P04: Medical Devices Import

E356 Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management (DSCM)

E356 Topic Tree

Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- Declaration of Pharmaceutical DG for Air Transport

Product Tracing, Recall and Disposal

- Product Tracing
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics

Medical Devices

Medical devices are critical to the delivery of healthcare. The term "Medical Devices", as defined in the Health Products Act 2007, covers a wide range of medical instruments used in the treatment, mitigation, diagnosis or prevention of disease or abnormal physical condition.

- HSA is the agency that regulates medical devices in Singapore under the Health Product Act 2007 and Health Products (Medical Devices) Regulation 2010. HSA also publishes guidance documents to clarify the regulatory requirements.
- The International Medical Device Regulators Forum (IMDRF) conceived in February 2011, is a forum to discuss future directions in medical device regulatory harmonization.

What is a Medical Device?

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of

(*a*) diagnosis, prevention, monitoring, treatment or alleviation of any disease;
(*b*) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(*c*) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(*d*) supporting or sustaining life;
(*e*) control of conception;
(*f*) disinfection of medical devices;
(*g*) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body

and 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.

(as defined in Health Product Act 2007)

Medical Device Classification

- **Medical devices may be classified into 4 risk classes.**

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

- **Classification of a medical device will depend upon a series of factors, including:**
  - How long the device is intended to be in use
  - Whether the device is invasive
  - Whether the device is implantable
  - Whether the device is active
  - Whether the device contains a drug or biologic component

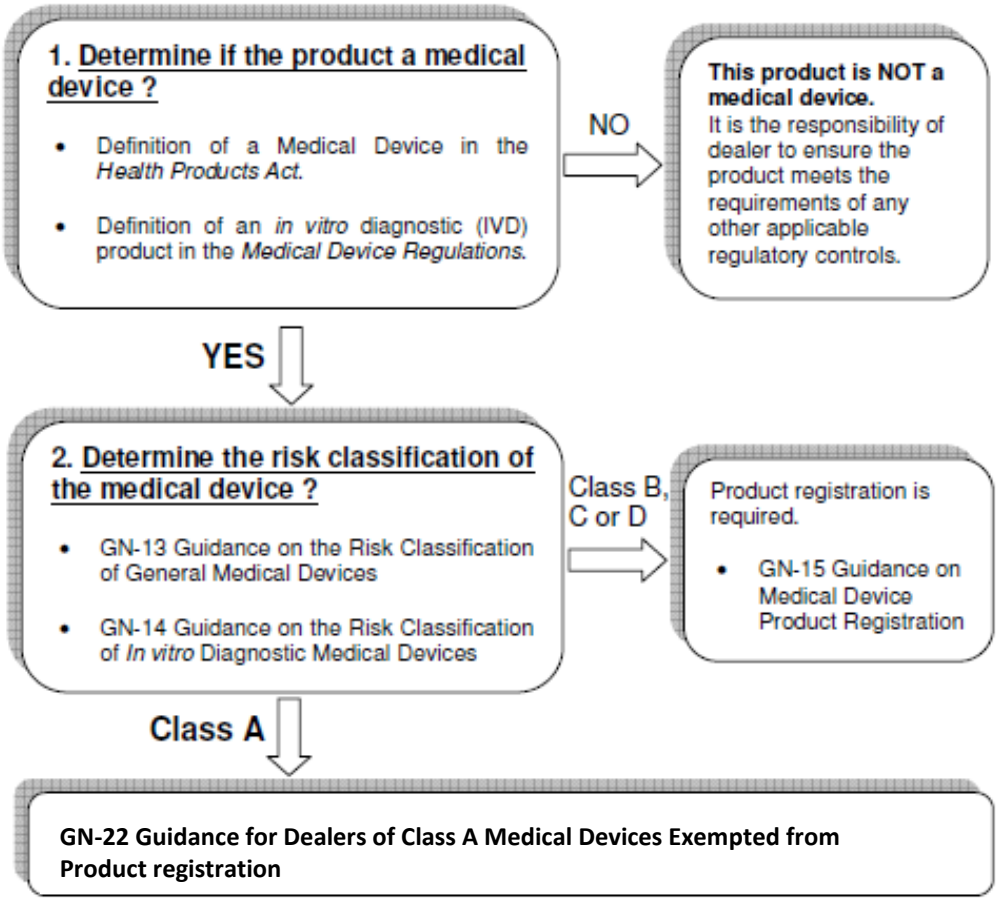
Medical Device Classification

- **The HSA medical device classification rules are adopted from the guidance developed by the Global Harmonization Task Force (GHTF) which has been replaced by IMDRF in 2011**
- **HSA has published a guidance document on the risk classification of general medical devices. (refer to the resource: *GN-13 Guidance on the Risk Classification of General MD*, updated in Sept 2018)**

Adobe Acrobat Document

Note: general medical devices are medical devices that are used directly in or on the human body, which exclude those used for *in vitro* examination. *In vitro* studies are biological processes or reactions happening outside the body, in artificial conditions, often in a test tube.

Process of determining classification of medical device



Determination of medical device risk class

Using the Rules-based system, the product owner should:

- **Decide if the product concerned is a medical device, using the appropriate definition;**
- **Document the intended purpose of the medical device; and**
- **Take into consideration ALL the rules that follow in order to establish the proper risk classification for the device, noting that where a medical device has features that place it into more than one risk class, risk classification should be based on the HIGHEST risk class applicable.**

Refer to resource: GN-13-Guidance on the Risk Classification of General Medical Devices (p14-28) for the risk classification rules.

Medical Device Regulatory framework

Pre-market: Product Controls

- All medical devices except Class A are to be registered prior to import and supply to Singapore.
- Class A medical devices are exempted from product registration as they are considered to be of low risk and include items such as “adhesive bandage to protect intact skin or wounds and intended for single use”.
- The dealers of medical devices are required to declare the list of Class A exempted medical devices that they are dealing with.
- Medical devices that are registered with the Health Sciences Authority (HSA) are listed in the ***Singapore Medical Device Register*** ***(SMDR).***
- Medical devices that have been submitted for product registration before certain stipulated deadlines but have not undergone the complete evaluation are placed on the ***Transition List***. Products on the Transition List can continue to be supplied in Singapore.

Medical Device Regulatory framework

On-market: Dealers Controls

- All medical devices manufacturers, importers and wholesalers to be licensed by HSA.

Post-market Controls

- Reporting of adverse events and Field Safety Corrective Actions (FSCA), prohibition against false or misleading advertisements, record keeping.

Why regulate medical devices?

Product Registration

- Allows HSA to identify and trace the medical devices available in Singapore.
- Products can be evaluated for their quality, safety and effectiveness before they are being introduced to Singapore market, hence safeguarding public health.

Dealer License

- Ensures that HSA is aware of all manufacturers, importers, suppliers and distributors of medical devices in Singapore.
- Provides assurance to HSA that licence holders have met the regulatory requirements and have documented procedures in place.
- Dealer’s Licences are valid for 12 months from date of approval

Three types of dealer's licences

Licensing of dealers is based on the activity performed by that company in relation to medical devices. There are three types of dealer's licences for dealing in medical devices:-

1) **Manufacturer's licence** - any company who manufactures medical devices in Singapore;
2) **Importer's licence** - any company who imports medical devices into Singapore;
3) **Wholesaler's licence** - any company who supplies medical devices by wholesale (which includes export) in Singapore.

NOTE: A licensed local manufacturer does not require a wholesaler's licence to supply by wholesale medical devices manufactured by the licensed manufacturer.

Refer to: Health Products Act, Chapter 122D, Sections 12 to 14

Three types of dealer's licences

Type of Licence	Certificate Required	Other Documents Required
1) Manufacturer's Licence	ISO 13485 certificate ***or*** Declaration of conformity to a QMS #	Declaration letter of non-dealing in Class A medical devices
2) Importer's Licence	ISO 13485 certificate ***or*** Good Distribution Practice for Medical Devices (GDPMDS) certificate ***or*** Declaration of exemption from GDPMDS *** ***or*** Declaration of conformity to a QMS #	Declaration letter of non-dealing in Class A medical devices
3) Wholesaler's Licence	ISO 13485 certificate ***or*** Good Distribution Practice for Medical Devices (GDPMDS) certificate ***or*** Declaration of exemption from GDPMDS *** ***or*** Declaration of conformity to a QMS #	N.A

Declaration of conformity is applicable for companies who manufacture, import or wholesale **Class A** medical devices only.

*** The activities for exemption are:**

Activity 1: Dealing with medical devices that are solely for export or re-export. The medical device will not be supplied in Singapore; or

Activity 2: Dealing with medical devices for non-clinical use. The medical device will not be used on any patient.

Key Regulatory Responsibilities of Dealer's License Holders

The key obligations of the licensee include

1. Labeling
2. Device advertising
3. Furnishing of information
4. Verification of quality, safety and efficacy of health product
5. Maintenance of records including distribution records and complaint handling.
6. Reporting of adverse events
7. Field Safety Corrective Action

GDPMDS – Good Distribution Practice for Medical Devices in Singapore

- Medical devices companies are required to implement quality management system, procedures and facilities to handle the medical devices in accordance to current Good Manufacturing or Distribution Practice of Medical Devices.
- Good Distribution Practice (GDP) is that part of quality assurance which ensures that products are consistently stored, transported and handled under suitable conditions as required by the marketing authorisation or product specification.
- Companies who are currently certified to ISO 9001:2008 will find that they have partially fulfilled the GDPMDS requirements.

GDPMDS Scope

1. **Introduction**
2. **Quality Management System – Documents needed include the Site Master File (SMF) and procedures.**
3. **Resource Management**
4. **Storage and Stock Handling – including calibration of equipment, storage conditions and installation / servicing of medical devices**
5. **Traceability**
6. **Medical Device Complaints**
7. Field Safety Corrective Action
8. Return of Medical Devices
9. Disposal of Medical Devices
10. Counterfeit, Adulterated, Unwholesome or Tampered Medical Devices
11. Internal Audits
12. Management Review
13. Outsourced Activities
14. Secondary Assembly

Enhancements to regulatory framework

Licensing of Class A medical devices dealers from June 2018

- **In line with the lower risk classification for Class A medical devices, all Class A medical devices (sterile and non-sterile) do not require product registration with HSA.**
- **These dealers (manufacturer and/or importer) are required to submit a declaration of the list of Class A medical devices that they deal in under the importer's and manufacturer's licences, via MEDICS. prior to import and supply in Singapore.**

Enhancements to regulatory framework

Class B device registration from Sep 2018

Evaluation Route	Criteria (at the time of submission)
Full	Not approved by any of HSA reference regulatory agencies
Abridged	Approval from at least 1 of HSA's reference regulatory agency
Immediate Class B registration – IBR	**For all Class B medical devices** □ Approval from at least 1 of HSA's independent reference regulatory agency □ Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdictions* □ No safety issues globally □ No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **OR** □ Approvals from at least 2 of HSA's independent reference regulatory agencies □ No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **For standalone medical mobile applications** □ Approval from at least 1 of HSA's independent reference regulatory agency □ No safety issues globally □ No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.

5 Reference Regulatory Agencies include European Union Notified Bodies, Health Canada, Japan Ministry of Health Labour and Welfare, United States Food & Drug Administration, Australia Therapeutics Goods Administration

Enhancements to regulatory framework

Class C device registration from Sep 2018

Evaluation Route	Criteria (at the time of submission)
Full	Not approved by any of HSA reference regulatory agencies
Abridged	Approval from at least 1 of HSA's reference regulatory agency
Expedited Class C registration - ECR	**ECR–1** □ Approvals from at least 1 of HSA's independent reference regulatory agencies □ Marketed for ≥ 3 years in the above independent reference regulatory agency's jurisdiction* □ No safety issues globally □ No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues. **OR** **ECR–2** □ Approvals from at least 2 of HSA's independent reference regulatory agencies
Immediate Class C registration - ICR	**For standalone medical mobile applications** □ Approval from at least 1 of HSA's independent reference regulatory agency □ No safety issues globally □ No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.

Standalone Mobile Medical Device applications refer to mobile applications (mobile apps) with medical purpose that are intended to function by themselves and are not intended for use with other hardware medical devices (e.g. medical sensors).

Enhancements to regulatory framework

Class D device registration from Sep 2018

Evaluation Route	Criteria (at the time of submission)
Full	Not approved by any of HSA reference regulatory agencies
Abridged	Approval from at least 1 of HSA's reference regulatory agency
Expedited Class D registration - EDR	Approvals from at least 2 of HSA's independent reference regulatory agencies No prior rejection/ withdrawal by/from any independent reference regulatory agencies or HSA (e.g. withdrawal/rejection/refusal to register of specific models in an application) due to quality, performance/efficacy or safety issues.

Medical Device Registration Fees

Each submitted application shall contain only one of the following:

- **a SINGLE medical device;**
- **one medical device FAMILY;**
- **one medical device SYSTEM;**
- **one medical device TEST KIT;**
- **one medical device IVD CLUSTER;**
- **one medical device GROUP;**
- **one dental grouping term (DGT).**

Based on GN-15-R7.1

Product Registration Fees

Risk Class	Application Fees	Evaluation Fees			
		R7► Immediate ◄	Expedited	Abridged	Full
Class B	$500	$900		$1,800	$3,500
Class C	$500	R7► $3000 ◄	$3,000	$3,500	$5,700
Class D	$500		$5,400	$5,700	$11,400
Class D (devices incorporating medicinal products)	$500			$10,000	$75,000

Turn Around Time for Product Registration

Based on GN-15-R7.1

Risk Class	TAT for Registration Routes (in working days)			
	R7 ► **Immediate** ◄	**Expedited**	**Abridged**	**Full**
Class B	Immediate Registration upon Submission		100	160
Class C	R7 ► Immediate registration upon submission (for Class C standalone medical mobile application only) ◄	120	160	220
Class D		180	220	310
Class D (devices incorporating medicinal products)			220	310

Solution to Today's Problem

	Description of medical device	Product Registration	TAT	Cost
1	**Insulin pen** used for patient's self-administration. Registered under Health Canada.	Class C, registered in 1 reference regulatory agency. To apply for product registration using the abridged evaluation route.	160 days	$500+ $3500 = $4000
2	**Syringes** without needles (Sterile and non-sterile)	Class A, exempted from product registration.	NA	NA
3	**Absorbable Suture**.	Class D. Product to be registered using the full evaluation route.	310 days	$500 + $11400 =$11900
4	**Aspirator**, a suction equipment. Registered under Health Canada as well as US FDA, has been marketed for 5 years with no safety issues.	Class B, registered in 2 reference regulatory agencies. Can register product under the Immediate Class B registration – IBR	0 day	$500 + $900 =$1400

Solution to Today's Problem

- With product registration, these products will be listed under the Singapore Medical Device Register (SMDR). HT will have to pay an annual retention fee in future if they want to continue to import these products into Singapore.
- HT will require the importer's licence where they will need to have the GDPMDS or ISO 13485 certification if they have not yet attained it.
- HT must ensure that there is a Quality Management System (QMS) in place for dealing in any Class A medical devices
- The medical device regulations is still undergoing a lot of changes and updates, dealers need to check HSA websites for updates regularly.
- **http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates.html**

Learning Outcomes

- Identify the needs to regulate Import / Storage / Distribution of Medical Devices
- Classify medical devices into appropriate categories as specified by local authorities
- Explain the regulatory requirements for importing and distributing medical devices in Singapore.