*The 18th ASIAN HARMONIZATION WORKING PARTY ( AHWP) ANNUAL MEETING*

*5 DECEMBER 2013*

# *UPDATES ON MEDICAL DEVICE REGULATION IN MALAYSIA*

# CONTENTS

- Background
- Structure of Medical Device Regulatory System
- Medical Device Act  2012 (Act737)
- Medical Device Authority Act 2012 (Act 738)
- Subsidiary Regulations Under Act 737: Medical Device Regulations (MDR) 2012
- Other Related Provisions

# BACKGROUND

**16 Feb 2005: Cabinet approved the proposal to develop Medical Device Regulatory Program in Malaysia**

**August 2005: Establishment of Medical Devices Control Division**

- Development of MD Bill & subsidiary legislations
- Establishment of an organization to implement MD Regulatory Program
- Development of MD Registration & Surveillance/ Vigilance System

# MEDICAL DEVICE REGULATION : OBJECTIVES

- **To address public health & safety issues**
  - pre-market control to assess safety, effectiveness and quality of medical devices
  - adequate information for the public and health professionals to make informed choices on medical devices
  - control over the usage of certain medical devices
  - 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 favourable environment for the growth of medical device industry

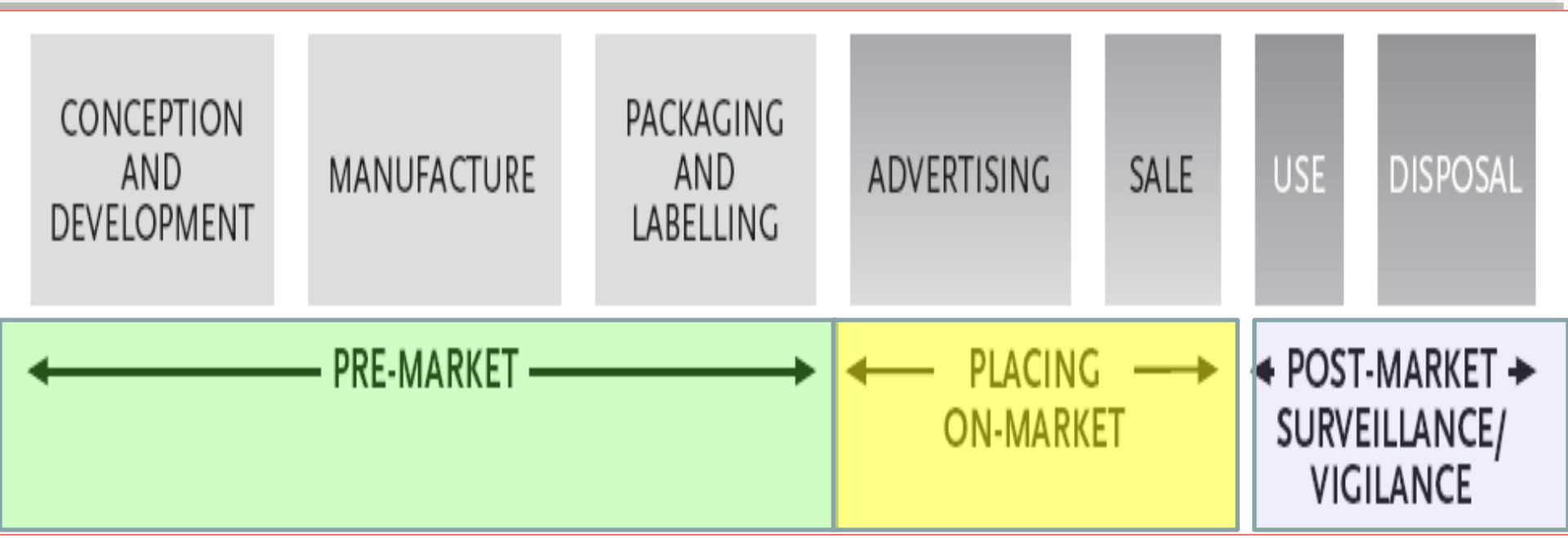
# HARMONISED MEDICAL DEVICE REGULATION

- Definition of medical device is based on [1]GHTF and WHO recommendation.
- Risk Based Classification and the Essential Principles of Safety & Performance of Medical Device (EPSP) is based on GHTF.
- Regulatory Model is based on WHO Model.

1 - Global Harmonization Task Force (www.ghtf.org)

# MEDICAL DEVICES REGULATORY FRAMEWORK IN MALAYSIA:

## WHO Regulatory Model



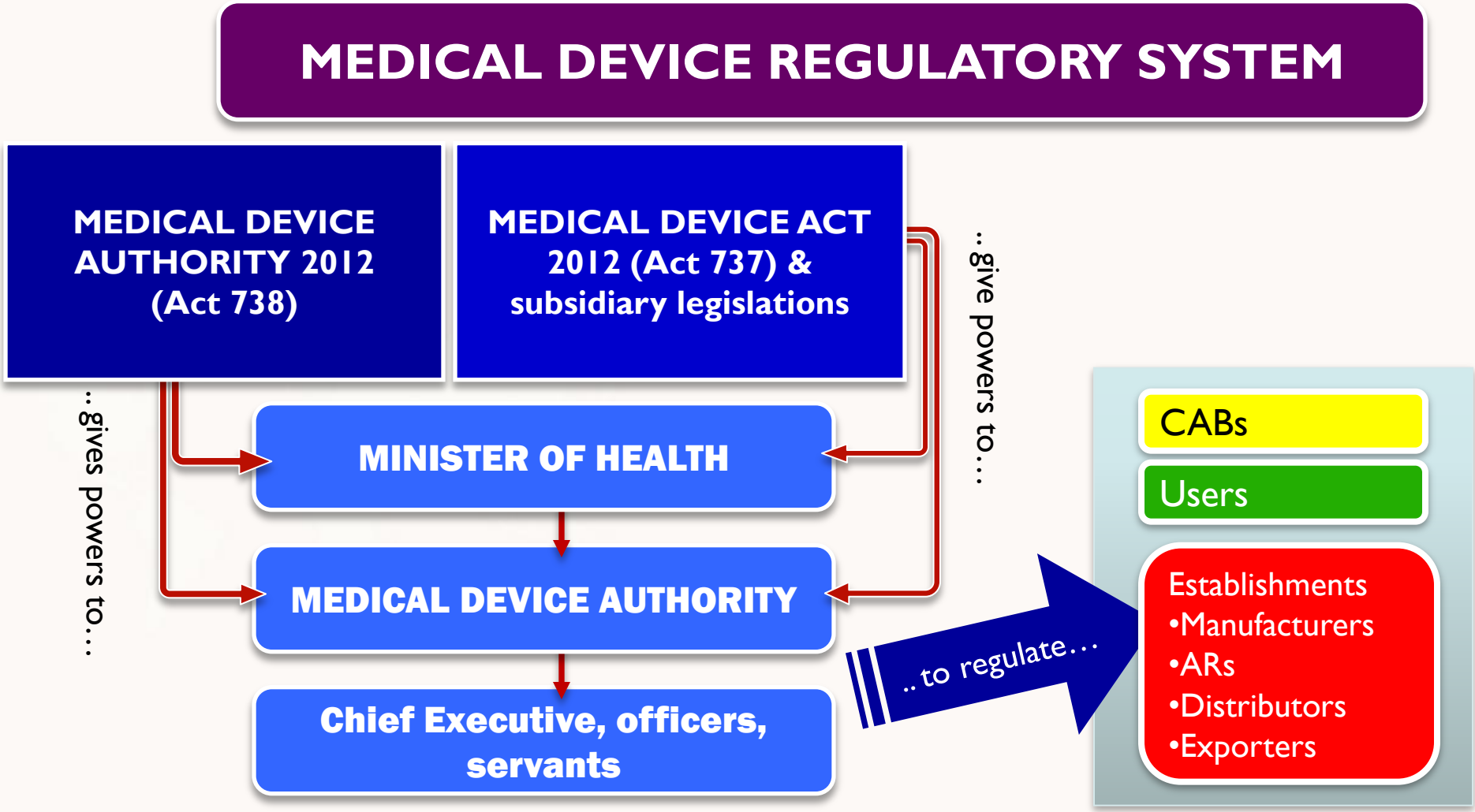

**Stages of Regulatory Control throughout the life cycle of medical device**

# STRUCTURE OF MEDICAL DEVICE 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 REGULATORY SYSTEM: INSTITUTIONAL STRUCTURE



# MEDICAL DEVICE AUTHORITY ACT 2012 (ACT 738)

## MEDICAL DEVICE AUTHORITY (MDA)

A body corporate with the following members

- DG of Health as the Chairman
- Chief Executive of the MDA
- Rep from Min of Finance
- Rep from 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 AUTHORITY ACT 2012 (ACT 738)

## MEDICAL DEVICE AUTHORITY

## CHIEF EXECUTIVE

### REGISTRATION, LICENSING & POST-MARKET

- Registration of Medical Devices
- Registration of CAB
- Licensing of Establishment
- Surveillance & Vigilance
- Usage
- Enforcement

### POLICY, CODE & STD & INDUSTRIAL ASSISTANCE

- Policy
- Code & Standard
- International Relations
- Audit
- Industrial Assistance
- Public Relations

### CLINICAL EVALUATION & TECH SUPPORT

- Clinical Evaluations
- Research
- Scientific References
- Information Mgmt & ICT

### ADMIN & MGMT SERVICES

- Human Resource
- Training
- Admin
- Finance
- Asset & Procurement

# MEDICAL DEVICE ACT 2012 (ACT 737) & SUBSIDIARY LEGISLATIONS -UPDATES

- **Act 737**
  - Gazetted in February 2012
  - To be enforced on a date appointed by the Minister in the Gazette (S1 Act 737): 30 June 2013

- **Medical Device Regulation (MDR) 2012**
  - Gazetted in December 2012
  - Effective date: 1 July 2013

- **Orders, other legislative tools**
  - Permit for Designated Medical Device
  - To be identified

- **Guidance documents, standards, guidelines, etc**
  - Based on needs

# LATEST UPDATES

- Upcoming:
  - 2nd part of the Regulation is in the pipeline
  - The coverage will be on designated medical device, post market requirements, advertising and usage (including maintenance, installation, T&C and disposal)
  - By 2015, mandatory enforcement will take place.

# MEDICAL DEVICE ACT 2012 (ACT 737) & SUBSIDIARY LEGISLATIONS

**PRE-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**

**PLACEMENT ON-MARKET**

**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

**POST-MARKET**

**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**

# ACT 737

## Act 737 consists of 80 sections and is divided into six parts:

- **PART I (PRELIMINARY)**
  - Section 1: Short title and commencement
  - Section 2: Interpretation

- **PART II (REGISTRATION OF MEDICAL DEVICE AND CONFORMITY ASSESSMENT BODY)**

  *Chapter 1: Registration of medical device*
  - Section 3 – Section 9

  *Chapter 2: Registration of conformity assessment body*
  - Section 10 – Section 14

- **PART III (LICENCE AND PERMIT)**

  *Chapter 1: Establishment license*
  - Section 15 – Section 25

  *Chapter 2: Designated medical device permit*
  - Section 26 – Section 36

# ACT 737

***Chapter 3: Duties and obligations of licensees or permit holders-*** *Provide requirements for* ***POST MARKET-***

- ***Section 37*** **– Section 42**

***Chapter 4: General duty*** *-specify the requirement on usage, operation, maintenance of medical devices & advertising of medical device.*

- **Section 43 – Section 44**

***Chapter 5: Export permit***

**Section 45 – Section 46**

- **PART IV (APPEAL)**

*Chapter 1: provides requirements for APPEAL against decision of authority*

- Section 47

- **PART V: ENFORCEMENT**

Section 48 – Section 66: *provides requirements for enforcement activities*

- **PART VI: GENERAL**
  - Section 67 – Section 80 : provides general requirements in relation to the provision of the Act (**Section 80** - **Saving and transitional)**

# MDR 2012

**MDR 2012 consists of 22 regulations, 6 schedules and 9 parts**:

- **Part I (Preliminary)** Regulation 1: Citation and commencement, Regulation 2: Interpretation
- **Part II (Conformity assessment procedure)** Regulation 3 – Regulation 4
- **Part III (Registration of medical device)** Regulation 5 – Regulation 7
- **Part IV (Registration of conformity assessment body)** Regulation 8 – Regulation 10
- **Part V (Establishment license)** Regulation 11 – Regulation 14
- **Part VI (Export permit)** Regulation 15
- **Part VII (Labelling requirements)** Regulation 16
- **Part VIII (Appeal)** Regulation 17 – Regulation 20
- **Part IX (Register)** Regulation 21 – Regulation 22

# MEDICAL DEVICE (SECTION 2, ACT 737)

"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 purposes of:
   - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
   - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
   - (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
   - (iv) supporting or sustaining life;
   - (v) control of conception;

# MEDICAL DEVICE (SECTION 2, ACT 737)

(vi) disinfection of medical devices;

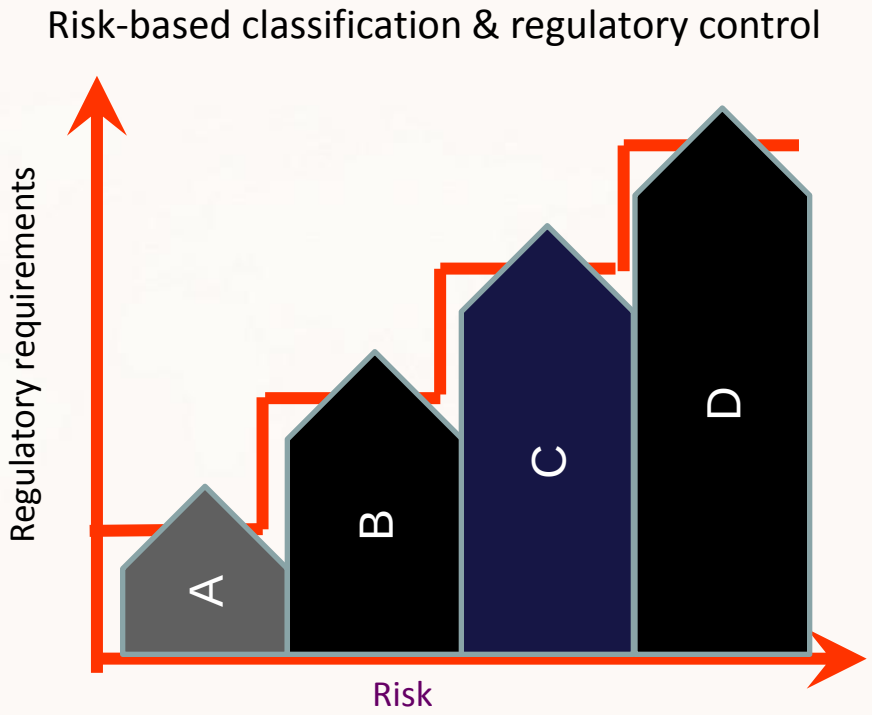
(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

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; and

(b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a MEDICAL DEVICE by order published in the *Gazette*.

# MEDICAL DEVICE ACT 2012 (ACT 737) & SUBSIDIARY LEGISLATIONS

## S3: Risk-based classification of medical device




**Reg4 MDR 2012: Level of regulatory control is proportional to the risk associated with the medical device (risk-based classification)**

# CONFORMITY ASSESSMENT

**Act 737: S4-9, S15-20, S79**

**Reg4 MDR 2012: 3rd Schedule**

**DoC**

- A DoC is a declaration made by the manufacturer of a device that the device is in conformity with the regulatory requirements
- DoC declares that the manufacturer guarantees that each piece of the device sold is in conformity with the regulatory requirements

**Elements of CA**

- Quality management system (QMS)
- Post-market surveillance (PMS) system
- Summary technical documentation
- Declaration of conformity (DoC)

**QMS**

- For manufacturer, ISO 13845
  - Class A & B: can exclude design control, process control, inspection & testing
  - Class C & D: full QMS
- PMS system
- Technical evaluation of sterilization process (if any)
- For LAR, importer, distributor: GDPMD

**Summary Technical Documentation**

- Format – ASEAN CSDT
- Compliance to EPSP *(GHTF recommendations - Essential Principles of Safety & Performance of Medical Devices)*
- Acceptable standards or equivalence will be widely used *(GHTF recommendations - Role of Standards in the Assessment of Medical Devices)*
- CAB determines the adequacy of the documented evidence to support attestation of conformity

**PMS System**

- Distribution records
- Complaint records
- Adverse incident reporting *(GHTF recommendations - Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices)*
- FSCA reporting *(GHTF recommendations - Medical Devices Post Market Surveillance: Content of Field Safety Notices)*

# REGISTRATION OF MEDICAL DEVICE

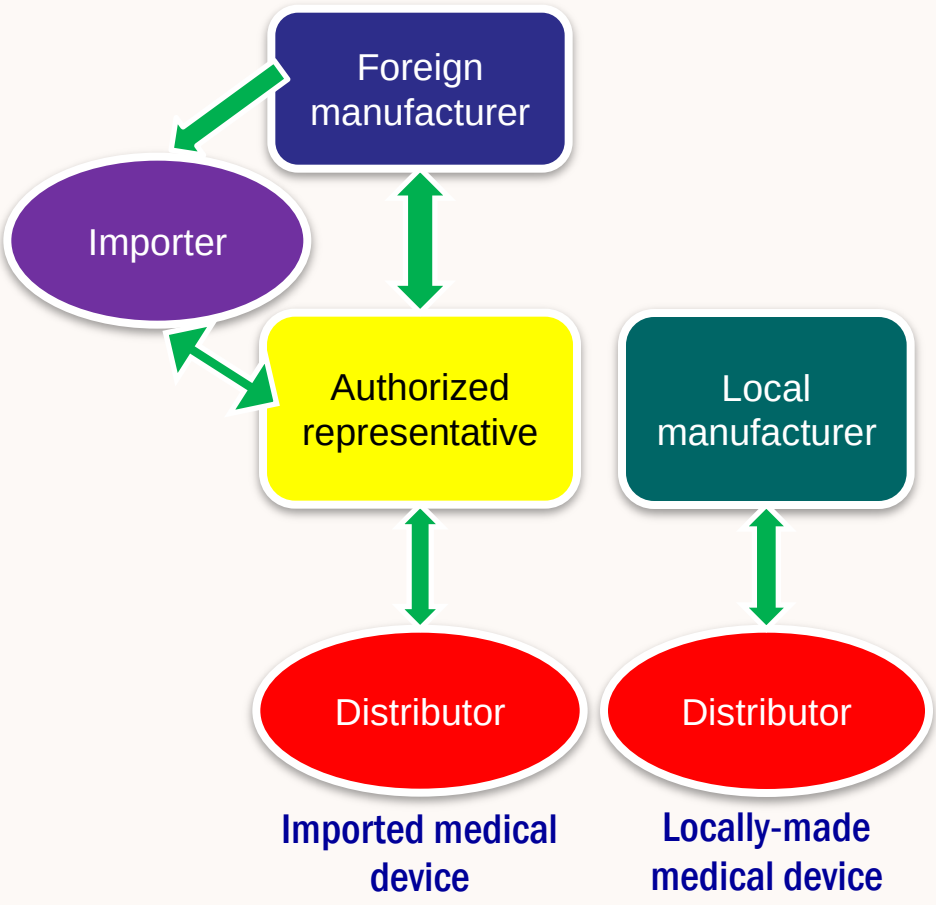
**S5 Act 737**
**Reg4 MDR 2012: 3rd Schedule**

- Who shall be responsible?
  - Licensed manufacturers or ARs
- What would be required?
  - Submission of evidence of conformity to the requirements of the law
- Upon approval, the medical device will be put in the Medical Device Register

# LICENSING OF ESTABLISHMENTS

**S15, S16 Act 737**
**Reg11 MDR 2012**

- Establishment means an "establishment" as defined in S2 Act 737 who is either a manufacturer, authorized representative (of foreign manufacturer), importer or distributor of medical devices
- 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




Types of establishments

# LICENSING OF ESTABLISHMENTS

**S15, S16 Act 737**
**Reg11 MDR 2012**

| Licensing requirements | Manufacturer (local) | Authorized rep | Importer | Distributor |
|---|---|---|---|---|
| • Establishment details | × | × | × | × |
| • Appropriate authorization | | × | × | × |
| • Procedures for; | | | | |
| – Distribution records | × | × | × | × |
| – Complaint handling | × | × | × | × |
| – Adverse incident reporting | × | × | × | × |
| – Field safety corrective action | × | × | × | × |
| • List of medical devices | × | × | × | × |
| • ISO 13485 | × | | | |
| • Good Distribution Practice for Medical Devices (GDPMD) | | × | × | × |

# NEW REGISTRATION & LICENSING SYSTEM

MeD@St

MEDICAL DEVICE CENTRALIZED APPLICATION SYSTEM

| | |
|---|---|
| ESTABLISHMENT LICENSING |  |
| MEDICAL DEVICE REGISTRATION |  |
| CAB REGISTRATION |  |

# EXPORT PERMIT

S45 Act 737

•An establishment may apply to the Authority for a permit to export a registered medical device in the prescribed form and accompanied by the prescribed fees

Reg 15 of MDR 2012

•Establishment is licensed

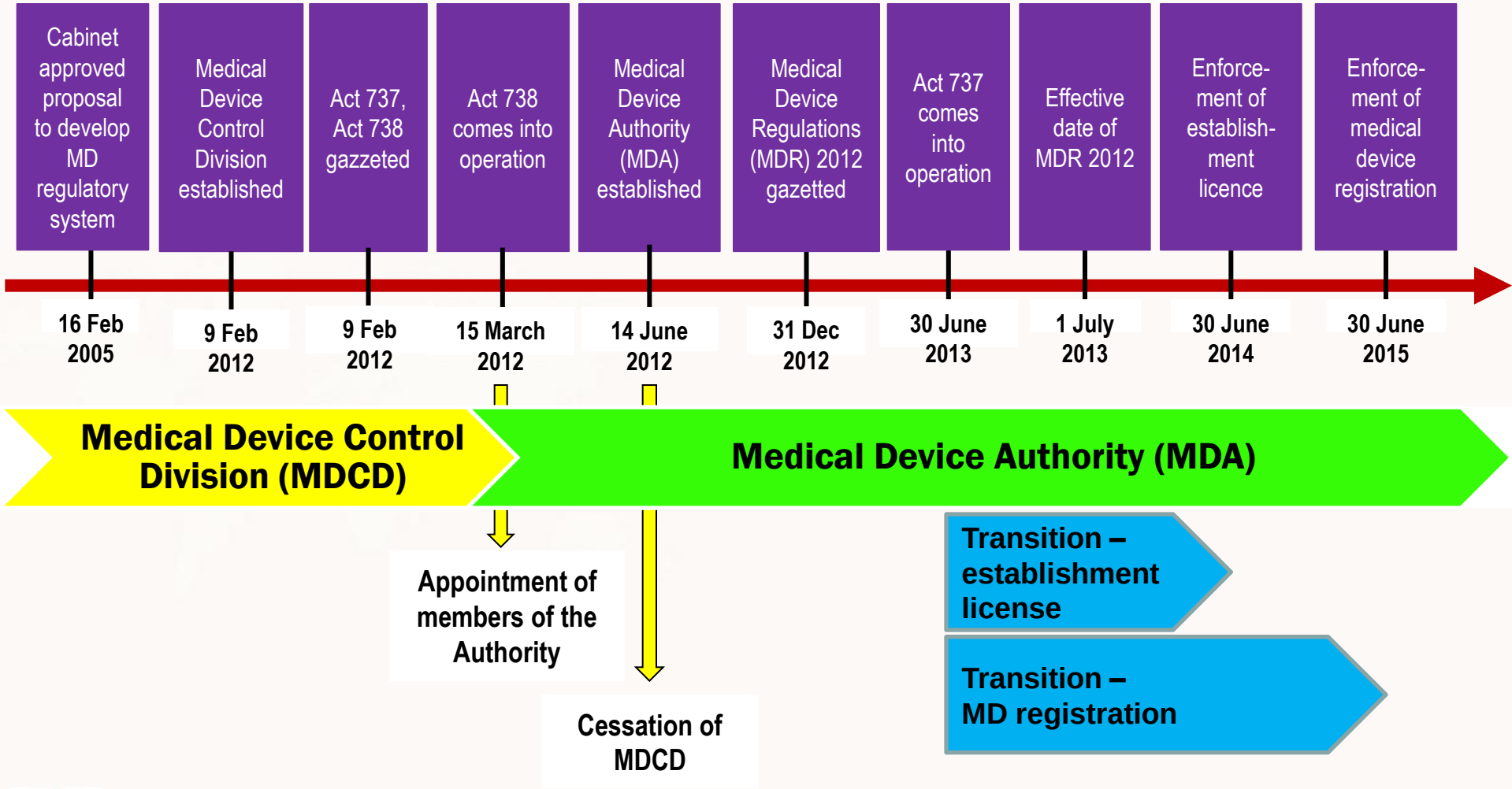
•Medical device is registered

# SAVINGS AND TRANSITIONAL

Act 737 Part VI: General

- Section 80: Savings and transitional
  - 80(1): A person who has imported, exported or place in the market any medical device prior to appointed date of the Act shall apply for registration of medical device within 24 months from the appointed date
  - 80(2): A person who has imported, exported or place in the market any medical device and intend to continue shall apply for establishment licence within 12 months from the appointed date
  - 80(3): A person in 80(1) or 80(2) may continue to import, export or place in the market the medical device pending determination of application

# PROGRESS REVIEW



# SUMMARY

- 2 main regulatory requirements for establishments dealing with medical devices
  - ✓ Registration of medical devices
  - ✓ Establishment licensing
- CA by registered CAB prior to registration & licensing
  - ✓ QMS, PMS, CSDT, DoC
  - ✓ Standards will be widely used
- Preparatory works are progressing
- Awareness & training will be conducted


Thank
You