MEDICAL DEVICE REGISTRATION

GS1 Malaysia Healthcare Seminar
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• Structure of Medical Device Regulatory System
• Medical Device Authority Act 2012 (Act 738)
• Subsidiary Regulations Under Act 737: Medical Device Regulations (MDR) 2012
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OBJECTIVES

Â 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

Â 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
STRUCTURE OF MEDICAL DEVICE REGULATORY SYSTEM
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

- **Come into operation on a date to be appointed by the Minister by notification in the Gazette**
STRUCTURE OF THE REGULATORY SYSTEM

MEDICAL DEVICE REGULATORY SYSTEM

MEDICAL DEVICE AUTHORITY 2012 (Act 738)

MEDICAL DEVICE ACT 2012 (Act 737) & subsidiary legislations

MINISTER OF HEALTH

MEDICAL DEVICE AUTHORITY

Chief Executive, officers, servants

Medical devices

Establishments

Manufacturers

ARs

Distributors

Importers

CABs

Users
MEDICAL DEVICE AUTHORITY

Act 2012 (Act 738)
MEDICAL DEVICE AUTHORITY (THE AUTHORITY)

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

Functions of MDA
- To implement, enforce, consider and recommend reform to the medical device laws
- To regulate all matters in relation to medical device, its industries and activities
- To encourage & promote the development of medical device industry
- 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

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

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
Cabinet approved proposal to develop MD regulatory system

Medical Device Control Division established

Act 737, Act 738 gazetted

Act 738 comes into operation

Medical Device Authority (MDA) established

Medical Device Regulations (MDR) 2012 gazetted

Act 737 comes into operation

Effective date of MDR 2012

Enforcement of establishment licence

Enforcement of medical device registration

16 Feb 2005

9 Feb 2012

9 Feb 2012

15 March 2012

14 June 2012

31 Dec 2012

30 June 2013

1 July 2013

30 June 2014

30 June 2015

Medical Device Control Division (MDCD)

Medical Device Authority (MDA)

Appointment of members of the Authority

Cessation of MDCD

Transition – establishment licence

Transition – MD registration
MEDICAL DEVICE ACT 2012
(Act 737)
ARRANGEMENTS OF SECTIONS

- Act 737 consists of 80 sections and is divided into six parts:
  - Part I (Preliminary)
  - Part II (Registration of Medical Device and Conformity Assessment Body)
  - Part III (Licence and Permit)
  - Part IV (Appeal)
  - Part V (Enforcement)
  - Part VI (General)
Quick Look at Act 737

- 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
Quick Look at Act 737

• Part III (Licence and Permit)
  
  Chapter 1: Establishment licence
  ▫ Section 15 – Section 25
  
  Chapter 2: Designated medical device permit
  ▫ Section 26 – Section 36
  
  Chapter 3: Duties and obligations of licencees or permit holders
  ▫ Section 37 – Section 42
  
  Chapter 4: General duty
  ▫ Section 43 – Section 44
Quick Look at Act 737

Chapter 5: Export permit
- Section 45 – Section 46

- PART IV (APPEAL)
  - Section 47

- PART V: ENFORCEMENT
  - Section 48 – Section 66

- PART VI: GENERAL
  - Section 67 – Section 80
ARRANGEMENTS OF REGULATIONS

- MDR 2012 consists of 22 regulations, 6 schedules and is divided into 9 parts:
  - Part I (Preliminary)
  - Part II (Conformity assessment procedure)
  - Part III (Registration of medical device)
  - Part IV (Registration of conformity assessment body)
  - Part V (Establishment licence)
  - Part VI (Export permit)
  - Part VII (Labelling requirements)
  - Part VIII (Appeal)
  - Part IX (Register)
Quick Look at MDR 2012

- **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
Quick Look at MDR 2012

• PART IV (REGISTRATION OF CONFORMITY ASSESSMENT BODY)
  ▫ Regulation 8 – Regulation 10

• PART V (ESTABLISHMENT LICENCE)
  ▫ Regulation 11 – Regulation 14

• PART VI (EXPORT PERMIT)
  ▫ Regulation 15
Quick Look at MDR 2012

- PART VII (LABELLING REQUIREMENTS)
  - Regulation 16

- PART VIII (APPEAL)
  - Regulation 17 – Regulation 20

- PART IX (REGISTER)
  - Regulation 21 – Regulation 22

First Schedule – Sixth Schedule
MEDICAL DEVICE REGISTRATION
**ACT 737 & SUBSIDIARY LEGISLATIONS**

- **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

- **MDR 2012**
  - Gazetted in December 2012
  - Effective date: 1 July 2013

- **Orders, other legislative tools**
  - Based on needs, eg exemptions
  - Being drafted

- **Guidance documents, standards, guidelines**
  - Based on needs
WHO & WHAT WILL BE AFFECTED?

(i) “establishment”
(ii) “authorized representative”
(iii) “manufacturer”
(iv) “medical device”

Who are they?
Refer to Section 2 of Act 737 for the interpretation
ESTABLISHMENT (SECTION 2, 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
MANUFACTURER (SECTION 2, 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
MANUFACTURER (SECTION 2, ACT 737)

(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.
**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;
MÉDICAL 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.
HOW REGISTRATION IS DONE?

Refer to
(i) Chapter 1 of Part II of Act 737 (Registration of medical device)
(ii) Part II of MDR 2012 (Conformity assessment procedure)
(iii) Part III of MDR 2012 (Registration of medical device)
HOW REGISTRATION IS DONE?

Act 737 Part I, Chapter 1:
Registration of medical device
• Section 3: Classification of medical device
• Section 4: Manufacturer’s obligation
• Section 5: Requirement for registration of medical device
• Section 6: Application for registration of medical device
• Section 7: Registration and refusal to register medical device
• Section 8: Power to impose additional conditions and to vary or revoke conditions
• Section 9: Power to cancel registration of medical device
CLASSIFICATION

- Act 737 Part II, Chapter 1 Section 3
  - Section 3 (1): Establishment shall classify its medical device based on the level of risk it poses, its intended use and vulnerability of the human body in accordance with the prescribed manner

- MDR 2102 Part II Regulation 3
  Regulation 3(1): classify based on rules in First Schedule (rules of classification of medical device) and grouped using the rules in Second Schedule
CLASSIFICATION

- **First Schedule: Rules of classification of medical device**
  - Appendix 1: Classification rules classify medical device, excluding *in vitro* diagnostic medical device
  - Appendix 2: Classification rules classify medical device for *in vitro* diagnostic medical device

- **Second Schedule: Rules of medical device grouping**
  - Appendix 1: List of methodology and cluster category for *in vitro* diagnostic cluster
**CLASSIFICATION**

Dispute over classification

- **Act 737 Part II, Chapter 1 Section 3**
  - *Section 3(2):* Any dispute over classification of medical device shall be referred to the Authority in the manner and within such period prescribed by Authority

- **MDR 2102 Part II Regulation 3**
  - *Regulation 3(2):* Request for decision over dispute over classification shall be made in writing to the Authority within 30 days from the date of dispute
  - *Regulation 3(3):* Authority notifies decision within 30 days from the date of request
MANUFACTURER’S OBLIGATIONS

• Act 737 Part II, Chapter 1 Section 4
  ▫ It is the manufacturer’s obligation to ensure a medical device
    • conforms to the prescribed essential principles of safety and performance;
    • is manufactured in accordance with good manufacturing practice and any written directive issued by the Authority; and
    • is labelled, packaged and marked in accordance with the prescribed manner
MANUFACTURER’S OBLIGATIONS

- MDR 2012 Part II, Regulation 4
  - Regulation 4(1): All medical device shall be subjected to conformity assessment according to requirements in Third Schedule
  - Regulation 4(2): Manufacturer shall collect evidence of conformity and appoint conformity assessment body to conduct conformity assessment
  - Regulation 4(3): Conformity assessment body shall issue report and certificate
  - Third Schedule: Conformity assessment procedure
MANUFACTURER’S OBLIGATIONS

MDR 2012 Part II, Regulation 4
THIRD SCHEDULE – CONFORMITY ASSESSMENT PROCEDURE

• PART I (PRELIMINARY)
  1) Application

• PART II (PROCEDURE FOR CONFORMITY ASSESSMENT)
  2) Collection of evidence of conformity by the manufacturer or authorised representative
  3) Conformity assessment by conformity assessment assessment body
  4) Report and certificate of the conformity assessment

• PART III (ELEMENTS OF CONFORMITY ASSESSMENT)
  Elements of conformity assessment
MANUFACTURER’S OBLIGATIONS

- Conformity assessment of quality management system
- Conformity assessment of post-market surveillance system
- Conformity assessment of technical documentation
- Declaration of conformity

5) Evidence of conformity for an imported medical device

6) Quality management system requirement for a manufacturer, an authorised representative of a foreign manufacturer, importer and distributor of medical device

7) Registration and licensing
MANUFACTURER’S OBLIGATIONS

Appendix 1 – Essential Principles of Safety and Performance of Medical Device
Appendix 2 – Common Submission Dossier Template (CSDT)
Appendix 3 – Declaration of Conformity
Appendix 4 – Requirement on quality management system

MDA_GD02EPSPMD
MDA_GD03CSDT
MDA_GD04ClassRule
MANUFACTURER’S OBLIGATIONS

MDR 2012 Part VII: Labelling Requirements

• Regulation 16: General provisions for labelling
  ▫ 16(1): Labelling shall be done according to Sixth Schedule
  ▫ 16(2): Labelling shall not contain any statement to the effect that the medical device is promoted or endorsed by the Authority or Ministry
  ▫ 16(3): Label shall be legible, permanent and prominent
  ▫ 16(4): Fine for offence under 16(2) – RM10K or 3 months imprisonment or both

Sixth Schedule
  • Part I: Preliminary
  • Part II: General provisions on labelling
  • Part III: Contents of labelling
REQUIREMENTS FOR REGISTRATION OF MEDICAL DEVICE

- Act 737 Part II Chapter 1
  Section 5: Requirement for registration of medical device
  ▫ 5(1): No medical device shall be imported, exported or placed in the market unless the medical device is registered under this Act
  ▫ 5(2): Fine for offence under subsection (1) – RM200K or 3 years or to both
APPLICATION FOR REGISTRATION

- Act 737 Part II Chapter 1
  Section 6: Application for registration of medical device
  - 6(1): Application shall be made to the Authority in the prescribed manner
  - 6(2): Application may be withdrawn any time before it is approved or refused
  - 6(3): Application shall be accompanied by prescribed fee and document or information specified by Authority
  - 6(4): Authority may request additional information, particulars, documents, sample
  - 6(5): Application shall be deemed to be withdrawn if additional information, particulars, document, sample is not given within specified or extension of time
REQUIREMENTS FOR REGISTRATION OF MEDICAL DEVICE

- MDR 2012 Part III

Regulation 5: Application for registration

- 5(1): Application shall be made in the forms to be determined by the Authority
- 5(2): Application shall be accompanied with:
  - Application fee in Fifth Schedule
  - Document or information as specified in the forms
  - Other additional information, document or sample (may be)
- 5(3): Other additional information, document shall be submitted within 90 days from the date of request
REQUIREMENTS FOR REGISTRATION OF MEDICAL DEVICE

MDR 2012 Part III

Regulation 6: Registration

- 6(1): Authority considers application and notifies its decision
- 6(2): Registration fee shall be as in Fifth Schedule
- 6(3): Registered medical device is kept in the Register for 5 years unless registration is cancelled

Fifth Schedule: Table of fees
REGISTRATION OR REFUSAL TO REGISTER

- Act 737 Part II Chapter 1
  Section 7: Registration or refusal to register medical device
  - 7(1): Authority may register medical device for a prescribed period and conditions, if it is satisfied that
    - Conformity assessment has been done
    - All requirements are complied with
    - Registration fee has been paid
  - 7(2): Authority may not register if 7(1) is not satisfied
POWER TO IMPOSE ADDITIONAL CONDITIONS

• Act 737 Part II Chapter 1
Section 8: Power to impose additional conditions and to vary and revoke conditions
  ▫ Authority may impose additional conditions, vary or revoke conditions on registration
POWER TO CANCEL REGISTRATION

• Act 737 Part II Chapter 1

Section 9: Power to cancel registration

▫ 9(1): Authority may cancel registration of medical device if the establishment holding the registration contravenes any provision of the Act or regulations, has breached any conditions of registration, or has been convicted of an offence under this Act

▫ 9(2): Authority shall give the establishment an opportunity to show cause against the cancellation, by notice in writing. Importation and supply shall be suspended upon receipt of the notice

▫ 9(3): The establishment shall not be entitled to any compensation for any loss and to any refund of registration fee
POWER TO CANCEL REGISTRATION

MDR 2012 Part III
Regulation 7: Cancellation of registration

- **7(1):** Authority notifies registration holder on cancellation, in writing
- **7(2):** Registration holder may submit show cause letter within 90 days from date of notification
- **7(3):** Registration may request for extension of time for show cause letter
- **7(4):** Authority considers application for extension of time
- **7(5):** Authority notifies in writing, if it decides to cancel registration
POWER TO CANCEL REGISTRATION

- 7(6): Registration holder shall return certificate within 14 days
- 7(7): Fine for offence under 7(6) - RM10K or 6 months imprisonment or both
OTHER RELATED PROVISIONS
**ESTABLISHMENT LICENCE**

- Act 737 Part III Chapter 1: Establishment licence
  
  **Section 15: Requirement for establishment licence**

  - 15(1): No establishment shall import, export or place in the market any medical device unless it holds establishment licence
  - 15(2): Fine for offence under 15(1) – RM200k or 3 years imprisonment or both
CONFORMITY ASSESSMENT BODY

Act 737 Part II Chapter 2: Registration of conformity assessment body

• Section 10: conformity assessment body
  ▫ 10(1): A conformity assessment body shall be a body registered under this Act to carry out conformity assessment
  ▫ 10(2): Person responsible of the conformity assessment body shall be Malaysian citizen
  ▫ 10(3): Conformity assessment body shall be independent

• Section 11: Requirement for registration of conformity assessment body
  ▫ 11(1): No conformity assessment body may carry out any conformity assessment unless it is registered under this Act
APPEAL

Act 737 Part IV: Appeal
• Section 47: Appeal against decision of Authority
  ▫ 47(1): Any person aggrieved by the decision of Authority may appeal to the Minister in the prescribed manner and period
  ▫ 47(2): Minister may confirm, reverse or vary the decision of Authority
  ▫ 47(3): Minister’s decision is final and binding

MDR 2012 Part VIII: Appeal
• Regulation 17: Notice of appeal
  ▫ 17(1): Notice of appeal shall be sent to Minister by registered post within 30 days from the date of the decision of the Authority
  ▫ 17(2): The notice shall contain particulars of appellant, the decision, the grounds of appeal, supporting information or document
  ▫ 17(3): The notice shall be accompanied with appeal fee in Fifth Schedule
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
FOR YOUR ATTENTION.