EPP Medical Device Regulatory

Country Report

Japan International Corporation of Welfare Services (JICWELS)

EPP Medical Device Regulatory

MALAYSIA

MEDICAL DEVICE ACT 2012 (ACT 737)

AND

THE REGULATORY FRAMEWORK

MEDICAL DEVICE AUTHORITY, Ministry of Health Malaysia ● Level 5, Menara Prisma, No 26, Persiaran Perdana, Precinct 3, 62675 Putrajaya ● http://www.mdb.gov.my ● mdb@mdb.gov.my

- INTRODUCTION: OVERVIEW OF REGULATORY FRAMEWORK
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- RISK-BASED CLASSIFICATION & REGULATORY CONTROL
- CONFORMITY ASSESSMENT
- REGISTRATION OF MEDICAL DEVICES
- LICENSING OF ESTABLISHMENTS
- POST MARKET ACTIVITIES

BACKGROUND

- **Cabinet approved the policy on the development and implementation of medical device regulation in 2005**

- **Why regulate medical devices?**
  - To address public health & safety issues
  - To facilitate medical device trade & industry
    - global market
    - growth of the industry

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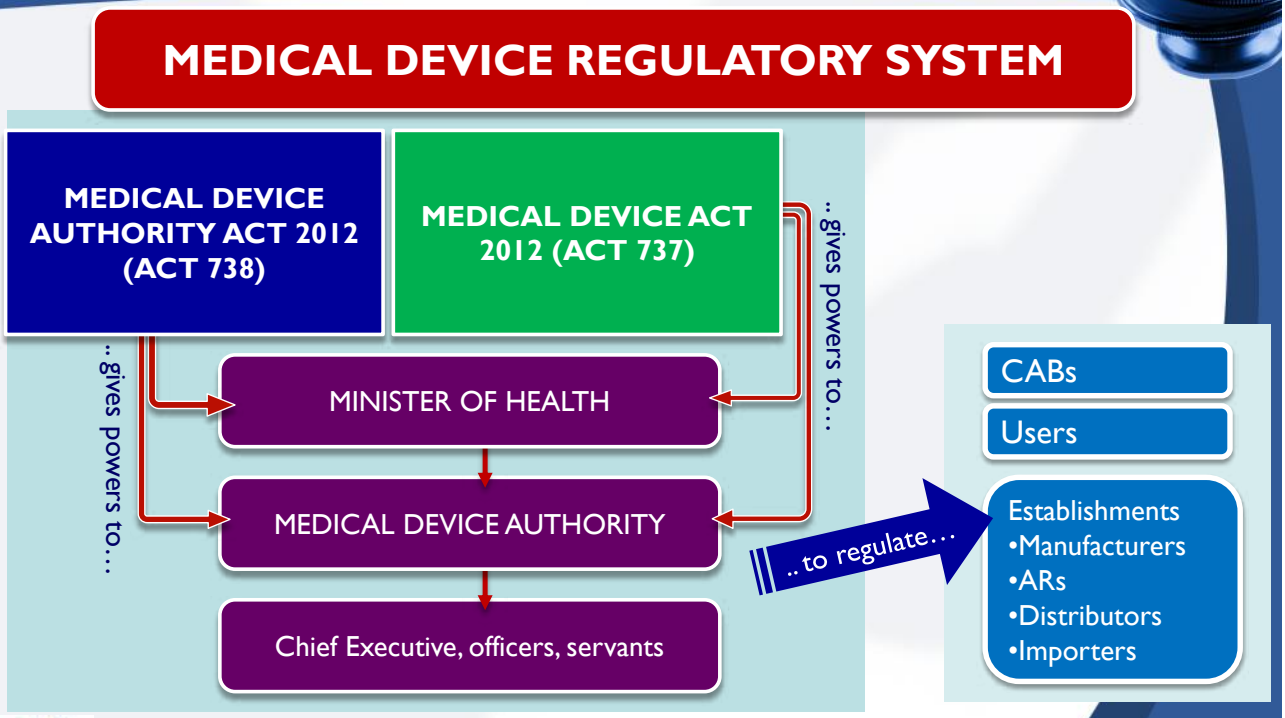
STRUCTURE OF THE REGULATORY SYSTEM



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STRUCTURE OF THE REGULATORY SYSTEM

- **Medical Device Act 2012 (Act 737)**
  - To regulate medical devices, the industry and to provide for matters thereto.

- **Medical Device Authority Act 2012 (Act 738)**
  - To provide for the establishment of the Medical Device Authority with powers to control and regulate medical device, its industries and activities, and to enforce the medical device laws, and for related matters.

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STRUCTURE OF THE REGULATORY SYSTEM

MEDICAL DEVICE AUTHORITY (MDA)

A body corporate with the following members

- DG of Health as the Chairman
- Chief Executive of the MDA
- a representative of Min of Finance
- a representative of Min of Health
- not more than five persons appointed by the Minister, who have expertise and experience in medical device matters

Committees appointed by MDA
- to assist it in the performance of the functions of the Authority

Functions of MDA

- To implement, enforce, consider and recommend reform to the medical device laws
- To perform the following
  - to regulate all matters
  - to encourage & promote the development
  - to provide consultancy & advisory service and any other services

  in relation to medical device, its industries and activities
- To utilize property of the Authority in such manner as the Authority may think expedient
- To impose fees or charges for services rendered

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OVERVIEW OF THE REGULATORY FRAMEWORK

PRE-MARKET	PLACEMENT ON-MARKET	POST-MARKET
PRE-MARKET ASSESSMENT Manufacturers of medical devices shall - • ensure their products conform to EPSP • establish appropriate quality system for manufacturing their products • collect evidence of conformity	**MEDICAL DEVICE REGISTRATION** • Manufacturers (or authorized representatives) apply to register medical devices & establishment license	**SURVEILLANCE & VIGILANCE** Establishments shall - • monitor safety & performance of products • carry out post-market obligations, eg complaint handling, FSCA, recall
CAB verifies evidence of conformity	**ESTABLISHMENT LICENSING** Importers/distributors shall - • ensure compliance to GDPMD & advertising requirements • apply for establishment license to import/distribute medical devices	**USAGE & MAINTENANCE** • Users shall use, maintain & dispose off medical devices appropriately

MDA issues licenses, registers medical devices and monitors compliance to requirements & takes appropriate actions in accordance with the provisions of the law

SCOPE OF THE REGULATION

Section 2 of Act 737

"establishment" means:

(a) a person who is either a manufacturer, importer, or distributor who is responsible for placing any medical device in the market but does not include a retailer; and

(b) an authorized representative appointed by a manufacturer having a principal place of business outside Malaysia,

and such person and authorized representative being:

(A) a person domiciled or resident in Malaysia; or

(B) a firm or company constituted under the laws of Malaysia, and carrying on business or practice principally in Malaysia

SCOPE OF THE REGULATION

Section 2 of Act 737

"manufacturer" means:

(a) a person who is responsible for:

(i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and

(ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or

(b) any other person who:

(i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and

(ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement,

but shall not include the following persons:

(A) any person who assembles or adapts medical devices in the market that are intended for individual patients; and

(B) any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices

SCOPE OF THE REGULATION

Responsible party	Regulated activities/responsibilities
Local manufacturer	• To ensure products meet EPSP and are manufactured in accordance with ISO 13485 • To apply for product registration • To monitor safety & performance and to take corrective actions on problems related to products in the market
Authorized representative	To act on behalf of foreign manufacturers with regard to the manufacturer's responsibilities under the Malaysian laws
Importer	To ensure compliance with requirements of good distribution practice for medical device (GDPMD), eg cleanliness & suitability of premises, storage & stock handling, traceability, product complaints, etc
Distributor	
CAB	To verify evidence of conformity to EPSP, ISO 13485, GDPMD

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RISK-BASED CLASSIFICATION & REGULATORY CONTROL

Section 3 of Act 737

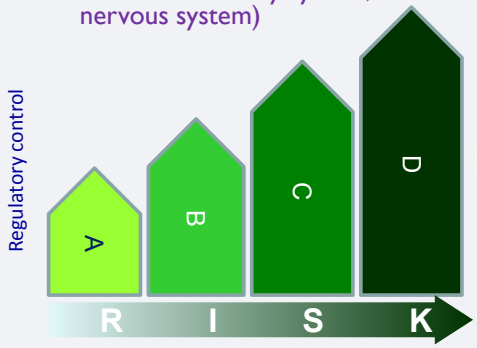
Classification of medical device

(1) A medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner.

(2) In the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the matter shall be referred to the Authority, in the manner and within such period as may be specified by the Authority, for its decision.

RISK-BASED CLASSIFICATION & REGULATORY CONTROL

- A classification of medical devices based on risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device
- It uses a set of classification rules based on:
  - intended use
  - duration of use (transient, short-term and long-term)
  - part of human body (non-invasive or invasive with respect to body orifices, surgically invasive interventions, central circulatory system, central nervous system)



Class	Risk Level	Device examples
A	Low	Simple surgical instruments, tongue depressor, liquid-in-glass thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes, walking aids
B	Low-Moderate	Hypodermic needles, suction equipment, anesthetic breathing circuits, aspirator, external bone growth simulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit, x-ray films
C	High-Moderate	Lung ventilator, orthopedic implants, baby incubator, blood oxygenator, blood bag, contact lens disinfecting/cleaning products, deep wound dressing, defibrillator, radiological therapy equipment, ventilator
D	High	Pacemakers and their leads, implantable defibrillators, implantable infusion pumps, heart valves, inter-uterine contraceptive devices, neurological catheters, vascular prostheses, stents

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CONFORMITY ASSESSMENT

Section 4 of Act 737

Manufacturer's obligations

A manufacturer shall ensure that a medical device:

(a) conforms to the prescribed essential principles of safety and performance;

(b) is manufactured in accordance with good manufacturing practice and any written directive issued by the Authority; and

(c) is labelled, packaged and marked in accordance with the prescribed manner

Manufacturers shall conduct **conformity assessment** to provide **objective evidence of safety and performance of** a medical device

CONFORMITY ASSESSMENT

Section 10 of Act 737

Conformity assessment body

(1) A conformity assessment body shall be a body registered under this Act to carry out conformity assessment of a medical device to be registered under this Act.

(2) The person who is in charge of and has overall control over a conformity assessment body shall be a Malaysian citizen.

(3) A conformity assessment body shall be independent and shall not have, acquire or hold any interest, directly or indirectly, in relation to:

(a) any medical device under its assessment;

(b) any shares in the establishment whose medical device is assessed by it; or

(c) any related company of the establishment whose medical device is assessed by it.

(4) A conformity assessment body shall not disclose any information received during the conformity assessment procedures carried out on any medical device.

(5) A conformity assessment body shall be audited by the Authority from time to time as may be deemed necessary by the Authority.

CONFORMITY ASSESSMENT

What is conformity assessment (CA)?

Systematic examination of evidence generated and procedures undertaken by the manufacturer under the requirements established by the Regulatory Authority to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices

Elements of CA

- QMS *(ISO 13485 or equivalent, GDPMD)*
- Post-market surveillance system
- Summary technical documentation *(CSDT)*
- Registration of medical device & licensing of establishment

What To Look For In CA?

Objective evidence for conformance to Essential Principles of Safety & Performance of Medical Device –

- 6 general principles
- 11 design and manufacturing

CONFORMITY ASSESSMENT

CA PROCESS & PARTIES INVOLVED

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established regulatory requirements and both the processes and conclusions are subject by the Regulatory Authority

Manufacturer conducts CA on;
(i) QMS & PMS
(ii) Product safety & performance
(summary tech doc & DoC

⇄ **CAB** reviews evidence of conformity

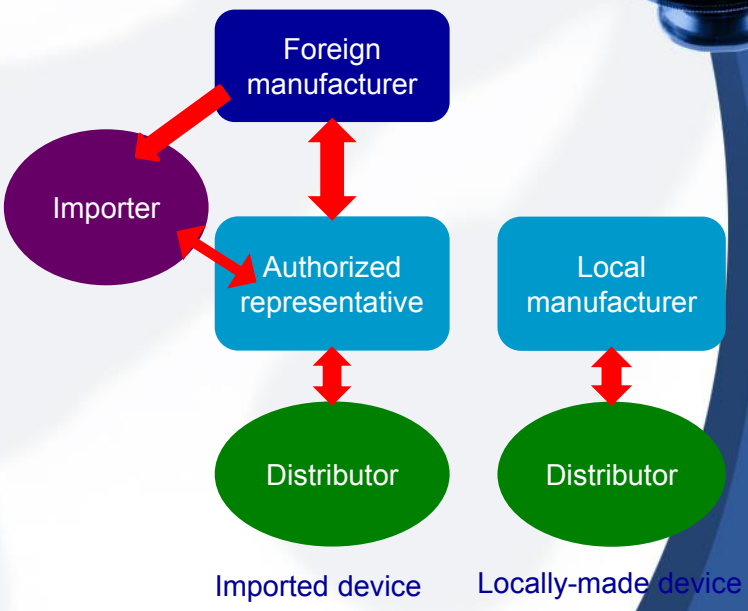
→ **Authority** reviews & registers product & licenses establishment

What is a CAB?

- A body authorized by the Authority to perform specified CA activities to determine whether the relevant requirements in technical regulations or standards are fulfilled
- CAB is independent of the organization that provides the product and is not a user of the product (3rd party)
- Authority will monitor the performance of the CAB and, if necessary, withdraw authorization

LICENSING OF ESTABLISHMENTS

- Establishment means a person/organization who is either a manufacturer, authorized representative (for foreign manufacturer), importer or distributor of medical devices, but does not include a retailer
- Different type of establishment has different roles & responsibilities – different set of control
- Establishment must possess valid license to carry out activities related to medical devices in Malaysia



Relationship between different establishments

POST-MARKET SURVEILLANCE & VIGILANCE

37. Distribution records

(1) …….maintain a distribution record in respect of each medical device manufactured, …...

(2) …..contain information as prescribed by the Minister.

(3) …….provide the distribution records to the Authority upon request.

38. Post-market surveillance and vigilance

(1) ……monitor the safety and performance of the medical device ….and put in place a post-market surveillance system …….

(2) ……report of adverse incident …. is properly recorded and fully evaluated.

39. Complaint handling

……establish and implement documented procedures and maintain records of reported problems or complaints

40. Mandatory problem reporting

(1) ……report to the Authority any incident that …..:

(a) ….the failure of the medical device or a deterioration in effectiveness, inadequacy in labelling or instructions for use ….thirty days from the discovery;

(b) has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur ….ten days from the discovery; or

(c) is a serious threat to public health …..forty-eight hours from the discovery.

(2) Any person who contravenes subsection (1) commits an offence ….

POST-MARKET SURVEILLANCE & VIGILANCE

41. Field corrective action

…..undertake corrective or preventive action in relation to a medical device imported and placed in the market which may include:

(a) the return of the medical device to the establishment;

(b) modification of the medical device;

(c) exchange of the medical device;

(d) destruction of the medical device; or

(e) specific advice on the use of the medical device.

42. Recall

(1) ….may recall any defective medical device at any time.

(2) …..on or before undertaking a recall ….., provide information as may be specified ……

(3) ….as soon as possible after the completion of a recall, report to …..action taken to prevent a recurrence of the problem.

(4) ….Authority may order the establishment to recall any medical device at any time due to patient safety and public health.

….Thank you for your attention

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Issues & Problems in Implementing of Medical Device Regulatory

Comparison of Regulatory Framework Between Japan and Malaysia

REQUIREMENT	JAPAN	MALAYSIA
ACT/ LAW	PMD Act , Medical Care Act	Medical Device Act 2012 (Act 737)
AUTHORITY	PMDA/ MHLW, Local Government	MDA, Local Government
NOMENCLATURE	JMDN/ GHTF	Global Medical Device Nomenclature (GMDN)/ GHTF
TECHNICAL DOCUMENTATION	STED	CSDT
CLASSIFICATION	III, IV : Approval by MHLW	A, B, C & D : Approval by MDA
CERTIFICATION	II : 3rd party certification body	Establishment & Conformity Assessment : CAB
	III, IV approved by PMDA	
POST MARKET	Adverse Event (AE) submit to PMDA/ MHLW	Adverse Event (AE) submit to MDA
	Good Vigilance Practice (GVP)	Post Market Surveillance (PMS)

Issues/ Problems – Pre Market

- Licensing
  - Tendering Agent

Background : Activities of tendering agent in Malaysia is just to prepare the invoice to user/ medical institution and did not keep any inventories (no warehouse). The issue is currently they are not being licensed since they are not fall under any establishment's definition. If any incident happen to the device, the action can't be taken on them since they are not abide under our jurisdiction.

Propose solution : They must have an establishment license and GDPMD certificate. However, only certain requirement of GDPMD need to be complied related to the business activities.

Issues/ Problems – Pre Market (2)

- Medical Device Registration
  - Reviewing Process of Registration Product

Background : By the month of February 2015, Malaysia will start the reviewing medical device product in the data base system. The reviewing time need to be efficient and numbers of application need to be increased within certain time of period.

Propose solution : Abridge process

We proposed to have abridge process to expedite reviewing process. Abridge process is to facilitate the registration of medical device in the timely manner. This include to recognise the certification of approval in the five founding members. As for Japan, Malaysia shall accept the certification standard for class II under the RCBs and for class III and IV with approval standard under the MHLW.

The checklist for EP's enable the applicant to understand what are the requirements for medical device approval/certification and how the conformity to each requirement can be shown.

The EP checklist is prepared in Technical Requirement.

- 422 EP's checklist for 920 class II (GHTF class B) Medical Device
- 29 EP's checklist for 61 Class III (GHTF Class C) Medical Device
- 8 EP's checklist for 21 Class IV (GHTF Class D) Medical Device

Issues/ Problems – Pre Market (3)

- **Quality Review**

Background : The quality of reviewer is differ from one to another. In order to have good understanding about the product, the quality of reviewer need to be upgraded.

Propose solution : In keeping up with our vision of having a system of quality review of medical devices, we devise strategies of the following :

- Having a close relationships with academician institute such as universities and medical institutions (study in the universities and exchange information).
- Role of associations in Malaysia such as FMM, MMDA, CFDA should be more active in investigate, study and policy proposal for the better medical care and medical devices.

Issues/ Problems – Pre Market (4)

- **Change Notification**

Background : After medical device has been approved, any changes related to the device either minor or major need to be notified to the Authority. Currently, we are in the midst of determine criteria on minor or major changes.

Propose solution :

To develop a criteria to determine minor or major changes of medical device registration.

Issues/ Problems – Post Market (1)

- **Complaint Handling**

Background : Complaint of medical device must be reported to the Authority. The issue is to determine the status of repeatable complaint of device (trending) whether it can be registered or otherwise.

Propose solution :

- To develop a criteria to determine the status of repeatable complaint of device (trending).
- At this moment, MDA is collecting the raw data to identify the trending of complaints. From that data, we will conduct an audit to the establishment for better understanding.

Issues/ Problems – Post Market (2)

- **Enforcement activities**

Background : We are in the midst of developing enforcement activities. The issue is to take action with the unregistered device in the market.

Propose solution : To work together with the other agencies such as police, local government, Ministry of Domestic Trade and Consumer Affair (MDTCA), Malaysia Communications and Multimedia Commission (MCMC) related to raiding activities.