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PHARMACEUTICAL & HEALTHCARE & MEDICAL INDUSTRY IN MALAYSIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

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HEALTHCARE & PHARMACEUTICAL INDUSTRY IN MALAYSIA

Industry Report
Publication date / September 2023

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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.

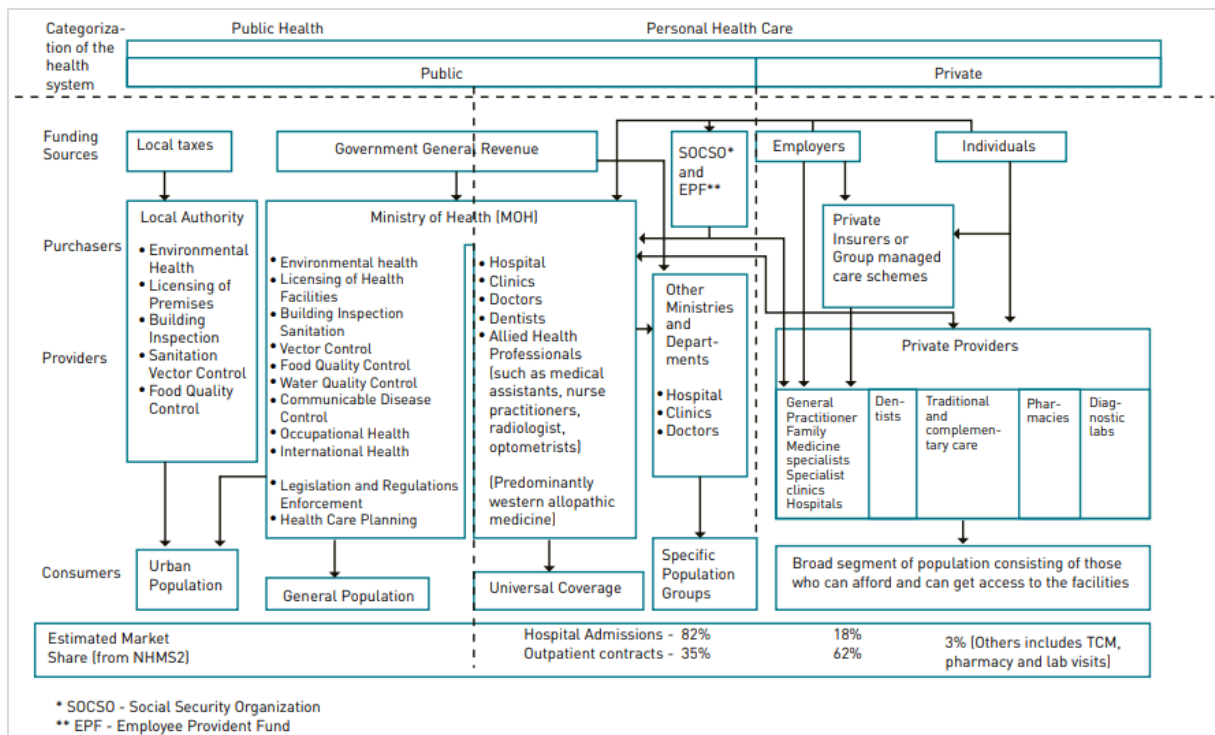


Figure 1: Healthcare System in Malaysia

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.

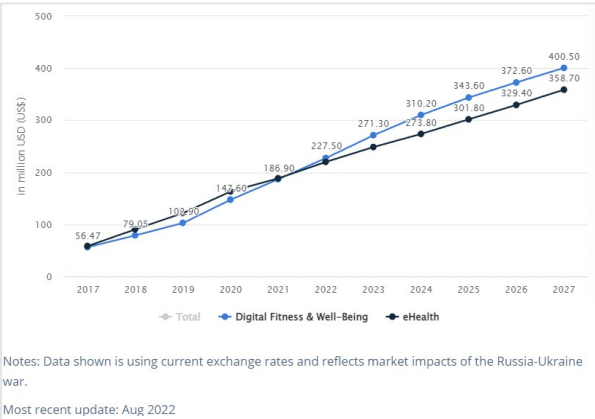


Figure 1: Revenue in the Digital Health Market
Source: Statista, 2022

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.



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).

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

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 Sompoo 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 (NPR)** 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 NPR** before being permitted for sale and marketing in the country.

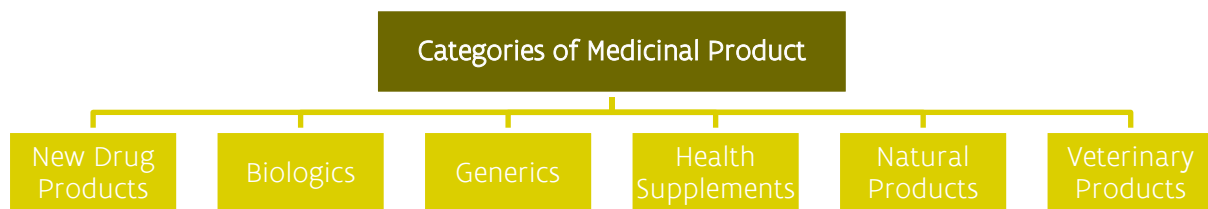


Figure 3: Categories of Medicinal Products
Source: Drug Registration Guidance Document, 2022

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.



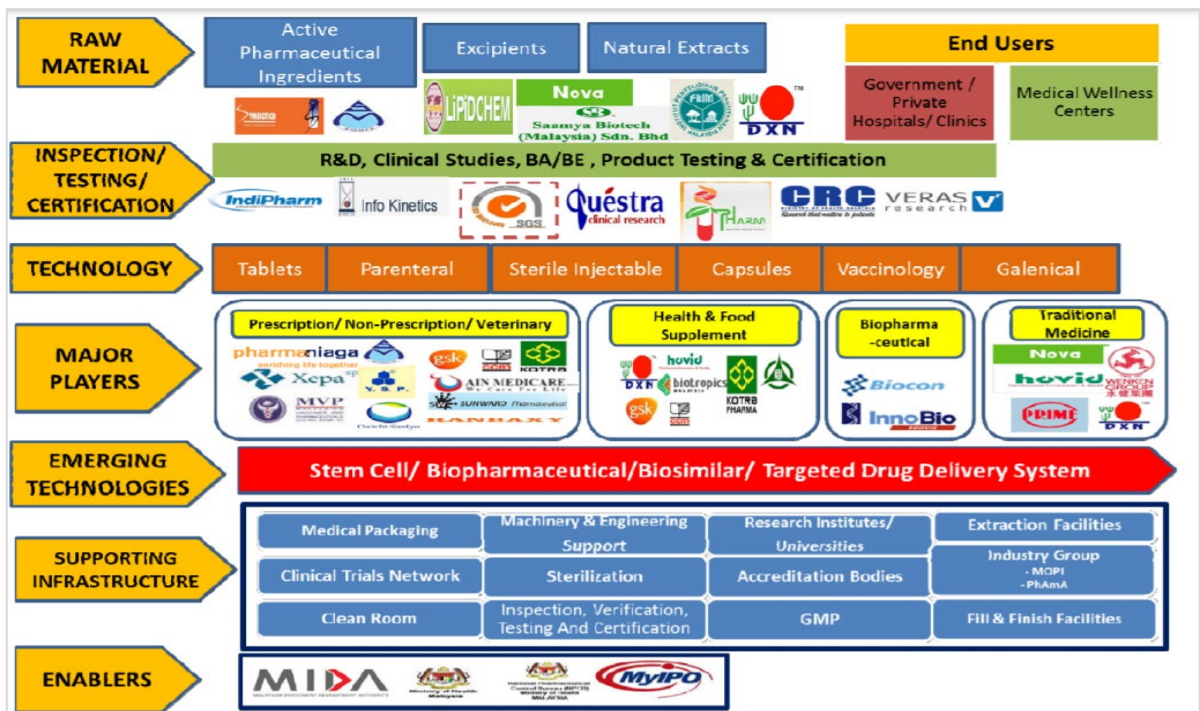


Figure 4: Pharmaceutical Industry Ecosystem in Malaysia
 Source: Ministry of International Trade and Industry (MITI)

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/EMA 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.

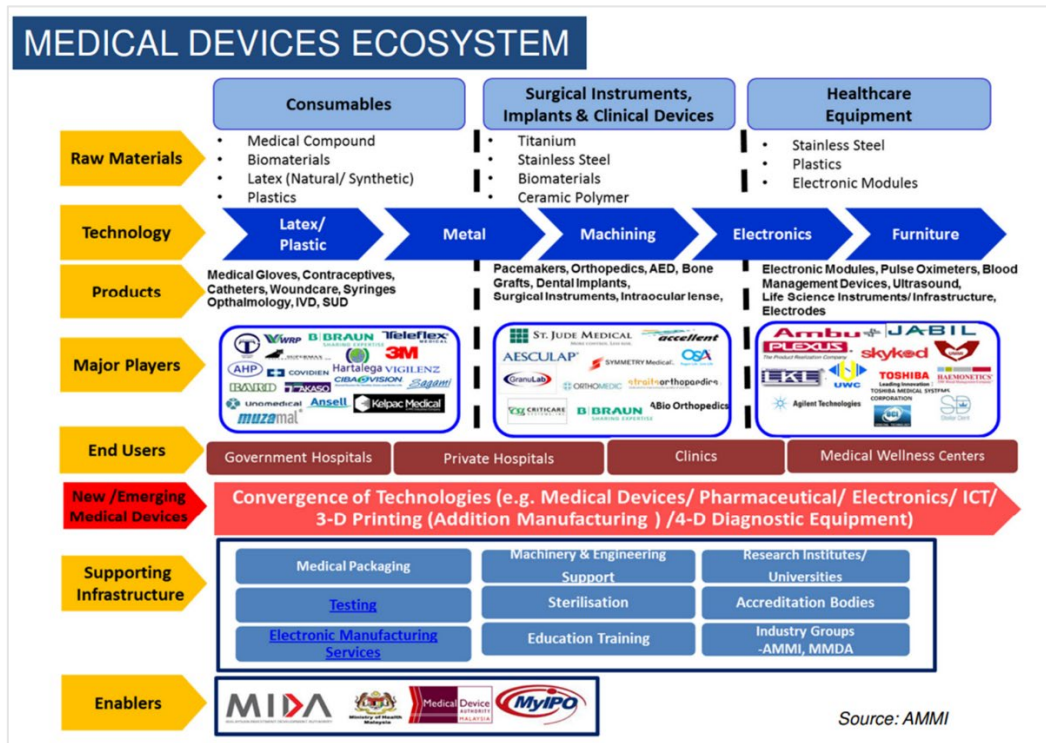


Figure 5: Medical Device Industry Ecosystem In Malaysia
Source: MIDA Malaysia, AMMI

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.

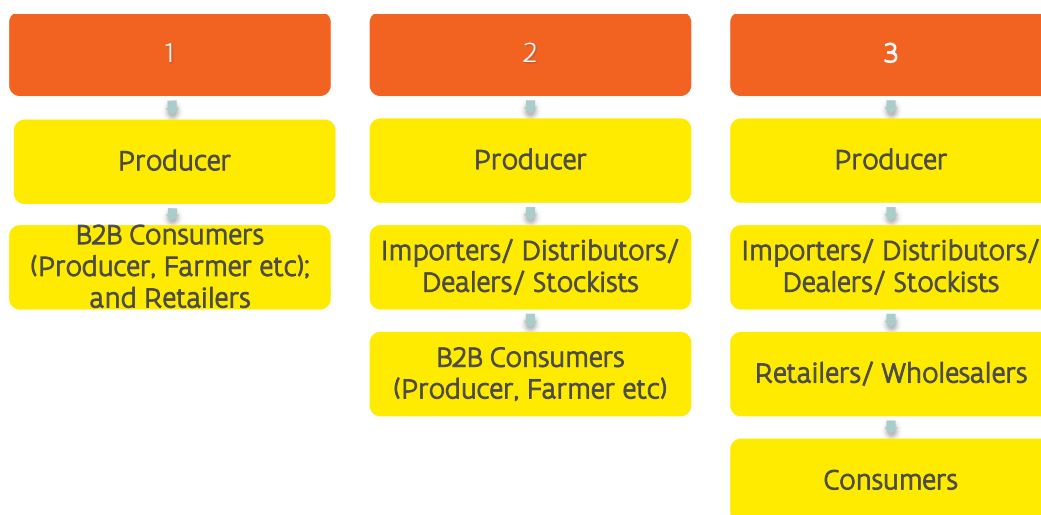


Figure 6: General Overview of Distribution Channels



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.



Official Portal
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH 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

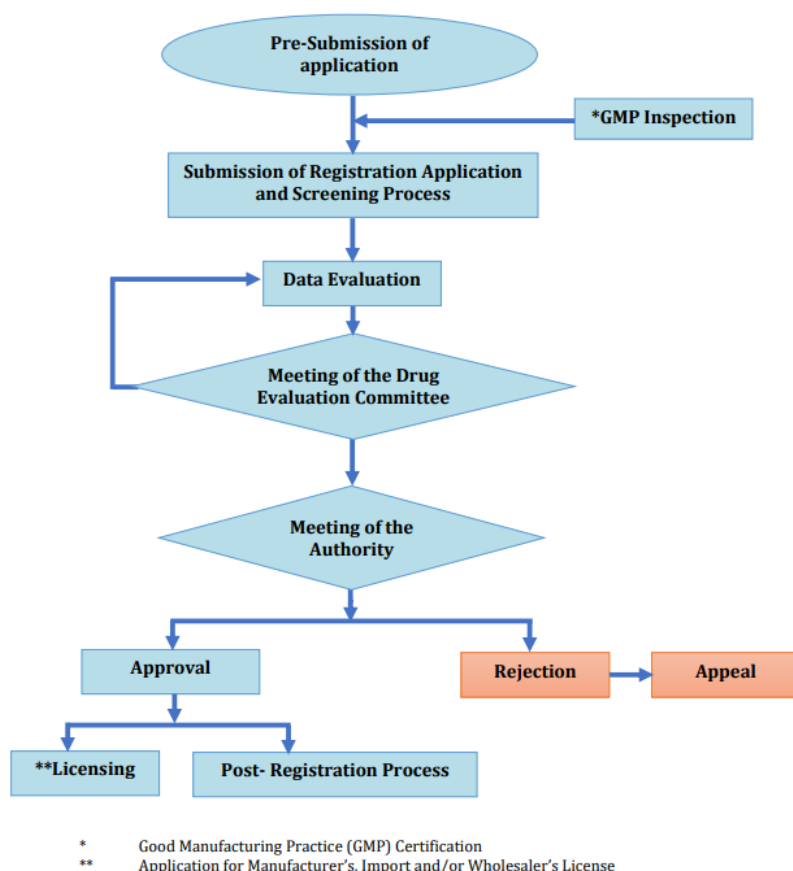


Figure 7: Overview of Product Registration Process
 Source: Drug Registration Guidance Document, 2022

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

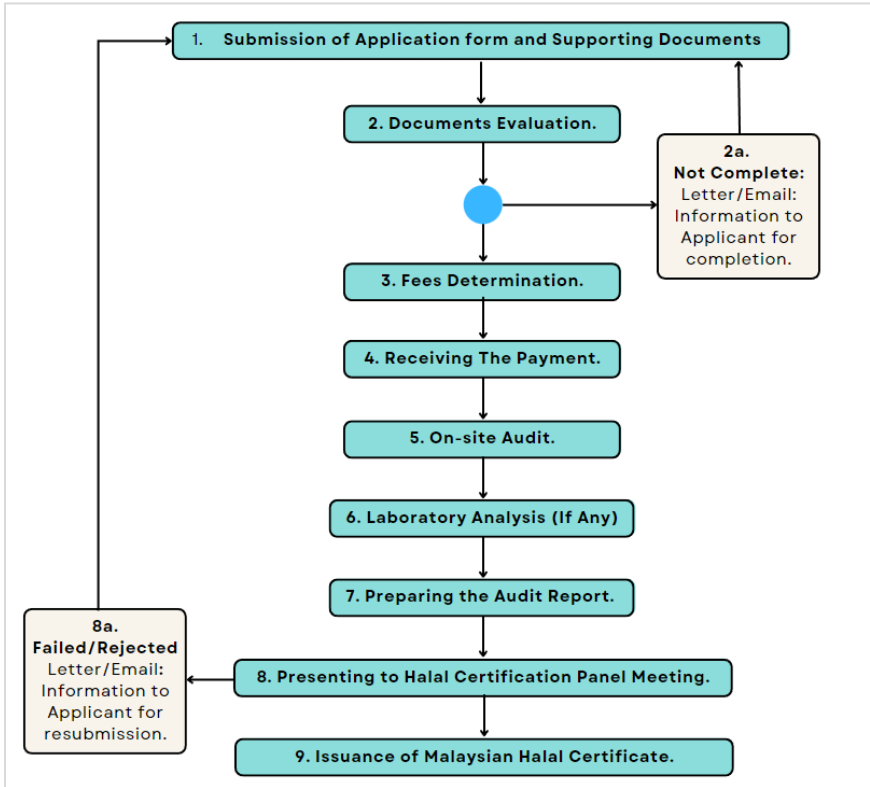


Figure 8: Process of Malaysian Halal Certificates For International Application
 Source: Halal Hub Division of Department of Islamic Development Malaysia

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/Licence, 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.mihasc.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.

SE-Asian Healthcare Show

SEACare

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.kotrpharma.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.



Disclaimer

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