Asia-Pacific
Economic Cooperation

2011/SOM1/SCSC/CON1/012
Session 7

Malaysia's Experience in Regulating the Medical Device Sector

Submitted by: Malaysia

APEC USA 2011

6th Conference on Good Regulatory Practice
Washington, D.C., United States
1-2 March 2011

Malaysia's experience in Regulating the Medical Device Sector

The Medical Device Control Division,
Ministry of Health Malaysia

Malaysian Scenario

Present status:

There is no statutory pre-market, placement on market,post market requirements for the registration and control of medical devices before they can be placed and used in Malaysia

Except:

- Radiation emitting devices e.g. x-ray, CT, mammo
- Act 304 – enforced since 1974

Regulatory status in Malaysia

Problems with Medical Device

- 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
- Facilitating medical device trade & industry
  - No facilitation of local manufacturers to market their products globally
  - No favourable environment for the growth of the 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)

Background: Cabinet Decision

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

August 2005: Establishment of Medical Devices Bureau

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

Policy Objectives

- To protect patients and consumers
- To ensure safety, quality and performance of medical device over device life cycle
- To facilitate trade

Aims of the Regulation

Ensure public health and safety

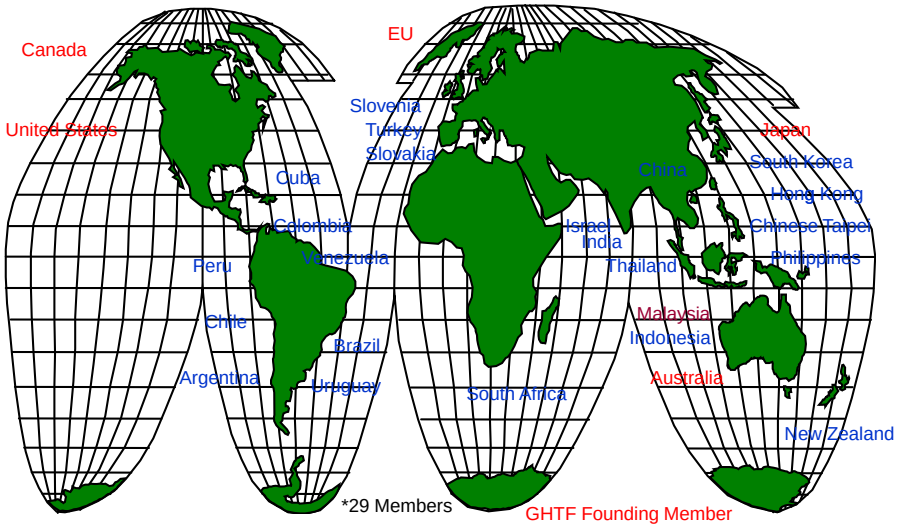
- Assurance for safety and performance
- Timely access for beneficial medical technologies
- Prevent dumping ground for unsafe and defective medical devices

Facilitate trade and industry

- Conducive environment for medical devices manufacturing
- Facilitate trade and export
- Promote health tourism

Global Scenario in Medical Devices Regulation

Countries that currently regulate, or are in the process of developing regulations for, medical devices



Regulations in Other Countries - Laws & authorities for medical devices

	Laws/regulations	Regulatory authority
US	Safety Medical Devices Act Medical Devices User Fee & Modernization Act Code of Federal Register Part 800 – 900	Center for Devices & Radiological Health, FDA
UK	Medical Devices Regulation 2002 under Consumer Protection Act 1987	Medicines & Healthcare Products Regulatory Agency
Australia	Therapeutic Goods Act 1989 Therapeutic Goods (Med Devices) Regulations 2002	Office of Devices, Blood & Tissue, TGA
Canada	Food & Drug Act Medical Devices Regulations (No 1101) Medical Devices Regulations (No 1162) – Amendment Medical Devices Regulations (No 1293) – Quality System	Medical Devices Bureau, Therapeutic Product Directorate
Japan	Pharmaceutical Affair Law Pharmaceutical Control Law Cabinet Orders & Ministerial Ordinances	Ministry of Health, Labour & Welfare
Korea	General regulations, has not had in place documents providing details for approvals specific to products	Medical Devices & Radiation Health Dept, Korean FDA

Regulatory status in various countries

Regulations in Other Countries - Laws & authorities for medical devices

	Laws/regulations	Regulatory authority
New Zealand	Medicines Act 1981 Medicines (Database of Medical Devices) Regulations 2003	Medicines & Medical Devices Safety Authority
China	The Regulation on Supervision & Administration of Medical Devices	State Drug Administration State Admin for Technical & Quality Supervision State Admin for Entry/Exit Inspection & Quaratine
Thailand	Medical Device Act 1988 Ministerial Regulations 1 – 7	Medical Device Control Division, Thai FDA
Philippines	Law governing medical devices is being drafted	Bureau of Health Devices & Technology, Dept of Health
Singapore	Health Products Act Medical Devices Regulations	Center for Medical Device Regulation, HSA
Indonesia	Health Law No 23 1992	Directorate of Medical Device Production & Distribution MoH

Regulatory status in various countries

Harmonization with the Global Harmonization Task Force Recommendations (GHTF)

- "Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety of health of users or, where applicable, other persons, provided that any risks which maybe associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety"
- (Essential principles of safety and performance of medical devices recommended by GHTF (SG1-NO20R5)

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

Framework of the Malaysian

MEDICAL DEVICE REGULATORY SYSTEM

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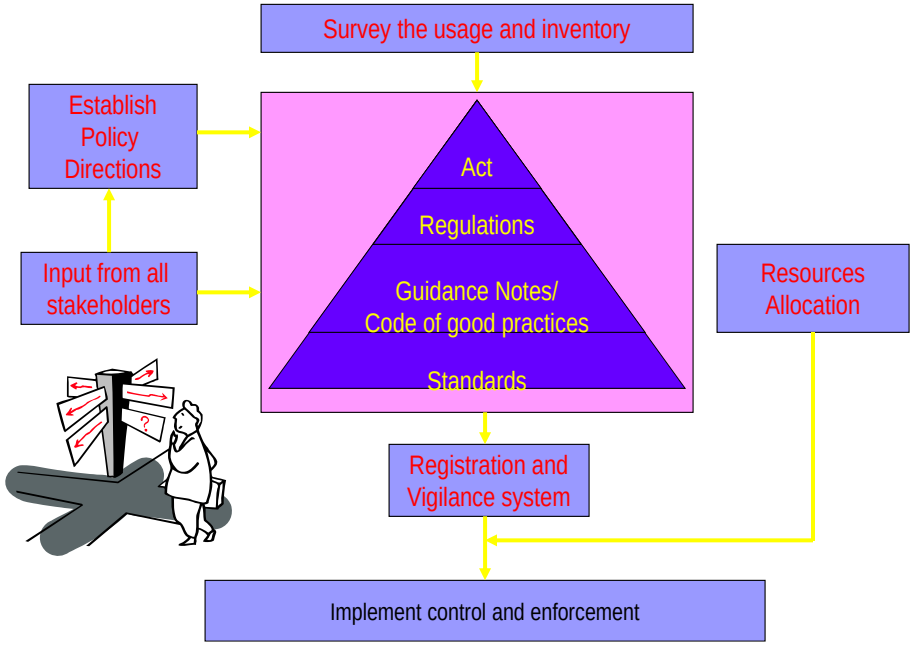

The Medical Device Regulatory Framework

Regulatory Framework

- **Definition of a medical device**
- **Pre-market requirements**
- **Requirements for placement on the market**
- **Post-market requirements**
- **Enforcement and investigation**

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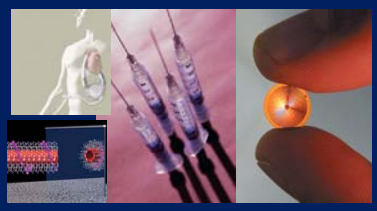
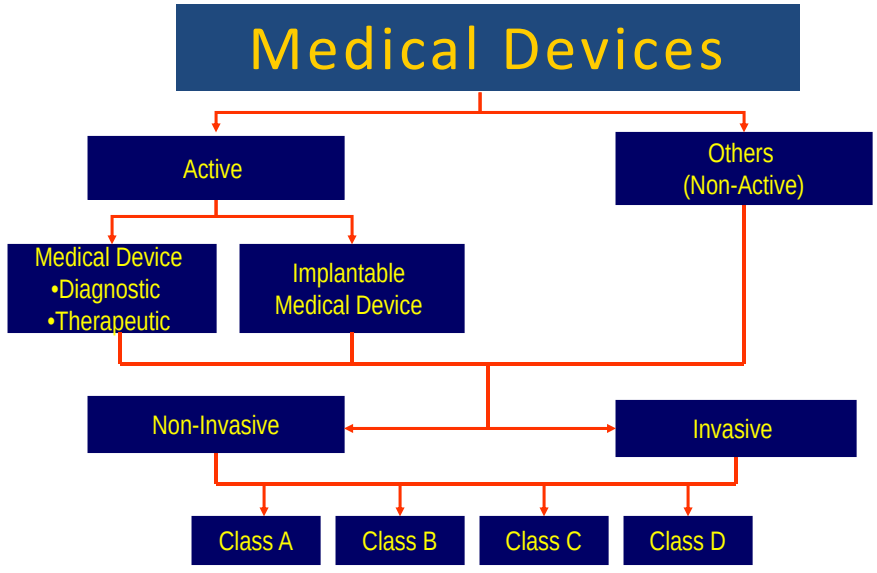
Definition

- **Range of medical devices**
  - Wide array of products with myriad uses
  - Complexity from simple to sophisticated system
  - Cover a wide spectrum of risk, whilst providing benefit to patients

Global market place:



400,000 different medical device products in some 10,000 product categories



Definition

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

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Definition

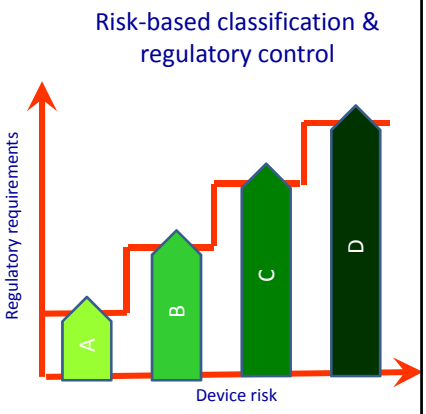
- **A Medical Device regulatory program applies to all medical devices on the Malaysian market**

What is a medical device?

The term "medical device" covers any products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs

Risk-Based Classification for Regulatory Control

- 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)
- Regulatory control should be proportional to the level of risk associated with a medical device



Risk-Based Classification & Regulatory Control

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, anaesthetic 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, orthopaedic 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 cathethers, vascular prostheses and stents

Scope of regulation

- Design & development
- Manufacture, import/ export
- Packaging, labeling, storage

- Distribution
- Supply
- Advertising

- Surveillance & vigilance
- Installation, T&C, maintenance, calibration, repairs
- Operation, usage
- Decontamination, decommission, disposal

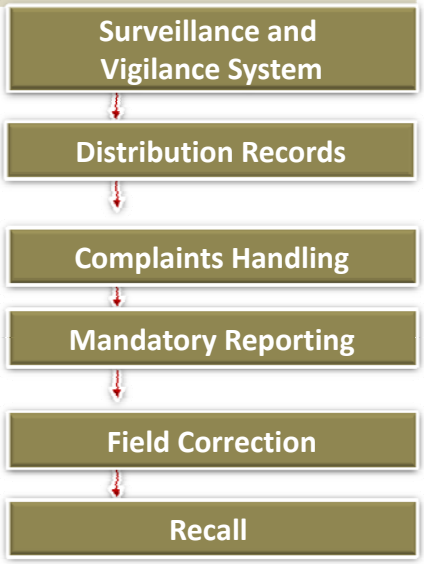
Pre-Market Requirements

- **What are the processes carried out to ensure that a medical device is safe, quality & perform as intended for?**

Define the Medical Device
↓
Classify according to risks
↓
Meets the essential principles
↓
Manufactured according manufacturing principles
↓
Labeling, packaging, marking
↓
Carry out Conformity assessment

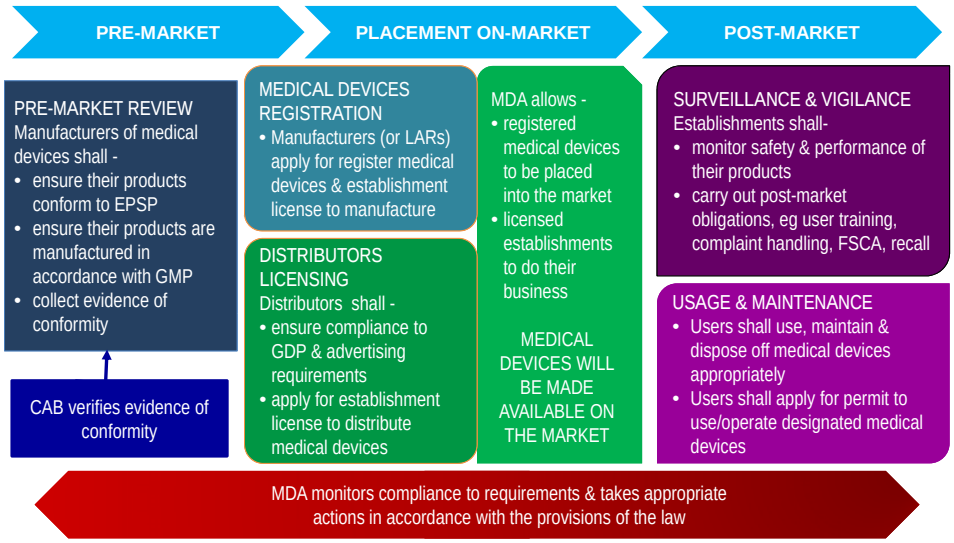
Post-Market Requirements

- Define the requirements to be fulfilled to. How to,
  - **continuously monitor safety and performance of medical devices on the market**
  - **take corrective actions on any problems related to medical devices on the market**



Performance Based Regulation

Overview of The Regulatory System



Essential Principles of Safety & Performance

- **A medical device shall conform to essential requirements of safety and performance**

Essential Requirements of Safety & Performance of Medical Devices

- 6 general requirements
- 11 design & manufacturing requirements

GHTF/SG1/N41R9:2005: Essential Principles of Safety & Performance of Medical Devices

Essential Principles 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/specified 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

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Essential Principles of Safety & Performance

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

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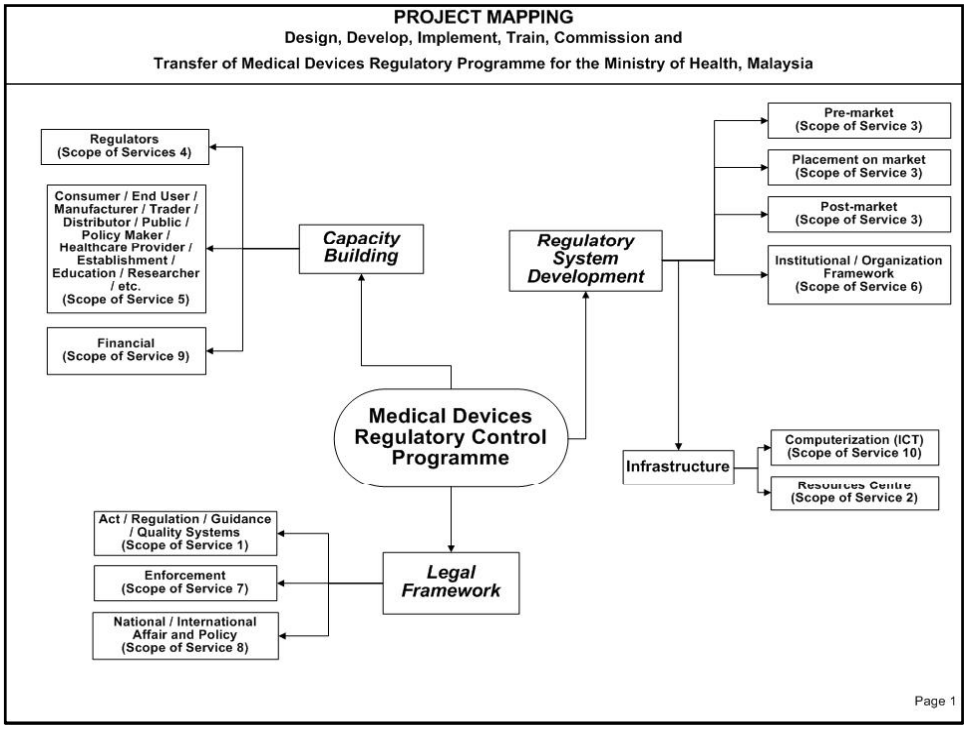
Who & What will be Regulated?

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

Coordination with Stakeholders



Empowerment

- 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
- Abridge system, whereby products can be registered easily if they have been approved by the 5 founding members of the GHTF.
- Conformity Assessments are carried out by a third party

Risk-Based Regulatory Control

Regulatory control is proportional to the level of risk associated with a medical device

Regulatory requirements	Class A	Class B	Class C	Class D
Technical documentation	• Prepare tech document	• Prepare tech document • Submit for review	• Prepare tech document • Submit for review	• Prepare tech document • Submit for review
Post-market surveillance system (PMS)	• Establish PMS • Maintain PMS	• Establish PMS • Maintain PMS	• Establish, maintain PMS • Make available for audit	• Establish, maintain PMS • Make available for audit
Quality mgmt system (QMS)	• Establish & maintain QMS excl design requirement	• Establish & maintain QMS excl design requirement	• Establish, maintain full QMS • Make available for audit	• Establish, maintain full QMS • Make available for audit
Declaration of conformity	• Prepare, sign & submit	• Prepare, sign & submit	• Prepare, sign & submit	• Prepare, sign & submit

Medical device class/risk

The Use of Harmonized Standards

- To demonstrate conformance to essential principles of safety and performance
- To demonstrate conformance to management and manufacturing standards
- Promoting harmonization by adopting international standards

- The use of standards helps in
  - improving productivity
  - improving market competitiveness
  - improving export capability
  - reducing cost

Thank You