Medical Device Regulatory Framework in Malaysia: Internal and International Activities and Strategies

The Medical Device Authority Malaysia
Strategic Plan

• MISSION : To provide regulatory control of medical device industry in Malaysia through compliance of the act by ensuring safety and performance of medical device product to protect public

• VISION : To become excellent medical device regulatory authority recognised globally

• CUSTOMER VALUE PROPOSITION:
  1. Attributes -(Reliability, Consistent, Efficient),
  2. Relationship -(Consultative, Customer-centric, Impartial),
  3. Image -(Rule of Law-”Ensure all documents process efficiently and effectively compliance to regulatory)
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)
The WHO Medical Device regulatory model?

The Medical Device Life Cycle
MEDICAL DEVICE AUTHORITY

http://www.mdb.gov.my

MEDICAL DEVICE REGULATORY SYSTEM

MEDICAL DEVICE AUTHORITY ACT 2012 (ACT 738)

MEDICAL DEVICE ACT 2012 (ACT 737)

MINISTER OF HEALTH

MEDICAL DEVICE AUTHORITY

Chief Executive, officers, servants

.. gives powers to...

CABs

Users

Establishments
- Manufacturers
- LARs
- Distributors
- Exporters

.. gives powers to...

.. to regulate...
Overview of The Regulatory System

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

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

MEDICAL DEVICES WILL BE MADE AVAILABLE ON THE MARKET

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

Conformity Assessment Body verifies

MDA monitors compliance to requirements & takes appropriate actions in accordance with the provisions of the law.
Medical Device Act 2012 (Act 737) - Objective and Control

- Market Access and Control
  - List of Products
  - Export Permit
  - Int. Standards
  - Harmonised Regulations

- Establishment Control
  - Manuf Licence
  - Dist. Importor AR
  - CAB Regist.
  - Advertisment
  - Cert. Of QMS
  - Product Testing

- Medical Device Product Control
  - Usage Permit Of DVD
  - Maint./Disposal
  - Product Registration

POST-MARKET VIGILANCE AND SURVEILLANCE SYSTEMS & ENFORCEMENT
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)
## Risk-Based Classification & Regulatory Control

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Device examples</th>
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<tbody>
<tr>
<td>A</td>
<td>Low</td>
<td>Simple surgical instruments, tongue depressor, liquid-in-glass thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes, walking aids</td>
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<tr>
<td>B</td>
<td>Low-Moderate</td>
<td>Hypodermic needles, suction equipment, anesthetic breathing circuits, aspirator, external bone growth simulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit, x-ray films</td>
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<tr>
<td>C</td>
<td>High-Moderate</td>
<td>Lung ventilator, orthopedic implants, baby incubator, blood oxygenator, blood bag, contact lens disinfecting/cleaning products, deep wound dressing, defibrillator, radiological therapy equipment, ventilator</td>
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<tr>
<td>D</td>
<td>High</td>
<td>Pacemakers and their leads, implantable defibrillators, implantable infusion pumps, heart valves, inter-uterine contraceptive devices, neurological catheters, vascular prostheses, stents</td>
</tr>
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</table>
Types of Establishments

- Local Authorized Representative (LAR)
- Distributor
- Importer
- Manufacturer

TYPES OF ESTABLISHMENT

CAB Verifies LAR, Distributor and Importer
<table>
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<tr>
<th>Key Issues</th>
<th>Recommendations</th>
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<tr>
<td>• Entry of Substandard products into the domestic markets</td>
<td>• <strong>To enforce compliance through the Medical Device Act</strong></td>
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<tr>
<td>• Early phase of regulatory compliance mechanism</td>
<td>• Enforce the Medical Device Act</td>
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<td>• Inability to penetrate global markets</td>
<td>• Enhance Medical Device Authority</td>
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<tr>
<td>• Lack of capacity development within industry</td>
<td>• Develop and implement regulations</td>
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<tr>
<td></td>
<td>• Implement establishment licensing</td>
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<td></td>
<td>• Implement Medical Device registration</td>
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<td></td>
<td>• Post market surveillance</td>
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<td></td>
<td>• <strong>To execute capacity development program</strong></td>
</tr>
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<td></td>
<td>• Training programs for regulators and industry players to comply to standards</td>
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<tr>
<td></td>
<td>• <strong>Economic transformation program</strong></td>
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<td></td>
<td>• Execute decisions made on Entry Points Projects</td>
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<td></td>
<td>• Facilitate the industry in achieving safe and quality medical device</td>
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<tr>
<td></td>
<td>• <strong>Establish Mutual Recognition Agreements (MRA)</strong></td>
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<tr>
<td></td>
<td>• Among ASEAN Member States (AMDD), USA, Japan, Australia, Canada and the EU in terms of capacity building and mutual understanding of regulatory requirements</td>
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</tbody>
</table>
ECONOMIC TRANSFORMATION PROGRAMME

NATIONAL KEY ECONOMIC AREAS:-
MEDICAL DEVICES
Core Business

Registration and Licensing

Policy, Code & Standards

Technical Evaluation

Finance & Management

STRATEGIC PLAN

- Product Registration
- Licensing of Establishment
- CAB Registration
- Vigilance & Surveillance
- CFS/Import permit
- Designated Devices

- Regulatory Auditing of:
  - QMS systems
  - Post marketing
  - Vigilance & Surveillance
- Policy and Industry Facilitation
- Development of Codes and Standards

- Scientific Evaluation
- Clinical evaluation
- ICT

- General Administration
- Human Resources
- Financial
Licensing, Registration and Enforcement Division

- Evaluation of application
- Development of guidelines
- Development of MeDC@St System
- Training for industry
- Advisory services
- Product Classification
- Complaint
- FSCA
- Recall
- Incident Reporting
- Raid
- Investigation
- Prosecution

Policy, Code and Standard Division

- Technical Evaluation Division

- Management of research studies
- Management of notification
- Development and review of information technology strategic plan
- Management of the implementation of ICT projects
- Development, management and analysis system
- Data security management information
- ICT maintenance and complaints management
- Training and ICT awareness programme
- Technical advisory services

Processes

- Bilateral/multilateral development cooperation
- Economic Transformation program
- Development of the guidance document
- Audit activities include compliance requirements for licensing and registration and regulatory audit include post market and surveillance and vigilance
- Awareness programmes to stakeholders
- Corporate communication
- Publicity
7 new medical device related EPPs will deliver the base for growth, contributing RM11.4 b in GNI and 86k jobs by 2020.

3-pronged approach:
- provide local base
- push exports
- move up the value chain

Leverage existing strengths and facilitate ease of business for medical devices entrepreneurs and move Malaysia from a nominal player to a Medical Device Hub in Asia Pacific.
Medical Device Industry Ecosystem in Malaysia

Materials: Rubber, Plastics, Steel, Electronics, etc.

Technology
- Consumables
- Surgical Instruments, Implants & Clinical Devices
- Healthcare Equipment
- Latex
- Plastic
- Metal
- Machining
- Electronics
- Furniture

Products
- Glove, Contraceptives, Catheters, woundcare, Orthalmology, IVD, SUD
- Pacemaker, Orthopedics, Surgical instrument
- Radiation equipment, Life Science Instrument, Electrodes, Hospital beds

Companies
- WRP
- B BRAUN
- Teleflex Medical
- Covidien
- Vigilenz
- Aesculap
- St Jude Medical
- Accilent
- Delphax
- Symmetry Medical
- Orthomedic
- Straits Orthopaedics
- Ansell
- Covidien
- Unomedical
- Ciba Vision
- FB
- Sky ked
- Jabil
- Plesus
- Polav
- Twin advance
- Small Bone Innovations
- Cuick
- LKL

Supporting Infrastructure
- Sterilization
- Packaging
- Certification
- Biocompatibility And Clinical Trial
- Industry Group
- Education Training
- Regulatory

- UM, USM, UKM, UniMap, PSDC
- Medsociate
- Neville Clarke

Medical Device Act 2012
Structure of the Industry

- **MNCs**
  - About 50 companies
  - Bigger share of export revenue
  - Follow global standards and are fully compliant

- **LLCs**
  - About 100 companies
  - Follow global standards and are fully compliant

- **SMEs**
  - About 150 companies
  - Targeting domestic market
  - Not fully compliant, some exceptions

Total: 400+ companies in Malaysia

1500 companies consisting of Authorised Representatives, Distributors, Importers and Exporters

Source: AMMI
Malaysia
Exports of Medical Devices

Total Exports in 2011: RM11.7 Billion

Source: Malaysia Statistics Department, MITI, MIDA, PEMANDU
7 important decisions

1. Financial Incentives
   Incentives and soft loans to local manufacturers through MIDA, MATRADE, SME Corp, MOSTI and local banks under BNM for 5 years from 2012

2. Import Duty Exemption
   Import duty exemption for components to be declared by Medical Device Authority

3. Testing Labs
   Two testing labs to be given financial assistance to attain Good Laboratory Practice

4. Off-take Agreement
   Off-take agreement between Government with ETP Participants

5. Human Capital Dev.
   Increased technical and vocational training to ensure the local industry can meet the global regulatory needs

6. Refurbished Systems
   Allow Govt. agencies to procure and use refurbished systems registered under the Medical Device Act

7. Awareness
   Increase awareness of local products and create the opportunity for collaboration
ECONOMIC TRANSFORMATION PROGRAMME: ENTRY POINT PROJECTS

**EPP 7: Scale Malaysia IVD industry**

Leverage research & patented technologies to set up Asian champion in neglected diseases prevalent in developing countries: TB, dengue, cholera in Africa, Asia and South America.

**EPP 8: Next generation of core SUD products**

Move the value chain towards high value products on core SUD products & build showcase for MD industry -- focus on catheters, woundcare and single-use components for instruments.

**EPP 9: Hub for high value medical devices contract manufacturing**

Becoming contract manufacturer for high value orthopedic products, e.g. screws and instruments for global MNC brands.
EPP 10: Create Malaysian clinical devices champions
Creating an enabling environment for Malaysian entrepreneurs to innovate in clinical devices and create their own brands in bone grafts and other orthopedic implants

EPP 12: Medical equipment refurbishment hub
Attract MNC to establish authorized medical equipment refurbishment facility in Malaysia for CT scanners, MRI and molecular imaging

EPP 13: Medical furniture and hardware cluster
Scale up the medical furniture and hardware industry by targeting home care market in developing countries and focusing on high-end hospital furniture for emerging markets
ASEAN MEDICAL DEVICE DIRECTIVE (AMDD)

ASEAN MEDICAL DEVICE PRODUCT WORKING GROUP
10 Nations in the Southeast Asia Region

- Philippines
- Vietnam
- Myanmar
- Laos
- Thailand
- Cambodia
- Brunei
- Singapore
- Malaysia
- Indonesia
Principles of ASEAN ECONOMIC COMMUNITY

ASEAN Economic Community (AEC 2015): key characteristics

- Free flow of goods
- Free flow of services
- Free flow of investment
- Free flow of capital
- Free flow of skilled labor

- Competition policy
- Consumer protection
- Intellectual property rights
- Infrastructure development
- Taxation & E-commerce

Single market and production base

Competitive economic region

Region of equitable economic development

Region fully integrated into the global economy

SME development
- Initiative for ASEAN integration

Coherent approach towards external economic relations
- Enhanced participation in global supply networks
Achieving the goals of AEC through harmonisation for medical devices

- Reduce time to market access & facilitate trade
- Reduce cost to market Medical devices
- Improve regulatory efficiency
- Enhancement of public health protection

- Common requirements for addressing product life cycle
- Reduce complexity needed to meet local requirements
- Facilitating cooperation among regulators
- Common and transparent premarket evaluation, post market surveillance and uniform quality system
ASEAN Consultative Committee on Standard Quality – Medical Device PWG

AGENDA

HARMONISED REGULATORY FRAMEWORK: THE ASEAN MEDICAL DEVICE DIRECTIVE

HARMONISED PREMARKET SUBMISSION FORMAT: ADOPTION OF THE COMMON SUBMISSION DOSSIER TEMPLATE

HARMONISATION

HARMONISED SET OF VOLUNTARY STANDARDS IN ASEAN: BASED ON IEC AND ISO STANDARDS

SHARING OF: POST MARKET SAFETY INFORMATION AMONG ASEAN MEMBER STATES
To facilitate the integration of the medical devices sector through elimination of technical barriers to trade in ASEAN

AMDD
.....signed 2014

GHTF
Recommendations

CSDT
Completed

GMDN-
Nomenclature for medical devices

Capacity building

Post marketing alert system..
AMDD STRUCTURE Uniform Regulatory Structure

MALAYSIA has transpose almost all AMDD articles in Act 737
Major Requirements of the ASEAN Medical Device Directive

- Licensing of Establishment
- Medical Device Registration
- Device Classification
- Definition Of Medical Device
- Common Submission Dossier Template
- Post-market requirements
- Establishment of ASEAN Medical Device Committee (AMDC)
- Clinical Trials
Impact Analysis on ASEAN Industry

- Harmonised Technical Requirements (CSDT)
- Common Definition
- Common Risk Classification
- Use of International Standards
- Post market vigilance and surveillance systems
- Opportunities for regulatory integration

- Teething Phase
- Industry’s own Expectations
CONCEPTUAL QUALITATIVE OVERVIEW OF CURRENT NATIONAL MEDICAL DEVICE REGULATORY SYSTEMS - TRENDS

NOTES:
• Position in clusters not necessarily significant
• Subjective assessment of many variables
• Variables not weighted
• Not all countries that regulate medical devices shown
• Some countries moving faster than others and with different paths

Reference: M. Gropp; Institute of Medicine, Washington, D.C; 2-3 March 2011
The reality of AMDD

- It defines submission of technical requirements to be harmonized
- It requires Member countries to register products and license establishments
- It states that development of the guidelines and standards that follows internationally recognized institutions and organisations
- Flexible in that Member states however, still retain their sovereign rights on how registration and licensing decisions
- It allows member countries to implement country specific measures of controls
- Focusing only on certain important aspect of medical device regulatory control and not aimed in harmonizing all of it
Challenges

• Language of AMDD
• The state of readiness of Member States to transpose the AMDD?
• Factors that can influence the speed of transposition
• Capacity Building
• PMS alert system
Thank you