EPP Medical Device Regulatory

Country Report

Japan International Corporation of Welfare Services (JICWELS)

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 ● Tel: 603-8889 2400 ● Fax: 603-8889 2500

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

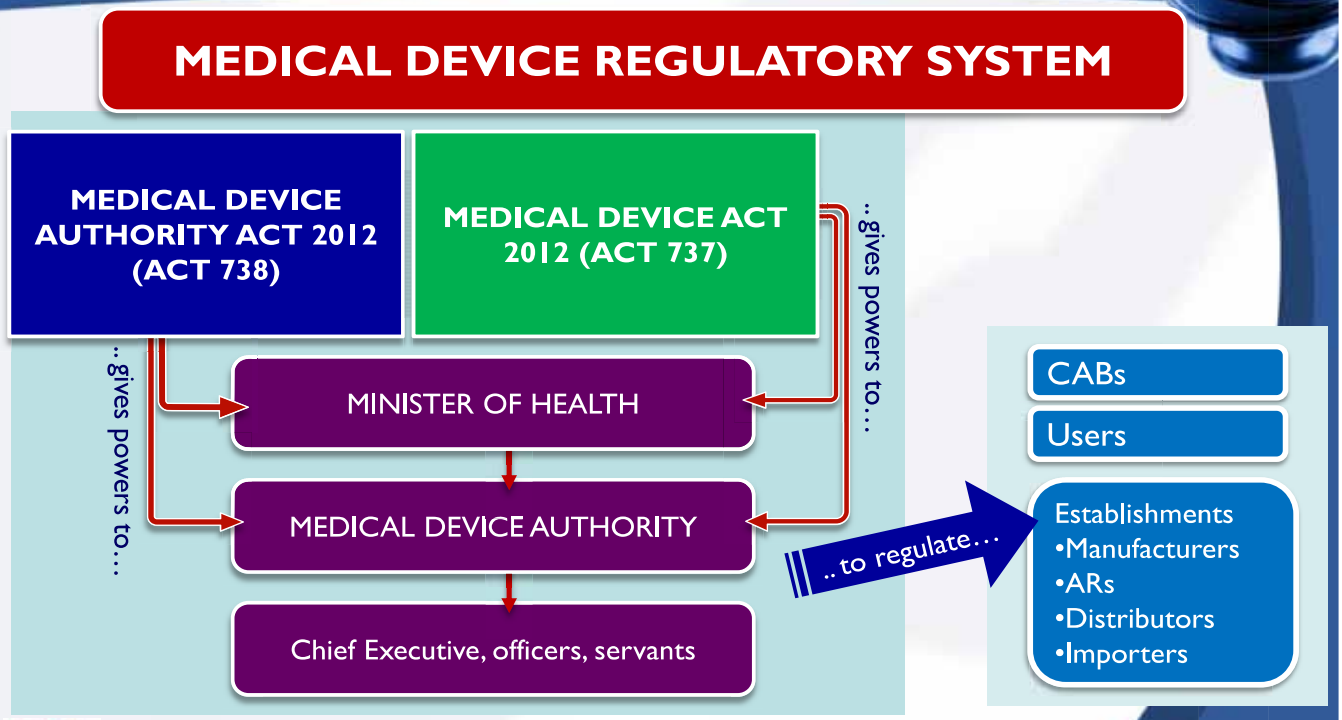
BACKGROUND

- **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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

STRUCTURE OF THE REGULATORY SYSTEM



Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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.

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

CAB verifies evidence of conformity

MEDICAL DEVICE REGISTRATION
- Manufacturers (or authorized representatives) apply to register medical devices & establishment license

ESTABLISHMENT LICENSING
Importers/distributors shall -
- ensure compliance to GDPMD & advertising requirements
- apply for establishment license to import/distribute medical devices

SURVEILLANCE & VIGILANCE
Establishments shall -
- monitor safety & performance of products
- carry out post-market obligations, eg complaint handling, FSCA, recall

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

Medical Device Control Division
MINISTRY OF HEALTH 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 Distributor	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
CAB	To verify evidence of conformity to EPSP, ISO 13485, GDPMD

RISK-BASED CLASSIFICATION & REGULATORY CONTROL

Section 3 of Act 737

Classification of medical device

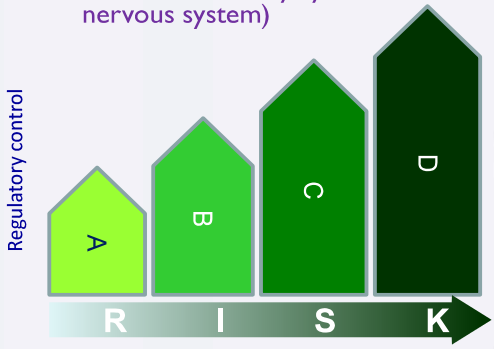
(1) A medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner.

(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.

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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)



Device risk/class

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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.

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

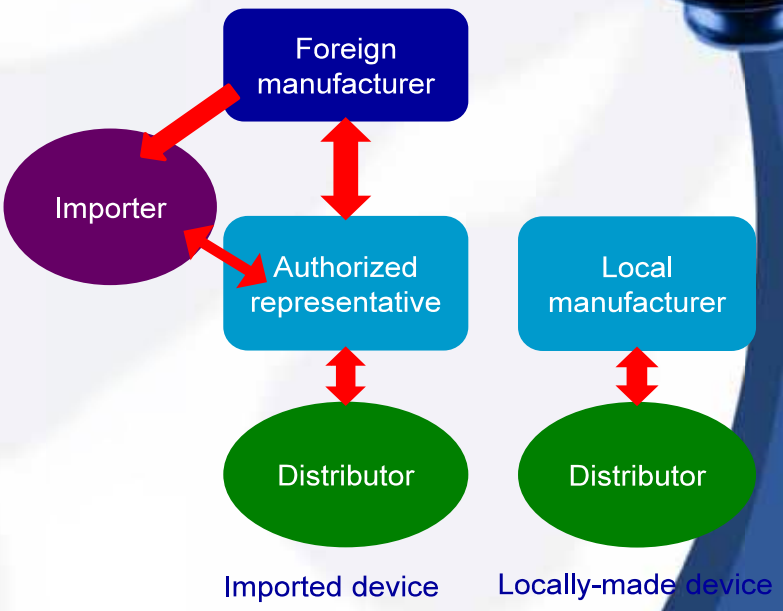
What is a CAB?

- 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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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 ….

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

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.

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

….Thank you for your attention

Medical Device Control Division
MINISTRY OF HEALTH MALAYSIA

EPP Medical Device Regulatory Program
- PRESENTATION SESSION -

Malaysia Medical Device Regulatory System - The Introduction

Malaysia

- Located in Asia continent – South East Asia – Member of ASEAN
- Consists of thirteen states and three federal territories
- Total landmass of 329,847 square kilometres (127,350 sq mi)
- Separated by the South China Sea into two similarly sized regions, Peninsular Malaysia and East Malaysia (Malaysian Borneo)
- Population: 30 millions
- Capital: Kuala Lumpur

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Medical Device Industry in Malaysia

- Around 1700 small to large players in the country - (manufacturing, distribution, sales)
- Export revenues of RM 11.7 Billion in 2013
- Investment - Foreign -> RM1.3 Billion (27.7%)
  - Local -> RM3.4 Billion (72.3%)
- Main export: rubber based medical devices, contact lenses, orthopaedic devices
- Market growth: 16%

Source: Malaysia Industry Development Agency (MIDA)

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Objectives Of Regulatory Framework

To address public health & safety issues

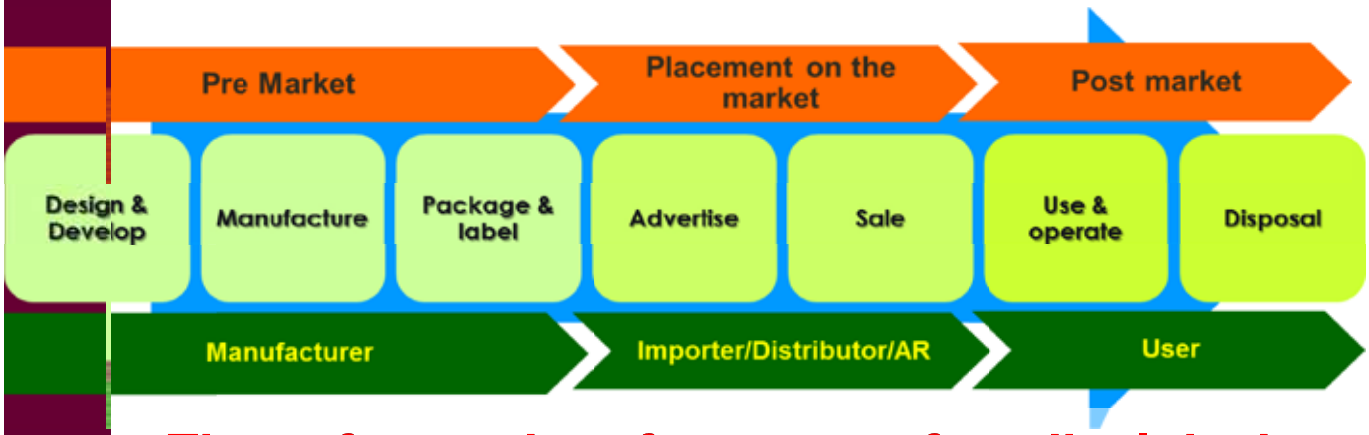
- Unavailability of pre-market control to assess safety, effectiveness and quality of medical devices
- Inadequate information for the public and health professionals to make informed choices on medical devices
- Lack of control over the usage of certain medical devices
- No post-market reporting system to identify and monitor medical devices with problems in the market

To facilitate medical device trade & industry

- To facilitate our local manufacturers to market their products globally
- To provide a favorable environment for the growth of medical device industry

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

The Medical Device Regulatory Framework

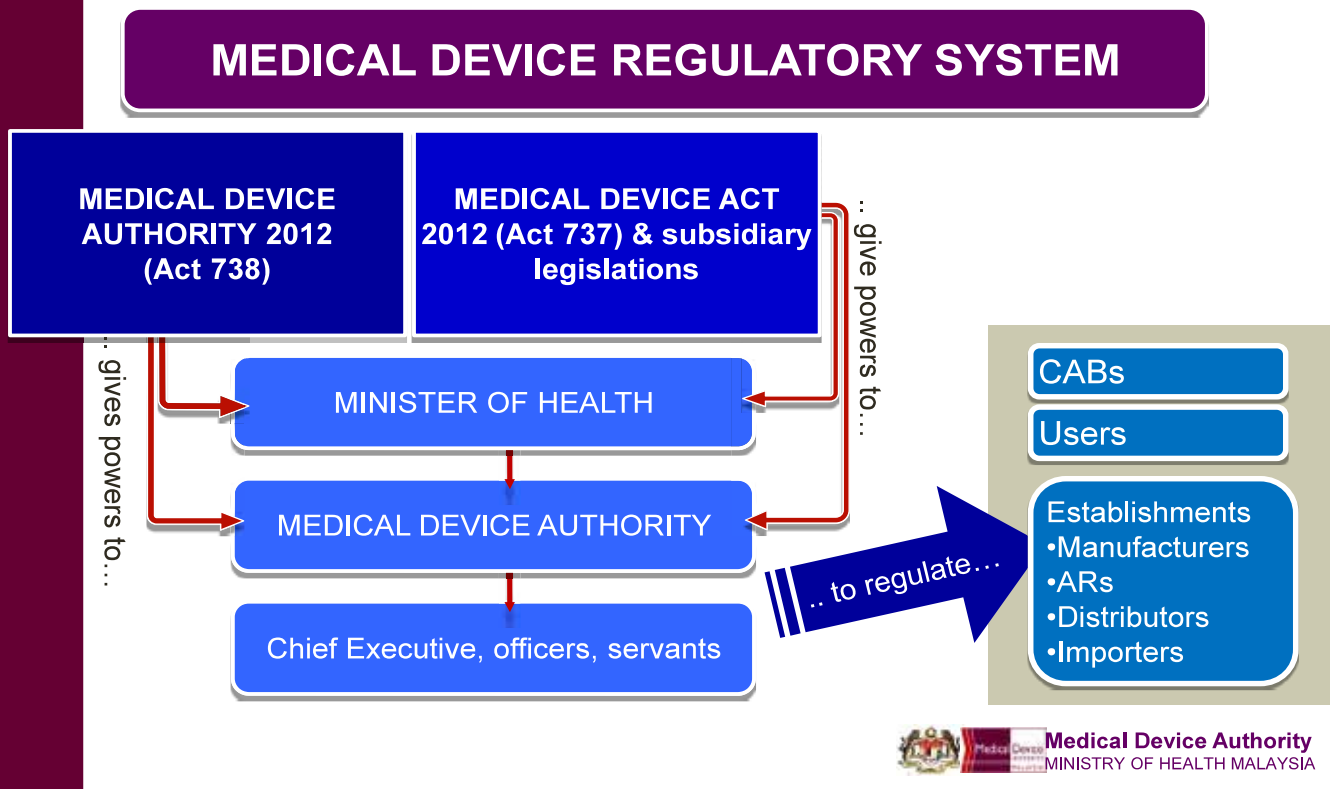


The safety and performance of medical device must be assured through out its life span.

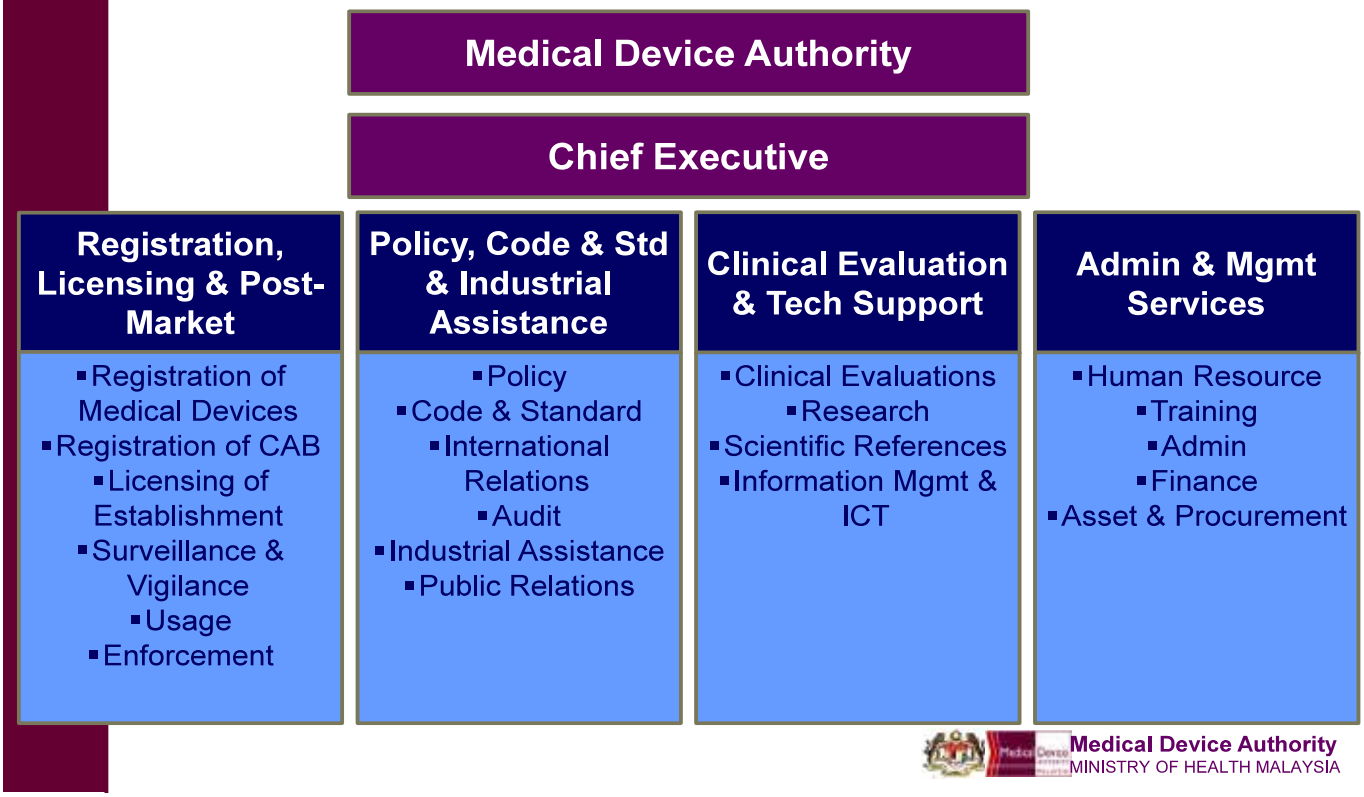
GHTF

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Medical Device Regulatory System: Institutional Structure



Medical Device Authority Organizational Structure



Medical Device Regulatory Framework

PRE-MARKET | **PLACEMENT ON-MARKET** | **POST-MARKET**

CONFORMITY ASSESSMENT
Manufacturers of medical devices shall -
- ensure their products conform to EPSP
- establish appropriate quality system for manufacturing their products
- collect evidence of conformity

CAB verifies evidence of conformity

MEDICAL DEVICE REGISTRATION
- Manufacturers (or LARs) apply to register medical devices & establishment license

ESTABLISHMENT LICENSING
Importers/distributors shall -
- ensure compliance to GDP & advertising requirements
- apply for establishment license to import/distribute medical devices

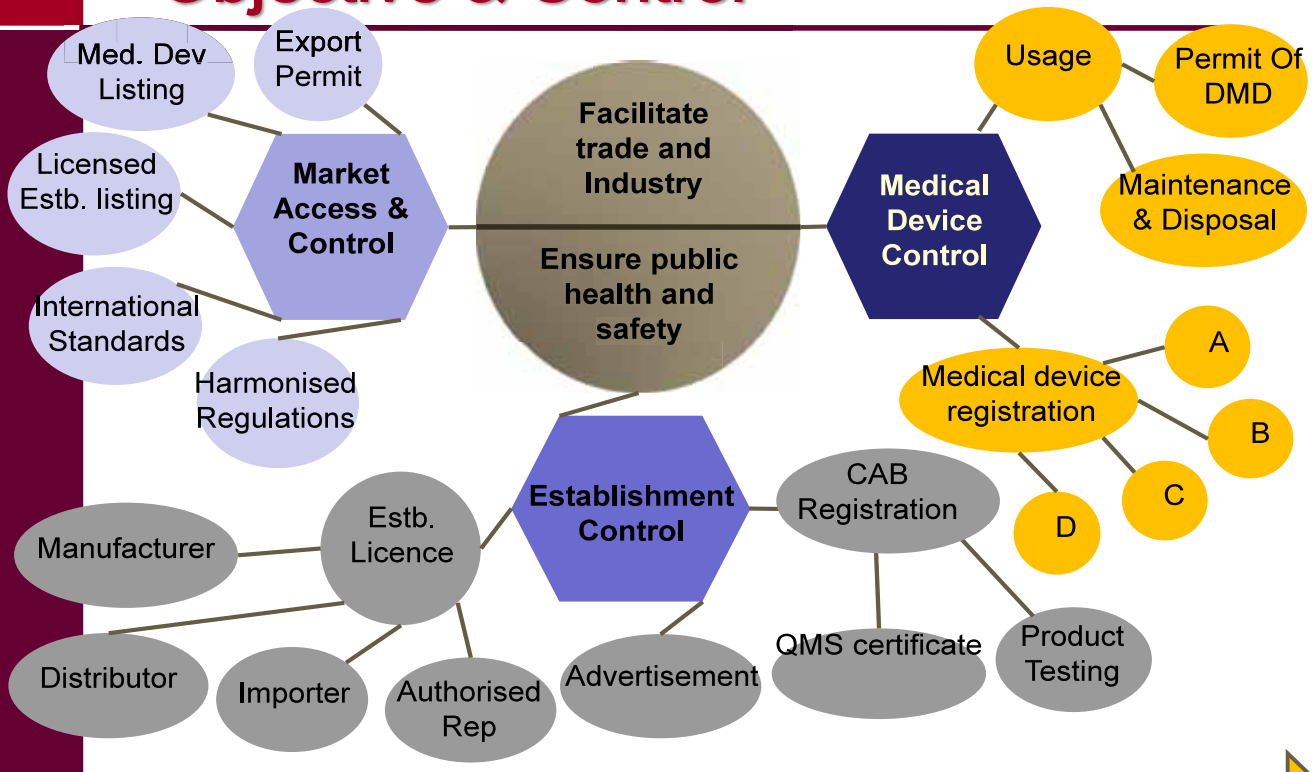
SURVEILLANCE & VIGILANCE
Establishments shall -
- monitor safety & performance of products
- carry out post-market obligations, eg complaint handling, FSCA, recall

USAGE & MAINTENANCE
- Users shall use, maintain & dispose off medical devices appropriately
- Users shall apply for permit to use/operate designated medical devices

MDA monitors compliance to requirements & takes appropriate actions in accordance with the provisions of the law

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Medical Device Act 2012 (Act 737) – Objective & Control



POST-MARKET VIGILANCE AND SURVEILLANCE SYSTEMS & ENFORCEMENT

Malaysia Medical Device Regulatory System - Issues and Future Improvement Plans

Control of OEM & Contract Manufacturer

Issue	Japan Regulatory Framework	Future Improvement Plan
OEM & Contract manufacturer is not required to be licensed under Medical Device Act 2012 (Act 737) as they are not under the purview of the Act. Therefore they are not qualify to apply for Export Permit as they are not dealing with registered medical device.	No control over the export activities as the exporter are required to comply with the regulatory requirements of the importing countries.	OEM & Contract manufacturer can apply for Manufacturing Certificate to facilitate trade.

Implementation of QMS requirements

Issue	Japan Regulatory Framework	Future Improvement Plan
Insufficient scope of QMS for licensed establishment who is dealing with new category of medical device.	Re-certification of QMS for additional scope to cater new product group	Requirement on re-certification by the CAB for new scope of QMS to cater new category of medical device to be imposed to the establishment.

*CAB - Conformity Assessment Body

13

Conformity assessment for medical device registration

Issue	Japan Regulatory Framework	Future Improvement Plan
All medical devices are subjected to conformity assessment procedure (review activities) by CAB for the purpose of registration.	Conformity assessment (review) for premarket approval is based on the class of medical device; Class I - registration without review; Class II & III (with certification standards) - review by RCB Class III (without certification standards) & IV - review by PMDA	For medical devices with premarket approval from GHTF founding countries are eligible for verification process. Otherwise, the devices will be subjected to full assessment. However, class A medical devices are exempted from conformity assessment procedure (review activities) by CAB

***CAB - Conformity Assessment Body**

Information to be submitted for conformity assessment

Issue	Japan Regulatory Framework	Future Improvement Plan
Authorized representative (AR) unable to obtain all evidence of conformity (technical information) to support compliance to EPSP from foreign manufacturers for conformity assessment procedure	Quality agreement is one of the element to be verified by DMAH of a foreign manufacturer as required under Article 65 of MO No. 169.	Improvisation of Letter of Authorization to include responsibilities of foreign manufacturer to provide all evidence of conformity to authorized representative (AR).

15

Medical Device Safety Measures

Issue	Japan Regulatory Framework	Future Improvement Plan
Detailed requirements on post market surveillance system is not yet established to be imposed to the establishment.	Good Vigilance Practice (GVP) is specified under Article 70 in MO No. 169 (QMS Ordinance) which give outline on responsibility to; - provide research report; - collect information from foreign manufacturers; - adverse incident reporting; - establish organization to handle safety management information	Development of requirements on post market surveillance system based on Japan GVP will be established.

Interactive system for incident or adverse reporting

Issue	Japan Regulatory Framework	Future Improvement Plan
No comprehensive and interactive system for incident or adverse reporting	Japan database for post market system is very comprehensive which includes; - Analysis of adverse event.	Upgrading of incident or adverse reporting system by establishing post market registry for medical device.

Sharing of safety information of medical device

Issue	Japan Regulatory Framework	Future Improvement Plan
Platform for sharing information on safety of medical device with other regulatory authorities has not been established.	Agreement with other regulatory authority has been established through; - Memorandum Of Understanding; - Confidentiality Agreement; - Joint Symposium	Establish agreement between other regulatory authority through MoU, MoI, Bilateral or Multilateral Agreement.

Control of technical personnel involve in maintenance of medical device

Issue	Japan Regulatory Framework	Future Improvement Plan
Specific requirements on control of technical personnel involve in maintenance of medical device has not been described in the Act and regulation.	The control of clinical engineers involve in maintenance of medical device is described in Clinical Engineers Act.	Prescription of requirements to control technical personnel need to be established.

Clinical Investigation of Medical Device

Issue	Japan Regulatory Framework	Future Improvement Plan
Specific regulatory requirements on clinical investigation for medical device has not been established.	Requirements on clinical investigation for medical device in Japan are addressed in Ministerial Ordinance on Good Clinical Practice for Medical Device	Specific regulatory requirements on clinical investigation for medical device need to be established.

Access to unapproved medical device

Issue	Japan Regulatory Framework	Future Improvement Plan
All medical devices are subjected to registration requirements under the Malaysia legislation. However, the registration requirements cannot be applied to medical devices which are imported/placed for the purpose of emergency situation.	In Japan, the Private Import Scheme allow the access to the device that is not available in the Japan market by a healthcare professional for his/her patient use, and this scheme is not limited to emergency cases only. However the consideration should take into account the followings : - patient consent; - the treatment cost is not covered under the reimbursement scheme.	The current policy on special access of medical device scheme need to be revised in order to include non-emergency cases too which are supported by justification.

mdb@mdb.gov.my

+603 8892 2400
+603 8892 2500

Medical Device AUTHORITY MALAYSIA

Level 5, Menara Prisma, No. 26, Persiaran Perdana, Presint 3, 62675 PUTRAJAYA, MALAYSIA
http://www.mdb.gov.my