Journal of Pharmaceutical and Biological Research
ISSN: 2347-8330 | CODEN (USA): IJCPNH |Publisher: Pharma Research Library
Home Page: https://pharmaresearchlibrary.org/journals/index.php/jpbr
DOI: https://doi.org/10.30904/j.jpbr.2023.4609
J. Pharm. Bio. Res., 2023; 11(2): 65–73

A Study on Medical Device Regulations Related to their Warning Letters and Product Recals in Association of Southeast Nations

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A B S T R A C T

The rapidly growing economies of the Southeast Asian countries offer attractive opportunities for the marketing of medical devices: Increasing affluence across Southeast Asia is expected to lead to a growing demand in health care products, like for example medical devices. This master thesis presents the current regulatory requirements for medical devices in the member countries of the Association of the Southeast Asian Nations (ASEAN) as well as Hong Kong SAR and China. ASEAN represents the following Southeast Asian countries: Singapore, Malaysia, Indonesia, Thailand, the Philippines, Vietnam, Laos, Brunei, Cambodia and Myanmar. To place a medical device on the market in any of these countries, highly diverse regulatory requirements have to be met at the present time: Out of the 10 ASEAN member states only five have medical device laws (Singapore, Indonesia, Thailand, the Philippines, Vietnam), while one maintains a voluntary registration system using administrative guidelines (Malaysia). The remaining four countries do not have laws or guidelines specifically aimed at medical devices at all. Similar to Malaysia, Hong Kong SAR utilizes a voluntary registration system based on guidelines, while China has its own medical devices law. Currently, there is no common definition of the term medical device in these countries, which leads to the fact that certain products may be subject to medical devices law in some countries, but not in others. Products for veterinary use, for example, have to fulfil national medical device requirements in Thailand and the Philippines at the moment, but not in any of the other countries. The requirements for registration differ widely with mandatory registration for all classes of devices and licensing requirements for manufacturers, importers and distributors in some countries, while in other countries, there are no requirements at all due to the lack of relevant legislation or administrative guidelines. The standard of adverse event reporting also varies and does not always form a part of the existing regulations. Therefore, it is the explicit aim of the ASEAN member countries to develop and harmonise regulatory control of medical devices in all its member countries with the introduction of the ASEAN medical device directive (AMDD). The AMDD will introduce a common set of rules in all member countries and is mainly based on the recommendations of the Global Harmonization Task Force (GHTF), a voluntary international group of medical device regulatory authorities and medical device trade associations from the European Union, the United States of America, Canada, Japan and Australia. The ASEAN member countries will be required to pass national laws implementing the AMDD over the next years. Singapore is the first country to fmalize this process in 2011, but the other countries will follow on their own time depending mainly on the resources available at the national level.

Keywords: Southeast Asian countries, ASEAN, veterinary use, GHTF, AMDD

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Article History
Received 22 June 2023
Revised 18 July 2023
Accepted 16 Aug 2023
Published 28 Oct 2023

Citation: Bhavitha Gogula, *et al.* A Study on Medical Device Regulations Related to their Warning Letters and Product Recals in Association of Southeast Nations. J. Pharm. Bio. Res., 2023; 11(2): 65-73.

C O N T E N T S

1. Introduction

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (ASEAN), hereinafter collectively referred to as "Member States" or singularly as "Member State"

MINDFUL that in the year 1992, the ASEAN Heads of Government declared that an ASEAN Free Trade Area (AFTA) shall be established in the region and that in 1995, they agreed to accelerate its implementation to the year 2003;

NOTING the ASEAN Trade in Goods Agreement which entered into force on 17 May 2010 provides for cooperation to supplement and complement the liberalisation of trade including, among others, the harmonisation of standards, conformity assessment procedures and technical regulations as a means of reducing technical barriers to trade; Mindful that the Declaration of ASEAN Concord II (Bali Concord II) adopted by the ASEAN Heads of Government during the 9th ASEAN Summit in Bali, Indonesia on 7 October 2003, commits ASEAN to deepen and broaden its internal economic integration and linkages, with the participation of the private sector, so as to realise an ASEAN Economic Community. MINDFUL that the establishment of the ASEAN Economic Community has been accelerated from 2020 to 2015 which will create ASEAN as a single market and production base reiterating their commitments to the Agreement on Technical Barriers to Trade of the World Trade Organization, which encourages the Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment and mandates, among other matters, the elimination of unnecessary obstacles to trade including those relating to technical regulations; recalling the ASEAN Framework Agreement for the Integration of Priority Sectors and the ASEAN Sectoral Integration Protocol for Healthcare signed on 29 November 2004 in Vientiane, Lao PDR; and having regard to the objectives of harmonized medical device regulations, common technical documents and the progress made in implementation.

The regulation of medical devices is a vast and rapidly evolving field that is often complicated by legal technicalities. For example, legal terms and their meanings are sometimes non-uniform even within one regulatory system. In an attempt to make this complex subject easier to grasp, this Guide presents a common framework that integrates the regulatory systems of the five countries or regions with the most advanced medical device regulations. Non-technical language, graphics, tables and memory anchors are used to present an overview of medical device safety issues and regulatory philosophy. The Guide begins by explaining how safety is a risk management issue, and how optimum safety and performance require cooperation among all who are involved in the life span of a medical device. The critical elements of medical device regulations are illustrated using a common framework for regulatory development; as well as the current regulatory tools of the Global Harmonization Task Force (GHTF) and all the key documents it has issued in the past three years. Understanding the different phases in the life span of a medical device and the common framework are first steps to successful harmonization and simplification worldwide

Medical Device Safety

Medical device safety and risk management:

Safety can only be considered in relative terms. All devices carry a certain degree of risk and could cause problems in specific circumstances. Many medical device problems cannot be detected until extensive market experience is gained. For example, an implantable device may fail in a manner that was not predictable at the time of implantation; the failure may reflect conditions unique to certain patients. For other devices, component failure can also be unpredictable or random. The current approach to device safety is to estimate the potential of a device becoming a hazard that could result in safety problems and harm. This estimate is often referred to as the risk assessment.

Hazard is a potential for an adverse event, a source of danger. Risk is a measure of the combination of (1) the hazard; (2) the likelihood of occurrence of the adverse event; (3) the severity or overall impact. Risk assessment begins with risk analysis to identify all possible hazards, followed by risk evaluation to estimate the risk of each hazard. In general, risk assessment is based on experience, evidence, computation, or even guesswork. Risk assessment is complex, as it can be influenced by personal perception and other factors such as cultural background, economic conditions, and political climates.

In practice, risk assessment of medical devices is based on the experience of health care professionals and on safety design engineering. In the United States, governmental risk assessment of medical devices is based mainly on recommendations from members of 16 medical specialty panels, and devices are categorized into three classes. In the European Union and Canada, the classification schemes for medical devices are predominantly rulebased. These rules categorize medical devices according to their perceived potential hazards. Canada assigns four classes of devices. The European Union assigns three classes with class II being sub-divided into IIa and IIb (effectively, also four classes). The Global Harmonization Task Force (GHTF) is proposing a harmonized scheme for medical device classification.

In classifying devices, potential areas of hazard that warrant consideration include the degree of invasiveness, duration of contact, the body system affected, and local versus

systemic effects. An invasive device is usually considered to have higher potential hazard than an equivalent non-invasive device (e.g. there are invasive and non-invasive blood pressure monitors). Similarly, devices that have a long duration of contact, that affect vital organs such the heart or the great arteries, or that have systemic effects are assigned higher classes of potential hazard or risk. The degree of regulation imposed on any device is proportional to its potential hazard. This approach is known as risk management. The first requirement of the "Essential principles of safety and performance of medical devices" recommended by the GHTF (SG1-N020R5) illustrates such an approach. It states that: Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This statement highlights the risk/benefit nature of medical devices. The goal, therefore, is to maximize benefit and minimize risk. Manufacturers of medical devices also use the risk management approach. The International Organization for Standardization (ISO) has produced a document (ISO 14971:2000) providing manufacturers with a framework including risk analysis, risk evaluation and risk control for risk management in medical device design, development, manufacturing as well as for monitoring the safety and performance of the device after sale. It is important to recognize that any of these phases can affect the safety and performance of a medical device. Examples of how each phase can create health hazards are described below:

Conception and development: The scientific principles upon which a device is based are fundamental to its safety and performance. For example, a cardiac pacemaker should deliver a minute electrical impulse of a certain size and shape that simulates the natural functioning of the heart. Significant deviation from this may compromise safety and performance. The more complex the device, the higher the risk of user error. Soundness of concept and adequacy of design, construction, and testing (including verification, validation and clinical trials) require the scrutiny of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks.

Manufacture:

Good, functional medical devices are produced when the manufacturing process is adequately managed. However, poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, even when the original prototype has been well-designed. This consideration has led to the development of good manufacturing practice (GMP) for drugs, biological products and medical devices. Now, GMP is more commonly referred to as "quality systems in manufacturing", and these are addressed later in this guide.

Packaging and labeling:

Properly packaged medical devices pose little risk to individuals handling them, even if the medical device is biohazardous. This highlights the importance of well-designed packaging systems in delivering clean, sterile and protected medical devices to the point of use. Shipping is one of the hazards a medical device and its packaging must survive. Subtle damage can result during transportation and handling unless the total packaging system is designed robustly and can withstand various stresses. Well-sealed packaging is essential for those medical devices that must be maintained sterile. Labelling is crucial in identifying the medical device and specifying instructions for its proper use. As for drugs, mislabelling of medical devices can result in serious consequences for the user. Hazard warnings or cautions and clear instructions for use are very important.

Advertising:

Advertisement has the potential to create expectations and powerfully influence the belief in a medical device's capabilities. It is important, therefore, that medical device marketing and advertising are regulated to prevent misrepresentation of a medical device and its performance. Misleading or fraudulent advertising of medical devices may increase sales. However, from the buyer's perspective, the purchase of an inappropriate medical device is a waste of money that may deprive the patient of more appropriate treatment and could lead to patient or user injury.

Sale: The sale of medical devices by the vendor is a critical stage that leads to the device being put into actual use. If the vendor is not subject to regulation, then there is higher risk of exposing the public to low quality or ineffective devices.

Use: Users of medical devices can have a profound effect on their safety and effective performance. Unfamiliarity with a certain technology or operating procedure, and the use of products for clinical indications outside the scope of those specified in the labelling, can cause device failure even in the absence of any inherent design or manufacturing defects. Within the clinical engineering community it is widely believed that user error underlies at least half of all medical device-related injuries and deaths. The re-use of disposable devices contrary to the manufacturer's instructions, and without proper control or precautions for minimizing associated risks, can be dangerous (see 6.3.7). The lack of, or inappropriate, calibration and maintenance of medical devices can seriously jeopardize their safety and performance. These issues are often overlooked or underestimated.

Disposal:

Disposal of certain types of devices should follow specific and stringent safety rules. For example, devices that are contaminated after use (e.g. syringes) or devices that contain toxic chemicals, can present hazards to people or the environment and must be disposed of properly. It is people who manage each phase in the life span of a medical

device, and these people should be identified and called on to participate in ensuring medical device safety.

Regulatory tools and general requirements:

The requirements for the three stages of regulatory control of the five founding members of the GHTF are summarized below. Note that although the different governing bodies use different terms, their functions are actually quite similar

Product control

Although different authorities have different systems of pre-market review, they all apply the risk management philosophy. All medical devices must satisfy safety and performance, quality system (some low-risk devices may be exempt) and labeling requirements. However, the degree of regulatory scrutiny increases with the potential risks of the medical device, as evidenced by the risk-based device classification system (SG1-N015R14) proposed by the GHTF. Authorities acknowledge product clearance for the market in various ways. In Australia, the Therapeutic Goods Administration issues an ARTG (Australian Register of Therapeutic Goods) number to devices cleared for the market. In Canada, a Device Licence is awarded by the Therapeutic Products Directorate. In the European Union, after receiving the EC certificate from a notified body, the manufacturer places the CE mark on or with the device. In Japan, a Shounin is issued by the Pharmaceutical and Medical Safety Bureau of the Ministry of Health, Labor and Welfare. In the United States, the manufacturer of the device receives a Marketing Clearance (510K) or an Approval Letter (PMA) from the FDA.

In Canada, devices of classes III and IV are subject to in-depth regulatory scrutiny, while class II devices require only the manufacturer's declaration of device safety and effectiveness before sale. Class I devices are exempted from pre-market submission, but they must still satisfy the safety, effectiveness and labelling requirements. In the European system, manufacturers of devices of classes II and III, as well as devices of class I with either measuring function or sterility requirements, must submit to the regulator (competent authority): (1) a Declaration of Conformity to the appropriate EC Directives, and (2) details of the conformity assessment procedure followed. In addition, for higher risk class devices that require design examination or type examination, the corresponding EC-Certificates issued by a notified body must also be submitted to the competent authority. Other medical devices of class I are exempt from pre-market submissions, although they must follow the essential principles of safety and performance in their design, construction and labeling requirements.

In Australia, all "registrable" devices must undergo rigorous pre-market evaluation before market entry. "Listable" devices are less rigorously regulated, but may be evaluated for safety (not efficacy) if there are regulatory concerns about the risk profile of the product. Devices manufactured for a particular person, or those built within a health facility and not commercially supplied, are exempt from the requirement to be registered or listed. Under some circumstances, the manufacturing facilities may need to be licensed. In Japan, class I devices are granted Todokede by the regional authorities. Some class II low-risk devices are granted Todokede if their safety and effectiveness have been established previously. All devices above class II must obtain a central government licence for market entry. The Ministry of Health, Labor and Welfare is working on the Pharmaceutical Administration Law (PAL) revision towards risk-based medical device regulation, in line with the GHTF principles. The new PAL revision should become effective in 2005.

In the United States, most Class III and new devices that are not substantially equivalent to a legally marketed product that does not require a Pre-Market Approval application, require clearance through the PMA or Product Development Protocol processes. Most class II and some class I devices require pre-market entry notification (termed 510k, an information package for the FDA, which is subject to less stringent review than the PMA process. The 510k submission must demonstrate how the proposed medical device is substantially equivalent to a medical device that is already on the US market. Most class I and some class II (low-risk) devices are exempt from 510k submission before sale, but are still subject to general control requirements.)

2. Methodology

ASEAN Medical Device Regulation

Indonesia Medical Device Regulatory System

Indonesia, with a population of more than 220 million, is a medical device market that has a large potential. However, foreign manufacturers of medical devices have always been faced with numerous obstacles and challenges in entering this market. This is despite the fact that Indonesia relies mainly on imported medical devices due to the lack of any established local manufacturer. Penetrating this huge market of medical devices is difficult due to the wide and extensive geographical boundaries in the country. Also, highly bureaucratic medical device import and trading regulations have made it more difficult for foreign manufacturers to enter the market. Indonesia also imposes tariffs of up to 30% on imported medical devices depending on the type, use, and value of these devices.4 Indonesia has a centralized healthcare system, headed by the Ministry of Health (Kementerian Kesehatan R.I.). The Ministry of Health purchases most of the medical disposables and hospital equipment for the 900 public hospitals around the country. Due to the highly rigid nature, there is limited budget for most of the hospitals in the country. Recent changes, however, have been encouraging in de-centralizing healthcare services in the country. This will spur the growth of the medical devices market in the country as individual regions collect and plan the healthcare budget individually themselves.

There is a market disparity in the standard of healthcare between rural and urban areas. The capital city, Jakarta, enjoys relatively good levels of primary care as well as a range of modern private specialist facilities, while healthcare coverage in remote regions tends to be insufficient.

The majority of the Indonesian medical device market is supplied by imports, which dipped by 1.5% over the previous year to US$ 348.4 million in 2009. Imports have grown at a CAGR of 35.2% in 2005–2009.5 During the 24th ASEAN Consultative Committee on Standards and Quality Meeting on August 3–4, 2004, the formation of a Product Working Group on Medical Device (ACCSQ-MDPWG) was proposed to implement specific measures on medical device under the road map for healthcare integration. This is to be in line with the ASEAN leaders' decision on the establishment of the ASEAN Economic Community (AEC) by 2020 and fast-track integration of the 11 priority sectors, including the healthcare sector. Therefore, as one of ASEAN member country, Indonesia is committed to the implementation of ASEAN Harmonization in 2014.

Regulating Authority

Medical devices in Indonesia are regulated by the Ministry of Health of the Republic Indonesia; Directorate of General Pharmaceutical Service and Medical Device; and Directorate of Medical Device Production and Distribution Development

Definition of Medical Device

A medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material, or other similar or related article

Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose of

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease
- Diagnosis, monitoring, treatment, or alleviation of or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.
- Supporting or sustaining life
- Control of conception
- Disinfection of medical device

Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body that does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means. 28.4.

Classification of Medical Devices

Medical devices are classified into three classes based on risk2:

Class I: In case of malfunction or misuse, these low-risk devices would not cause serious harm. The evaluation of these health instruments shall focus on the quality and the product.

Class IIa: In case of failure or misuse, these medical devices can result in a significant impact on the health of patients, but not a serious accident. Before distribution, such health instruments will have to comply with a sufficient requirement for evaluation, but they do not require a clinical test.

Class IIb: In case of failure or misuse, these medical devices can have significant effect on the health of patients, but not a serious accident. Before distribution, these health instruments shall have to comply with a complete requirement for evaluation, including a risk analysis and security facts for the evaluation, but they do not require a clinical test.

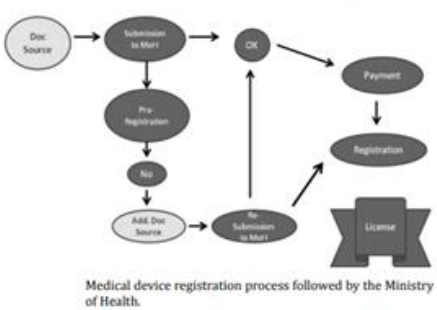
Class III: The failure or misuse of these medical devices can result in serious implications for patients or nurses/operators. Before distribution, these health instruments shall have to comply with a complete requirement for evaluation, including a risk analysis and security facts for the evaluation, and they also require a clinical test. Currently Indonesia does not have any guidelines on combination products. Therefore, it is strongly recommended that prior to the registration process, the product specification, intended use, and product claims be discussed with the Ministry of Health staff to ensure the classification of the product. Attached classification of product from legal manufacturer on application is recommended as reference.

Registration of Medical Devices

All medical devices (for all classes) with each code should be registered with the Ministry of Health before they can be freely imported, distributed, and sold in the market. Unit package that needs to be registered depends on unit sales. Safety, quality, and efficacy of the product will be considered during evaluation to grant marketing authorization. Abridged evaluation is not recognized by Indonesia authority. A full assessment is required for all classes of product. Approval status from others countries serves only as reference for the Ministry of Health staff in the reviewing process.

Process

The application must have distribution license "IPAK" from the Ministry of Health and the company that as applicant officially appointed by the source company or the legal manufacturer as the sole agent. This letter of appointment from source/legal manufacturer explains that the representative company in Indonesia has authorization to register, import, and distribute the product in Indonesia. The minimum appointment granted by the source company is two years, and this document needs to be legalized by the Indonesian embassy. It should be noted that the company that has the right to import the product is the same company that is the license holder for the products. Currently, application is done by submitting the hard copy of registration documents and follow-ups directly to the Ministry of Health. English and Indonesian are the acceptable languages for the documents.



Medical device registration process followed by the Ministry of Health.

Fig.1

Regulatory Action for Changes and Device Modifications: This is not specified in the regulations. Changes can be registered via a data amendment process, variation, or re-registration, and the requirements are judged on a case-by-case basis. Any changes that have an impact on the following should be considered:

(1) Size
(2) Packaging specification
(3) LABELING
(4) tax payer number (NPWP)

Post Market Surveillance System

There can be severe consequences of faulty or substandard medical devices for public health and safety. Regulatory bodies all over the world are thus striving to achieve an optimal system of medical device controls that accommodates a device in all its permutations and combinations, balancing quality and safety with faster access to the market. Regulatory systems need to be in place to manage the potential residual risks posed to the intended user. Because of this, the Indonesia authority is developing a post market surveillance process for medical devices. Post market surveillance mechanisms are required to monitor the medical devices already in the market. This is essential for such devices. In the event of any complications, the authorities are able to direct swift corrective actions. In Indonesia, post market surveillance is still voluntary. However, it has been recommended by the authority for cases that have adverse health consequences for the patient or cause death. In such cases, it is mandatory for the company to report to the authority in 24 hours with details of the corrective action.

3. Results and Discussion

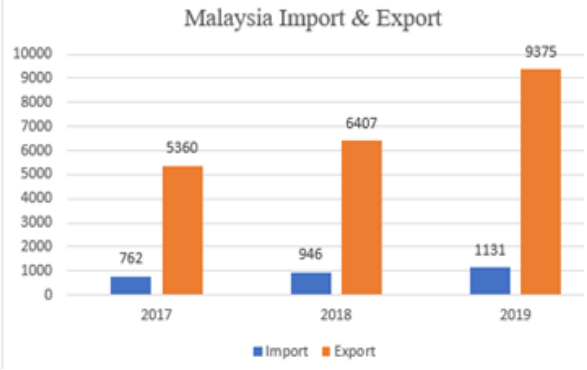


Fig.1

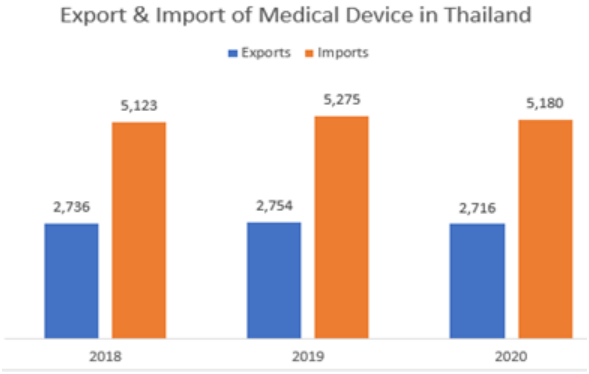


Fig.2

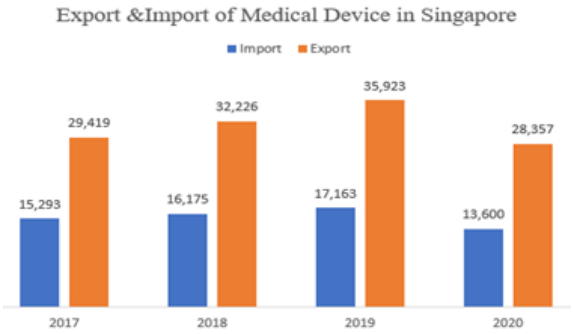


Fig.3

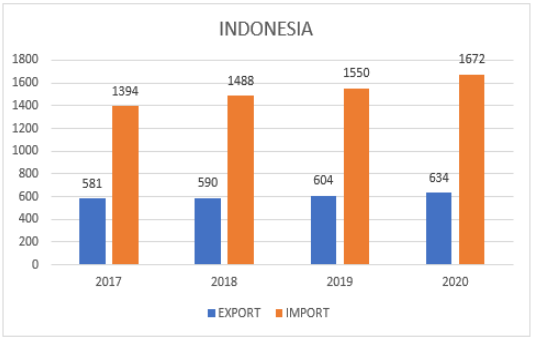


Fig.4

ASEAN Medical Device Imports & Exports

Malaysia

Is an upper-middle-income economy with the third highest purchasing power per capita in the 10-member Association of Southeast Asian Nations (ASEAN). Malaysia's healthcare expenditures are expected to double to $28 billion by 2028. The U.S. maintained its position as the top exporter of medical and dental equipment to Malaysia for three consecutive years (2017-2019), exporting $267 million in 2019. Despite the U.S. position as the leading supplier, Malaysian providers are most familiar with technologies from the United Kingdom, Australia, and Europe due to long-standing historical, education, and socio-economic connections. For 2019, the US is the leading exporter of medical instruments and appliances including electro-medical and sight-testing, and dental fittings and accessories. It is ranked second for x-rays, dental cement, fillings, bone reconstruction cement, and medical lubricating gel for operations and physical examinations. Cameras for the medical and surgical field, forensic and criminology use is ranked third.

In 2019, Malaysia's imports of the medical device industry were USD$1,13 billion, and U.S. products represented 23.5 percent of the import market and are the top exporting country of medical devices to Malaysia. In addition to the U.S., other top exporters of medical devices to Malaysia are Japan, Germany, Singapore, China, Mexico, South Korea, France, Switzerland, Netherlands, and Thailand. In Malaysia, the type of medical devices imported and exported differ significantly while the import and export countries are similar. Malaysia usually imports higher classification/ category of medical devices not manufactured locally.

There is a slight decrease in exports from Malaysia in 2019 due to the U.S.- China trade war. Top export destinations for Malaysian products are the United States, Germany, Japan, Netherlands, Belgium, China, Singapore, Australia, Ireland, South Korea, Indonesia, and Brazil. Malaysia is the world's largest medical gloves producer. Major Malaysian export categories are: surgical and examination gloves, other medical instruments, apparatus, and appliances, catheters, syringes, needles and sutures, electromedical equipment, ophthalmic lenses including contact lenses, dental devices and appliances, medical and surgical X-ray apparatus, and medical furniture.

Thailand

In 2020, the value of Thailand's medical device market was approximately $6 billion. In 2020, to cope with Covid-19, local manufacturers increased their production of personal protective equipment (PPE). Although imports of medical devices used for Covid-19 patients, such as ventilators, increased, imports of medical devices, in general, decreased by approximately 20 percent. That is because the majority of public and private hospitals have focused their budgets on Covid-19 treatment.

In April 2021, the Thai Food and Drug Administration (Thai FDA) issued new medical device regulations as part of an effort to align the country's regulatory system with rules established in the ASEAN Medical Device Directive (AMDD). The new regulations require technical data for all medical devices: this data is to be submitted using the ASEAN Common Submission Dossier Template format. There is also a new fee schedule with increased application fees.

Singapore's healthcare market is expected to grow to $49.4 billion by 2029. Healthcare spending, comprising both public and private healthcare expenditure, is expected to account for 5.9% of GDP and could go up to 9% by 2029. This increase is largely attributed to rising government spending on healthcare, as well as the local population's consumption of healthcare services, given the aging population and a trend towards earlier diagnosis of chronic conditions, close monitoring and follow-up. Government healthcare expenditure is estimated to grow to $36 billion by 2029 while private healthcare expenditure is forecast to be $13.5 billion, according to a Fitch Solutions market insight report.

In 2020, imports of medical equipment and supplies to Singapore increased by 6% over the previous year. U.S. medical equipment and supplies accounted for 22% of market share in 2020 and this has averaged between 22-26% over the last few years. On average, more than 70% of products imported into Singapore are subsequently re-exported. The outlook for 2021 will likely see an increase in imports and local production. This is due to the ongoing global pandemic, stabilizing of supply chains, calibrated opening of borders and a slow return to normalcy. Medical supplies including test kits, vaccines and personal protective equipment will continue to see demand as these are deemed essential. Based on available data, the market for medical devices is anticipated to grow this year and imports are expected to increase by approximately 8%.

Medical devices are regulated under the Health Products Act and Health Products (Medical Devices) regulations. Singapore's Health Sciences Authority (HSA) oversees the system of statutory control aimed to safeguard the quality, safety and efficacy of medical devices available in Singapore. Almost all medical devices are regulated. Class A medical devices supplied in a non-sterile state are exempted, however, Class A sterile, Class B, C, and D medical devices are subject to product registration requirements. Classification rules are adopted from the guidance developed by the Global Harmonization Task Force (GHTF).

The Ministry of Health aims to license telemedicine services in mid-2022 as part of the phasing in of the upcoming Healthcare Services Act. The Health Services Bill is expected to replace the Private Hospitals and Medical Clinics Act in 2023. The broadened scope of this new Act will include healthcare services, allied health and nursing services, traditional medicine and complementary and alternative medicine.

ASEAN has been developing a uniform system for registering and assessing medical devices across the ten-member countries. Various ASEAN economies have started adoption of the ASEAN Medical Device Directive (AMDD). This requires ASEAN countries to adopt uniform classification criteria for medical devices. This bodes well for U.S. medical device manufacturers as they will be able to easily access a common medical device market with a market size of more than 600 million people. Adherence to the basic principles of the AMDD in ASEAN will likely take place over the next few years.

Indonesia

As the fourth most populous country in the world, Indonesia's medical device and equipment sector presents excellent opportunities for U.S. manufacturers of innovative products. Although the government has implemented local content requirements and import tariffs, Indonesia continues to rely on imported innovative medical devices and equipment. Total imports of medical devices and equipment grew from $1,488 million in 2018 to $1,550 million in 2019 and are expected to reach $1,627 million in 2020. China was the leading supplier in 2019, with an import share of over 20 percent, Germany was the number two supplier, accounting 15 percent of total imports. And U.S. products accounted for approximately 11 percent of imports

Vietnam

Economic growth and demographic changes are driving demand for healthcare services throughout Vietnam, and not just in the two economic centers of Hanoi and Ho Chi Minh City. Public, provincial-level hospitals funded by the governments are undergoing upgrades of their facilities and opening new departments for specialty treatment. Such developments are creating new opportunities for medical

devices in Vietnam. The country represents a potentially large healthcare and medical equipment market. According to Business Monitor International (BMI), Vietnam's healthcare expenditure was estimated at $16.1 billion in 2017, which represented 7.5 percent of the country's GDP. BMI forecasts that healthcare spending will grow to $22.7 billion in 2021, recording a compound annual growth rate (CAGR) of approximately 12.5% from 2017 to 2021. In particular, Vietnam's public healthcare expenditure is predicted to increase at a CAGR 9.5% in the period of 2016–2021 compared with 17.2% in the period of 2011-2016. This is partly due to the government's effort in promoting partnerships between public and private healthcare providers to share the cost. Private healthcare expenditure is expected to grow at a CAGR of 7.5%, with a large part of the growth due to increased insurance coverage for employees.

4. Conclusion

The market potential for medical devices in the region is immense. With the exception of Singapore, the local medical device manufacturing markets in the ASEAN countries are not sophisticated, relative to more developed economies. In other words, not many medical devices are made by local manufacturers. For example, the Philippines imports 100 percent of its medical equipment, while Vietnam, Indonesia and Thailand import more than 85 percent of their medical devices. Just as the region's member countries are diverse in terms of development, economy, religion and culture, opportunities in the health care market are heterogeneous as well. Considering this, product segmentation will be one of the best strategies to enter the market. For example, those that produce higher end devices can focus on Singapore, which is wealthy, before expanding into middle-income economies like Malaysia and Thailand. Meanwhile, lower-end devices would sell well in price-sensitive market such as Vietnam and the Philippines, which explains the growing presence of inexpensive equipment from China and South Korea. Aside from the aforementioned growth drivers, the ASEAN medical device market still has ample room for growth, and market access and penetration are expected to improve in the coming years, with the signing of the ASEAN Medical Device Directive (AMDD) in 2015 by all 10 ASEAN countries. The agreement, scheduled to take effect in 2020, aims to harmonize medical device regulations and common technical documents, allowing for better penetration of medical devices in the region. Although the AMDD will not create a single market like the EU, where a product certified for sale in one member state can be sold in all others, the agreement will make it easier for an organization that registers a medical device in one ASEAN country to be registered in other member countries.

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