Global GS1 Healthcare Conference, Seoul, South Korea April 2014

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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Health Sciences Authority of Singapore

About AHWP

AHWP
ASIAN HARMONIZATION WORKING PARTY

About AHWP

- Asian Harmonization Working Party (AHWP) was established as a non-profit organization in 1996.

  A group of experts comprising Medical Device Regulatory Authorities ("**Regulatory Authorities**"**[RA]**) and medical device industry & government agencies other than Medical Device Regulatory Authorities ("**Industry**").

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About AHWP

Goals

To study and recommend ways to

- ❖ harmonize MD regulations in the Asian and other regions
- ❖ establish harmonized requirements, procedures and standards.
- ❖ to coordinate with the GHTF/IMDRF, APEC and other related international organizations to this end

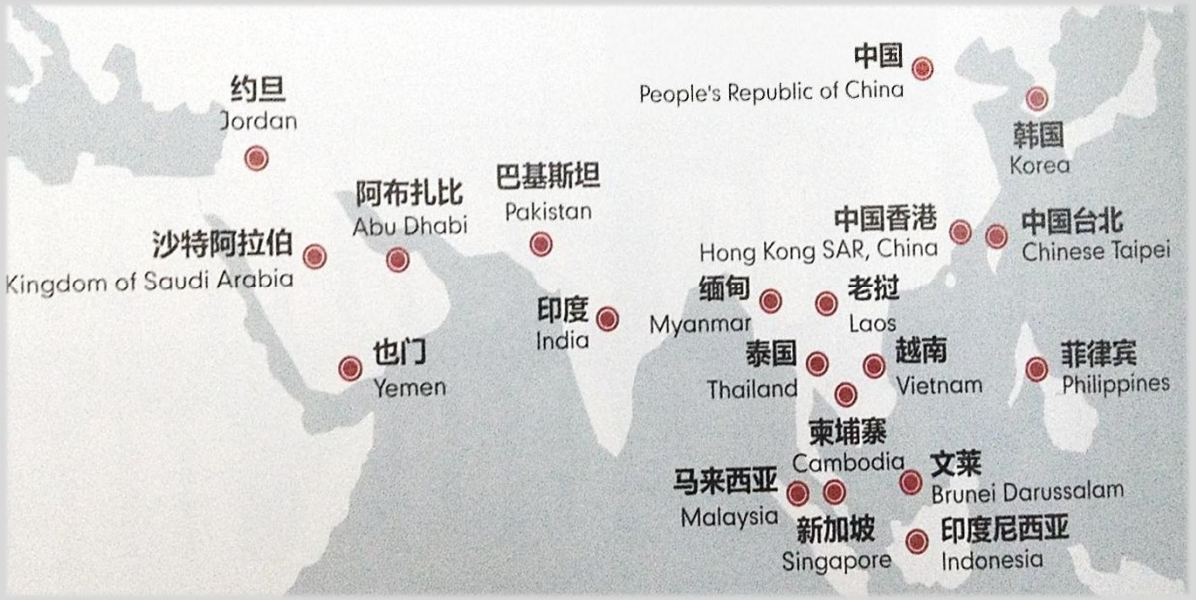
Roles

- ➢ Operates on a consensus basis - decisions and resolutions on key issues and controversial matters
- ➢ Presented for adoption by member economies through at AHWP Meetings
- ➢ Work closely with international and regional organizations to identify areas of compatibility and cooperation towards

About AHWP

List of 23 Member Economies (2014)

- Abu Dhabi
- Brunei Darussalam
- Cambodia
- Chile
- Chinese Taipei
- Hong Kong SAR, China
- South Africa
- State of Kuwait
- Thailand
- Vietnam
- Yemen
- India
- Indonesia
- Jordan
- Kingdom of Saudi Arabia
- Korea
- Laos
- Malaysia
- Myanmar
- Pakistan
- People's Republic of China
- Philippines
- Singapore



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Liaison Members:
GS1, DITTA

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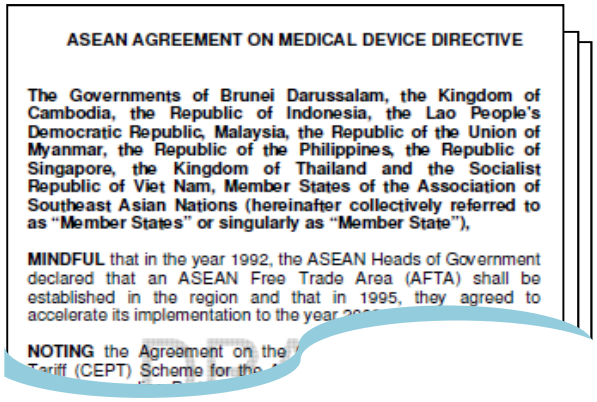
On the Road to Harmonisation…
ASEAN Agreement on Medical Device Directive

- 10 AHWP members

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

- Brunei Darussalam
- Cambodia
- Indonesia
- Thailand
- Vietnam



ASEAN AGREEMENT ON MEDICAL DEVICE DIRECTIVE

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (hereinafter collectively referred to as "Member States" or singularly as "Member State"),

MINDFUL that in the year 1992, the ASEAN Heads of Government declared that an ASEAN Free Trade Area (AFTA) shall be established in the region and that in 1995, they agreed to accelerate its implementation to the year

NOTING the Agreement on the Tariff (CEPT) Scheme for the

- An initiative as part of the ASEAN Economic Community Blueprint (Year 2020), based on convergence of interests of ASEAN Member Countries
- To achieve harmonisation and standardisation, with a view to facilitate trade within the region

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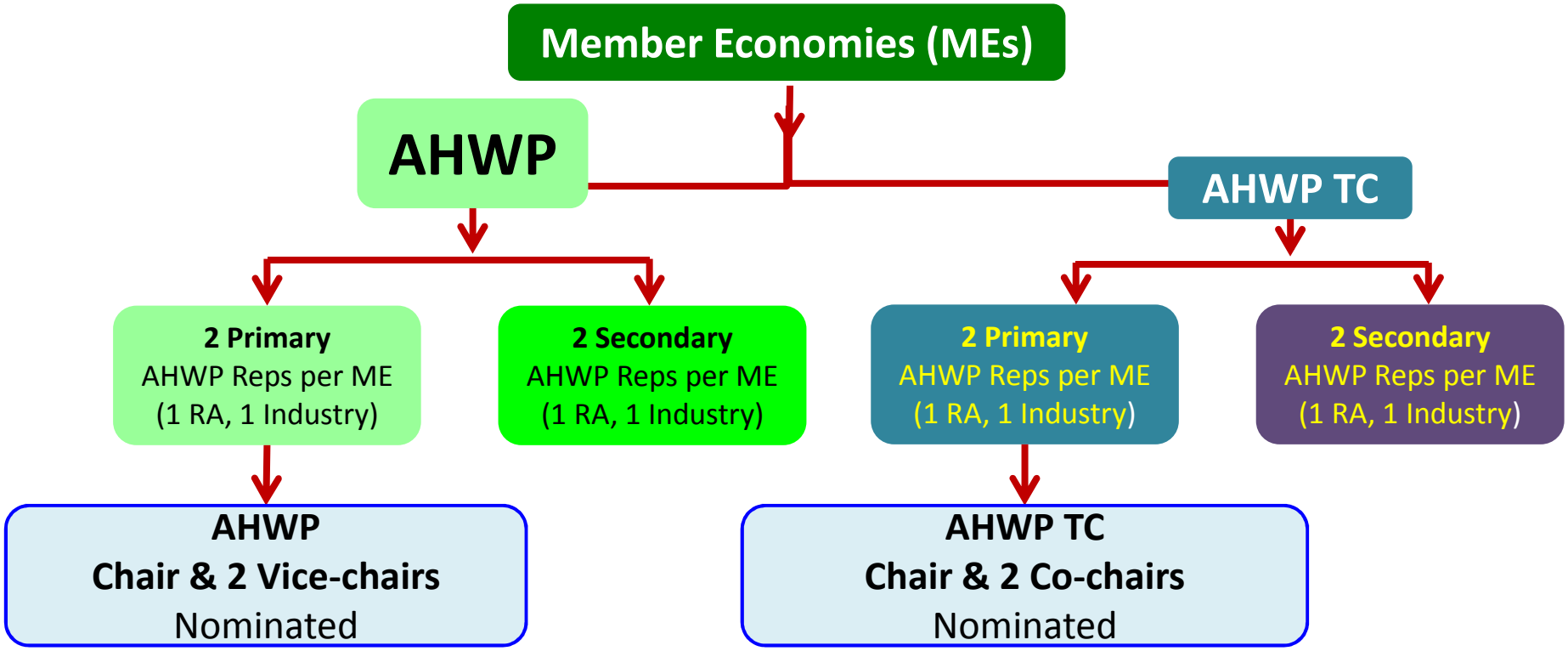
AHWP Membership & Leadership

Membership to AHWP and AHWPTC (executive arm) is subject to majority vote by existing Member Economies.



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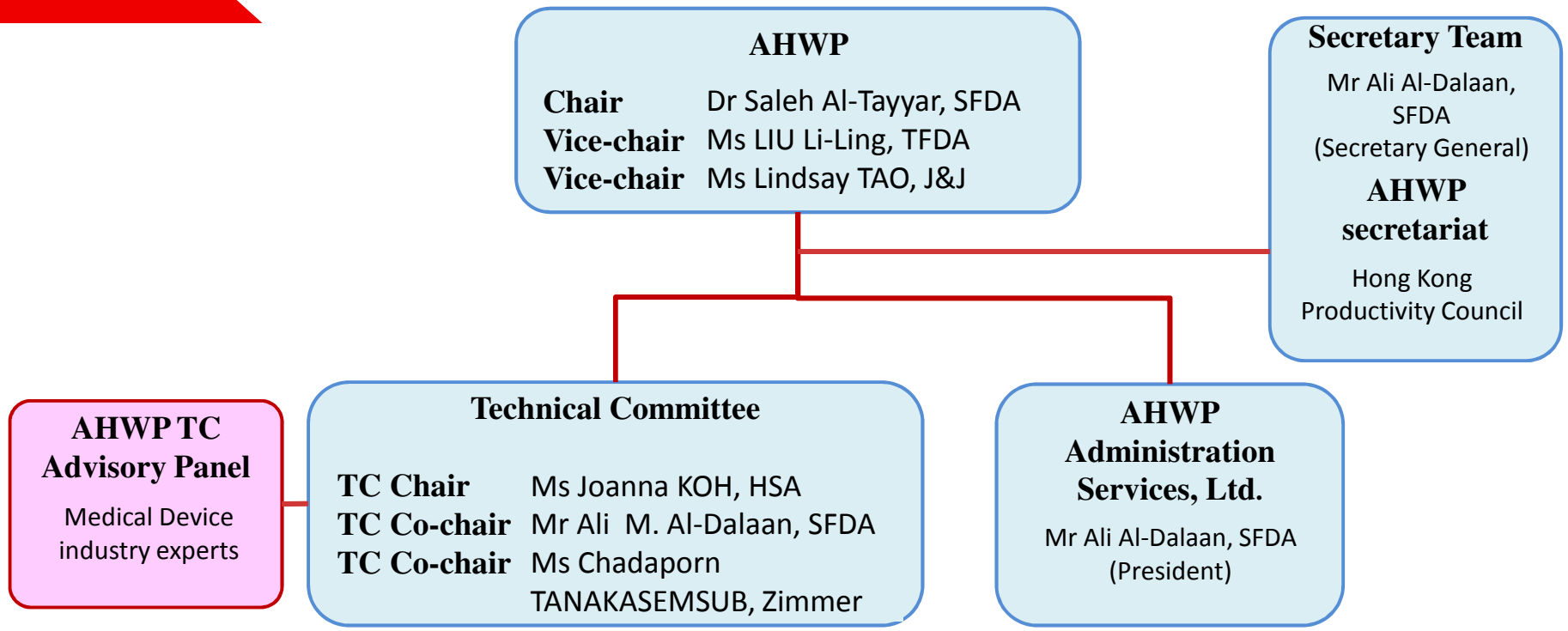
AHWP Organization Structure

2012-2014



AHWP Administration Limited

- ASL is the legal arm of AHWP.
- Incorporated on 12 April 2011, Registered Office in Hong Kong.
- Mission and Goals:
- ASL is established are to **administer and execute any mandates of the AHWP**.
- Use of Income and Property
  - The income and property of ASL shall be applied solely towards the promotion of the objects of ASL
  - Shall not be paid or transferred, directly or indirectly, to the Members of ASL

AHWP Technical Committee

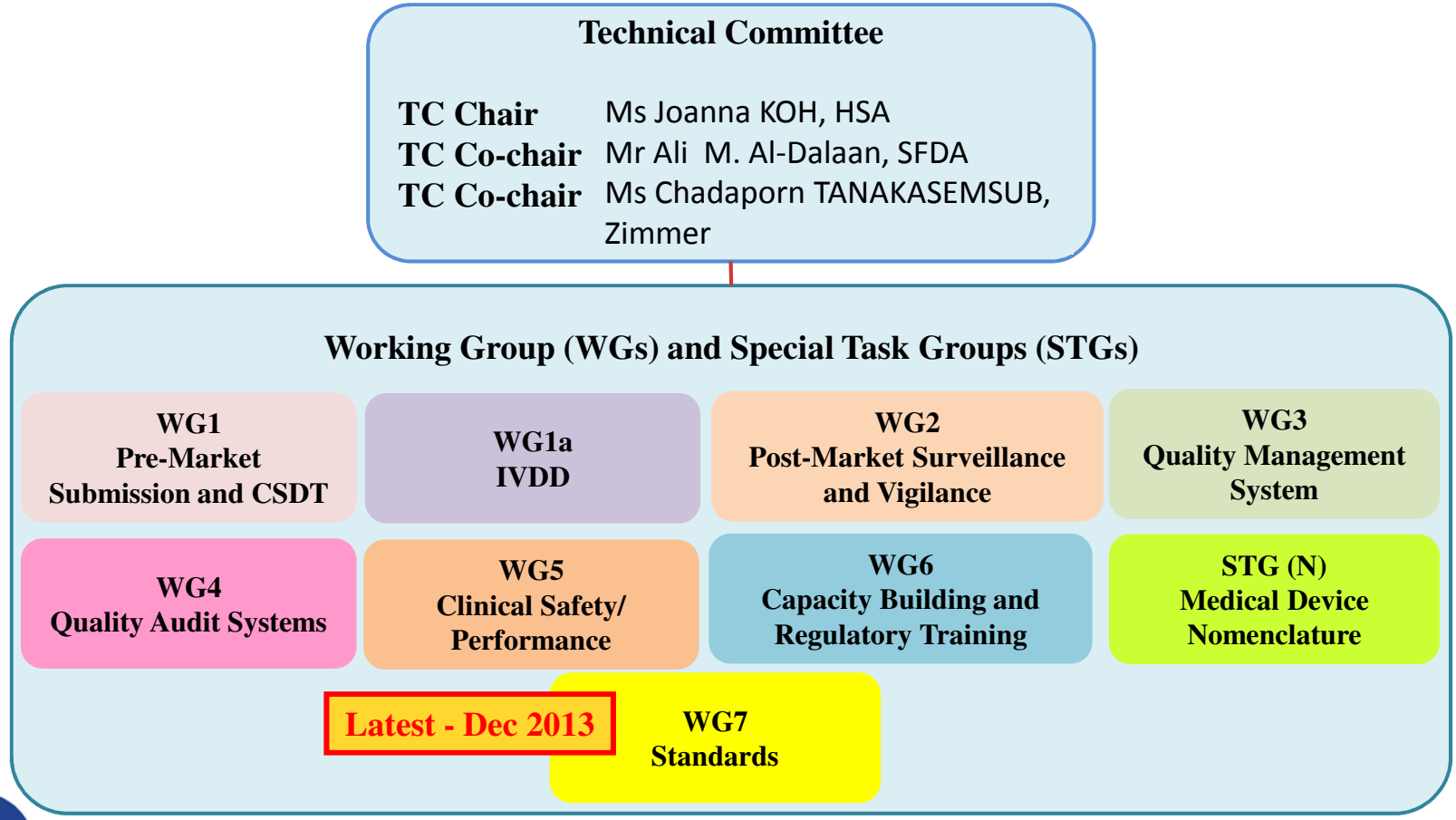
AHWPTC is the executive arm of the Working Party.

It performs the following roles and responsibilities to support the Working Party:

- Execute decisions & resolutions of AHWP;
- Make recommendations to the AHWP Chair;
- Submit resolutions related to the AHWP's policy, direction, organization, structure, operation ;
- Provide expert opinion & advice;
- Develop technical documents & policy papers;
- Plan & organize meetings, training, seminars, workshops, etc;
- Work with related organizations;
- Report on progress of its activities at AHWP meetings.

AHWP Technical Committee

- 8 **Working Groups** (WGs) and 1 **Special Task Group** (STGn)
- Each Group has 1 Chair (Regulator) and 1 Co-chair (Industry)



AHWPTC WG Work Items (1)

WG1
Pre-Market Submission and CSDT

- Mapping of CSDT to STED
- Combination products guidelines
- Software Medical Device classification & guidelines
- Medical device grouping for product registration guidelines

WG1a
***In Vitro* Diagnostic Devices**

- Development of AHWP IVD guidances
- Best practices for IVD clinical evaluation and investigation
- Affordable and Accessible IVD Medical Devices (Collaboration with LSHTM and GHTF)

AHWPTC WG Work Items (2)

WG2

Post-Market Surveillance and Vigilance

- Harmonized definitions (AE, FSCA)
- AE reporting forms (incl. electronic)
- Safety Alert Dissemination System (SADS) Upgrade
- AE Reporting Requirements & Timelines

WG3

Quality Management System

- Joint AHWP -WG3 GHTF SG3 activity
- Collaboration & contribution to ISO 13485, version 2003
- QMS adoption & implementation (survey &guidance development)
- Develop QMS for importers, distributors & small manufacturers

AHWPTC WG Work Items (3)

WG4
Quality Audit Systems

- Audit & Development training module development
- Auditing for **importers & distributors** guidelines

WG5
Clinical Safety/ Performance

- Mapping with ICH GCP, SG5 GN and latest version of ISO 14155
- Contribute to next ISO/TC 194/WG 4 "Clinical investigations of medical devices in humans"
- Regulation & implementation of Clinical Investigation

AHWPTC WG Work Items (4)

WG6
Capacity Building and Regulatory Training

- Develop training strategy for AHWP TC
- Source for relevant online course providers
- Training on AHWP guidances & standards

WG7
Standards

- Develop Guidelines for application of standards for Mes
- Strategize harmonisation / convergence of ME's national standards to international standards

STG (N)
Medical Device Nomenclature

- Harmonization work in device nomenclature / UDI
- Participation of nomenclature work at IMDRF and WHO
- GMDN pilot program (China)

Liaison: Potential role of GS1 in WGs and UDI

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AHWPTC Work on UDI

- Member of the IMDRF UDI working group on guidance UDI System for Medical Devices (Version 2.0)
- Conducted workshops aligned with IMDRF global model for member economies on UDI implementation at the AHWP & ASEAN Meetings,

Future work item (WG7)

- Establish a standard for implementation of UDI for AHWP member economies – Adoption of existing guidelines

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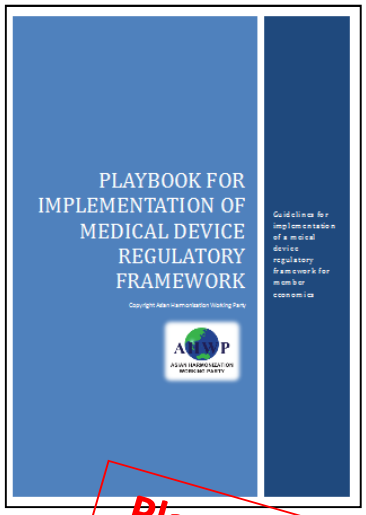
On the Road to Harmonisation…

AHWPTC Initiative: MD Playbook

Objective

- Develop a set of guidelines for MEs for a harmonised medical device (MD) regulatory framework in their implementation of controls

(Build on the experiences from other MEs who hv implemented controls & faced the challenges)



Playbook: Role of Liaison Members

In view of need for:

- Guidance on implementation of basic MD frame work elements, which otherwise wld be left to MEs

Working towards…

- Predictable & harmonised regulatory environment across Asia
  - Unified standards for product registration, establishment licencing, distribution and post-market

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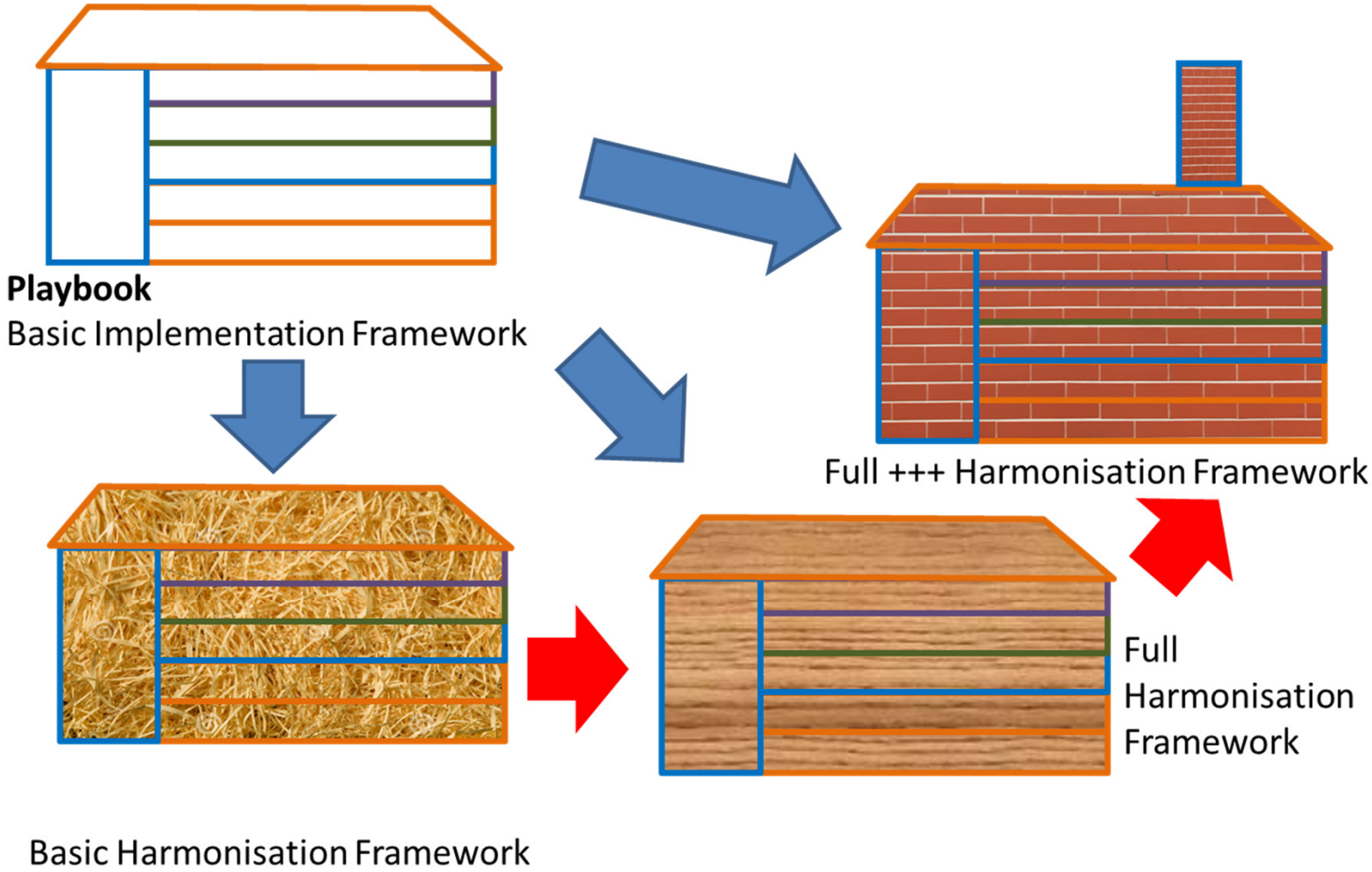
The Framework for the Building Blocks



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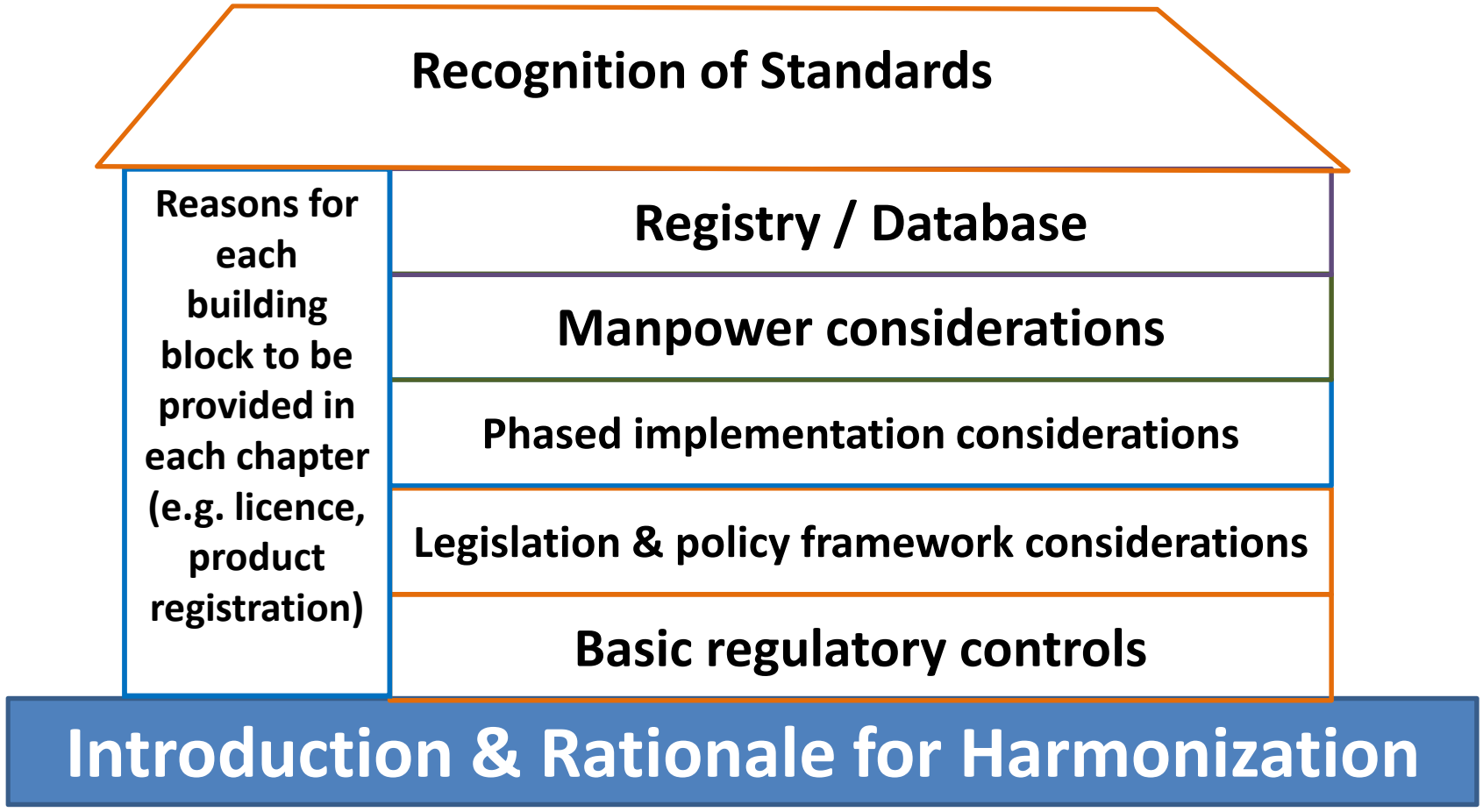
Elements of the Playbook
Providing the Framework



AHWP Highlights for 2013/14

- **1st Intl Conference on Food, Drug & Medical Devices**
  - Held in Sharm El Shiekh, Egypt in March 2013
  - Harmonisation of Regulations for Middle East National Regulators
- **2nd Global Medical Device Conference (WHO)**
  - Held in Geneva, Switzerland in Nov 2013
  - Sharing of Harmonisation steps for MD Controls
- **1st AHWP – RAPS Joint Conference**
  - Held in Kuala Lumpur, Malaysia in Dec 2013
  - Over 300 participants
  - Movement to build up capacity building for Members

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