# Regulatory Updates on Singapore Medical Device Market

Pacific Bridge Medical
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# Outline

- Overview of Singapore
- Overview of the Medical Device Market
- Profile of Health Sciences Authority (HSA)
- Overview of the Medical Device Regulatory Framework
- Product Registration Process
- New Regulations
- Post-Marketing Surveillance Responsibilities
- Advertisement and Promotion
- Reimbursement
- Future Trends

# Overview of Singapore

# Singapore: Demographics

- Population: 4.7 million
- Life expectancy: 82 years
- Major ethnic groups
  - 77 % Chinese
  - 14% Malay
  - 8% Indian
- Language
  - Four official languages: Mandarin Chinese, English, Malay, and Tamil


Source: CIA World Factbook

# Singapore: Economy

- 2011 GDP $303.7 billion
- 2011 per capita GDP $59,813

Summary of the 2011 Singaporean medical device market:

- Total health care expenditure: $11.5 billion
- Market Size (US$ millions) $450 million
- As % of total health expenditure 4.1%
- As % of GDP 0.15%

# Singapore: Medical Device Regulatory Authorities

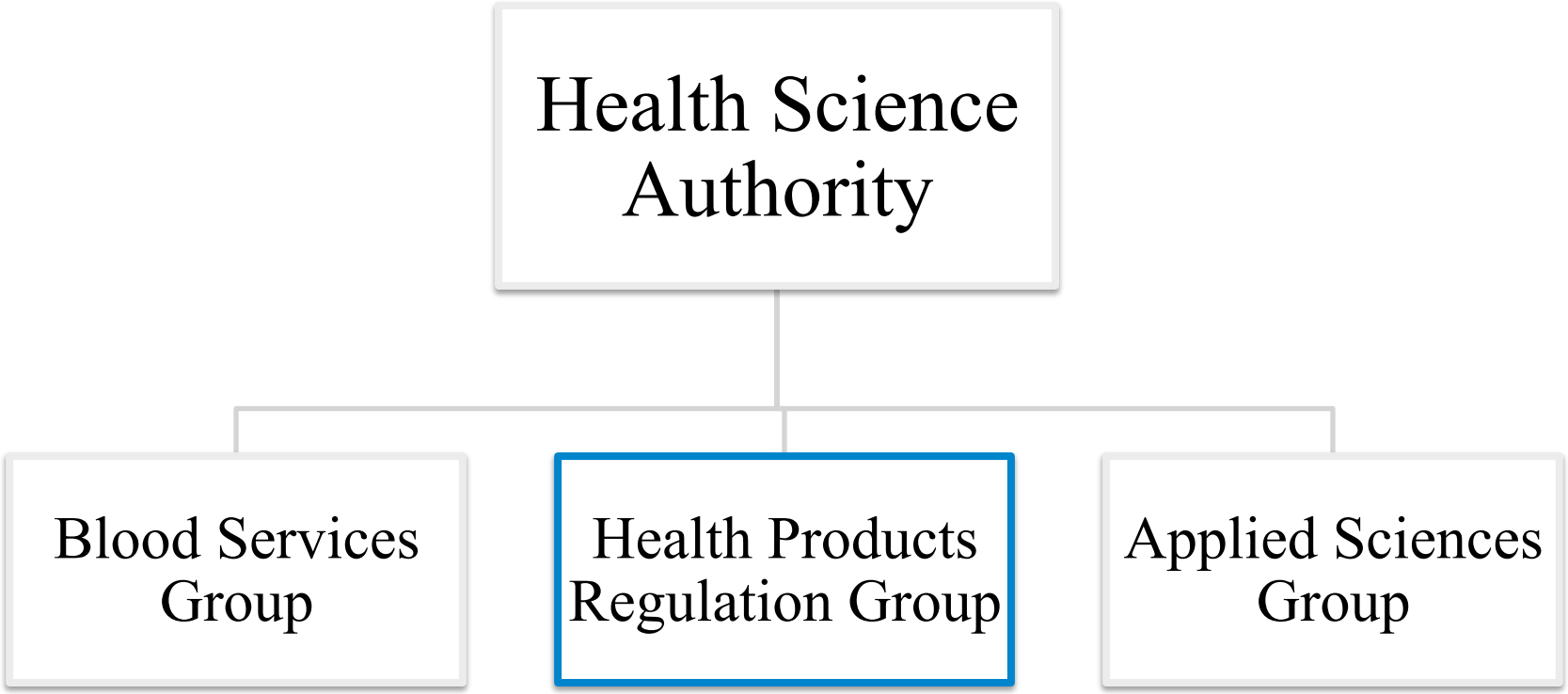
Health Sciences Authority ( HSA )

- Founded in April 1, 2001
- Equivalent to the U.S. FDA
- Responsible for the regulation of medical devices, drugs, national blood bank, and healthcare services.
- www.hsa.gov.sg

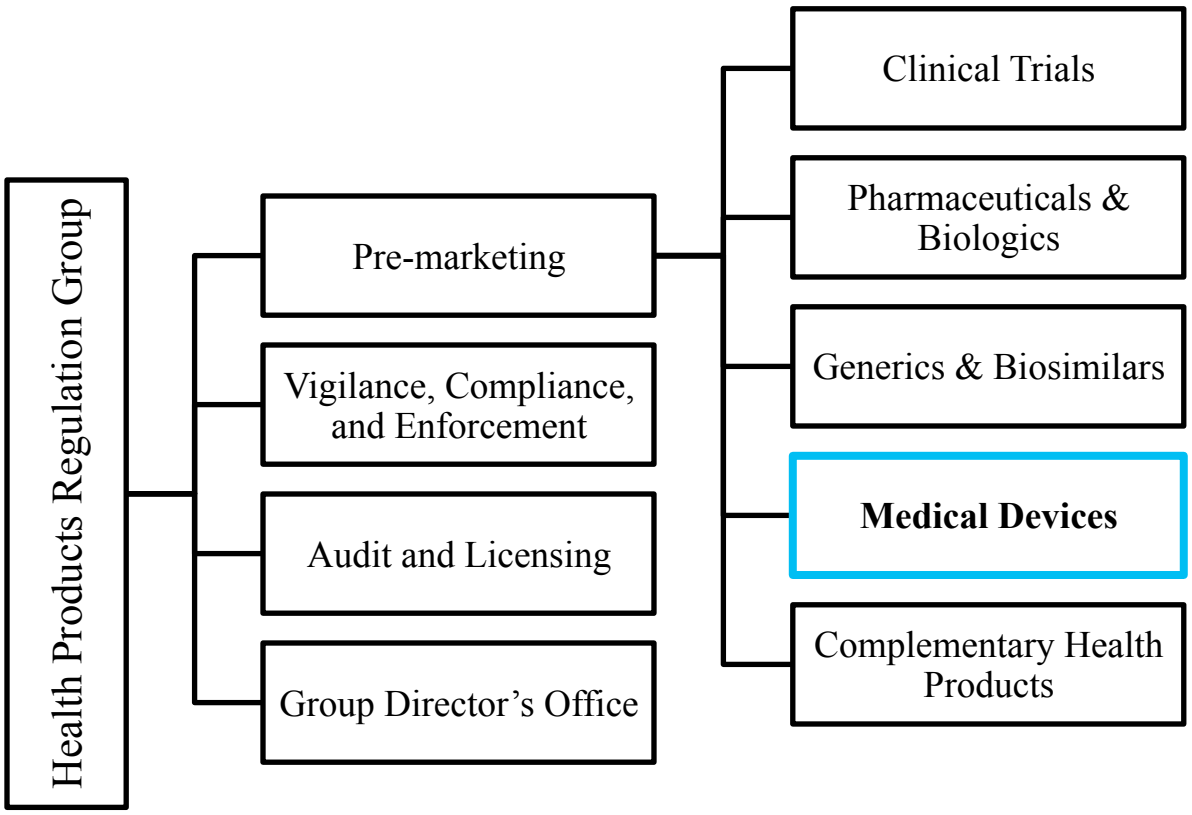
Centre for Medical Device Regulation ( CMDR )

- Conducts mandatory safety registration, certification, and inspection for certain devices.

# HSA: Organizational Structure



# Health Products Regulation Group: Organizational Structure



# HSA: Key Personnel

- Senior Executives
  - CEO and Director of Health Products Regulation: Dr. John Lim
  - Chairman: Professor Edison Liu

- Health Products Regulation Group
  - Director of Medical Device Branch: Joanna Koh
  - Acting Director of Clinical Trials: Foo Yang Tong
  - Director of Audit and Licensing: Sia Chong Hock
  - Director of Vigilance, Compliance, and Enforcement: Chan Cheng Leng

# Medical Device Regulatory Framework: Overview

- **Registration of Products**
  - Medical devices must be registered with HSA before it can be supplied in Singapore
  - Annual renewal of the listing of the device in the Register is required
  - Products can only be imported and supplied in SG if they are on the, Singapore Medical Device Register (SMDR), Transition list or through an authorisation route

- **Supply/Distribution Chain Control**

  Manufacturer, Importer, Wholesaler licences

- **Post-marketing activity**
  - Advertising & promotion
  - Recalls
  - Distribution Records
  - Clinical Trials

# Medical Device Regulatory Framework: Definition of a Registrant

REGISTRANT, in relation to a registered "medical device" means the person who applied for and obtained the registration of the "medical device" under the Health Products Act

- Required to register with HSA to submit product registration applications via Medical Device Information & Communication System (MEDICS)
- Must be Singapore-based companies registered with Accounting and Corporate Regulatory Authority (ACRA)
- Need to obtain a Letter of Authorization from the Product Owner for each product registration application submitted

# Medical Device Regulatory Framework
# Definition & Classification of Medical Devices

- Formal definition of a medical device in Singapore:

**'Medical device'** means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article;

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- 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
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

# Medical Device Regulatory Framework
# Classification of General Medical Devices

Risk presented by a device depends substantially on its intended purpose and effectiveness of risk management techniques applied during design, manufacture and use

**Factors influencing device classification:**

- **duration** the device is **in contact** with the body
- degree of **invasiveness**
- whether the device delivers **medicinal products or energy** to the patient
- whether intended to have a **biological effect** on the patient
- **local versus systemic effects**

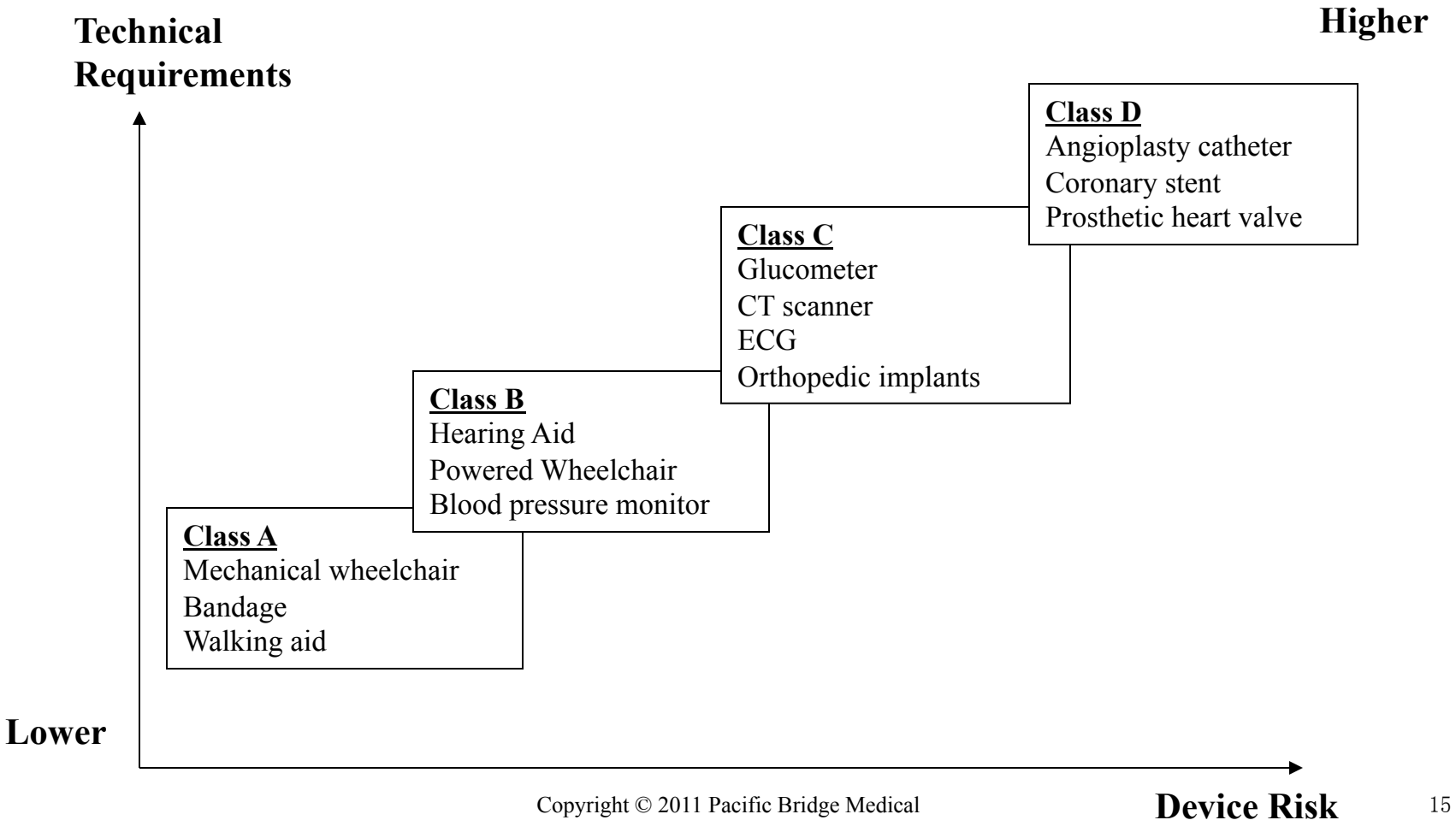
**Who is responsible for determining classification of product?**

- Risk classification is determined by **product owner**

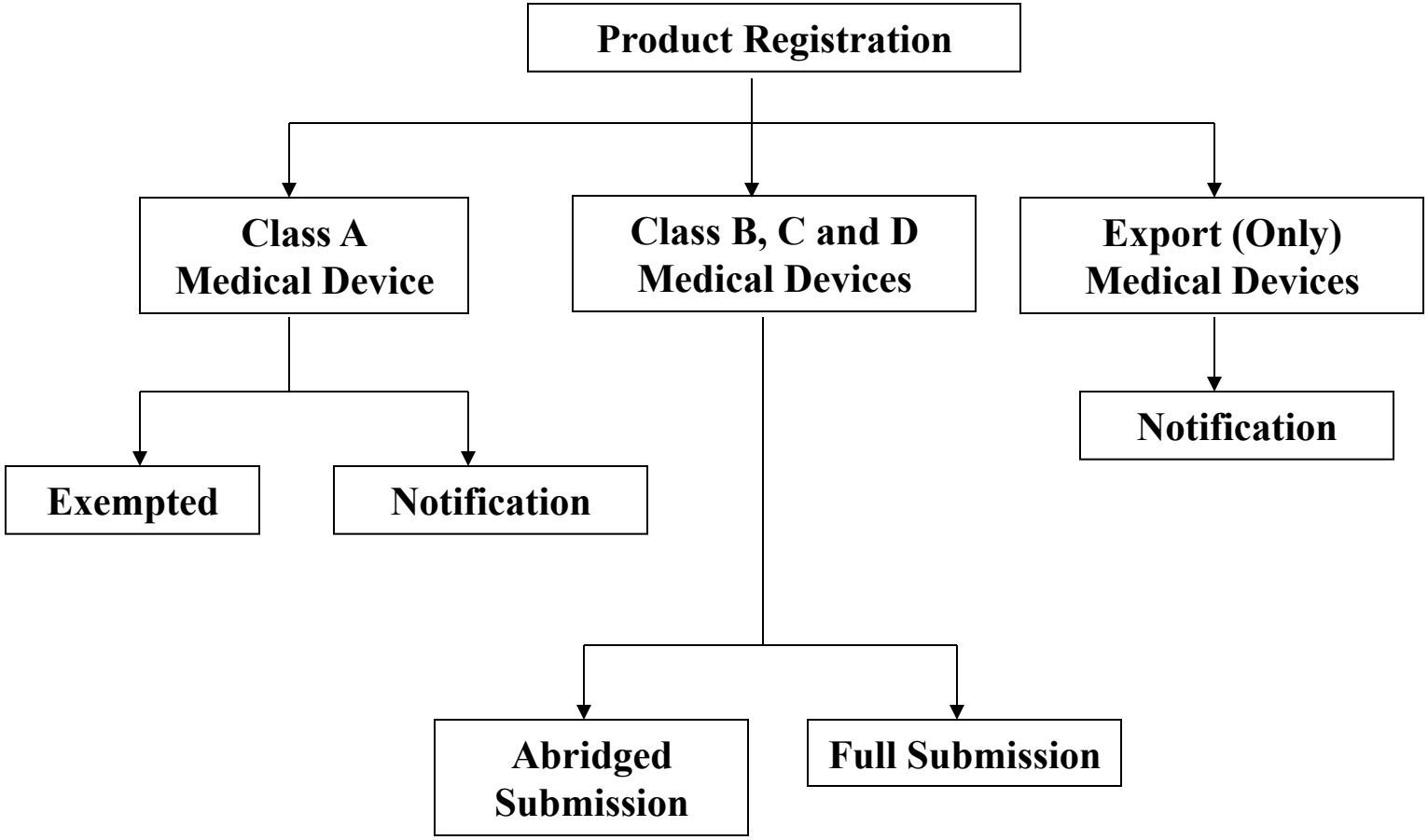
# Medical Device Regulatory Framework
# Classification of General Medical Devices

| CLASS | RISK LEVEL | DEVICE EXAMPLES |
|---|---|---|
| A | Low Risk | Surgical retractors / tongue depressors |
| B | Low-moderate Risk | Hypodermic Needles / suction equipment |
| C | Moderate-high Risk | Lung ventilator / bone fixation plate |
| D | High Risk | Heart valves / implantable defibrillator |

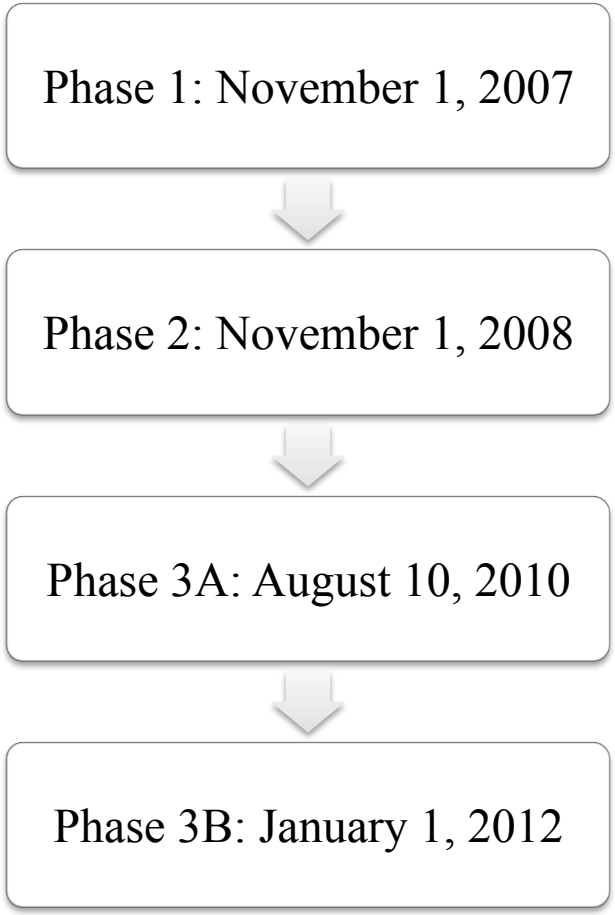
# Medical Device Regulatory Framework
# Classification of General Medical Devices



# Medical Device Regulatory Framework
# Product Registration Routes



# New Medical Device Registration Requirements
# Four Phases of Implementation



# New Medical Device Registration Requirements: Phases 1 & 2

- Phase 1: November 1, 2007
  - Dealers are required to begin reporting Field Safety Corrective Action (FSCA) and Adverse Events (AE).
  - Dealers are now required keep records of distribution and complaints.

- Phase 2: November 1, 2008
  - Dealers of medical devices begin to apply for licenses. Dealers must apply for license by the start of Phase 3A on August 10, 2010.
  - Registration of Class C and D medical devices begin. Applications for product registration must be submitted by the start of Phase 3A on August 10, 2010.
  - Registration of Class A and B medical devices begin. Registration continues until the start of Phase 3B on January 1, 2012.

# New Medical Device Registration Requirements: Phases 3A & 3B

- Phase 3A: August 10, 2010
  - All Class C and D medical device products must be registered with the HSA by this date. Products that are NOT registered are prohibited.
  - All manufacturers, importers, or wholesalers of medical devices must be licensed by this date. This is true for medical devices of all classes.

- Phase 3B: January 1, 2012
  - Class A and B medical device products must be registered with the HSA by this date.
  - All medical devices must be registered. Unregistered medical devices, regardless of class, are prohibited.

# New Medical Device Regulations: Class A & B Devices

- To be in full compliance with the new regulations for Class A and Class B medical devices, the following steps are required:
  - November 1, 2007
    - Dealers of Class A & B medical devices must begin post-marketing responsibilities. These include reporting of adverse events and defects, notification of recalls, and maintenance of distribution records.
    - False advertisements and promotions are prohibited.

# New Medical Device Regulations: Class A & B Devices

- November 1, 2008
  - Product registration of Class A & B medical devices starts.
  - Manufacturers, importers, and wholesalers of Class A & B medical devices may begin to apply for licenses from the HSA.

- November 30, 2011
  - Submit application for medical device to be listed on the Transition List.
    - Class B devices must qualify for abridged evaluation to be eligible. Criteria for eligibility for abridged evaluation will be discussed in subsequent slides.

# New Medical Device Regulations: Class A & B Devices

- November 30, 2011 cont.
  - After this date, if no application for Transition List inclusion has been submitted for a Class A or B medical device, that medical device can be sold legally until January 1, 2012. After this date, sale of the product is prohibited unless medical device approval (product license) is granted by the HSA.

# New Medical Device Regulations: Class A & B Devices

- January 1, 2012
  - Class A & B medical devices with a pending Transition List application may continue to be sold past this deadline.
  - If the application is approved, the medical device will be removed from the Transition List and will be listed on the Register.
  - If the application is rejected or withdrawn
    - The medical device will be removed from the Transition List and will be prohibited from sale.
    - The HSA will export any existing stock of the medical device from Singapore.

# New Medical Device Regulations: Class A & B Devices

- January 1, 2012 cont.
  - After this date, Class A & B devices which miss the Transition List deadline (November 30, 2011) are prohibited from sale.
    - These medical devices are considered unregistered. To be legally sold after this date, the medical device must undergo the product registration process. If approved, the medical device will be listed on the Register.

# New Medical Device Regulations: Class C & D Devices

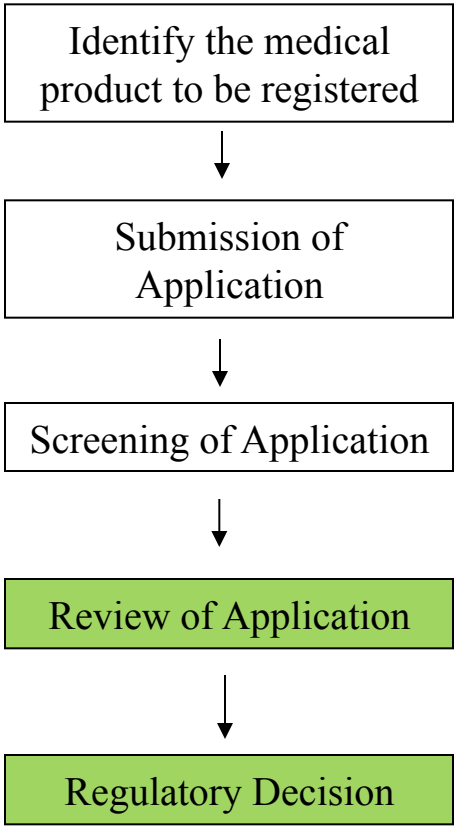
- To be in full compliance with the new regulations for Class C and Class D medical devices, the following steps are required:
  - November 1, 2007
    - Dealers of Class A & B medical devices must begin post-marketing responsibilities. These include reporting of adverse events and defects, notification of recalls, and maintenance of distribution records.
    - False advertisements and promotions are prohibited.

# New Medical Device Regulations: Class C & D Devices

- November 1, 2008
  - Product registration of Class C & D medical devices starts.
  - Manufacturers, importers, and wholesalers of Class C & D medical devices may begin to apply for licenses from the HSA.

- August 10, 2010
  - Class C & D medical devices must be registered with the HSA by this date to be legally sold. Unregistered Class C & D medical devices are prohibited.
  - Manufacturers, importers, and wholesalers of Class C & D medical devices must be licensed by the HSA to legally deal with Class C & D medical devices.

# Product Registration ("Notification"): Class A Medical Devices




**Review of Application**

•Purpose of review is to determine if:

- the Class A device is correctly classified
- the intended use or indications of use is appropriate for the design of the device

**Regulatory Decision**

•Class A devices will be listed on the Register after verification of the risk classification and product claims

# Submission Routes for Class B, C, and D Medical Devices

**Abridged Submission:**

•ONLY for medical device already registered or approved in the following reference agencies:

1. Australia – Therapeutic Goods Administration (TGA)
2. Canada – Health Canada
3. European Union – CE marked as medical device
4. Japan – Ministry of Health, Labor and Welfare (MHLW)
5. US – FDA

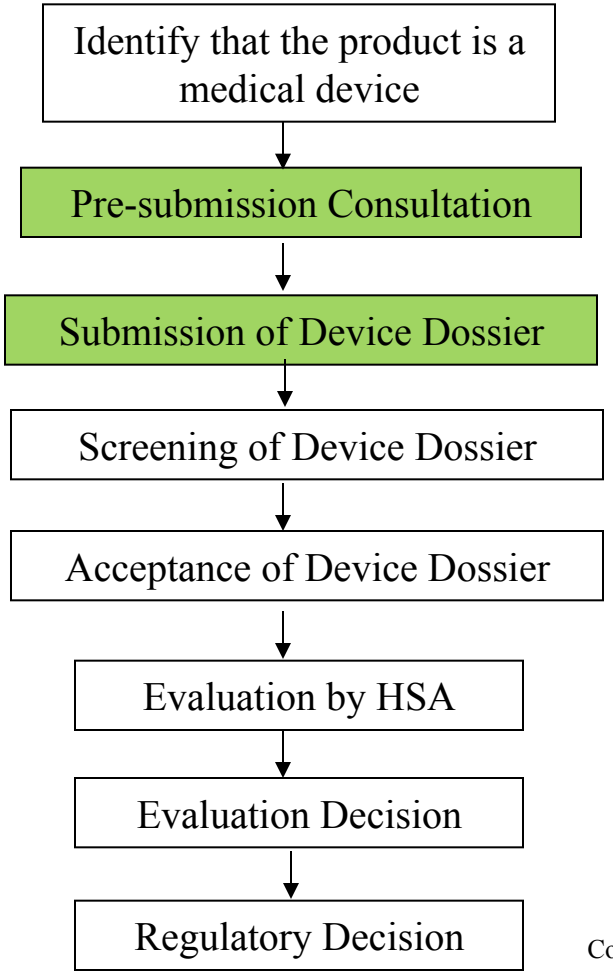
•All aspects of device **quality including packaging, labeling, instruction of use, intended of use, indications of use** of the device for sale in **Singapore** shall be the same as that approved by the **reference agency**

**Full Evaluation**

•All other medical devices that do not meet the criteria for abridged submission

•Registrants are required to submit complete and detailed data sets

# Product Registration ("Marketing Clearance"): Class B, C, and D Medical Devices (Full Evaluation)



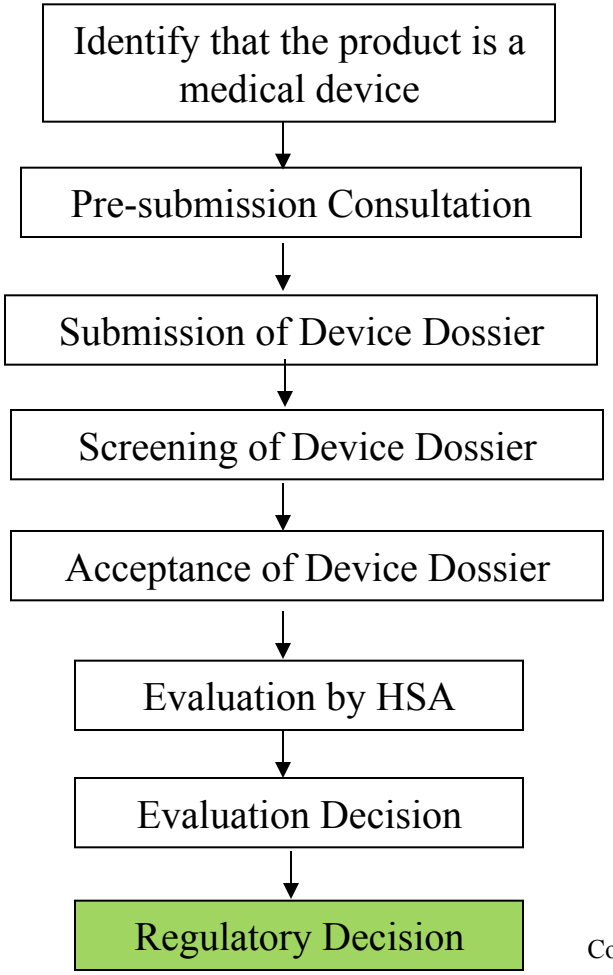

**Pre-submission Consultation**

•Registrant is advised to request for a consultation session with the Authority if there are specific issues with the submission dossier

**Submission of Device Dossier**

•Submit device dossier online via MEDICS system

# Product Registration ("Marketing Clearance"): Class B, C, and D Medical Devices (Full Evaluation)




**Regulatory Decision**

•Register-able Device – Registrant to submit a "Product Registration Application" to list the device on the Register

• Registrants to ensure full compliance with conditions of registration

[need to update this information – see GN-15 for relevant info]

# HSA Product Registration Requirements: Medical Device Dossier Preparation

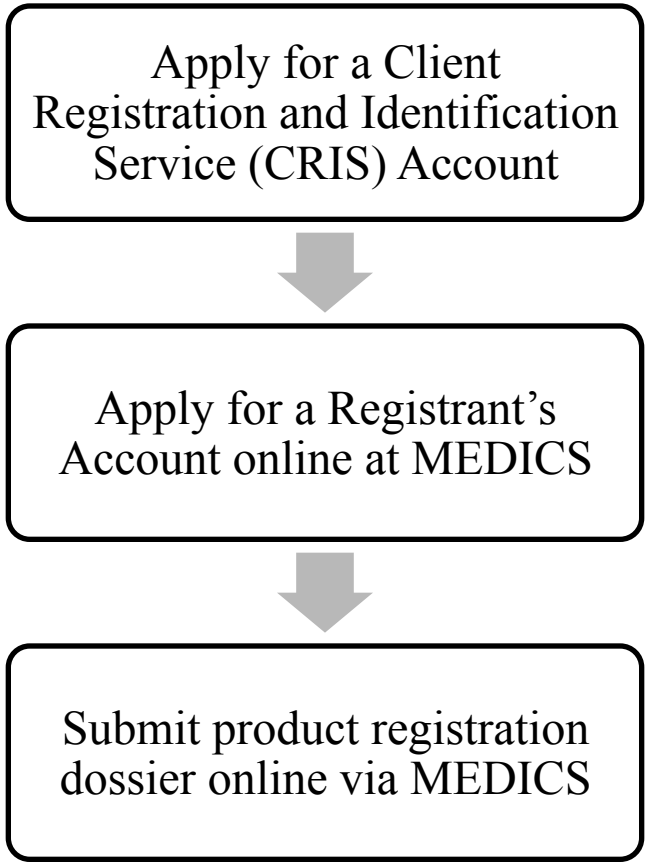
- Medical device product registration in Singapore uses the Association of Southeast Asian Nations (ASEAN) Common Submission Dossier Template (CSDT)
  - Intended to provide a common template for the submission of medical device information to regulatory authorities of ASEAN member countries (Singapore, Malaysia, Thailand, Brunei, Indonesia, Philippines, Cambodia, Laos, Myanmar, Vietnam)

# HSA Product Registration Requirements: Medical Device Dossier Preparation

- The CSDT dossier must :
  - Be prepared in English
  - Have as Annexes copies of labeling, Certificates and Reports that are referenced within the CSDT submission
  - Be signed off by the Product Owner for all Reports

- Sample components of the CSDT device dossier:
  - Description of the medical device and its features
  - Intended use, and indications
  - Instruction of use
  - Warnings, precautions, and potential adverse effects
  - Alternative therapies
  - Materials
  - Relevant data and summaries of test evaluations, such as biocompatibility

# HSA Product Registration Requirements: Medical Device Dossier Submission Procedure



# Medical Device Product Registration: Annual Renewal for Class B, C, and D Medical Devices

- Annual Renewal of Product Registration by the Registrant is required
- Renewal notices will be sent to the Registrant

# Medical Device Product Registration: Change Notification for Class B, C, and D Devices

- Registrants are required to notify the Authority for changes to any information declared at the point of application or after Registration.

- The HSA charges a set fee for each change notifications that is dependent on (1) the classification of the medical device, and (2) on whether the change is a technical or an administrative change.

- For significant changes, approval for the change must be given by HSA before the changed device products can be supplied in Singapore.

# Medical Device Product Registration: Fees & Timeframes

- No indication from the HSA on the timeframes for medical device product registration

- Required government fees:
  - Application fee
  - Evaluation fee
  - Annual retention fee for SMDR listing

# Medical Device Product Registration: Fees

- Application fee:
  - Class A: S$25 (US$20)
  - Class B, C, and D: S$500 (US$415)

- Evaluation fee:

| Risk Classification | Abridged evaluation | Full evaluation |
|---|---|---|
| Class B | S$1,800 (US$1,500) | S$3,500 (US$3,00) |
| Class C | S$3,500 (US$3,000) | S$5,700 (US$4,800) |
| Class D | S$5,700 (US$4,800) | S$11,400 (US$10,000) |

# Medical Device Product Registration: Fees

- Annual retention fee for SMDR listing:

| Risk Classification | Fees | Start of annual fee scheme |
|---|---|---|
| Class A | S$25 (US$20) | August 10, 2011 |
| Class B | S$35 (US$30) | |
| Class C | S$60 (US$50) | January 1, 2013 |
| Class D | S$120 (US$100) | |

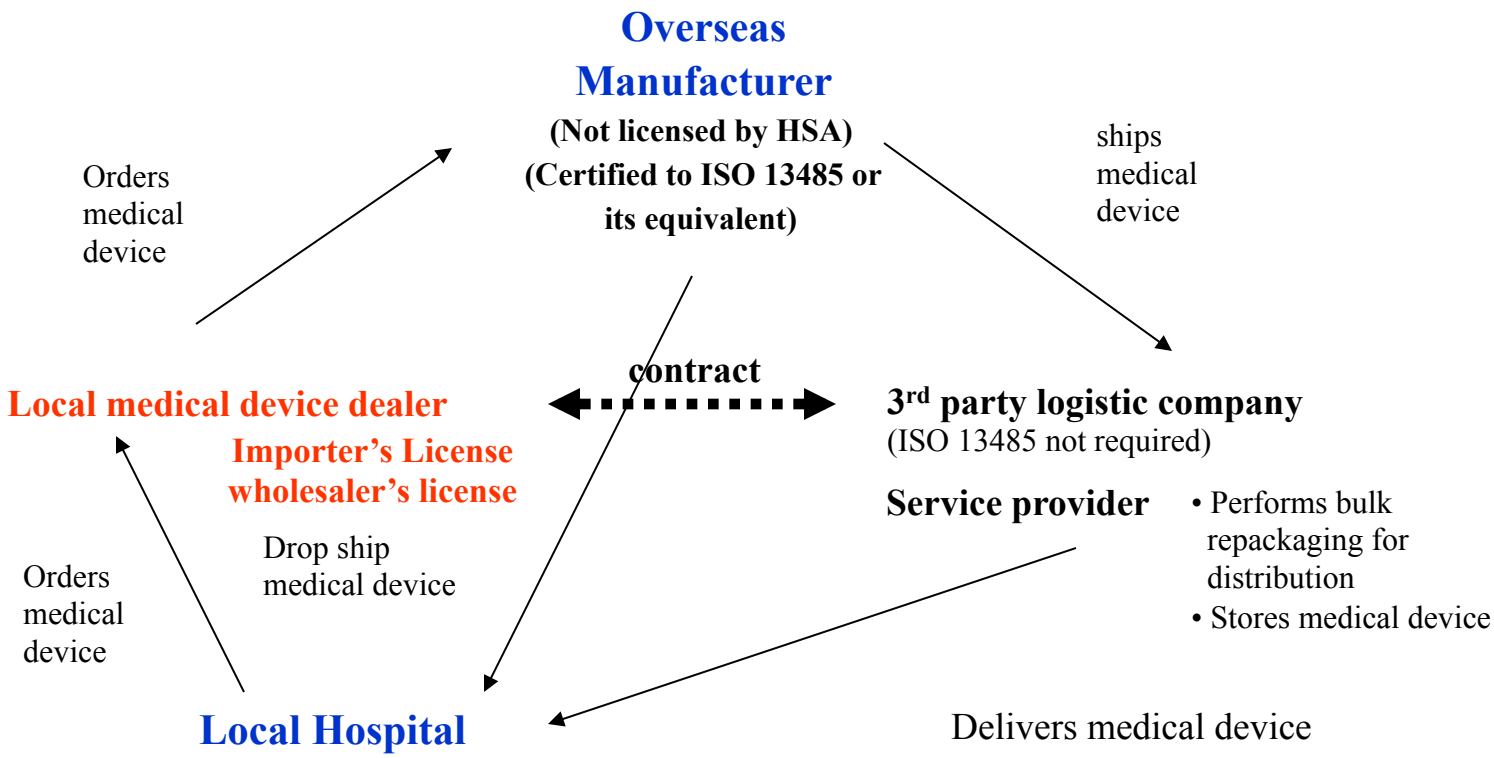
# Authorisation Routes

| Routes | Purpose |
|---|---|
| Supply on Named-Patient Basis | To seek exemption from product registration for the import and supply of an unregistered medical device for supply to named-patient |
| Authorisation Route for Supply on Request of PHMC-Licensed Facility | To seek exemption from product registration for the import and supply of an unregistered medical device to a clinical laboratory, medical clinic or private hospital licensed under the PHMC Act (Cap. 248) |
| Authorisation Route for Export of Unregistered Medical Devices | To seek exemption from product registration for the import of an unregistered medical device solely for re-export |
| Authorisation Route for Supply for Non-Clinical Purpose | To seek exemption from product registration for the import of an unregistered medical device to supply for non-clinical purpose.<br>e.g. for display at exhibition, training purposes, supply of unregistered *in-vitro* diagnostic medical device for research-use only purposes, etc |
| Authorisation Route for Import on Consignment Basis (Consignment Registered Route) | For dealer not authorised by the Registrant to seek authorisation from HSA for the import of a registered medical device |
| Authorisation Route for Import on Consignment Basis (Consignment UnRegistered Route) | To seek authorisation* to import a single consignment of low-utilisation unregistered medical devices under an entity's importer's licence. **NO SUPPLY** |

# Additional HSA Requirements: Manufacturer, Importer, and Wholesaler Licenses

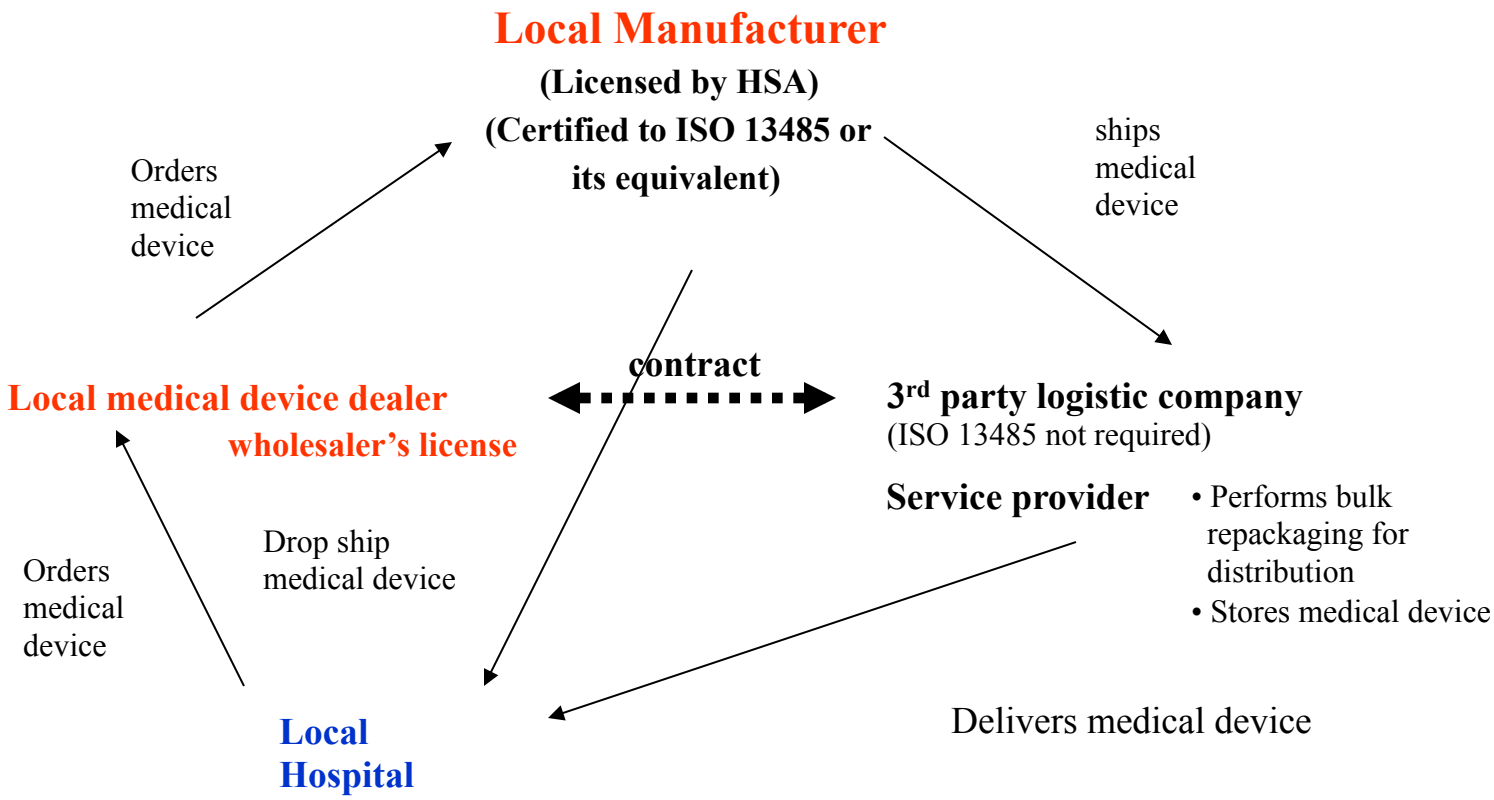
| Activities | Licenses |
| --- | --- |
| Manufacture of medical devices in Singapore | Manufacturer's License |
| Import of medical devices into Singapore | Importer's License |
| Wholesale of medical devices in Singapore, including export of medical devices out of Singapore | Wholesaler's License |

# Who needs a Singapore License?




**Important: This is a simple illustration of a typical route in which a device is imported into Singapore for use by our Hospital. It is intended to provide general guidance only, and not meant to be an interpretation of any written law**

# Who needs a Singapore License?

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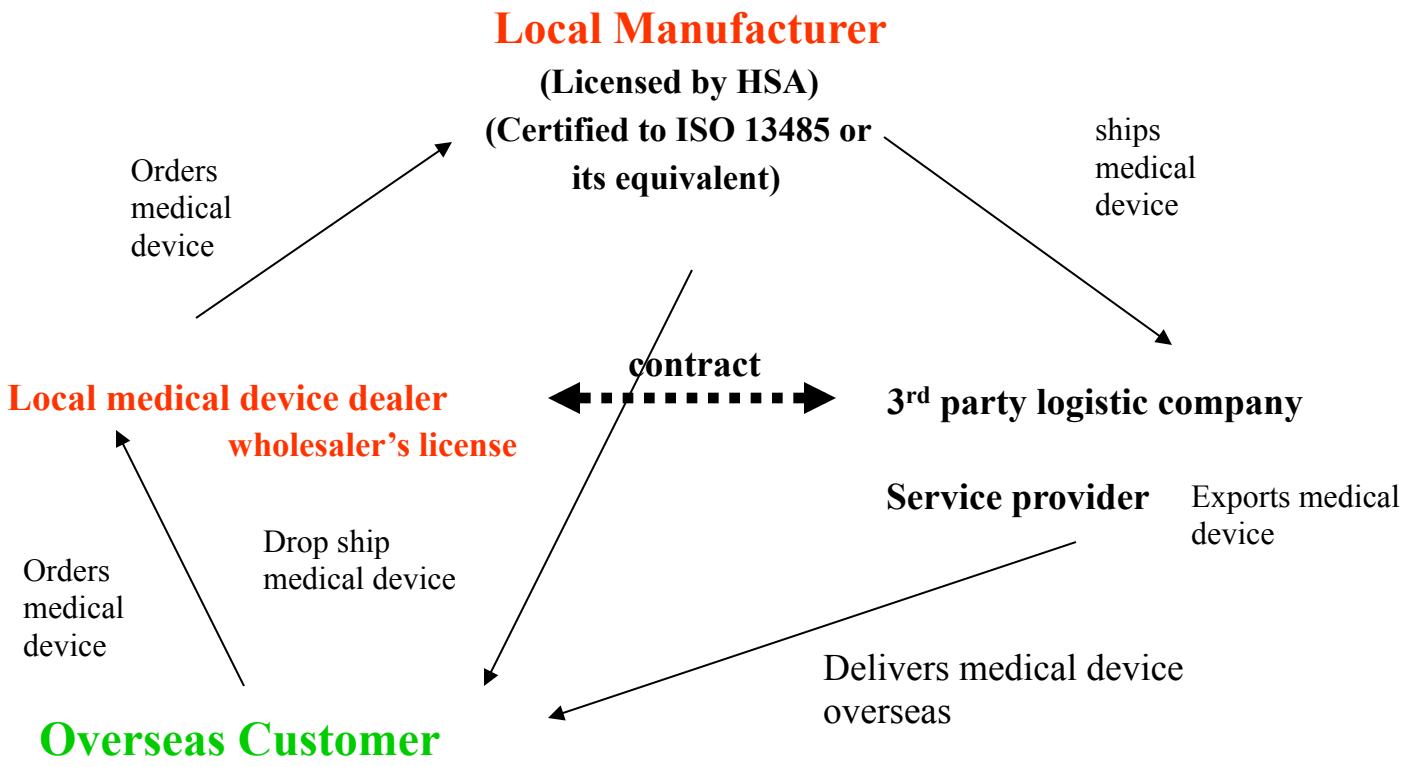


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# HSA License Requirements and Procedure

- **Manufacturer's License Requirements**
  - Quality Management System Certificate (ISO 13485:2003 certificate)
  - List of Exempted Class A medical devices manufactured
- **Importer's License Requirements**
  - Good Distribution Practice for Medical Devices (GDPMDS) certificate
  - List of Exempted Class A medical devices imported
- **Wholesaler's License Requirements**
  - GDPMDS certificate
- Procedure:
  - Apply for manufacturer's, importer's, and wholesaler's licenses online via MEDICS

# HSA License Requirements and Procedure

- Starting September 1, 2011, the HSA requires the following fee scheme for both application and renewal of dealer licenses:

| License | Fees |
|---|---|
| Manufacturer | S$1,000 (US$830) |
| Importer | S$1,000 (US$830) |
| Wholesaler | S$1,000 (US$830) |

# Good Distribution Practice for Medical Devices (GDPMDS)

- To ensure the quality of distribution chains for medical devices, such that systems are in place for
  - Proper packaging and storage
  - Documentation of supply & distribution
  - Recall reporting system
  - Adverse event assessment & reporting

- Examples of required documentation include records on
  - Site master file
  - Assembly and materials control
  - Packaging and labeling
  - Storage
  - Return and disposal

# Post-Marketing Surveillance Responsibilities: Adverse Events (AE)

- ADVERSE EVENT:
  "Any event or other occurrence, that reveals any defect in any medical device or that concerns any adverse effect arising from the use thereof."

- Medical device manufacturers, importers, and wholesalers are required to report adverse events to the HSA within a given window of time:
  - 48 hours for AEs that poses a serious public health threat
  - 10 days for AEs that has led to the death or other serious deterioration in health risk of a patient, user of the device, or any other individual

- An additional final report to follow-up is required within 30 days of filing the initial report.

# Post-Marketing Surveillance Responsibilities: Field Safety Corrective Action (FSCA) Reporting

- FIELD SAFETY CORRECTIVE ACTION (FSCA):
  "an action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device."

- The HSA may require product owners to initiate a FSCA if post market surveillance shows device use is associated with an unacceptable risk.

- Example actions:
  - Device modification, such as labeling and instructions for use
  - Device exchange, return, or destruction
  - Advice provided by the device owner regarding product use

- Product owners must submit a final report to the HSA within 21 days of FSCA initiation.

# Post-Marketing Surveillance Responsibilities: Other Post-Marketing Surveillance Responsibilities

- Complaint handling
  - Manufacturers, importers, and wholesalers of medical devices must maintain records of complaints on the medical device.
  - The HSA requires these records to be retained for 5 years past the estimated useful life of the device.

- Distribution records
  - Manufacturers, importers, exporters, wholesalers, and medical device registrants and required to record information on the distribution of medical devices.
  - Records must be maintained for the longer of two time periods: the estimated useful life of the medical device, or two years after device shipment
  - Example information:
    - Date shipped
    - Control numbers (lot, batch, or serial numbers)
    - Date shipped

# Medical Device Regulatory Framework
# Advertisement & Promotion

No person shall :

- (a) advertise any product or cause any product to be advertised as a health product if that product is not a health product; or

- (b) advertise any registered health product or cause any registered health product to be advertised in such a way as to represent the registered health product as being usable for any purpose other than that for which it has been registered.

# Medical Device Regulatory Framework
# Advertisement & Promotion

No person shall :

- (c) advertise any health product or cause any health product to be advertised in a false or misleading way.

- (d) advertise any health product or cause any health product to be advertised unless the advertisement complies with and is undertaken in accordance with such requirements as may be prescribed

# Medical Device Regulatory Framework
# Advertisement & Promotion

Penalty :

- Any person who contravenes shall be guilty of an offence and shall be liable on conviction to a fine not exceeding S$20,000 (about US $17,000) or to imprisonment for a term not exceeding 12 months or to both.

# Reimbursement

- No scheme at the present moment
- No plans at this time to implement a reimbursement system in the future

# Future trends

- The new HSA regulations are subject to change because after new medical device regulations are put into practice, the HSA may continue to amend the regulations according to what works and what does not work.
- Medical device companies are advised to regularly check in for new medical device updates in Singapore that may affect the regulation of their products and their legal compliance.
- Change notification procedures and Clinical trials requirements will be formalised and implemented

# Thank you for your consideration!

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