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REGISTRATION AND APPROVAL PROCESS OF MEDICAL DEVICES IN INDIA AND SINGAPORE

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Abstract:

A medical device is any device intended to be used for medical purpose. Thus what differentiates a medical device from an everyday device is its intended use. The CDSCO is the key medical regulatory organization in India science and technology and the ministry of health and family welfare. The approval and registration process and the recent market growth of medical devices is prepared and compared CDSCO medical regulatory organization with that of the medical device branch of health sciences authority (HSA) Which is the member of associate of south east asian nations(ASEAN).So my discussion is about comparison, registration and approval process of medical devices in India and Singapore.

Keywords: *Medical device approval process, regulatory requirements, registration process, market growth.*

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INTRODUCTION TO MEDICAL DEVICE:

Definition:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 medical purpose(s) of [1]:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, 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 devices

[1] Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. The term ―medical device‖ includes such technologically simple items as ice bags and tongue depressors on one end of the continuum and very sophisticated items such as cardiac pacemakers and proton therapy devices on the other end. Broadly based on the function of medical device they may be classified as preventive care device, assistive care device, diagnostic device and therapeutic device. Perhaps these are the unique challenges like safety concerns and diversity of products coupled with the sheer number of different devices in market that makes the development of an effective and efficient regulatory scheme a unique challenge for domestic as well as international regulatory bodies. Regulators and governments count on standards to help develop better regulation.

A medical device is any device intended to be used for medical purposes. Thus what differentiates a medical device from an everyday device is its intended use. Medical devices benefit patients by helping health care providers diagnose and treat patients and helping patients overcome sickness or disease, improving their quality of life. Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country. As a general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase.

Some more examples of Medical Devices:

- Band aids
- RMI
- Bone screws both removable or permanent
- Syringes
- Dental implants
- Defibrillator
- ECG

CLASSIFICATION OF MEDICAL DEVICES:

	Class A	Class B	Class C	Class D
Risk level	Low Risk	Low-moderate Risk	Moderate-high Risk	High Risk
Example	Thermometers / tongue depressors	Hypodermic Needles / suction equipment	Lung ventilator / bone fixation plate	Heart valves / implantable defibrillator
Certification by Notified body as part of Conformity assessment	Not required. Sole responsibility of manufacturer	Yes, for the manufacturing facility quality management system	Yes, for the design and manufacture of MD	Yes, for the design and manufacture of MD
ICAC marking	Required	Required	Required	Required
Registration with CLAA	Required	Required	Required	Required
Manufacturing Licence	Issued by State FDA	Issued by State FDA	Issued by CLAA	Issued by CLAA post join inspection by CLAA & State licencing authority

DEFINITIONS:

Adverse Even Effectiveness: A device is clinically effective when it produces the effect intended by the manufacturer relative to the medical conditions. For example, if a device is intended for pain relief, one expects the device to actually relieve pain and would also expect the manufacturer to possess objective evidence, such as clinical test results, that the device does in fact relieve pain. Effectiveness can be thought of as efficacy in the real world clinical environment.

Efficacy: Not used in this guideline, generally means effectiveness under an ideal controlled setting.
Incident: An unusual (unexpected) event associated with the use of a medical device. May or may not lead to problems. All incidents should be investigated for potential problems (see section 6.3.8).
Manufacturer: Any person who produces medical devices.
Performance: Means technical performance plus effectiveness (see section 2.2).
Person: Includes an establishment (in that case, person-in-charge or person responsible).
Placing on-market: "Pre-market" and "post-market" are established regulatory terms. "Post-market" really refers to when the products are on the market. "Placing onmarket" ai 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.

INDIA:

REGULATORY BODIES [2]:
The **Central Drug Standards Control Organization (CDSCO)** is India's main regulatory body for pharmaceuticals and medical devices.
The Drug Controller General of India (DCGI) is the key official within the CDSCO. The DCGI is responsible for the approval of the manufacturing of certain drugs (vaccines, large volume parenteral, blood products, r-DNA derived), specific medical devices, and new drugs.
In India, the manufacturing, import, sale, and distribution of medical devices are regulated under **India's Drugs & Cosmetic Act and Rules (DCA**).

Regulations on Medical Devices in India [3]:
Undoubtedly, the medical devices and surgical instruments are currently not covered under the regulatory framework in India. However, any device which is intended for internal or external use in the diagnosis, treatment, mitigation or prevention of

disease or disorder in human beings or animals, as may be specified by the Central Government by notification in the Official Gazette would be considered as a drug under the D&C Act and provisions of D&C Act and Rules made therein would be applicable on such device. From time to time, Ministry of Health and Family Welfare, Government of India vide gazette notifications has notified certain medical devices as drugs under the D&C Act.

Prior to 2005, only medical devices such as disposable hypodermic syringes, tubal rings, condoms, metered dose inhalers, were required to be registered in India. In 2005, the Ministry of Health and Family Welfare (MOHFW) vide gazette notification dated 6 October 2005[5] further notified 10 sterile devices ("Notified Medical Devices") to be considered as drugs and consequently regulated their import, sale and manufacture under Section 3(b) (iv) (defined below) of the D&C Act.

APPROVAL PROCESS OF MEDICAL DEVICES IN INDIA [4]:

Step 1:
Medical devices and IVDs are regulated by the Drug Controller General of India (DCGI) within the Central Drugs Standard Control Organization (CDSCO), part of the Ministry of Health and Family Welfare. The regulatory framework for medical devices is based on the Medical Device Rules, 2017. Only a limited number of medical devices and IVDs require registration in India. A full list can be found in the CDSCO's List of Medical Devices and In Vitro Diagnostics Along with their Risk Class**.**

Step 2:
Appoint an India Authorized Agent to interact with the CDSCO on your behalf. Your Agent must have a valid wholesale license (Forms 20B and 21B/21C), and be granted Power of Attorney to manage your registration and device importation in India.

Step 3:
Some IVDs require in-country performance testing through the National Institute of Biological (NIB).

Step 4:
Compile device application (Form MD-15), including manufacturing facility information, device technical information, ISO 13485 certificate, IFU, testing results (if applicable), clinical data (if applicable), proof of approval in the US, EU, Australia, Canada, or Japan, plus proof of approval in your home country (satisfied by CFS/CFG).

Step 5
File registration applications with the CDSCO and pay fees. All documents must be in English.

Step 6
The CDSCO reviews applications and may require a Technical Presentation. Novel devices will also undergo a Subject Expert Committee (SEC) review.

Step 7
The CDSCO will issue a Registration Certificate. The Certificate does not expire; however, registration maintenance fees are due every five years.

Step 8
Once approved, only your India Authorized Agent may import products. However, you can obtain multiple registrations for the same device through different Authorized Agents

REGISTRATION OF MEDICAL DEVICES [5]:

Medical devices defined as drugs must be registered with the Ministry of Health and have an import license to be sold in India. Other devices are not subject to this yet but will be under the new legislation. Medical devices not defined as drugs only require an import license. Medical devices defined as drugs are subject to the current legislation the Drug and Cosmetics Act and the Guidelines for Import and Manufacture of Medical Devices.

Quality systems for medical devices do not exist, although CE-marked or FDA approved products are preferred because of their quality and performance. Manufacturers of medical devices defined as drugs must apply Good Manufacturing Practices (GMP) and conduct suitable tests to prove the product quality. The quality systems shall concern design, development and manufacture. This kind of devices also requires risk management in form of ISO 14971.

The registration shall be done according to Rule 24A of the Drugs and Cosmetic Act and Form 40 shall be filed. The applicant can be the manufacturer, the importer or the responsible agent in India.

The Drugs Controller General India (DCG (I)) wants applicant details such as name, address and contact number of the applicant. The department also wants name and addresses of the manufacturer and the manufacturing premises, the importer, the local authorized representative and the local manufacturer if there is one. A copy of the Plant Master File shall be submitted with the application. The information required in the Plant Master File is described in the Clarifications on Guidelines for Import and Manufacture of Medical Devices.

Information on approval in other countries such as US clearance, CE certificate or approval in Australia, Canada or Japan shall be documented and copies of ISO or EN certificates submitted. A list of countries where the product is sold and a list of countries

where the product has been withdrawn from the market and the reasons for the withdrawal are required.

Product information, a GMP certificate and a master file are necessary. The master file shall have a description of components and materials used and information on the manufacturing process including flow charts, quality assurance procedures and process controls, risk management according to ISO 14971 and test protocols and reports for stability, biocompatibility, toxicology and validation/verification of sterilization where these tests are applicable.
Labeling of devices according to GHTF guidelines or ISO specifications is accepted.

MARKET GROWTH [6]:

According to a recent study released by ResearchAndMarkets.com, the global medical device market is expected to reach $409.5 billion by 2023, increasing at a compound annual growth rate of 4.5%. Key factors driving this growth include the rapidly aging global population, innovations in technology, and the rising prevalence of cardiovascular diseases and other chronic ailments.

The increase in cardiovascular diseases is particularly affecting the cardiology equipment sector, with advancements in electrocardiographic technologies dominating headlines lately. Globally speaking, the U.S. cardiovascular market is particularly hot—due, in large part, to the nation's propensity to adopt new technologies, as well as increasing research activities pertaining to the development of new cardiac technologies.

It's a good thing, indeed, researchers say, since although healthcare professionals know very well that life expectancy and emerging economies are increasing expenditure Medical Devices Market Overview

Both the global medical device market and global medical equipment market are witnessing a surge in technology-based expansion. Technologies such as digital solutions, cloud solutions, remote care, and telehealth are some examples driving the growth of medical device and medical equipment industry. Other important trends propelling the growth of this sector are a rise in chronic diseases, increase in healthcare expenditure government support for technologically superior devices.

SINGAPORE:

Regulatory bodies:

Medical devices in Singapore are regulated by the Medical Device Branch of the Health Sciences Authority (HSA). Singapore is a member of the Association of Southeast Asian Nations (ASEAN) and its regulatory system is based on the Health Products Act 2007 and Health Products (Medical Devices).

About Medical Devices Regulations:

In Singapore, medical devices are regulated by the HSA to safeguard public health and safety. They are defined as health products which have a physical or mechanical effect when used on human bodies and are used to:
Diagnose, alleviate or treat a medical condition
E.g. X-ray machines, contact lenses, artificial (prosthetic) knee
Measure or monitor functions of the body
E.g. blood pressure or blood sugar monitoring machines
Products which are used to maintain or support general well-being, such as body toning equipment, magnetic accessories and massagers, are **NOT** medical devices and hence not regulated by HSA.
The laws which govern medical devices sold in Singapore are the Health Products Act (Act) and Health Products (Medical Devices) Regulations. All product owners are required under these laws to register their medical devices and obtain the dealer's license with HAS [7].

THE MEDICAL DEVICE APPROVAL PROCESS IN SINGAPORE EXPLAINED [8]:

Step 1
Medical Devices in Singapore are governed by the Health Sciences Authority (HSA). Determine the classification of your medical device according to HSA Guidance GN-13.
Class A products which are non-sterile do not have any registration requirements, and may skip directly to Importation. For Class A sterile devices, and Classes B, C, and D, follow the steps below.
Step 2
For systems, product families or other multi-component devices, determine your most favorable grouping strategy according to HSA Guidance GN-12.
Step 3
Appoint a Singapore Registrant to coordinate and submit your device registration application to the HSA.
Step 4
For classes B, C and D, if your device has been approved for sale in one or more reference markets (Australia, Canada, the Europe, Japan or the USA)

qualify for an Abridged, Expedited, or Immediate (Class B only) submission process.

Step 5

Prepare Submission Dossier using ASEAN Common Submission Dossier Template (CSDT) format. Provide proof of compliance with reference market's QMS requirements. Abridged/Expedited submission: Summary data can be submitted for pre-clinical and clinical data. Additional details for Classes B, C, and D may be found in HSA Guidance GN-15.

Step 6

Registrant submits application electronically via the Medical Device Information and Communication System (MEDICS). Pay fee.

Step 7

Appoint a registered importer to bring your device into Singapore.

Step 8

For Class A Sterile devices, HSA verifies classification.

For Classes B, C, and D devices, HSA verifies classification and performs detailed evaluation of your application.

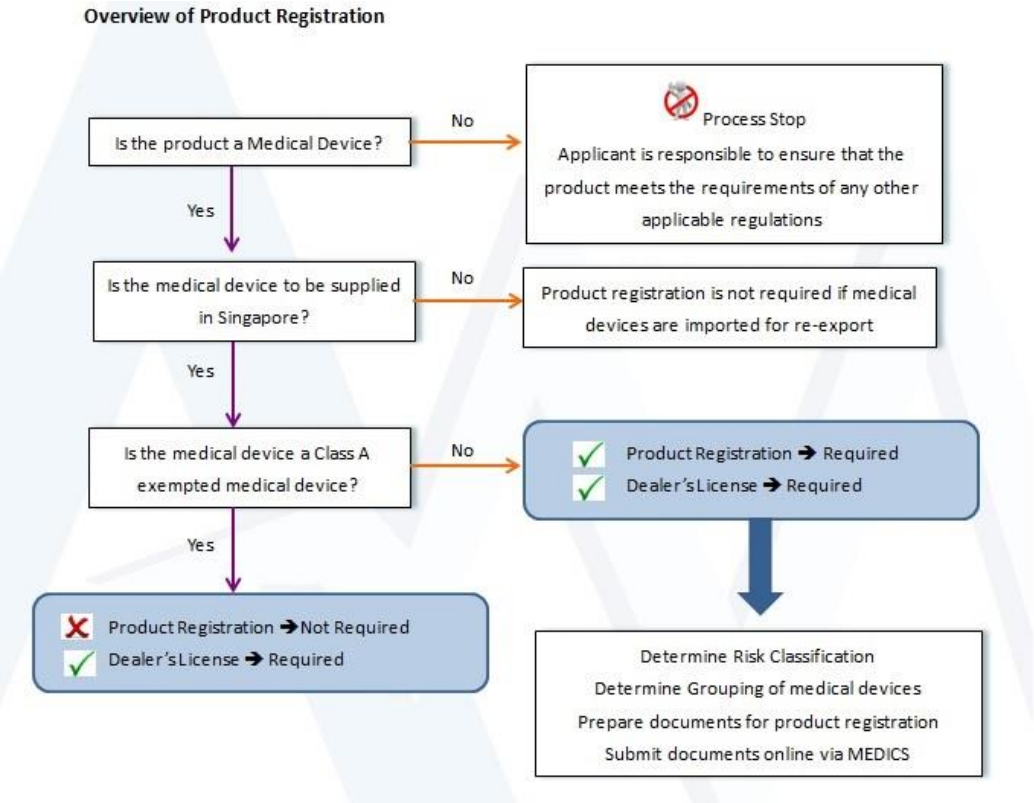
Step9

you may now begin marketing your device in Singapore. Registrations do not expire but you must pay fees annually to maintain your registrationsselling or dealing with them.

Registering medical devices in Singapore [9]:

All healthcare facilities or other companies distributing medical equipment in Singapore are required to register all the devices they **import**. In order to do so, they must file an application form with the HSA through the Medical Device Information and Communication Systems. They will receive a Client Registration and Identification Service (CRIS) account through which they will be able to register their products.

Our Singapore company formation agents can offer more information on applying for special licenses and permits when importing goods into the city-state.



MARKET GROWTH:

Singapore Medical Device Market Overview:

Singapore Medical device revenue increased at a double digit CAGR during 2012-2017. The market is in the growing stage with rise in number of foreign players. This was driven by expansion of healthcare institutions and increased demand for home care devices such as Elderly Care -Monitoring Systems

(sensors at home, applications, and wearable devices). Singaporeans' strong demand for better healthcare creates an excellent market for foreign medical device companies, who supply more than 85% of the country's devices. Leading importers include the US, Germany and Japan. At present, more than 60% of products imported into Singapore are subsequently re-exported.

Singapore Medical Device Market Segmentation:
By type of Medical Device: Consumables have accounted for the largest share in terms of revenues in Singapore Medical Devices market in 2017. This is followed by diagnostic imaging products, patient's aids, orthopedic & prosthetics and dental products. Others which include Point of Care Testing devices, radiation oncology devices, therapy system and testing and measurement systems have accounted for remaining share of the overall market revenue.

By End Users: Ministry of Health which controls most of the hospitals and significant proportion of the clinics in Singapore has accounted for largest share of the medical devices in Singapore in 2017. Other healthcare institutions such as private hospitals and clinical laboratories have accounted for the remaining share.

Competitive Landscape of Singapore Medical Device Market:
The medical device market in Singapore is fragmented with increasing focus on providing medical products, services and data intelligence services to its end users (public hospitals, private hospitals and others) to aid in delivering high quality care in a cost effective way to their patients. Market players are competing on product customization and technology.

Domestic manufacturers focus on consumables and foreign players focus on high-end devices. International players have started to focus on new consumer centric models such as e-commerce, home health care, and DIY health concepts. Major companies include QT Vascular, Biosensors International, Becton Dickinson, Optimal Medical Products Pte Ltd, B. Braun Singapore Pte Ltd, Alcare Pharmaceuticals, and Kingston Medical Supplies Pte Ltd

Singapore Medical Devices Market Future Potential:
The market is estimated to register single digit CAGR growth during 2017-2022. Digitalization is a key trend in healthcare with the electronic patient record in place and improving communication systems are being considered. Telehealth and remote monitoring are being trialed for future implementation.

There is also a shift from treatment to preventive care and health promotion, where mobile applications and wearable devices or the Internet of Things will see an increased uptake. The opportunities are in personal health management, health screening, disease management, preventive care products, access to homecare resources and support, health IT solutions, data sharing, and advanced technologies that would enable integrated healthcare [10].

COMPARISION TABLE FOR MEDICAL DEVICES TO INDIA AND SINGAPORE:

S.no.	MEDICAL DEVICES	INDIA	SINGAPORE
1.	Regulatory Body	CDSCO (Central Drug Standard Control Organization)	HAS (Health Sciences Authority)
2.	Classification	No specific classification	HAS imposes different registration groups for each classification
3.	Legal basis	Drug & Cosmetic Act 1940	HAS (Health Sciences Authority)
4.	Registration	Notified medical devices, IVD that require registration in INDIA	For registration of medical devices the registrant is required to obtain the dealer's license from the HSA
5.	Quality system	Schedule M111, ISO 13485	ISO 13485 OR GDPMDS certificate
6.	Verification	File application, as well as verification of compliance with US,EU,AUSTRALIA	Verified under Singapore medical device register (SMDRA).90.

7.	Required documents	Cover Letter and apostil led authorization letter Filled form 40 Filled chelana for the payment of fees Power of attorney (Manufacturers authorization to his agent in INDIA) Wholesale license Notarized or apostil led certificates: free sales certificate, ISO 13485 certificate, full quality assurance certificate, CE design examination certificate 28 Declaration of conformity Inspection or audit report Device and plant master file (according to the Annexes of the respective guidance documents)	Authorized representative Product registration in ASEAN and CSDT CSDT must be in English All documents must be in PDF format
8.	Registration period	Valid for 3 years	Depending on class
9.	Language	Hindi, English	English,Chinese,Mandarin , Malay
10.	Time to approval	6-9 months	A period of 12 months from date of approval
11.	Market	Emerging market	Emerging market

CONCLUSION:

The overall study concludes that there are interesting comparisons and difference between medical devices regulatory systems across India and Singapore. In the process of medical device development lot of research work has to be carried out during the development phase .But the research related activities has to be in accordance to the procedures adopted by the health agency.

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