

FLANDERS INVESTMENT & TRADE MARKET SURVEY



HEALTHCARE AND MEDICAL SECTOR IN THAILAND

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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. 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:

¹ - 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 <u>Eastern Economic Corridor (EEC)</u>, 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 <u>Medical and Comprehensive Healthcare</u> and <u>Investment Promotion Guide 2023</u>.

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.² 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).

² 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

 Al technology for emergency diagnosis
 Al Paramedic helps quickly evaluate emergency cases. It also enables ER crews to handle minor injuries and illnesses at the scene.

Al for screening and initial illness diagnosis

Sirinaj Hospital employs 56 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.

Al 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.

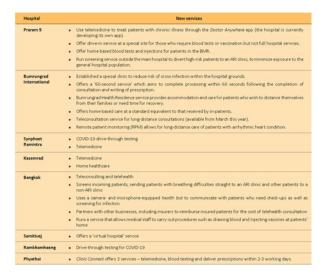
· Smart inventory for drugs and equipment management

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
- . ClouDr has a platform for taking care of patients with various diseases and delivering prescription drugs
- 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):



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:

- o 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

- o **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, <u>Public Procurement World—Thailand</u> (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), <u>ASEAN Medical Device Directive</u>, 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, inclision 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 Specified to solve	
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	(Required to make the declaration of specifications)	
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) <u>ASEAN Medical Device Directive</u>, <u>Annex 6</u>, 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 <u>Medical Device Regulations Manual</u> and Duties of Medical Device Establishments at <u>www.medical.fda.moph.go.th</u>, 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.³

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),⁴ 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.

³ "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;

⁴ 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

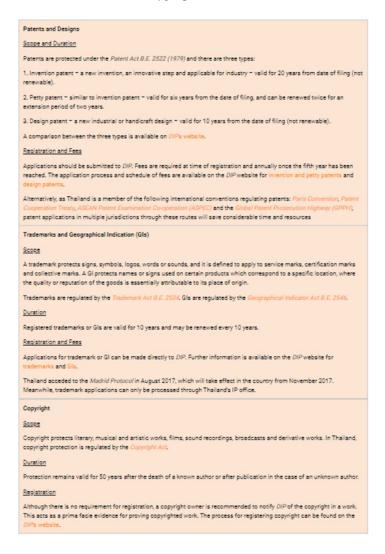
Remark: A Q&A guide to life sciences regulation in Thailand.

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):



 $Source: HKTDC \ Research \ (\underline{https://research.hktdc.com/en/article/MzU2MTg5NTAx)}$

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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