Facilities and Services were developed, in order to ensure safe and quality practices of traditional and complementary medicine and catalyse the development of the T&CM industry in Malaysia. The growth of the T&CM industry is expected to create revenue worth RM 20 billion by 2027.

The latest 12th Malaysia Plan (2021-2025) sees obvious influences from the ramifications of COVID-19 and the importance of a robust healthcare system. With its "Game Changer V: Revitalising the Healthcare System in Ensuring a Healthy and Productive Nation", it seeks to embrace a whole-of-nation approach for better

management of future outbreaks and health crises. In order to revitalise healthcare services, resources and responsibilities will be consolidated and healthcare services will be redesigned through collaboration between the public and private sectors. There are also plans to introduce more sustainable health financing and to digitalise and accelerate the delivery of healthcare services.

Among the goals and targets in the area of healthcare and medical advances are:

- National Vaccine Development Roadmap
- Malaysia Institute of Contagious Diseases to be established in Bandar Enstek in 2022
- National Health Literacy Policy
- improving the doctor to population ratio to 1:400, and hospital beds per 1,000 population to 2.06
- reducing the gap in access to healthcare, notably in rural areas

The advent of the 2019 pandemic has underscored the imperative to be prepared for future crises by developing local capabilities in vaccine R&D and manufacturing. The National Vaccine Development Roadmap is a strategic initiative aimed at enhancing Malaysia's capacity to produce vaccines. It is predicated on the vision of attaining self-sufficiency in this domain within a decade. The overarching objectives of the roadmap encompass the domestic manufacturing of vaccines, the attainment of sufficient development to facilitate the transition to homegrown vaccine production, and the establishment of a robust vaccine infrastructure that contributes to the biotechnology ecosystem, all by the year 2030.

As announced during the Twelfth Malaysia Plan presentation, the government has decided to establish a "National Centre for Disease Control" (NCDC) in Bandar Enstek in 2022, serving as a Special Diagnostic and Reference Laboratory to prevent infectious diseases in the future. The construction progress of the NCDC began in October 2021 and has reached 45 %, as of the present moment. It is expected to be fully completed by July 2026.

National Biotechnology Policy (2005-2020 & 2022-2030)

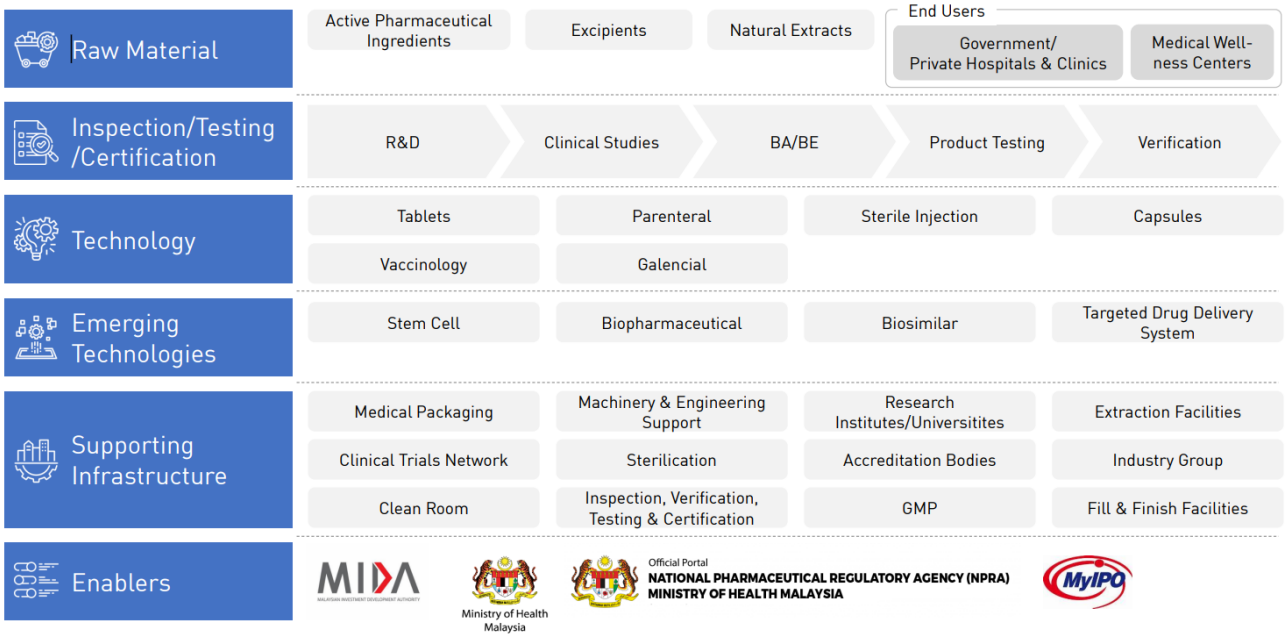
In Malaysia, the biotech industry has transitioned from its traditional applications towards renewable, non-toxic, and cost-competitive products. Launched in 2005, the National Biotechnology Policy (NBP) outlined the development of three biotech economic sectors; namely, agriculture, healthcare, and industrial manufacturing, with a steadily growing biotech ecosystem comprising various innovation centres and academic research entities. The goal was to develop biopharmaceutical and biomedical solutions that would enhance the quality of healthcare provision for the domestic and global markets. An example of such a solution is the advent of personalised or precision medicines, where rather than having drugs and medicines created on a 'one-size-fits-all' basis, modern genomics make it possible to tailor specific medications for individuals depending on the makeup of their DNA.

An updated policy was launched in 2022: the National Biotechnology Policy 2.0 (NBP 2.0) which focuses on agricultural biotech for food security, healthcare, industrial biotech, circular economy, and bio-innovation development until 2030. NBP 2.0 aims to strengthen the existing ecosystem and resolve challenges related to food security, pandemic management, and climate change crises management. Among the targets are to have 30 % globally active BioNexus status companies, contribution of 5 % to GDP by biotech companies, creation of 3 bio-innovation firms with unicorn status.

The NBP 2.0 will assist local companies to move up the value chain by adopting cutting-edge technology to compete in global markets. The Government encourages active participation from stakeholders such as the MBDC; National Institutes of Biotechnology Malaysia (NIBM); local venture capital companies and government-linked companies (GLCs) to support the biotech industry's growth and explore participation in the global market; and commercial banks to offer financing. Further funding assistance of RM5 million was allocated to the Bio-based Accelerator (BBA) programme to boost the development of local companies in the biotechnology industry.

3. PHARMACEUTICAL INDUSTRY

The current ecosystem of Malaysia's pharmaceutical industry*



*Information extracted from MITI's report on the Pharmaceutical Industry 2017 (latest available)

As with most countries, the pharmaceutical industry in Malaysia has been growing steadily. In 2024, the projected revenue in the pharmaceuticals market in Malaysia was expected to reach €1.579 billion, with an anticipated annual growth rate of 4.51 %, as measured by the compound annual growth rate (CAGR) from 2024 to 2029, to achieve an estimated market volume of almost €2 billion by 2029. Due to rising healthcare costs, Malaysia's pharmaceutical market is experiencing a surge in demand for generic drugs.

Major local companies tend to focus mainly on generic and halal drugs, particularly antibiotics, painkillers, health supplements and injectables. Malaysia has the capability to produce almost all dosage forms, including sterile preparations such as eye preparations, injections, soft gelatine capsules and time-release medications. In January 2002, Malaysia was admitted as the 26th member of the Pharmaceutical Inspection Cooperation/Scheme (PIC/S).

The market structure of Malaysia's pharmaceutical sector is characterized by a three-level supply chain: manufacturers of generic medicines and importers of originator and generic medicines; wholesalers and distributors; and providers of medicines to patients and end users.

As for distribution channels, Malaysia has a robust healthcare system with **two tiers**: public and private. The distribution channels include:

1. **Hospital Pharmacies**: These serve patients within hospitals and medical centers.
2. **Retail Pharmacies/Drug Stores**: These are accessible to the general public for over-the-counter (OTC) medications.
3. **Other Channels**: These may include specialized clinics, e-commerce platforms, and direct sales from pharmaceutical companies.

Malaysia's strategic location in Southeast Asia, along with its supportive infrastructure and business-friendly policies, makes it an attractive hub for pharmaceutical manufacturing and distribution.

The government also invests heavily in local R&D, in its efforts to improve Malaysia's standing particularly in biotechnology. Meanwhile, foreign-owned companies either have a manufacturing presence or are licensed importers which rely on their local subsidiaries for distribution.

Per MIDA's 2022-23 report, there are more than 275 pharmaceutical manufacturers in Malaysia licensed by the Drug Control Authority (DCA), Malaysia's governing body for the registration, licensing, and monitoring of pharmaceutical, health, and personal care products under the Ministry of Health (MOH). Of this figure, 176 of the manufacturers (64 %) are categorised as traditional medicine and health supplement producers, 88 (32 %) as being pharmaceutical producers, and 11 (4 %) are veterinary products producers.

Malaysia's manufacturing industry also complies with certifications and international standards such as the European Good Manufacturing Practice and ISO 17025, while the country is also a member of the PIC/S convention, meaning that its products are generally accepted worldwide.

The pharmaceutical products in Malaysia can be broadly classified as:

- New Drug Products (NDPs) including new chemical entities (NCEs)
- Generic products (both prescription medicine and OTC)
- Biologics
- Health and food supplements
- Traditional & complementary medicine (TCM)
- Veterinary products

Key sectors of development in this industry include manufacturing of generic drugs, herbal medication, Active Pharmaceutical Ingredients and other value-added items like vaccines, biopharmaceuticals, NCEs or novel delivery systems. Other topics of interest include Halal pharmaceuticals, specialised pharmacotherapy, and solutions to combat counterfeit products.

New Drug Products

NDPs are defined as any pharmaceutical product that has not been previously registered in accordance with the provisions of the CDCR 1984. An NDP may be classified according to the following categories:

- New NCE (single/ combination products with an active substance never registered by DCA)
  Defined as an active moiety/ radiopharmaceutical substance that has not been registered in any pharmaceutical product.
- Hybrid NCE (single/ combination products with registered active moieties)
  All other products registrable at New Drug Section which do not fall under (a).
  - Examples of Hybrid NCE (combination) products:
    i. Combination of registered chemical entities
    ii. Combination of registered chemical entity(s) in new chemical form(s)
    iii. Combination of registered chemical entity(s) in new chemical form(s) and registered chemical entity(s)

  - Examples of Hybrid NCE (single) products:
    i. Registered chemical entity in a new chemical form
    ii. Registered chemical entity in a new dosage form
    iii. Registered chemical entity in a new dosage strength with a change in dosing/ posology
    iv. Registered chemical entity for use by a new route of administration
    v. Registered chemical entity for new indication(s), dosage recommendation(s) and/or patient population(s)
    vi. A generic product for which its innovator has never been registered by DCA

Generic Products (both prescription medicine and OTC)
A product that is essentially similar to a currently registered product in Malaysia. The term generic is not applicable to biologic products. Generic may be further classified into two groups :

- Scheduled Poison (Known as Controlled Medicine/ Controlled Poison): Products containing poisons as listed in the First Schedule under Poisons Act 1952.
- Non-scheduled Poison (Known as Non-Poison or "Over-the-Counter", OTC): Products containing active ingredients which are not listed in the First Schedule under Poisons Act 1952; and is excluding active ingredient which is categorized under health supplements or natural products or cosmetics.

For a generic product in which the reference innovator product has never been registered in Malaysia, there are specific requirements including:

i. Nonclinical Overview, Nonclinical Summary & List of Key Literature references, by referring to studies by the innovator product
ii. Clinical Overview, Clinical Summary & List of Key literature References, by referring to studies by the innovator product
iii. Bioequivalence study report(s)
iv. other pivotal study reports, if applicable
v. Risk Management Plan (RMP)
vi. Consultation with local clinical specialists

APIs

Active Pharmaceutical Ingredients (APIs) refer to any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical drug and that, when used, becomes an active ingredient of that pharmaceutical drug. The API market is surging due to the increased demand for pharmaceutical drugs, which in turn is driven by the ageing population, rising prevalence of chronic diseases such as cancer, diabetes, cardiovascular, neurological, and infectious diseases.

A recent study by Fitch Solutions cites that the pandemic has disrupted upstream supply of active pharmaceutical ingredients (APIs) from China and the manufacturing of finished products in India, which should lead to both pharmaceutical companies and governments diversifying their supply sources, either by 'near-shoring' production to regional peers or 'reshoring' to the country of sale. Southeast Asian countries will most likely be the potential beneficiaries, and Malaysia is one of the countries to have already put forward plans to attract overseas investments, as it seeks to capitalise on this trend among major global drug companies to outsource their manufacturing operations, by contract manufacturing generic and patented products.

Biologics

Biologics, also referred to as "biological medicine", are medicine made up of large, complex molecules grown in living cells rather than synthesized chemically and are becoming increasingly important for the treatment of major diseases. The vast majority of biologics are derived from living sources: humans, animals, microorganisms; i.e., they are naturally occurring or synthetic versions of naturally occurring products.

Biologics are now available for treatment of cancer, high cholesterol, rheumatoid arthritis and asthma. Biologics that are produced by companies other than the originator company are called biosimilar medicines (often referred to as biosimilars). Since biosimilars are not exactly identical to biologics, the regulatory pathways are different, and the registration requirements for biosimilars are much more stringent than for generic medicines which are based on chemical molecules. Biosimilar manufacturers have a higher threshold to meet to register their medicines. They must demonstrate that their biologic medicine product is similar to an already registered, well-established medicinal product in terms of quality, safety, and efficacy. To do this, companies seeking registration must submit clinical trial data for phases 1, 2, and 3 as well as comparative studies to demonstrate safety and clinical comparability with the originator product.

The NPRA specifies the use of biologics in a wide range of products such as: vaccines, blood products, monoclonal antibodies (therapeutics), recombinant proteins (including but not limited to insulins, hormones, erythropoetins and other hematopoietic factors), cytokines (including but not limited to interferons, interleukins, colony-stimulating factors, tumour necrosis factors), cell and gene therapy products (CGTPs). This list excludes:

- Metabolites from microorganisms; e.g. antibiotics and some hormones;
- Macromolecules produced by chemical synthesis; e.g. peptides/ oligo-nucleotides produced by chemical synthesis;
- Whole blood or cellular blood components.

Note: CGTPs are regulated under a separate framework. The Guidance Document and Guidelines for Registration of Cell and Gene Therapy (CGTPs) Products in Malaysia provides information for manufacturers, applicants, healthcare professionals and the general public on legal arrangements in Malaysia for the registration of CGTPs and was compulsory as of 1 January 2021.

Health Supplements

As a subsector of pharmaceutical products, the National Pharmaceutical Regulatory Agency (NPRA) defines Health Supplements as any product used to supplement a diet and to maintain, enhance and improve the health function of the human body. It can be presented and administered in small unit dosage forms such as capsules, tablets, powder and liquids but shall not include any sterile preparations (i.e. injectables, eye drops).

A health supplement may contain one or more, or the following combinations:

- 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, metabolite;
- Synthetic sources of ingredients mentioned in (1) and (2) may only be used where the safety of these has been proven.

In 2023, the Malaysia Vitamins and Supplements Market was valued at almost RM 5.383 billion according to Euromonitor - and the industry is expected to grow up to RM 7.85 billion in 2028. This growth can be attributed to a number of factors such as the renewed awareness for health since COVID-19, the advances in supplement technology, but also the greater awareness of the importance of good nutrition. NPRA received a total of 1,787 new product applications in 2022, of which 1,419 products were registered. 584 of those applications were regarding health supplement products, out of which 451 got registered.

Leading product categories are vitamins, especially vitamin C and multivitamins with sugar-free versions becoming increasingly popular; weight loss supplements (including slimming teas); probiotics; and herbal or traditional products. Organic and halal or vegetarian supplements also see high potential in the Malaysian market.

Malaysia's health supplement industry is mainly met by imports; either in the form of finished goods or raw materials for local assembly. Local importers and manufacturers also often collaborate with foreign suppliers to source materials for their own manufacturing, create their own formula, or acquire private label products, especially in the case of direct selling companies.

According to Euromonitor International, Malaysia's vitamins and supplements market was valued at almost RM5.383 billion in 2024 and the industry is expected to grow to RM7.85 billion by 2028.

Traditional & Complementary Medicine (T&CM)

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, or parts thereof, in the unextracted or crude extract form and homeopathic medicine (as defined under the CDCR 1984). It shall not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances.

The inclination towards herbal products (almost one-third of consumers) is due to the cultural backgrounds of the different Malaysian ethnic groups – Malays, Chinese and Indians all have a longstanding history with herbal medication, which continues to be passed down even in modern times.
The Malaysian government is also one of the few that has integrated T&CM into their healthcare system, including establishing a comprehensive framework involving key ministries. The Ministry of Health (MOH) oversees T&CM practices, while the Ministry of Human Resources and Ministry of Higher Education handle the education and training of T&CM practitioners. The Ministry of Agriculture and Food Security ensures the availability and quality of medicinal plants, while the National Pharmaceutical Regulatory Authority (NPRA) and the Medical Device Authority (MDA) oversee regulatory aspects of T&CM products.

In 2013, the Government officially recognised the T&CM Act, linking it to public health and implementing measures to ensure safety and quality. As part of these efforts, T&CM units have been established in 15 selected public hospitals, providing T&CM services to patients.

Further commitment to T&CM was the launch of the National T&CM Blueprint 2018-2027, part of MOH's efforts to regulate and professionalise T&CM practice and practitioners nationwide.

Halal Pharmaceuticals

The halal pharmaceutical industry in Malaysia has grown and developed in recent years. Focusing on adhering to Islamic principles in the production and distribution of medicines, Malaysia has emerged as a leader in formally regulating its local sector, introducing the Malaysian Standard MS2424:2012 Halal Pharmaceutical Guidelines in 2012, which was later expanded to include biopharmaceuticals in 2019. This is supported by stringent certification processes, regulatory bodies and 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 the Department of Islamic Development Malaysia (JAKIM). JAKIM oversees the certification processes and sets stringent standards for halal pharmaceuticals in the country, encompassing the sourcing of raw materials, manufacturing processes, handling, and distribution of pharmaceutical products.

This has led to Malaysia's halal pharmaceutical industry's high credibility and trust which complies with the framework that aligns with international pharmaceutical regulations. The government has also implemented the Halal Industry Master Plan 2030 (HIMP 2030), a comprehensive framework aimed at leveraging Malaysia's strengths for the holistic development of its halal industry.

As the global Muslim population increases, Malaysian-made and halal-certified pharmaceuticals are not only important for their local market but are also exported to other countries in the region notably Singapore and Indonesia, as well as Japan and China.

LEGISLATION & REGULATIONS

Pharmaceuticals

The main authorities for pharmaceutical products are the Drug Control Authority (DCA) and the National Pharmaceutical Regulatory Agency (NPRA), while the Department of Islamic Development Malaysia (JAKIM) is also involved for any and all products that need to be halal-certified.

The main laws for the regulation on poison and sale of drugs of the pharmaceutical sector include the following:

- Dangerous Drugs Act 1952 (revised 1980);
- Poisons Act 1952 and regulations;
- Sale of Drugs Act 1952;
- Control of Drug and Cosmetics Regulations 1984 (CDCR);
- Directive on Data Exclusivity 2011 under the CDCR;
- Registration of Pharmacists Act 1951 and regulations; and
- Medicines (Advertisement and Sale) Act 1956 and regulations.

These laws define pharmaceutical products and govern licensing, production, import, wholesaling, distribution, prescribing, dispensing and the overall use of medicines in Malaysia.

These legislative acts have undergone various amendments over time to address emerging issues related to the use, sale and distribution of poisons and drugs. The Poisons Act 1952 is the governing legislation that regulates the manufacture, import, export, sale and possession of poisons in Malaysia. The Act classifies poisons into three categories: The first category comprises highly toxic substances that are not intended for medical purposes. The second category includes substances that are used for medical purposes but may pose a risk if not used correctly. The third category consists of substances that are used for medical purposes and are considered safe if used correctly.

According to the Poisons Act 1952, it is illegal to manufacture, import, export, sell or possess any poisons without a license. Substances categorised as 'Schedule III poisons' – that is, substances used for medical purposes but not considered harmful – can be sold without a licence, provided that sellers maintain records of all transactions.

Moreover, the Act stipulates that all poisons must be accompanied by a warning label that explicitly denotes their status as such, emphasising the necessity for caution and safety measures. Failure to comply with these stipulations can result in legal consequences, including financial penalties, incarceration, or both.

The Dangerous Drugs Act 1952 is the legislative foundation governing the possession, manufacture, import, export and trafficking of dangerous drugs within the Malaysian jurisdiction. The Act categorises dangerous drugs into three distinct classifications:

- Group A consists of drugs that are considered to be highly addictive and devoid of recognised medical value.
- Group B consists of drugs that are considered to be less addictive than those in Group A, but still devoid of recognised medical value.
- Group C consists of drugs that have recognised medical value, but can be abused if not used correctly. Possessing, manufacturing, importing, exporting or trafficking any of the aforementioned drugs without a license is illegal. However, Group C drugs can be possessed and used for medical purposes. However, it is important to note that the same regulations apply to the manufacture, import, export and trafficking of these substances, which also require a licence.

The main document guiding the process of drug registration in Malaysia is the Drug Registration Guidance Document (DRGD), now into its third edition (9th Revision Jan 2025). There is a separate registration guideline for pharmaceutical products for animal use, the so called Registration Guideline of Veterinary Products (REGOVP), issued by the Director of Pharmaceutical Services under Regulation 29, Control of Drugs and Cosmetics Regulations 1984.

In Malaysia, the Biotechnology Section of the Centre for Product Registration of the NPRA is responsible for the registration of biologics/biopharmaceuticals and biosimilars in accordance with the Sale of Drugs Act, the CDCR and the DRGD. Appendix 4 of the DRGD also sets out the Guidelines on Registration of Biologics while Appendix 11 covers the Regulatory Control of APIs.

The NPRA regulates every biologic as a new product and considers it "high risk", stressing strict compliance with GMP. There is a separate Guidance Document and Guidelines for Registration of Biosimilars in Malaysia (2008), where the information is adopted from the EMA guidelines, in particular the guidelines on similar biological medicinal products containing biotechnology-derived proteins as active substances, with some adaptations for Malaysian application.

In April 2021, the NPRA also released a Guidance Document for the Lot Release of Biological Products Manufactured in Malaysia, to oversee the quality of biological products locally produced, which includes vaccine and plasma derived medicinal products.

Cell and gene therapy products (CGTPs) is regulated as biologic products. Unlike biotechnology products which are mostly purified proteins of cells, CGTPs contain living and functional cells. Therefore, CGTP is regulated under a separate framework: Guidance Document and Guidelines for Registration of Cell and Gene Therapy (CGTPs) Products in Malaysia. The guideline was implemented as of January 1, 2021. The updated version of the document was released on February 22, 2022 and builds upon the original framework.

All companies are required to hold an NPRA licence before they can manufacture, import, or sell by wholesale pharmaceutical products. As these licences can only be held by a locally registered entity, most importers establish locally registered offices and maintain marketing and sales teams who actively and directly market to providers in the private and public sectors. Companies that do not have a registered office in Malaysia usually appoint their distributor to register and market their products.

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

An appointed local agent who is the PRH should be authorized in writing by the product owner to be the holder of the product registration and will be responsible for all matters pertaining to quality, safety and efficacy of the product. This shall include updating any information relevant to the product/application.

Health supplements

Health supplements, depending on the ingredients, could fall under one of two categories, and therefore different authorities. The main authorities for pharmaceutical products are the Drug Control Authority (DCA) and the National Pharmaceutical Regulatory Agency (NPRA), while supplements that are not pharmaceutical-grade would be undertaken by the Food Safety and Quality Division (FSQD) of the Ministry of Health or the Ministry of Agriculture and Food Industries (MAFI). Lastly, the Department of Islamic Development Malaysia (JAKIM) is also involved for any and all products that need to be halal-certified.

The main laws for the regulation of the pharmaceutical sector include the following:

- Poisons Act 1952 and regulations;
- Sale of Drugs Act 1952;
- Control of Drug and Cosmetics Regulations 1984 (CDCR);
- Directive on Data Exclusivity 2011 under the CDCR;
- Registration of Pharmacists Act 1951 and regulations; and
- Medicines (Advertisement and Sale) Act 1956 and regulations.

These laws define pharmaceutical products and govern licensing, production, import, wholesaling/distribution, prescribing, dispensing and the overall use of medicines in Malaysia. The main

document guiding the process of drug registration in Malaysia is the Drug Registration Guidance Document (DRGD), now into its third edition (First Revision July 2021).

All regulations pertaining to food products can be found in the Food Act 1983 and Food Regulations 1985l. Natural products are required to be registered with the DCA, under the purview of NPRA, before they can be marketed in Malaysia. Natural products with therapeutic claims must be manufactured in a Good Manufacturing Practice (GMP) Compliance premise which follows Pharmaceutical Inspection Co-Operation Scheme-Guide to Good Manufacturing Practice for Medicinal Products (PIC/S) guideline. Under the NPRA, essential oils are registered as cosmetics (not pharmaceutical), and only for external application.

Natural ingredients that contain active ingredients listed under the Poisons Act 1952 or active ingredients that cause side effects may be denied NPRA approval. Detailed lists of forbidden botanical ingredients can be found in this guidance document, from pages 11-30 and 45-48.

Due to strict halal requirements in the country, alcohol is generally not permitted in food supplements, or if an item contains alcohol it has to be labelled as such, and sold in a special "non-halal" section. For pharmaceutical or medicinal products, special dispensations may be made if the alcohol is irreplaceable and required for the efficacy of the medicine, but it would have to be reviewed and approved by the Department of Islamic Development Malaysia (JAKIM), in addition to the usual approvals from MOH.

For all products to be marketed in Malaysia, they must be registered with DCA even though they have been registered in other countries.

Import Regulations

Exporters of medical devices and pharmaceuticals need approval from the respective regulatory authorities prior to market entry. As of July 1, 2016, all medical devices imported into Malaysia first need approval from the Malaysian Medical Device Authority (MDA), while the implementation of pharmaceuticals and nutritional supplements registration and cosmetics notification is overseen by the NPRA.

All companies are required to hold an NPRA licence before they can manufacture, import or sell pharmaceutical products. Such licences can only be held by a locally registered entity. The applicant for product registration shall be known as the Product Registration Holder (PRH) and must be a locally incorporated company, corporate or legal entity, with a permanent address and be registered with the Companies Commission of Malaysia (with the scope of business related to the health/pharmaceutical product). Hence most importers establish registered offices in the country.

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

An appointed local agent who is the PRH should be authorized in writing by the product owner to be the holder of the product registration, and will be responsible for all matters pertaining to quality, safety and efficacy of the product. This shall include updating any information relevant to the product/application.

All kinds of foodstuffs to be imported into Malaysia, e.g. meat, fruits, vegetables and processed food, require an import approval from the Food Safety and Quality Division (FSQD) under the Ministry of Health (MOH). In order to import dairy products into Malaysia, it is first necessary to obtain an Importer Registration with the Malaysian Quarantine and Inspection Services Department (MAQIS). Furthermore, specific types of goods may also require an Import Licence from the Ministry of International Trade and Industry (MITI), particularly those that are hazardous, environmentally sensitive or regulated to protect public safety. In addition, businesses must first register with the Companies Commission of Malaysia before applying for an important license from MITI. The overarching objective of this licensing regime is to safeguard the public interest, foster fair trade practices, and ensure that imported goods meet the stipulated Malaysian safety and quality standards.

Malaysia has a zero-tariff policy for imported pharmaceutical products, including medicine, medical creams, medicaments containing vitamins. However, dietary supplements are subject to a 5 % Sales and Services Tax (SST). Sales Tax is a key tax in Malaysia's import tax structure and plays a crucial role in regulating the import of goods into the country. It encompasses two categories: The first category is designated as Sales Tax on Taxable Goods, while the second is designated as Sales Tax on Low-Value-Goods (LVG). The rate of the SST varies according to the product category, as determined by its HS code, and ranges from 10 % or 5 % to specific rates for certain products.

The Malaysian Dietary Supplement Association (MADSA) has been endeavouring to secure the removal of the 5 % sales tax on dietary supplements and for less stringent regulations on new formulations since at least 2021. However, at the present time, almost all dietary supplements in Malaysia are still subject to a 5 % sales tax.

Import Duty, otherwise referred to as Customs Duty, represents a pivotal tax on goods entering Malaysia from overseas. The method of calculation employed is based on either the ad valorem basis, as a percentage of the value of the goods, or on a specific basis, as a fixed sum per unit. The rate of duty may range from 0 % to 60 %, and is determined by the Malaysian Customs Department.

Dietary supplements in Malaysia are currently subject to import duties of 5 %, depending on their HS code and ingredients, as well as the 5 % SST. MADSA has persistently advocated for policy modifications as they believe this imposes a financial burden on Malaysians trying to maintain or improve their health; however, no formal declaration has been issued to substantiate a diminution in these levies.

4. VETERINARY SCIENCE

Veterinary Science in Malaysia focuses on the health of both domestic and wild animals, specifically reagrding the control, treatment, and prevention of the transmission of diseases. The main types of animals handled are livestock and companion animals, though there are of course specialists for wildlife and zoo animals. While the conservation and welfare of animals (especially wildlife) falls under NRES, the DVS has an Animal Welfare Code of Practice related to the Animal Welfare Act of 2015 (overseen by the Ministry of Agriculture).

Livestock

Employing roughly 10 % of the Malaysian labour force, the agriculture, fisheries and forestry sectors account for about 8 % of the Malaysian GDP. While agriculture's main sector is the oil palm industry at 37.1 %, the livestock industry is also a vital contributor, with a 16.1 % value share, with the leading segment being poultry.

According to the Department of Statistics Malaysia, the Malaysian livestock industry grew 23.2 % to RM 1.4 billion in 2023. These numbers underline the increasing demand for livestock and related products to meet domestic consumption and industrial needs.

Poultry is one of Malaysia's key investments in its livestock sector, as it appeals to virtually its entire population (as opposed to beef or pork which have religious restrictions). The segment is the most advanced of the livestock sector and is self-sufficient, producing 98.4 % of the national demand for poultry meat and 113 % of the demand for chicken and duck eggs. Most new farms are built as environmentally-controlled closed poultry houses with various degrees of automation. The value of chicken exports in 2023 was RM 726.7 million, an increase of 27 % compared to 2022. The value of chicken egg exports was RM671.2 million in 2023, catering to the demands of regional markets. It is expected that around 314 million chicken will be raised in Malaysia in 2025.

While Malaysia is currently largely dependent on imports for its beef and dairy requirements, the government is making great efforts to improve its production of both meat and dairy cattle to become more self-sufficient, especially since strict halal certification procedures and dairy quotas and facility registrations limit imports. In 2022, there were approximately 720,000 cattle in Malaysia. Malaysia's beef self-sufficiency rate was estimated to be around 27 % in 2023, but the country is determined to achieve its 50 % self-sufficiency level target for beef by 2030. This could be achieved by redeveloping mega cattle farms to meet local meat supply needs. At the same time, this could put Malaysia back on the right track towards achieving its self-sufficiency level target in time. Nevertheless, the ruminant industry remains dominated by the external sector and the value of imports for live cattle surged to RM108.7 million in 2023 in order to meet domestic consumption. The main countries for livestock imports were Australia, New Zealand and Thailand, collectively accounting for 84.8 % of all Malaysian livestock imports.

When it comes to fresh milk, it was estimated in 2020 that over 77 % of dairy cattle farmers in Malaysia follow a small-scale farming system, meaning they have fewer than 30 cows, leading to lower milk production and therefore a dairy shortage. However, since 2023, Malaysia has been experiencing significant growth in the dairy sector, building a robust foundation of approximately 282,000 dairy cattle and an impressive milk production volume of around 1.9 billion litres processed annually. The milk market is expected to show a volume growth of 5.9 % in 2026.

Despite being a Muslim-majority country, the swine industry in Malaysia is sustained by the Chinese and expatriate population, which ranks Malaysia 39th in pork consumption with 5.64kg consumed per individual per year. As of 2023, Malaysia is the 52nd largest exporter of pig meat worldwide, exporting USD 2.42 million in pork that year, with the main destinations being Brunei, Indonesia and Brazil. At the same time Malaysia is the 25th largest importer of pork worldwide. In 2023, pork imports were worth USD 197 million, primarily coming from Spain. In 2020 , there were 470 farms with in total about 1,47 million pigs. Over the past years, smaller farms have been closing, but bigger farms have been expanding their production capacity.

The Department of Veterinary Services (DVS), under the purview of the Ministry of Agriculture, is the responsible body for:

- the control and prevention of zoonotic diseases, including sanitary inspections;
- maintaining animal health status and promoting animal nutrition and welfare;
- the development of a sustainable livestock industry and wholesome animal-based food production;
- controlling the import-export flow of animals and their by-products; and
- the development of technology and optimisation in animal-based industries.

The corresponding department for the Bornean states of Sabah and Sarawak are DVS Sabah and DVS Sarawak respectively.

Companion Animals

In 2022, there were 6 million dogs and 5 million cats in Malaysia, however, only 398.000 of those dogs and 658.000 were in ownership. More than half of Malaysians (51,1 %) own companion animals (pets) and out of the remaining population not owning a pet, 26.2 % stated, that they are interested in getting one. As an Islamic country, where approximately two-third of the population is Muslim, the breakdown of pets follows a similar pattern. 77.7 % of pet owners have at least one cat, making cats the most popular companion animal. This is followed by dogs representing 14.9 % of all pets and Tropical Fish with 13.2 %.

Petcare as a market sector in general has been growing consistently in the past few years, with most pet owners considering their pets as part of the family and therefore willing to spend more for better-quality products and services. The pet food segment grew by 37.2 % between 2017 and 2022, driven by the pet population which experienced a similar increase with 30.5 % during that same period. The Malaysian Pet Food Market has an estimated value of USD 317.3 million in 2024, growing at an estimated CAGR of 6.9 % over the 2024-2029 period.

Some of the more common illnesses seen in Malaysian companion animals:

- Cat flu and conjunctivitis, commonly seen in cats, especially kittens. Although preventable through vaccination, often cats (often adopted off the street) might not be vaccinated.
- Chronic kidney disease (CKD). Statistics have shown that one in every three cats over the age of 10 has CKD, which is highly prevalent among senior/geriatric cats.
- Arthritis/Osteoarthritis. Commonly seen in large breeds of dogs, but known to be underdiagnosed with cats or smaller dogs as the signs are often overlooked or unknown to the owners.
- Cataracts. Common in senior dogs, with higher prevalence among certain breeds as well as due to trauma and injury.
- Heartworm. Dogs are more susceptible but unmedicated cats are also at risk, due to the prevalence of mosquitos (transmission vector) in Malaysia.
- Dental and ear infections.

Veterinarians

In 2023, there were a total of 3,463 veterinarians nationwide registered with the Malaysian Veterinary Council, of which only 2,236 had applied and received their Annual Practicing Certificate. Based on the demand for veterinarians from various projects, this is not sufficient. Malaysia needs an excess of 6,000 veterinarians nationwide to fulfil the ideal ratio of 1:5000.

The need is especially important in clinical practice such as treating pets, and due to the high demand, temporary practising permits are given to qualified individuals where there is a lack of vets in the country. Foreign veterinarians are also recruited to fill this gap, mostly from Indonesia and India, and are given approvals to work in Malaysia.

There are a total of 650 companion animal practices in Malaysia. Currently, animal shelters are not allowed to hire full-time veterinarians to be based at their premises and are required to outsource treatment to a clinic.

While most people are only aware of veterinarians' role in treating animals, the Malaysian Veterinary Council also has vets involved in controlling zoonotic diseases and conducting tests to prevent outbreaks, and each state has a surveillance programme to control such diseases.

Another significant duty of veterinarians lies in food production, where their expertise is needed to increase the productivity of farmers and ensure food from farms is safe to be consumed, both by monitoring animal feed and ensuring the animals used for meat are disease-free. Food production is therefore one of the major sectors in need of vets, with only about 150 food animal veterinarians registered.

Veterinary Products

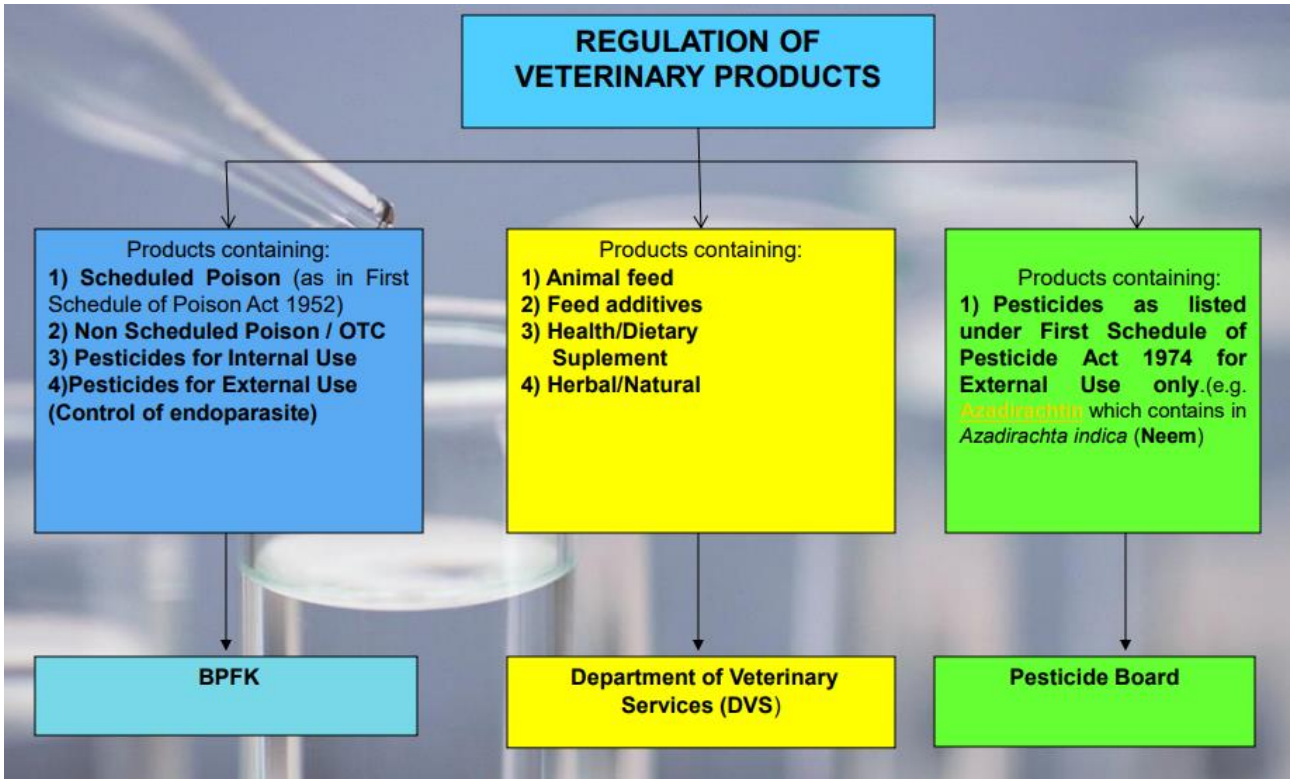
Refers to pharmaceutical products for animal use. These products are controlled by the Department of Veterinary Services (DVS) to protect the health of the consumer from food producing animals as well as to ensure that foods obtained from animals treated with veterinary products must not contain residues of the drug (Minimum residual limit, MRL) or its metabolites which might constitute a health hazard for the consumer. Other roles of DVS are to ensure only quality and safe products are registered and marketed in Malaysia. The implementation of the regulations on veterinary products shall be on all products containing scheduled poisons and non-scheduled poisons intended to be administered to the animals for medicinal purposes. Under the Feed Act 2009, DVS also controls:

- Dietary/health supplements and herbal/natural preparations
- Medicated Feed
- Premixes (antibiotics for prevention and growth promotion)

LEGISLATION & REGULATIONS

Veterinary Products

The governing acts for veterinary medicine are the Control of Drug and Cosmetics Regulations 1984 (CDCR) and the Animal Act 1953; the governing bodies are the Drug Control Authority (DCA), the National Pharmaceutical Regulatory Agency (NPRA) and the Department of Veterinary Services (DVS). Per DVS, the following flowchart explains the regulation of veterinary products:



Source: DVS

Product Registration

A 'product' as defined in the Regulations means:

(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;
(b) a drug to be used as an ingredient of a preparation for a medicinal purpose

Any change to the above defined parameters may result in the need to apply for a new product registration or an application for approval of an amendment (variation) to the existing product registration.

Any drug which includes any substance, product or article, intended to be used, or capable or purported or claimed to be capable of being used on humans or any animals, whether internally or externally, for a medicinal purpose is required to be registered with the DCA. (For biologics, the DVS handles the registration while import permits are issued by MAQIS – Malaysian Quarantine and Inspection Services - if necessary.)

'Medicinal purpose' means any of the following purposes: (i) alleviating, treating, curing or preventing a disease or a pathological condition, or symptoms of a disease; (ii) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition; (iii) contraception; (iv) inducing anaesthesia; (v) maintaining, modifying, preventing, restoring or interfering with, the normal operation of a physiological function; (vi) controlling body weight; (vii) general maintenance or promotion of health or well-being.

The classification of veterinary products should be done using the Product Classification Application NPRA 300.1 form, where only one medicinal product is allowed per form. A fee of RM300 per application is imposed for the processing, with a timeframe of 14 working days.

The authority accepts only web-based online submissions. The applicant for product registration shall be known as the Product Registration Holder (PRH) and must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia.

If you are appointing a distributor/agent as your representative, the applicant should be authorized in writing by the product owner to be the holder of the product registration and be responsible for all matters pertaining to quality, safety and efficacy of the product. This shall include updating any information relevant to the product/ application. The authority will register products with specific brand/ proprietary name for only one PRH. The same brand/ proprietary name is not allowed for other product registration holders. Registration of same product in all aspects but with different product name by the same PRH is not allowed by the Authority.

All data and information including supporting documents for product registration such as certificates, letters and product labels shall be in English or Bahasa Malaysia.

The registration of a product shall be valid for 5 years or such period as specified by the authority (unless sooner suspended or cancelled by the authority). Renewal of product registration must be done six (6) months prior to the expiry of the validity period of product registration.

For all products to be marketed in Malaysia, they must be registered with DCA even though they have been registered in other countries. For more details, please refer to NPRA's FAQ page.

Import Regulations

Per an amendment made to the Control of Drugs and Cosmetics Regulations in 2006, all products are required to be registered with the DCA prior to being manufactured, sold, supplied, imported, possessed or administered, unless the product is exempted under the specific provisions of the Regulations.

For imported products, PRH must provide acceptable evidence to show that the manufacturer of the product follows an internationally accepted standard of Good Manufacturing Practice (GMP) and recognized by the Authority in Malaysia, before the products are registered with the Authority. Foreign manufacturers are also subjected to GMP conformity assessments through acceptable GMP evidence or GMP inspection.

Imported products will also need to furnish either a: (i) Certificate of Pharmaceutical Product (CPP) from the competent authority in the country of origin; OR (ii) Certification for Free Sale (CFS) and Good Manufacturing Practice (GMP) from the relevant competent authorities as deemed acceptable by the DCA. CPPs are mandatory for sterile preparations.

CPPs shall be in the format of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce if issued by the Health Authorities listed in the WHO Certification Scheme. CPPs issued by EMA for products registered through the centralized procedure in EU will be accepted. CPPs issued by the manufacturer or other authorities are not acceptable. If more than one manufacturer is involved in the manufacture of a product, GMP certification should be available for all the manufacturers.

For a product be imported into this country and be exported again without being registered, special permission for 'Kebenaran Mengimport Keluaran Tidak Berdaftar Bagi Maksud Dieksportkan Semula' for unregistered product shall be obtained for this purpose from NPRA. Other special permission 'Kebenaran Mengimport Keluaran Tidak Berdaftar Bagi Maksud Tujuan "In Transit"' shall be obtained from the Enforcement Division, Pharmacy Services Programme for the purpose of in transit only.

For complete details, you may refer to the Registration Guideline of Veterinary Products (REGOVP), last updated January 2024.

5. BIOTECHNOLOGY, CLINICAL RESEARCH & TRIALS, RARE DISEASES

Biotechnology

Biotechnology has experienced phenomenal growth rates in the past few years across the globe; a trend further punctuated by the COVID-19 pandemic. In Malaysia, the bioeconomy market had a value of RM 149.1 billion in 2020 and is projected to reach RM 181.2 billion by 2030, indicating a 15 % annual growth.

The Malaysian biotech industry has moved on from its traditional applications towards renewable, non-toxic, and cost-competitive products. Among the focuses are "omics", i.e. transcriptomics, metabolomics, genomics, proteomics, especially as it pertains to critical care or personalised medication. Biotechnology in the agricultural realm would also play an important role, as Malaysia looks to shore up its food security.

The Bioeconomy Corporation is the lead development agency for the bio-based industry in Malaysia, under the purview of Ministry of Science, Technology and Innovation (MOSTI). They are guided by and responsible for executing the objectives of the National Biotechnology Policy. They award BioNexus status to qualified companies, and also run the Bio-based Accelerator Programme.

The 2005-2020 National Biotechnology Policy strove for Biotechnology to make Malaysia a developed knowledge economy by 2020. The National Biotechnology Policy envisioned biotechnology to become a new economic engine for Malaysia.

It was underpinned by nine policy thrusts:

1. Agriculture Biotechnology Development
2. Healthcare Biotechnology Development
3. Industrial Biotechnology Development
4. R&D and Technology Acquisitions
5. Human Capital Development
6. Financial Infrastructure Development
7. Legislative and Regulatory Framework Development
8. Strategic Positioning
9. Government Commitment

The implementation of the National Biotechnology Policy encompassed three main phases: Phase I (2005-2010) focused on Capacity Building by establishing advisory and implementation councils. It ensured education and training of knowledge workers and developed the legal and the IP framework.

Phase II (2011-2015) brought Science to Business by developing expertise in drug discovery and development based on natural resources. It developed new products, intensified investment promotion and strengthened branding. It led to the creation of knowledge-intensive jobs. Phase III (2016-2020) took care of the Global Presence by consolidating strengths and capabilities in technology development. It strengthened innovation and technology licensing and promoted global Malaysian companies, intending for Malaysia to generate at least 20 global Malaysian companies by 2020.

The National Biotechnology Policy 2.0 (NBP 2.0; *note: currently only available in Malay*) represents a progression from its predecessor, with the objective of fortifying Malaysia's biotechnology ecosystem while addressing pressing national challenges, including food security, pandemic preparedness, and the climate crisis. The policy seeks to enhance socio-economic conditions, particularly in the domains of healthcare and agriculture, through the utilisation of local biotechnology solutions. It underscores the deployment of advanced technologies, such as stem cells for medical treatments and enzyme technology to enhance food security. This initiative is in alignment with Malaysia's ambition to achieve high-tech nation status by 2030, positioning Science, Technology, and Innovation as pivotal drivers in the era of the Fourth Industrial Revolution.

BioNexus Status is a special status awarded to qualified companies undertaking biotechnology activities. These companies are eligible for fiscal incentives, funding, and other guarantees to increase their growth, including investment facilitation and advisory services. Apart from the overall benefits and support, companies are assured a list of privileges as stipulated in the BioNexus Status Bill of Guarantees, which includes freedom of ownership, access to shared laboratories, research centres of excellence and other related facilities and continuous support and other assistance from the Malaysian Bioeconomy Development Corporation (MBDC), under the purview of MOSTI.

Meanwhile, the Bio-based Accelerator (BBA) programme helps bio-based start-ups, micro businesses, and large companies in infusing science, technology, automation, and strategic investment into their business operations. The programme also identifies and provides facilitation to overcome gaps in skills, technology adoption, financial resources, regulatory compliance, and product marketability, in order to empower bio-based companies in the agriculture, industrial, and healthcare sectors.

Other significant contributors to Malaysia's Bio-economy include the National Institutes of Biotechnology Malaysia (NIBM), a consortium of 3 biotechnology institutes:

- Malaysian Institute of Pharmaceuticals & Nutraceuticals (IPHARM)
- Agro-Biotechnology Institute Malaysia (ABI)
- Malaysia Genome Institute (MGI).

Research, Clinical Trials, Bioequivalence Centres

According to MIDA, the Clinical Research Centre (CRC) comprises a network of 17 centres around the country and acts as a one-stop-centre, by providing a single point of contact to access all Ministry of Health hospitals and clinics, to conduct clinical trials in Malaysia. These clinical trial centres are linked to more than 50 general and district hospitals, and over 100 health clinics as potential sites for clinical trials with access to 17 million patients in the public healthcare system in Malaysia.

There are also several private entities which conduct clinical trials; these are generally private hospitals or University hospitals. There are four Bioequivalence Centres, with one public institution, the School of Pharmaceutical Sciences of the University of Science Hospital Malaysia (Hospital USM).
Clinical Research Malaysia was established by the Malaysian Ministry of Health in 2012, to advance global health solutions by providing speedy and reliable end-to-end clinical research support for quality studies.

The main centre for blood donation is the National Blood Centre (Pusat Darah Negara), located in the Klang Valley. Aside from this, there are fixed donation centres at the blood banks of selected government hospitals. There are also mobile blood donation programs conducted actively to make it easier for the general public to come forward to donate their blood. These mobile sessions are conducted at government as well as private offices and buildings, factories, institutes of higher learning as well as shopping centres.

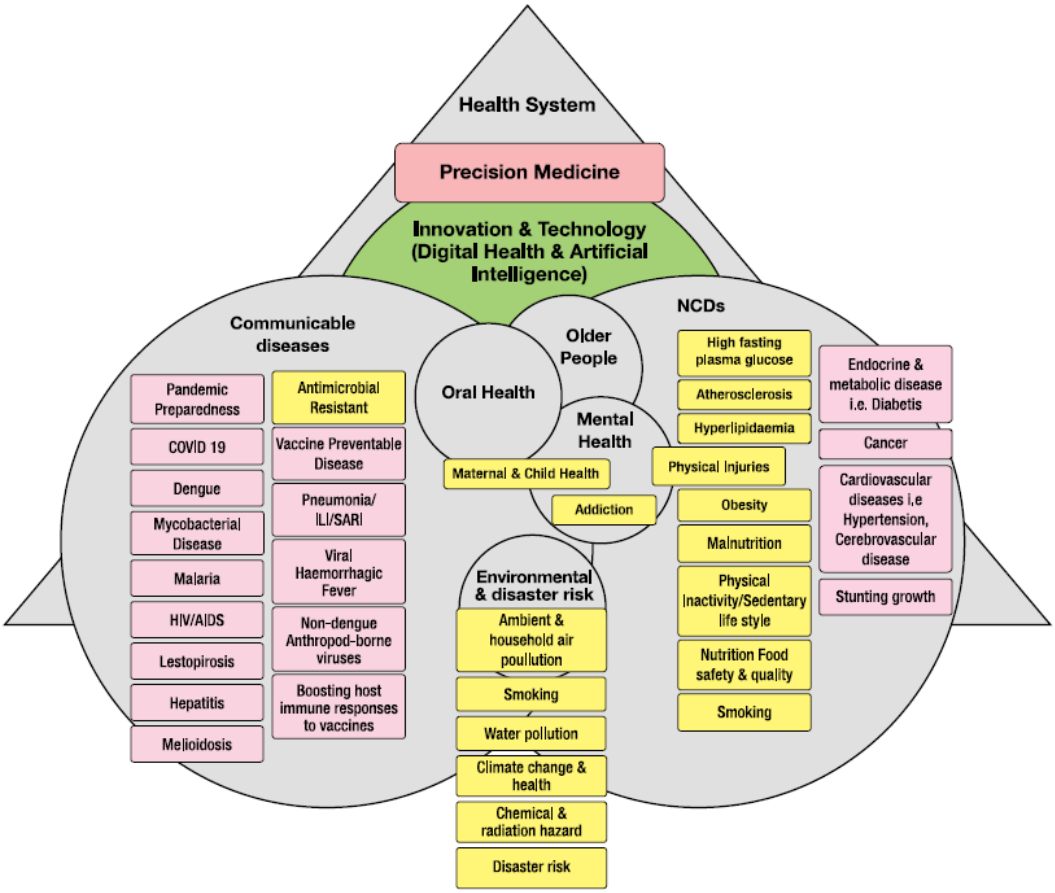


Figure 1. Graphic illustration of priority research areas, diseases and risk factors as identified through the databases search

Source: 12th Malaysia Plan.

Note: The grey triangle represents the health system encompassing all areas of research to achieve UHC. The green circle represents technology across all priority areas. The grey circles represent disease and area of research priorities guided by 12MP. The size of the circles indicates the importance of the respective research area as ranked by search finding and expert opinions. The pink boxes within the grey circles illustrate the priority diseases that were identified within the priority research areas. The yellow boxes illustrate the priority risk factors identified and associated with the priority diseases. Precision medicine is an approach across all diseases.

According to the 12th Malaysian Plan, the Health Research Priorities are:

- Health technology & health system
- Communicable and non-communicable diseases
- Aging Population
- Environment and disaster risks
- Nutrition, food safety, quality
- Oral health

In order to improve health status, the burden of disease among Malaysians should continue to be an integral guide to the development of national research priorities. The burden of disease refers to death, disability and hardship of various kinds that result from illnesses. Research that addresses critical gaps in information and evidence to support these strategies will be considered priority research.

The latest National Health and Morbidity Survey (NHMS) 2023 found a high prevalence of noncommunicable diseases (NCDs) among the Malaysian population, such as diabetes (15.6 %), hypertension (29.2 %), hypercholesterolemia (33.3 %), overweight and obesity (54.4 %), and depression (4.6 %).

Meanwhile for communicable diseases, dengue fever remains a growing problem. Although Malaysia practices various control measures, the incidence rate of dengue fever keeps rising, with a 235.6 % increase in cases reported between December 31st 2022 and June 10th, 2024. Tuberculosis (TB) also remains a great public health threat, given the 5.5 % increase of reported TB cases from 2022 to 2023. For most conditions mentioned above, considerable knowledge exists on effective interventions with established practice guidelines developed locally and globally. However, research is needed on how best to apply such interventions in the Malaysian context.

Clinical research had an estimated market value of USD 54.2 million in 2021, with a focus mostly on interventional treatment such as drugs, biologics, and bioavailability or bioequivalence (BA/BE), in the sectors of infectious diseases, oncology, cardiology, haematology. There are currently 6 Research Clusters:

- Clinical pharmacy
- Pharmacy policy and practice
- Pharmacoeconomics and outcome-based research
- Pharmaceutical development analysis
- Regulatory and enforcement
- Pharmacoepidemiology & data analysis

Challenges

While there are multiple guidelines available (e.g. Good clinical practice, Guidelines on use of human biological samples in research, BA/BE, Standards for stem cell, cord blood banking, Ethics guide, etc) there is however no overarching legal framework. There were plans for a Clinical Trial Act by 2025, incorporating intervention-based clinical research, quality of clinical research, and data protection but this has yet to materialise.

Other challenges are constraints for university and hospitals which include overworked staff and limited access or availability to perform studies. Generally, clinical research is conducted in Malaysia at university hospitals, Ministry of Health hospitals and increasingly at private medical centers across the country. Academic clinicians belonging to the other 15 medical schools nationwide do not have access to their own university hospitals but have to rely on state government hospitals for teaching. The constraints facing these hospitals make research activities limited.

There have previously also been issues with transparency and lack of trial sites, this has been reduced with creation of Clinical Research Malaysia (CRM), an organization established to enable the research ecosystem in Malaysia. This also aims to reduce the research gaps when informing policy or decision makers, and intensify the use of R&D findings in policy development.

Recruitment of participants

With regards to recruitment of participants for clinical trials, there are a number of pathways. For example, there are private hospitals that do it themselves:

- Sunway Medical: https://www.sunwaymedical.com/en/clinical-research-centre
- Pantai Hospital: https://www.pantai.com.my/kuala-lumpur/clinical-research/join
- Penang Adventist Hospital: https://pah.com.my/clinical-services/clinical-research-centre

One of the main agencies, Clinical Research Malaysia, hastheir own program "FACT" (Find A Clinical Trial) which allows for self-registration. They also have a campaign "I am Aware" to make people aware of clinical trials. The guidelines for Clinical Trials Phase 1 can be found here.

The Society of Clinical Research Professionals Malaysia (SCRPM) has written a Guide to Conducting Clinical Trials in Malaysia. In general, there are no restrictions on the methods of recruitment, only the requirements that participants must be fully informed.

Please note that the above parties are private entities. Under the Ministry of Health (MOH) or public hospitals and research centers, there are the following departments or responsible agencies:

- Clinical Research Center (CRC), a department of the Ministry of Health has published various guidelines on clinical research, which also includes "International Ethical Guidelines".
- National Pharmaceutical Regulatory Agency (NPRA) - Any research center or ethics committee conducting clinical trials on pharmaceutical products/drugs must be approved/accredited by NPRA.
- National Committee for Clinical Research (NCCR)
- National Medical Research Register (NMRR): a digital platform for research documents at the MOH. They have also published their guidelines on clinical trials, as well as share documents and information on all registered doctors and trials.
- Medical Device Authority (MDA) are the responsible agency for medical devices. More information: https://portal.mda.gov.my/index.php/industry/exemption/clinical-research-performance-evaluation
- MOH: Guidelines for Conducting Research in MOH Institutions & Facilities
- Malaysian Research Ethics Committee

Other Ethics Committees include:

- Joint Penang Independent Ethics Committee (JPEC)
- There are also „Research Ethics Committees" at various Malaysian Universities that conduct trials:
    - UMMC (https://www.ummc-mrec.org/)
    - UKM (https://www.ukm.my/jepukm/wp-content/uploads/2023/09/1.-UKM-JEP-GP00-Guidelines-For-Ethical-Review-Of-Clinical-Research-Or-Research-Involving-Human-Subjects.pdf)
    - USM (http://www.crichs.usm.my/images/downloads/2013/ResearchEthicsSeminarforArtsBasedandHybridSchools/ResearchEthicsPolicyinUSM_NHO.pdf)
    - UiTM (https://rec.uitm.edu.my/)

Rare Diseases

Much like in many other countries, Rare Diseases in Malaysia remain an underserved segment of the healthcare industry, due to several factors – firstly the high cost of research, treatment, and management of diseases, as well as the low rate of prevalence and lack of information and awareness among the public. There is also a scarcity of experts in the matter, with only 14 clinical geneticists in Malaysia attached mostly to University Hospitals in the capital city Kuala Lumpur.

Nevertheless, things have improved significantly in recent years: Malaysia has been involved in the Rare Disease Network under APEC's Life Sciences Innovation Forum since 2018, while in 2019, the Ministry of Health (MOH) set up a National Framework for Rare Diseases to create a governance committee for those suffering from such ailments in Malaysia. Then-Deputy Minister Dr Lee Boon Chye said the committee would advocate health education to the public, screening, and diagnosis of rare diseases, as well as boost pre-partum diagnosis and examination, clinical management, reference system, data collection and research.

Under this framework, "Rare Disease" has been defined as a life-threatening and/or chronically debilitating rare condition as listed in the Malaysian Rare Disease List (Pages 23-40), wherein the criteria for inclusion are:

1. There are confirmed patients in Malaysia
2. The disease affects fewer than 1 in 4,000 people in Malaysia
3. The disease is a severe condition
4. Its inclusion is approved by the national advisory committee

Governance of Rare Diseases services would also be improved by drafting policies and strategies related to acquisition and access to orphan drugs and limited products in Malaysia. The government is focusing on long-term plans for rare diseases in Malaysia, such as encouraging research and development in rare diseases, ensuring that laws and regulations protect the rights and interests of rare disease patients, and working with insurance companies to protect rare disease patients.

In the long term, the ministry aspired to create a registration base of rare diseases to collect and analyse data for developing and monitoring the health of the patients – this was scheduled in the 12th Malaysia Plan, and has so far established a list of 500 rare disease cases in the country.

Based on the prevalence of 1 in 4000, there is an estimated 8000-10000 people with a rare disease in Malaysia. According to Rare Diseases Malaysia, among the top five rare diseases in Malaysia are Marfan syndrome; Prader Willi syndrome; Osteogenesis imperfecta; Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like episodes (MELAS); and mucopolysaccharidosis type (MPS) type two.

In March of 2022, the MOH added another RM1 million allocation to the Genetics Lab at Tunku Azizah Hospital in KL to strengthen laboratory testing for patients with rare diseases. This follows allocations of RM250,000 to Hospital KL since 2008 for outsourcing of diagnostic tests for patients suspected of having rare diseases; RM16 million in 2019 and RM16.5 million in 2020 for treatment of rare diseases; and RM10 million in 2021 for follow up treatments of rare diseases.

Furthermore, a Rare Disease Trust Fund will be established in partnership with patient advocacy groups to create sustainable funding for treatment of rare diseases in Malaysia. Under the same strategic plan, the MOH has also formed a guideline for easy access to orphan medications under the Malaysian Orphan Medicine Guideline. The definition of an orphan medicine is a medicinal product that is primarily intended to treat, prevent or diagnose a rare disease.

According to local advocacy groups, some of these medicines can cost each patient over RM1 million a year, which is a significant burden, especially when considering that most patients will need these medicines for life.

While Malaysia is one of the few countries in the region that provides public subsidies and dedicated funds for rare diseases such as for ERT, funding for treatment is often contingent on charities, public and industrial subsidy or OOP payments. Additionally, even with the availability of innovative drugs being developed, they are often not registered with the Health Ministry's Medicine Formulary but can only be provided via special approvals on a case-by-case basis.

Aside from Rare Diseases Malaysia, the primary advocacy group, other foundations include Rare Diseases Alliance Foundation Malaysia, the Malaysian Rare Disorders Society, and the Malaysia Lysosomal Diseases Association.

LEGISLATION & REGULATIONS

Registration and Import Procedure

The process for designation and registration of Orphan Medicines falls under the purview of the National Pharmaceutical Regulatory Agency (NPRA), the body in charge of regulating and registering all pharmaceutical products, including traditional medicine and health supplements, as well as cosmetic products, in the country.

The mechanism to allow for such an unregistered treatment to be brought into Malaysia, where there are no other suitable options or alternative treatments available, is that the healthcare facility treating the patient may submit an Import Permit application for the importation and use of an unregistered medicine.

This is done via the Application for Medicines of Special Approval or Application to Import Product for the Treatment of Life-Threatening Illnesses, and the processing and evaluation of such applications will be expedited by the Pharmaceutical Services Programme in order to ensure timely access to the medicine needed for the treatment of the patient's condition.

Orphan medicines can be categorised as either emergency treatment, which is required immediately to save the patient's life or prevent permanent disability, or lifetime treatment, which is required for long-term or maintenance therapy for the disease.

While the designation of orphan medicine is subject to NPRA's decision with input from the Drug Evaluation Committee (DEC), any local, registered health- or pharmaceutical-related company or legal entity can apply for a drug to be designated as an orphan medicine through the NPRA.

The application must be submitted before a product is registered as a New Chemical Entity or a Biologic product, and the DEC will decide whether or not to grant the designation of orphan medicine within 45 working days upon receipt of the application.

The Product Registration Holder (i.e. the company or legal entity making the application) is required to provide the product information, the proposed rare disease and condition, as well as the scientific rationale for the orphan medicine use when applying for the orphan medicine designation.

When a drug has been granted the designation of orphan medicine, it will be automatically granted priority review status for registration, and the review process will then be completed within 120 working days. Subsequently, the Product Registration Holder is responsible for monitoring any drug-related adverse effects, submitting regular safety reports and alerting the NPRA to any global safety issues relating to the drug.

Critical Care Pharmacy Service

Critical Care Pharmacy Service (CCPS) in Malaysia was initiated in early 2000 and provides specialized pharmacotherapy service in critically ill patients who may require special considerations, or present with complex pathophysiology changes.

As a result, the pharmacotherapy in this population becomes complex and challenging as the changes may affect drug pharmacokinetics, which could affect drug dosing. As a standard of care while in the intensive care unit (ICU), the critically ill patient may receive various medications such as sedative agents, analgesics, inotropes, vasopressors, neuromuscular blocking agents which require close monitoring.

Optimising medication is a central and key role expected of pharmacists in all clinical areas, not only in critical care. By working as a team in critical care setting, critical care pharmacists are able to see the entire case-mix and thus are able to manage the pharmaceutical care of an extreme range of health problems, as well as quickly assimilate information and management paths for conditions.

The implementation of critical care pharmacy service in Malaysia has impacted on the patient's overall care, through provision of pharmaceutical care in collaboration with other healthcare professionals. Critical care pharmacists, as integral members of interprofessional teams in the ICU, must work together, especially with the treating physician, to ensure the safe and effective use of medications in critically ill patients, the delivery of optimal care, and risk reduction of any adverse events.

For more details on the standard of care, as well as pharmacotherapeutic recommendations by the CCPS, the latest update of the Critical Care Pharmacy Handbook (2020) published by the Pharmaceutical Services Programme of MOH covers Pharmacotherapy in Critical Care, special considerations, as well as common clinical issues and management in critically ill patients (e.g. shock, renal dysfunction, liver dysfunction, cardiovascular issues, pulmonary disorders, hematologic disorders, DVT, pulmonary embolisms, ulcers, delirium, etc).

6. MEDICAL EDUCATION & TRAINING

Malaysia's medical services sector is classified in the Malaysian Standard Industrial Classification under codes 8511, 8512, 8519 for human services, and 8520 for veterinary services. All medical and health care practices must be registered with the Companies Commission of Malaysia (CCM), while all practitioners must be registered with the Malaysian Medical Council (MMC), which oversees the medical profession in Malaysia. The Medical Programme of the MOH acts as the largest provider of the country's healthcare services and has a pivotal role in shaping the development of secondary and tertiary services.

Medical training usually takes 5 years, with newly graduated doctors required to perform at least 2 years of housemanship and 2 years compulsory government service, in public hospitals throughout the nation, the aim of which is providing adequate coverage of medical needs for the general population outside city centres. However, the government's contract system introduced in 2016 has led to numerous issues for contract doctors who face job insecurity and unequal pay, causing them to leave public service at the end of their contracts.

There is a significant shortfall in the medical workforce, especially of highly trained specialists (as many as 4,000 across both the public and private sectors), leading to the specialised medical care and treatment having limited availability, generally only in large cities. Efforts to bring newer facilities to other areas are hampered by lack of such expertise.

The MOH has created 16.347 new positions across various roles in 2024. It offered 3,200 permanent positions to medical officers, 350 to dental officers and 400 to pharmacy officers. Furthermore, it will introduce a rotation system in order to improve the placement of medical officers in urban and rural sectors, and to address the shortage of workers in the sector. As of Sept 30, 2024, data of the MOH showed that out of the 299.672 healthcare personnel serving in the ministry, 266.898 are permanent staff and 32.774 are on contract. There are 7.720 medical specialists, 44.030 medical officers, 7.626 dental officers, 12.775 pharmacists, 70.075 nurses and 9.798 assistant medical officers.

Medical Training in Malaysia

Medical education in Malaysia is overseen by the Malaysian Medical Council (MMC), which sets standards for medical education and registration. Medical education in Malaysia is conducted in both public and private institutions.

Medical Schools in Malaysia generally offer a five-year undergraduate medical degree program for future doctors. The first two years of the program focus on basic medical sciences, such as anatomy, physiology, and biochemistry, while the remaining three years focus on clinical training in hospitals and clinics.

It is compulsory for newly graduated students to work in governmental hospitals under the housemanship program (also called internship) for a duration of at least two years that combines service and training roles. This Internship may be longer at the discretion of each trainee supervisor regarding their knowledge, skills, competency and attitude in each particular discipline, but the total duration of the internship training should not exceed six years.

At the end of their internship and upon being given full registration as a doctor, every practitioner has to serve a minimum continuous period of two years within the public services according to section 40 of the Malaysian Medical Act 1971. As defined under Article 132 of the Federal Constitution, this service may be completed in a government healthcare facility, the Ministry of Health, or other government agencies as determined by the Director General of Health. During this period, they are required to rotate through various departments, including internal medicine, surgery, pediatrics, obstetrics and gynecology, and others.

Once the internship is completed, graduates are required to sit for the Medical Qualifying Examination (MQE) to obtain full registration with the MMC. Upon completing 2 years of housemanship, a houseman will then be promoted to the rank of Medical Officer (MO), where they can move into private practice as an MO, or upon

completing a year as a Medical Officer, can continue to specialize, which can take 3-6 years depending on which discipline.

Doctors who wish to specialize in a particular field must undergo further training and obtain a postgraduate qualification in their respective specialty. Specialty training in Malaysia is conducted through various pathways, including the Master of Medicine (MMed) program, the Membership of the Royal Colleges of Physicians (MRCP) program, and the Fellowship of the Royal Colleges of Surgeons (FRCS) program. In order to be a registered medical specialist in Malaysia, 4-5 years of postgraduate study is needed in addition to 2-4 years of supervised training as a specialist.

Nursing courses in Malaysia

Upon completing the Malaysian Certificate of Education, Sijil Pelajaran Malaysia (SPM), the equivalent of O Levels, interested students can enrol into a 3-year Diploma in Nursing, after which they proceed to sit for the Malaysian Nursing Board Exam to become a registered nurse (RN). There is a required 2-3 years of service in a hospital, clinic, or a relevant institution in the industry.

Shortly after, an RN may pursue a post-basic nursing course to receive advanced level training in a specific area before proceeding with an undergraduate degree. It is also possible to enrol in an undergraduate programme immediately after the required service.

To become an advanced practice registered nurse in a specialised field, e.g. certified nurse specialist, nurse anaesthetist, or nurse practitioner, a master's degree is required. Nurses who desire to advance further can choose to enter a doctoral programme, allowing them to be a clinical nurse specialist before becoming a nurse administrator, or to be a clinical instructor before advancing to become a lecturer.

To ensure that only licensed and competent nurses are providing care, the Malaysian Nursing Board was founded to protect the welfare of patients. It outlines safe nursing care standards and issues licences to practice nursing according to the Nurses Act 1950. As such, student nurses trained locally or abroad must register themselves with the board to be eligible to practice nursing legally in Malaysia.

Similar to doctors, nurses must obtain an Annual Practising Certificate from the board and their details will be recorded on the Register of Practising Nurses in Malaysia, allowing them to practice in places like hospitals, private clinics, schools, government organisations, and nursing homes.

Malaysia's Health Minister, Dr. Dzulkefly Ahmad, warns of a looming 60 % shortage of nurses by 2030. He advocates for a joint effort between public and private sectors to tackle this issue. (HealthCareAsia).

Parallel Pathway
The parallel pathway system for medical training in Malaysia is a system that allows medical graduates to pursue specialty training in parallel pathways, depending on their preferences and circumstances. It was designed to allow training of Internal Medicine Trainees in a way that does not jeopardise services to patients. While Specialist training in the country is largely provided by the public universities through a structured multi-year Masters programme, the country is still facing a shortage of specialists to meet the requirements of both the private and public sectors.

The Ministry of Health (MOH) allocates about 1,500 scholarships for the Masters training programme each year. Unfortunately, the Universities are able to offer only 750 to 800 training positions. The Universities are unable to cope with the increasing demand for specialist training. In acknowledging the constraints of the Universities, the MOH has embarked on providing support for 'alternate' or 'parallel' pathways for its doctors to become specialists.

Under this pathway, medical graduates can choose to pursue specialty training in private hospitals or clinics, instead of public hospitals or universities. The 'alternate pathway' not only provides greater opportunities for specialist training, it also accords some flexibility to the trainees. It allows trainees to pursue specialist training fairly early in their career and without disruption to their service to the MOH. Because of the large clinical load in the MOH facilities, the trainees gain sufficient clinical opportunities to fulfil the educational requirements and achieve competence in their relevant specialty.

While there are advantages of the 'parallel pathway' for specialist training, such as allowing private healthcare providers to participate in the training of medical specialists, which can help to improve the quality of medical care in the private sector, the system has also faced some criticism for potentially creating disparities in the quality of medical training and for the lack of oversight and standardization in the selection and training of medical specialists.

In 2024, there are 1,400 doctors undergoing training in the family medicine parallel pathway with FRACGP (1,058) and MICGP (345). It is noteworthy that 102 individuals have successfully completed their training but have not yet registered on the NSR. While the Fellowship of the Royal Australasian College of General Practitioners (FRACGP) is on the MMC's list of recognised qualifications, the Irish College of General Practitioners (MICGP) is not.

The financial obligations for each officer pursuing parallel pathway training are outlined as follows: RM250,000 for six years in Cardiothoracic Surgery, RM180,000 for four years in Plastic Surgery, RM100,000 for four years in Family Medicine (MICGP) and RM60,000 for four years in Family Medicine (FRACGP).

LEGISLATION & REGULATIONS

Requirements
In the Malaysian context, it is a prerequisite for medical graduates to undertake a minimum of two years of clinical training, designated as housemanship, prior to attaining full registration with the Medical Council of Malaysia (MMC). This clinical training period is intended to ensure that medical practitioners possess the necessary competencies to practice.

It is an irrefutable fact that medical practitioners require a significant amount of formal education, and the Malaysian Medical Council (MMC) has set specific academic benchmarks for medical education in Malaysia. Currently, achieving 3B in core science subjects (Biology, Chemistry, Physics, and Mathematics) is a standard requirement for progressing to pre-university programmes that lead to medical school. The CGPA of 3.0 at STPM/Matriculation/A-Level is a widely recognised benchmark for entry into medical programs in Malaysia, as it ensures students have the academic capability to handle the rigorous demands of medical education. However, the Malaysian Medical Council and the Education Ministry are planning to raise the bar in an attempt to solve the influx issue while simultaneously producing Doctors of higher quality.

The Malaysian Standards for Medical Specialist Training 2019 were approved by the MMC in June 2019, and all existing and new medical specialties will have to meet these standards. An existing Medical Specialty is one that is recognised and already listed in the National Specialist Register (NSR). A new Medical Specialty is one that is not yet on the list of specialties recognised by the National Specialist Register. The Specialty

Subcommittees for Education (SSC-Edu) are responsible for evaluating submissions for recognition of training programmes of medical specialties conducted by education training providers.

The practice of medical practitioners is primarily governed by the Medical Act 1971 and subsidiary legislation, such as the Medical Regulations 2017. In accordance with the provisions enshrined within the Medical Act 1971, all medical practitioners are obligated to register with the Malaysian Medical Council (MMC) to legally practice medicine within the Malaysian jurisdiction. The MMC's fundamental objective is to ensure that medical practitioners meet the requisite standards of knowledge, skill and competence to provide safe and effective medical care. Registration is contingent upon the possession of a recognised basic medical degree, as enumerated in the Second Schedule of the Medical Act 1971.

Furthermore, practitioners must possess adequate professional indemnity insurance to practice. This provision is intended to ensure that patients are protected in the event of malpractice. Practitioners are further obliged to engage in Continuing Professional Development (CPD) programs to maintain and update their medical knowledge and skills.

The Medical Council (MMC) is responsible for the regulation of the medical profession, including ensuring compliance with the Medical Act 1971, monitoring the ethical conduct of practitioners, and taking disciplinary action against those who violate professional standards. Newly qualified practitioners are required to complete a compulsory service period in government healthcare facilities. This is part of a national effort to ensure adequate healthcare coverage. The Medical Act 1971 was enacted to consolidate and amend laws related to the registration and practice of medical practitioners. It was also enacted to provide for a probationary period for newly registered practitioners and to regulate their qualifications and conduct.

Veterinarians

All vets must be registered with the Malaysian Veterinary Council, which falls under the purview of the DVS. The prevailing veterinary associations are the Veterinary Association Malaysia (MAVMA), and the Malaysian Small Animal Veterinary Association (MSAVA). There are also smaller associations such as the Malaysian Association of Farm Animal Veterinarians (MAFAV, no website available) and the Malaysian Society of Animal Production (MSAP).

Veterinarians are subject to the Veterinary Surgeons 1974 (Act 147), and for the Bornean states, the Veterinary Public Health Ordinance Sarawak 1999 and the Sabah Animal Ordinance 1962. They are required to prove their Continuing Professional Development (CPD) before being granted their Annual Practice Certificate (APC). The guiding principle is that all Veterinary Surgeons must, for the betterment of their professional standing, keep up with ever-growing knowledge and developments relevant to their fields of practice. In 2015, the MVC appointed MAVMA to be the coordinator for the assessment and to award CPD points for any related event within the veterinary fraternity in Malaysia.

Overview of CME / CPD credits for healthcare employees in Malaysia

The Malaysian Medical Association (MMA) is the body that represents registered medical practitioners in Malaysia. In 1994, it introduced a national Continuing Medical Education (CME) system on a voluntary basis for all doctors in the country. The name of the grading system was changed to MMC CPD Grading System in July 2006; CPD being a broader term that encompasses all types of professional development activities, including CME.

To facilitate the development of CPD and accord it legitimacy, Malaysia amended its Medical Act, 1971 to make CPD a mandatory requirement for fully registered medical practitioners. The Medical (Amendment) Act 2012 and the Medical Regulations 2017 that came into force on 1st July 2017 require doctors to keep abreast with advances and developments, and to acquire compulsory CPD points for the renewal of the Annual Practicing Certificates (APCs) and their revalidation of specialist status in the National Specialist Register (NSR).

The Malaysian Medical Council (MMC) is responsible for overseeing the CME/CPD accreditation process and ensuring that healthcare professionals meet the minimum CME/CPD requirements to maintain their registration and practice licenses.

The MMC has mandated the following CPD Administrators: the MMA CPD System, the MyCPD System of the Ministry of Health (a web-based system that records CPD points for all Ministry of Health staff), and the Academy of Medicine of Malaysia Medical Specialist CPD System to record CPD points.

The CPD point system is a mechanism for recording CPD based on the time spent on an educational activity, as well as recording attendance. Educational activities that are eligible for CPD points are those that support and improve professional development and practice: The MMC, in consultation with the MOH, MMA, and AMM, has identified several different types of learning that count as CPD activities, grouped into eight categories (A1 to A8) in the MMC-CPD Grading System (2020).

In this latest grading system, CPD points can be awarded not only for attendance at meetings and conferences but also for work-based learning and quality improvement activities. The scope of scholarly activities has been expanded, and an additional category has been added for professional development activities including leadership role in medical societies, **self-development courses** and community activities.

All registered medical practitioners are encouraged to participate in the MMA CPD System. Members of MMA are automatically registered in the system. Non-members must register to participate in the MMA CPD System; they must provide their MMC full registration number so that their status as a registered medical practitioner can be ascertained before registration is confirmed.

Requirements

Per the Continuing Professional Development (CPD) Guidelines by the MMC, the CPD Requirements for renewal of an APC are:

- A minimum of 20 CPD points per CPD year for the renewal of APC
- The quality and relevance of CPD activities matter more than the quantity of CPD points
- The collection of CPD points for the application of APC for a CPD year shall be from 1st July to 30th June, e.g. CPD points for the application of APC for 2021 shall be from 1st July 2019 to 30th June 2020.
- There is no maximum limit to the number of CPD points a medical practitioner may obtain in the given CPD year
- Extra CPD points earned in a CPD year cannot be carried over to the next year
- A medical practitioner is expected to keep up to date and participate in CPD if they seek to maintain their APC during any career breaks

CPD Providers

Medical societies and Healthcare Institutions with enough resources and expertise to conduct CPD activities on a regular basis are encouraged to seek 'Approved Provider status' from CPD administrators. Accredited Provider status will confer organisations a one-time approval for all the CPD activities to be conducted for the CPD year. The MMC has set out criteria for the providers in their Quality Standards and these criteria have to be fulfilled to ensure that CPD activities have strong educational content and are relevant to the practitioners.

As of October 2020, 508 active CPD providers had re-registered with the MMA CPD System via the MMA CPD Portal, from the following categories (in order of largest number of providers):

- Specialist bodies and societies
- Government hospitals
- Private hospitals and medical centres
- Departments in the Ministry of Health
- Universities, colleges and institutes

A mobile application for CPD providers and doctors was launched in May 2017; with its advent, it has become possible to work with CPD providers offering online CPD modules. The websites of these providers are linked to the MMA CPD Portal via an application programming interface (API) and CPD points are accredited to the user's MMA CPD mobile application upon successful completion of each module. At present, the education websites with CPD online modules linked to the MMA CPD Portal include those of MIMS Education, Docquity, Medcomet, Prezcapture and the Malaysian Thoracic Society.

In addition to these institutions, the Malaysian Medical Association (MMA) and the Academy of Medicine Malaysia (AMM) also offer CME / CPD activities for healthcare professionals.

7. MARKET ENTRY

Actors & Institutions

The main players in the medical sector in Malaysia are the Ministry of Health (MOH; KKM in Malay) and their various divisions, notably the Medical Device Authority for all matters related to medical devices, the National Pharmaceutical Regulatory Agency for matters related to pharmaceuticals, and the National Institutes of Biotechnology for matters related to the development of the biotechnology industry.

While public hospitals are owned and run by the MOH, there are a number of private hospital operators, namely IHH, KPJ, Pantai Hospitals, Park City, Sunway, Columbia Asia, Gleneagles and Prince Court among the most renowned. Almost all of them belong to the Association of Private Hospitals Malaysia (APHM). The promotion of Medical Tourism in Malaysia is handled by the Malaysia Healthcare Travel Council.

Medical technology falls under the purview of the Malaysian Science and Technology Information Centre (MASTIC), a division of the Ministry of Science, Technology and Innovation (MOSTI). All medical regulations, standards, and certifications are under their respective divisions within the MOH.

Other external stakeholders also include university hospitals and non-governmental organisations; there are a number of associations for practitioners of various fields of medicine, including dental, TCM and surgical. A comprehensive list can be found in our "Contact" section later in this report.

Import Tariffs

While Malaysia has a zero-tariff policy for imported pharmaceuticals, other countries in ASEAN retain tariffs and some regulatory barriers, although there is a move towards greater harmonization. In a comparative study on generic drug registration requirements among the 10 ASEAN countries, Malaysia and Singapore are viewed as having well-established regulations and being stricter on the quality and safety of drugs.

It is also worth noting that ASEAN Health and Economic Sectors officials are currently engaged in the final stage of discussions for the establishment of the ASEAN Pharmaceutical Regulatory Framework (APRF), supplementing the ASEAN Pharmaceutical Regulatory Policy (APRP) that was adopted in June 2022 among member states. While the APRP provides a basis for structuring regulatory systems for pharmaceutical products across ASEAN, with the goal of enabling the reduction of trade barriers and enhancing harmonisation of regulatory requirements and collaboration between regulators, as well as ensuring timely access to high quality, safe and efficacious products, the final objective is an ASEAN free market for pharmaceutical items.

The APRP provides guiding principles that will apply to approval and recognition arrangements, harmonisation of regulatory requirements and practices by governmental institutions and associated supporting mechanisms of ASEAN member states, for human pharmaceutical products placed on the ASEAN market. The scope of the APRP includes pharmaceutical products such as, vaccines, antidotes, and other critical or life-saving pharmaceuticals, and all activities related to the development, testing, manufacture and distribution of these products.

The eventual framework would lead to greater opportunities for companies that establish themselves in the region, allowing them to access a wider target audience – Southeast Asia, home to 698 million inhabitants, is one of the fastest growing economic regions in the world.

Standard import tariffs by HS codes and exceptions:

Code	Description	Import Rate	SST
3001	Drüsen und andere Organe - Glands and other organs	0 %	0 %
3002	Menschliches und tierisches Blut Antisera udgl - Human and animal blood Antisera etc.	0 %	0 %
3003	Arzneiwaren nicht für den Kleinverkauf - Medicinal products not for retail sale	0 %	0 %
3004	Arzneiwaren für den Kleinverkauf - Medicinal products for retail sale	0 %	0 %
3005	Watte Gaze Binden Heftpflaster udgl - Cotton wool Gauze Bandages Adhesive plasters etc.	0 %	0 %
3006	Andere pharmazeutische Waren - Other pharmaceutical goods	0 %	0 %
300693	Placebos and blinded (or double-blinded) clinical trial kits for a recognised clinical trial, put up in measured doses	0 %	Up to 10 %

Processing Fees

Processing fees as stipulated under Regulation 8, Control of Drugs and Cosmetics Regulations 1984:

No.	Category of Product	* Processing Fees (RM)	Analysis Fees (RM)	Total Fees (RM)
1	Pharmaceutical (New Drug Products / Biologics)	1 000	Single active ingredient: 3 000	4 000
			Two or more active ingredients: 4 000	5 000
2	Pharmaceutical (Generic / Health supplement)	1 000	Single active ingredient: 1 200	2 200
			Two or more active ingredients: 2 000	3 000
3	Natural Product	500	700	1 200
4	Natural products with therapeutic claim	1 000	Single active ingredient: 3 000	4 000
			Two or more active ingredients: 4 000	5 000

Processing and Analysis Fee for Product Registration

Every application for registration shall be accompanied with a processing and analysis fee, as specified below (effective 1st January 2007)

No.	Category of Product	Processing Fees (RM)	Renewal Fees (RM)
1	Innovator/ New Chemical Entity	1 500	1 000
2	Pharmaceutical a) Generic (Scheduled Poison) b) Generic (Non-Scheduled Poison)	1 500	1 000
3	For Export Only (FEO) a) Generic (Scheduled Poison) b) Generic (Non-Scheduled Poison)	500	500

Charges for Applications of Licenses

After a product is registered, the applicant shall apply for a manufacturer/import/wholesale license. The process fees are specified below:

License	Timeline	Processing Fee	Validity
1. Manufacturer	4 working days upon receipt of complete application	1 000	1 year
2. Import	4 working days upon receipt of complete application	500	1 year
3. Wholesale	4 working days upon receipt of complete application	500	1 year

Timeline

No.	Product Category	* Duration (Inclusive screening process)
(A)	Full Evaluation	
1	New Drug Products	245 working days
2	Biologics	210 working days
3	Generics (Scheduled Poison)	210 working days
4	Generics (Non-Scheduled Poison)	210 working days
No.	**Product Category**	*** Duration (Inclusive screening process)**
(B)	Abridged Evaluation	
5	Generics a) Single active ingredient b) Two (2) or more active ingredients	 116 working days 136 working days
6	Natural Products a) Single active ingredient b) Two (2) or more active ingredients	 116 working days 136 working days
7	Health Supplements a) * Single active ingredient b) * Two (2) or more active ingredients * Applicable for: i) General or Nutritional Claims; and ii) Functional Claims (Medium Claims) c) Disease Risk Reduction Claims (High Claims)	 116 working days 136 working days 245 working days

*Upon receipt of complete application

Source: NPRA, Appendix 9 Fees

General Legislation

Infrastructure

Healthcare is a highly regulated affair in Malaysia. Among the most important regulations in the Private Healthcare sector are the Private Healthcare Facilities and Services Act 1998 and the Private Aged Healthcare Facilities and Services Act 2018, which regulate licensing, approval and registration processes, as well as responsibilities and quality control for private healthcare facilities, and for those providing elderly care respectively. These acts also details the restrictions and the basis for any fines, rescission/suspensions of approvals, or terms of further action as deemed necessary.

Life Science, Biotechnology, and Research

Other relevant acts include:

- Human Tissues Act 1974: makes provisions with respect to the use of parts of human bodies of deceased persons for therapeutic purposes and for purposes of medical education and research.

- Prevention and Control of Infectious Diseases Act 1988: governs efforts to control the import and spread of infectious diseases, including preventive and countermeasures to take in such cases.

- Pathology Laboratory Act 2007: In principle, this Act governs the National Pathology Laboratory and seeks to ensure that it is accountable to the public, meets required standards of practice, participates in Quality Assurance programmes, is run by qualified staff, complies with safety requirements and is subject to continuous audit.

Services

The General Surgical Services Operational Policy 2018 covers the quality of surgical services and advancement of subspecialties, ensuring conformance to the highest international standards. It also highlights areas of special attention and current solutions. This policy will be reviewed in the year 2023 and updated if necessary.

To legally practice medicine in Malaysia, medical practitioners are required to be registered with the Malaysian Medical Council (MMC). The license to operate a private healthcare facility will only be awarded to a qualified Malaysian medical practitioner.

Foreign practitioners who wish to practice in Malaysia are required to obtain the necessary approval from the MMC for a full registration certificate / annual practising certificate / temporary practising certificate and the National Specialist Register (NSR) for specialist credentialing.

Other legislation related to medical services include (in chronological order):
Nurses Act 1950: provides for the registration of nurses for the sick.

Medical Act 1971(Amended 2012): consolidates and amends the law relating to the registration and practice of medical practitioners and for national purposes.

Dental Act 1971: Regulates and provides a framework for practice of dentistry and dental services in Malaysia, including the setup of the Malaysian Dental council that oversees the space.

- **Repealed and replaced by the Dental Act 2018 (Act 804), effective Jan 1, 2022.** Among the new provisions are a Professional Qualifying Examination for the purpose of the registration of dentists, the registrations of dental specialists and dental therapists, and the need to collect points for Continuing Professional Development (CPD) and Professional Indemnity.

Optical Act 1991: provides for the registration of persons practising as opticians and optometrists, to control the practice of optometry, and related matters.

Malaysian Health Promotion Board Act 2006: establishes a board to deal with coordination of health issues, as well as promotion, advice and programs to improve population health.

Guidelines on Aesthetic Medical Practice 2015: ensure the safety of aesthetic medical practice in Malaysia. These guidelines define the scope of practice allowed, the minimum level of competency required and the process of registration for medical practitioners. Like any other fields of medical practice, these practitioners are subject to the Code of Professional Conduct and other related laws governing medical practice.

Allied Health Professions Act 2016: regulates allied health professions which were previously unregulated, and establishes a council to regulate and control registration, quality, and practice of allied health professionals.

Traditional and Complementary Medicine Act 2016: provides for the establishment of the T&CM Council to regulate the T&CM services in Malaysia and related matters.

Procurement & Tenders Process For Hospitals

While there is no specific legislation in Malaysia that dictates procurement in general, government procurement processes are largely governed by the treasury instructions and treasury circulars ("Treasury Instruments") issued by the Malaysian Ministry of Finance (MOF).

eProcurement (also known by its Malay name "ePerolehan") is an electronic procurement system that enables suppliers to offer their products and services to the Government via an online platform. This system acts as an alternative medium for suppliers of products and services to register / renew their Ministry of Finance (MOF) Certificate.

According to the General Hospital Operational Policy by the Medical Development Division of the Ministry of Health Malaysia, procurement of hospital supplies or specific items shall be coordinated by the relevant department. The procurement process should include the activation of three various committees i.e. Specification, Technical, and Financial, and the Hospital Management Committee shall establish a system that is transparent to ensure that the procurement process is carried out in accordance with Treasury Instructions. The respective head of the department shall be responsible for preparing the technical specifications.

Policies & Initiatives

Malaysia Telemedicine Blueprint 1997

The Telemedicine Blueprint established by the MOH in July 1997 was an initiative by the Malaysian government to employ the use of telehealth in the country's healthcare system. There were 4 main components in the blueprint that were later restructured into seven components in 2000, and then reorganised yet again after an integration with the Integrated Health Enterprise (IHE) in 2007, into five major components:

- Lifetime Health Record (LHR) & Services
- Lifetime Health Plan (LHP)
- Health Online
- Teleconsultation (TC)
- Continuing Professional Development (CPD)

The Blueprint envisioned that by the year 2020, the nation's health care system would be transformed with developments of advanced health systems by harnessing the power of information and multimedia technologies. Unfortunately almost all of the goals were not met and the pilot projects remained

uncompleted, mostly due to the fact that the technology of the time was not sufficiently mature or integrated, andthe cost was prohibitive.

While there were initial plans to revise and relaunch an updated plan in 2020/2021, this has still not materialised. In 2024 there was a proposition that the Act be abolished as it no longer covers current practices and is inefficient compared to the creation of a new legislation.

In its stead, however, there are concrete developments in the sector, especially with the partnership between MOH and DoctorOnCall (DOC), an online medical video consultation startup, which has since expanded to a full range of online medical services. They developed a virtual health advisory platform to address COVID-19 concerns and allow the public to access virtual consultations with doctors for free.

The partnership later developed further in the medical tourism sector, with a Memorandum of Understanding signed in 2021 with MHTC, to facilitate patient care continuity for their 75 member hospitals. The collaboration allowed the patients of these hospitals, both local and international, to continue consultations with their doctors in Malaysia while travel restrictions were in place.

The importance of telemedicine guidelines also lends itself to pharmaceutical services notably the delivery of medicine done after digital consults, as well as the digital recruitment of participants for clinical trials.

National Strategic Plan on HIV & AIDS 2016-2030

While the HIV/AIDS epidemic in Malaysia has seen steady progress, it remains a concern with an estimated total of 87,581 people living with HIV, with an incidence rate of 0.2 per 1000 population (latest report in 2020). The plan focuses on strategies and action plans to build on increased collaboration between the government and civil society organisations, improving the quality of health services through extensive training and capacity building of the community-based organizations and service providers, and ensuring a continuum of care between medical and paramedical health facility-based staff and outreach workers.

Malaysia Strategy Framework for Emerging Diseases and Public Health Emergencies II (MySED II, 2017-2021)

The scope of MySED II is to strengthen and further improve public health security systems and aims to provide a high-level framework that can give a common direction and approach to detailing hazard-specific strategies, such as how to prepare for biological and natural hazards. MySED II strengthens the core public health functions as well as many key health systems including the health workforce, service delivery, information & technology systems, and leadership & governance to support a more resilient health system. The revised strategy under the framework added "Public Health Emergencies" to the initial title "Emerging Infectious Disease", reflecting its core focus on Public Health Emergency Preparedness (PHEP).

MySED II has six interlinked objectives:

1. Strengthen effective preparedness for emerging diseases and public health emergencies
2. Reduce the risk of emerging diseases and public health emergencies
3. Strengthen early detection and assessment of outbreaks and public health emergencies
4. Strengthen rapid and appropriate response and recovery to emerging diseases and public health emergencies
5. Build strategic partnerships and sustainable financing for public health preparedness and response
6. Strengthen prevention through healthcare

And eight focus areas:

1. Public health emergency preparedness
2. Surveillance, risk assessment and response
3. Laboratories
4. Zoonoses
5. Prevention through healthcare

6. Risk communication
7. Regional preparedness, alert and response
8. Monitoring and evaluation

Strategic Framework of The Medical Programme 2021-2025

To ensure the goals of the 12th Malaysia Plan can be achieved, the Medical Programme developed its own strategic framework, which denotes a shift towards more emphasis on person-centred care in its effort to improve its services. This includes reorienting health service delivery away from hospital-centric acute care to a model that emphasises on accessibility, promotion of health, disease prevention and effective management of chronic debilitating illness, through a comprehensive community-based outreach programme. This also involves better integration with primary care counterparts.

The Medical Programme has identified key issues and challenges and developed strategies and implementation plans for the next five years. Among the major challenges are:

- Changing socio-demographic
- Increasing prevalence / incidence of non-communicable diseases
- Emergence and re-emergence of infectious diseases
- Increasing economic burden and scarce financial resources
- Rapid development of technology
- Old/outdated health facilities and equipment
- Unmet human resource needs

The Medical Programme will continue to play its role in intersectoral collaboration, international commitment, the development of the health industry and research.

The budget of the Medical Programme was distributed to 30 Financial Activities as listed below, covering a wide range of clinical specialties, subspecialties and other supporting services. 64 % of doctors (including medical specialists), 56 % of pharmacists and 70 % of nurses in the MOH were placed under the Medical Programme.

- Management of headquarters & state health departments
- Hospital management
- Emergency & outpatient
- General inpatient
- General medicine
- General surgery
- Obstetrics & gynaecology
- Paediatric
- Orthopaedic
- Anaesthesia & intensive care
- Ophthalmology
- Otorhinolaryngology
- Dermatology
- Neurology
- Nephrology
- Neurosurgery
- Urology
- Plastic surgery
- Radiotherapy & oncology
- Diagnostic imaging
- Pathology
- Pharmacy & supply
- Dietetic & food
- Cardiothoracic
- Nuclear medicine
- Respiratory medicine
- Psychiatry & mental health
- Rehabilitative medicine, Traditional & complementary medicine
- Transfusion medicine
- Forensic medicine

Figure 2 List of Services with Dedicated Code of Financial Activities under the Medical Programme, Ministry of Health Malaysia.
Source: Ministry of Finance Malaysia

*List taken from the Framework report.

Subsidies & Fiscal Incentives In The Medical Sector

When it comes to the medical sector, the Malaysian government mostly provide incentives in the following:

Research and Development
Malaysia's government continues to offer a wide range of incentives and financial assistance to attract investments in Research and Development (R&D) activities. To obtain financial assistance, there are different programmes, such as the "High Value and Complex Product Development Programme" (HVA) by the Ministry of International Trade and Industry (MITI). It is a form of financial support to enable the development of high value-added and complex products in certain sectors, including the Medical Devices Industry. Another programme is the Malaysia Grand Challenge (MGC), created by the Ministry of Science, Technology and Innovation (MOSTI) in January 2021. It offers five fund schemes, aiming to develop a R&A ecosystem with a focus on experimental development in certain areas, including Medical and Healthcare.

Furthermore, the country offers numerous potential R&D collaboration partners, offering investors opportunities to work with various entities to undertake R&D in Malaysia, such as Government Research Institutes (GRIs). The Institute for Medical Research (IMR) is one of at least 26 public research institutes and works under the purview of the Ministry of Health. Its R&D areas include pathology services, biochemical genetic testing for inborn errors of metabolism (IEM), molecular diagnostics for genetic diseases, detection of trace elements and metal in biological fluids, transplantation, allergy diagnosis, primary immunodeficiencies, molecular diagnosis of leukaemias, multiple myelomas and the diagnosis of infectious diseases.

The 12MP announced the government's plan to revise existing tax incentives in the private healthcare subsector to attract the involvement of more research-based organisations and increase foreign direct investment (FDI) in clinical research. This is to promote Malaysia as a regional hub in clinical research, especially in the fields of cardiology, oncology, rheumatology, fertility, and genetic diseases. Efforts will also be undertaken to increase domestic investment in the pharmaceutical industry through the commercialisation of R&D findings to secure a sustainable medicine supply in Malaysia.

Manufacturing (Pharmaceutical Products)
The Manufacturing of Pharmaceutical Products remains one of the country's promoted activities. The Income Tax (Incentive for Manufacturers of Pharmaceutical Products Scheme) Rules 2022 was gazetted on February 17th, 2022, and aims to attract investment in pharmaceutical products including vaccines by giving rare preferential corporate income tax rates to the companies approved for the incentive. It targets at both new and existing companies and allows an income tax rate of 0 % to 10 % for a period of 10 years and an income tax rate of 10 % for the subsequent period of 10 years.

To be eligible, the application for approval had to be made by December 2022. Furthermore, the company must be resident in Malaysia, possess a Ministry of International Trade and Industry manufacturing licence or a hold a letter of exemption from the MIDA, and must be incorporated under the Companies Act 2016. Its pharmaceutical products (including their formulation) must be manufactured in Malaysia; however, filling, finishing and packaging are excluded from this rule.

As part of the Budget 2023 announcement, it was proposed to extend the tax initiative for three years to further encourage the manufacturing of pharmaceutical products. This would have made it effective for applications received by MIDA from January 1st, 2023, until December 31st, 2025. However, the tax incentive was ultimately not included in Budget 2023 on February 24th, 2023. It remains to be seen if new extensions or proposals will be put forth to replace this incentive, but given the country's goal of developing the industry, this can be expected.

More details on all the above can be found on the MIDA and MDEC websites.

Trends & Opportunities For Austrian Companies

Industry analysts expect the pharmaceutical industry to be strengthened, as the New Industrial Masterplan 2030 (NIMP) rolled out in late 2023 indicates a government allocation of MYR 8.2b (US$1.8b) to enhance the competitiveness of the country's manufacturing sector across 21 industries, including the pharmaceutical sector. Among other things, the master plan promotes research, development of innovative pharmaceuticals and medical devices, improved collaboration among organizations and global firms, as well as increased support in the workforce. It also pushes for a stronger regulatory framework and a wider export market for locally made pharmaceutical products including APIs, vaccines, and medicines.

According to Fitch Solutions, they believe that by capitalising on these strategies, Malaysia can attract more investments and position itself as a regional leader in the pharmaceutical industry. While foreign investments might be limited due to existing price controls, local investments will be encouraged by government incentives. The firm projects medicine sales in Malaysia to rise to MYR 15.5b (US$3.3b) by 2027 from MYR 11.2b ($2.5b) in 2022, which equates to a 6.7 % CAGR.

Below are some trends and new developments in the field of Healthcare and Life Science in Malaysia.

Digitalisation (Telemedicine and E-Commerce)
Private healthcare services will focus on the adoption of Fourth Industrial Revolution (4IR) technologies to increase efficiency and effectiveness in service delivery, in particular the use of AI, IoT, and BDA to strengthen the provision of holistic end-to-end care and to enable real-time analysis and provide high quality healthcare services. A shift by private hospitals towards becoming smart hospitals will also increase the demand for the supporting tech, especially as it applies to infrastructure.

In the public sphere, ongoing consolidation of services, including mobile healthcare teams and planned flying doctor services, will necessitate the right technology for seamless communication and transfer of information. The government is also exploring the possibility of using AI to help doctors arrive at more accurate diagnoses, as well as connecting global insurers to patients.

Plans are in development for an integrated data system encompassing the public and private sector to capture and manage comprehensive information, including health registries, disease surveillance and economic activities related to healthcare. This system will facilitate the sharing of data and information between public and private healthcare providers and will require technology enabling real-time data analysis to assist evidence-based, effective, and accurate decision-making.

Another trend is the increasing use of e-commerce for pharmaceutical purchases and consultations, allowing for greater convenience and accessibility for consumers. According to We Are Social's 2024 report for Malaysia, an estimated USD 130 million was spent on OTC pharmaceuticals in 2023, signifying a year-on-year growth of 18.2 %. Meanwhile the adoption of digital healthcare and treatment has also accelerated, with some 10.16 million users (+3.1 % from 2022), spending a value of USD 190.2 million (+10.3 %), which equates to an average USD 18.72 spent per user. Online consultations recorded approximately 780 000 users spending USD 116.3 million which equates to an average USD 149 spent per user per consultation. Considering in-person consultations are usually RM30-RM125 (ca. USD 7-28) for general practitioners and RM80-RM235 (ca. USD 18-50) for specialists, this indicates a willingness to pay more for convenience and time-saving.

Silver Generation
Another promising prospect is senior assisted living care and health management. Malaysia is expected to become an aged nation by 2030, requiring innovative solutions to ensure its population remains healthy. In 12MP, the government has planned to introduce financial incentives to promote adoption of advanced healthcare technology among private aged healthcare facility providers and homecare monitoring. It also plans to introduce laws to protect the rights of older persons and establish a comprehensive long-term care framework, enhancing the quality and services of caregivers as well as invigorating the social care industry, where caregivers for the aged will be promoted as a professional career. In addition, collaboration between public and private healthcare providers in broadening palliative care services will be strengthened.

All these measures would therefore lead to strong potential growth in the development of senior care infrastructure, medical and digital technology, and training or certification. For example, in enhancing the wellbeing of older persons, the Physical Planning Guideline for the Elderly was introduced in 2018 as a guide in planning and designing suitable accommodation for the elderly and care centres, which creates demand for better products. Also enacted in 2018 was the Private Aged Healthcare Facilities and Services Act [Act 802], which stipulates minimum standards at private facilities to safeguard the rights of older persons in receiving quality care.

Currently, many seniors – especially those of middle- and lower-income classes – are taken care of at home by a family member (or in the case of upper income classes, a personal caretaker is hired) but a shift towards assisted living centres for the elderly is foreseen. This is due to the convergence of a few factors: decreasing family sizes and higher levels of education make it harder to have a family member "dedicated" to caretaking, as most people choose to enter the workforce; longer lifespans also bring about more challenges that an untrained person would be ill-equipped to deal with, as well as illnesses that may arise. As mentioned, this shift would largely implicate the B40 and M40, therefore affordable concepts would have high potential for rapid development, especially as there are still few players in this field.

Medical Tourism

As Medical Tourism remains a key focus for the government, with concrete plans and generous financial allocations related to its development found in 12MP, Budget 2022 and the Healthcare Travel Blueprint – infrastructure, technology, and services in this field will continue to see promising prospects. Due to the industry's focus on cardiology, oncology, fertility, and surgical procedures, which are seen as "high intensity revenue services", these sectors in particular could be of interest for Austrian companies to offer their expertise or explore hospital partnerships. Dental procedures are also seeing a post-COVID-19 rebound, as both local patients and medical tourists return to their dentists and orthodontists, creating niche potential in offering more subspecialty procedures.

Medical tourism-adjacent products and services also have a good future, as the government continues its efforts to package medical treatment with other offers in the country. This includes the promotion of exclusive high-end medical tourism packages for premium healthcare travellers. The areas that could reap the benefits of this are wellness centres, post-surgery recovery or rehabilitation products, self-monitoring medical devices, and digital technology to allow for follow up consultations when the patient has returned home.

Gaps & Challenges In Healthcare Delivery

These are some of the major gaps, issues, and challenges as identified by the MOH:

1. Human Resources & Training: There is an inadequate number of specialists to provide active 24-hours cover in all hospitals, and a shortage of allied health professionals namely AMO and nurses. Limited training for specialists (only 60 candidates per year) and limited skill labs also impede the acquisition of talent.

2. Infrastructure and Equipment: Notably, the government identifies inadequate biomedical equipment especially for emergency critical care services. There is also a limited budget for reagent for point-of-care testing and consumables, limited clinical space for Observational Medicine Services, limited numbers of ambulances and personnel for pre-hospital care services, and poor integration of health databases among the public healthcare institutions.

3. Health Inequity and Inequality: Despite achievements in ensuring quality healthcare services, the major issue of mixed performance and inadequate provision of services to rural and remote areas remains. This is particularly notable in aspects like the doctor-to-patient ratio, or emergency response time.

4. Increasing Burden: Malaysia also faces an increasing incidence of double burden diseases. Incidence rates of communicable and non-communicable diseases are on the rise while some diseases have re-emerged, leading to a high number of avoidable premature deaths among Malaysians and a higher demand for better healthcare services. In public hospitals and clinics, overcrowding and long waiting times for treatment continue to affect the quality of service delivery.

5. Unsustainable Financing: The mismatch of resources across different levels of healthcare services and unsustainable healthcare financing has worsened during the COVID-19 pandemic. Rising healthcare costs and high levels of subsidies in providing healthcare services, particularly in curative treatment, have increased government expenditure and threaten the financial sustainability of the Government in providing quality public healthcare.

Other issues where Malaysia would be open to solutions include:
- logistics such as track and trace, procurement, or delivery to rural areas;
- solutions for NCDs and aging population;
- combatting illegal and/or counterfeit medicine; and
- development and manufacturing of Halal products.

Conclusion
As Malaysia gears up to improve its national healthcare services, it will require strong partnerships not only from local firms, private and public healthcare operators, but also from foreign partners who are able to work with them on R&D, knowledge transfers, as well as access to the right technologies that support their goals. This is where Austrian companies could enter the market to offer both their solutions as well as expertise and experience.

Malaysia's strong R&D and manufacturing ecosystem, as well as generous fiscal benefits and incentives, also provide Austrian companies with a good base for expanding their presence in Southeast Asia.

8. CONTACTS – MINISTRIES, AGENCIES & ASSOCIATIONS

Ministry of Health (MOH)
The Malaysian Ministry of Health is the governing body for all matters related to healthcare policies and institutions. Its Key Divisions include Family Health Development, Disease Control, Health Education, Nutrition, Public Health Development, Medical Development, Traditional and Complementary Medicine, Nursing, Oral Healthcare, and the National Pharmaceutical Regulatory Agency.

Malaysian Investment Development Authority (MIDA)
MIDA is the government's principal agency responsible for overseeing and drive investment into the manufacturing and services sectors in Malaysia. MIDA assists companies that intend to invest in the manufacturing and services sectors, as well as facilitates the implementation of their projects. The services provided by MIDA include offering information on investment opportunities and facilitating companies seeking joint venture partners. It also evaluates the following applications for projects in the manufacturing sector and selected services sub-sectors: Manufacturing licenses, Tax incentives, Expatriate posts, and Duty exemptions.

Ministry of International Trade and Industry (MITI)
The Ministry of International Trade and Industry (MITI) is responsible for international trade, industry, investment, productivity, small and medium enterprise, development finance institution, halal industry, automotive, steel, and strategic trade. MITI plans, legislates and implements international trade and industrial policies to ensure Malaysia's rapid development, encourage foreign and domestic investment, and promote Malaysia's exports by enhancing national productivity and competitiveness in the manufacturing and services sector.

Medical Device Authority (MDA)
MDA is the government agency entrusted with serving the Malaysia medical device's industry. It is a federal statutory agency under the Ministry of Health Malaysia responsible for implement and enforce the Medical Device Act 2012 (Act 737). The main objectives of the Act are to address public health and safety issues related to medical devices and to facilitate medical device trade and industry.

Malaysian Digital Economy Corporation (MDEC)
MDEC is responsible for leading the ICT and digital economy growth in Malaysia. This includes assisting companies in the digital medical and health tech sector with their entry into and development in Malaysia, through incentives, sandbox projects and other customizable offers.

Malaysian Healthcare Travel Council (MHTC)
Malaysia Healthcare Travel Council (MHTC) is an agency under the Ministry of Health tasked with facilitating and promote the healthcare travel industry of Malaysia by coordinating industry collaborations and building valuable public-private partnerships, both domestically and internationally. It also coordinates promotional activities for Malaysian healthcare providers and related stakeholders. While the healthcare travel industry will be private sector-driven, the Government will assume an active role to facilitate its growth.

Malaysian Medical Association (MMA)
The Malaysian Medical Association (MMA) is the main representative body for all registered medical practitioners in Malaysia. The MMA represents all doctors: private and public, Specialists and General Practitioners, Medical Officers and House Officers, as well as Medical students.

Association of Private Hospital Malaysia (APHM)
This association representing private hospitals and medical centres in Malaysia and currently has over 100 members throughout Malaysia. APHM member hospitals are key partners with public sector healthcare providers in delivering comprehensive medical care to all Malaysians through its member hospitals. The APHM plays an important role in raising standards of medical care within the country.

Federation of Private Medical Practitioners' Association Malaysia (FPMPAM)
The FPMPAM is the national body representing doctors in private practice in Malaysia. FPMPAM is committed to improving the quality of private health care through continuing medical education, continuing professional development of its members, ethics advocacy and public outreach programs. Founded in 1989, it consists of seven state-level associations and has over 5,000 members.

Malaysian Dental Council (MDC)
The MDC provides certificates and registration for dental practitioners and regulates the standards and requirements in the dental sector, thus ensuring the high quality of dental services in Malaysia.

Malaysian Dental Industry Association (MDIA)
MDIA is a dynamic community that gathers all of Malaysia's dental dealers who are both directly and indirectly specialty service providers, wholesalers, importers, exporters and retailers from the dental industry. MDIA is dedicated to the progressive development of the dental industry by providing the industrial platform for communication, knowledge sharing and market exploration initiatives.

Malaysian Private Dental Practitioners' Association (MPDPA)
MPDPS (Malaysian Private Dental Practitioners' Society), as it was initially named, was formed in 1966. Its objective is to complement the activities of the Malaysian Dental Association, and also to uphold and represent the interests of Private Dental Practitioners.

College of Surgeons of Malaysia (CSAMM)
With the goal of maintaining and promoting the highest standards of surgical practice in the country, the College represents the diverse interests of surgical specialties and actively promotes the art and science of the various surgical disciplines.

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