Medical Device Regulatory System in Malaysia

Seminar and Business Networking Session (B2B) Programme for Outsourcing Opportunities in Medical Device and Machinery & Equipment Industries –

Intensifying Malaysia as a Global Solution Provider in Outsourcing/Contract Manufacturing

Eastern & Oriental Hotel, Penang
31 October 2013
OBJECTIVES OF REGULATORY SYSTEM

• To address public health & safety issues
  – Assessment of safety and performance of medical devices
  – Necessary information to make informed choices on medical devices
  – Usage of certain medical devices
  – Identification and monitoring of medical devices in the market

• To facilitate medical device trade & industry
  – Local manufacturers to enter global market
  – Growth of medical device industry
**INSTITUTIONAL STRUCTURE**

**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

... gives powers to...

... to regulate...

Establishments
- Manufacturers
- ARs
- Distributors
- Importers

Medical devices

CABs

Users
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 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
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**

**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

- **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

**Placement on-Market**
- **Usage & Maintenance:** Users shall use, maintain & dispose off medical devices appropriately
  - Users shall apply for permit to use/operate designated medical devices

**Post-Market**
- **Surveillance & Vigilance:** Establishments shall -
  - monitor safety & performance of products
  - carry out post-market obligations, eg complaint handling, FSCA, recall

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

- S2: All products that meet the definition of “medical device” shall be registered prior to placement into the market.
- S2: All “establishment” shall be licensed to conduct activities relating to manufacturing, importing, representing foreign manufacturer, distributing medical devices in Malaysia.
- S10-14: Conformity assessment bodies (CABs).

Types of “establishment” & regulated activities/responsibilities

- Manufacturer
  - To ensure medical devices meet EPSP and are manufactured in accordance with good manufacturing practice.
  - To apply for registration.
- Authorized representative
  - To ensure compliance with requirements of good distribution practice (GDPMD).
  - To monitor safety & performance and to take appropriate corrective/preventive actions.
  - To act on behalf of foreign manufacturers with regard to the manufacturer’s responsibilities under Act 737.
- Importer and distributor
  - To ensure compliance with requirements of good distribution practice (GDPMD).
“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;
(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
“medical device” means
(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.
“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” 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.
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 EPSP;
  – 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

MDR 2012 Part II, Regulation 4

• Reg 4(1): All medical device shall be subjected to conformity assessment according to requirements in Third Schedule
• Reg 4(2): Manufacturer shall collect evidence of conformity and appoint conformity assessment body to conduct conformity assessment
• Reg 4(3): Conformity assessment body shall issue report and certificate
Evidence of Conformity, Conformity Assessment (CA), Registration, Licensing

S4, S5, S15, S16, S79 Act 737:

- Medical device regulation is based on safety and performance of medical device throughout its life cycle
- CA shall be conducted to provide objective evidence of conformity/compliance to—
  - Essential Principles of Safety and Performance for Medical Devices (EPSP)
  - Act 737 and its subsidiary legislations
- The Authority verifies evidence of conformity during registration of medical device and licensing of establishment
- Only registered medical devices are allowed to be placed into the market by licensed establishments
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
• Section 6: Application for registration of medical device
• MDR2012 Regulation 5 - detailed procedural requirements

Reg4 MDR 2012: 3rd Schedule
• Who shall be responsible? - Licensed manufacturers or ARs
• What would be required? - Submission of evidence of conformity
Upon approval, the medical device will be put in the Medical Device Register
**MEDICAL DEVICE REGISTRATION**

- **Medical device?**
  - **Class B/C/D**
    - **CA by CAB**
      - 1) Technical file: CSDT, DoC
      - 2) QMS, PMS
    - **Comply with requirements?**
      - Yes
        - 1) Application forms
        - 2) DoC
        - 3) Cert QMS (ISO 13485)
        - 4) Evidence of registration from reference agency
        - 5) CSDT
          - Class B/C: clinical evidence, if required
          - Class C/D: clinical evaluation
      - No
        - **Complied with registration requirements?**
          - Yes
            - **Pay fee**
          - No
            - **Applicant**

- **Class A**
  - **Grouping:**
    - Single
    - System
    - Kits
    - Group
    - IVD cluster
  - **Grouping:**
    - Single
    - System
    - Kits
    - Group
    - IVD cluster
  - **Class?**
    - **Yes**
      - 1) Application forms
      - 2) DoC
      - 3) Cert QMS (ISO 13485) or manufacturer’s attestation
      - 4) Evidence of registration from reference agency
      - 5) CSDT
        - Class A sterile: QMS, QMS for sterile service or process validation report
        - Class A (M): QMS or process validation report
      - 4) Simplified CSDT
    - **No**
      - **Stop**
CA Procedure and Parties Involved

CA is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established regulatory requirements and both the process and conclusions are subject to further review by the Authority.

Manufacturer conducts CA on:
(i) QMS
(ii) PMS system
(iii) Summary tech doc (CSDT)
(iv) Declaration of conformity (DoC)

CAB reviews evidence of conformity

Authority reviews & registers medical devices & issues licenses for establishments

What is a conformity assessment body (CAB)?
- A body registered 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
- Authority will monitor the performance of the CAB and, if necessary, withdraw authorization

Act 737: S4-9, S15-20, S79
Reg4 MDR 2012: 3rd Schedule
**Elements of CA**

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

**QMS**
- For manufacturer, ISO 13845
- For AR, importer, distributor: GDPMD
- PMS system
- Technical evaluation of sterilization process

**PMS System**
- Distribution record
- Complaint record
- Adverse incident reporting
- Field corrective action reporting

**Summary Technical Documentation**
- Format – CSDT
- Compliance to EPSP
- Acceptable standards or equivalence will be widely used CAB determines the adequacy of the documented evidence to support attestation of conformity

**DoC**
- A declaration made by the manufacturer of a medical device that each piece of the device sold is in conformity with the regulatory requirements
- DoC shall be signed by the manufacturer
SUMMARY TECHNICAL DOCUMENTATION

CSDT

- Executive summary
- Relevant essential principles and method used to demonstrate conformity
- Description of medical device
- Summary of design verification and validation documents
- Pre-clinical studies
- Software validation studies
- Medical devices containing biological material
- Clinical evidence
- Use of existing bibliography
- Medical device labeling
- Risk analysis
- Manufacturer information
- Special requirement for medical device used in clinical investigation
**Essential Principles of Safety & Performance of Medical Device**

### General principles
Medical device should be designed & manufactured in such a way that:
- no compromise to clinical condition or safety of patients, or safety and health of users or other persons
- control the risk so that residual risk is brought down to an acceptable level
- suitable for one or more of the functions within the scope of the definition of a medical device
- characteristics and performances should not be adversely affected to such a degree that they compromise the health or safety of patient or user and other persons during the lifetime of the device
- characteristics and performances during their intended use will not be adversely affected under transport and storage conditions
- benefits must be determined to outweigh any undesirable side effects

### Design and manufacturing principles
- Chemical, physical and biological properties
- Infection and microbial contamination
- Manufacturing and environmental properties
- Devices with a diagnostic or measuring function
- Protection against radiation
- Requirements for medical devices connected to or equipped with an energy source
- Protection against mechanical risks
- Protection against the risks posed to the patient by supplied energy or substances
- Protection against the risks posed to the patient for devices for self-testing or self-administration
- Information supplied by manufacturer
- Performance evaluation including where appropriate, clinical evaluation
**Level of CA**

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

<table>
<thead>
<tr>
<th>Class</th>
<th>QMS</th>
<th>PMS system</th>
<th>Summary tech doc</th>
<th>DoC</th>
</tr>
</thead>
</table>
| Class A, Class A(S) Class A(M) | • Establish & maintain QMS  
• Can exclude design & development control  
• May be audited for special cases | • Establish & maintain adverse event reporting procedure for audit  
• Class A: may be audited to investigate specific safety or regulatory concerns | • Prepare, make available upon request.  
• Class B: reviewed for conformity to EPSP | Prepare, sign & submit for review |
| Class B          | Establish, maintain full QMS make available for audit               |                                                                           | Prepare & submit for review                                                    |                                                                     |
| Class C          |                                                                    |                                                                           |                                                                                |                                                                     |
| Class D          |                                                                    |                                                                           |                                                                                |                                                                     |
Risk-based classification & regulatory control

- 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

- MDR2012 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

- MDR2012 Second Schedule: Rules of medical device grouping
  - Appendix 1: List of methodology and cluster category *for in vitro* diagnostic cluster
Licensing of Establishments

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.

Establishment must possess valid license to carry out activities related to medical devices in Malaysia.
Authorizations

S15, S16 Act 737
Reg11 MDR 2012

Authorization: Appropriate authorization from the respective establishment is required as a pre-requisite for the issuance of license
- **Authorized Rep (AR) must be authorized by foreign manufacturer**
- **Importer must be authorized by authorized rep to import devices on its behalf**
- **Distributor must be authorized by manufacturer/authorized rep (AR) to distribute devices on its behalf**
- **An entity may apply for license for different types of establishment**

Manufacturer as defined in Section 2 of Act 737: definition of “manufacturer”
Authorized representative as defined in Section 2 of Act 737: definition of “manufacturer”
- Authorized representative must be natural or legal person with business registration in Malaysia.
- It must maintain linkage with its foreign manufacturer and should be able to obtain the support of its foreign manufacturer whenever required.

Distributor: Any natural or legal person in the supply chain authorized by the manufacturer/authorized representative to further the availability of medical devices to the end-user. In some circumstances, more than one distributor may be involved in this process
Importer: Any natural or legal person authorized by authorized representative, who first makes a medical device manufactured in other countries, available in the Malaysian market
# Requirements for Licensing of Establishments

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

<table>
<thead>
<tr>
<th>Licensing requirements</th>
<th>Manufacturer (local)</th>
<th>Authorized rep (AR)</th>
<th>Importer</th>
<th>Distributor</th>
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<tbody>
<tr>
<td>• Establishment details</td>
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<td>• Appropriate authorization</td>
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<td>• Procedures for;</td>
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<td>– Distribution records</td>
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<td>– Complaint handling</td>
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<td>– Adverse incident reporting</td>
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<td>– Field safety corrective action</td>
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<td>• List of medical devices</td>
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<td>• ISO 13485</td>
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<tr>
<td>• Good Distribution Practice for Medical Devices (GDPMD)</td>
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• Medical Device Centralised Online Application System
• A web-based online *application forms* for Establishment Licensing and Medical Device Registration
• Only ONE ACCOUNT needs to be created by an applicant to do any of those applications
Establishment Licensing

- Establishment details
- Person responsible for establishment
- Contact person details
- Quality Management System
- Post-market surveillance system
- Medical device details
- Attestation for establishment licensing

Medical Device Registration

- General information on medical device
- Information on manufacturer of medical device
- Grouping of medical device
- CSDT and its supporting documents
- Post-market vigilance history
- Declaration of Conformity
- Attestation for medical device registration
THE STEPS

Start

Go to website [www.mdb.gov.my](http://www.mdb.gov.my)

Create an account

- Validate the email address provided

Make an application
- Establishment licensing
- Medical Device Registration

Log in to the system

Successful?

No

Yes
**Post-Market Control**

- Post-market surveillance
  - A post-market data collection system especially for high-risk medical devices
  - Done as a condition for product approval and to re-affirm product safety

- Adverse event reporting
  - A timely dissemination of information
    - to prevent recurrence of similar incident
    - to ensure timely intervention of adverse incident and necessary remedial action

- Manufacturer/representative should;
  - report adverse incidents that suggest that death or serious injury of a patient has been caused/contributed by the use of medical device
  - investigate and carry out follow-up actions, eg product recall, and report the results to the Authority

- Healthcare professionals are encouraged to notify manufacturer/representatives of adverse incidents
Post-Market Surveillance & Vigilance

Sections in Act 737
37. Distribution records
38. Post-market surveillance and vigilance
39. Complaint handling
40. Mandatory problem reporting
**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
MDR 2012
Reg 5, 6, 8, 9, 11, 12, 13, 15, 17 & 22
5th Schedule

Medical device registration
- Application fee
- Registration fee

Establishment license
- Application fee
- License fee
- Renewal fee

Export permit
CAB registration
- Application fee
- Registration fee
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
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
Please visit us at [www.mdb.gov.my](http://www.mdb.gov.my) for further information

Link to Act 737 and MDR2012