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HEALTHCARE AND MEDICAL SECTOR

IN SOUTH & SOUTHEAST ASIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

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Market Study

HEALTHCARE AND MEDICAL SECTOR IN SOUTH & SOUTHEAST ASIA

Publication date / September 2023

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CONTENT

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Market Study

HEALTHCARE AND MEDICAL SECTOR IN INDIA

Publication date / September 2023

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CONTENT

1. OVERVIEW OF INDIAN HEALTHCARE SYSTEM

Healthcare has become one of India's largest sectors, both in terms of revenue and employment. The Indian healthcare sector is growing at a brisk pace due to its strengthening coverage, services and increasing expenditure by public as well private players.

India's healthcare delivery system is categorized into two major components – public and private. The Government, i.e. Public Healthcare System, comprises limited secondary and tertiary care institutions in key cities and focuses on providing basic healthcare facilities in the form of Primary Healthcare Centres (PHCs) in rural areas. The private sector provides a majority of secondary, tertiary and quaternary care institutions with a major concentration in Metros, Tier-I and Tier-II cities.

India's competitive advantage lies in its large pool of well-trained medical professionals. India is also cost-competitive compared to its peers in Asia and western countries. The cost of surgery in India is about one-tenth of that in the US or Western Europe. The low cost of medical services has resulted in a rise in the country's Medical Tourism, attracting patients from across the world. Moreover, India has emerged as a hub for R&D activities for international players due to its relatively low cost of clinical research and access to validated and regulated data.

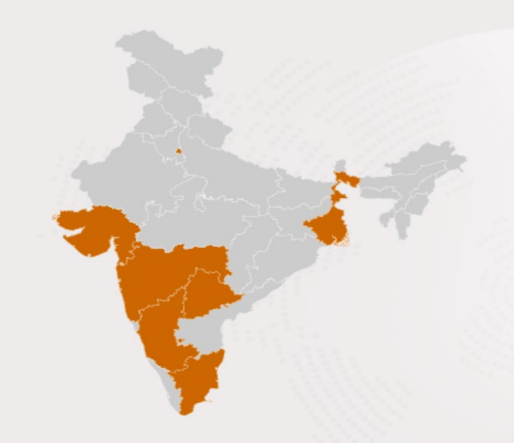
1.1 MARKET SIZE

The Indian Healthcare sector is expected to record a three-fold rise, growing at a CAGR of 22% between 2016–2022 to reach US$ 372 billion in 2022 from US$ 110 billion in 2016.

In the Economic Survey of 2022, India's public expenditure on healthcare stood at 2.1% of GDP in 2021-2022 against 1.8% in 2020-2021. In FY22, premiums underwritten by health insurance companies grew to US$ 9.21 billion.

The Indian Medical Tourism market was valued at US$ 2.89 billion in 2020 and is expected to reach US$ 13.42 billion by 2026. India has been ranked 10th in the Medical Tourism Index (MTI) for 2020-2021 out of 46 destinations by the Medical Tourism Association.

The e-Health market size is estimated to reach US$ 10.6 billion by 2025.



MAJOR LIFE SCIENCES / HEALTHCARE CENTERS IN INDIA:

- Hyderabad
- Bangalore
- Chennai
- Pune
- Mumbai
- Delhi
- Ahmedabad
- Kolkata

1.2 MAJOR SEGMENTS IN THE INDIAN LIFE SCIENCES / HEALTHCARE SECTOR

India's Healthcare industry comprises Hospitals, Medical Devices and Equipment, Health Insurance, Clinical Trials, Telemedicine, Medical Tourism, and more importantly R&D ecosystem. A detailed sector report on Medical Devices, MedTech, Pharmaceuticals and R&D is enclosed.

1.2.1 Life Sciences R&D:

Indian Life Sciences R&D ecosystem has evolved as one of the vibrant innovative ecosystems to contribute through its large pool of highly innovative talent and building world's most favoured Pharm API manufacturers' ecosystem built over several decades.

1.2.2 Hospitals and Infrastructure:

The hospital industry in India accounts for 80% of the total healthcare market. It was valued at USD 61.79 Billion in FY17 and is expected to reach USD 132 Billion by 2023 growing at a CAGR of 16%-17%.

1.2.2.1 Opportunities in Hospitals and Infrastructure:

The hospital industry in India is witnessing huge demand from both global and domestic investors. India's hospital bed density is less than half the global average of three hospital beds per 1,000 population, implying that an estimated 2.2 million beds will be required over the next 15 years.

There are nearly 600 investment opportunities worth USD 32 billion in the hospital/ medical infrastructure sub-sector on Indian Investment Grid (IIG), a platform maintained by Invest India for showcasing investment opportunities by sector.

1.2.3 Health Insurance:

Health insurance contributes 20% to the non-life insurance business, making it the second largest portfolio. Multiple stakeholders constitute India's health insurance ecosystem including insurance companies, beneficiaries, provider hospitals, third-party administrators, intermediaries, reinsurers, start-ups, diagnostics, pharmacies, value-added service providers, Government regulators and Government-funded social insurance schemes.

1.2.3.1 Opportunities in Health Insurance:

A growing middle class, coupled with a rising burden of new diseases, is raising the demand for health insurance coverage. Many companies offer health insurance coverage to employees, driving the market penetration of insurance players.

1.2.4 Medical Tourism:

Medical Tourism or Medical Value Travel was estimated to be worth USD 5–6 billion in mid–2020. Several factors make India a popular medical tourism destination. These include presence of world-class hospitals and skilled medical professionals; superior quality healthcare; low treatment costs; credibility in alternative systems of medicine as well as increased global demand

for wellness services like Yoga and meditation. Popular specialities for Medical Tourism in India include cardiac care, orthopaedics, organ transplantation, neurosciences, oncology and bariatrics.

Wellness tourism that builds on India's strengths in Ayurveda and Yoga, in particular, is a fast-emerging and growing segment within India's Medical Tourism sector. Several major players like Apollo and the Manipal Group are setting up wellness centres, with traditional healthcare remedies. Many hotels / resorts in the country, especially in the southern States, are establishing Ayurveda Centres.

1.2.4.1 Opportunities in Medical Tourism:

Growth of the medical tourism segment is additionally creating investment opportunities in advanced diagnostic equipment as well as institutions for training professionals, both nursing and paramedical.

1.2.5 Home Healthcare:

In 2020, the Indian home healthcare market was valued at approximately USD 6.2 billion. It is expected to grow at a CAGR of 19.2% and reach USD 21.3 billion by 2027.

Technology-enabled healthcare companies offer sophisticated critical care at home, including advanced facilities like respiratory services, sleep apnoea care, palliative care, cancer support services, post trauma / accident care and specialised rehabilitation services.

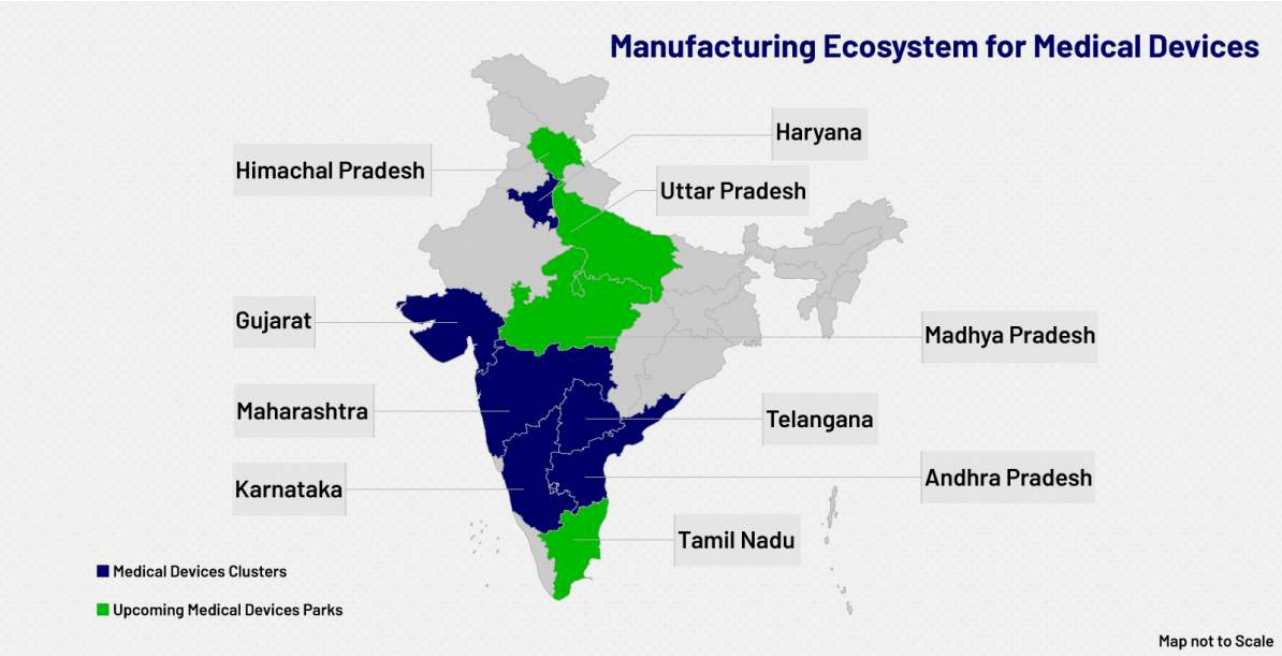
Adoption of home healthcare solutions in India is currently at a relatively nascent stage. However, it is a sunrise sector with tremendous potential for growth in the years to come on account of a rising elderly population, increase in the incidence of chronic diseases necessitating long-term care, enhanced demand for constant personalised care, as well as increasingly nuclear family structures in urban areas.

2. MEDICAL DEVICES AND HEALTHTECH MARKET IN INDIA

2.1 MEDICAL DEVICES SECTOR

The Medical Device sector in India has grown significantly in the last decade. A wide range of medical devices, from consumables to implantable medical devices, are produced in India with a majority being disposables like catheters, perfusion sets, extension lines, cannulas, feeding tubes, needles, and syringes, as well as implants like cardiac stents, drug-eluting stents, intraocular lenses, and orthopaedic implants.

The current market size of the medical devices industry in India is estimated at US$ 11 billion, represents a sunrise sector of the Indian economy. The medical devices industry in India is poised for significant growth with the market size expected to reach US$ 50 billion by 2025. 100% FDI is allowed under the automatic route for both brownfield and greenfield setups.



2.1.1 Market Size:

Medical Devices are segregated into five major segments:

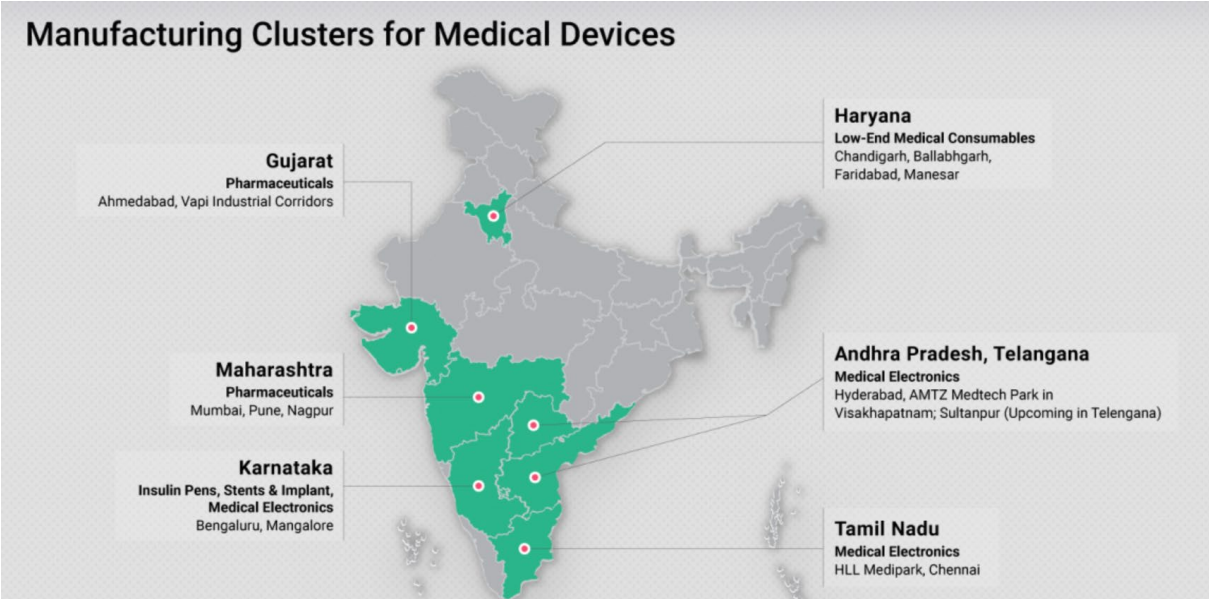
- Consumables & Disposables include needles and syringes, etc.
- Diagnostic Imaging includes MRI, X-Ray, Ultrasounds, etc.
- Dental Products includes dentures, braces, etc.
- Orthopaedics & Prosthetics include knee implants, artificial joints, etc.
- Patient Aids include hearing aids and pacemakers, etc.

Around 65% of the manufacturers in India are mostly domestic players operating in the consumables segment and catering to local consumption with limited exports. Large Multinational Corporations lead the high-technology end of the Medical Devices market in India with extensive service networks.

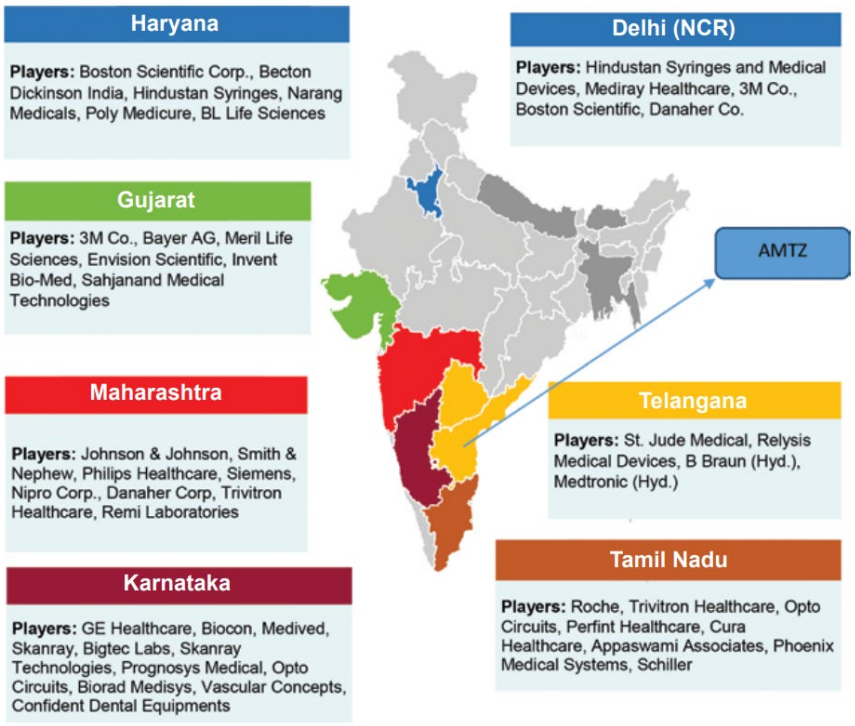
As of May 2021, the medical devices market is estimated to be at US$ 12 billion in India. India is the 4th largest Asian medical devices market after Japan, China and South Korea, and among the top 20 medical devices markets globally.

India's wearable market grew 93.8% YoY in the July–September 2021 quarter, shipping 23.8 million units. Noise maintained its lead for the sixth straight quarter with a 26% market share in the third quarter, followed by Boat (23.1%), Fire-Boltt (15.3%), Realme (7.3%) and Amazfit (4.8%).

The manufacturing is developing in scale and geography. There are six Medical Devices Manufacturing "Clusters" in the country:



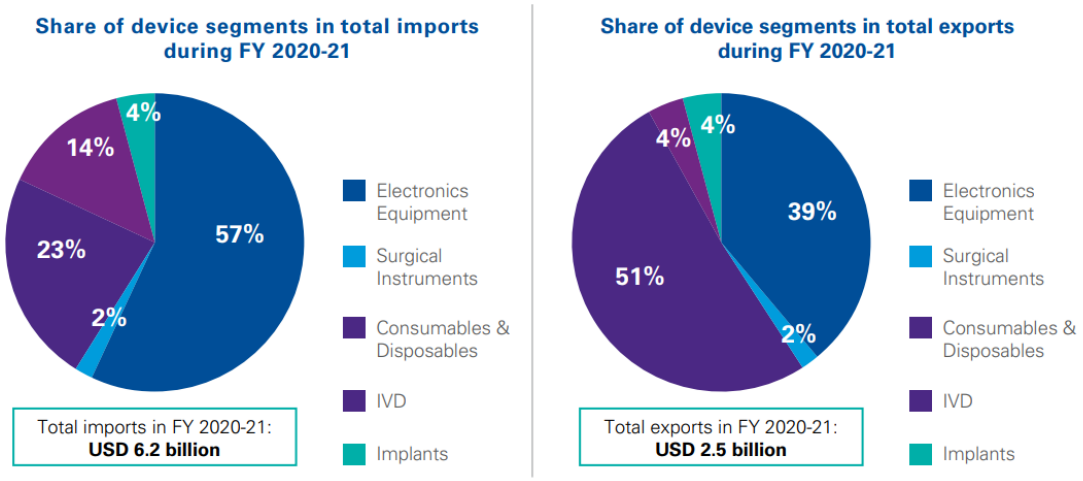
Over the years, keys states in India have been housing Indian and Multinational medical device players as illustrated below.



Existing Players in the Medical Device State Clusters in India

Source: Report by Department of Pharmaceuticals – Government of India

2.1.2 Export and Import Trends:



Share of Device Segments in total Imports & Exports in the Indian Medical Devices Sector

Source: Invest in India Statistics – KPMG Report

India has a 75% to 80% import dependency on medical devices. Export of medical devices from India stood at US$ 2.53 billion in FY21 and are expected to rise to US$ 10 billion by 2025.

2.2 HEALTHTECH / MEDTECH SECTOR IN INDIA

MedTech (Medical Technology which is Medical Devices + Technology) is a segment under the larger umbrella of healthcare systems which focuses on designing and manufacturing a wide range of medical products / devices for diagnosis, prevention, monitoring, treatment and patient care. It encompasses a broader scope as opposed to medical devices and includes medical devices with IT connectivity. It also includes devices such as smart inhalers, robotic surgery, wireless brain sensors, 3D printing, artificial organs, and health wearables.

Indian MedTech was worth US$ 10.36 billion in 2020 and is expected to increase at a CAGR of 37% in 2020–2025 to reach US$ 50 billion. The Indian government's support in terms of outlining favourable regulations & schemes and allowing 100% FDI are driving the HealthTech / MedTech sector. These factors are also attracting international companies to set up production facilities in India.

The segments of Medical Devices (discussed earlier) / MedTech / HealthTech products often tend to overlap in respective segments and based on the interpretation of definition. Moreover, the regulatory authority is also common, making the interpretation more important in market positioning.

2.2.1 Market Size:

The Indian HealthTech / MedTech market is at a nascent stage; however, it is expected to grow exponentially in the country owing to the rising ageing population, favourable government policies & regulations, increasing health insurance penetration, and growing medical tourism. This sector is expected to record a five-fold rise at a CAGR of 37% to reach US$ 50 billion in 2025, from US$ 10.36 billion in 2020.

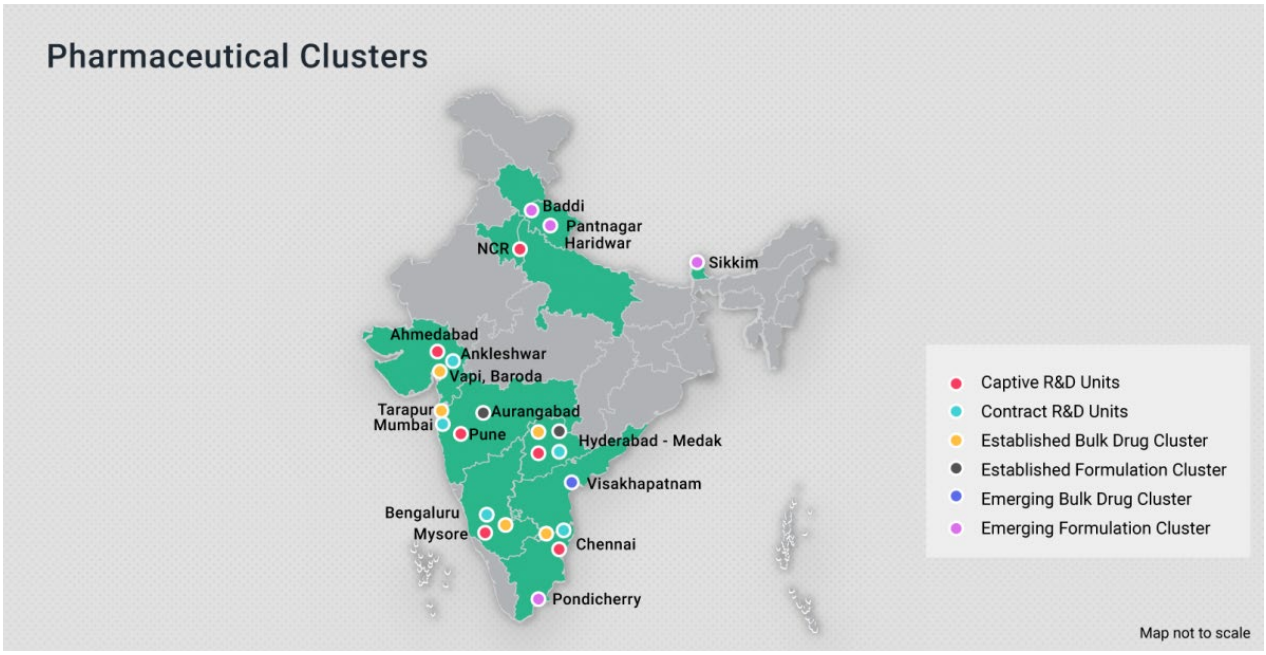
India is home to several start-ups, which are developing capabilities for design and manufacturing of high-tech products and leveraging technologies such as 3D printing, artificial intelligence, smart sensors and others to manufacture medical devices and provide digital healthcare solutions.

International companies are also entering the Indian MedTech market by either setting up their facilities or acquiring local companies. A few of the international MedTech companies – including 3M, Becton Dickinson, Abbott Vascular, Boston Scientific and GE Healthcare – have set up manufacturing facilities in the country.

3. PHARMACEUTICAL MARKET IN INDIA

The Indian Pharmaceutical industry is currently ranked third in pharmaceutical production by volume growing at a CAGR of 9.43%. India has the greatest number of pharmaceutical manufacturing facilities that are in compliance with the US Food and Drug Administration (USFDA) and has 500 API producers that make for around 8% of the worldwide API market.

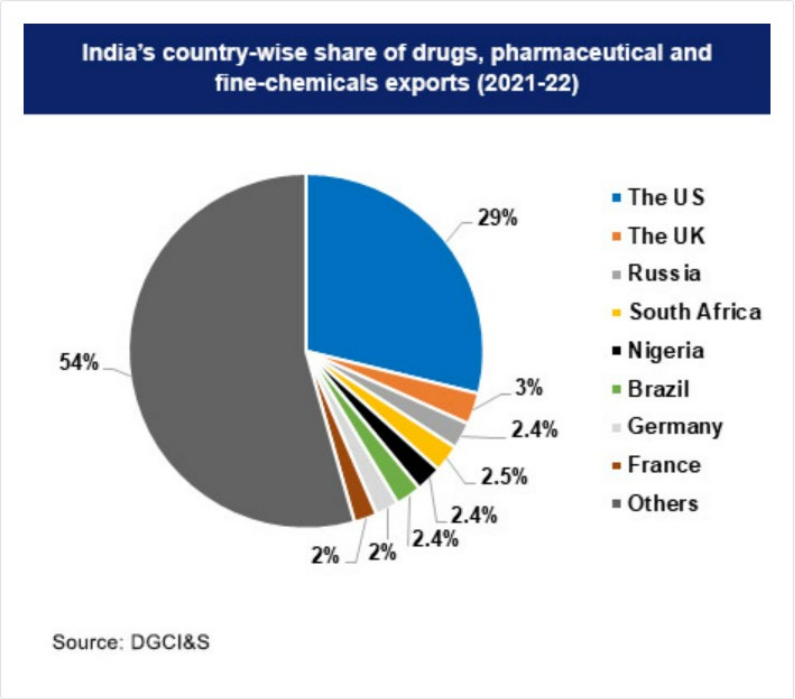
Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. The domestic pharmaceutical industry includes a network of 3,000 drug companies and around 10,500 manufacturing units. Presently, over 80% of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms. India is known as the "Pharmacy of the World" due to the low cost and high quality of its medicines.



100% Foreign Direct Investment (FDI) in the pharmaceutical sector is allowed under the automatic route for greenfield pharmaceuticals. 100% FDI in the pharmaceutical sector is allowed in brownfield pharmaceuticals; wherein 74% is allowed under the automatic route and thereafter through the government approval route.

3.1 MARKET SIZE

According to the Indian Economic Survey 2021, the domestic market is expected to grow triple times in the next decade. India's domestic pharmaceutical market stood at US$ 42 billion in 2021 and is likely to reach US$ 65 billion by 2024 and further expand to reach US$ 120-130 billion by 2030.



4. MARKET TRENDS IN THE INDIAN HEALTHCARE SECTOR

India's healthcare sector has grown rapidly over the last 5 years, particumarly, with a Compound Annual Growth Rate (CAGR) of approximately 22% since 2016. Healthcare has become one of the largest sectors of the Indian economy, in terms of both revenue and employment.

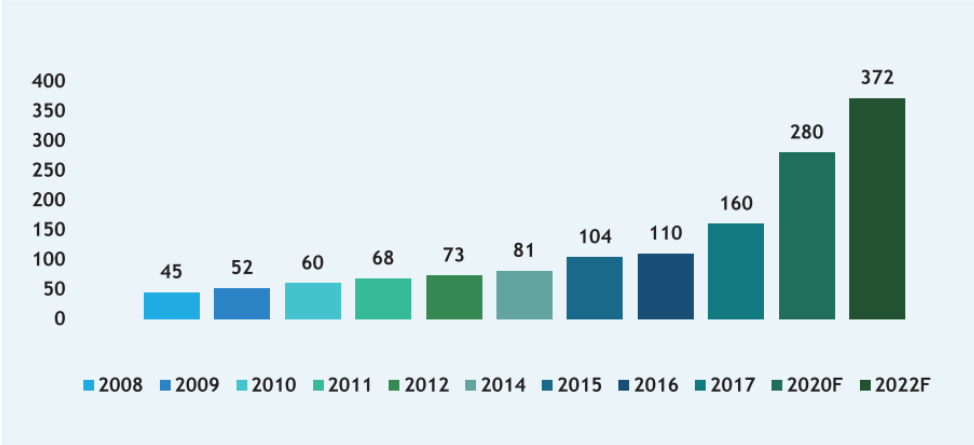


Figure 2: *Growth Trend of India's Healthcare Sector (USD Billion)*[2]

Note: *Compound Annual Growth Rate (2008-2022): 16.28%*

India has been one of the fastest-growing emerging economies over the last two decades, receiving large FDI inflows, which have grown from US$ 2.5 Billion in 2000-2001 to US$ 50 Billion in 2019-2020.

4.1 FUTURE OF THE HEALTHCARE SECTOR

- As of 2021, the Indian healthcare sector is one of India's largest employers as it employs a total of 4.7 million people.
- In the Union Budget 2023-2024, INR. 89,155 crore (US$ 10.76 billion) was allocated to the Ministry of Health and Family Welfare (MoHFW).
- The Indian Government is planning to introduce a credit incentive programme worth INR. 500 billion (US$ 6.8 billion) to boost the country's healthcare infrastructure.
- The hospital industry in India is forecasted to increase to INR. 8.6 trillion (US$ 132.84 billion) by FY22 from INR. 4 trillion (US$ 61.79 billion) in FY17 at a CAGR of 16–17%.
- Rising manpower as there is an availability of a large pool of well-trained medical professionals in the country.

4.2 FUTURE OF THE MEDICAL DEVICES SECTOR

The Indian Government has identified medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthening the manufacturing ecosystem. The Production Linked Incentive Scheme (PLI) Promoting Domestic Manufacturing of Medical Devices and Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) have been introduced to provide an impetus to India's vision of becoming a global manufacturing hub for medical devices.

India's surgical robotics market is estimated to expand at a CAGR of 20% (2017-25) to hit the size of US$ 350 million by 2025. India is also emerging as a strong market for wearables, with approximately 2 million units sold in 2017, expected to reach 129 million units in 2030.

4.3 FUTURE OF THE HEALTHTECH / MEDTECH SECTOR

Key enabler for the MedTech sector is secure data that can be stored and analysed easily. Under the National Digital Health Mission, the government is planning to introduce a unique digital health-card for all citizens. This will have an individual's entire medical record and can be used by doctors to understand the individual's medical history. This initiative will be supported by MedTech solutions.

Presently, a high-level committee under the chairmanship of the Drug Controller General of India is mulling over a new drugs, cosmetics and medical devices bill. The Ministry of Chemicals and Fertilizers has also issued a draft policy with the objective of simplifying regulatory processes to boost innovation and incentivising private investment in research. This is particularly key as the prevalent MedTech themes include AI and machine learning, diagnostic tools for home use, remote patient monitoring systems and digital health tools and wearables.

With advancements in e-Pharmacy, telehealth, and DTx, digital health market in India is expected to gain more steam in 2023 and customize global solutions for local use.

Together, Pharma & MedTech manufacturing can bring billion s in 2023 investment encouraged by PLI scheme and China Plus One Strategy with undertones of Industry 4.0, and customized R&D for India.

Booming startup ecosystem catalyzing SasS revolution coupled with advancements in Digital Health Stack will continue to drive growth in India's healthcare SaaS industry.

5. MARKET OUTLOOK AND OPPORTUNITIES FOR FLANDERS ECOSYSTEM

We have been positioning Flanders' Life Sciences for several years, and there is a wide range of synergy between the province of Telangana, South India, and Flanders, Belgium, that is noted and, linkages have been built in pockets. It is important to note the evolution of history of engagement with Flanders and Telangana. It already includes several renowned personalities in the Life Sciences segment from Flanders who have been keynote speakers and recognized for their remarkable contributions, including Prof. Marc Van Montagu, Dr. Ajit Shetty (who also chairs the International Advisory Board of BioAsia – the flagship annual Life Sciences event of the Telangana Region), Dr. Paul Stoffels, and Dr. Peter Piot, among others.

An initiative between the Telangana ecosystem and Flanders ecosystem players on strengthening cooperation between Telangana and Flanders was discussed for long-term cooperation on innovation in Life Sciences with the Flanders' ecosystem. Each region has complementary strengths that fit well within the discussions to build further with integrated efforts and actions. A broad and focused initiative is being built to explore a long-term partnership between Flanders and Telangana focused on promoting bilateral business and research cooperation.

Flanders was positioned as the International Region Partner at BioAsia 2023 where the United Kingdom was the Partner Country. The Flanders Institute of Biotechnology (VIB), cluster organization Flanders.bio, and Flanders Vaccine evinced interest in the initiative and were present at the BioAsia 2023 event to help position Flanders as the innovative R&D ecosystem to explore cooperation and to build synergies with institutions. Our structural partners VIB, Flanders.bio, and Flanders Vaccine have committed to engage in this long-term interaction with the Telangana – Hyderabad ecosystem.

In reciprocation, a delegation comprising representatives from the Government of Telangana and South Indian Companies, accompanied by the Trade & Investment Commissioner of Flanders, Belgium, for South India, Bangalore, visited Flanders to attend the Road Trip Flanders' Biotech and Life Sciences Ecosystem, State of the Union, and Knowledge for Growth (May 30 – June 1, 2023).

The long-term engagement between the ecosystems is envisaged to have regular interaction, attend and engage in events organized by both ecosystems. It is proposed to build the action on a long-term basis, and an internal team shall steer and monitor the cooperation between Flanders and Telangana over a period of the next 3-4 years as part of the participation in BioAsia in South India and in the Knowledge for Growth event in Flanders to ensure tangible outputs and ecosystem gains on both sides.

Based on the discussions, several cooperation streams and potential projects under discussion proposed potential areas of cooperation between Flanders and Telangana ecosystems in the identified areas of cooperation during BioAsia 2023 and the Road Trip and Knowledge for Growth event 2023.

After successfully participating in the BioAsia 2023 in Hyderabad, FIT Bangalore made efforts to identify the potential and interested players from South India to visit the Life Sciences Ecosystem in Flanders upon the invitation of our partner organisation – Flanders.bio for the Road Trip Flanders' Biotech and Life Sciences ecosystem, State of the Union and Knowledge for Growth (May 30 –June 1, 2023).

In addition to the Road Trip and the Knowledge for Growth Conference, the second meeting for Flanders – Telangana Life Sciences Cooperation was organised on June 2, 2023, in Antwerp, Belgium.

The main takeaway from the Coordination Meeting held on June 2, 2023, is VIB, Flanders.bio and Flanders Vaccine ecosystems will visit Hyderabad and take part in BioAsia 2024, with speaker slots and meeting point for B2Bs between the two ecosystems. The respective Project Investigators and institutions are engaging with respective ecosystem players to develop joint activities facilitated by Flanders Investment & Trade – Bangalore.

FIT Bangalore (Email: bangalore@fitagency.com) will continue to play the role of anchor coordinator to steer and monitor the cooperation. The Flanders presence in BioAsia as an International Region Partner will continue in 2024 and 2025. With this initiative as the anchor, FIT envisages to support and handhold the Flanders Life Sciences / Healthcare ecosystem to build connections with the respective ecosystem.

The interested stakeholders from Flanders ecosystem may reach out to us.

6. MARKET APPROACH AND DISTRIBUTION CHANNELS

The Healthcare sector constitutes diverse products and service offerings, as such it demands a different marketing approach for different products and services. It becomes even more distinct than other markets due to the very nature of the Indian market which is in itself very diverse. Accordingly, different products and services need to be positioned on case-by-case basis.

The general rule is to be focused and to start small either segment-wise or geography-wise depending upon the company's market entry capacity. In order to position the relevant products and services, different marketing channels are used, such as Agency Representation, Distributorship, Joint Venture and/ or subsidiary presence in the market depending upon the size and extent of market entry to the Indian market. To be efficient and prudence in market approach, a tailor-made business/ strategic plan can be drafted based on conversations with ecosystem players/ consultants/ exploratory visits.

We highly recommend an exploratory visit as a prerequisite for drafting the entry plan, as explained earlier, on India's market diversity and to understand culture.

7. LEGISLATION

The Healthcare sector is largely governed by several legislations which are natural to the sector and also market specific. It is important to note the respective approvals that are required for introducing products such as Medical Devices, in R&D activities, in drug development and other compliances such as Pharmacovigilance Services. The over-arching regulation of IP is another major aspect which needs to be safeguarded through contractual agreements.

There are different authorities which govern and implement the legislations the links of which are provided below.

Central Drugs Standard Control Organization (CDSCO)

Website: https://cdsco.gov.in/

National Pharmaceutical Pricing Authority – Department of Pharmaceuticals, Government of India

Website: https://www.nppaindia.nic.in/

8. SECTOR-RELATED TRADE SHOWS IN INDIA

BioAsia

Website: https://2023.bioasia.in/
https://lifesciences.telangana.gov.in/life-sciences-grid/other-initiatives/bioasia/

iPHEX

Website: https://iphex-india.com/

Bengaluru Tech Summit

Website: https://www.bengalurutechsummit.com/

India Pharma & India Medical Devices

Website: https://www.indiapharmaexpo.in/

PharmaTech Expo

Website: https://pharmatechexpo.com/

Pharma Live Expo & Summit

Website: https://pharmalivexpo.com/

Medicall Expo India

Website: https://www.medicall.in/

Medical Fair India

Website: https://www.medicalfair-india.com/

PharmaLytica

Website: https://www.pharmalytica.in/

Indian Pharma Expo

Website: https://indianpharmaexpo.com/

India Med Expo

Website: https://www.indiamedexpo.com/

Health Tech India

Website: https://healthtechindia.in/

Global PHT Expo & Summit

Website: http://www.globalpht.com/

India MedTech Expo

Website: https://indiamedtechexpo.in/

India Medical Device

Website: http://www.indiamediexpo.in/

Asia Labex

Website: https://asialabex.com/

FAMDENT

Website: https://www.famdent.com/

9. SECTOR-RELATED ASSOCIATIONS, RELEVANT AUTHORITIES AND COMPANIES

The following names are the links of the respective organizations / associations to navigate to understand their activities and reach out to them as the case maybe. *(Kindly click on the name to direct you to the website link of the organization.)*

9.1 HEALTHCARE SECTOR

Ministry of Health & Family Welfare – Government of India	Indian Council of Medical Research (ICMR)	Indian Medical Association
Healthcare Federation of India (NATHEALTH)	Indian Dental Association	Hospital Services Consultancy Corporation India Limited (HSCC India Ltd.)
	Central Drugs Standard Control Organization (CDSCO)	

9.1.1 Network / Group Chain of Hospitals in India:

Apollo Hospitals	Asian Institute of Medical Sciences (AIMS)	Aster DM Healthcare
Billroth Hospitals	Fortis Healthcare	Gleneagles Global Hospitals
Krishna Institute of Medical Sciences (KIMS)	Hinduja Healthcare	Manipal Hospitals
Metro Group of Hospitals	Narayana Health	Vasan Health Care Private Limited
Wockhardt Hospitals	Rainbow Hospitals	Batra Hospital & Medical Research Centre
Privat Healthcare Group	Sir Ganga Ram Hospital	Max Healthcare
Medanta – The Medicity	Institute of Liver and Biliary Sciences (ILBS)	Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute
	Lilavati Hospital & Research Centre	

9.2 MEDICAL DEVICES / MEDTECH SECTOR

Association of Indian Medical Device Industry (AIMED)	Association of Diagnostics Manufacturers of India (ADMI)	Medical Technology Association of India (MTaI)

9.2.1 List of Medical Devices / MedTech Companies in India:

Transasia Bio-Medicals Limited	Medtronic India Private Limited	Agappe Diagnostics Limited
Renalyx Health Systems Private Limited	Molbio Diagnostics Private Limited	Translumina Therapeutics Private Limited
Healthium Medtech Limited	Ascent Meditech Limited	Allied Medical Limited
Sahajanand Medical Technologies Limited	MedPrime Technologies Private Limited	Tynor Orthotics Private Limited
B.S. Imaging Solutions Limited	Bharat Enterprises (BioPlus)	Max India Limited
Delhi Hospital Supply Private Limited	Explore Medical Accessories	General Medical Inc. *(Indian Division of Narang Medical Limited)*
Greathealth Trexim Private Limited	Innovious Healthcare Private Limited	Kannu Impex (India) Private Limited
Life Plus Healthcare (P) Limited	Medtech Devices	Narang Medical Limited
Narula Udyog (India) Private Limited	Meditech Electronics	Ortho Beckem Inc.
GWS Surgicals LLP	GPC Medical Limited	JSB Healthcare
Panacea Biotec Limited	Hindustan Syringes & Medical Devices Limited	Medi Safe International India
Accurex Biomedical Private Limited	Mectron Dental India Private Limited	Shree Pacetronix Limited

9.3 PHARMACEUTICAL SECTOR

Central Drugs Standard Control Organization (CDSCO)	Pharmaceuticals Export Promotion Council (Pharmexcil)	National Pharmaceutical Pricing Authority – Department of Pharmaceuticals, Government of India
Bulk Drug Manufacturers Association of India	Federation of Pharma Entrepreneurs India	Indian Drug Manufacturers' Association
Indian Pharmaceutical Alliance		Organization of Pharmaceutical Producers of India

9.3.1 Large Pharmaceutical Companies in India:

Sun Pharmaceutical Industries Limited	Divi's Laboratories Limited	Cipla Limited
Dr. Reddy's Laboratories Limited	Glenmark Pharmaceuticals Limited	Torrent Pharmaceuticals Limited
Lupin Limited	Alkem Laboratories Limited	Zydus Lifesciences Limited
	Aurobindo Pharma Limited	

10. REFERENCE WEBSITES

- India Brand Equity Foundation (IBEF)
  https://www.ibef.org/
- Invest India – National Investment Promotion & Facilitation Agency
  https://www.investindia.gov.in/
- Department of Pharmaceuticals – Government of India
  https://pharmaceuticals.gov.in/
- NITI Aayog – Government of India
  https://niti.gov.in/
- KPMG Report – 2021 Healthcare CEO Future Pulse
- Deloitte-CII Report on Medical Technology Industry in India
- Medical Device – Manufacturing in India – A Sunrise – Report by WHO India and AMTZ
- Frost & Sullivan – India 2023 Top 5 Trends to Watch for in Healthcare

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CONTENT

1. OVERVIEW OF HEALTHCARE SYSTEM

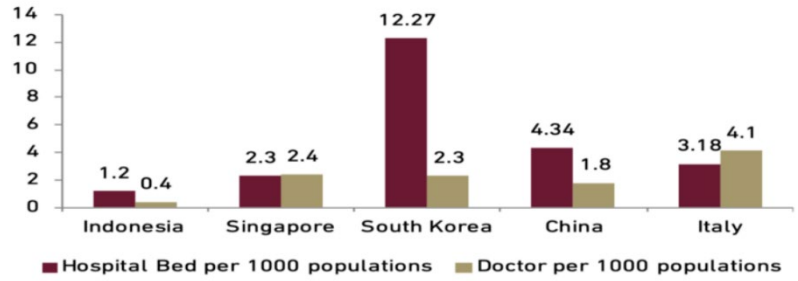
Indonesia introduced its universal healthcare program, the JKN, in 2014, which has since grown into the world's largest, covering over 200 million people. The program is run by the Social Security Administrator for Health (BPJS) agency, and every citizen as well as expats working in the country are mandated to join the program. All companies in the country are responsible for registering their employees and paying a percentage of their premiums. Those registered with the BPJS program are eligible to receive free health services ranging from simple dental check-ups to serious procedures, such as organ transplant.

Roughly 20 million Indonesians are covered by private health insurance, although this is dwarfed by the number covered by the JKN program. Additionally, as businesses in the country are obliged to enroll their employees in the program, many have chosen not to participate in private health insurance schemes. The ranks of those that can afford private insurance are, however, increasing as the middle and affluent class demand faster and a better-quality service. Private insurers will play an important role as an add-on to public coverage like the JKN which, although providing a free service, will only pay up to patient limits.

In the private sector, the employer must pay four percent and the employee the remaining one percent. For civil servants, the government contributes three percent while the employees contribute two percent. In addition to the employee, the premium also covers their spouse and up to three dependent children up to the age of 21. Starting from June 2020, the government has been doubling premiums for the program, hoping this can reduce the program's deficit which reached US$2.3 billion in 2019.

The Health Ministry aims to expand and standardize the country's thousands of integrated health services posts (Posyandu) and community health centers (Puskesmas) so that it can provide primary healthcare to all ages and conduct lab testing as well as screen for deadly illnesses, such as cancer, strokes and tuberculosis.

According to world bank data, the ratio of hospital beds in Indonesia for every 1000 populations is only 1.2, lower than Singapore with 2.3, or South Korea with 12.27. The doctor ratio for every 1000 population is only 0.4, lower compared to other countries. In terms of spending, healthcare spending is still low, at 2.9% of GDP, lower than the average of countries with low-income level 6.1% of GDP, and also lower than the average of East Asia Pacific countries with 7.4% of GDP. Even with the currently low healthcare spending, most private hospitals are already overcrowded and profitable, which implies a huge growth opportunity. Hence, there is still much room for improvement on Indonesia's Healthcare sector.



Source: WDI World Bank, Ciptadana Sekuritas Asia

Also, approximately 40% of Indonesia's 275 million citizens are living on less than USD$ 3.10 per day. The archipelago geography poses a significant challenge to providing accessible healthcare throughout the nation. Vital infrastructures, such as roads, are poorly available especially in the eastern part of Indonesia. Furthermore, healthcare currently takes up only 5 -6% of Indonesia's state budget and a small fraction of this is made available to regional governments. This data alone indicates the difficult effort to provide equal healthcare services to all.

Consequently, individuals residing in Indonesia's rural and distant regions frequently encounter the following problems:

- Weak primary healthcare services
- Almost non-existent secondary specialized care
- 62.9% of population lack access to hospitals
- 60.8% of population lack access to primary healthcare facilities (Puskesmas, Pustu, Midwife)

Even though the infrastructure is in place, significant numbers of primary healthcare facilities have no doctors; mostly in Papua (45.2%), Maluku (44.9%), Papua Barat (40%), Sulawesi Tenggara (29.5%), and NTT (20.5%).

Comparison of Number of Healthcare Providers in Jakarta vs. Eastern Indonesia

Low Doctor-to-Patient Ratio:
Jakarta: 1 Doctor vs. 350 People
Maluku + Papua: 1 Doctor vs. 4000 People

Jakarta: ~27,000 Registered Doctors vs. 10.3m People
Maluku + Papua: ~1,700 Registered Doctors vs. 6.5m People

Stunting, a consequence of inadequate nutrition during both the prenatal period and early childhood, leads to irreversible and debilitating growth impairment. Children affected by stunting will never reach their full potential height and experience restricted brain development, consequently affecting their cognitive capabilities. According to global malnutrition standards, Indonesia falls into the category of having a high prevalence of malnutrition.

- 1/3 Children (under 5yo) Are Malnourished
- 30% Stunting (Low Height for Age)
- 16.6% Wasting (Low Weight for Height)
- 17.5% Under Weight (Low Weight for Age)
- Infant Mortality Rate 60/1000

2. MEDICAL DEVICES AND HEALTH TECH MARKET

The Indonesian medical device and lab equipment industry continues to grow significantly. According to data, provided by the International Trade Administration at the US Dept. of Commerce, the market size of the Indonesian medical device and lab equipment reached some US$3.85 billion in 2022, up from $2.85 billion in 2019. The International Trade Administration determines market size by adding the amount of imported medical devices with the number of devices produced locally, and then subtracting the total with the number of devices that are exported.

That estimate finds further supported in the data from the Ministry of Investment, also known as the Indonesian Investment Coordinating Agency or BKPM. Their records highlight a significant upsurge in the number of medical devices and equipment production facilities, rising from 193 in 2015 to 891 in 2021—a remarkable 361.6% increase in just five years.

One of the catalysts behind this progress is the implementation of a national health insurance scheme known as Jaminan Kesehatan Nasional, or JKN.

In tandem with this, Indonesia aspires to develop its own cutting-edge medical technologies. Historically, the nation has heavily relied on imported medical technologies such as dental x-ray machines, CT scanners, and ventilators. A 2020 Ministry of Health report revealed that approximately 94 percent of medical devices in the country are imported. In 2021 alone, Indonesia imported medical devices and equipment worth Rp 12.5 trillion. Local production predominantly focuses on disposable items such as surgical masks, gloves, and hospital beds.

While imported products dominate the market, primarily encompassing sophisticated medical instruments, exports of medical devices amounted to less than US$267 million in 2019. These exports were largely composed of low added-value products like masks, surgical gloves, and hospital furniture.

These imports predominantly consist of technologically advanced medical instruments and infrastructure, including diagnostic tools, medical lasers, CT scans, and other diagnostic equipment. However, even basic medical devices such as tweezers and scissors for eye surgery are part of this landscape. Several high-tech medical devices, like units for radiotherapy, cardiotocography, electrical mucus suction, mobile X-rays, mammography, digital panoramic imaging, dental X-rays, cryosurgery equipment, and dental elevators, among others, are yet to be manufactured within Indonesia.

Given this, the Indonesian government continues to drive the development of the local medical device industry. The issuance of Presidential Instruction (Inpres) No. 2/2022 on accelerating the utilization of domestically produced goods for government tenders is the latest move in this direction. Through this instruction, the government anticipates local medical device

manufacturers will eventually produce middle-class medical technology and healthcare devices by 2035 to fulfill domestic demand. Although domestic medical device producers already manufacture basic items such as surgical gloves, bandages, orthopedic aids, hospital furniture (e.g. patient beds and drawers), wheelchairs, portable sterilizers, disposable gowns, anesthesia machines, coronary stents, medical needles, and surgical thread. Data from the Ministry of Health indicates that the national medical equipment industry displayed growth trends in early 2018.

For the foreseeable future, the Indonesian market will continue to grow with comparatively low competition from local manufacturers, and the country will remain highly dependent on imports for its medical devices. On the other hand, medical device manufacturers/distributors, pharmaceutical companies, and medical technology firms can tap into a large market while helping Indonesia to improve its medical facilities.

The demand for medical devices will be propelled by the expansion of private and government hospitals and clinics, as well as enhancements to existing facilities. Another driving factor behind this anticipated demand is the surge in non-communicable diseases, for the diagnosis of which advanced and high-tech equipment is required.

It is anticipated that the ability of foreign manufacturers to import medical devices will become less cumbersome, particularly as the government persists in reforming regulations to improve the ease of doing business. Moreover, Indonesia is a member of the ASEAN Medical Device Directive (AMDD), a set of directives designed to harmonize regulations across the region. This necessitates medical device manufacturers to register their devices in any member state where they conduct production.

Prominent foreign firms already established in the country include Siemens, GE Healthcare, and Pfizer. These companies have greatly benefited from the implementation of the JKN program, particularly for equipment such as MRI machines, PET-CT scanners, and ICU equipment, among others.

Indonesia's strategy in integrating digital technology into health care services propels the development of digital health care. COVID-19 contact tracing, vaccination, and even telemedicine is served under the digital healthcare umbrella. Despite these feats, questions arise: *to what extend have Indonesia's digital health services helped consumers? How confident are medical practitioners with the accuracy of diagnosis via digital consultation? What challenges and opportunities await the digital healthcare sector in Indonesia? What will be the future of traditional hospitals?* Further understanding from sector stakeholders' perspectives will be beneficial for the future of Indonesia's health care.

In a country with only 0.4 doctors per 1,000 population, coupled with the challenge of its geography spanning over 17,000 islands, telemedicine emerges to provide healthcare access to even the remotest regions while alleviating the strain on the existing healthcare system.

The incorporation of information and communication technology (ICT) into healthcare will also expedite reforms in Indonesia's healthcare sector. The utilization of healthcare apps, for example, holds the potential to revolutionize how hospitals and doctors manage their records, gather, and exchange patient data.

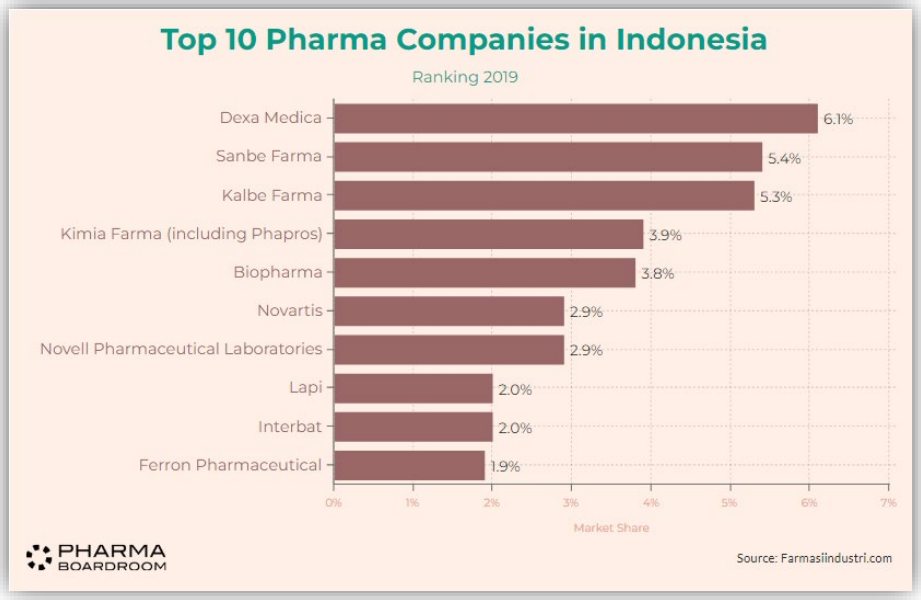
The COVID-19 pandemic has accelerated the growth of digital healthcare and will likely become the new standard in the region post-COVID-19. The local healthcare app, Alodokter, has witnessed over 30 million active users since March 2020 (one and a half times higher than pre-COVID-19 levels). Another telemedicine app, Halodoc, along with the ride-hailing giant GoJek, has collaborated with the Ministry of Health to provide COVID-19 diagnostics in remote areas.

To enhance connectivity across the archipelago, the government has undertaken the Palapa Ring Project, which endeavors to offer access to 4G internet services to more than 500 regencies across the country. This extensive project, costing US$1.5 billion, involves the installation of 35,000km (21,747 miles) of undersea fiber-optic cables and 21,000km (13,000 miles) of land cables, spanning from the westernmost city in Indonesia, Sabang, to the easternmost town, Merauke. Additionally, these cables traverse every district from the northernmost island, Mianagas, to the southernmost island, Rote.

3. PHARMACEUTICAL MARKET

According to a report by Indonesia's Drug and Food Supervisory Body (BPOM), the current count of active pharmaceutical manufacturers in Indonesia stands at approximately 208. These manufacturers encompass 4 state-owned corporations, 35 multinational corporations, and 169 Indonesian national private corporations. Furthermore, the Indonesian Ministry of Health's data from 2021 indicates the presence of approximately 200 drug manufacturing industries, 17 pharmaceutical raw drug industries, 132 traditional medicine industries, and 18 natural product extract industries.

Given that the majority of these corporations are primarily engaged in drug formulation or manufacturing, it's important to recognize that this focus results in a considerable demand for imported pharmaceutical raw materials (APIs). Indonesia continues to heavily rely on imported pharmaceutical raw materials. At the ASEAN level, for instance, the Indonesian pharmaceutical market accounts for 27% of the total ASEAN pharmaceutical market.



Indonesia's pharmaceutical industry has witnessed annual growth ranging between 10-13 percent, largely propelled by the implementation of national health insurance. This policy has significantly benefited the industry, which stands as the largest within ASEAN. Notably, the industry's sales surpassed US$9 billion in 2019 and reached US$10 billion in 2021.

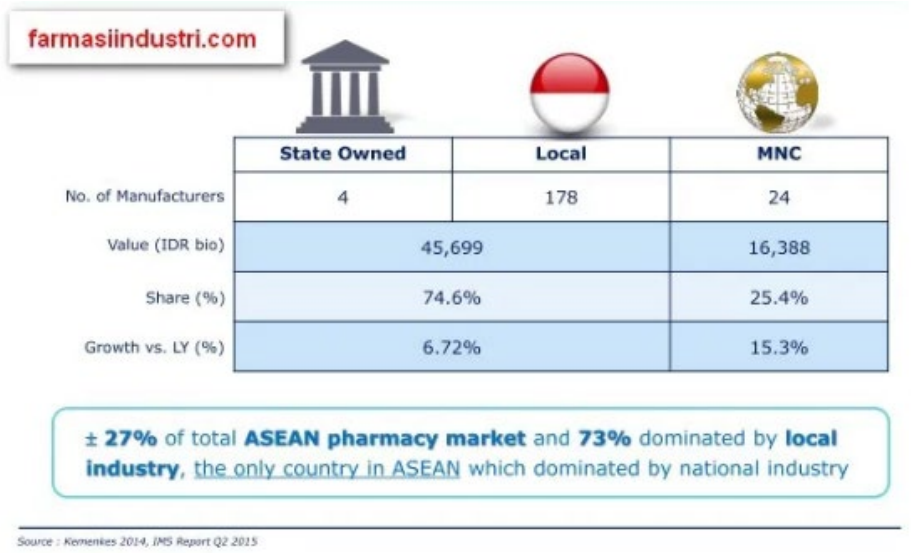
Around 60 percent of the market consists of prescription medicines, while 40 percent comes from over the counter (OTC) drugs. However, a significant portion of both categories comprises generic drugs, constituting the largest segment of the pharmaceutical market. These generics make up approximately 70 percent of the local drug market by volume, amounting to approximately US$700 million.

The JKN program has particularly boosted the sales of the country's generic drug products. The BPJS agency has stipulated that up to 90 percent of the drugs listed in the Essential Medicines List must be generics. Local producers dominate this sector, including industry leaders like Kalbe Farma (the largest private pharmaceutical company in the region), as well as state-owned enterprises Kimia Farma and Biofarma, which together account for approximately 75 percent of the market share.

Around 90 percent of the raw materials employed in drug production, however, are imported. This has prompted the government to revise the Negative Investment List (NIL) to allow foreign investors 100 percent ownership of factories engaged in producing these crucial raw materials.

Despite the government's encouragement of generic drug use to manage costs, these types of medications yield a very low-profit margin, approximately 20 percent compared to 60 percent for branded medications. The industry is also not conducive for innovative drug manufacturers in the near term due to limited spending on research and development, a shortage of qualified scientists, and challenges in enforcing patents and other forms of intellectual property protection.

- Growth in the pharmaceutical industry is expected to reach 12-13 per cent per annum.
- The pharmaceutical market is worth IDR 84 trillion (USD 6 billion) and is claimed to reach $10.11 billion by 2021.
- Over the counter (OTC) pharmaceuticals amount to IDR 48.8 trillion (USD 3,483 million) in 2018. It is expected to grow by 1.3 per cent per year (CAGR 2018-2021).
- For OTC pharmaceutical, per person revenues of IDR 183,250 (USD 13.08) are generated, in relation to total population figures.
- The Indonesian Pharmacists Association reported that about 95 per cent of raw material for medicine is imported.
- Foreign ownership of pharmaceutical firms has increased from 75 to 100 per cent.
- Indonesia is home to more than 30,000 medicinal plants out of the 40,000 globally known medicinal plants.



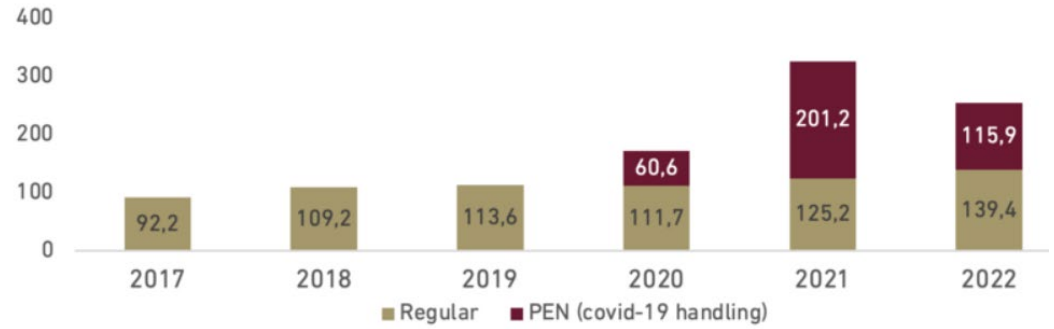
4. MARKET TRENDS

There's the country's lack of hospitals and medical professionals, especially specialist doctors, as issues that would have to be addressed. To this end, the Health Ministry plans to equip each of the country's 514 regencies and cities with a hospital that can accommodate moderate-level surgical operations, such as heart stent operations or tumor removals, while each province will have its own advanced hospital. The Health Ministry also aims to address the country's lack of doctors by increasing the quota for medical students and lecturers, on top of providing more scholarship opportunities.

According to world bank data, the ratio of hospital's bed in Indonesia for every 1000 populations is only 1.2, lower than Singapore with 2.3, and South Korea with 12.27. The doctor ratio for every 1000 populations is only 0.4, lower compared to other countries. In terms of spending, healthcare spending is still low, at 2.9% of GDP, lower than the average of countries with low-income level 6.1% of GDP, and also lower than the average of East Asia Pacific countries with 7.4% of GDP. Even with the currently low healthcare spending, most private hospitals are already overcrowded and profitable, which implies a huge growth opportunity. Hence, there is still much room for improvement on Indonesia Healthcare sector.

Another aspect of the transformation would be the development of a "big-data" record keeping system, called Satu Sehat (one health), that would integrate patient health data across all health sectors. Close to 3,000 health centers in Java and Bali, or around 70 percent of the total health centers there, and 370 hospitals on the two islands, or around 30 percent of the total, have been integrated into the Satu Sehat system.

5. INDONESIA'S HEALTHCARE BUDGET



Source: Finance Ministry, Ciptadana Sekuritas Asia

Indonesia's current healthcare crisis presents an opportunity for reform, translated into six major areas:

1. Primary care: Routine immunization and screening
2. Secondary care: Optimizing the national hospital distribution
3. Health systems resilience: Form reserve health personnel and increase capability for emergency countermeasures
4. Healthcare financing: Allocate investments in the healthcare sector
5. Healthcare human resources: Implement a scholarship roadmap and open up academic training across the country
6. Healthcare technology: Data collection and integration into the Biomedical & Genome Science Initiative (BGSi) with support from East Ventures

Parallel to the significant reforms, the ministry is also reinvigorating the structure and network of primary health services and public health laboratories, ensuring that each transformation reaches every corner of Indonesia. This encompasses measures such as standardizing services in Posyandu, enforcing digitalization standards, and incorporating preventive care.

Among these reforms are changes to the "Posyandu Prima" program, aimed at revitalizing the numerous integrated health services posts (Posyandu) dispersed across the country. There's also a restructuring of the National Health Insurance (JKN) program and the provision of scholarship opportunities for numerous medical students. These reforms work in tandem with the revitalization efforts to create a comprehensive health service structure that ensures every Indonesian benefits. This involves standardizing services at Posyandu, enforcing digitalization standards, and incorporating preventive care.

It would be misleading to suggest that the pandemic has solely revealed vulnerabilities in the health system. Long-standing issues in Indonesia's health system, such as gaps in health infrastructure, the availability and quality of health workers, and inequities in healthcare access, have been apparent for a considerable time.

In a broader sense, Indonesia continues to struggle with poor sanitation. Clean water access is challenging outside major cities, leading to the prevalence of illnesses like diarrhea,

gastroenteritis, and contagious diseases such as typhoid, paratyphoid fever, dengue fever, and malaria. Additionally, as per the World Trade Organization, about 70% of men over the age of 20 in Indonesia are smokers. This contributes to an increase in non-communicable diseases like cancer, stroke, heart disease, and diabetes, necessitating products for chronic disease management.

The country's health sector has consistently received insufficient investment, with only about three percent of GDP allocated to healthcare. The decentralization in 2001 shifted much of the control of public health expenditure and service delivery to local governments, which in turn led to debates about geographical disparities in health infrastructure and services. Persistent gender disparities in health are also evident.

In the years following 2001, the health sector underwent a series of reforms, including efforts to enhance the quality of health workers in 2013, and most notably the implementation of universal healthcare in 2014. Nonetheless, experts contend that further reforms are necessary to address the challenges posed by the country's evolving demographic and epidemiological landscape.

Indonesian hospitals are additionally burdened with outdated and obsolete equipment, causing the healthcare rating of Indonesia to rank lower than its ASEAN peers. These issues have compelled affluent Indonesians to spend around $600 million to seek medical treatment in Singapore, Malaysia, and Australia. It's noteworthy that 69 percent of all medical tourists in Malaysia originate from Indonesia.

6. MARKET OUTLOOK AND OPPORTUNITIES

For the foreseeable future, the Indonesian market will continue to grow with relatively low competition from local manufacturers and the country will remain heavily reliant on imports for its medical devices. On the other hand, medical device manufacturers/distributors, pharmaceutical companies, and medical technology firms can tap into a large market while helping Indonesia to improve its medical facilities.

Imported products dominate the market and largely consist of sophisticated medical instruments, such as diagnostic tools and medical lasers, CT scanners and other diagnostic equipment. Indeed, many high-tech medical devices such as units for radiotherapy, cardiotocography, electrical mucus suction, mobile X-ray, mammography, digital panoramic, dental X-ray, cryosurgery, dental elevator.

Aside from being an importer of high-tech equipment, Indonesia is also an importer of basic medical devices such as tweezers and scissors for surgery. However, domestic medical device producers do already manufacture many basic items such as surgical gloves, bandages, orthopedic aids, hospital furniture (e.g. patient beds and drawers), wheelchairs, portable sterilizers, disposable gowns, anesthesia machines, coronary stents, medical needles and surgical thread.

It is expected that the ability of foreign manufacturers to import medical devices will become less cumbersome, especially as the government continues to reform regulations on ease of doing business. Further, Indonesia is also a member of the ASEAN Medical Device Directive (AMDD), a set

of directives that aim to harmonize regulations across the region and require medical device manufacturers to register their devices in any member state where they have production.

Established foreign firms who already have a foothold in the country are Siemens, GE Healthcare, and Pfizer. These companies have greatly benefited from the rollout of the JKN program for equipment such as MRI machines, PET-CT scanners, and ICU equipment, among others.

6.1 MARKET OPPORTUNITIES FOR HOSPITALS AND HEALTHCARE FACILITIES

Indonesia has 2,925 hospitals providing just over 318,000 beds, or 1.17 beds per thousand population – the lowest rate in ASEAN.

Approximately 63 percent of the country's hospitals are privately managed, and the low number of hospital beds reflects the growing opportunity for foreign investors to fill the shortfall. There is an increasing demand for new hospitals in second-tier cities such as Surabaya and Bandung as more of the population engage with the universal healthcare program.

The government has allowed foreign investors to have 67 percent ownership in private hospitals and 70 percent ownership for investors from ASEAN. This is also the case for private health clinics, although foreign investors are limited to specialized medical services and not basic medical clinic services.

The main challenges for hospital operators will be recruiting doctors (the country only has 0.4 doctors per 1,000 population) in addition to choosing the right location to build the hospitals. The opportunity lies in second-tier cities as bed occupancy is still low and thus there is potential for growth. Furthermore, second tier cities offer lower property prices and hence profitability is usually higher than in first tier areas such as Jakarta.

7. MARKET APPROACH AND DISTRIBUTION CHANNELS

7.1 INVESTMENT OPPORTUNITIES IN INDONESIA

The New Investment List contains significant changes to foreign direct investment (FDI) in Indonesia. These changes were foreshadowed by the enactment in November 2020 of Law No. 11 of 2020 regarding Job Creation (the Omnibus Law) and include liberalization of certain aspects of the healthcare and pharmaceutical sectors.

In the healthcare and pharmaceutical sectors, the Omnibus Law has amended the following laws:

- Law No. 36 of 2009 regarding Health (Health Law);
- Law No. 44 of 2009 regarding Hospitals (Hospital Law);
- Law No. 5 of 1997 regarding Psychotropics; and
- Law No. 35 of 2009 regarding Narcotics.

Further government regulations are expected to be issued to implement these changes, one of which has already been issued – Government Regulation No. 47 of 2021 on Administration of the Hospitals Sector (the Hospitals GR).

7.2 DISTRIBUTION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

Foreign ownership restriction in the wholesale distribution business, including in the pharmaceutical sector, has been the subject of numerous changes over the last few decades, primarily because protectionist sentiment has generally favored distribution by local companies.

The New Investment List has eliminated the foreign ownership restriction pertaining to the distribution of raw materials for pharmaceutical products, as specified in the 2016 Negative List.

The New Investment List is silent on the distribution of finished pharmaceutical products. In theory, that should make this line of business open to 100 percent foreign ownership. However, in the past, unwritten policies of the MOH and Indonesia's Food and Drug Administration (BPOM) have made it difficult for foreign investors to establish foreign-owned distributors of finished pharmaceutical products in Indonesia, even though this business line was not expressly restricted under the 2016 Negative List.

Yet, it may take some time to determine how the new regulations and policies of relevant regulators will interface with these new FDI rules. We will continue to monitor developments in this area.

7.3 MANUFACTURING AND DISTRIBUTION OF HEALTH EQUIPMENT

The manufacturing of Class A health equipment, encompassing medical diagnosis equipment, is now permissible with 100 percent foreign ownership if undertaken in collaboration with cooperatives or micro, small, and medium enterprises (CMSMEs). This stands in contrast to the previous constraint of a maximum 33 percent foreign ownership stipulated in the 2016 Negative List.

Manufacturing of Classes B, C and D – covering more sophisticated health equipment – remains open to 100 percent foreign ownership. The previous "special licence" from MOH seems to have been removed by the New Investment List.

Distribution of health equipment (all types), previously capped at 49 percent under the 2016 Negative List, is now also open to 100 percent foreign ownership.

7.4 PRIVATE HOSPITALS AND MAIN (SPECIALIST) CLINICS

Private hospitals, encompassing both general and specialist facilities, alongside main (specialist) clinics, are experiencing a significant shift toward liberalization. Previously subject to a 67 percent foreign ownership limit (or 70 percent for ASEAN investors), these restrictions have been eliminated by the New Investment List. Notably, this removal of foreign ownership and location constraints extends to regions that were previously excluded, including locales like Makassar and Manado.

However, foreign investors should exercise caution and awareness of existing sectoral requirements that remain applicable. Among these is adherence to the Hospitals GR, which mandates foreign-owned hospitals to fall within Class A or B designations. Moreover, MOH Regulation No. 26 of 2018 on Electronically Integrated Licensing Service in the Healthcare Sector (amended by sub-sector regulations on hospital classification and licensing) necessitates that foreign-owned main clinics be situated adjacent to or in proximity with a Class A or Class B hospital. Additionally, these clinics are obligated to integrate their information management systems with the nearby hospital, as stipulated by the MOH 26 Reg.

In essence, although significant relaxation measures have been put in place, foreign investors should still be aware of the existing sector-specific requirements that hold importance in the regulatory framework.

7.5 MEDICAL LABORATORY CLINICS

Medical laboratory clinics were not expressly covered by the 2016 Negative List, suggesting that they were 100 percent open for foreign investment. However, in practice, unwritten policies of the MOH and BKPM in some circumstances imposed a foreign ownership cap of 67 percent, matching the restrictions for main clinics under the 2016 Negative List.

Under the New Investment List, it appears that medical laboratory clinics remain 100 percent open to foreign investment but now require local partnership with a CMSME. We will continue to monitor developments in this area as well.

Meanwhile, primary healthcare facilities such as primary clinics (klinik pratama) – including general medical services clinics, private maternity facilities, residential health services, and basic healthcare service facilities – remain off-limits for foreign investment.

Business Line	Previous Regulation	Positive Investment List
Hospital	67% foreign ownership (70% for ASEAN investors)	Open for 100% foreign ownership for the hospital with a minimum number of 200 beds
Medical Device Distributor	Maximum 49% foreign ownership	Open for 100% foreign ownership
Medical Device Testing	Maximum 67% foreign ownership	Open for 100% foreign ownership

7.6 EXPORTING TO INDONESIA

In Indonesia, the exclusive authorization of medical device registration and distribution lies with medical device distributor companies. This presents a significant hurdle for foreign entities and investors aiming to enter the industry.

Indonesia's medical device industry was worth US$4.5 billion in 2019 with the majority (US$2.8 billion) coming from imported medical devices like diagnostic tools and medical lasers. On the contrary, the export of the same plunged to US$267 million.

Following are some of the factors expected to further stimulate the demand for importing medical devices in Indonesia:

- Expansion of private and government hospitals and clinics
- Enhancements to the existing medical facilities
- Use of diagnosing devices for the rise in non-communicable diseases
- Liberalizing of government regulations
- Seamless process of importing medical devices for foreign manufacturers.

To import medical devices, a local company must acquire a distribution license known as Izin Penyalur Alat Kesehatan (IPAK) issued by the Ministry of Health Republic of Indonesia (MOH RI). This procedure can be initiated through an e-registration online system, rendering the process both straightforward and efficient. The requisite documents that need to be prepared for medical device registration with MOH RI include:

- Executive Summary with a brief on marketing history, Intended uses and indications, regulatory clearances and pending approvals in other countries, and important safety or performance information

- Essential Principles Checklist
- Declaration of Conformity
- Device Description
- Design Verification and Validation
- Device Labeling
- Risk Analysis
- Manufacturer Information

8. LEGISLATION

Specific regulations oversee healthcare assets, contingent upon the nature of the products or services provided. The Ministry of Health (MOH) assumes authority over healthcare service licenses, encompassing establishments such as hospitals, pharmacies, medical clinics, clinical laboratories, and optical and other healthcare facilities. Licenses for each healthcare service provider are issued by the MOH. The MOH also holds the mandate for overseeing medical devices, necessitating that any such devices possess marketing authorization from the MOH prior to distribution. In alignment with these regulatory roles, the MOH introduced MOH Regulation 14 of 2021 addressing the Standards of the Licensing System in the Healthcare Sector.

Additionally, the Drugs and Food Monitoring Agency (BPOM) has established specific regulations tailored to the category of food and drugs. For instance, BPOM Regulation No. 27 of 2020 delineates the Criteria and Procedure for Health Supplements Registration, while BPOM Regulation No. 11 of 2020 outlines the Criteria and Procedure for Health Supplements Registration. Under the aegis of BPOM regulations, all food and drug products are mandated to secure marketing authorization from BPOM before distribution within Indonesia.

During the process of business combination, the transfer of these licenses and marketing authorizations isn't directly accommodated, as Indonesia does not recognize automatic transfers of licenses. Such 'transfers' of marketing authorizations or licenses transpire through a two-step sequence:

- de-registration of previous marketing authorizations or licences; and
- reapplication for new marketing authorizations or licences by the new entity at the relevant government authority.

8.1 INVESTMENT REGULATION

Manufacturing of pharmaceutical products and raw materials

The New Investment List no longer contains any foreign ownership restriction for the manufacturing of finished pharmaceutical products, which is now open to 100 percent foreign ownership. Under the 2016 Investment List, foreign ownership in this business segment was capped at 85 percent.

Raw materials manufacturing remains open to 100 percent foreign ownership. The 2016 Negative List had already removed the previous 85 percent foreign ownership cap because the domestic pharmaceutical industry still lacks the capacity to develop raw materials. A very high percentage of the raw materials used in manufacturing pharmaceutical products in Indonesia is still being imported, mainly from China and India.

9. TRADE SHOWS

Indonesia Hospital Expo
https://hospital-expo.com/

Indo Health Care Expo
https://indohealthcareexpo.com/

Further information can be obtained by contacting FIT Jakarta, who have more details available on import data and import regulations as well as on importers / distributors of medical equipment.

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FLANDERS
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Market Study

HEALTCARE & PHARMACEUTICAL INDUSTRY IN MALAYSIA

Industry Report

Publication date / September 2023

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CONTENT

1. VERVIEW IF THE MALAYSIAN HEALTHCARE SYSTEM

Malaysia is well-known globally for its high-performing healthcare system based on a well-trained workforce, excellent infrastructure and quality service delivery. With 95 out of 100 scores, Malaysia was ranked first in the Best Healthcare in the World category of the 2019 International Living Annual Global Retirement Index. Kenanga Research predicted that the healthcare industry will continue to grow, supported by growing healthcare expenditure, rising medical insurance coverage, and an ageing population demographic.

The healthcare industry is one of Malaysia's National Key Economic Area's (NKEA) focus areas on investment and policy development. Malaysia's healthcare industry recorded a market size of RM66.3 billion (approx. € 14.07 billion) in 2019 and is expected to reach RM 154 billion (approx. € 32.68 billion) by 2027 at a CAGR of 8.79% (2017 – 2027). In addition, rapid technological development and rising consumer health consciousness encouraged industry players to look into new market opportunities and transform their current goods and services.

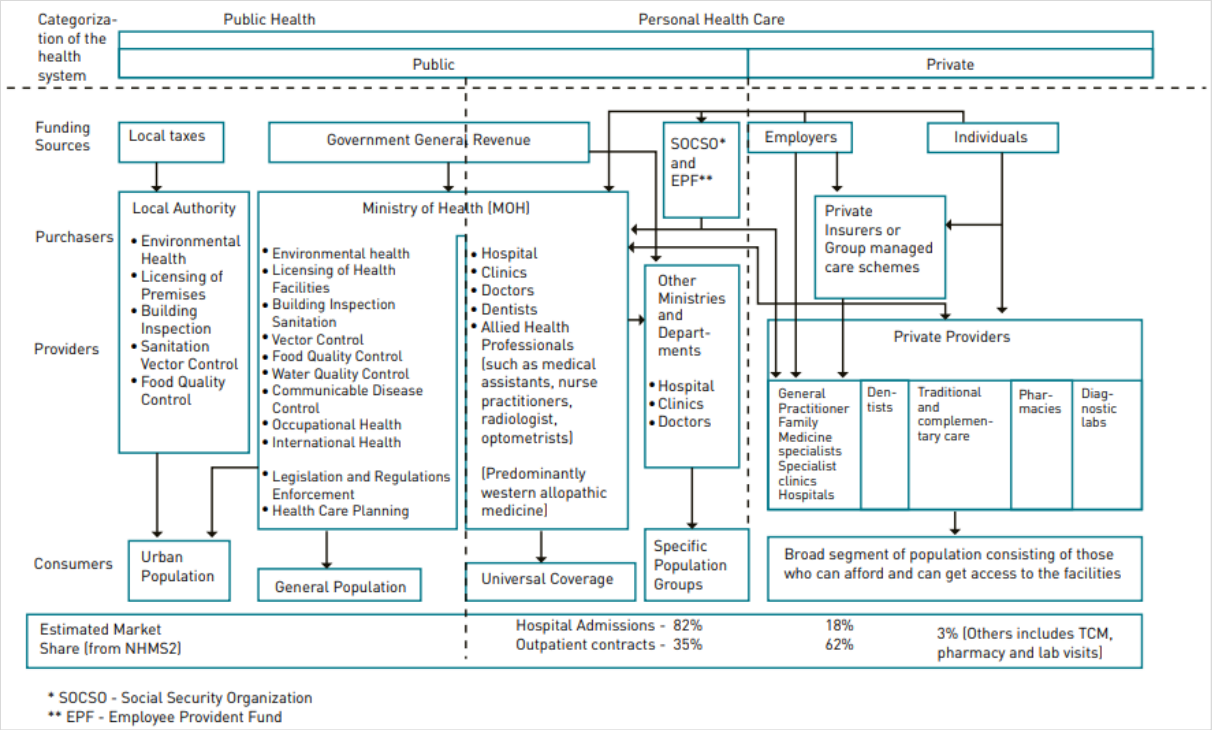

Figure 1: Healthcare System in Malaysia

The industry operates in a **two-tier system**: **Government-run healthcare system** (for Malaysians); co-exists with the **Private healthcare system** (for Malaysians and international patients). According to the Ministry of Health (MOH), there are 145 hospitals and over 2,000 health clinics, including Mother and Child and village clinics. In addition, the Malaysian government subsidises up to 98% of public healthcare costs. Moreover, private hospitals' healthcare costs are higher than public hospitals. For example, the cost of primary healthcare treatment or first-line treatment for Malaysians ranges from RM1 to RM5 (approx. € 0.20 - € 1) in public hospitals and RM30 to RM250 (approx. € 6.10 - € 50.40) in private hospitals (general practitioner visits or specialist consultation).

The **Ministry of Health (MOH)**, through its federal, state, and district offices, centrally manages the healthcare industry in Malaysia. The Ministry of Higher Education oversees university teaching hospitals, the Ministry of Defense oversees several military hospitals and medical facilities, the Department of Orang Asli Development administers health services for the indigenous population, the Department of Social Welfare operates nursing homes for the elderly, and the Ministry of Home Affairs oversees drug rehabilitation programmes.

On top of that, Malaysia also boasts a vibrant civil society with many non-governmental organisations (NGOs). For instance, the Family Planning Association offers reproductive health services, and the Red Crescent Society and St. John's Ambulance mainly offer emergency ambulatory and relief services. The Lion's Club also contributes to rehabilitative services. Numerous NGOs also provide care for patients with cancer and hospitalisation and operate community-based psychosocial and rehabilitation centres and halfway houses.

1.1 DIGITAL HEALTHCARE

In Malaysia, demand for digital healthcare is skyrocketing, driven by the country's ageing population and rising life expectancy, physician and nurse shortage, advancements in communication infrastructure and technology, quick uptake of smartphones, and industry consensus that healthcare IT can revolutionise how care is delivered. More **healthcare platforms** were established to accommodate the demand for digital healthcare, such as Doc2Us and Door2Door Doctor.

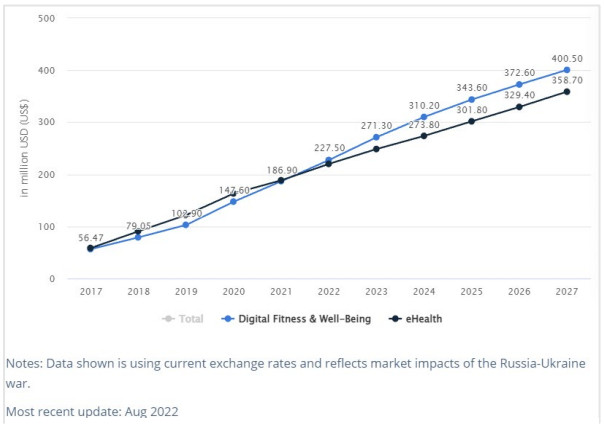

Figure 1: Revenue in the Digital Health Market
Source: Statista, 2022

Digital health market includes a wide range of technologies, including telemedicine, connected wearables, and mobile health apps, which has experienced substantial expansion due to the pervasive use of the internet and smartphones and the shifting trend towards better lives and improved well-being. The booming digital health sector led to the establishment of Digital Health Malaysia (DHM). Four Special Interest Groups (SIGs) are under DHM to look at: regulations, knowledge dissemination, R&D, certifications and go-to-market strategies.

1.2 MEDICAL TOURISM

Malaysia has become a top **medical tourism destination** in the region. In 2019, Malaysia recorded 1.26 million healthcare tourist arrivals, with a total of RM1.7 billion in hospital receipts. Most healthcare travellers come from Indonesia, China, India, Bangladesh, Japan, the United Kingdom, the Philippines, Australia, Singapore and the United States. The highly sought-after medical procedures in the country are cardiology, fertility treatment, oncology, orthopaedics, general health screening, aesthetics, dental and neurology.

Figure 2: Digital Healthcare Sector in Malaysia
Source: The Edge Markets, 2019

Malaysia has seen an increase in the number of medical institutions certified by the **Malaysia Healthcare Travel Council (MHTC)**, which is not limited to medical tourism, with 79 hospitals and clinics (elite and ordinary). International healthcare organisations such as the Australian Council on Healthcare Standards (ACHS), Accreditations Canada, and the CHKS Accreditation Unit acknowledge elite hospitals (UK).

1.3 MEDICAL HEALTH INSURANCE MARKET

The Malaysian medical health insurance market is highly competitive and comprises domestic and foreign insurers. Leading companies include Allianz General, Prudential Assurance Malaysia, Great Eastern General Insurance Malaysia, Berjaya Sompo Insurance, Etiqa Insurance, Lonpac Insurance, Zurich Life Insurance Malaysia and Tokio Marine Insurance Malaysia. Increasingly, companies are involving themselves in social media and re-branding to lifestyle and wellness companies. Malaysia generally has three types of Medical Health Insurance (MHI) policies: hospitalisation and surgical insurance, dread disease or critical illness insurance, and long-term care insurance.

1.4 AGED-CARE FACILITIES

Based on the United Nations, Malaysia is transitioning into an aged nation, with the number of people aged 60 and above projected to reach 6.3 million by 2040. Dr. Tan Maw Pin, a respected geriatrician, highlights the growing demand for aged-care facilities in the country. The situation is pressing, with only 90 government-aged care facilities, 350 registered, and over 1,000 unregistered aged-care centres available. Moreover, government welfare homes and non-profit organisations already operate at full capacity, leading to stringent requirements and lengthy waiting lists. Even affordable private aged-care facilities are witnessing high occupancy rates.

The Department of Social Welfare (JKMM) oversees public welfare aid, health services, facilities, and social protection in old folks/retirement homes, while the Ministry of Health (MOH) regulates nursing homes, which are classified into three categories: Long-term/Permanent, Short-term,

and Day-care. Presently, aged-care facilities in Malaysia are operated by the private sector, non-profit organisations, and government welfare bodies. These facilities can be broadly categorised into Day-Care Centers, Specialised Services, Service Providers, and Retirement Villages/Independent Living. Malaysia is committed to ensuring the well-being and quality of life for its elderly citizens, actively working to provide a comprehensive and diverse range of aged-care options.

2. PHARMACEUTICAL INDUSTRY IN MALAYSIA

Malaysia has a robust pharmaceutical industry, with support from the Malaysian government to develop the national healthcare system via innovative healthcare solutions to the Malaysian. The pharmaceutical industry has contributed over RM6 billion toward Malaysia's gross domestic product (GDP), and by 2024, the industry will potentially contribute another RM10 billion. According to the Drug Control Authority (DCA) of the Ministry of Health (MOH), as of December 2019, there were 263 licensed manufacturers, with 182 categorised as producers of traditional medicine, 70 producers of pharmaceuticals, and 11 companies as producers of veterinary products.

The **National Pharmaceutical Regulatory Agency (NPRA)** regulates the pharmaceutical industry under the Ministry of Health Malaysia. All **drugs/medicine in pharmaceutical dosage forms and cosmetics must be registered with the Drug Control Authority (DCA) under NPRA** before being permitted for sale and marketing in the country.

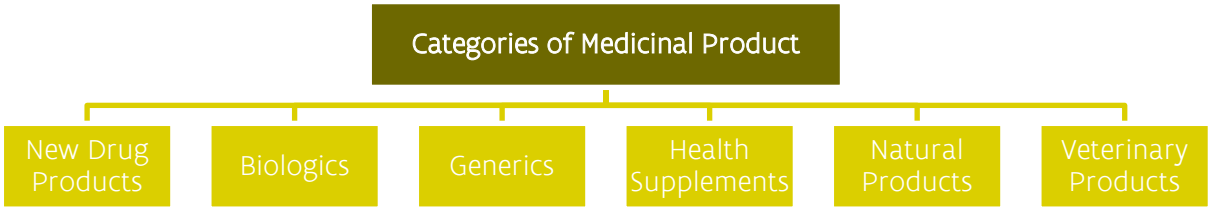

Figure 3: Categories of Medicinal Products
Source: Drug Registration Guidance Document, 2022

Products manufactured by the industry include new drug products, biologics, generics (prescription and OTC products), traditional medicines, and health and food supplements. Local pharmaceutical companies produce generic drugs, traditional medicines and herbal supplements and contract manufacturing for foreign multinational corporations (MNCs). The local players can produce almost all dosage forms, such as tablets, capsules, drops, powders, creams, ointments, eye preparations, injectables, syrups, and ophthalmic and nasal preparations.

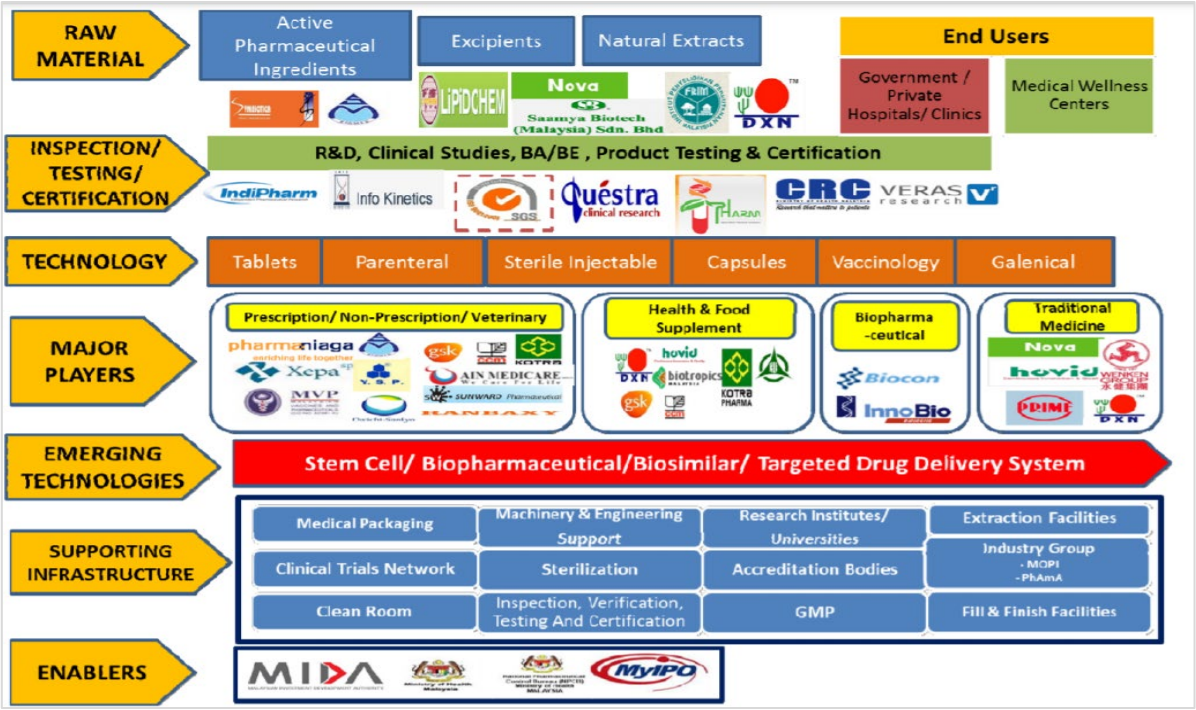

Figure 4: Pharmaceutical Industry Ecosystem in Malaysia
Source: Ministry of International Trade and Industry (MITI)

Among the major local pharmaceutical companies are Pharmaniaga Manufacturing, Duopharma Biotech, Kotra Pharma and Hovid. They are mainly focused on generic drugs, particularly antibiotics, painkillers, health supplements and injectables. Major MNCs such as Glaxo Smith Kline, B.Braun, Y.S.P Industries, Ranbaxy and Sunward Pharmaceutical have established their production facilities in Malaysia. In addition, prominent global industry players, such as Pfizer (USA), Schering-Plough, Eli Lilly & Co., AstraZeneca (UK) and Novartis International AG (Switzerland), mainly function as licensed importers and distribute their branded drugs through local companies. In addition, research-based MNCs ensure Malaysia has access to internationally-tested and accepted drugs, backed by their strong R&D capabilities. Local and foreign players are engaged in biopharmaceutical APIs and FDA/EMEA cGMP-compliant services, specialising in monoclonal antibodies and recombinant proteins.

Pharmaceutical products are distributed in 4 main channels: **community pharmacies (36%), general practitioners (15%), private hospitals (18%) and government hospitals (31%)**. Furthermore, the rise in health awareness and disposable income among Malaysians supports the sales growth in pharmaceutical products, such as vitamins, supplements, generic drugs, and OTC products. Besides, e-commerce and digital health are also booming.

According to the United Nations COMTRADE database, Malaysia's imports of pharmaceutical products were US$2.74 billion, and export was US$413.85 million in 2021. Pharmaceutical products manufactured in Malaysia are sold to EU member countries, Australia and Canada, with Malaysia admitted as the 26th member of the **Pharmaceutical Inspection Co-operation/Scheme (PIC/S)** in January 2022. PIC/S ensures member countries conform to good manufacturing practices and guidelines and mutually recognise the inspection standards of members.

In addition, as a signatory to the ASEAN Framework Agreement on Services (AFAS) and the World Trade Organization (WTO), Malaysia must open its local market to foreign competition. The

General Agreement on Tariffs and Trade (GATT) did, however, include a unique provision that provided some protection for medical products and services.

2.1 HALAL PHARMACEUTICALS MARKET

The global Halal pharmaceuticals market is set to grow to approximately € 94 billion by 2024 from approximately € 84 billion in 2019, especially in the preventive care segment. Halal pharmaceuticals refer to products containing ingredients permitted under the Shariah law. Malaysian Standard, MS 2424 2012, describes the general guidelines in the manufacturing and handling of halal pharmaceuticals. It serves as a basic requirement for halal pharmaceuticals in Malaysia.

The competent authority shall issue the halal certificates - the **Department of Islamic Development (JAKIM)** in Malaysia. As of 1st December 2020, there are 84 foreign Halal certification bodies & authorities recognised by JAKIM.

3. MEDICAL DEVICES INDUSTRY IN MALAYSIA

Malaysia is Southeast Asia's largest medical device market, with a market worth RM6.44 billion (approx. € 1.45 billion), and public sector procurement accounts for about 50%. Malaysia supplies 60% and 80% of the global medical gloves and catheters markets, respectively. In Malaysia, the medical devices industry spans many sectors, such as rubber and latex, textiles, plastics, machinery and engineering support, and electronics. The industry was also identified as one of the growth areas under the Healthcare NKEA.

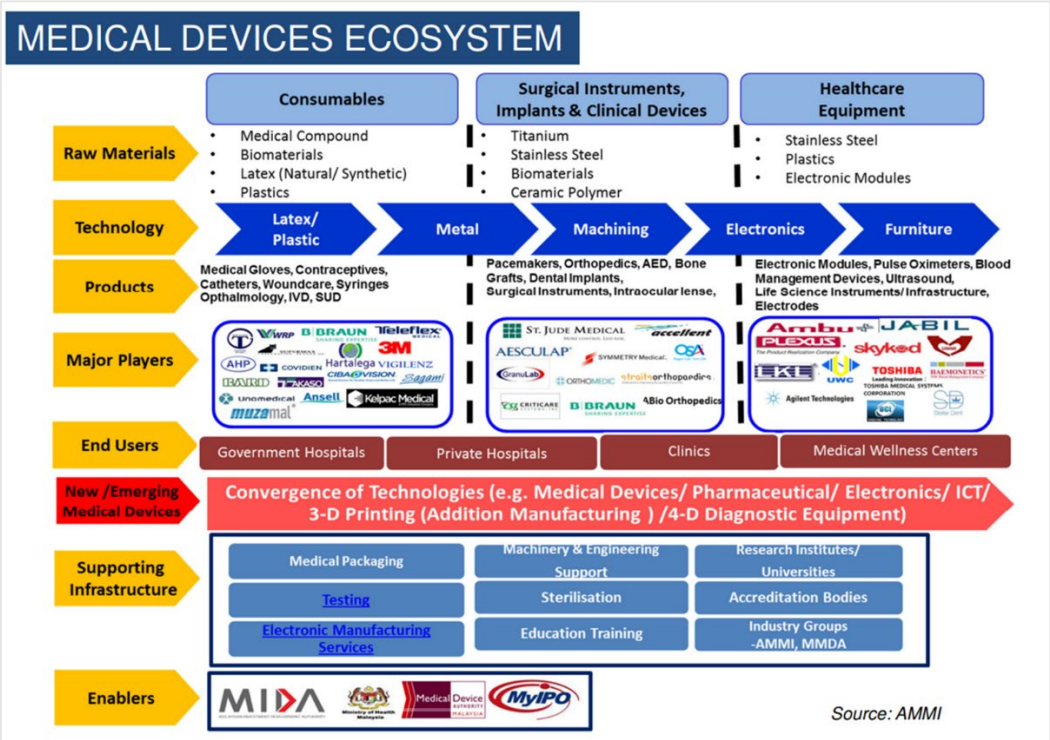

Figure 5: Medical Device Industry Ecosystem In Malaysia
Source: MIDA Malaysia, AMMI

Over the years, Malaysia's medical devices industry has evolved into manufacturing advanced products such as 3D-printed, patient-specific implants and heart valves. According to the **Ministry of Investment, Trade and Industry (MITI)**, Malaysia's export of medical devices was valued at RM29.99 billion in 2020. Over 90% of the local-manufactured are for exports, and over 50% are exported to the US, Germany, Japan and China.

Malaysia has a robust ecosystem of supporting industries and global conformity assessment bodies present in the country. **Over 200 companies (manufacturing, distributing, and selling)** are represented in the well-connected industry ecosystem, with around 109 SMEs, 50 local large businesses, and 30 multinational corporations (MNC). Notably, more than 95% of the investments are FDI, evidence that MNCs dominate the industry. In addition, many big MNCs made Malaysia their offshore location for manufacturing operations and producing higher value-added medical devices, such as Abbott, B. Braun, St. Jude Medical, Boston Scientific, Symmetry Medical, Resmed, Ciba, and Haemonetics.

3.1 RUBBER GLOVES: GLOBAL LEADER

Malaysia is the world's largest producer and exporter of rubber gloves and ranks seventh as the leading natural rubber producer. According to DOSM, as of June 2019, Malaysia has 55 glove manufacturers. Key players in the sector, including Top Glove, Hartalega, Kossan Rubber and Supermax, are exporting gloves to over 195 countries. Top Glove Corporation Berhad, the leader of the Malaysian glove market, is currently the world's biggest supplier of nitrile and latex medical gloves, with high-volume orders from Asia, Europe and the USA.

According to the Malaysian Rubber Export Promotion Council (MREPC), Malaysia meets around 60% of the international market's demand for medical gloves (including examination and surgical gloves). In addition, Malaysia is recognised as a major producer and supplier of latex threads and catheters. There are 108 Latex Products producers of gloves, condoms, catheters, latex threads, and other products in Malaysia.

4. MARKET OPPORTUNITIES

4.1 HEALTHCARE AND HEALTH TECHNOLOGY

- Telemedicine and Digital Health: In Malaysia, the demand for telemedicine and digital health solutions has been rising, particularly in light of technological advancements and the growing demand for remote medical care. Telehealth platforms, remote monitoring, and digital health solutions specialists from Flanders may discover opportunities to work with Malaysian healthcare providers.
- Medical, Health and Wellness Tourism: Malaysia has become a popular destination for medical tourism due to its high-quality medical services and affordable pricing compared to other nations. Flanders-based businesses can look into the potential to provide specialised medical services or form alliances with Malaysian facilities.
- Training and Education: There is an increasing need for qualified healthcare workers in Malaysia. Flanders businesses with healthcare education and training expertise could work with nearby organisations to offer training courses or certifications.
- Health-Focused E-Commerce Platforms: Flanders companies can collaborate with Malaysian e-commerce platforms to offer health and wellness products online.
- Health IT Systems: Malaysian healthcare organisations now heavily invest in information technology systems, which presents opportunities for Flanders companies.
- Healthcare Consultancy Services: There is a demand for consultancy services in areas such as hospital management, healthcare quality improvement, and regulatory compliance.
- Elderly Care Services: The ageing population in Malaysia presents opportunities for Flanders companies to provide elderly care services, including assisted living facilities and home healthcare.
- Healthcare Waste Management: Flanders companies can provide expertise and solutions for healthcare waste management, including waste disposal and recycling.
- Medical Tourism Insurance: Flanders insurance companies can collaborate with Malaysian healthcare providers to offer medical tourism insurance packages.
- Mental Health Services: Flanders mental health services providers and therapists can explore opportunities to provide counselling and therapy services in Malaysia.

4.2 PHARMACEUTICALS INDUSTRY

- Generic Pharmaceuticals: Flanders companies can explore opportunities in supplying generic pharmaceutical products to the Malaysian market. Moreover, the government is positioning Malaysia as a manufacturing hub of generics globally, posing the opportunity for joint ventures in developing generic pharmaceutical products.
- Biopharmaceuticals and Biotechnology: Flanders companies engaged in biopharmaceutical research and development can explore collaborations with Malaysian research institutions and pharmaceutical companies to develop biotechnology-based drugs and therapies.
- Personalised Medicine and Precision Medicine: The trend towards personalised medicine and precision medicine presents opportunities for Flanders companies capable of developing and delivering personalised treatments in Malaysia.
- Herbal Medicines: There is wide interest among Malaysian pharmaceutical companies to collaborate with foreign pharmaceutical companies and research institutions to produce new medicinal drugs.
- Veterinary Products: Flanders companies can explore opportunities in Malaysia by supplying a diverse range of high-quality veterinary products and medications. These products may include pharmaceuticals for companion animals and livestock, vaccines for various diseases, nutritional supplements, diagnostic tools, and equipment used in veterinary clinics and farms.
- Nutraceuticals, Dietary Supplements and OTC Products: The rise in Malaysian concerns about their health and wellness supports the sales growth in vitamins, supplements, generic drugs, and OTC products. For instance, analgesics, antipyretics, antibiotics and cough medicines are the most popular OTC pharmaceuticals. Flanders companies can explore opportunities to supply these products to the local market.
- Halal Pharmaceuticals: Potential collaboration with local companies to develop Halal-certified and locally produced medicines.
- Digital-Pharmaceutical Services: Developing and using digital services or applications across the drug manufacturing value chain. Flanders companies with technical expertise for pharmaceutical-centric services can explore potential collaboration with local companies.
- Clinical Trials and Research Collaborations: Flanders companies and institutions engaged in pharmaceutical research and development can collaborate with Malaysian research institutions and hospitals to conduct clinical trials and research studies.
- Contract Manufacturing and Outsourcing: Flanders manufacturers can consider contract manufacturing and outsourcing services for Malaysian pharmaceutical companies looking to expand their product lines.

4.3 MEDICAL DEVICES INDUSTRY

- Rehabilitation and Physiotherapy Equipment: The growing rehabilitation and physiotherapy equipment demand in Malaysia poses export opportunities for Flanders companies.
- Dental Products and Equipment: Dental supplies, instruments, and equipment are in demand in the Malaysian healthcare sector.
- Medical Devices and Equipment: Flanders companies can export various medical equipment and devices to Malaysia, including Electromedical equipment, Cardiovascular devices, Joint replacements, Orthopaedic devices, In-vitro diagnostic products, Wound

care management products, Medical imaging and diagnostic equipment and Products from the convergence of technology.

- **Minimally Invasive Surgical Instruments**: Flanders companies can find opportunities to supply local hospitals and surgical centres with advanced surgical instruments and devices used in minimally invasive surgeries, such as laparoscopy and endoscopy.
- **Medical Device Distribution and Representation**: Flanders companies can explore partnerships with Malaysian distributors to expand their market reach. Local distributors can assist in navigating the regulatory landscape and provide insights into the preferences and needs of the Malaysian healthcare market.
- **Telemedicine and Remote Monitoring Solutions**: Flanders companies specialising in telehealth platforms, telemedicine devices, and remote monitoring solutions can find opportunities to collaborate with local healthcare providers and telemedicine companies.
- **Digital Health and Healthcare IT**: Flanders companies with expertise in healthcare IT, electronic health records (EHR), health information exchange (HIE), and other digital health technologies can offer their solutions to the Malaysian market.
- **Smart Medical Devices and IoT Integration**: Flanders companies that can provide smart medical devices with IoT capabilities, allowing for data monitoring and remote management, can address the demand for connected healthcare solutions.
- **Research and Development Collaborations**: Flanders companies or institutions involved in medical device research and development can collaborate with Malaysian research institutions, hospitals, and universities to develop innovative medical technologies that address specific healthcare challenges in Malaysia.

5. MARKET APPROACH & DISTRIBUTION CHANNELS

5.1 CHANNEL OF DISTRIBUTION

The proper selection of distribution channels is instrumental to successfully penetrating a new market or introducing a new product, depending on how the company wants to position itself in the new market.

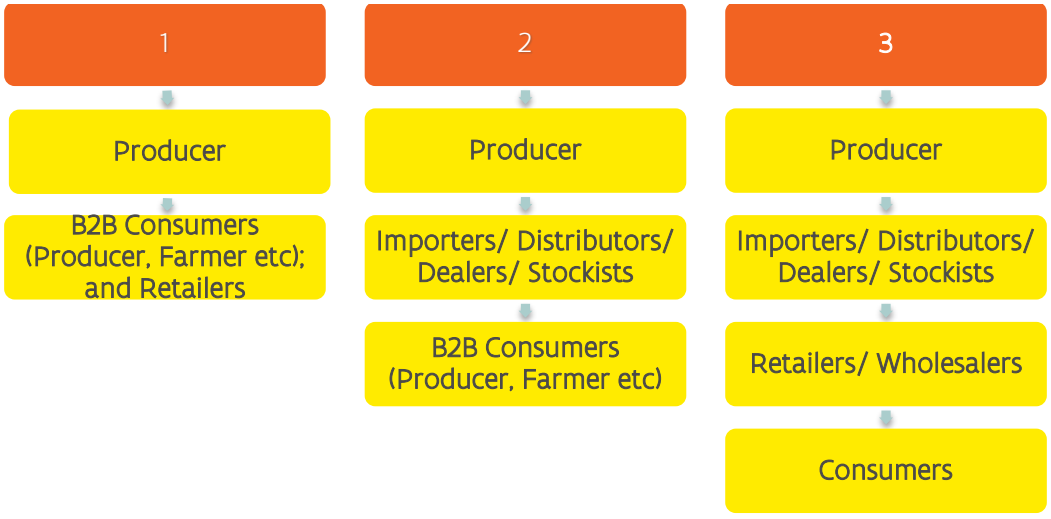

Figure 6: General Overview of Distribution Channels

5.2 MARKET ENTRY MODE

Flemish companies are strongly encouraged to work with a local partner. Working with a local partner offers numerous advantages, including an in-depth understanding of the local business landscape, culture, and consumer preferences. By partnering with reliable local partners, such as distributors, wholesalers, and retailers, Flemish companies can gain valuable insights into the market dynamics, regulatory requirements, and potential challenges they may encounter during their expansion efforts. Their established networks and market knowledge can significantly expedite the process and ensure a more efficient market entry.

Flanders Investment and Trade (FIT) Malaysia can support Flemish companies in their expansion and market entry. FIT Malaysia can assist in identifying the most suitable market entry strategy tailored to the specific needs and offerings of the Flemish companies. FIT Malaysia deeply understands the local business environment and has a wide network of contacts across various industries. FIT Malaysia can offer tailored market insights, regulatory guidance, and insights into the competitive landscape, enabling Flemish companies to make informed decisions.

Flemish companies also can utilise Malaysia as a strategic gateway to the ASEAN region and beyond – Asia Pacific. The ASEAN region's GDP has been surging for a few years now, indicating the region's growing economy. Malaysia, Thailand, and Indonesia are the three most appealing ASEAN nations to foreign exporters, accounting for more than half of the ASEAN bloc's population and more than 60% of its GDP, providing excellent prospects for exporters targeting the mid-market segment.

Moreover, FIT can facilitate valuable connections between Flemish businesses and potential local partners and assist in establishing fruitful collaborations. By leveraging the expertise and support offered by FIT Malaysia, Flemish companies can navigate the complexities of the Malaysian market, enhancing their prospects for sustainable growth and success in the region.

6. LEGISLATION AND PRODUCT REGISTRATION

6.1 NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

The **National Pharmaceutical Regulatory Agency (NPRA)** is responsible for safeguarding the nation's health through scientific excellence in regulating medicinal products and cosmetics. **Drug Control Authority (DCA)** is the executive body established under the Control of Drugs and Cosmetics Regulations 1984, responsible for ensuring the safety, quality and efficacy of pharmaceuticals, health and personal care products marketed in Malaysia.

DCA roles include:

- Registration of pharmaceutical products and cosmetics
- Licensing of premises for importers, manufacturers and wholesalers
- Monitoring the quality of registered products in the market
- Adverse Drug Reaction Monitoring

Drug Registration Guidance Document (DRGD) will serve as the reference guide for the registration process, including quality control, inspection & licensing and post-registration activities of medicinal products. Although the legal requirements of other related legislations have been included, applicants are reminded that it is their responsibility to ensure that their products comply with the requirements of these legislations, namely:

- Sale of Drugs Act 1952;
- Dangerous Drugs Act 1952;
- Poisons Act 1952;
- Medicines (Advertisement & Sale) Act 1956;
- Control of Drugs and Cosmetics Regulation 1984 (Amendment 2006);
- Patent Act 1983; and
- any other relevant acts.

Regulation 7 (1) (a) of the Control of Drugs and Cosmetics Regulation 1984 (Amendment 2006) requires all products to be registered with the DCA prior to being manufactured, sold, supplied, imported or processed or administered unless the product is exempted under specific provisions of the Regulation.

Any drug in a pharmaceutical dosage form intended to be used, capable or purported or claimed to be capable of being used on humans or animals, whether internally or externally for medical purposes, must be registered with the DCA. More information can be obtained through the website: https://www.npra.gov.my/index.php/en/

6.1.1 Pharmaceutical Product Registration Process Overview

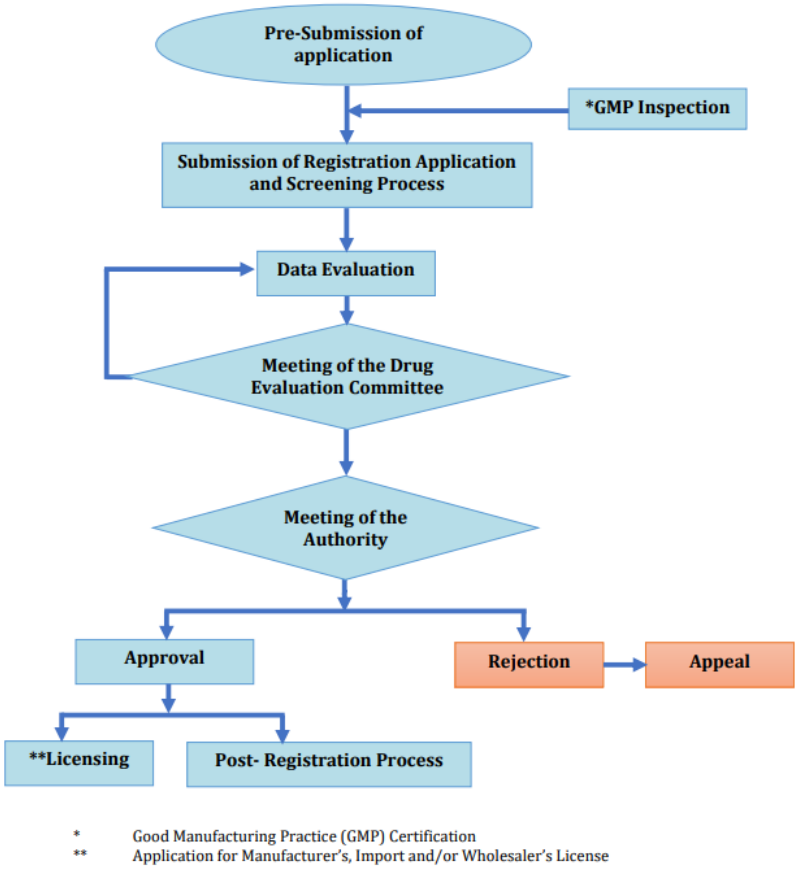

Figure 7: Overview of Product Registration Process
Source: Drug Registration Guidance Document, 2022

6.2 DEPARTMENT OF ISLAMIC DEVELOPMENT (JAKIM)

The competent authority shall issue the halal certificates - the **Department of Islamic Development (JAKIM)** in Malaysia. As of 1st December 2020, there are 84 foreign Halal certification bodies & authorities **recognised by JAKIM**.

The use of the HALAL logo on the labels of pharmaceutical products is not allowed on pharmaceutical products, except for OTC products (products containing substances not scheduled in the Poisons List), traditional products, dietary supplements and also cosmetics, provided that such products have been certified and approved as HALAL by JAKIM. However, halal certification is not mandatory for pharmaceutical products in Malaysia but is essential to access the total Malaysian market.

Website: http://www.halal.gov.my/

6.2.1 Halal Certificates Registration Process Overview

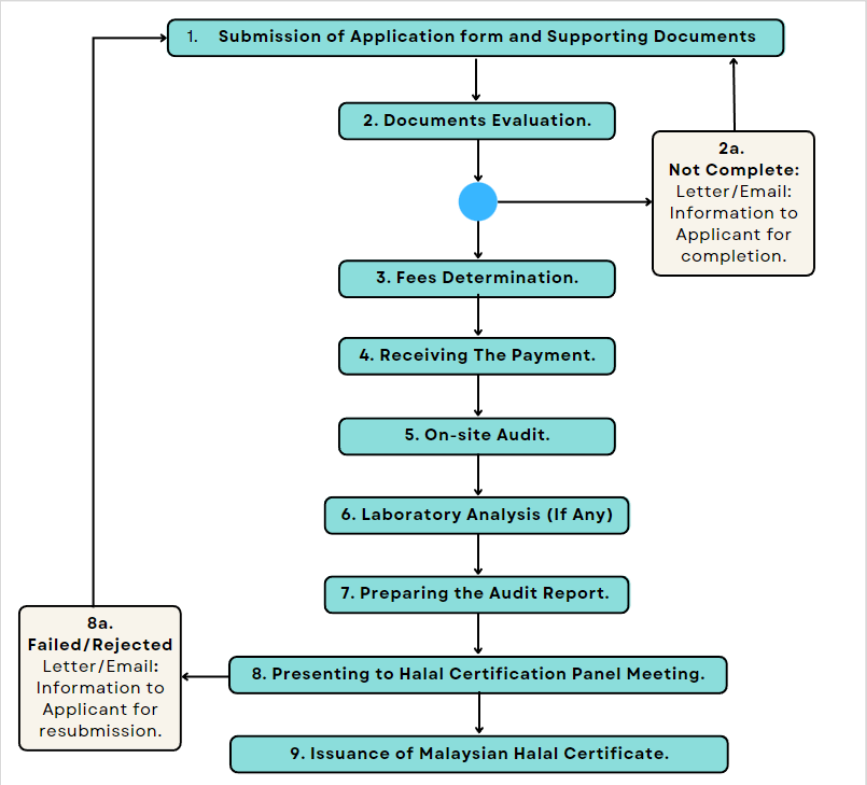

Figure 8: Process of Malaysian Halal Certificates For International Application
Source: Halal Hub Division of Department of Islamic Development Malaysia

6.3 MEDICAL DEVICE AUTHORITY

The Medical Device Authority (MDA) is a government agency governed by the Ministry of Health to oversee Malaysia's Medical Devices industry in enforcing the Medical Device Act 2012 (Act 737). In addition, MDA is responsible for regulating Conformity Assessment Bodies (CABs), Users and Establishments (Manufacturers, Local Authorised Representatives (LARs), Distributors and Exporters). Website: https://portal.mda.gov.my/

6.3.1 Medical Device Registration Process Overview

MeDC@st v.20 (Medical Device Centralised Online Application System) is a web-based system for Establishment Licensing, Medical Device Registration and Export Permit. It is a centralised system where users can use one account to apply for multiple applications.

Figure 9: Establishment Registration Process Flow
Source: Medical Device Authority Malaysia

6.4 IMPORT TAXES

6.4.1 Royal Malaysian Customs Department (RMCD)

The **Royal Malaysian Customs Department (RMCD)** is the government agency responsible for administrating its indirect tax policy, border enforcement and narcotics offences. **Harmonised Commodity Description & Coding System (HS Codes)** was created and used by the Royal Malaysian Customs Department to classify commodities when they are being declared at the custom frontiers of exporters and importers for trade with non-ASEAN countries.

Moreover, **the requirement for a Health Certificate, Certificate of Analysis, Import and Export Permit/License, labelling other relevant licenses/permits/regulations, and import processes vary based on product types**. In addition, designated government agencies are responsible for licenses/permit issuance for different industries.

For trade information reference, kindly log on to JKDM HS Explorer. Malaysia currently does not have an FTA with Belgium; thus, tariff information should refer to the **Customs Duties Order 2022 (PDK 2022)**. FIT Malaysia also can assist you in finding trade information. Please do not hesitate to contact us via the FIT Official Portal or by email/phone.

6.5 TRADE BARRIER

Malaysia is not a party to the World Trade Organization (WTO) Agreement on Government Procurement (GPA). As a result, foreign companies do not have the same opportunity as some local companies to compete for contracts and, in most cases, are required to take on a local partner before their bids are considered.

In domestic tenders, preferences go to ethnic Malay, or Bumiputra, suppliers over other domestic suppliers. Procurement often goes through intermediaries rather than being conducted directly by the government. The procurement can also be negotiated rather than tendered. International tenders are generally invited only where domestic goods and services are unavailable.

6.6 FREE TRADE AGREEMENT (FTA)

Malaysia has signed and implemented **16 FTAs – 7 bilateral FTAs and 9 regional FTAs**. Malaysia has 7 bilateral Free Trade Agreements (FTAs) with Australia, Chile, India, Japan, New Zealand, Pakistan, and Turkey. - 7 bilateral FTAs and 9 regional FTAs. In 2022, Malaysia implemented two mega-FTAs: Regional Comprehensive Economic Partnership (RCEP) and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). In 2022, trade with countries covered by regional and bilateral FTAs accounted for 67.3% of Malaysia's total trade, valued at RM1.916 trillion. Exports to FTA countries amounted to RM1.069 trillion, while imports were valued at RM847.06 billion.

As of July 2023, Malaysia **does not have a Free Trade Agreement (FTA) with the European Union (EU)**. However, negotiations for the Malaysia-European Free Trade Association Economic Partnership Agreement (MEEPA) were initiated in November 2012. The 13th round of trade negotiations for MEEPA took place from 11th to 14th October 2022, signifying ongoing efforts to establish a comprehensive economic partnership between Malaysia and the European Free Trade Association (EFTA) member countries. More information on the website: https://fta.miti.gov.my/

7. TRADE SHOWS

Below trade event details are subject to changes from time to time. Flemish companies are advised to contact **Flanders Investment & Trade Malaysia** for a comprehensive list of trade events with up-to-date information. Please do not hesitate to contact us via the Flanders Investment & Trade Official Portal or email/phone.

7.1 MALAYSIA INTERNATIONAL HALAL SHOWCASE (MIHAS)

Profile: MIHAS is the number one Halal industry platform, catering to international and local players in halal food, pharmaceuticals, finance, fashion, tourism, and more. With global participation from trade commissions, government agencies, and market leaders, it transcends the ASEAN region, making it a dynamic and influential event in the Halal economy.

Website: https://www.mihas.com.my/

7.2 APHM INTERNATIONAL HEALTHCARE CONFERENCE & EXHIBITION (APHM)

Profile: The APHM International Healthcare Conference & Exhibition showcases developments within the healthcare sector that contribute towards a healthy and productive nation. APHM continues to play a significant role in ensuring quality, patient safety and good governance in its member hospitals. Exhibitors include Providers, Suppliers & Industry players, hospitals, management etc., for the healthcare & medical industry.

Website: https://aphmconferences.com/

7.3 SOUTHEAST ASIAN HEALTHCARE & PHARMA SHOW (SEACARE)

Profile: SE-Asian Healthcare Show has been held in Kuala Lumpur for over 20 years with a comprehensive show profile spanning hospital equipment and solutions to diagnostics, lab and rehab. Over-the-counter products, packaging, herbals and cosmetics represent the pharmaceutical industry.

Website: https://abcex.com/

7.4 LAB ASIA

Profile: LABASIA has become a trading platform for efficient communication between suppliers and key buyers, bringing many business opportunities for laboratory instrument enterprises. Lab Asia provides solutions for laboratory professionals, creates a more accurate and deep-seated communication platform for domestic and foreign instrument brand companies, and promotes the R&D development, testing and analysis technology in pharmaceutical and biotechnology fields.

Website: https://www.lab-asia.com/

7.5 MALAYSIA INTERNATIONAL DENTAL SHOW (MIDS)

Profile: The Malaysia International Dental Show (MIDS) is one of the leading international shows in Malaysia, organised by both the dental institution and trade associations, namely MAHSA University and the Malaysia Dental Industry Association (MDIA). MIDA presents an excellent platform to network with dentists, practice managers, hygienists, dental nurses, technicians and laboratory owners.

Website: https://mids.com.my/

8. LIST OF IMPORTERS, ASSOCIATIONS, RELEVANT AUTHORITIES

8.1 PHARMACEUTICALS INDUSTRY

- Apex Pharmacy Marketing Sdn. Bhd.: https://www.apexpharma.com.my/
- AR Dental Supplies Sdn. Bhd.: https://www.ardental.com.my/
- Dynapharm (M) Sdn. Bhd.: http://dynapharm.com.my/
- Kotra Pharma Sdn. Bhd.: https://www.kotrapharma.com/
- Medicell Pharmaceutical (Malaysia) Sdn. Bhd.: https://www.medicellpharma.com/
- Pharmaniaga Berhad: https://pharmaniaga.com/
- Medi-Diagnostic Solutions (M) Sdn. Bhd.: https://medi-diagnostic.com/
- DKSH Holdings (Malaysia) Berhad: https://www.dksh.com/my-en/home
- Rhone Ma Holding Berhad: https://www.rhonema.com/
- Range Pharma Sdn. Bhd.: https://rangepharma.com/
- Asia Veterinary Sdn. Bhd.: http://www.asiavet.com/
- Weissen Company (M) Sdn. Bhd.: https://www.weissen.com.my/
- Yenher Agro Products Sdn. Bhd.: https://www.yenheragro.com/
- National Pharmaceutical Regulatory Agency (NPRA): https://www.npra.gov.my/
- Ministry of Health of Malaysia: https://www.moh.gov.my/

8.2 MEDICAL DEVICES INDUSTRY

- Medi-Life (M) Sdn. Bhd.: https://medi-life.com.my/
- DKSH Holdings (Malaysia) Berhad: https://www.dksh.com/my-en/home
- MAHSA Technologies Sdn. Bhd.: https://mahsatech.com.my/index.php
- Kumpulan Saintifik F.E. Sdn. Bhd. https://www.ksfe.com.my/
- Medigene Sdn. Bhd.: https://www.mdgsb.com.my/
- United Italian Trading (M) Sdn. Bhd.: https://www.uitm.net/
- San-Tronic Medical Devices Sdn. Bhd.: https://san-tronic.n.my/index.php
- UG Medical Services Sdn. Bhd.: https://www.ugmedical.com/index.html
- Lap Tech Medical Sdn. Bhd.: https://www.laptechmedical.com.my/
- Transmedic Healthcare Sdn. Bhd.: http://www.transmedicgroup.com
- Medika Supplies Sdn. Bhd.: https://www.medikasupplies.com/
- Malaysia Medical Device Association (MMDA): http://www.mmda.org.my/
- Association of Private Hospitals Malaysia (APHM): https://hospitals-malaysia.org/
- Association of Malaysian Medical Industries (AMMI): https://ammi.com.my/
- Medical Device Authority (MDA): https://portal.mda.gov.my/

8.3 ADDRESS LIST OF IMPORTERS

We want to clarify that our report does not include direct contacts. For address lists and direct contacts, we recommend contacting FIT Malaysia directly. They can assist you in obtaining a comprehensive list of relevant references and direct contacts that align with your specific requirements. Please feel free to contact FIT Malaysia for further assistance in this regard.

9. INTERESTING WEBSITES

9.1 MALAYSIAN INVESTMENT AGENCIES

- Malaysian Investment Development Authority: www.mida.gov.my
- Invest Selangor: www.investselangor.my
- Invest Kuala Lumpur: www.investkl.gov.my
- Invest Melaka: www.investmelaka.com.my
- Invest Penang: www.investpenang.gov.my
- Invest Johor: www.investjohor.gov.my
- Invest Kedah: www.investkedah.com.my
- Invest Perak: www.investperak.gov.my
- Invest NS: www.investns.com.my
- Pahang State Development Corporation: www.pknp.gov.my

9.2 MALAYSIA ECONOMIC CORRIDORS

- East Coast Economic Region Development Council: www.ecerdc.com.my
- Northern Corridor Implementation Authority: www.ncer.com.my
- Iskandar Regional Development Authority: www.irda.com.my
- Sabah Economic Development and Investment Authority: www.sedia.com.my
- Regional Corridor Development Authority: www.recoda.com.my

10. FLANDERS INVESTMENT AND TRADE MALAYSIA: CONTACT

I hope this gives you a good overview and some initial ideas on entering the ASEAN market by using Malaysia as the gateway to the Asian region. For more information or if you like to schedule a phone call to discuss your further needs. Please do not hesitate to contact us, and you can speak directly to a Flemish service team member to discuss any other assistance you might require to plan your successful entry to the ASEAN markets by using Malaysia as the gateway.

Mr. Thomas Bernthaler

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FLANDERS
INVESTMENT
& TRADE

Market Study

HEALTHCARE AND MEDICAL SECTOR IN MYANMAR

Publication date / September 2023

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CONTENT

1. SUMMARY

Myanmar, the second-largest inland country in Southeast Asia, covers 676,552.7 square km with a population of 54.82 million, and with 67 years of life expectancy in 2020. Its GDP reached $53,702 million in FY 2019-2020 and the World Bank forecasts its 3% growth in 2023. The nation's imports were valued at US$19,050.9 million in FY 2019-2020, with China serving as the primary trading partner, alongside other significant partners like Thailand, Japan, the US, and Singapore, showcasing Myanmar's economic importance. In 2021, the EU ranked as Myanmar's fourth-biggest trade partner after China, Thailand and Singapore, accounting for 7.2% of the country's total trade. It exported pharmaceutical products to Myanmar amounted to € 63 million in 2021, and € 84 million in 2022, a remarkable growth of 32.5%.

Myanmar's healthcare sector is provided by both the private and public sectors, majority supplies rely on foreign imports. Recently, Myanmar has undergone drastic moments in the global COVID health crisis, political and macroeconomic landscapes. How is the sector structured and changed? Which are the key fundamental points to know and where are the opportunities for Flemish companies located in this in-depth market study.

2. OVERVIEW OF THE HEALTHCARE SYSTEM

2.1 DEMOGRAPHY

Myanmar's total population was 54.82 million in 2020 with the annual growth rate of 0.87% according to the Myanmar Health Statistics 2020. Myanmar's population by the age groups in million are stated in the below table.

Population Structure	2014		2016		2018		2020	
	No.	%	No.	%	No.	%	No.	%
0-14 years	15.02	28.9%	14.98	28.3%	14.89	27.6%	14.76	26.9%
15-59 years	32.35	62.2%	33.04	62.4%	33.74	62.6%	34.41	62.8%
60 + years	4.62	8.9%	4.90	9.3%	5.24	9.7%	5.65	10.3%
Total	51.99	100%	52.92	100%	53.86	100%	54.82	100%
Female	26.92	51.8%	27.47	51.9%	28.02	52.0%	28.57	52.1%
Male	25.07	48.2%	25.45	48.1%	25.85	48.0%	26.25	47.9%
Sex Ratio (M /100 F)	93.1		92.7		92.3		91.9	

Population Estimates by Age Groups (in million) 2014-2020

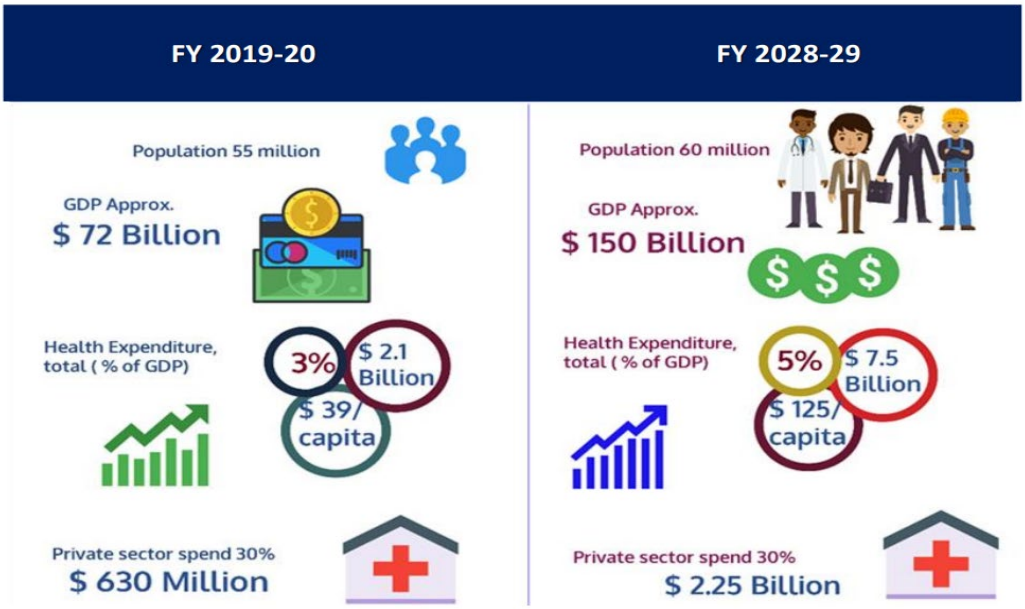
Source: The 2014 Myanmar Population and Housing Census, Thematic Report on Population Projections for the Union of Myanmar, States/Regions. Rural and Urban Areas, 2014-2050. Census Report Volume 4-F, Department of Population, Ministry of Labour, Immigration and Population.

2.2 HEALTH INDICATORS

Life expectancy in Myanmar has risen from 64.7 years in 2014 to 67 years in 2020 for both sexes, as per Myanmar Health Statistics 2020. According to WHO (2020), the four main non-communicable diseases (NCDs) contribute 71% to all deaths, with cardiovascular disease followed by cancers, chronic respiratory disease and diabetes. Meanwhile, the primary causes of hospitalization were pregnancy, childbirth, and puerperium infectious/parasitic diseases, injury/poisoning/external causes, digestive system diseases, and respiratory system diseases according to Myanmar Health Statistics. In addition to health threats raised by WHO, regarding smoking culture and betel chewing are concerned factors in Myanmar.

2.3 HEALTHCARE EXPENDITURE

As per Myanmar Health Statistics, approximately one in five people sought primary health care services from public health facilities in 2019. On the other hand, the total health expenditure increased from € 1,323 million to € 2,096 million from the year 2014 to 2018. As stated by Konema, Myanmar's health expenditure per capita surged from US$ 5 in 2001 to US$72 in 2020, showing an average annual growth rate of 16.93%. According to the World Bank, the per capita income in Myanmar was US$ 1,211 in 2021. The below graph issued by Pun Hlaing Silom Hospitals (PHSH), one of the leading healthcare providers in Myanmar, stated the healthcare landscape forecast in 2028-2029 including health expenditure.



Myanmar Healthcare Landscape Current Vs Forecast

On the other hand, there is an income decline of 9.5% (US$ 1,095.7) in 2022 due to the current political landscape and economic slowdown. It is hoped that the situation will be better and that healthcare, the backbone sector of the country, will gain stability aligned with the previous forecasts.

Due to liberalization of Myanmar's insurance market with 17 life insurers and 9 general insurers, an increasing number of people are opting for health coverage, which helps more people to access superior healthcare services both locally and internationally. Despite the obstacles presented by rising inflation and decreased individual income, this suggests a promising outlook for the growth of medical services within the local context.

2.4 HEALTHCARE PROVIDERS

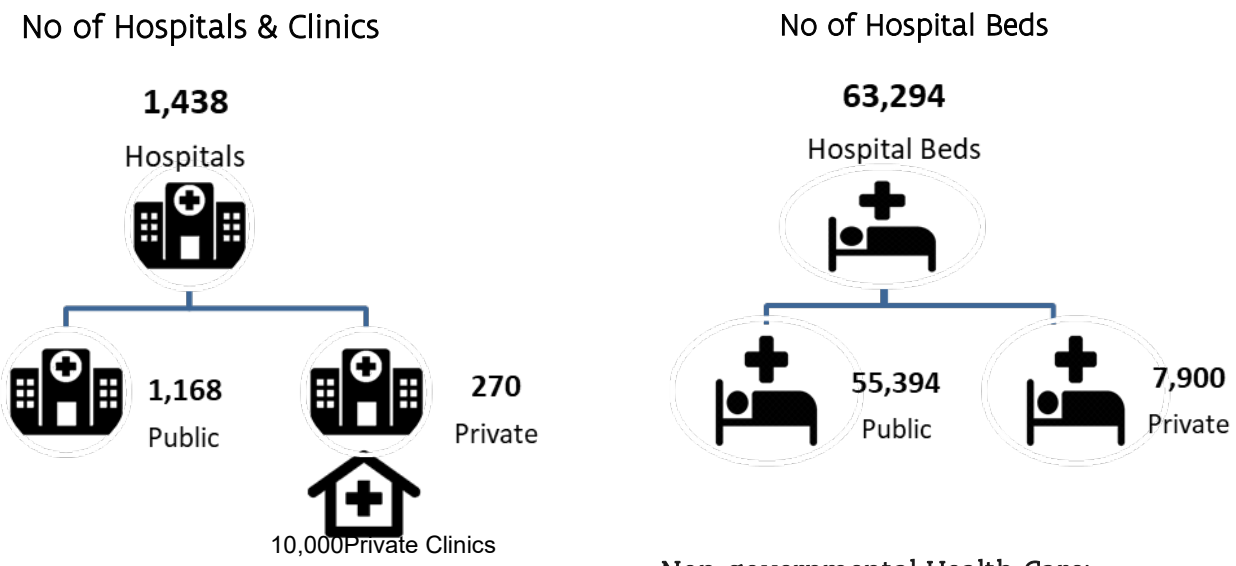
There are three broad categories lying within healthcare providers of Myanmar such as Public, Private and Non-Profit healthcare providers.

- Public Health Sector: Myanmar public health sector, under supervision of Ministry of Health (MOH), holds 86% of the total healthcare service in the country. According to Myanmar Health Statistics, there are 1,168 public hospitals with a capacity of 55,394 beds nationwide in 2019. On average, public hospitals in Yangon served over 10,000 outpatient clients and more than 12,000 inpatient patients daily in 2018. In rural regions, where 70% of total population inhabits, primary treatment options are provided by rural health centres, sub-rural health centres and small private clinics operated by both government and non-profit organisations.

- Private Health Sector: According to Myanmar Medical Services report of 2022, there are approximately 270 private hospitals and over 10,000 private clinics, which primarily operate in the larger cities such as Yangon, Nay Pyi Taw, and Mandalay. Selected services can be reached to rural areas. Besides, there are many charity hospitals run by private sectors, serving the low-income households in Myanmar. It is still required to expand the healthcare network across the country, and there are business opportunities for private healthcare providers.

Due to the higher health demand against the shortage of facilities, technology, and healthcare professionals, middle- and high-income Myanmar people frequently seek top-tier medical services in neighbouring countries such as Thailand, Malaysia, India, Singapore for their check-ups and treatments, showcasing an increasing demand in healthcare utilization. Oxford Business Group reports that these medical journeys abroad amount to annual expenditure of around US$600 million by Myanmar patients. This situation indicates the crucial need for Myanmar to enhance its healthcare infrastructure, refine its care delivery systems, and enhance the overall quality of healthcare services. Some groups of companies in the healthcare sector are willing to take the opportunity to revise outbound medical tourism and express their interests in upgrading their facilities in medical equipment and in digital technology solutions. Some business leads have recently visited not only local trade fairs but also international trade fairs including Arab Health.

Number of Hospitals and Clinics in Myanmar



- Non-governmental Health Care:

Myanmar's healthcare sector receives the attention and assistance from the International Development Community. Community-based organisations, international and local non-governmental organisations such as Myanmar Red Cross Society, civil society organisations provide public healthcare services, working together with Myanmar Medical Association (MMA). The main international organizations providing technical and financial assistances to promote the health status of Myanmar people are the WHO, the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the Japan International Cooperation Agency (JICA), the Asia Development Bank (ADB) and the World Bank. The United Nations Office on Drugs and Crime (UNODC), the United States Agency for International Development (USAID), the Australian AID, the United Kingdom Department of International Development (DFID), the Korea International Cooperation Agency (KOICA), and the Thailand International Cooperation Agency (TICA) also play certain roles in the support of healthcare systems in Myanmar.

3. MEDICAL DEVICES AND HEALT TECH MARKET

The country heavily relies on imports to meet the growing local demand for quality healthcare products. The imported medical devices cover a diverse range of essential healthcare needs. These include dental appliances, orthopedic appliances (such as crutches, surgical belts, and trusses), fracture appliances, artificial body parts, hearing aids, and other wearable or implanted devices designed to compensate for defects or disabilities. Myanmar's primary medical device imports originate from the United States, India, Turkey, and Sri Lanka. Other significant sources include Germany, the Netherlands, Australia, Japan, Taiwan, and Indonesia. According to Volza's Myanmar Import data, a total of 612 medical device import shipments were recorded as of today, involving 46 Myanmar importers and sourcing from 43 suppliers. Notably, the top three importers are the U.S. (148,033 shipments), India (147,091 shipments), and Turkey (46,082 shipments).

The medical devices market in Myanmar is expected to expand significantly, with a projected market value of US$214 million in 2023. Among the various segments, Cardiology Devices are anticipated to lead with a projected volume of US$32 million, showcasing the growing demand for advanced cardiac care solutions as per Statista. Despite foreign currency exchange rate fluctuations recently, the thriving medical devices and supplies sector in Myanmar, combined with recent import regulatory improvements in August 2022 and the country's reliance on imports, presents a lucrative opportunity for Flemish companies looking to contribute to this vital industry.

3.1 HEALTHCARE TECHNOLOGY

Limited internet access in remote areas makes it difficult to operate telehealth services. According to the report of E-commerce Connectivity in the Myanmar Healthcare sector, 90% of wards and villages in Myanmar have access to mobile, yet only 44% of the total population has internet in the country according to the World Bank. GlobalData said that telecom services revenue in Myanmar was valued at US$2 billion in 2022. The telecom market size is expected to grow at a marginal (CAGR) of 0.8% with enhanced broadband connectivity and boosted mobile adoption. According to 6Wresearch, the telehealth market in Myanmar is anticipated to grow throughout 2020-2026.

The healthcare landscape in Myanmar shows promising opportunities for advancements in medical technology. There are over 30 HealthTech startups in Myanmar as of 2023, which offer healthcare services such as healthcare websites, counselling applications, monitoring and tracking body vitals, platforms for patients, tele-healthcare services and medical record management solutions.

- Evidence-based Care: The Yangon Centre for Evidence-Based Healthcare has been a pioneering force in applying evidence-based healthcare practices in collaboration with JBI, a global research institute headquartered in South Australia, for over 15 years.

- Predictive & Personalized Healthcare: Pun Hlaing Hospital has taken a significant step forward with the launch of the "Live Healthy 4P Clinic." This initiative uses the 4P medicine model (Predictive, Preventive, Participatory, and Personalized) to deliver customized healthcare programs and services. Such efforts pave the way for more

comprehensive and individualized patient care, indicating an avenue for Flemish businesses to contribute.

- Home-Based and Telemedicine Services: Mobile clinics, predominantly in the private sector, offer home-based healthcare services, catering to elderly individuals with screening, consultations, and treatments provided by a team of healthcare professionals. Additionally, the deployment of telemedicine services in regions with accessible mobile networks has ensured broader reach, highlighting the effectiveness of such services in reaching a larger population.

- HOPE telecare, a joint venture with a local company and a Malaysian company, for telemedicine services. It will include a digital healthcare platform for public users to access healthcare professionals and information, as well as a blockchain to store records, and to develop a digital signature system.

- Health and Mobile Apps: The vibrant landscape of health and mobile apps in Myanmar is largely driven by start-up companies. This dynamic environment provides opportunities for innovative health applications, enabling efficient healthcare access and solutions for a tech-savvy population.

- Klenic, a cloud-based web platform software, for improving the hospital management technology such as digitizing medical records and queuing management.

4. PHARMACEUTICAL MARKET

The pharmaceutical market in Myanmar holds significant competitive potential within the ASEAN region, drawing increasing interest from Flemish companies while maintaining a heavy reliance on imports. The Myanmar Chamber of Commerce for Pharmaceuticals & Medical Devices (MCCPMD) reports that a substantial 90% of medicines and medical products are sourced from foreign markets, and annual importation includes more than 5,000 categories of medicines. In FY 2022-2023, Myanmar imported medicines and related products amounting to **US$171.565 million from India**, **US$53.137 million from China**, and **US$44.129 million from Thailand**, as disclosed by the Ministry of Commerce. Additionally, Belgian brands, including **Fysiomed** and **Alcon Couvreur N.V.**, have established a presence in the market through distribution by Snow Everest Co., Ltd and Grand Pharmaceutical Co., Ltd. Notably, Myanmar imported pharmaceutical products worth **US$14.52 million from Belgium in 2022**, as per the United Nations COMTRADE data. Despite price fluctuations due to inflation (from 5% - 10%) (source: Global New Light of Myanmar), the import trend is expected to persist, offering an enticing opportunity for Flemish pharmaceutical product providers.

India stands as the primary supplier, accounting for 40-45% of total imports, closely followed by Bangladesh, China, Thailand, Indonesia, Pakistan, and Vietnam, as revealed by research conducted by Trust Ventures Partners. Furthermore, Myanmar imports pharmaceuticals from the USA, Korea and Europe such as Germany, Belgium.

In the Myanmar pharmaceutical landscape, over 100 pharmaceutical distributors operate, with market leaders such as Mega Lifesciences (Thailand), DKSH (Switzerland), Sealion (Myanmar) and so on. Notably, pharmacy sales in Myanmar are primarily dominated by the Yangon and Mandalay regions, collectively representing 60% of the total market. Government adopts a tender system to procure medicines for its hospitals, in the acquisition of medical supplies, equipment, and services.

The domestic manufacturing pharmaceutical industry is currently in its early stages, fulfilling only 10% of the demand. There is a state-owned Burma Pharmaceutical Industry (BPI), and other remarkable private manufacturers include Sun Pharma (India), AA Medical Products (Myanmar), Zifam Myanmar (Australia), as well as traditional medicine producers such as FAME Pharmaceutical (Myanmar) and June Pharmaceutical (Myanmar).FAME Pharmaceutical stands as the market leader in traditional medicines, even exporting to neighboring countries. In 2022, Myanmar exported pharmaceutical products worth US$8,450 to Malaysia, as indicated by the United Nations COMTRADE database. The technology and collaboration in this area opens a wide business opportunity for Flemish companies.

However, the issue of counterfeit products threatens the population and market competition in the country. In 2017, Yangon disposed of counterfeit medicines worth over US$1.32 million, as reported by the Myanmar News Agency. Myanmar has committed to international cooperation against the counterfeit medicine trade since 2018. Nevertheless, the rise of e-commerce and social media during the COVID-19 pandemic has facilitated the distribution of counterfeit drugs in Southeast Asia, including Myanmar, with millions of daily orders on these platforms, as reported by the SEA IP SME Helpdesk.

5. MARKET OUTLOOK AND OPPORTUNITIES

The healthcare sector in Myanmar faces several significant challenges that have a profound impact on the delivery of healthcare services. Among the most pressing issues are the weak enforcement of rules and regulations, still limited public health insurance coverage, challenges in the timely delivery of medical supplies across the country, and a shortage of healthcare providers. Besides, current operational challenges for importers to Myanmar are the slower administrative process concerning license approvals, and the high inflation rate. For Flemish companies seeking to operate in Myanmar's healthcare sector, it is crucial to engage with reliable local business partners. This step ensures a comprehensive understanding of the updates on the regulations and facilitates a smoother entry into the market.

However, there are First-Mover Advantages in this highly underserved market, especially given the increasing aging population of 54 million, high disease prevalence, growing demand for healthcare services and medical devices by the population as well as local healthcare providers. Therefore, Flemish companies have promising avenues for offering solutions to local healthcare providers (Leads), especially in various areas:

- Medical Devices: Majority import reliance market, especially for diagnostic tools and imaging systems.
- Pharmaceutical Product Supply: Meeting the demand for high-quality pharmaceuticals in Myanmar presents a strategic opportunity for Flemish companies.
- Medical Equipment Importation and Supplies: The healthcare facilities and pharmaceutical manufacturers in Myanmar require a steady supply of medical equipment and accessories.
- Technical Expertise: With a growing demand for advanced healthcare solutions, technical expertise in fields like big data, cloud computing, artificial intelligence (AI) for patient care management, robotics, and evidence-based care
- Cutting-edge Medical Services: predictive and personalized healthcare systems, innovative home-based services, device-based solutions, telemedicine platforms, and health-focused mobile applications
- Healthcare Infrastructure Design and Management: The increasing awareness and willingness of the healthcare providers for expanding and improving their healthcare facilities development

By capitalizing on these diverse opportunities, Flemish companies can contribute to Myanmar's healthcare landscape while achieving meaningful business growth. Besides, the healthcare sector has shown some stability from some regulatory reliefs recently. Private hospitals and healthcare importers are willing to explore advanced diagnostics, upgraded treatment approaches, medical services, healthcare infrastructure, digital transformation in hospitals, and the establishment of private medical institutes and training centers.

6. MARKET APPROACH AND DISTRIBUTION CHANNELS

The market approach for Flemish companies entering into the Myanmar healthcare sector involves a strategic and comprehensive master plan, tackling the dynamic changes in the country's healthcare environment. To access this market, you need to follow the right channels, exercise patience and build good commercial and trust relationships.

- Market Evaluation: Flemish companies may assess the market landscape for a particular healthcare product through the prospective meetings with private hospitals, market leader companies, health tech companies and government associations to fulfill specific market demands.

- Partnership Cultivation: Flemish companies can strengthen strategic partnerships with Myanmar distributors and health tech entrepreneurs to gain valuable market insights and establish a credible brand presence.

- Navigating regulations: Flemish companies can ensure compliance with Myanmar's dynamic regulations and import protocols through the collaboration with relevant industry associations and local importers, streamlining the process of introducing their products to the Myanmar market.

The distribution channels in Myanmar are gradually improving, particularly with the international logistic service providers. Yangon region serves as a dominant distribution center for goods which are brought in by sea and air, while Mandalay region plays a vital role for cross-border trades from China and Thailand. Yangon port is a major distribution hub, managing more than 90% of the country's regular maritime exports and imports.

7. LEGISLATION

7.1 IMPORT LICENSE APPLICATION PROCESS

Flemish companies must complete import license applications through Myanmar Tradenet 2.0 portal or the Border Trade Online System (BTOS) for import license processing at border posts. License requirements are reviewed annually, with occasional changes throughout the year. The Myanmar Customs Information System (MCIS) and Myanmar Automated Cargo Clearance System (MACCS), managed by the Ministry of Planning and Finance (MOPF) are oversee the operations. In June 2023, the government made amendments to the types of commodities that will be imported under the Automatic Licensing System and Non-automatic Licensing System through border trades. Out of the various commodities transported through shipping, 1,525 types including pharmaceutical goods regarding dental filling, first aid boxes/kits, Laboratory, hygienic or pharmaceutical glassware, whether or not graduated or calibrated, will now be governed by the Automatic Licensing System. To find out types of commodities for a specific import license, please visit this link.

7.2 PROHIBITED GOODS

Myanmar prohibits the importation of certain goods,, which are subject to frequent and sometimes sudden changes. To gather an update list, please contact the FIT office.

7.3 IMPORT TARIFFS

Myanmar, as a member of the World Trade Organization (WTO), has limited coverage of its goods and services under international tariff standards. However, its tariffs are generally comparable to or lower than other regional countries, ranging from 0 to 40%. For detailed custom tariff rates for healthcare related items, visit the Customs Department website.

7.4 LABELING REQUIREMENTS

Myanmar follows Codex guidelines and ASEAN Common Principles for food labeling. As per the Consumer Protection Committee Directive, labels on pharmaceuticals together with telecommunication products, diet products, commodity products, and business activity products must include specific details in the Myanmar language, either alone or combined with another language.

Due to the complexity and continuous evolution of import laws and regulations in Myanmar, many importers rely on the expertise of professionals such as freight forwarders and customs brokers to handle and manage their import transactions. It is recommended to the FIT office for timely updates.

8. TRADE SHOWS

Myanmar

Name: MEDEX Myanmar and Pharmatech Myanmar 2023
About: Myanmar International Medical and Pharmaceutical Equipment & Supplies Exhibition
Date : 5 -7 Oct 2023
Venue: Myanmar Expo Hall at Fortune Plaza, Yangon, Myanmar
Website: https://10times.com/medex-myanmar
Frequency: Triennial

Name: Lab Myanmar 2023
About: International Exhibition & Conference on Laboratory, Analytical, Biotechnology and Scientific Instruments & Technology in Myanmar
Date: 5 -7 Oct 2023
Venue: Myanmar Convention Center, Min Dhamma Road, Yangon, Myanmar
Website: www.neventum.com/tradeshows/myanmar-lab-expo
Frequency: Annual

Name: International Conference on Health Care Reform, Health Economics and Health Policy
About: International Conference on Health Care Reform, Health Economics and Health Policy aims to provide the opportunity for direct communication between young researchers and affiliated personalities to discuss their knowledge on the subject and build connections.
Date: 14 Nov 2023
Venue: Bago, Myanmar
Website: https://conferencealerts.co.in/event/1879044

Singapore

Name: Medical Fair Asia 2024
About: the region's leading healthcare event that connects you both in-person and digitally to a global MedTech audience. For the latest in healthcare technology and innovations, medical equipment, medical manufacturing, supplies and solutions. FIT Myanmar will engage with local importers to visit the fair and try setting up B2Bs with Flemish companies.
Date: 11 Sep - 13 Sep 2024
Venue: Marina Bay Sands, Singapore
Website: www.medicalfair-asia.com

UAE

Name: Arab Health 2024
About: Arab Health is the most significant event for the healthcare industry that plays an instrumental role in bringing together regional and international policy drivers, thought leaders, and healthcare professionals through trade and innovation.
Date: 29 Jan - 1 Feb 2024
Venue: Dubai World Trade Centre
Website: https://www.arabhealthonline.com/en/Home.html

9. LIST OF IMPORTERS, ASSOCIATIONS AND RELEVANT AUTHORITIES

Please contact the FIT Yangon office for more information on this.

10. REFERENCES

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FLANDERS
INVESTMENT
& TRADE

Market Study

HEALTHCARE AND MEDICAL SECTOR IN SINGAPORE

Publication date / September 2023

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CONTENT

1. OVERVIEW OF HEALTHCARE AND MEDICAL SECTOR IN SINGAPORE

Singapore's healthcare ecosystem is highly regarded among the best in the world in terms of its high standard of medical care and efficient healthcare delivery. According to the World Health Organisation (WHO), Singapore healthcare system ranks sixth globally and it offers the fourth best healthcare infrastructure in the world. Singapore is also the healthcare and medical hub for the region. Primary healthcare in Singapore refers to the first line of care in the community provided through an island-wide network of outpatient polyclinics and clinics run by private general practitioners (GPs). The healthcare system in Singapore is divided into two sectors namely statutory boards (public) and institutions (private).

The public healthcare system in Singapore comprises of several public hospitals, specialist centers, polyclinics and community hospitals whereas the private healthcare sector in Singapore operates independently and it has a significant role in providing additional medical services, specialized care and personalized treatment options to exclusive clientele and medical tourism. Singapore is home to several private hospital groups, medical centers and specialized centers for specific medical conditions. There are also private clinics/practitioners which include general practitioners and specialists. Patients tend to visit private practitioners for non-emergency medical issues and personalized care.

Basic care at public hospitals is heavily subsidized in Singapore. Singapore's employees inject around 37 percent of their salaries in mandated savings account called Central Provident Fund (CPF) that may be spent on healthcare, housing, education, and insurance, with part of this being contributed by their employers. The national health insurance scheme in Singapore is a system unique in the world built around the "three M's", known as MediSave, MediShield Life and MediFund. It provides basic health insurance coverage for Singapore citizens and permanent residents. It is also common in Singapore that individuals purchase additional private health insurance plans for better coverage especially for private healthcare services.

Singapore has a very well-established regulatory framework for the healthcare sector. The Ministry of Health (MOH) oversees and regulate both the public healthcare system and private healthcare system in Singapore. Medical devices are regulated by the national regulatory agency, Health Sciences Authority (HSA). The regulations and requirements for medical devices in Singapore are based on the Health Products Act and its subsidiary legislation, specifically the Health Products (Medical Devices) Regulations.

The Singapore government procurement system is considered fair and transparent. Government tenders are publicly announced on its one-stop e-procurement portal - www.gebiz.gov.sg. Hospital procurement in Singapore is centralized to optimize cost savings and standardization across healthcare institutions and there is a tendering process for the procurement exercise. SingHealth Group Procurement Office (GPO) and National Healthcare Group Procurement (NHGPO) are the central procurement entity for the two public hospital groups in Singapore.

Singapore places great emphasis on healthcare research and innovation. There are several academic medical centers in Singapore that combine healthcare delivery, medical education, and research such as the National University Health System (NUHS) and the SingHealth Duke-NUS Academic Medical Center. Research organizations such as the Agency for Science, Technology

and Research (A*STAR) and the National Medical Research Council (NMRC) were set up to support and fund research initiatives in biomedical sciences, clinical research and health services research.

From July 2023, Singapore's HealthTech agency, formerly known as IHiS launched its new identity, **Synapxe**. Synapxe (https://www.synapxe.sg/) is the national HealthTech agency responsible for creating intelligent technological solutions to support Ministry of Health (MOH) and public healthcare.

List of projects under Synapxe include:

- HealthHub
- National Electronic Health Record (NEHR)
- Next Generation Electronic Medical Record (NGEMR)
- National Harmonised Integrated Pharmacy System (NHIPS)
- National Billing System (NBS)

Pharmaceutical and biomedical industries are leading drivers of economic growth in Singapore. Being pro-business and having a thriving research and development landscape, Singapore has become one of the few countries that are able to export more pharmaceutical products than it imports. [1] These factors have attracted foreign investors to use Singapore as a manufacturing base for a wide range of products including Active Pharmaceutical Ingredients, drug products and biologics drug substances. Some of the major international players with presence in Singapore include Abbott, Amgen, Becton Dickinson, GlaxoSmithKline, Medtronic, Merck Sharp & Dohme, Novartis and Pfizer. Vaccination played a significant role in response to the pandemic in Singapore. Prior to Covid-19, Singapore did not have any vaccine production facility. Now, five pharmaceutical companies have committed to set up vaccine production facilities here.

The MedTech sector in Singapore is also a growing segment for Singapore's healthcare industry. Singapore is home to more than 60 multinational MedTech companies undertaking a range of activities from regional headquarters and manufacturing to research and development, including several CDMOs for Medtech devices. In 2018, the MedTech sector contributed S$13.3 billion to Singapore's economy. Many MedTech projects are supported by the public healthcare clusters through clinical advisory, co-development and test-bedding. The industry is seeing more investors who is willing to support early-stage startups including foreign companies looking to expand their footprint in Asia.

Singapore is an open economy and there is no barriers to entry. All goods imported into Singapore are subject to a **8.0% goods and services tax (GST).** There are **4 categories** of dutiable goods:

- Intoxicating liquors
- Tobacco products
- Motor vehicles
- Petroleum products and biodiesel blends

[1] https://www.aseanbriefing.com/news/singapores-healthcare-industry-gateway-to-aseans-healthcare-market/

2. PUBLIC HEALTHCARE SYSTEM

Primary healthcare (refers to first line of care) is provided by a network of outpatient polyclinics and clinics run by private general practitioners (GPs). Currently, there are 23 polyclinics and approximately 1,800 GP clinics in Singapore. The primary care services include:

- Outpatient medical treatment
- Medical follow-ups after discharge from hospital
- Maternal and child health
- Immunisation
- Health screening and education
- Diagnostic and pharmaceutical services

There are 3 public healthcare clusters in Singapore: SingHealth Group, National Healthcare Group & National University Health System.

2.1 SINGHEALTH GROUP

SingHealth is Singapore's largest cluster of healthcare institutions, comprising a network of public hospitals, specialty centers, and primary care clinics. It consists of four public hospitals, two community hospitals, five national specialty centers, and a network of eight polyclinics.

- Singapore General Hospital (SGH)
- Changi General Hospital (CGH)
- Sengkang General Hospital
- KK Women's and Children Hospital (KKH)
- National Cancer Centre Singapore (NCCS)
- Singhealth Community Hospitals
- SingHealth Polyclinics
- SingHealth DukeNUS Academic Medical Centre
- National Heart Centre Singapore (NHCS)
- Singapore National Eye Centre
- National Neuroscience Institute
- National Dental Centre

2.2 NATIONAL HEALTHCARE GROUP

The National Healthcare Group (NHG) is one of the major healthcare clusters in Singapore. NHG operates several hospitals, national specialty centres, and polyclinics. Tan Tock Seng Hospital (TTSH) is the largest hospital in the group and serves as the tertiary hospital for the cluster.

- Tan Tock Seng Hospital (TTSH)
- Institute of Mental Health (IMH)
- Khoo Teck Puat Hospital (KTPH)
- National Skin Centre
- Yishun Community Hospital
- Woodlands Health Campus
- Admiralty Medical Centre
- John Hopkins Singapore
- Primary Care Academy
- NHG Pharmacy
- NHG College
- Centre for Medical Technologies & Innovation (CMTi)

2.3 NATIONAL UNIVERSITY HEALTH SYSTEM

The National University Health System (NUHS) is one of the three public healthcare clusters in Singapore with an integrated Academic Health System and Regional Health System. Their member institutions come under one Academic Health System comprise of tertiary, acute and community hospitals, national specialty centres, polyclinics, a medical centre and academic health sciences institutions.

- National University Hospital
- Ng Teng Fong Hospital
- Alexandra Hospital
- National University Cancer Institute, Singapore (NCIS)
- National University Centre for Oral Health, Singapore (NUCOHS)
- NUS Yong Loo Lin School of Medicine (NUS Medicine)
- NUS Faculty of Dentistry (NUS FOD)
- NUS Saw Swee Hock School of Public Health (NUS SSHSPH)
- National University Polyclinics (NUP)
- Jurong Medical Centre (JMC)
- NUHS Diagnostics & NUHS Pharmacy
- National University Heart Centre, Singapore (NUHCS)

3. PRIVATE HEALTHCARE SYSTEM

In the **private healthcare** sector, there are two major hospital groups that operate the majority of the private healthcare institutions in Singapore: **Parkway Pantai and Raffles Medical Group**.

3.1 PARKWAY PANTAI LTD – IHH HEALTHCARE

Website: https://www.ihhhealthcare.com/

Parkway Pantai is Southeast Asia's largest private healthcare provider with hospitals in several countries such as Singapore, Malaysia, Brunei and Hong Kong. It is a wholly owned subsidiary of Kuala Lumpur based IHH Healthcare whose largest shareholder is Malaysian state investment agency Khazanah Nasional. Parkway Pantai owns four hospitals in Singapore and the Parkway Shenton network of over 30 primary care clinics island wide as well as a wide range of specialty and ancillary services such as Parkway Cancer Centre, Parkway Radiology, Parkway Laboratories (including Angsana Molecular & Diagnostics), Parkway Rehab and Parkway Emergency Services.

- Gleneagles Hospital
- Mount Elizabeth Hospital
- Mount Elizabeth Novena Hospital
- Parkway East Hospital

3.2 RAFFLES MEDICAL GROUP

Website: https://www.rafflesmedicalgroup.com/

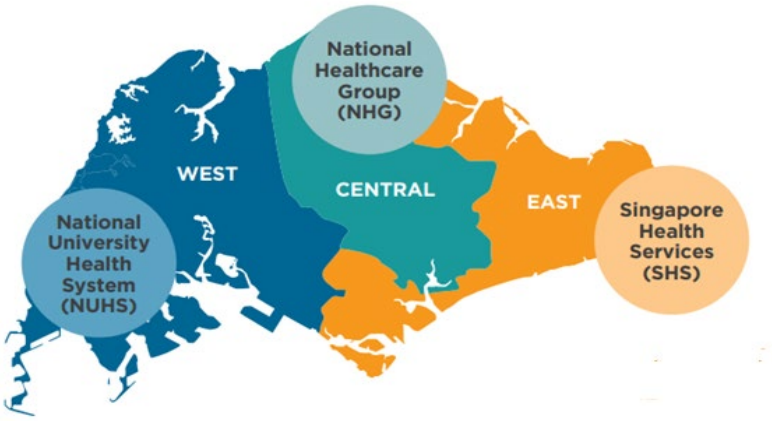
Raffles Medical Group (RMG) is one of the largest private healthcare providers in Asia, with hospitals and clinics located in several countries such as Singapore, China, Japan, Vietnam and Cambodia. RMG owns Raffles Hospital in Singapore, which specializes in obstetrics and gynecology, cardiology, oncology, and orthopedics.

RMG has a network of clinics with general practitioners, specialists and dental surgeons and owns Raffles Hospital, a tertiary care hospital in Singapore which accommodates surgical centres, medical laboratories and 24 specialist centres in various areas like Obstetrics & Gynaecology, Cardiology, Oncology and Orthopaedics.

RMG has its own consumer healthcare division, Raffles Health, which develops and distributes nutraceuticals, supplements, vitamins and medical diagnostic equipment.

4. DEVELOPMENT WITHIN THE HEALTHCARE AND MEDICAL SECTOR IN SINGAPORE

In order to work towards a healthier Singapore, Ministry of Health (MOH) has developed a Healthier SG strategy. Under the Healthier SG strategy, Singaporeans will be encouraged to seek primary care with a family physician/General Practitioner (GPs) of their choice as the first line of care. MOH partners with the three healthcare clusters to support the General Practitioners (GPs) who would eventually support the residents for different health needs and care episodes to ensure continuity of care.



Singapore represents a promising market for health IT systems when it comes to advanced mobile health and telemedicine than other markets. Telemedicine is already in place since 2017 with a number of providers including WhiteCoat, MyDoc, Doctor Anywhere, Speedoc, MaNaDr, SATA CommHealth, Doctor World, Parkway Shenton, BetterHealth, HiDoc, and Rescu. In an effort to develop this sector, the Singapore government launched a regulatory sandbox with these telemedicine providers to co-create governance and regulatory framework for the sector in 2018. During the pandemic, the use of teleconsultation and telemedicine became essential to ease the burden of the healthcare system. From mid-2022 onwards, telemedicine service providers are required to be licensed under the new Health Services Act (HSA). One of the most recent projects, which aims to help BioMedtech start-ups, is the launch of Co11ab Novena within Health City Novena. Co11ab Novena (https://www.co11ab.sg/) is a S$15 million incubator and partnership between National Technological University of Singapore (NTU), Agency for Science, Technology and Research (A*STAR) and National Healthcare Group (NHG) that aims to facilitate the clinical adoption of new technologies. It will provide BioMedTech startups with access to industry knowledge, mentorship and financial support for their research & development leading to commercialization of their innovations.

5. OVERVIEW OF HEALTHCARE R&D IN SINGAPORE

Singapore has a well-established reputation as a center for scientific R&D and innovation capability in Asia. The Agency for Science, Technology and Research (A*STAR) is a leading public sector R&D agency that bridges the gap between academia and industry through open innovation.

Its R&D activities span across different biomedical sciences domains: MedTech, pharmaceuticals and biologics, and biomedical research.

The list of the most outstanding R&D institutes and centers in Singapore (non-exhaustive):

- Singapore Eye Centre
- Cancer Science Institute of Singapore
- Mechanobiology Institute, Singapore
- Bioinformatics Institute
- Bioprocessing Technology Institute
- Genome Institute of Singapore
- Institute of Bioengineering and Nanotechnology
- Institute of Medical Biology
- Institute of Molecular and Cell Biology
- Experimental Therapeutics Centre

6. CHALLENGES & TRENDS WITHIN THE HEALTHCARE SECTOR IN SINGAPORE

The major challenges and trends within the healthcare sector in Singapore are ageing population, increasing chronic disease burden, slower workforce growth and rising healthcare costs. The ageing population is growing rapidly with an estimate of 1 in 4 citizens being over the age of 65 by 2030.

Ministry of Health Singapore (MOH) has set in place plans to adopt IT technology including data analytics and AI (artificial intelligence) to improve patient care and its strategies to develop the healthcare workforce of the future include equipping them with new skills, growing a Singapore core in the workforce, and tapping into technology to improve efficiency and patient experience.

According to the Future Health Index Survey conducted by Royal Philips, Singapore had the third-highest percentage (28 per cent) of healthcare professionals who said they use AI to improve diagnostic accuracy. The Future Health Index survey polled nearly 3,200 healthcare professionals from 15 countries, including 201 in Singapore. Based on the survey findings, AI is used more for administrative tasks, for functions such as staffing and scheduling patient appointments. [2]

Mature markets like Singapore stands out as a market to introduce digital health solutions due to low barriers to adoption as people are willing to try one or more of the many digital health innovations available on the market.

Some key considerations for Belgian companies looking to enter in Singapore's healthcare and medical sector:

- "3 Beyonds" Strategy

[2] Article: https://www.straitstimes.com/singapore/health/singapore-ranked-no-3-in-survey-on-use-of-ai-in-healthcare

- Beyond healthcare to health: Preventive care
- Beyond hospital to community: Community care
- Beyond quality to value: Affordable & sustainable healthcare

- Leverage partnerships

  - Partnerships with universities for R & D projects to leverage on government funding (Example: NUS and NTU)
  - Public-private partnership with agencies such as A*STAR, Enterprise Singapore (ESG), National Research Foundation (NRF) and SGInnovate
- Innovation in healthcare

  - Telemedicine (Example: Scheduling appointments, order medication and palliative care)
  - AI & Robotics (Example: AI on back office operations and clinical activities)
  - Data Analytics (Example: using Big data for patient monitoring)

7. RELATED AUTHORITY

7.1 MINISTRY OF HEALTH (MOH)

Website: https://www.moh.gov.sg/

MOH and its statutory boards are responsible for regulating Singapore's healthcare system. All Healthcare facilities such as hospitals, medical centres, community health centres, nursing homes, clinics (including dental clinics), and clinical laboratories (including x-ray laboratories) are required to apply for a licence under the Private Hospitals & Medical Clinics (PHMC) Act/Regulations. All Healthcare facilities are also required to maintain a good standard of medical / clinical services under the PHMC Act/Regulations.

7.2 HEALTH SCIENCES AUTHORITY (HSA)

Website: https://www.hsa.gov.sg

Health Sciences Authority (HSA) regulate health products, serve the administration of justice, secure the nation's blood supply, and safeguard the public's health. The regulatory process for medical devices are as such:

- Medical Device Registration

All medical devices intended for sale or supply in Singapore must be registered with the HSA before they can be marketed. This applies to both locally manufactured devices and imported devices.

- Risk Classification

Medical devices are categorized into four risk classes (A, B, C, and D), with Class A representing the lowest risk and Class D representing the highest risk. The risk classification determines the regulatory requirements and the level of scrutiny during the registration process.

- Product Listing

Some low-risk medical devices, such as Class A devices, are exempted from full registration but must be listed with the HSA. The product listing allows the HSA to keep track of the devices available in the market.

- Authorized Representative

Foreign manufacturers without a local presence in Singapore must appoint an Authorized Representative (AR) who is a resident of Singapore. The AR acts on behalf of the manufacturer and is responsible for liaising with the HSA.

- Documentation Requirements

Manufacturers are required to submit various documents during the registration process, including device descriptions, technical specifications, labeling, instructions for use, and evidence of conformity with applicable standards.

- Quality Management System

Manufacturers must have a quality management system (QMS) in place that complies with the relevant international standards, such as ISO 13485. The QMS ensures the consistent quality and safety of the medical devices.

More up to date information on the regulation and requirements can be retrieved from the website of HSA - https://www.hsa.gov.sg.

7.3 AGENCY FOR INTEGRATED CARE (AIC)

Website: https://www.aic.sg

The Agency for Integrated Care (AIC) was formed as an independent corporate entity under MOH Holdings (MOHH) to work with stakeholders and partners in developing the Community Care Sector.

7.4 AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH (A*STAR)

Website: https://www.a-star.edu.sg/

The Agency for Science, Technology and Research (A*STAR) is Singapore's lead public sector agency that spearheads economic oriented research to advance scientific discovery and develop innovative technology.

8. HEALTHCARE AND MEDICAL RELATED TRADE EVENTS

Medical Fair Asia
Date: 11th September to 13th September 2024
Venue: Marina Bay Sands Convention Centre
Website: https://www.medicalfair-asia.com/

9. ASSOCIATION

9.1 SINGAPORE MEDTECH CONSORTIUM

Website: http://sgmedtech.com.sg/

The Singapore Medtech Consortium is a group of Singapore-based companies from Venture Capitalist, Manufacturers & Distributors spearheaded by Racer Technology. They provide end-to-end manufacturing solutions in the areas of in-vitro diagnostics, wearables and life science tool consumables.

9.2 SINGAPORE MEDICAL ASSOCIATION

Website: https://www.sma.org.sg/

The Singapore Medical Association (SMA) is the national medical organisation representing the majority of medical practitioners in both the public and private sectors.

9.3 SINGAPORE DENTAL ASSOCIATION

Website: http://sda.org.sg/

The Singapore Dental Association (SDA) is the professional association of dentists dedicated to serving both the public and the profession of dentistry.

9.4 THE PHARMACEUTICAL SOCIETY OF SINGAPORE

Website: https://www.pss.org.sg/

The Pharmaceutical Society of Singapore (PSS) is the professional organisation representing pharmacists in Singapore.

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Market Study

HEALTHCARE AND MEDICAL SECTOR IN THAILAND

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State of the Art

CONTENT

1. OVERVIEW OF HEALTHCARE SYSTEM

Thailand's healthcare industry has experienced remarkable growth and development, comprising robust public and private healthcare providers. The successful implementation of Universal Health Coverage ensures basic healthcare for all citizens. The thriving medical tourism sector attracts global medical tourists with its high-quality yet affordable healthcare services. Government policies supporting the industry align with the Thailand 4.0 initiative and the S-Curve development strategy, aiming to become a regional Hub of Wellness and Medical Services. The increasing elderly population drives demand for specialized healthcare services, especially in chronic disease management and long-term care. Stakeholders are addressing this demographic shift through policies promoting healthy aging and geriatric care. The Covid-19 pandemic has accelerated digital transformation, leading to significant growth in telemedicine, remote monitoring, and digital health solutions. With changing consumer needs and ongoing efforts to enhance accessibility, quality, and innovation, Thailand's healthcare industry holds promising opportunities for growth and development.

1.1 HEALTHCARE FACILITIES

There were a total of 38,512 healthcare facilities in Thailand (as of 2017), consisting of 35% public facilities (i.e. public health centers, district public health offices, and community and general hospitals), and 65% private facilities (i.e. private clinics and hospitals). In terms of size and medical services offered, healthcare facilities [based on a geographic information system (GIS)] can be divided into three levels namely; primary, secondary and tertiary care facilities[3]. Primary care facilities represented 98.3% of the total, comprising more than 9,800 public health and district health promotion centers and 24,800 private clinics. Secondary and tertiary care facilities made up 1.7% or 664 facilities, including 294 (0.8%) public hospitals [managed by Ministry of Public Health (MOPH), local administrative bodies, state enterprises or Bangkok Metropolitan Administration (BMA)], and 370 (0.9%) private hospitals.

1.1.1 Public Hospitals

Public hospitals mainly serve patients who are covered by the Universal Health Coverage (UHC) and middle-low-income earners because of cheap prices, good facilities and high skilled doctors (especially in leading medical schools). As such, they are always overcrowded.

1.1.2 Private Hospitals

Most people with high spending power prefer private hospitals which are more convenient and provide better services. Private hospitals (offering a total of 36,000 beds) can be divided into 3 groups based on the number of registered beds as follows:

[3] - Primary care includes public health centers, municipal centers, community health centers, community hospitals, general hospitals, and others. These may be in either the private or public sector.
- Secondary care is divided into 3 levels: (i) basic secondary care, comprising community hospitals, general hospitals, and state and private medical units that have in-patient facilities to treat general conditions; (ii) mid-level secondary care, including medical institutes that offer common specialist treatments; and (iii) upper-level secondary care, comprising medical institutes that offer less common specialist treatments.
- Tertiary care is provided by some general hospitals, teaching hospitals, specialist hospitals or other public or private units, offering treatments in sub-specialties or interventions that use advanced equipment, e.g. treatment of heart disease.

- Large hospitals (more than 249 beds)
  There are 22 large private hospitals in Thailand, making up only 6% of all private hospitals in the country. They provide a total of 7,162 beds, accounting for 19.9% of all beds in private hospitals. The majority of these large hospitals, around 90%, are situated in Bangkok and other major cities because of the concentration of middle to high-income consumers and medical tourists in these areas.

- Medium-size hospitals (31-249 beds)
  Within the range of medium-sized hospitals, there exist 255 hospitals, constituting 67.5% of the total. These hospitals provide a collective capacity of 27,069 beds, accounting for 75.2% of the available beds.

- Small hospitals (1-30 beds)
  Among the category of small hospitals, there are 101 hospitals, representing 26.7% of the total. These particular hospitals provide a total of 1,766 beds, accounting for 4.9% of the overall bed capacity.

Competitiveness and profitability of private hospitals can be determined by their size. Large hospitals tend to have stronger financial stability and extended business network. To increase market share and secure long-term growth, large hospitals have been investing more to expand their premises, increase the range of facilities, establish centers for specialist and complicated treatments (to penetrate niche segments), and expand into overseas markets. Mid-sized and small stand-alone hospitals face greater challenges because their main source of revenue is mostly from the lower-middle income groups (with the exception of hospitals that participate in the social security system or that offer specialist treatment which guarantee their income). To stay competitive in the market, these hospitals tend to raise fund in the capital market for business expansion or partner with large hospital chains.

Currently, there are 62 Thai private hospitals accredited by Joint Commission International (JCI) for meeting international standards. These hospitals have elevated their standards by developing and upgrading services (e.g. developing specialized medical centers, expanding cooperation with business partners, creating comprehensive medical and health centers and utilizing digital technology) to attract medical tourists. Thailand is in the 4th place with JCI accredited healthcare centers, following the United Arab Emirates (195), Saudi Arabia (93), and China (84). (Ninkitsaranont, 2020)

1.2 HEALTHCARE INSURANCE

All Thai citizens have been insured by the Universal Health Coverage (UHC) enacted by the National Health Security Act B.E. 2545 (2002). The National Health Security Office (NHSO) was established by this Act to manage UHC since 2002. In 2021, 99.61% of the total Thai population of 67.25 million were covered by three different schemes of UHC as follows:

Civil Servant Medical Benefit Scheme (CSMBS)

CSMBS managed by Comptroller General's Department under the Ministry of Finance and financed solely by annual budget allocation from the general tax, is a non-contributory scheme providing health care benefits to government officials and their dependents (spouse, parents, and up to 3 children). In 2021, around 8% of population (5.27 million people) were covered by this scheme. Providers under CSMBS are all public hospitals. Civil servants may seek care at

private hospitals under certain conditions for In-Patient emergency care with the limited level of reimbursement and Elective surgery in selectively contracted private hospitals with some cost sharing (NHSO, 2021; Srithamrongsawat, 2021).

Social Security Scheme (SSS)

SSS managed by Social Security Office under the Ministry of Labour, is funded by tri-partite contributions (based on an employee's gross salary) including employer (5%), employee (5%) and the government (2.5%) and covers employees, and employers with one or more employees in the private sector. It also provides care for self-insured people. In 2021, around 18% of population (12.46 million people) were covered by SSS. SSS members are required to choose and register with their preferred public or private hospitals contracted to SSS (NHSO, 2021).

Universal Coverage Scheme (UCS)

UCS, implemented in 2002, is managed by the National Health Security Office (NHSO) under the Ministry of Public Health (MOPH). UCS is a non-contributory scheme funded by the annual government budget and other income sources. Most Thais who are not covered by CSMBS and SSS receive health coverage through UCS. In 2021, there were 47.74 million people registered with UCS constituting 71% of the total population. UCS members are automatically registered by NHSO. UCS contracts primary medical care units to provide ambulatory services to patients. They serve as the first point of contact for referrals to public and private providers for specialized and complicated treatments. ((NHSO, 2021; Jongudomsuk et al., 2015).

Residents who are not eligible for public health insurance, such as self-employed individuals, unemployed people, visitors, etc., can voluntarily purchase private health insurance, which grants them access to facilities specified in the contract. People who can afford it, prefer private hospitals for convenience and better services. In 2021, Thailand's private medical insurance premium market valued at 19 billion Baht, accounting for 7.13% of the total non-life insurance direct premiums (IPRB, 2022).

1.3 GOVERNMENT POLICIES

The government has developed several policies and measures to support the healthcare industry as follows:

1.3.1 Medical Hub

Since 2004, the Thai government has promoted the Medical Hub Policy which was intended to make Thailand 'the center of excellence for medical services within the region' by implementing the strategic plan 'Medical Hub of Asia (2004–2008)' which was designed as a guideline for related agencies to cooperate and develop the advanced medical industry ecosystem. This strategic successfully attracted medical tourists to Thailand, rising 2 folds during 2002-2006 and reaching 1,373,000 persons in 2008. The government has continued to promote the Medical Hub Policy, at present, the 10-year Medical Hub Strategic Plan (2016-2025) has been implemented (Marohabutr, 2020). The medical hub industry is one of the 10 targeted industries promoted as the "New Engine of Growth" under Thailand's 4.0 policy. The 4 major areas to be focused are medical service hub, wellness hub, academic hub, and product hub (including the medical device

and pharmaceutical industries prioritized as top targets for investment) (Yamada Consulting Group, 2020).

Investment incentives for the healthcare industry are part of the Thai government's policies to promote the country as a hub for wellness and medical services. Thailand Board of Investment (BOI) provides a wide range of tax and non-tax incentives for projects that meet national development objectives. Information on policies, criteria for promotion, incentives, etc. is available at Investment Promotion Guide 2023.

BOI also offers incentives to Eastern Economic Corridor (EEC), a project developed as ASEAN's hub for the new growth industries. The healthcare Industry is one of the targets in EEC area which will lead Thailand to be the hub of medical tourism and medical care in ASEAN and the world. The pharmaceuticals and medical device manufacturing sectors are among the government's targeted industries eligible for further investment support in the form of financial assistance with research and additional tax waivers. More details can be found at Medical and Comprehensive Healthcare and Investment Promotion Guide 2023.

Apart from BOI incentives, there are several types of support provided by other government agencies and organizations, e.g. BIOTEC, National Science and Technology Development Agency (NSTDA), Thailand Science Park (TSP), National Innovation Agency (NIA), Thailand Center of Excellence for Life Sciences (TCELS), etc. (BOI, n.d.).

1.3.2 E-Health Strategy

The E-Health Strategy is being prepared by the Ministry of Public Health (MOPH) to serve as a framework for driving digital technology. It is a mechanism for the development of the national health system, including paradigm shift, reform of digital technology operations and health innovation in all sectors, i.e. public and private manufacturing sectors as well as health services. MOPH is currently implementing the E-Health Strategy, Ministry of Public Health (2017 – 2026), details are available at https://ict.moph.go.th/upload_file/files/eHealth_Strategy_ENG_141117.pdf.

1.3.3 National Plans on the Elderly

Thailand has completed the 2nd National Plan on the Elderly (NPE) (2002 – 2021) which served as the key strategic plan for creating safety and a good standard of living for the elderly managed by the Department of Older Persons, the Ministry of Social Development and Human Security. At present, the Action Plan for the Elderly, Phase 3 (2023-2037) has been implemented which is a continuation of the previous plan in order to visualize and support the long-term direction of the operation on the elderly and the ageing society. Information can be found at https://www.dop.go.th/download/laws/th1653553501-843_0.pdf.

2. MEDICAL DEVICES AND HEALTH TECH MARKET

2.1 MEDICAL DEVICES

The medical devices sector comprises medical devices and medical equipment.[4] It generated high revenue to the country, contributing ~1.2% to GDP in 2020. The sector has continued to grow as a result of the increasing patients and ageing population. In 2021, the value of Thailand's medical device market was ~6 billion USD (207 billion Baht) (International Trade Administration, 2022; Tunpaiboon, 2021),).

Production

According to the Food and Drug Administration (FDA), Thailand produces ~39.5 billion Baht of medical devices and equipment annually of which 70% are exported and 30% are for local consumption (Yamada, Consulting Group (2020). Thailand mostly produces uncomplicated medical devices and uses raw materials available in the country, e.g. rubber (Thailand is the world's major producer.) and plastic (Thailand has a well-established petrochemical industry). Medical devices and equipment produced in Thailand can be divided into 3 groups as follows:

- Single-use devices: Products in this group include rubber gloves/medical gloves which have high-potential and are competitive in the global market. Exports of this product category contributes 90% of total rubber gloves sales. Producers of single-used devices make up ~43% of the total number of medical device producers.
- Durable medical devices: Important products are hospital beds, examination tables and wheelchairs. The total medical device producers account for 28%.
- Reagents and test kits: Products include test kits for diabetes, kidney disease, and hepatitis. Producers are mostly joint ventures with global producers investing in Thailand, accounting for 6% of the total industry (Tunpaiboon, 2021).

[4] Medical devices include items used in the medical, nursing and midwifery professions to provide treatments for bodily conditions such as X-Ray equipment, ultrasound machines, reagent and test kits, and dental devices. Medical equipment refers to surgical and medical equipment e.g. scalpels, thermometers, blood-pressure monitors, and items such as disposable gloves and masks.
Base on their use, medical devices and equipment can be divided into 3 categories as follows:
1) Single-use devices (or disposable items) for general medical treatments and normally not high-tech, e.g. syringes, hypodermic needles, tubes, catheters, cannulas, disposable gloves, etc.
2) Durable medical devices with at least one year lifespan, e.g. first aid kits, wheelchairs, medical beds, technical equipment used in medicine, surgery and dentistry, electrical diagnostic tools, and x-ray machines
3) Reagents and test kits for diagnosis of illnesses and conditions and chemical kits for testing samples collected from patients (e.g. blood, serum, plasma, etc.)

Import

Thailand mostly imports durable medical devices mostly including more advanced medical and surgical instruments and infrastructure (e.g. ultrasound equipment, x-ray machines, electrocardiogram (ECG) & electroencephalogram (EEG) monitors, ophthalmological equipment, etc.). Single-use devices are also imported. Together, these account for 80.7% of the total import value. In 2020, products were majorly imported from USA (22.7%), China (16.9%), Germany (10.4%), and Japan (7.6%) (Geeta, 2023; Tunpaiboon, 2021).

Export

Thailand's exports of medical devices contributes to 70% of the total production. Most exported products are single-use devices (i.e. rubber gloves, medical rubber gloves, catheters & medical tubing, syringes & hypodermic needles, and bandages & dressings), accounting for 90% of export value. In 2020, the major export markets were USA (29.6%), Japan (11.7%), the Netherlands (5.7%), and Germany (5.6%), respectively. Most of manufacturers and exporters are foreign-owned companies with production facilities in Thailand (Tunpaiboon, 2021).

2.2 HEALTH TECH

Thailand's health tech market was valued at 700 million USD (24 billion Baht) in 2022. It was expected to grow further to 1.6 billion USD (55 billion Baht) in 2026 at 14.7% CAGR per year (Thailand Convention & Exhibition Bureau, 2022).

The healthcare industry in Thailand has undergone rapid integration of digital health technologies that promotes the overall efficiency of operations and accessibility to consumers. The rising demand for health services in the overall healthcare providers has promoted the growth of health tech.

The government has actively supported the digital health ecosystem by encouraging the adoption of digital advancement among relevant parties, promoting investments, enhancing digital skills, and developing infrastructure through various measures, e.g. the Ministry of Public Health's eHealth strategy 2017–2026, the 20-year national strategy, BOI incentives for research and development in technology and innovation, etc. The Covid-19 pandemic has strengthened the role of digital technology in health services. At a time of intense pressure on Thailand's public health, consumers and healthcare professionals became more reliant on digital health solutions. In recent years, there were various digital solutions developed aiming to tackle the challenges in the healthcare sector. Some of examples of the public hospitals are as follows:

- Siriraj Hospital, a large public hospital, was a pioneer in digital healthcare in Thailand. Its developed digital healthcare technology can be seen below (Seven Peaks Software. (n.d.):

Siriraj and the Future of Patient Care in Digital Health

Digital healthcare technology developed by Siriraj Hospital

- **AI technology for emergency diagnosis**
  AI Paramedic helps quickly evaluate emergency cases. It also enables ER crews to handle minor injuries and illnesses at the scene.
- **AI for screening and initial illness diagnosis**
  Siriraj Hospital employs 5G technology and artificial intelligence to rapidly evaluate symptoms and make early diagnoses, allowing doctors to better monitor patients' health. The major benefit of this medical technology is enabling doctors to check on patients anytime, anywhere.
- **AI that aids in the accurate diagnosis of disease**
  A medical professional's training and experience are essential for making an accurate diagnosis. Siriraj Hospital developed this pathology with artificial intelligence technology to aid in the rapid diagnosis of sickness. It minimizes mistakes made in assessing serious conditions.
- **Smart inventory for drugs and equipment management**
  Supplying medical equipment and medicine is a persistent problem for many large healthcare facilities. Because of this, Siriraj Hospital has created a Smart Inventory system that uses AI to monitor the distribution of medical supplies and determine whether there are sufficient quantities.
- **Medlinker** has partnered with over 50,000 physicians to create innovative tools to help people with diabetes, liver disease, and kidney disease, and has also partnered with online pharmacies and pharmaceutical companies.
- **ClouDr** has a platform for taking care of patients with various diseases and delivering prescription drugs to them.

- Other public hospitals, KBank with five public hospitals to develop Digital Healthcare Platforms.

Leading private hospitals developing e-health services during the Covid-19 are shown in the following table (Ninkitsaranont, 2020):

Hospital	New services
Praram 9	• Use telemedicine to treat patients with chronic illness through the *Doctor Anywhere* app (the hospital is currently developing its own app). • Offer drive-in service at a special site for those who require blood tests or vaccination but not full hospital services. • Offer home-based blood tests and injections for patients in the BMR. • Run screening service outside the main hospital to divert high-risk patients to an ARI clinic, to minimize exposure to the general hospital population.
Bumrungrad International	• Established a special clinic to reduce risk of cross-infection within the hospital grounds. • Offers a '60-second service' which aims to complete processing within 60 seconds following the completion of consultation and writing of prescription. • Bumrungrad Health Residence service provides accommodation and care for patients who wish to distance themselves from their families or need time for recovery. • Offers home-based care at a standard equivalent to that received by in-patients. • Teleconsultation service for long-distance consultations (available from March this year). • Remote patient monitoring (RPM) allows for long-distance care of patients with arrhythmic heart condition.
Synphaet Ramintra	• COVID-19 drive-through testing • Telemedicine
Kasemrad	• Telemedicine • Home healthcare
Bangkok	• Teleconsulting and telehealth • Screens incoming patients, sending patients with breathing difficulties straight to an ARI clinic and other patients to a non-ARI clinic • Uses a camera- and microphone-equipped *health bot* to communicate with patients who need check-ups as well as screening for infection • Partners with other businesses, including insurers to reimburse insured patients for the cost of telehealth consultation • Runs a service that allows medical staff to carry out procedures such as drawing blood and injecting vaccines at patients' home
Samitivej	• Offers a 'virtual hospital' service
Ramkhamhaeng	• Drive-through testing for COVID-19
Phyathai	• *Clinic Connect* offers 3 services – telemedicine, blood testing and deliver prescriptions within 2-3 working days.

Source: Krungsri Research

3. PHARMACEUTICAL MARKET

In 2021, Thai pharmaceutical market was valued at 193 billion Baht. Local production made up 30% while imports accounted for 70%. Thailand has high dependency on both imported pharmaceuticals and raw materials (Tunpaiboon, 2022; Bangkok Post, 2022) .

3.1 PRODUCTION

Players in this sector comprise government manufacturers and private manufacturers as follows:

- Government manufacturers:
    - The Government Pharmaceutical Organization (GPO), a Thai state enterprise under the Ministry of Public Health (MOPH), was established to produce pharmaceutical products and medical supplies to support the country's public health. GPO plays an important role in manufacturing and distributing medicines to the public hospitals. It also represents as the supply security partner in Universal Health Coverage (UHC) (being responsible for procurement and distribution of drugs in the special projects under the National Health Security Office (NHSO) and the Social Security Office (SSO) via the Vendor Managed Inventory (VMI) system (Suchonwanich et al., 2020).
    - The Defense Pharmaceutical Factory (DPF), under the Ministry of Defense, was established to produce, purchase and analyse medical and pharmaceutical products to supply and distribute to the military, government agencies and public.
- Private manufacturers
    - Local companies with a majority of Thai shareholders produce general-purpose low-cost generic drugs. Around 75% of pharmaceutical companies in Thailand are local, e.g. Berlin Pharmaceutical Industry, Biolab, Greater Pharma, Siam Pharmaceutical, Thai Nakorn Patana, etc.
    - Multinational corporations (MNCs) produce original drugs. They mostly established their operations in Thailand to import and distribute their products, or to contract Thai producers to re-pack their imported drugs or to produce their own brands. Some prominent MNCs in Thailand are, for example, AstraZeneca, GlaxoSmithKline (GSK), Merck, Novartis, Pfizer, Roche and Sanofi-Aventis. Those with production facilities in Thailand are AstraZeneca, GlaxoSmithKline (GSK), Novartis, Pfizer, Roche, and Sanofi-Aventis (Tunpaiboon, 2022 ; Pharma Choices, 2023). More information on MNCs in Thailand is available at Pharmaceutical Research and Manufacturers Association (PReMA).

According to the Thai Food and Drug Administration (FDA), in 2021, there were 151 pharmaceutical manufacturers achieving the Good Manufacturing Practice (GMP) standards. Only 8% of them were able to producer active pharmaceutical ingredients given that there is limited capacity in producing active pharmaceutical ingredients in the country. As such, most of them are imported, e.g. aluminum hydroxide, aspirin, sodium bicarbonate, or deferiprone to mix and produce the finished generic drugs in-house. Thailand also limits its R&D mainly on vaccine

development (e.g., for HIV, influenza/bird flu, and most recently, for the Covid-19) (Tunpaiboon, 2022).

3.2 IMPORT

Thailand mostly imports high-cost products that cannot be produced in the country, e.g. anemia treatments, antibiotics, and cholesterol-lowering drugs. Pharmaceutical imports account for 1.0% of the total imports to Thailand. Major export countries are Germany, USA, France and India, There has been a significant increase in the imports of low-cost generics from India in the past years as result of the government's cost-containment policies and strict pricing controls to manage growing medicine demand due to the rise of disease burden. Overall, generic medicines remain important in the market supported by the government's policy to reduce expenditures on medicines (Pharmaceuticals Export Promotion Council of India, 2020; Tunpaiboon, 2022;).

3.3 EXPORT

Thailand generally exports low-value generics to countries in Southeast Asia, and so almost 60% of exports are to neighboring countries, i.e. Cambodia, Laos, Myanmar and Vietnam. In the past 5 years, export value was growing at an average of 5.1% annually (Tunpaiboon, 2022).

4. MARKET TRENDS

The healthcare industry in Thailand is witnessing several significant trends in the past years as follows.

4.1 SHIFT IN DEMOGRAPHICS WITH AN AGING POPULATION

Thailand is an aged society since 2022, with 20% of its population aged 60 or above. It is expected that the country will become the complete aged society in 2032, meaning that the elderly aged 60 or older will be ~30% of total population (Kasikorn Research Center, 2019). This demographic change creates a growing demand for healthcare services and facilities to cater the elderly.

4.2 RISING PREVALENCE OF COMPLEX DISEASES AND NON-COMMUNICABLE DISEASES (NCDS)

The number of patients with chronic conditions, e.g. cancer, heart disease, and diabetes, is increasing, leading to a greater demand for modern, hi-tech medical equipment, especially for diagnostic purposes During 2016-2019, NCDs caused ~320,000 deaths/year, representing ~75% of total deaths. There are 5 diseases, i.e. cancer, stroke, heart attack, diabetes, and high blood pressure, causing about 75,000 deaths/year. The number of patients was forecasted to rise around 1.5 times by 2030 (BOI, n.d.; The Nation, 2023).

Medical biotechnologies, e.g. vaccines, genomics, and biopharmaceuticals (Tissue, Plasminogen Activator, Insulin, Therapeutic and Antibodies are needed to treat NCDs and cancer) are now under the spotlight and attract multiple manufacturers to launch and scale up their businesses (BOI, n.d.).

4.3 MEDICAL TOURISM

Thailand is an attractive destination for medical care and treatment. This is supported by the government's plans to turn Thailand into a medical tourism hub, and the ability to offer world-class services at affordable prices. During 2016-2018, the medical treatment expenditure rose by 31% CAGR. In 2019, 3.5 million medical tourists spent 600 million USD (21 billion Baht) in Thailand, making it the world's 5th most prominent market, according to the World Travel and Tourism Council. Wellness tourism is one area of Thailand's medical tourism industry that is growing rapidly. From 2013-2015, the growth rate was 7% on annual average. The sector has been recovering from the impacts of the Covid-19 since the relaxing restrictions in the last quarter of 2022 (Yamada Consulting Group, 2020; Travis, 2022).

4.4 SHIFT IN CONSUMER BEHAVIOUR TOWARDS HEALTH CONSCIOUSNESS

The Covid-19 pandemic has emphasized the importance of preventive medicine and wellness, leading individuals to prioritize their health and seek related products and services (Prasarnphanich, 2022).

4.5 INTEGRATION OF DIGITAL HEALTH TECHNOLOGIES AND E-HEALTH SOLUTIONS

Digital health transformation has been rapidly developed in Thailand's healthcare industry with the support of the government. Telemedicine, mobile applications, and other digital tools are being adopted to enhance healthcare delivery and improve accessibility for patients.

4.6 UPGRADING AND DEVELOPING HEALTHCARE FACILITIES

Thai healthcare facilities, including medical machinery and devices, continue to expand to meet the increasing demand from both local and overseas patients. The overwhelming dependence on public hospitals, which are often operating beyond capacity, and the growing elderly population have made public hospitals develop their facilities to cater the rising number of patients. While, private hospitals are actively responding to the increasing demand from high-income earners and foreign patients by upgrading existing facilities and constructing new projects. This expansion has led to an overall increase of 2,000 beds in 2022. Private hospitals are also venturing with other businesses (e.g. hotels, real estate, insurance, etc.) into the development of wellness centers and luxury senior communities (Ninkitsaranont, 2020).

4.7 GOVERNMENT SUPPORT AND INVESTMENT PROMOTION TO ATTRACT MEDICAL RELATED INVESTMENT

In the 1Q2021, there were 14 applications submitted to the BOI for investment support from projects based in the medical industry. The investment was worth a total of 13.37 billion Baht of which 25% were foreign investors. High-technology manufacturing equipment used on their production lines would have to be imported (Tunpaiboon, 2021).

5. MARKET OUTLOOK AND OPPORTUNITIES

The market outlook for the healthcare industry in Thailand is optimistic. Healthcare expenditure is expected to reach 47.9 billion USD (1.7 trillion Baht) in 2026. The pharmaceutical market is forecasted to expand by 5-6% annually from 2023 to 2025, while the medical device market is expected to grow by 7-8% annually. Medical Tourism market in 2024 will value at 500 billion Baht, surging at a 13.7% CAGR. These rising markets will be supported by the aforementioned trends, providing promising opportunities for related businesses. To capitalize on these opportunities, foreign suppliers can focus on catering to the aging population's healthcare needs, including NCD treatment and care. Medical tourism presents opportunities for pharmaceuticals, complex medical devices, and equipment. Increased healthcare spending on wellness and preventive healthcare, and the integration of technology in healthcare services also offer avenues for growth. The government's investment promotion schemes aim to attract more production concentrated on innovative and high-tech goods, thus this generates opportunities for suppliers of machinery, equipment, and materials (Alliance Experts, n.d.; Tunpaiboon, 2021; Ninkitsaranont, 2021).

6. MARKET APPROACH AND DISTRIBUTION CHANNELS

For market entry, it is necessary to appoint a local importer/distributor as all medical products must be registered before importing and marketing in Thailand. Thai laws require a Thai person/entity to apply for an import license and a premise license for import, sales and storage of products. The importer/distributor typically ensures regulatory requirements are met including product registration and customs clearance. Moreover, with better local market knowledge, business practices and network, the importer/distributor can assist in market penetrate and expansion.

To supply medical products to public hospitals, foreign exporters have to rely on local importers/distributors as public hospitals do not import products directly. Pharmaceuticals and medical devices must be approved by FDA before importation, especially the latter which needs maintenance and after sales services. Public tender invitations are normally published on the website of each responsible government agency. Public procurement is required to comply with the Government Procurement and Supplies Management Act, B.E. 2560 (2017) (the "Procurement Act"). For details please see, Public Procurement World–Thailand (Baker McKenzie, n.d.).

Likewise, private hospitals buy medical products from local importers/distributors for the same reasons. Each hospital has its own procurement department. A group of hospitals may establish a central unit to manage the procurement within the group. As for the retail channel or Over The Counter market, products are also supplied by local importers/distributors.

7. LEGISLATION

7.1 REGULATORS AND LAW COMPLIANCE

The Ministry of Public Health (MOPH) oversees healthcare in Thailand, along with several other non-ministerial government agencies.

7.1.1 Food and Drug Administration (FDA)

FDA under MOPH, was established to protect public health/consumer rights. This process includes pre-market evaluation, clinical trials, and post-market monitoring to ensure that the products are safe and effective. FDA regulates the manufacture, import, and distribution of regulated products to ensure that they comply with strict safety and quality standards through its 2 divisions, namely Medical Device Control Division (MDCD) and Drug Control Division (DCD).

7.1.1.1 Medical Device Control Division (MDCD)

MDCD evaluates the safety, quality, and efficacy of new medical devices before they are allowed to be sold in Thailand. The regulatory process is based on the Medical Device Act B.E. 2551 (2008) and updated by the Medical Device Act/Ordinance B.E. 2562 (2019) (Issue 2).

7.1.1.2 Product classification and registration

Prior to importation of medical devices into Thailand, an importer/distributor must obtain an import license granted by FDA. The licensed importer has responsibilities to register medical devices (imported for commercial purposes) with FDA. To register the products, it is important to know the categories of medical devices which have different requirements to comply with (Adcock et al., 2023).

Medical devices in Thailand are classified into 4 categories in accordance with Notifications of MOPH enforced since 2021 which conform to ASEAN Medical Device Directive (AMDD), ASEAN Medical Device Directive, Annex 2 guidance as follows:

Class	IVD, Risk Level	Non-IVD, Risk Level	Group of Control
1	Low risk to individual and public health, e.g., examination gloves, enema devices	Low, e.g., adhesive bandages, gauze dressing, incision drapes, dental patient chair	Listing (Required to make the notification)
2	Moderate risk to individual or low risk to public health, e.g., urinary catheters, stents, dental aspirator tips	Low to Moderate, e.g., hydrogel dressing, devices to remove carbon dioxide from the blood and/or adding oxygen	Notified (Required to make the declaration of specifications)
3	High risk to individual or moderate risk to public health, e.g., bone cement, stents and valves (Pulmonary), Intraocular lenses	Moderate to High, e.g., haemodialysers, dressing for severe wound	
4	High risk to individual and public health, e.g. cardiovascular catheters	High	Licensing (Required to be granted permission)

Source: BOI (https://www.boi.go.th/upload/content/Infopack_MedDevice.pdf)

The dossier requirements and evaluation fees differ according to classification. Applications for Class 2-4 products (Notified/Licensed products) are required to submit in the Common Submission Dossier Template (CSDT) ASEAN Medical Device Directive, Annex 6, while that for Class 1 (Listed products) are less restricted, cost less and have shorter review period as detailed in the table below (Asia Actual, 2021).

Risk Classification	Registration Type	Submission Fee	Specialist Review Fee (Novel Devices)	Approval Fee	Total Fee (with Specialist Review)	Max Review Time*
Class 1	Listing	500 Baht (US$ 17)	N/A	2,000 Baht (US$ 67)	2,500 Baht (US$ 84)	Auto-Approved
Class 2	Notification	1,000 Baht (US$ 33)	38,000 Baht (US$ 1,267)	10,000 Baht (US$ 333)	49,000 Baht (US$ 1,633)	250 days
Class 3	Notification	1,000 Baht (US$ 33)	38,000 Baht (US$ 1,267)	10,000 Baht (US$ 333)	49,000 Baht (US$ 1,633)	250 days
Class 4	Licensing	1,000 Baht (US$105)	53,000 Baht (US$ 1,767)	20,000 Baht (US$ 667)	74,000 Baht (US$ 2,539)	300 days

Source: Asia Actual (https://asiaactual.com/thailand-3/medical-device-registration/#toggle-id-1)

Furthermore, digital health software is categorised as a type of medical device which includes software and accompanying accessories employed for the purposes of disease diagnosis, monitoring, prevention, or treatment. Notably, these actions are undertaken without a primary intended impact through immunological, metabolic, or pharmacological approaches. Digital health software necessitates compliance with the 3 primary regulatory frameworks as follows:

- Medical Device Act
- Personal Data Protection Act
- National Cyber Security Act.

If a digital health product is intentionally used as a medical device, it is therefore regulated by the Medical Device Act. Prior to importation of the product into Thailand, it is advisable for the importer to consult with MDCA in advance whether such a product is considered as a medical device and required to register (Adcock et al., 2023).

7.1.1.3 Regulations

Medical devices are regulated by Medical Device Act (No. 2) B.E. 2562 (2019), https://thaimed.co.th/wp-content/uploads/2022/10/Medical-Device-Act-2nd-Edition-BE-2562-2019.pdf, as the main law. Information on other related supporting laws can be found at https://medical.fda.moph.go.th/relevant-laws-and-standards/category/search-for-legal-information?page=1.

FDA provides Medical Device Regulations Manual and Duties of Medical Device Establishments at www.medical.fda.moph.go.th, which gathers all relevant medical device regulations and describes duties of all parties engaged in manufacture, import, sale and marketing of medical devices in Thailand (available in Thai only).

Some specific laws on permit requirements based on product classification (translated into English) are as follows:

Notification of the Ministry of Public Health Re: Groups of Medical Devices or Medical Devices for which Manufacturers and Importers Must Declare Specifications (No. 2) B.E. 2563 (2020), at www.thaimed.co.th

Notification of the Ministry of Public Health Re: Groups pf Medical Devices or Medical Devices that Must Be Registered by Manufacturers and Importers B.E. 2563 (2020), at www.thaimed.co.th

Notification of the Ministry of Public Health, Re: Groups of Medical Devices of Medica Devices for which the Manufacturers and importers Must Obtained License B.E. 2563 (2020), at www.thaimed.co.th

Personal Data Protection Act, B.E. 2562 (2019), https://thainetizen.org/wp-content/uploads/2019/11/thailand-personal-data-protection-act-2019-en.pdf

Cybersecurity Act, B.E. 2562 (2019), https://thainetizen.org/wp-content/uploads/2019/11/thailand-cybersecrutiy-act-2019-en.pdf

Useful links:

Life Sciences Regulation in Thailand: Overview
https://ca.practicallaw.thomsonreuters.com/6-500-8489?transitionType=Default&contextData=(sc.Default)&firstPage=true

Remark: A Q&A guide to life sciences regulation in Thailand.

7.1.1.4 Drug Control Division (DCD)

DCD is the licensing and registration authority for the manufacturing, import and sales of drugs in Thailand.

- **Product classification and registration**

Similar to medical devices, prior to importation of drugs into Thailand, an importer/distributor must obtain an import license granted by FDA. The licensed importer has responsibilities to register drugs with FDA. Drugs in Thailand are classified into 2 major groups including modern drugs and traditional drugs which have different regulations to comply with.[5]

Modern drugs (or chemical drugs) are further categorised into 3 groups, including generics, new generics and new drug, each of which has different registration requirements. There are other classifications of drugs, namely biological drugs and narcotic drugs, which are subject to distinct regulations for compliance (Jitruknatee et al., 2020; Adcock, et al., 2023).

Registration requirements for modern drugs are as follows:

- Generic drug registration requires only dossiers on product manufacturing and quality control along with product information;
- New generic drug registration requires dossiers of bio-equivalence studies in addition to the required dossiers for generics submission;
- New drug registration requires a complete set of product dossiers (Idconic, 2023).

Traditional and herbal medicines were reclassified as herbal products, following the implementation of the Herbal Products Act B.E. 2562 (2019),[6] Herbal products can be classified into 3 groups, based on the risk level of their indications or health claims, and the government's policies, as follows,

- Notification Herbal Product

  The criteria for Notification Herbal Products are the least restricted. They require a well-established history, widespread use, and bibliographical evidence. The Thai FDA has an FDA-recognized list of "official formulations" for Notification Herbal Products.

[5] "modern drug" means a drug intended for use in the practice of modern medicine or healing arts or the cure of an animal disease; "traditional drug" means a drug intended for use in the practice of the traditional healing arts or the cure of an animal disease which appears in a pharmacopoeia of traditional drug notified by the Minister, or a drug notified by the Minister as a traditional drug, or a drug of which formula has been registered as that of a traditional drug;
[6] Traditional and herbal medicines include: Products notified by the Minister, on the recommendation of the Committee, for the treatment, cure and relief of human illnesses or the prevention of diseases, including: Thai traditional drugs; developed herbal drugs; traditional drugs for use in humans; and drugs derived from the knowledge of alternative medicine.

- Detailed Notification Herbal Product

  Herbal products in this category undergo a less intensive review than Licensed Herbal Products. Detailed Notification Herbal Products stem from official formulations, like ingredient combinations.

- Licensed Herbal Product

  It is the most restrictively controlled group of herbal products. Any herbal product not meeting the prerequisites for Detailed Notification or Notification Herbal Products is categorized under this class (Adcock et al., 2022).

- **Regulations**

The main law regulating the pharmaceutical industry is Drugs Act, B.E. 2510 (1967) as amended (Drug Act), together with ministerial regulations and notifications https://faolex.fao.org/docs/pdf/tha181028.pdf. Information on other related supporting laws can be found at https://drug.fda.moph.go.th/home-law-1/.

Useful links:

Life Sciences Regulation in Thailand: Overview, https://ca.practicallaw.thomsonreuters.com/6-500-8489?transitionType=Default&contextData=(sc.Default)&firstPage=true

Remark: A Q&A guide to life sciences regulation in Thailand.

7.1.2 Department of Intellectual Property (DIP)

DIP, under the Ministry of Commerce, is the authority overseeing Thailand's Intellectual Property (IP) system.

- An overview of main IP rights

The table below provides an overview of scope and duration as well as registration and fees of main IP rights (patents, trademarks and copyright):

Patents and Designs

Scope and Duration

Patents are protected under the *Patent Act B.E. 2522 (1979)* and there are three types:

1. Invention patent – a new invention, an innovative step and applicable for industry – valid for 20 years from date of filing (not renewable).

2. Petty patent – similar to invention patent – valid for six years from the date of filing, and can be renewed twice for an extension period of two years.

3. Design patent – a new industrial or handicraft design – valid for 10 years from the date of filing (not renewable).

A comparison between the three types is available on *DIP*'s website.

Registration and Fees

Applications should be submitted to *DIP*. Fees are required at time of registration and annually once the fifth year has been reached. The application process and schedule of fees are available on the *DIP* website for invention and petty patents and design patents.

Alternatively, as Thailand is a member of the following international conventions regulating patents: *Paris Convention*, *Patent Cooperation Treaty*, *ASEAN Patent Examination Co-operation (ASPEC)* and the *Global Patent Prosecution Highway (GPPH)*, patent applications in multiple jurisdictions through these routes will save considerable time and resources

Trademarks and Geographical Indication (GIs)

Scope

A trademark protects signs, symbols, logos, words or sounds, and it is defined to apply to service marks, certification marks and collective marks. A GI protects names or signs used on certain products which correspond to a specific location, where the quality or reputation of the goods is essentially attributable to its place of origin.

Trademarks are regulated by the *Trademark Act B.E. 2534*. GIs are regulated by the *Geographical Indicator Act B.E. 2546*.

Duration

Registered trademarks or GIs are valid for 10 years and may be renewed every 10 years.

Registration and Fees

Applications for trademark or GI can be made directly to *DIP*. Further information is available on the *DIP* website for trademarks and GIs.

Thailand acceded to the *Madrid Protocol* in August 2017, which will take effect in the country from November 2017. Meanwhile, trademark applications can only be processed through Thailand's IP office.

Copyright

Scope

Copyright protects literary, musical and artistic works, films, sound recordings, broadcasts and derivative works. In Thailand, copyright protection is regulated by the *Copyright Act*.

Duration

Protection remains valid for 50 years after the death of a known author or after publication in the case of an unknown author.

Registration

Although there is no requirement for registration, a copyright owner is recommended to notify *DIP* of the copyright in a work. This acts as a prima facie evidence for proving copyrighted work. The process for registering copyright can be found on the *DIP*'s website.

Source: HKTDC Research (https://research.hktdc.com/en/article/MzU2MTg5NTAx)

- Regulations

- Patent

Patent Act B.E. 2522, as Amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542, https://www.ipthailand.go.th/images/633/Patent-Act-Edit.pdf (the main law)
Other relevant supporting laws, https://www.ipthailand.go.th/th/patent-008.html

- Trademark

  Trademark Act B.E. 2534 Amended by Trademark Act (No. 2) B.E. 2543 and Trademark Act (No. 3)B.E.2559, https://www.ipthailand.go.th/th/dip-law-2/item/trademark-act-b-e-2534-amended-by-trademark-act-no-2-b-e-2543-and-trademark-act-no-3-b-e-2559.html (the main law)
  Other relevant supporting laws, https://www.ipthailand.go.th/th/trademark-008.html

- Copyright

  Copyright Act B.E. 2537 (1994), Amended By Copyright Act (No.2) B.E. 2558 (2015), Copyright Act (No.3) B.E. 2558 (2015), Copyright Act (No.4) B.E. 2561 (2018) ,Copyright Act (No.5), B.E. 2565 (2022), https://www.ipthailand.go.th/th/dip-law-2/item/copyright_act2537-2022.html (the main law)
  Other relevant supporting laws, https://www.ipthailand.go.th/th/copyright-007.html

Useful links:

European Commission, South-East Asia IP SME Helpdesk : Thailand IP country factsheet, https://data.europa.eu/doi/10.2826/965972

Intellectual Property Rights in Thailand: Overview by Tilleke & Gibbins, https://uk.practicallaw.thomsonreuters.com/w-030-9027?transitionType=Default&contextData=(sc.Default)&firstPage=true#co_anchor_a287233

7.2 TAXATION

Generally, an imported product is subject to an import tariff charged on an CIF price plus a 7% value added tax (VAT) based on the sum of CIF price and import duty. Imported medical devices are levied differently depending on HS codes applied. Most medical devices are exempted from import tariffs, whereas pharmaceutical products are mostly subject to a 10% import tariff. Information on import tariffs and other import requirements can be searched on Access2Markets database of the European Union, https://trade.ec.europa.eu/access-to-markets/en/home.

7.3 OTHERS

7.3.1 Free trade agreement (FTA) between Thailand and the European Union (EU)

At present the free trade agreement (FTA) between Thailand and the European Union (EU) does not exist. Both parties have agreed to restart negotiations on FTA that were suspended after the military took power in a coup in 2014. Thailand and the EU will begin talks in the autumn of 2023.

7.3.2 Market entry barriers

There are some entry barriers to be aware of when considering entry into the market.

- Regulatory and licensing requirements

Thailand's healthcare sector is highly regulated, with strict requirements for licensing and compliance. Obtaining the necessary licenses and permits for healthcare facilities, medical devices, pharmaceuticals, and healthcare services can be a complex and time-consuming process.

- Competition and established players

Thailand's healthcare industry is very competitive, with well-established players. There are pharmaceutical MNCs operating in Thailand. Information on those companies can be found at https://old.prema.or.th/prema-member/#memberslist.

- Market access and distribution

Gaining market access requires local partners to facilitate import procedures and to assist in establishing effective distribution channels.

8. TRADE SHOWS

MEDLAB ASIA & ASIA HEALTH - on 16-18 August 2023, at IMPACT Exhibition Center, Bangkok

InterCare Asia – on 31 August-2 September 2023, at QSNCC, Bangkok

Thailand LAB INTERNATIONAL – on 6-8 September 2023, at BITEC, Bangkok

MEDICAL FAIR THAILAND – on 13-15 September 2023, at BITEC, Bangkok

PharmaTechAsia 2024 / PROPAK ASIA 2024 – on 12-15 June 2024, at BITEC, Bangkok

CPHI SOUTH EAST ASIA - on 10-12 July 2023, at QSNCC, Bangkok

9. LIST OF IMPORTERS, ASSOCIATIONS, RELEVANT AUTHORITIES

Please contact the FIT Bangkok office for more information on this.

10.INTERESTING WEBSITES

Asia Actual (https://asiaactual.com/)

Bangkok Post (https://www.bangkokpost.com)

BOI (https://www.boi.go.th)

Journal of Health Science (https://thaidj.org/)

Kasikorn Research (https://www.kasikornresearch.com/EN/

Krungsri Research (https://www.krungsri.com/th/research/home)

Pacific Prime (https://www.pacificprime.com/)

Pharmaboardroom (https://pharmaboardroom.com/)

The Nation (https://www.nationthailand.com/thailand/economy/40021233)

The Pharmaceutical Research and Manufacturers Association (PReMA) (https://old.prema.or.th/)

Thomson Reuters Practical Law (https://uk.practicallaw.thomsonreuters.com)

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