

# AUSSEN WIRTSCHAFT BRANCHENREPORT MALAYSIA

# HEALTHCARE (MEDICAL DEVICES, INFRASTRUCTURE, TECHNOLOGY, SERVICES)

MARKTEINTRITT UND STAATLICHE FÖRDERUNGEN TRENDS UND CHANCEN FÜR ÖSTERREICHISCHE FIRMEN VERANSTALTUNGEN UND MESSEN KONTAKTE UND LINKS

AUSSENWIRTSCHAFTSCENTER KUALA LUMPUR NOVEMBER 2022





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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 32.5 million in 2020, consisting of 29.8 million (91.7%) Malaysian citizens and 2.7 million (8.3%) non-citizens. The slight decrease in population compared to 2019 is largely due to the departure of non-citizens in the wake of the Covid-19 pandemic. The Malaysian population is made up of a wide variety of ethnic groups, with the majority (69.4%) being Bumiputras ("Son of the Soil"). 24% of the Malaysian population is under the age of 15 and 69.3% are between the ages of 15 and 64, making the average population relatively young. 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 55th out of 157 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 estimated at USD 11,400 in 2021, only behind Singapore and Brunei, and has almost doubled since 2005, seeing a strong recovery from the 2020 drop to USD 10,350, and continuing its upward trajectory to reach over USD 13,270 as of April 2022. 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 today. 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 (ranking 12<sup>th</sup> for Ease of Doing Business in 2020). This has been a major contributor to job creation and income growth. After the global financial crisis in 2009, the Malaysian economy recorded average growth rates of around 6%. However, this growth slowly flattened out over the years and was 4.3% 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 shrunk by -5.6% in 2020, rebounding slightly to +3.1% in 2021. The 2022 forecast by the World Bank (as of Sept 2022) is +6.4%.

In 2021, Malaysia was under a state of emergency between January to August, and a resurgence in cases prompted the government to declare a nationwide lockdown on June 1<sup>st</sup> to curb the spread of the coronavirus. The tightening of containment measures will push the country back into recession for the first half of this year. However, the year end's modest recovery was achievable due to the country's strong vaccination rollout as of July 2021. As of May 1 2022, almost 98% of the adult population, and 82% of the general population have been fully vaccinated.

The nation's borders fully reopened on April 1 2022, allowing Malaysians and international tourists quarantine-free entry, provided they have been fully vaccinated and test negative. This should lead to a strong economic recovery, as the tourism sector was one of the strongest contributors to GDP.

Key indicators	2022[a]	2023[b]	2024[b]	2025[b]	2026[b]	2027[b]
Real GDP growth (%)	6	4	4.5	5.3	5.1	5
Consumer price inflation (av; %)	3.4	2.6	1.7	1.9	2.2	2.1
Government balance (% of GDP)	-6.1	-5.6	-5.5	-5.2	-5	-4.5
Current-account balance (% of GDP)	1.6	1.4	1.7	1.6	1.9	1.6
Short-term interest rate (av; %)	2.4	3.4	3.5	3.5	3.5	3.7
Unemployment rate (%)	3.9	4	3.9	3.7	3.6	3.5
Exchange rate M\$:US\$ (av)	4.42	4.51	4.33	4.2	4.1	4.01

The current economic indicators per the Economist Intelligence Unit (EIU) forecasts (as of November 2022) are as follows:

[a] EIU estimates.

[b] EIU forecasts.

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" by 2024. 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.

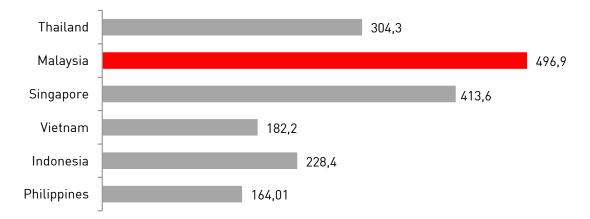
In the long run, economic growth will depend on increasing productivity levels. Although the productivity level in Malaysia has risen sharply over the past 25 years, it was still below that of several regional countries by comparison. Ongoing reform efforts are crucial.

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 2021 to the most important ASEAN countries in million euros (source: Statistics Austria, 2022)

With 402.7 million euros in Austrian exports, Malaysia ranked first among the ASEAN buyer countries in 2020. Thailand was in second place with EUR 365.8 million, followed by Singapore and Vietnam. Due to the effects of Covid-19, all of the countries saw a steep drop from 2019, but the recovery in 2021 was particularly promising for Malaysia: **Austrian exports to Malaysia reached 496.9 million euros**. This reflects a strong recovery with a +23.4% YoY growth and reaffirms Malaysia's position as most important buyer of Austrian goods and services in the ASEAN region. Only Singapore experienced a stronger recovery, but in terms of export volumes, still ranks after Malaysia, at 413.6 million euros. It is also important to note that some of the export goods reported for Singapore also have their final destination in Malaysia. On the contrary, exports to Thailand declined strongly, falling by 16.8% to 304.3 million euros. The rapid recovery positions Malaysia as the biggest and one of the most promising future markets for Austrian companies in the region.

Pertaining to medical devices and apparatus (HS 9018 – 9022), Austria exported a total of EUR 13,750,804 worth of merchandise to Malaysia and imported EUR 1,074,503. The value of exports (EUR) from Austria are:

Code	Description	2020	2021
9018	Instruments and appliances used in medical, surgical, dental or veterinary sciences	8,236,273	9,212,661
9019	Mechano-therapy, massage appliances; psychological aptitude testing apparatus; ozone, oxygen, aerosol therapy, artificial respiration or other therapeutic respiration apparatus	30,138	47,148
9020	Breathing appliances and gas masks; excluding protective masks having neither mechanical parts nor replaceable filters	0	9
9021	Orthopaedic appliances; including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other which are worn, carried or implanted in the body	3,503,848	4,488,722
9022	X-ray, alpha, beta, gamma radiation apparatus; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like	2,222	2,264

(source: Statistics Austria, 2022)

Austria is also the **3**<sup>rd</sup> **biggest foreign investor** (after the Netherlands and Singapore) in Malaysia, bringing in RM 18.92 billion (USD 4.54 billion) in 2021.

# Malaysia's Healthcare System

The Malaysian healthcare system is two-tier, 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 in-patient boarding are heavily subsidised. However, due to crowds, long queues, and lesser availability of facilities, many citizens (if able) opt instead to go to private clinics or hospitals, which are faster and have perceived better service. Therefore, despite an approximate 52.5% of total healthcare expenditure coming from the public sector (latest data, 2020), private hospitals outnumber public ones, with 60% of the existing structures (208 vs 135). 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 skew heavily to public healthcare, especially outside of city centres.

In 2020, the total allocation to healthcare in the national budget was RM 30.6 billion (USD 7.4 billion). However, despite a sharp growth in health expenditure of +6.9% YoY, with a value of RM 63.8 billion (USD 15.0 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%.

In 2021, this increased marginally as the country spent some RM 72.7 billion on its total health expenditure, approximately 5% of GDP. For the 2021 national budget, a RM 1.3 billion (+4.3%) increase was allocated, making a total of RM 31.9 billion (USD 7.6 billion/ EUR 6.35 billion) including funding for development, maintenance and upgrades of facilities and medical equipment. Key sectors of development for the government included improving access to healthcare, especially for rural areas; tele- and e-medicine; health tourism; and the management of Non-Communicable Diseases (NCDs).

Meanwhile, in Budget 2022, the Government allocated RM 32.4 billion to the Ministry of Health (MoH), the second-highest allocation, with 54% of the amount destined for emoluments and 13.5% earmarked for development expenditure, as well as a significant increase in the allocations for public health of more than RM 200 million, benefiting areas such as disease control, health education and promotion, and family health development. RM 100 million is being allocated to sponsor 3,000 contract medical and dental officers to pursue specialist training, while over 10,000 contracts will be extended for a 4-year period.

Malaysia's Covid-19 response is a testament to the capacity of its healthcare system. While sudden policy changes and political interference led to case surges, the overall reaction and handling of the disease proved that the country has the ability to manage and contain a pandemic – Malaysia was initially one of the best countries in bringing their case numbers down to zero, and also had one of the fastest vaccination rollouts in Southeast Asia. It remains one of the highest fully vaccinated countries in the world (top 20).

The impact of Covid-19 in 2020 also led to an increase of RM652 million for the recruitment of new contract health personnel, a total allocation of RM 1.9 billion. Budget 2021 also saw the new National Development Scheme with an allocation of RM 1.4 billion to support the domestic supply chain and increase production of locally produced medical devices (notably masks and gloves). Additionally, there are concessions of RM1.4 billion for medical laboratories and stores privatization. For 2022, RM 4 billion was provided specifically to manage Covid-19, with half of this amount funding the vaccination rollout. The remaining RM 2 billion will be to enhance the capacity of public health facilities including purchasing medicine, health kits, and PPE.

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Hospitals	208 private : 145 public (135 hospitals, 10 special institutions)				
Medical Clinics	7,988 private : 3,182 public				
Healthcare Provider to	Doctors 1:482	Nurses 1:302			
Patient Ratios	Dentists 1:3017	Pharmacists 1:1720	)		
Life Expectancy	M 72.6years	<b>F</b> 77.6 years			
Childhood Immunisation	BCG 98.48%	DPT-HIB 98.39%			
Coverage	Hepatitis B 97.3%	<b>MMR</b> 97.67%	<b>Polio</b> 98.39%		
Covid Vaccination Coverage	81.8% of total popul	ation	93% of teens (12-17 years)		
(*as of 1 May 2022)	97.6% of adults (18 y	ears and above)	43.3% children (5-11years)		

A brief summary of key metrics in 2020 (latest available data):

# Health Concerns in Malaysia

Non-communicable Diseases (NCDs) are a primary concern in Malaysian healthcare, as Ischaemic heart diseases remained as the principal causes of death, representing 17% of the 109,155 medically certified deaths in 2020. This was followed by Pneumonia (11.4%), Cerebrovascular diseases (8.3%), Transport accidents (2.9%) and Malignant neoplasm of trachea, bronchus, and lung (2.5%). Ischaemic heart diseases were the principal cause of death across all three major ethnicities, and for the population above 41 years of age. Below 40 years, the principal cause of death was transport accidents.

Malaysia has the dubious honour of having the highest rate of diabetes in Southeast Asia (18.3%), and an adult obesity rate of 50.1% (30.4% reported to be overweight, and 19.7% obese). The prevalence of childhood obesity is also increasing at an alarming rate in Malaysia, with 29.8% of children in the 5-17 years age range being overweight (15.0%) or obese (14.8%).

About 8.1% of the adult population in Malaysia, or 1.7 million people, have all three risk factors for diabetes, hypertension, and high cholesterol, the main NCDs. Approximately 8 million adults have high cholesterol with a 38.1% prevalence rate. By 2030, more than 66,000 Malaysians are expected to be newly diagnosed with cancer each year, and a third of the population are currently suffering from hypertension.

On the other end of spectrum, malnutrition is also a concern, as the prevalence of childhood stunting in children aged below five years in Malaysia has increased to 21.8% in 2019. Furthermore, one out of five Malaysians (21.3%) were estimated to have anaemia, representing 4.6 million people. The majority of them are women, with an estimate 30% of women of reproductive age (15-49 years) reported to have anaemia; an MOH survey in 2019 noted that 16% of women in Malaysia had light anaemia, 13% moderate anaemia, and 1% severe anaemia.

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 of May 1 2022, Malaysia has seen about 4.45 million cases, with 35,500 deaths, for a fatality rate of 0.8%. 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.

<b>Top 5 Common Diseases 2020</b> (last available data)					
Disease	Туре	Incidence	per 100 000	Mortality/100 000	
Covid-19 (*as of 1 May 2022)	Communicable	4,449,507	13,607.05	799.64	
Dengue	Communicable	129,578	397.71	0.56	
HFM	Communicable	52,176	160.14	0	
ТВ	Communicable	26,352	80.88	3.69	
Food Poisoning	Communicable	16,583	50.9	0.03	
Cardiovascular Disease	Non-communicable	176,408	541.13	37.04	
Cerebrovascular Disease	Non-communicable	46,453	142.49	2.24	
Diabetes	Non-communicable	29,523	90.56	5.99	
Cancer	Non-communicable	130,858	401.4	21.52	
Non-viral Respiratory Disease	Non-communicable	347,815	1066.92	37.05	

Top 5 Common Diseases 2020 (last available data)

source: MOH report on NCDs, MOH Health Facts 2020

# **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 forecasted 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. 15 projects (39.5%) with investments of RM 2.2 billion were for the manufacturing of medical devices other than medical gloves and face masks, mainly for high-end and high-value-added 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, ageing population (14.3% over 60 by 2030 and increased life expectancy) and increasing incidence of non-communicable diseases. The emergence of new and recurring pathologies; and a continued focus on developing the medical tourism sector, as well as the country's commitment to undertake a medium to long-term reform of its healthcare sector and increase its healthcare spending are also contributing factors to this growth. In Budget 2022, the MOH provided specific treatment allocations for radiotherapy, oncology, nutrition, mental health, blood transfusion medicine, and rehabilitation and traditional and complementary medicine.

In tandem with rising global demand for personal protective equipment (PPE) due to Covid-19 crisis, Malaysia's exports of rubber products notably rubber gloves hit record growth in 2020, jumping 103% to RM 35.26 billion from the previous year. According to MARGMA, the growth continued in 2021 with a rate of 7.8%, to achieve export values of RM 38 billion, or 280 billion gloves. Post-Covid, the industry looks to remain robust with demand seeing annual growths of 10-12%, although export revenues are expected to shrink due to lower selling prices. Surgical masks also saw a +407.5% (RM 61.1 million) growth in 2020. While this eased in 2021, it is still almost 50% above 2019 numbers.

Covid-19 has also jumpstarted the country's telemedicine programme, as well as increased the demand for new technology related to healthcare (AI, robotics, imaging) especially those that increase efficiency and reduce dependency on face-to-face contact. Emerging technologies will be leveraged to support the initiatives for better provision of healthcare services. This presents ample opportunities for Austrian companies in the sector who might have technological advancements suitable for the market.

Malaysia's formerly thriving health tourism sector has also been significantly affected by international border closures, with a 481% drop in healthcare tourist arrivals in 2021 from 2019 (1.3 million down to 270,000). To address this, the government has launched the Malaysia Healthcare Travel Industry Blueprint 2021-2025 that will be rolled out in two phases, namely the Recovery Phase (2021-2022) and the Rebuild Phase (2023-2025). The Malaysian Healthcare Travel Council (MHTC) has been given a budget of RM 20 million in 2022 to achieve its goal of attracting RM 800 million in revenues for the same year.

In November 2021, the government also introduced the Agenda Nasional Malaysia Sihat (ANMS, "Healthy Malaysia National Agenda"), a long-term plan to "guide the nation towards making healthy living a culture as it steers out of the Covid-19 pandemic". ANMS is to be implemented for 10 years and is based on four thrusts, namely:

- enhancing promotion of healthy living
- enhancing health services
- empowering personal health
- improving environmental cleanliness

# 12th Malaysia Plan (12MP, 2021-2025)

The Malaysian government regularly sets its strategic goals and formulates fundamental commitments to the 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 to reduce the gap in quality of healthcare between rural and urban areas, to developments in the 9<sup>th</sup> 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 11<sup>th</sup> 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 T&CM industry is expected to create revenue worth RM 20 billion by 2027.

The latest 12<sup>th</sup> 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 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

# Strategic Framework of The Medical Programme 2021-2025

Realising the need for an inclusive, sound, and comprehensive plan for the Medical Programme and to ensure the goals of the 12<sup>th</sup> Malaysia Plan can be achieved, the Medical Programme spearheaded an initiative to develop a strategic framework of its own under the guidance and leadership of the Deputy Director-General of Health (Medical). It is by far the largest Programme under the technical arms of the Ministry of Health Malaysia, complimenting the functions of five other Programmes namely the Public Health, Research and Technical Support, Dental, Pharmacy and Food Safety and Quality. The Medical Programme received RM 13.62 billion of operating budget in 2019 or an average of RM 13 billion/ year between 2016 – 2019, constituting 54% of overall annual budget received by the Ministry of Health.

There are five divisions and one unit under the Medical Programme, whose main agenda includes the continuance and enhancement of its stewardship and governance in healthcare, and maintaining quality and safety. Seven strategies have been identified with a total of 61 implementation plans:

- Strategy 1 strengthen healthcare services delivery in hospitals
- Strategy 2 optimise resource management including facility, equipment and financing
- Strategy 3 enhance capacity and capability of human resource for health
- Strategy 4 strengthen governance and stewardship of healthcare system
- Strategy 5 strengthen safety and quality in delivery of healthcare system
- Strategy 6 leverage the use of information technology to improve efficiency
- Strategy 7 promote safe and quality practices of traditional and complementary medicine.

# 3. MEDICAL DEVICES

Malaysia has a thriving medical device industry, with an expected CAGR of 8.4% between 2017-2022, and a market size of USD 1.55 billion in 2020, expected to reach USD 2 billion by 2022. It is one of the leading countries in the world (largest in ASEAN) for medical device manufacturing, contributing 67% of the world's supply of medical gloves, 80% of catheters, and over 20% of condoms. Other manufactured products include medical apparatus, syringes, needles and sutures, electro-medical equipment, ophthalmic lenses, dental devices, and medical furniture. While central Malaysia attracts latex-related medical device companies such as those in glove and condom manufacturing because of its proximity to raw materials, Penang is making a name for itself in non-glove medical device manufacturing or, more specifically, medical technology. Devices manufactured in Penang tend to be on the higher end of the value scale, such as cardiovascular products or orthopaedic implants and tools. Malaysia's export of medical devices registered a +24.9% growth (RM 29.99 billion) in 2020, with PPE like gloves and surgical masks forming the majority of the items. Locally developed and manufactured Covid-19 rapid test kits also gained market share, leading to the strong potential of diagnostics as a growing subsector.

However, there is still a void in higher classification/ category of medical devices not manufactured locally, which the country imports. Total import value for medical devices (HS 9018-9022) in 2020 was RM 4.98 billion, and RM 5.64 billion in 2021. The government is therefore trying to both encourage local production, as well as attract foreign multinationals to invest in manufacturing plants and make Malaysia their Asian/Southeast Asian hub. Malaysia is promoting its ability to provide world-class medical products and technologies as it evolves to produce higher-value-added and technologically advanced products. Currently home to over 200 manufacturers, the majority of them are nonetheless involved in medical glove production.

As Malaysia has a mature manufacturing industry for semiconductors, E&E, precision engineering, and plastic products industries, this creates an end-to-end ecosystem that is an attractive destination for global medical device manufacturers. The government is therefore also targeting the second and third tiers of manufacturers for the parts and components of medical devices, which should have increased opportunities to be integrated into the global supply chain of this industry.

According to the Malaysian Investment Development Authority (MIDA), all medical devices exported from Malaysia are monitored and regulated by the Medical Device Authority (MDA), a regulatory body created under the Ministry of Health. Most domestic medical device manufacturers comply with international standards such as ISO 13485, US FDA 21 CFR Part 820, and the CE Mark. Over 90% of medical devices manufactured in the country are earmarked for export.

Data from MIDA's 2021 Malaysia Investment Performance Report also indicates, by the breakdown of total investment into the Medical Device sector, its strong growth. A total of RM 7.7 billion (RM 3 billion FDI) has been approved for 38 projects in 2021 alone, of which 22 are new projects and the other 16 are for expansion or diversification, also leading to the creation of 12,498 new jobs.

We foresee high growth potential in the following sub-sectors of Medical Devices: electro-medical equipment, cardiovascular devices, orthopaedic devices, in-vitro diagnostics, wound care and management, dental, and finally products converging on the use of advanced technology like ICT, IoT, 3D printing, and track-and-trace systems. Other emerging technologies would also benefit from the government's push to improve health service access, e.g. e-hailing/delivery, virtual consultations, and an online patient database.

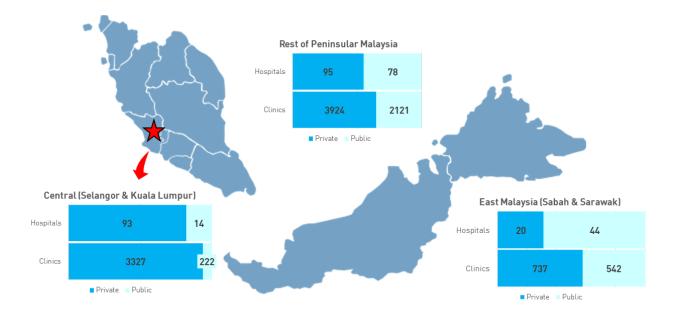
Different medical devices and their respective distribution channels would also require the appropriate licenses by manufacturers, importers, distributors, agents, or representatives. Permission to purchase would also vary based on type of device and channel, where items from pharmacies are generally OTC and easily obtained, whereas purchasing from a hospital would require a doctor's prescription.

# 4. MEDICAL INFRASTRUCTURE

Malaysia has very well-developed medical infrastructure, notably in its private healthcare sector. This is not to say that there are not excellent public healthcare facilities, as in fact most of the latest and most advanced technologies can be found in government hospitals. However, due to the subsidised fees, limited availability, shortage of staff, and mismanagement of these resources, there is often higher demand and longer wait times for their use. A recent report by the Auditor-General in 2019 found almost 20% of medical equipment in public hospitals was over 20 years old and 11.5% was beyond economic repair, indicating a failure in equipment management to meet their optimal period of use or to have a maintenance system in place.

Meanwhile, private healthcare operators often invest heavily into developing their overall premises, due to the high demand for qualitative health management, and robust ROI – despite higher fees, most patients who opt for private healthcare are either covered by insurance or pay out-of-pocket.

Due to the costs, the distribution of private vs public facilities generally also trends in line with the urbanrural divide and level of income: Central Peninsular Malaysia (the capitals Kuala Lumpur and Putrajaya, and the surrounding state of Selangor) which sees both the highest level of urbanization and income, skews heavily to private facilities, while East Malaysia, which is much less developed, depends largely on public healthcare. The rest of the Peninsula is more balanced, but again sees more private services in developed states like Penang and Johor compared to Pahang or Terengganu.



The map below provides more details:

The well-established private healthcare facilities supported with experienced and internationally-recognised doctors and well-trained medical staff have made Malaysia a top destination for medical tourism both regionally and globally. (In Malaysia, only private healthcare providers are allowed to cater to health tourists.) According to the Malaysia Healthcare Travel Council, the country attracted 1.3 million international healthcare tourists in 2019, generating a total of RM 1.7 billion in hospital receipts. Most of these travellers come from Indonesia, China, India, Bangladesh, Japan, United Kingdom, Philippines, Australia, Singapore and the United States.

Malaysia has 17 JCI-accredited hospitals (Joint Commission International) and has won several awards from the International Medical Travel Journal since 2014, including being named "Medical Travel Destination of the Year" in the years 2015, 2016, 2017, and 2020. The MHTC has maintained that it remains dedicated to expanding and enhancing the country's dominance in this field.

# **Specialised Facilities**

In the public sector, Malaysia also invests in Mobile Health Clinics, in order to reach and serve the rural population who might have difficulty accessing a healthcare provider. These include buses, boats and helicopter teams who provide primary medical as well as dental services.

Other government healthcare facilities for specialised treatment, R&D centres or laboratories include:

- 28 Major Specialist Hospitals providing resident specialist services or acting as referral centres.
- National Blood Centre the country's central blood bank and centre for blood-related services e.g. transfusion medicine and transplants.
- National Institute of Forensic Medicine conducts post-mortem examinations on bodies brought in by the police to determine the cause of death, as a medicolegal autopsy can only be performed in a Government hospital by a fully registered Government Medical Officer according to Section 330 Criminal Procedure Code.
- National Cancer Institute (NCI) a specialised cancer medical treatment centre (radiotherapy, oncology, nuclear medicine, oncological surgery, palliative care) that also conducts research and education.
- National Poison Centre (NPC) the centre for drug and poison information, as well as poisoning management and reduction.
- National Institutes of Health (NIH) a research body under the MOH. conducting health research to
  ensure the wellbeing of the people. NIH was approved under the 7<sup>th</sup> Malaysia Plan and was officially
  launched in August 2003.
- Institute for Medical Research (IMR) the biomedical research arm of the MOH. Research programmes of the Institute are aligned with the health research priority areas and health needs of the country. The IMR undertakes research to advance scientific knowledge as well as to provide for informed decision making and formulation of effective preventive and control programs and activities. Research is also carried out with the purpose of developing enabling technologies or products in the detection and diagnosis of disease, monitoring of disease progression and targeted therapy. They also conduct up to 300,000 specialised diagnostic tests per annum and offer scientific and technical training programmes.
- Clinical Research Centre CRC possesses sophisticated facility and equipment, state of the art technology, and trained human resources, to facilitate their teams in Clinical Epidemiology, Healthcare Statistics, Biostatistics, Bibliography, and ICT.
- Medical Radiation Surveillance Division enforces the licensing, registration, monitoring, and control of radiology and medical radiation devices.

For medical laboratories, there are a total of 71 accredited medical testing labs: 24 government, 41 private, and 6 in a public institute of higher learning. There is also the National Public Health Laboratory in Sungai Buloh, managed by the Disease Control Division, Public Health Department under the MOH.

In the private sector, there are of course similar specialist and treatment centres, medical research and testing facilities, and other facilities such as nursing homes, maternity and confinement centres, hospices, mental health and haemodialysis centres.

# Ambulances

There is a general lack of ambulances to serve the Malaysian population. The last point of data collection back in 2010 indicated a ratio of 0.28 ambulance per 10,000 population. While this has certainly improved, it remains a sector to be developed, something that was particularly obvious during the recent Covid-19 crisis.

Following the increase of Covid-19 cases in June 2021, the Health Ministry decided to procure an additional 500 ambulances for the use of government hospitals and clinics nationwide, at an estimate cost of RM 300 million: it advertised its offer of tenders to procure 490 ambulances together with medical equipment for the use of hospitals and clinics nationwide. Most of these ambulances are meant to be "negative pressure" and also feature HEPA filters and UV lamps for patients with infectious diseases. The cost of a negative pressure ambulance is estimated to be between RM 500,000 and RM 600,000, compared to a completely equipped "standard" ambulance which costs between RM 150,000 – RM 200,000.

Most of the ambulance services in Malaysia are public, however demand of private services has increased sharply due to several factors:

- Public ambulances cannot be used for patients at private hospitals, but private ambulances are accepted at both
- Most of the private ambulance companies in Malaysia have 24-hour support lines and GPS tracking
- Difficulty of access to public ambulances due to high demand
- Centralisation of public emergency services call centres delays dispatching of services (all calls made to MERS999, even those from East Malaysia, are routed to the capital in Putrajaya)
- Faster response of private ambulance services (a national audit in 2018 found that public hospital ambulances in the Klang Valley take up to 87 minutes to reach the incident site in critical emergencies)

There are approximately 15 private ambulance service providers nationwide, 10 of them operating in the Klang Valley. Demand has almost doubled in 2021 to cope with the surge in Covid-19 cases, which has pushed the health infrastructure to the limit.

There is limited regulation on private ambulance services, but vehicles must conform to a standard level of equipment and personnel to be a qualified ambulance. Ambulance charges typically run between RM 200-400 per trip, depending on time, distance and medical equipment.

Within the 11MP, the government had set a goal of 8 minutes for Emergency Response Times by 2020. However, this was far from being met, with the final time of 15 minutes. This target was not revised in 12MP. As of March 2022, St. John Ambulance Malaysia (SJAM) and the Malaysian Red Crescent Society (MRCS) have joined hands in enhancing ambulance services and emergency response in the country.

# **Challenges & Outlook**

Generally, the overall problem in the healthcare infrastructure sector is underinvestment which lead to "insufficiencies" particularly within government health facilities including clinics and hospitals.

- Weaknesses within the emergency and trauma (A&E) departments
- Staff shortages due to high patient traffic
- Insufficient funding
- Inadequate medical equipment

However, in recent years, the healthcare sector has seen a rise in government expenditure, with an increase in medical facilities and higher-quality treatments. The implementation of the B40 healthcare scheme (for the lowest 40% income group) is one of the key initiatives that will expand healthcare services and addresses lack of access to new treatments and therapies for people in this low-income bracket, especially when it comes to non-communicable diseases like cancer.

Investment in private healthcare facilities is one of the main areas of promotion by MIDA, which also undertakes policy advocacy with relevant stakeholders and supports various healthcare investment promotions. The Malaysian government also continues its commitment to attract investments in private healthcare by extending incentives for private hospitals and ambulatory care centres (ACC) until 31 December 2022.

However, foreign equity for private healthcare facilities is subject to the approval by the Ministry of Health's Special Committee on Foreign Equity Participation.

# Upcoming projects

Notable recent or upcoming projects in the private sector are:

- Sunway Medical Centre in Seberang Jaya (RM 180 million)
- YES 5G Smart Ambulance service: Strategic partnership between YTL Communications and First Ambulance Services for enhanced emergency care
- Dialysis Centre, Columbia Asia Hospital Klang in Mutiara Bukit Raja
- KL WELLNESS City: healthcare-based integrated mixed-development township in Bukit Jalil (RM 11 billion)
- Paragon Globe and Selgate Corp's Sepang Medical Centre (est. RM 80 100 million)
- Singapore-based TE Asia Healthcare's SGD 90 million investment into cardiac hospitals and orthopaedic centre
- KMI Healthcare's strategic development plan including four new hospitals in the next five years
- Cengild Medical's expansion of its existing medical centre at Nexus@Bangsar South (Kuala Lumpur) and building of two new medical centres specialising in gastrointestinal, liver diseases, and obesity.

In the public sector, most plans have been laid out by the government via the 12MP and the annual Budgets:

- Under the second Rolling Plan of 12MP, the MOH plans to build the Malaysian Institute of Infectious Diseases in Bandar Enstek (Negeri Sembilan). Another approved project is the Kapar Hospital in Selangor. Both these hospitals will boast a capacity of 300 beds each.
- As part of their healthcare system revitalisation plan, the MOH wants to continue improve and ensure equal access to public health centres – currently 92.6% of the population have easy access (within 5 km) – with a focus on East Malaysia. This includes the construction of teaching hospitals for UM Sabah and UM Sarawak; new health clinics in Penampang, Beaufort (Sabah), Samarahan, Sarikei, and Miri (Sarawak); a new regional blood centre in Sabah; and a state public health and food safety laboratory in Sarawak.
- RM 4.38 billion had been approved under the Building Allocation in Budget 2022, covering physical health facilities development, including the building of hospitals and new clinics, as well as to upgrade, renovate and repair existing health facilities.

# 5. MEDICAL TECHNOLOGY

As previously mentioned, Malaysia is extremely well-developed in terms of medical technology as the government does invest in the latest equipment for its key public facilities, while in parallel there is private sector investment to maintain its stronghold on international medical tourism. Therefore, there exists strong potential for providers of high-tech medical equipment, as long as there is convincing proof of improvements and/or benefits from already existing machines/treatments.

In particular, Malaysia's focus on oncology, cardiology, fertility treatment, aesthetics, dental treatments, orthopaedics, and neurology lead to great opportunities for companies providing new technologies or treatments in each of these sectors. This is especially true in the private sector where the players compete to distinguish or promote themselves: having the latest state-of-the-art equipment is often one of their selling points to their patients.

The needs, and therefore opportunities, obviously differ by practice: for example, with oncology and cardiology, new surgical devices, imaging tech, or screening and detection services that promise better accuracy or efficiency would be sought after; while aesthetic and fertility centres (as "voluntary" procedures) would focus on technology that can provide better patient experience, aside from tangible results.

Robotics in healthcare is a more transversal technology - from simple laboratory robots used to carry out repetitive tasks, to highly complex surgical robots that aid human surgeons or even those that are capable of executing entire operations, their applications are manifold. Their potential in rehabilitation and physical therapy, in support of long-term conditions, or in end-of-life care, allowing people to remain independent for longer, is also being increasingly recognised by local healthcare actors – who increasingly invest in medical or delivery robots – and the government, as demonstrated by the plans mentioned in 12MP to do the same.

# **Digital Healthcare**

A new focus in medical technology is the subset of telehealth: while still in its infancy despite the nation's Telemedicine Act passed in 1997, telemedicine in Malaysia is a growing field. While not much has happened in the first 20 years since the Act, it has begun to pick up speed in the last few years with the advancement and proliferation of new technologies and telecommunication systems. Additionally, as seen with many other digital technologies, the Covid-19 pandemic has accelerated the development, demand, implementation, and acceptance of new tele-medical technologies.

The rapid spread of Covid-19 and the subsequent lockdown measures interrupted healthcare service delivery and access in Malaysia: Many general consultations and non-essential procedures or surgeries were postponed to give precedence to treating Covid-19 patients, as well as to mitigate the risk to both doctors and patients. This happened in both the public and private sphere, but as treatments were initially all contained to government facilities, this left the private healthcare sector in particular languishing and needing innovation to survive. Telehealth quickly emerged as a solution: deployed correctly and adequately, it would allow many consultations to proceed, ensure continuity of care, and deliver routine healthcare services from afar.

The most common practical application of telehealth thus far is related to telecommunications, i.e., teleconsultations via video call. In Malaysia, there are at least four start-ups delivering such e-health services, aside from private hospital operators branching out to create their own telehealth platforms or services. For instance, the Sunway Medical Centre Velocity (SMCV) and Parkway Pantai of IHH Berhad Group have set up teleconsultation services to allow patients to receive health advice from specialists or medical officers from home. While this still remains largely a patient-oriented service (connecting patients to doctors, nurses, and pharmacists), future plans would likely include connecting to other hospitals, universities, or other world-class research centres, in order to facilitate education programs, medical conferences, and of course for consultation purposes.

These services are generally on-demand models, which allow patients to bypass their existing GPs to access a healthcare provider as and when needed. While this improves patient convenience, it also creates risks such as fragmentation or duplication of care and the commodification of healthcare services; potential compromise of patient safety, as each new consultation creates new patient data, both medical and personal; and poses a threat to the viability of existing brick-and-mortar facilities with each shift towards a digital landscape.

An older project of the Malaysian government (launched in 2011) is the programme to renew prescriptions via mail. Medicine via Post targets patients with chronic diseases: once they receive a certification from a pharmacist that their condition is stable and that they understand how to properly use their medication, they are eligible for this service where they only pay minimal delivery costs. This has been expanded upon during the pandemic, with digital interfaces and services being offered. Private pharmacies have also developed their own platforms or partnered with delivery services to offer their products to customers. Unfortunately, many patients still experienced disruptions to their continuity of care, due to the time needed for the development and rollout of new schemes, and also the strain on the country's logistics providers.

However, in Malaysia, the disruption of continuity of care is generally due to the lack of a corresponding electronic medical record (EMR) system that allows different health care practitioners to review a patient's records. While the pilot for an EMR has been rolled out by the MOH, which aims to facilitate the transfer and sharing patient information across the 145 government hospitals nationwide, this remains in the early stages, with only a quarter of the institutions using EMRs. This initiative would also be limited to public hospitals and does not include private facilities. In the private sector, while further developed, EMRs are generally restricted to the same hospital or group: for example, in 2021 SMVC became the first hospital to launch its laboratory information system through its SunMed Go app and its PACS system, which provide patients access to their medical reports.

The government, seeing the need for a seamless EMR, has mooted the idea of converting MySejahtera (its Covid-19 vaccine verification and contact tracing app) into a medical record application, as it has already been adopted by a vast majority of the population, therefore removing the major obstacle of public implementation. However, controversies linked to the ownership of the app and its data has put pause on this proposal.

Artificial Intelligence (AI), Internet of Things (IoT), and Big Data Analytics (BDA) also have a large role to play in Malaysia' healthcare. The availability of accurate and comprehensive data and information is vital in providing better services to customers – the conjunctive use of these three technologies would allow for collection, analysis, and prediction of patient data to improve diagnoses, efficiency, and treatment. When it comes to patient experience, these technologies can also be leveraged upon – from basic tasks like streamlining registrations and appointments, to monitoring and providing interactions with high-risk or elderly patients, Malaysia as one of the most connected countries in the world (128% mobile internet penetration in 2021) is a prime destination for the rollout of such tech.

# Recent and Upcoming projects:

- Electronic Medical Record Initiative: revitalised in 12MP, which aside from facilitating data transfer, also aims to digitise lifetime records of individuals
- DoctorOnCall, Malaysia's largest digital health platform has announced multiple partnerships with insurance companies and health industry stalwarts, and continues to develop themselves as a cornerstone platform in digital health. Their latest project seeks to reshape healthcare providerpatient relationships and interactions, allowing for teleconsultation and home monitoring aside from enabling patients to search and identify suitable, reputable and verified doctors, treatments or products, and make bookings for physical appointments.
- SUNWAY Healthcare Group (SHG) is investing RM 50 million over the next five years to adopt an EMR-integrated Hospital Information System (HIS) to enhance patient information management across its subsidiaries.

# 6. MEDICAL SERVICES

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.

The secondary and tertiary level of care in hospitals encompasses a spectrum of services from pre-hospital care, emergency, ambulatory, diagnostic, therapeutic including surgical-based and medical-based services, intensive care, rehabilitative care to palliative care. Secondary and tertiary care serve as an important component in the delivery of healthcare services in Malaysia, as over 70% of total health expenditure by the public sector was spent on curative care. Changes in sociodemographic profile, increasing disease burden, limited resources including human capital and higher public expectations are among factors that will pose a great challenge to the development of secondary and tertiary services in the future. The impact of Covid-19 has also led to an increased focus on the healthcare industry and workforce.

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 in 2022 pledged the creation of almost 9,000 permanent positions for medical, dental, and pharmacy officers until 2025, and added contract extensions of up to four years for another 10,000 staff. The government has also, in its Budget 2022, allocated funding of RM 100 million for the specialist training of 3,000 contract officers. It is nevertheless inadequate for both the projected national requirements of doctors, and for the number of doctors under contract, thus remaining a point of contention for many.

# **Medical Tourism**

While general medicine remains the backbone of the industry, the government seeks to develop the health tourism industry, which relies on the private and specialist healthcare services. Historically, Malaysia's healthcare travel industry enjoyed consistent growth between 2015 to 2019, with a CAGR of 16.3%.

As a whole, the industry has set priority focus areas in cardiology, oncology, fertility treatment, and hospital partnerships. Aesthetics medicine is also rapidly gaining market share. Other sought-after medical procedures in the country are orthopaedics, general health screening, dental and neurology.

The country has over 30 advanced heart treatment centres, including the renowned National Heart Institute that was the first in the Asia Pacific to implant a Micra AV pacemaker — the world's smallest pacemaker.

Over the years, cancer treatment in Malaysia has seen significant improvement with hospitals offering world-class facilities and technology, as well as comprehensive cancer treatment and fully integrated care through special cancer centres.

Meanwhile, the success rate of first-time in vitro fertilization (IVF) in Malaysia is high, between 55-60%, well above the global average of 35%, making it a popular destination for couples looking to conceive. The prices are also a fraction of procedures performed in many other countries.

The affordability of medical treatments in Malaysia is a key selling point, as healthcare treatment prices are governed by the MOH through the 13<sup>th</sup> Fee Schedule to ensure affordability for Malaysians and healthcare travellers alike. This means the prices are highly competitive in the region and far cheaper than in most Western countries, despite a similarly high level of quality and expertise – surgeries in Malaysia cost an average of 60% less than in neighbouring Singapore, and up to 80% less than the United States, especially when the currency exchanges are taken into account. For example, knee replacement surgeries cost USD 10900 in Malaysia, compared to USD 16,700 in Singapore and USD 35,000 in the United States, while heart bypass surgeries cost an average of USD 20,800 in Malaysia vs USD 54,500 in Singapore and USD 123,000 in the United States during the 2018-2019 period.

Malaysia's positioning as a halal hub in the medical services sector is also a boon for medical tourism, as it is able to provide for specific amenities such as gelatine-free products or halal-certified centres. This enables it to attract a high level of interest from neighbouring country Indonesia, but also other Muslim countries in the Middle East.

# 7. MARKET ENTRY

# **ACTORS AND 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 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 under the MOH.

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

# **LEGISLATIONS & POLICIES**

# **Medical Devices**

The key governing acts are the Medical Device Act 2012 (Act 737), Medical Device Authority Act 2012 (Act 738), and Medical Device Regulations 2012, though there are various amendments and additions made thereafter for related sectors such as advertising (Medical Device (Advertising) Regulations 2019) and operations. MDA Act 737 governs all medical devices imported into the country. This regulation specifies requirements and procedures for medical device registration, conformity assessment body (CAB) registration, establishment licensing, export permit, and appeal.

A full list of legislations for medical devices including Exemption Orders can be found on the MDA page, while guidance documents for assessment and permits can be found here. Some key documents are:

- Guidance on Classification for General Medical Devices
- Requirements for Labelling of Medical Devices
- Conformity Assessment Guidance Document

#### **Registration and Import**

Per Act 737, all medical devices are to be registered under the Act before it can be imported, exported or placed in the market. The term "medical device" covers any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs. Such devices must be registered with the MDA, which as the governing body also authorises and issues licences to manufacturers, importers, distributors, and agents.

For imported items, a foreign manufacturer must have an authorised representative (AR) in Malaysia, with an Establishment License, who will apply for the registration. This can be an importer/distributor or a subsidiary, as long as they are a registered company in Malaysia.

Once registered, the products can be distributed according to its product category. The classification is done according to risk level, and the costs of registration vary by the respective classes. The MDA imposes an Application Fee for all classes, which is followed by Registration Fees for successful approvals to issue the formal registration certificate of the device (applicable for classes B-D). For medical devices that contain a medicinal product, the registration fee is RM 5,000 no matter the classification. Processing times vary but once issued, the certificates are valid for 5 years and renewable a year before expiration.

Class	Description	Application Fee	<b>Registration Fee</b>	Turnaround time
А	Low risk	RM 100	N/A	30 days
В	Low-medium risk	RM 250	RM 1,000	100 days
С	High-medium risk	RM 500	RM 2,000	180 days
D	High risk	RM 750	RM 3,000	220 days

There are also costs for the application of ARs and Establishment Licences, shown below. These applications take up to 21 working days for the processing, after which the licenses are valid for 3 years and renewable a year before expiration.

Application Fee:RM 250 (EUR 50)Licensing Fee:Manufacturer and Authorised Representatives: RM 4,000 each (EUR 800)<br/>Distributors and Importers: RM 2,000 (EUR 400)Requirements:QMS (ISO 13485) for local manufacturers<br/>GDPMD for all other categories.

Most foreign companies wishing to enter the Malaysian market find that a local distributor or agent is a good first step: local distributors are typically responsible for handling customs clearance, dealing with established wholesalers/retailers, marketing, and handling after-sales service. Local agents are also useful in the case a foreign company wishes to bid for tenders or sell to the Government of Malaysia, Government Linked Companies (GLC), as certain priority sectors require a local and/or joint venture partner that is classified as a Bumiputera (Malay) company. Additionally, a local presence is important to develop relationships and can often influence the success of a project or deal.

With larger companies, they can also explore establishing a local office or production facility, which is looked upon favourably by the government and GLCs which then provide incentive measures for foreign investment. A local subsidiary also allows the company to benefit from any subsidies given to Malaysian companies and undertaking the abovementioned responsibilities themselves would be a cost-saving measure in the long-term.

# 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 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 of elderly care respectively. It also details the restrictions and the basis for any fines, rescindments/suspensions of approvals, or terms of further action as deemed necessary.

Disposal of Medical Waste is another highly regulated matter in Malaysia. As it falls under scheduled waste, it is subject to the Environmental Quality (Scheduled Wastes) Regulations 2005 under the Department of Environment. Subsidiary legislation includes Environmental Quality (Prescribed Premises) (Scheduled Wastes Treatment and Disposal Facilities) Order 1989; and the Environmental Quality (Prescribed Premises (Scheduled Wastes Treatment and Disposal Facilities) Regulations 1989. The generators of scheduled waste need to keep an updated inventory of scheduled waste generated, treated, and disposed as per regulation, and notify the DOE accordingly. Scheduled wastes may be stored, recovered, and treated within the premises of a waste generator. Incineration, disposal, off-site storage, and waste generators shall conform to the requirements of the consignment note system when transporting waste, and the treatment shall only be carried out at prescribed premises licensed by the DOE. Most clinical waste is incinerated, depending on the waste hazard level. Autoclaving is not common but when applied, is used for highly infectious clinical waste. Chemical and hazardous clinical waste such as radioactive and chemotherapy waste should not be autoclaved. Any radioactive waste generated by a medical facility is sent to the Malaysia Nuclear Agency for further treatment and disposal.

The MOH has issued the Policy on Safety of Land Ambulances 2019 which serves as a guide for the managerial and operational group to ensure ambulances safety in pre-hospital care services for the MOH. The policy covers the establishment of Ambulance Safety Committees (ASC) at National, State, Health and Hospital levels, and also details the procurement of land ambulances and their specifications, which must adhere to current Technical Specifications of Land Ambulances (TSLA). The TSLA emphasises service needs, safety and protection of all individuals in the vehicle and requires that the design, construction, modification and testing processes of ambulance shall comply with local or international standards. Road worthiness of land ambulances are also discussed, as well as the operation of the vehicle, its medical and communication equipment, and driving policy, including the recruitment and training of ambulance drivers. Of particular interest is that ambulances shall be equipped with hands-free communications devices (to allow exchange of information through various medium between the vehicles and the coordinating MECC) and a Navigation System or equivalent for tracking and monitoring purpose.

Other relevant acts related to Medical Infrastructure 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.

Mental Health Act 2001: provides a framework for the comprehensive care of those with mental disorders. It has provisions for the establishment of private and government psychiatric hospitals, psychiatric nursing homes and community mental health centres.

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.

Occupational Radiation Protection in Medical Interventional Procedures: for the use of radiation equipment in the healthcare field, including the locations of such equipment and safeguards required.

# Technology

The Telemedicine Act 564 established in 1997 is a Malaysian law enacted to provide for the regulation and control of the practice of telemedicine and for matters connected therewith. It covers who can practice telemedicine, how to apply to practice telemedicine, and the setting of telemedicine practice standards. However, Virtual Consultations are also guided by the Medical Act 1971 regulating the practice of medicine in Malaysia. An Advisory Guideline was issued during the Covid-19 pandemic by the MMC, which put a limitation on tele-consultation being permitted only for continuation of care and not new cases. The HIMS Blueprint proposal in 2013 outlines the policies and strategies in Health Information Management, of which the scope includes technical and operational aspects of telemedicine (Health Information Management and Support Services) in MoH and related agencies. However these guidelines tend to regulate the professionals rather than the platforms, technologies, or services; for telehealth products the only available regulations are under Medical Devices (Acts 737 and 738).

When it comes to data, the Personal Data Protection Act (PDPA) governs how organisations across sectors, including healthcare, process personal data. Meanwhile, patients of private healthcare practices in Malaysia also have their data protected under the Private Healthcare Facilities and Services Act, while the Ministry of Health must comply to Cybersecurity acts and guidelines by lead agencies such as MAMPU (Malaysian Administrative Modernisation and Management Planning Unit), National Cyber Security Agency (NACSA) and Chief Government Security Office (CGSO). Finally, the Communications and Multimedia Act 1998 by the Ministry of Multimedia and Communication also covers legal and technical aspects of information sharing on the internet.

# 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 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 qualified Malaysian medical practitioner.

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

Other legislation related to medical services include (in chronological order): Nurses Act 1950: to provide 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: Regulation and 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, 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: to ensure the safety of aesthetic medical practice in Malaysia. These guidelines define the scope of practice allowed, 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.

# 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 healthcare system. There were 4 main components in the blueprint which were later restructured into 7 components in 2000, and then reorganised yet again after an integration with Integrated Health Enterprise (IHE) in 2007, into 5 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 uncompleted, mostly due to the fact that the technology of the time was not sufficiently mature or integrated, with prohibitive cost.

While there were initial plans to revise and relaunch an updated plan in 2020/2021, this has still not materialised. In its stead, however, are concrete developments in the sector, especially with the partnership between MOH and DoctorOnCall (DOC), an online medical video consultation startup, that 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.

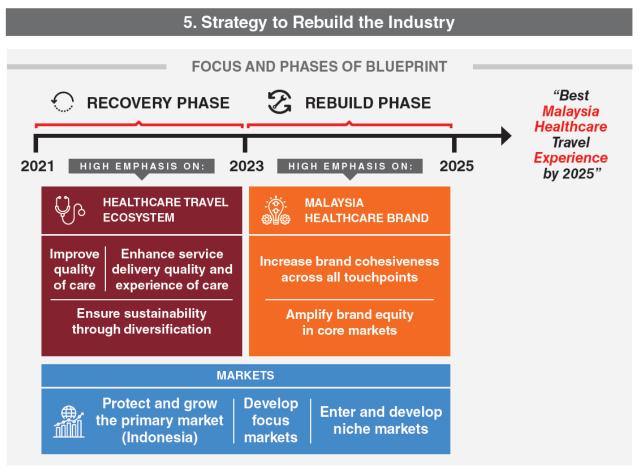
The partnership later developed further in the medical tourism sector, with a Memorandum of Understanding signed in 2021 with MHTC, to facilitate patient care continuity for their 75 member hospitals. The collaboration allowed the patients of these hospitals, both local and international, to continue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

# 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 87,581 people living with HIV, an incidence rate of 0.2 per 1000 population (latest report in 2020). This plan focuses on strategies and action plans to build on an increasing collaboration between the government and the 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 continuum of care between medical and paramedical health facility-based staff and outreach workers.

# Malaysia Healthcare Travel Experience Blueprint 2021-2025

The Malaysia Healthcare Travel Industry Blueprint addresses the industry's performance and ecosystem, as well as the impact of Covid-19 and its resulting challenges. It also sets a Strategic Framework with key objectives and measures to achieve its targets for 2025.



\*Image taken from the Blueprint.

It will be rolled out in two phases:

- The Recovery Phase (2021-2022) will focus on promoting quality offerings and enhancing patient experience through digitalisation efforts
- The Rebuild Phase (2023-2025) aims to foster collaborations to promote niche offerings such as Fertility and Cardiology Hubs, the Centre of Excellence for Oncology, and the Flagship Medical Tourism Hospital Programme.

The MHTC has been given a budget of RM 20 million in 2022 to promote the country's medical tourism sector internationally and is targeting a revenue of RM 800 million in 2022.

As a holistic plan, the Blueprint also involves stakeholders such as:

- Immigration Department of Malaysia
- Malaysia Airports, Airline and Ferry Operators, and Medevac
- Tourism Malaysia, Hotel Associations, Wellness Providers
- Overseas partners including government regulators

# Eleventh & Twelfth Malaysia Plans

Under the Eleventh Malaysia Plan (11MP, 2016-2020), the MOH released its accompanying **Specialty and Subspecialty Framework for MOH Hospitals**, which included a list of hospitals that were identified for upgrades or construction. The Framework serves a comprehensive guide for service planning and facility development, detailing the challenges and requirements per specialty, of which there are over 70 services listed, including:

- Emergency Medicine & Trauma Services
- Cardiology, Haematology, Respiratory Medicine (Pulmonology)
- Gastroenterology, Nephrology, Hepatology, Endocrinology, Urology
- Neurology, Rheumatology, Dermatology
- Orthopaedics, Otorhinolaryngology, Ophthalmology
- Radiotherapy & Oncology, Transfusion Medicine, Nuclear Medicine
- Geriatrics, Palliative Medicine, Adult Intensive Care
- Obstetrics & Gynaecology
- Paediatrics & Various Subspecialties, including Neonatology, Developmental and Adolescents
- Various Surgeries including Plastic & Reconstructive Surgery
- Anaesthesia & Subspecialities
- Sports & Rehabilitation
- Forensic, Genetics, Infectious Disease, Pathology

The provision and development plans for these services continue to be consolidated under 12MP, alongside further plans:

- Malaysia Healthcare System Reform Blueprint to be introduced to transform the national healthcare system, including public sector transformation, private sector regulatory reform, sustainable health financing, and the introduction of new policies for oral health, mental health, immunisation, and food safety.
- **Electronic Medical Record** (EMR) initiative will be rolled out in phases to create a lifetime health record and ensure seamless flow of information between healthcare facilities.
- A **National Health Literacy Policy** will be introduced to improve the public's knowledge and understanding of basic health information and services.

# 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 detail hazard-specific strategies, for example how to prepare for biological and natural hazards. MySED II strengthens the core public health functions as well as many key health systems such as 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 of 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 12<sup>th</sup> 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 emphasise on accessibility, promotion of health, disease prevention and effective management of chronic debilitating illness, through 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 roles in intersectoral collaboration, international commitment, development of 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 gramme. Management of headquarters & state health departments Hospital management Emergency & outpatient General inpatient I modicine Programme.

- Paediatric
- Orthopaedic
- Anaesthesia & intensive care

- Pathology

- Orology
   Plastic surgery
   Radiotherapy & oncology
   Diagnostic imaging
   Inclusion data in the 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.

Ein Service der AUSSENWIRTSCHAFT AUSTRIA

# 8. SUBSIDIES & FISCAL INCENTIVES IN THE MEDICAL SECTOR

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

# Manufacturing (Medical Devices)

Manufacturing of Medical Devices and Apparatus remains one of the country's Promoted Activities. Hightech medical device manufacturers investing in Malaysia are eligible to be considered for up to 100% Income Tax Exemption (ITE) and 100% Investment Tax Allowance (ITA) on their statutory income for five years. Under the PENJANA scheme, Malaysia is also offering a special Relocation Incentive until December 2022 for new medical device investments. Certain regions or states that are promoting manufacturing activities in this sector also offer further incentives in addition to federal grants.

However, incentives are also dependent on criteria such as the level of investment, knowledge/technology transfer, and links to the local ecosystem, in order to determine the company's pioneer status and subsequently the amount of ITA or ITE given.

Manufacturing sector policies also include local company incorporation and Manufacturing Licence application for manufacturing projects, with no restrictions on foreign equity ownership as policies generally encourage free movement of funds for foreign investments in Malaysia. There are also import duty exemptions for raw materials, components and equipment in the sectors.

# Investment into Private Healthcare centres (Hospitals and ACCs)

New or expansion/refurbishment projects of private hospital and ambulatory care centres are eligible for an ITA, i.e. an income tax exemption of 100% allowance on the qualifying capital expenditure incurred within a period of 5 years. This allowance can be offset against 100% of the statutory income for each year of assessment of the medical service operations.

In order to benefit from this scheme, healthcare facilities will be subject to the conditions below:

- Registered with the Malaysia Healthcare Travel Council after obtaining accreditation
- Obtained operating license from the Ministry of Health.
- For each private healthcare facility:

a) The healthcare travellers shall form at least 10% of its total patients for each year of assessment;b) At least 10% of its gross income from that qualifying project for each year of assessment is generated from healthcare travellers.

Additionally, MHTC-endorsed facilities are entitled to a double deduction incentive on expenditures that occurred during the process of obtaining accreditation from the following bodies:

- Joint Commission International Accreditation (JCA) (USA)
- Malaysian Society for Quality in Health (MSQH) (Malaysia)
- CHKS Accreditation Unit (CHKS) (UK)
- The Australian Council on Health Care Standards (ACHS) (Australia)
- Accreditation Canada (Canada).

# **Training and Education**

For Technical, Vocational Education and Training (TVET) and Private Higher Education Centres, the incentive offered is 100% ITA of the qualifying CAPEX incurred within a period of 10 years, to be offset against 70% of statutory income. The required criterium are:

- Approved by MOHE / MOHR / Licensing Body / Registrar.
- Min 70% of students enrolled are registered in technical/vocational/science training.
- Min 70% of students sitting for examinations must be in the technical or vocational or science field.

Equity Restriction is limited to 51% foreign equity for Private Colleges or College Universities, but there are no restrictions (i.e. 100% foreign equity is allowed) for Private Universities or TVET Centres.

# **Research and Development**

Currently, incentives available for R&D activities differ according to the nature of the activities undertaken and business model. R&D companies may apply as R&D Status Company which allow it an ITA of 100% of qualifying CAPEX incurred within 10 years and can be offset against 70% of statutory income. A contract R&D company that qualifies for pioneer status is also eligible for the option of 100% ITE on statutory income for five years. Third-party companies who make use of their service are also eligible for Double Deduction on approved expenditure.

The 12MP announced the government's plan to revise these existing tax incentives in the private healthcare subsector to attract 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 commercialisation of R&D findings to secure sustainable medicine supply in Malaysia.

# **Digital Technology**

Depending on the scope of technology, there are also programmes by the Malaysian Digital Economy Corporation such as achieving MSC status, which allows a company to qualify for special tax exemptions, or the Global Testbed Initiative (GTI) program which aims to bring new digital technology producers to Malaysia by positioning the country as a global testbed hub.

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

# 9. TRENDS AND OPPORTUNITIES FOR AUSTRIAN COMPANIES

# Covid-19 Impact & Post-Pandemic Recovery

Like most countries, Malaysia was badly affected by Covid-19 which forced the country into several lockdowns, known as Movement Control Orders (MCO) since March 2020. International and state border closures also had a severe impact on medical tourism.

While initially well-controlled, the later surges of cases led Malaysia to severely straining its healthcare infrastructure and workforce capacity – at several points, hospitals nationwide were overrun with patients and were confronted with the problem of how to prioritise patients for use of ICUs, ventilators, and other facilities. Ongoing issues with contract medical officers were compounded with a shortage of staff and subsequent demand for non-stop service and led to large swaths of doctors going on strike or resigning.

Covid-19 also exposed flaws in the healthcare delivery system, when there were gaps in accessing treatment – due to lack of facilities – or vaccines in rural areas. Many patients were also diverted from public facilities into private ones, leading to a temporary shift in focus for private healthcare operators.

More promising was the efficacy of the country's vaccination rollout, which despite initial hiccups now sees almost 98% of Malaysian adults and close to 82% of its total population fully vaccinated, one of the fastest in Southeast Asia. The public's general acceptance of the vaccines and their willingness to adhere to mask mandates and other Standard Operating Procedures (SOPs) including contact tracing also demonstrates the effectiveness of healthcare messaging when done cohesively – a lesson that can be adapted for future use.

The first signs for recovery in the sector can be seen in the relieving of Covid-19 management in the private sector, and its return towards elective procedures (put on hold during the past two years) as well as medical tourism as borders reopen. There have also been strong indicators of a healthcare system reform, as displayed by not only the Government's plans, but also initiatives taken by different players in the field.

# Trends

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

# Telehealth

Private healthcare services will focus on the adoption of 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 of private hospitals towards becoming smart hospitals 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 planned would 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 sharing of data and information between public and private healthcare providers and will require tech enabling real-time data analysis to assist evidence-based, effective, and accurate decision-making.

Finally, other digital health technologies, including health IT, wearables, and health sensors are also seeing higher demand among general consumers.

# **Data Security**

Closely related to the telemedicine sector is digital security – a series of recent events in Malaysia related to patient information leaks and risks of data abuse have led to greater scrutiny and interest in safeguarding medical and personal data. This includes the purported selling of the government contact tracing app MySejahtera to a private entity, as well as the leak of over a million medical scan images via unprotected access of DICOM (Digital Imaging and Communications in Medicine).

Currently, personal data and information sharing are governed by general acts, and there are no specific medical data protection laws at a federal level. The nearest option is that private healthcare practices are subject to the Private Healthcare Facilities and Services Act, which includes data protection, while the Ministry of Health must comply to Cybersecurity acts and guidelines, but this leaves room for interpretation and loopholes between the private and public sectors, especially as federal and state governments are exempted from application of PDPA 2010.

Another challenge for healthcare organisations in particular is that cyber security breaches may not stem from the organisation itself but could be a result from a breach in a third-party vendor; and enforcement in this sector is a problem. Furthermore, in the overall scheme of things, digital security in Malaysia remains a weak point, and the government, health ministry and other private healthcare actors seek technology that would help them to protect them from security breaches.

This is particularly important as the MOH is in the midst of implementing the EMR system as mentioned prior, and other federal plans such the adaptation of MySejahtera to store users' electronic health records or to monitor their health for research purposes and service provision. Involving patient and citizen data nationwide, it will be a prime target for hackers and maintaining data protection will be critical.

# **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 thus 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 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 we foresee a shift towards assisted living centres for the elderly. 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; while longer lifespans bring about more challenges that an untrained person will 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 by 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 would 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 see a good future, as the government continues their 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 once again digital technology to allow for follow up consultations when the patient has returned home.

# Sanitation

Previously a slightly neglected sector, this has, post-Covid-19, transformed as awareness amongst medical staff, consumers, and the general public has heightened. Hygiene and sanitation of common areas has become a priority, with companies and property owners/operators of public spaces investing heavily in UV sterilisation, air filtration, self-sanitising touch surfaces, and other solutions to reassure their patrons of their safety within the space. Products or technology in this field that could speed up the process, and/or increase efficiency of sanitation will see great potential.

Consumer products promoting sanitation or hygiene are also in high demand: since March 2020, purchases of air purifiers have surged, while hand sanitisers and UV sterilisers have also seen skyrocketing sales.

# **Medical Waste**

The disposal of Medical Waste is another sector that sees strong demand for solutions. As a highly regulated matter in Malaysia, the generators of medical waste (hospitals, clinics, laboratories) have to adhere to strict guidelines and procedures. However, such processes are often not streamlined or tracked, leading to safety risks, information loss, or inefficacy of treatment. Technologies that are able to improve on these aspects (e.g. tracing systems, bio-waste identification, hazard alerts) would see strong potential.

The increase of medical waste during the pandemic (18% YoY increase 2019-2020) also leads to a need for technologies able to treat hazardous waste in a safe and efficient manner, that also reduces environmental impact. As most clinical waste is incinerated, the emissions also have to be controlled for safety.

# Gaps & Challenges In Healthcare Delivery

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

- Human Resources & Training: There is an inadequate number of specialists to provide active 24 hours a day cover in all hospitals, and 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: Of note, the government identifies inadequate biomedical equipment especially for emergency critical care services. There is also 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 remain. This is particularly notable in aspects like doctor to patient ratio, or emergency response time.
- 4. Increasing Burden: Malaysia also faces 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 higher demand for better healthcare services. In public hospitals and clinics, overcrowding and long waiting time 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 a high level of subsidies in providing healthcare services, particularly in curative treatment increased Government expenditure and threaten the financial sustainability of the Government in providing quality public healthcare.

# Conclusion

While the Malaysian government certainly has ambitious plans and the need to achieve them, there has been a history of problems during execution, oftentimes due to mismanagement or bureaucratic changes, but for the most part, because of costs or (particularly in the case of digital health management/security) lack of access to the right technologies. It would be in this space that Austrian companies could enter the market to offer both their solutions but also expertise and experience.

# **10. EVENTS AND TRADE FAIRS IN THE SECTOR**

# ASEAN Senior Care and Wellness Expo (AGExpo)

#### Kuala Lumpur | 13 - 16 May 2022

**Note:** Recognising the increasing demand of elderly care as the Malaysian ageing population continues to grow, The ASEAN Senior Care and Wellness Expo (AGEXPO) is the first exhibition in Malaysia specially tailored to senior citizens. The exhibition focuses on the well-being and needs of the elderly, aims to provide knowledge in its conference and forums, and to introduce long-established and emerging products and service providers in the professional field of aged care, lifestyle, wellness and healthcare industries.

# Association of Private Hospitals Malaysia (APHM) Exhibition & Conference

#### Kuala Lumpur | 31 May – 02 June 2022

**Note:** The Association of Private Hospitals of Malaysia (APHM) is an Association representing private hospitals and medical centres in Malaysia and has been in existence since 1972 and currently has over 100 members throughout Malaysia. APHM member hospitals are key partners with the public sector healthcare providers in bringing comprehensive medical care to all Malaysians through its member hospitals. APHM plays an important role in its objective of helping to raise standards of medical care within Malaysia.

#### International Medical Exhibition & Conference (IMEC Expo)

#### Kuala Lumpur | 19 – 21 July 2022

**Note:** IMEC Expo aims to offer a symbiotic platform for Sourcing, Procurement, Engagement and Communication for medical markets. Spurred by the Covid-19 pandemic, increased awareness and sourcing for medical and healthcare needs have grown. They project over 10,000 trade visitors from the medical healthcare system including public and private hospitals, nursing homes, pharmacies and educational institutions.

#### ASEAN Healthcare Transformation Summit

# Kuala Lumpur | 6 – 8 September 2022

**Note:** ASEAN Healthcare Transformation is Southeast Asia's most interactive meeting for healthcare professionals creating critical platform for dialogue focusing on business models and innovation that is disrupting the industry. This two-day summit themed "Leveraging Human Touch and Technology in the Connected Health Era" will highlight many best practices in the healthcare landscape, transformation solutions in healthcare, emerging trends in the industry and new health-tech to stay relevant in a challenging and complex operating environment.

# Events of AußenwirtschaftsCenter Kuala Lumpur

Please visit https://wko.at/aussenwirtschaft/my -> Veranstaltungen for more details on the events below.

# Group Exhibition and Austria Showcase: Medical Infrastructure & Technology

(in conjunction with **APHM**)

Kuala Lumpur, Malaysia | 31 May - 02 June 2022

Physical exhibition with an Austrian Pavilion at the APHM expo; an Austrian Panel during the conference to highlight advances in Austrian technology, infrastructure, and services; as well as networking events and B2B meetings with local companies and stakeholders.

#### Webinar on Life Science in Malaysia

#### Online | 04 October 2022

A webinar featuring local experts to give an overview of the Life Science, Pharmaceutical and Biotechnology industries in Malaysia, as well as the trends and opportunities for Austrian companies.

# 11. 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. 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 to oversee and drive investment into the manufacturing and services sectors in Malaysia. MIDA assists companies which intend to invest in the manufacturing and services sectors, as well as facilitates the implementation of their projects. The services provided by MIDA include providing information on the opportunities for investments, as well as facilitating companies which are looking for joint venture partners. They also evaluate 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 that will ensure Malaysia's rapid development, encourages foreign and domestic investment, and promotes 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 to serve the Malaysia medical device's industry. It is a federal statutory agency under the Ministry of Health Malaysia to 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 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 to facilitate and promote the healthcare travel industry of Malaysia by coordinating industry collaborations and building valuable public-private partnerships, at home and abroad. 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 is for 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 is an Association representing private hospitals and medical centres in Malaysia and currently has over 100 members throughout Malaysia. APHM member hospitals are key partners with the public sector healthcare providers in bringing comprehensive medical care to all Malaysians through its member hospitals. The APHM plays an important role in its objective of helping to raise 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 improve 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 Malaysia's dental dealers that are both directly and indirectly specialty services providers, wholesalers, importers, exporters, 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 exploring initiatives.

#### Malaysian Private Dental Practitioners' Association (MPDPA)

MPDPS (Malaysian Private Dental Practitioners' Society), as it was initially christened, 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 interest of surgical specialties and actively promotes the art and science of the various surgical disciplines.

# AUSSENWIRTSCHAFT AUSTRIA

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