AHWP TC Playbook
Scope & Content

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“Why?” – Recap of Need & Purpose

- Member Economies are largely import & distribution medical device markets
- Non-homogeneous market profiles
  - regulatory jurisdictions, economic development status, healthcare infrastructure, reimbursement systems and languages

<table>
<thead>
<tr>
<th>Country</th>
<th>% of Medical Devices Imported</th>
</tr>
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<tbody>
<tr>
<td>Malaysia</td>
<td>90%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>&gt;87%</td>
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<tr>
<td>India</td>
<td>72%</td>
</tr>
<tr>
<td>Thailand</td>
<td>67%</td>
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Data source: Medtech World 2013, ubmcanon.com/medical
Playbook Scope

• Intended to guide AHWP member economies (and others) in the implementation of a model regulatory system
• Applicable to countries with no framework or existing framework
• International regulatory convergence
• Highlights considerations e.g. national legal frameworks & resources, implementation priorities

Playbook Chapters

- Chapter 1: Introduction & Rationale for Harmonization
- Chapter 2: Basic regulatory controls
- Chapter 3: Legislation & policy framework
- Chapter 4: Phased implementation
- Chapter 5: Manpower
- Chapter 6: Registry / Database
- Chapter 7: Recognition of Standards
Regulatory model outlined in the Playbook is built on the foundation of the Global Harmonization Task Force (GHTF) guidance documents.

Advanced Regulatory Controls

- Classification & conformity assessment of MDs
- Oversight of QMS audits of dealers
- Clinical investigation & clinical performance study controls

Basic Regulatory Controls

- Quality management systems (QMS)
- Post-market surveillance and vigilance
- Definitions & qualification of ‘medical device’ (MD)
- Registration / licensing of MDs & dealers

Implementing a Regulatory Framework
Playbook Content: Considerations addressed

• Implementation: where to start?
  – Is there a gauge of the market profile?
  – Effort to identify & engage stakeholders
• What are the distribution of device types in the country? This is necessary to determine regulatory controls.

• Are controls relevant across device types? E.g.:
  - Implants
  - Surgical instruments
  - Radiation equipment
  - In-vitro diagnostic reagents
  - Medical software

• Titrate controls – what depth of pre-market controls a would device need?
Playbook Content: Considerations Legislation & Policy

• Robust Legislation & Transparent Policy Framework
  – Both new & existing frameworks
  – **Considerations** when putting legislation and policies in place

- Establish Transitional steps
- Capacity Building in Regulations & Policy Development
- Identification & Engagement of stakeholders
- Constant refinement
- Gap analyses of weakness in existing controls, e.g. Advertisement, Import controls, Environmental controls
- Playbook Content: Considerations Legislation & Policy
• Transition periods coherent in timing & sequence
• Clear communication with stakeholders
• Example of phased implementation steps:
Playbook Content: Considerations
Manpower / Resource

• To what extent are human resources sufficient to enable the Regulatory Authority to do its job?
• Considerations to be made in planning resources / capacity building
Knowing the purpose of databases is knowing what information to have in a database.

- Gauge local profile of medical device activities & products
- Identification of stakeholders
- Using information to identify trends
Playbook Content: Considerations

Essential Principles of Safety & Performance and Recognition of Standards

• Essential Principles of Safety & Performance
  – GHTF: 6 general safety & performance principles
    14 principles for non-IVD medical devices
    12 principles for IVD medical devices

• Purpose & benefits of standards

• Mechanism for medical device standards recognition
Playbook Elements
Providing the Tools for Planning a Framework

Phased Implementation – Voluntary Phase

Training of Stakeholders & Staff

Phased Implementation of Mandatory Controls

Full Implementation

Continued enhancement

Chapters 2 & 4
Chapter 5
Chapters 3 & 5
Chapters 3, 6 & 7
Chapter 4
“Mindset”

• This Playbook has set out **not** as a prescription of regulatory controls or pathway to implementation to countries.

• It intends to provide considerations for a regulatory framework & build on foundation of existing resources.

A house needs to..

• Provide shelter
• Protection from the elements
• Security & comfort
• Serve the needs of its inhabitants
Houses around the World

Adapted to the needs of the environment and landscape

What is the spirit behind implementing (this) regulatory control?
Thank You

Acknowledgments

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