AHWP TC Playbook

Scope & Content

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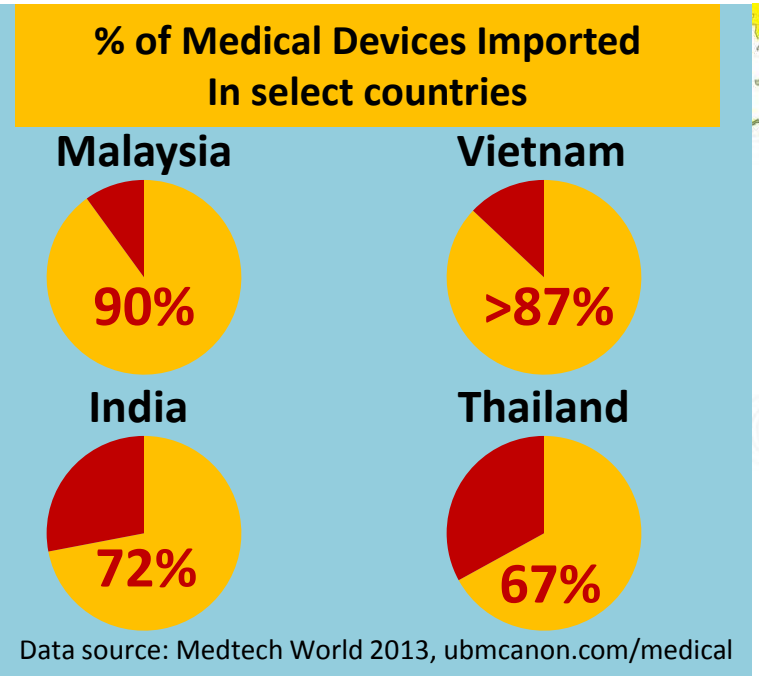
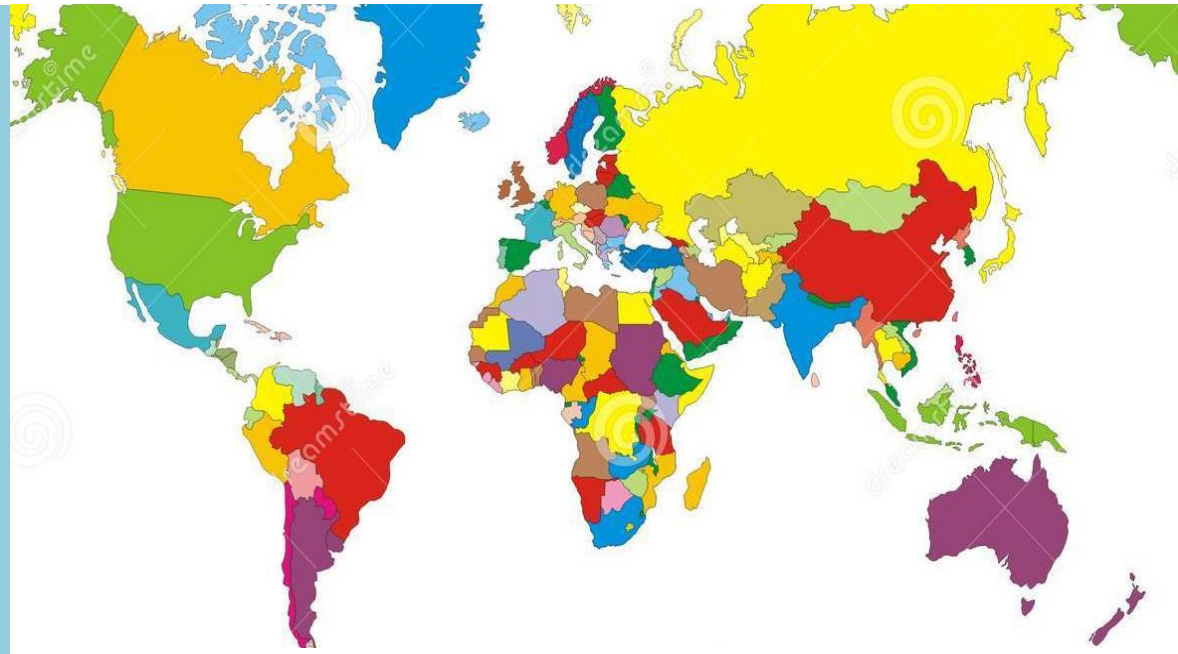
“Why?” – Recap of Need & Purpose

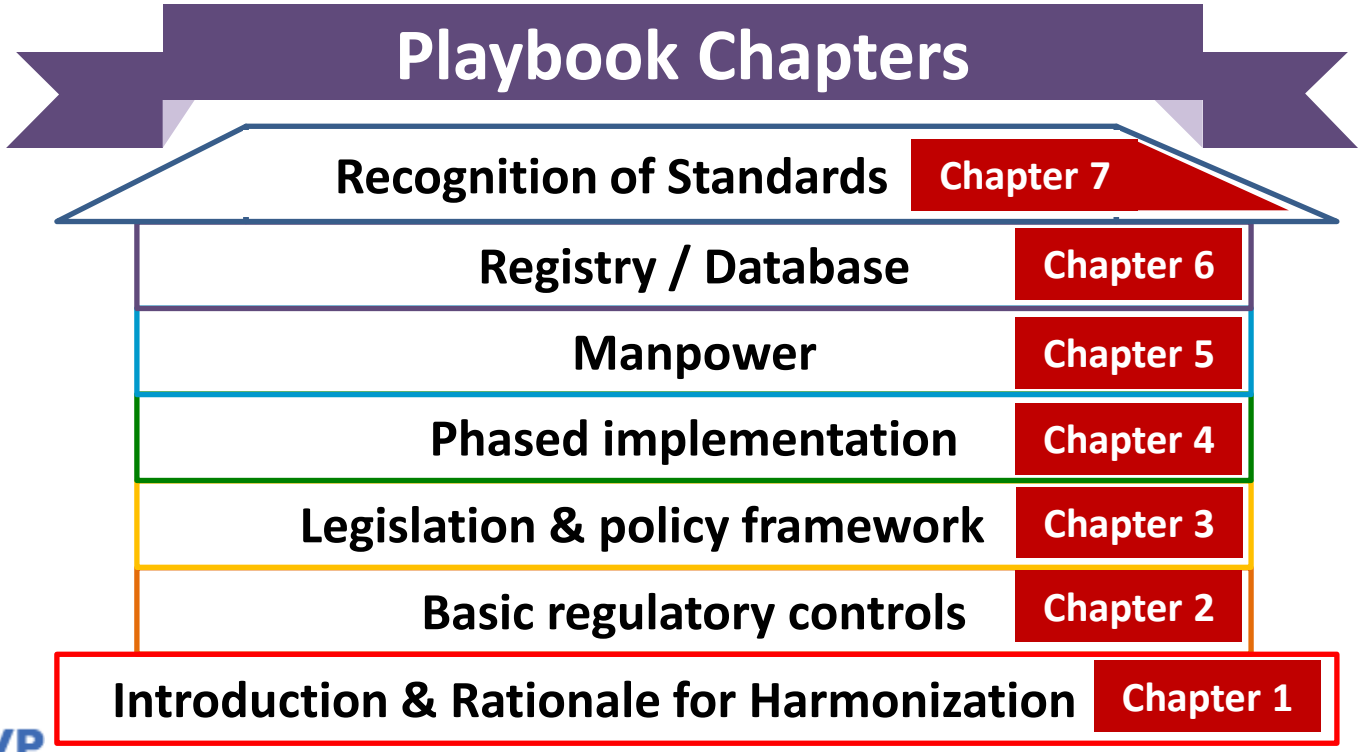
- Member Economies are largely import & distribution medical device markets
- Non-homogeneous market profiles
  - regulatory jurisdictions, economic development status, healthcare infrastructure, reimbursement systems and languages





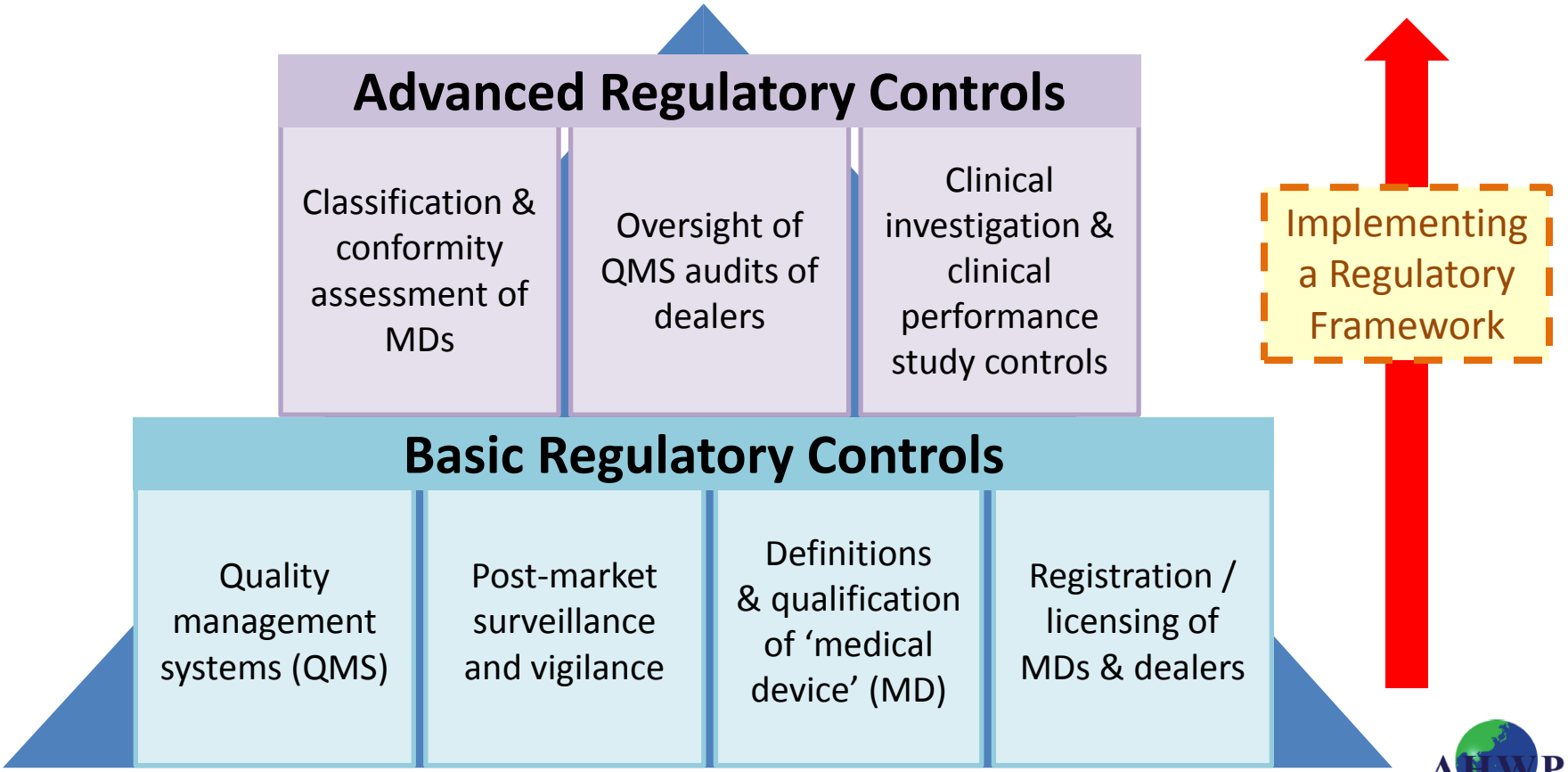
Playbook Scope

- 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



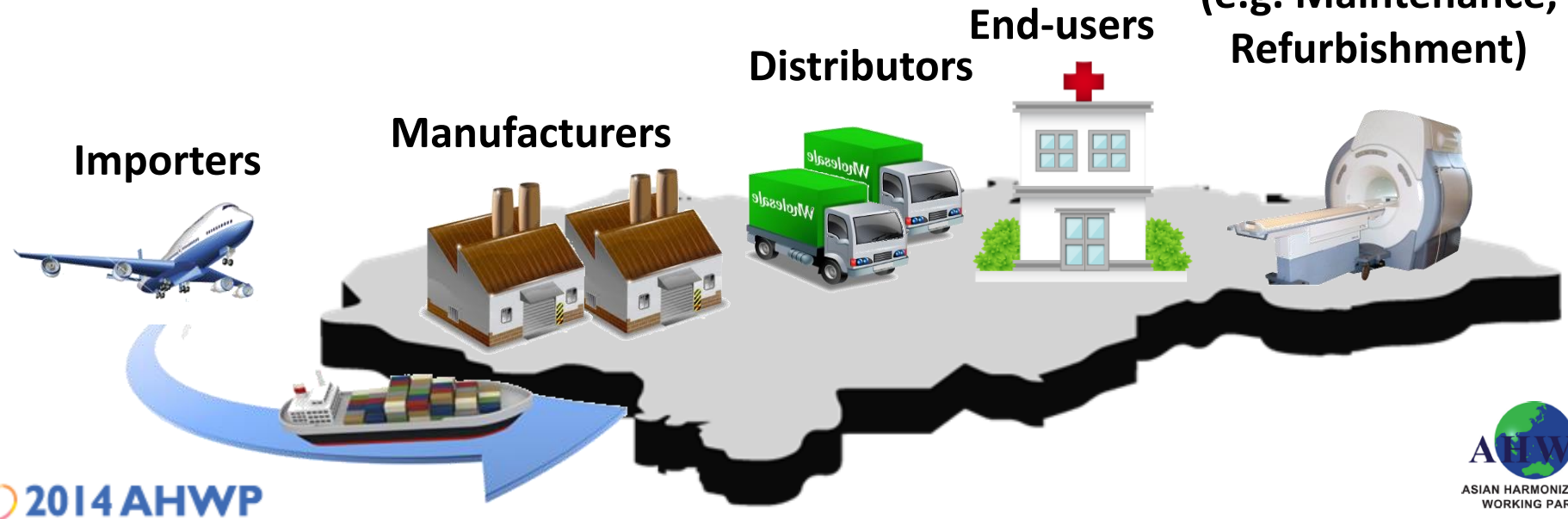
Framework of Medical Device Controls

Regulatory model outlined in the Playbook is built on the foundation of the Global Harmonization Task Force (GHTF) guidance documents.



Playbook Content: Considerations addressed

- **Implementation: where to start?**
  - Is there a gauge of the market profile?
  - Effort to identify & engage stakeholders

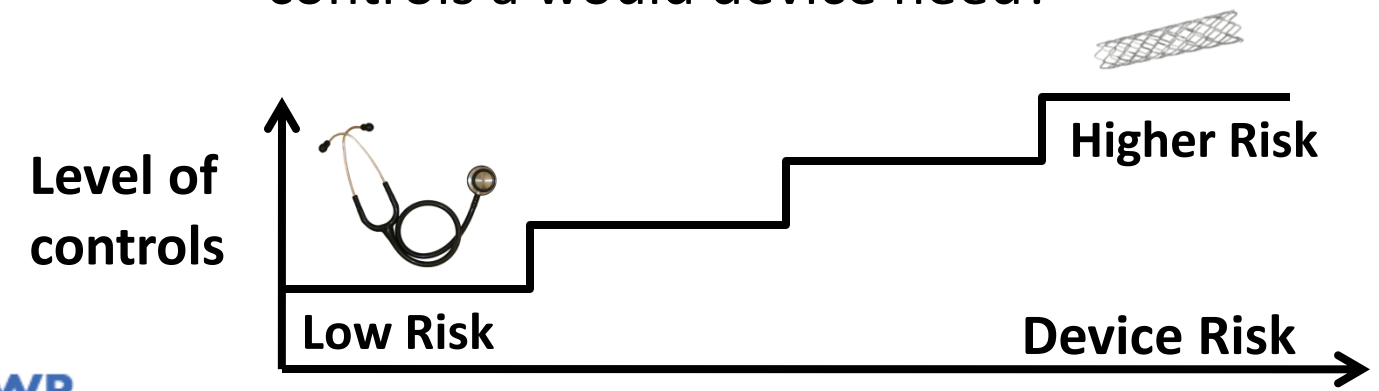


Playbook Content: Considerations
Market Profile

- What are the distribution of device types in the country? This is necessary to determine regulatory controls.

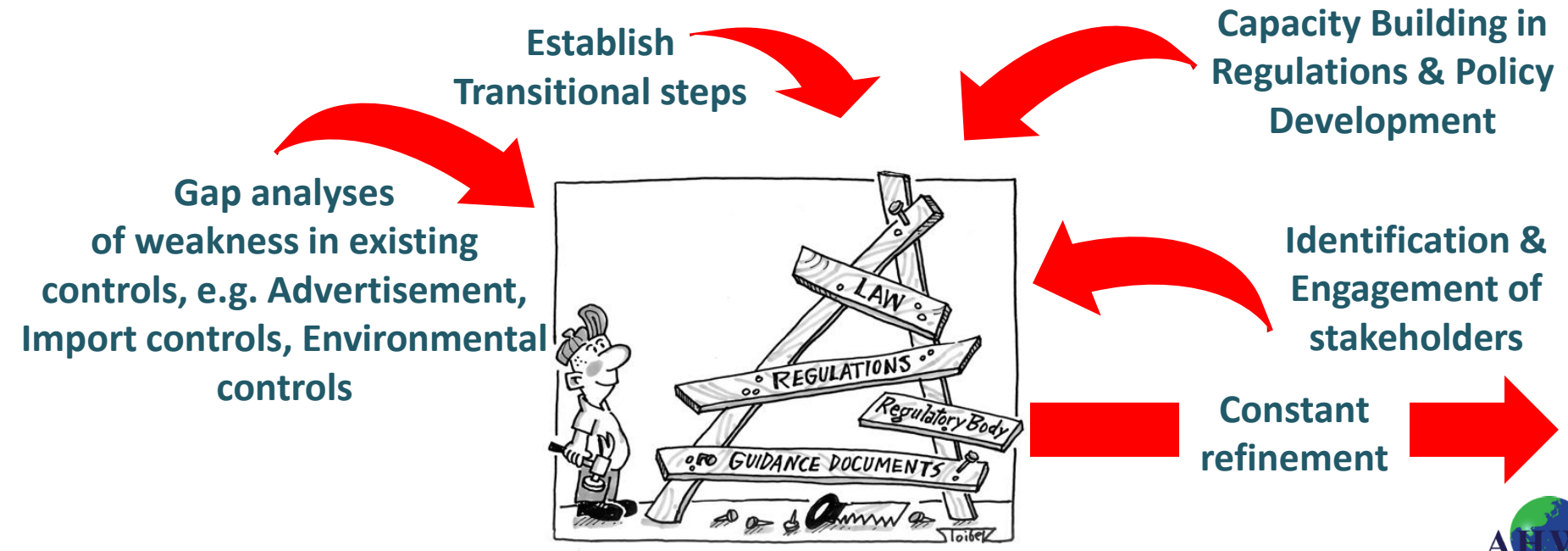
- Are controls relevant across device types? E.g.:
  - Implants
  - Surgical instruments
  - Radiation equipment
  - In-vitro diagnostic reagents
  - Medical software

- Titrate controls – what depth of pre-market controls a would device need?



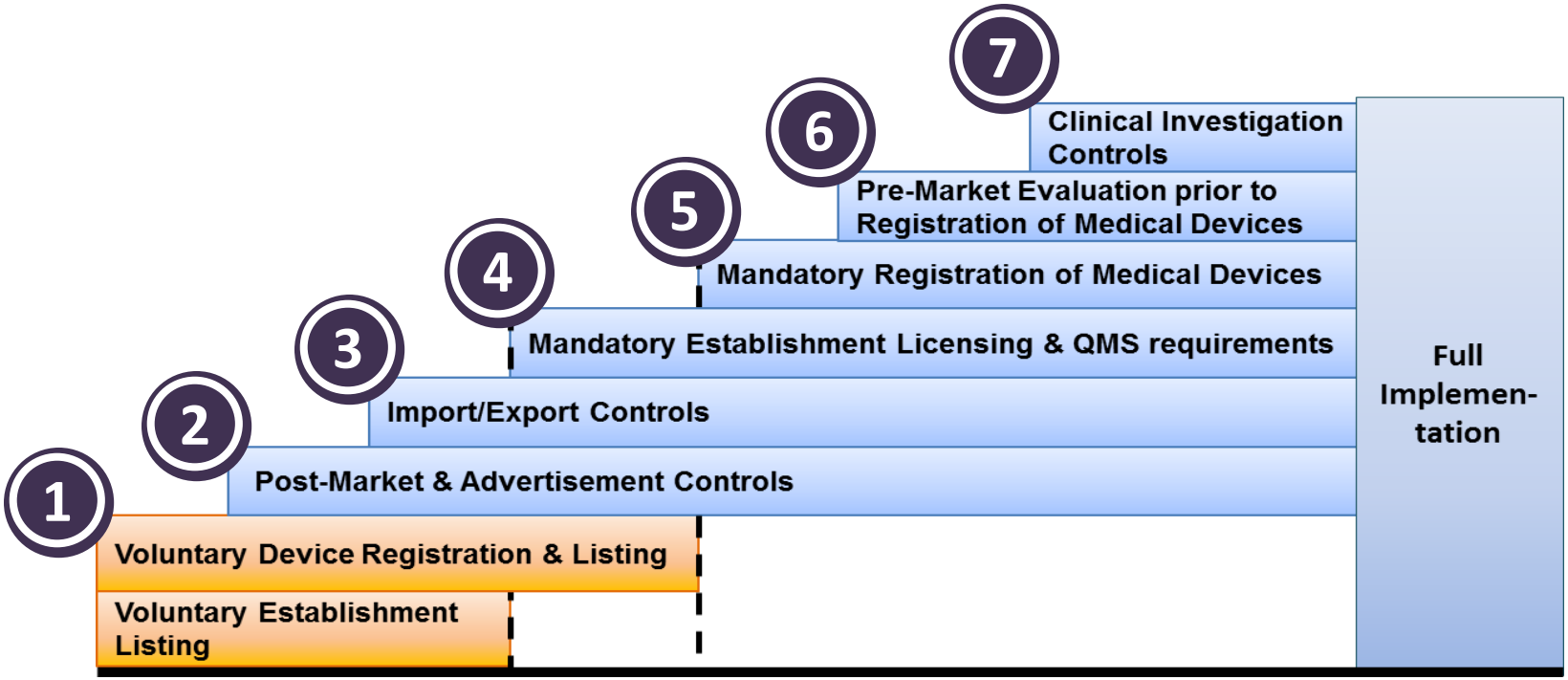
Playbook Content: Considerations
Legislation & Policy

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



Playbook Content: Considerations
Phased Implementation

- 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

Types of Regulatory Activities

Phase of Implementation

Volume / Distribution of regulatory activities

Expertise

Capacity Building
Providing the tools to optimally fulfill responsibilities

Playbook Content: Considerations
Registration Databases

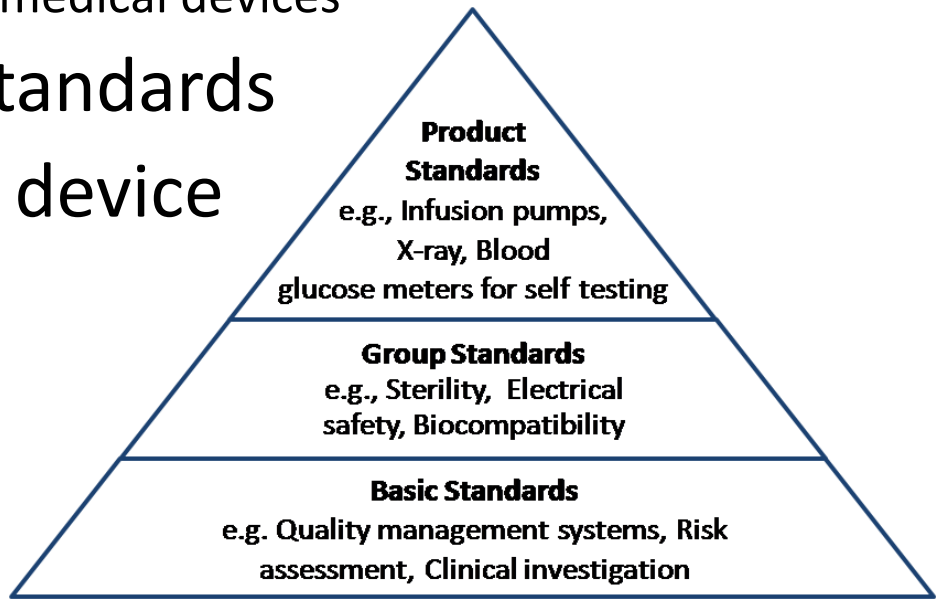
Knowing the purpose of databases is knowing what information to have in a database.

- 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

Chapters 3 & 6

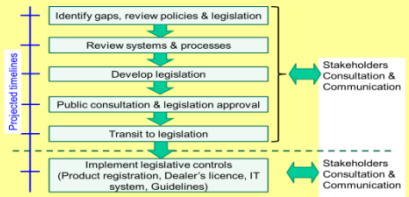
Chapter 3 & 6

Phased Implementation –Voluntary Phase

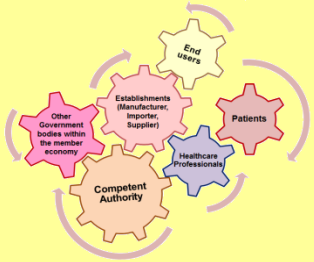
Phased Implementation Planning

Manpower & Resource Determination

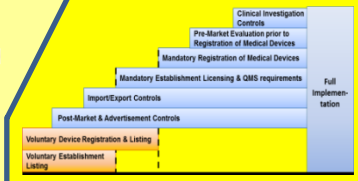
Development of Legislation & Policy



Training of Stakeholders & Staff



Phased Implementation of Mandatory Controls



Full Implementation of a regulatory framework

Continued enhancement

Chapters 2 & 4

Chapter 5

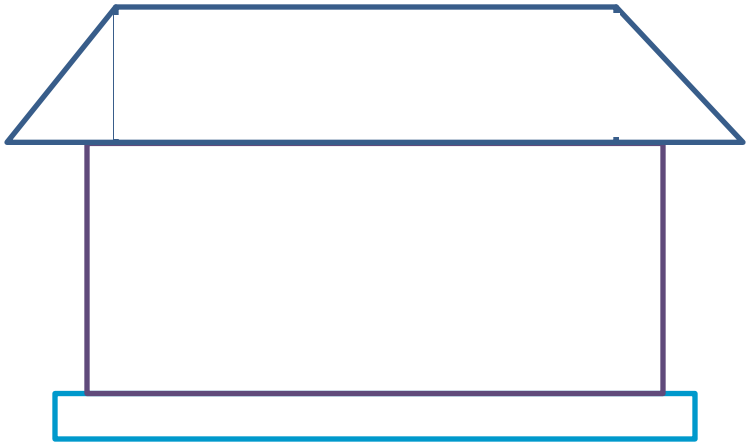
Chapters 3 & 5

Chapters 3, 6 &7

Chapter 4

“Mindset”

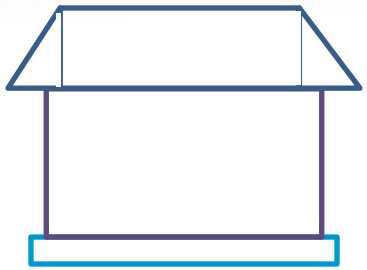
- This Playbook has set out **not** as a prescription of regulatory controls or pathway to implementation to countries.
- It intends to provide considerations for a regulatory framework & build on foundation of existing resources



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

AHWP Leadership

AHWP Chair Dr Saleh Al-Tayyar
Vice Chair Ms Lindsay Tao
former Vice Chair Ms Liu Li-Ling

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