Regulation Of Medical Devices in Malaysia

National Regulatory Conference, May 2013
Malaysia currently imports around 95% of the medical device for its consumption

In Malaysia, the medical device industry is a highly diversified industry that produces a broad range of products and equipment ranging from medical gloves, implantable devices, orthopaedic devices and dialysers to diagnostic imaging equipment and minimal invasive surgical equipment and other devices which can be used for medical, surgical, dental, optical and general health purpose.
Malaysia
Exports of Medical Devices

Total Exports in 2011: RM11.7 Billion

Source: Malaysia Statistics Department, MITI, MIDA, PEMANDU
Medical Device Cluster in Koridor Utara
Why Regulate Medical Devices?

• 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 favourable environment* for the growth of medical device industry
World Health Organization guidance

“Governments need to put in place policies that will address all elements related to medical devices, ranging from access to high quality, affordable products, through to their safe and appropriate use and disposal. ...

Policies will be unsuccessful unless they are translated into national regulations that are enforced by legislation and correlating sanctions, and that form an integral part of the overall national health system.”

Source: Medical device regulations: Global overview and guiding principles; World Health Organization, Geneva; 2003
(At: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf)
Guiding Principles

- The primary goal is to **protect public health and safety**
- The level of **regulatory control should be proportional to the degree of risk**
- Expedites timely availability and access to safe and beneficial medical devices and to prevent unsafe and ineffective medical devices from entering the market
- Elements of **control from design through disposal** stages shall be put in place to ensure continued safety and quality
- In-line with **global harmonization** effort to minimize regulatory barriers, facilitate international trade, improve access to new technologies and to reduce the cost of implementing regulation
HARMONISATION (Non Tariff Barrier)

- Recommendations from the World Health Organisation (WHO)
- Recommendations from the Global Harmonisation Task Force
- In line with the World Trade Organisation’s (WTO) Agreements
- ASEAN’s Medical Device Directive
- Recommendations from Asian Harmonisation Working Group (AHWP)
Malaysian Medical Device Act: A Harmonized Regulatory Approached

- Definition of Medical devices
- Pre-market requirements
- Requirements for placement on the market
- Post-market requirements
- Enforcement and investigation
- Miscellaneous (e.g., Standards, Designated Devices)
Current Status

- Medical Device Act (Act 737) 2012
- Medical Device Authority Act (Act 738) 2012
  - Passed by Lower House of Parliament: 3 Oct 2011
  - Passed by Upper House of Parliament: 7 Dec 2011
  - Date of Royal Assent: 30 Jan 2012
  - Date of publication in Gazette: 9 Feb 2012
    - Appointed date for the Medical Device Authority Act is 15 March 2012
    - Appointed for the Medical Device Act is 30th June 2013

- Medical Device Regulations 2012
  - Appointed date of the Medical Device Regulations is 1st July 2013
Institutional Structure of Medical Device Regulatory System

MEDICAL DEVICE AUTHORITY (Act 738) 2012

MEDICAL DEVICE ACT (Act 737) 2012

MINISTER OF HEALTH

MEDICAL DEVICE AUTHORITY

Chief Executive, officers, servants

...gives powers to...

...to regulate...

CABs

Users

Establishments
  • Manufacturers
  • LARs
  • Distributors
  • Exporters
Medical Device Authority Act (Act 738) 2012 – The Authority

**MEDICAL DEVICE AUTHORITY (MDA)**

A body corporate with the following members
- DG of Health as the Chairman
- Chief Executive of the MDA
- Representative from the Min of Finance
- a representative from the 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 perform the following in relation to medical device, its industries and activities:
  - to regulate all matters
  - to encourage & promote the development
  - to provide consultancy & advisory service and any other services
- 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
The WHO Medical Device regulatory model?

The Medical Device Life Cycle
MEDICAL DEVICES LIFE CYCLE IN HEALTHCARE FACILITIES

- Procurement
- Use
- Maintenance
- Disposal
- New Purchases, Replacement Planning, According to User requirements
- Installation/Testing & Commissioning/Acceptance
- Hosp. Devices register
- Device Assessment-HTA
- MDB Devices register
- Active Medical Devices
- Field Safety Corrective Actions
- Incident reporting
- Training
- Competency Register
- Devices register
Elements of Regulatory Program

**DEVICE**
Safety, quality and performance, ERSP

**ACTIVITIES**
Pre-market, placement on the market, post-market

**USE**
Usage, personnel, maintenance
Medical Device Lifecycle – What are the Regulatory Activities?
Overview of The Regulatory System

**PRE-MARKET**

**PRE-MARKET REVIEW**
- Manufacturers of medical devices shall -
  - ensure their products conform to EPSP
  - ensure their products are manufactured in accordance with GMP
  - collect evidence of conformity

**MEDICAL DEVICES REGISTRATION**
- Manufacturers (or LARs) apply for register medical devices & establishment license to manufacture

**DISTRIBUTORS LICENSING**
- Distributors shall -
  - ensure compliance to GDP & advertising requirements
  - apply for establishment license to distribute medical devices

**POST-MARKET**

**MDA allows -**
- registered medical devices to be placed into the market
- licensed establishments to do their business

**SURVEILLANCE & VIGILANCE**
- Establishments shall-
  - monitor safety & performance of their products
  - carry out post-market obligations, eg user training, 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

CAB verifies evidence of conformity
Essential Principle of Safety & Performance

1) No compromise on clinical condition and safety of patients, health and safety of users and other persons when use under the conditions and for the purposes intended

2) In the design and construction of medical device, hazards, associated risks and foreseeable misuse from the intended use should be identified, eliminated/reduced; any residual risks that cannot be eliminated, protection measures should be taken and should be informed to users

3) Medical device should achieve the intended/specifed performance and be designed, manufactured and packed in such a way that it is suitable for the functions within the scope of the definition of medical device

4) Characteristics and performances should not be adversely affected by stresses during normal conditions of use and proper maintenance

5) Characteristics and performances during the intended use should not be adversely affected under transport and storage conditions

6) The benefits outweigh any undesirable side effects
| 1) | Chemical, physical and biological properties |
| 2) | Infection and microbial contamination |
| 3) | Manufacturing and environmental properties |
| 4) | Devices with a diagnostic or measuring function |
| 5) | Protection against radiation |
| 6) | Requirements for medical devices connected to or equipped with an energy source |
| 7) | Protection against mechanical risks |
| 8) | Protection against the risks posed to the patient by supplied energy or substances |
| 9) | Protection against the risks posed to the patient for devices for self-testing or self administration |
| 10) | Information supplied by the manufacturer |
| 11) | Performance evaluation including, where appropriate, clinical evaluation |
What is a medical device?

“Medical device” is 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:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease;
   - compensation for an injury;
   - investigation, replacement, modification, or support of the anatomy or of a physiological process;
   - supporting or sustaining life;
   - control of conception;
   - disinfection of medical devices;
   - providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

and

b) 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.
Risk-Based Classification

- Medical device is classified based on the risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device.

- Risk-based classification:
  - Class A (low)
  - Class B (low moderate)
  - Class C (high moderate)
  - Class D (high)

Risk-based classification & regulatory control

Regulatory requirements

Device risk
## Who & What will be Regulated?

<table>
<thead>
<tr>
<th>Responsible parties</th>
<th>Regulated activities/responsibilities</th>
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<tbody>
<tr>
<td>Local manufacturers</td>
<td>• To ensure products meet essential principles of safety &amp; performance (EPSP) and are manufactured in accordance with good manufacturing practice (GMP)</td>
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<tr>
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<td>• To apply for product registration</td>
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<td>• To monitor safety &amp; performance and to take corrective actions on problems related to products in the market</td>
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<td>Exporters</td>
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<tr>
<td>Local authorized representatives (LARs) of foreign manufacturers</td>
<td>To act on behalf of foreign manufacturers with regard to the manufacturer’s responsibilities under the Malaysian laws</td>
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<tr>
<td>Importers</td>
<td>To ensure compliance with requirements of good distribution practice (GDP), eg cleanliness &amp; suitability of premises, storage &amp; stock handling, traceability, product complaints, etc</td>
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<tr>
<td>Distributors</td>
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<tr>
<td>Conformity assessment bodies (CABs)</td>
<td>To verify evidence of conformity to EPSP, GMP, GDP</td>
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<tr>
<td>Users of medical devices on patients</td>
<td>• To ensure competencies of users &amp; persons involve in maintenance of medical devices</td>
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<td>• To apply for permit to use designated medical devices</td>
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MEDICAL DEVICE REGULATION APPLICATION

MANUFACTURER

Product Lifecycle Start

Definitions

The Essential Principles/Standards

QMS Design Control/ Risk Analysis

QMS Design Control/ Risk Assessment

QMS GMP

Device Classification

Device Requirements/Intended Use

Design Input/ Specifications

Design

Design Verification

Pilot Production

Device Validation

Technical Information

CSDT

Conformity Assessment

Registration of Medical Device

Approval Registration

Post Market Surveillance and Vigilance

QMS Maintenance and Servicing

Placing On The Market

Market Performance

Obsolescence

QMS and Risk Management are applicable throughout the complete product lifecycle

QMS GMP

Labelling

Manufacturing

AUDITS – Internal and External Certification

Coverage of the complete quality management system

Product Lifecycle End
The process of medical device registration in general

1. Medical device?
   - Yes: Group the medical device
     - Yes: Conduct the conformity assessment
       - No: Classification of medical device
       - Yes: Conduct the conformity assessment
   - No: Classification of medical device

2. Assessment by CAB
   - Yes: Approval?
     - Yes: Pay fee
       - No: Conduct the conformity assessment
   - No: Conduct the conformity assessment

3. Evaluation
   - Yes: Decision
     - Yes: MEDICAL DEVICE REGISTER
     - No: Conduct the conformity assessment
   - No: Conduct the conformity assessment

4. Decision
   - Yes: Stop
   - No: Conduct the conformity assessment
Empower the industry to self declare for Class A devices

Manufacturer themselves choose the regulatory control route of medical devices they manufacture based on the risk classification

Conformity Assessments are carried out by third party
Now to Mandatory Phase: The Timeline

- MD Act 737, MDA Act 738 Gazetted
- Appointed date for MDA
- Establish Corporate Office
- Appointed Date for the Act 737
- Appointed Date for the Medical Device Regulations
- CAB Registration
- Establishment Registration
- Device Registration
- Mandatory Phase

- 9/2/12
- 15/3/12
- 14/6/12
- 31/6/13
- 1/7/13
- 1/7/13
- 1/7/13
- 1/7/15

Voluntary
- Appointment of members of MD Authority
- Cessation of MDB
- Appointment of Chief Executive of MD Authority

Transition
- 24 months

Mandatory
- Enforcement

Preparation & development of regulations, guidance documents & standards for the implementation of MD Act
Thank You