ASIAN HARMONIZATION WORKING PARTY

17th AHWP TC Meeting
4 Dec 2013

Mrs Joanna Koh

AHWP TC Chair

3rd AHWP TC Leaders Meeting, Bangkok Summary

- 1st meeting of AHWP TC Advisory Committee with TC leaders

- Presentation by AHWP TC to TC Advisory:
  - AHWP TC strategic framework elements
  - AHWP member economies current status
  - SWOT analysis
  - Workplan summaries to date of WGs 1-6 presented (preceding slides)

- Feedback & sharing from TC Advisors on AHWP TC activities to date
- Agreed on setting priority work on playbook for AHWP members
- Recommendations from TC Advisors taken back for AHWP TC to act on

Sharing from TC Advisors (Re-Cap - Details)

Recommendations

1. Strategy

a) Identification of elements of a comprehensive regulatory system needed to be addressed in the **AHWP regulatory model** (ARM) for IVD and MD

b) Identification (through gap analysis) of **building blocks** that needed for the purpose in the regional context to develop the ARM (considering the differences among member economies)

2. Three levels of documents which will lead to AHWP's Best Practices

a) Focusing more on the creation of AHWP unique documents in addition to the adoption of GHTF/IMDRF* ones [Level 1]

b) **Interpretive documents** on existing documents – lead to capacity building [Level 2]

c) Collaborative decisions on **borderline issues** – by making AHWP's decision and setting of position on standards (e.g. determine borderline definition/inclusion of certain product as MD) [Level 3]

* GHTF documents can be regarded as level 1 or 2 doc

regulatory model can be regarded as level 0

Sharing from TC Advisors (Re-Cap - Details)

Recommendations

3. Process

a) Need more governance and oversight to **verify work items** fit in the approved ARM

b) Address recruitment, qualified, balanced, consistent **participation on work group**

c) Industrial participation is not limited to multi-national corporations (MNC) especially if topics are directly related to local environment

d) Need to **clarify the meaning of adoption or implementation** for AHWP

4. Structure and International alignment

a) Consider a more flexible working structure not like GHTF

b) Roles of TC advisors

c) Determine the AHWP liaison activities

d) Consider to form a focus group (special task group - STG) on standards

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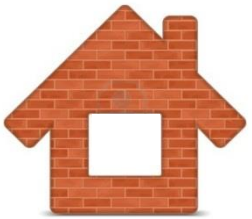
Progress on Recommendations

TC Advisor Recommendations Summary

1. Playbook for regulatory controls & implementation

2. Gap analysis process (identifying building blocks) in reviewing GHTF guidance documents for adoption in regional context



3. Set up a STG to work on the harmonisation of standards for MDs *(WG7)*

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Progress on Recommendations to date

Playbook for regulatory controls & implementation	Gap analysis process in reviewing GHTF guidance documents	Set up a STG to work on the harmonisation of standards for MDs
Identification of proposed elements in playbook Preliminary overview of each element outlined	Prelimiary Process of Gap Analysis Proposed Propose training of AHWP members on how to writing a guidance	Set up for endorsement at the TC meeting, the formation of the WG7 for Standards

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1. Playbook

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Playbook Elements Proposal

- AHWP lays out basic requirements for a harmonized regulatory framework, **but** many details of the implementation & framework are left to individual countries

There is need for:

- Predictable regulatory environment for medical devices across Asia
- Unified standards for product registration, distribution and post-market surveillance

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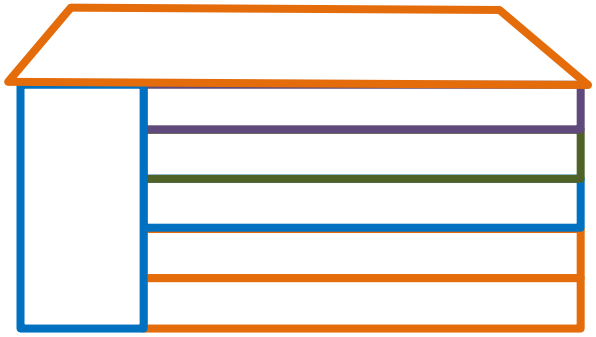
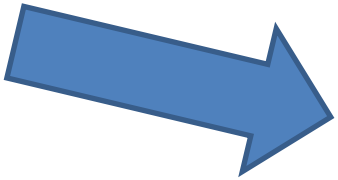
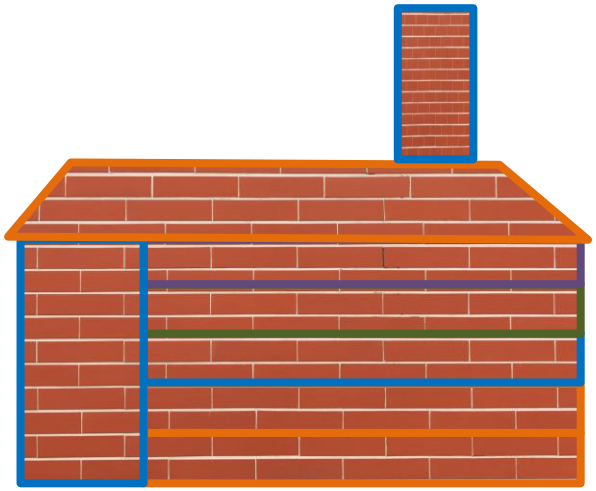
The Framework for the Building Blocks



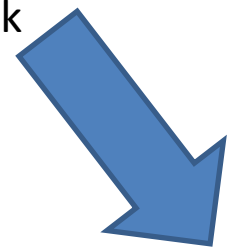
Playbook

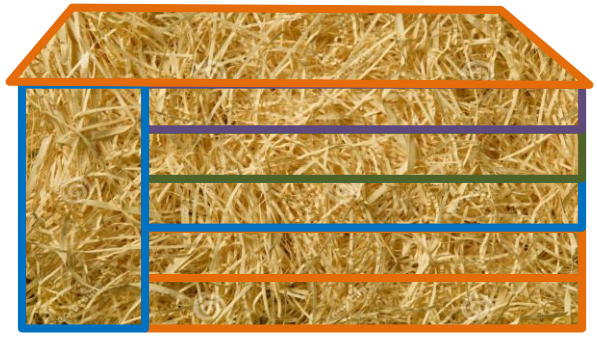
Basic Implementation Framework



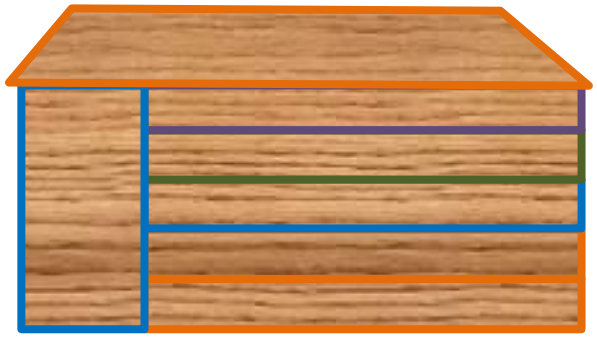


Full +++ Harmonisation Framework





Basic Harmonisation Framework



Full Harmonisation Framework

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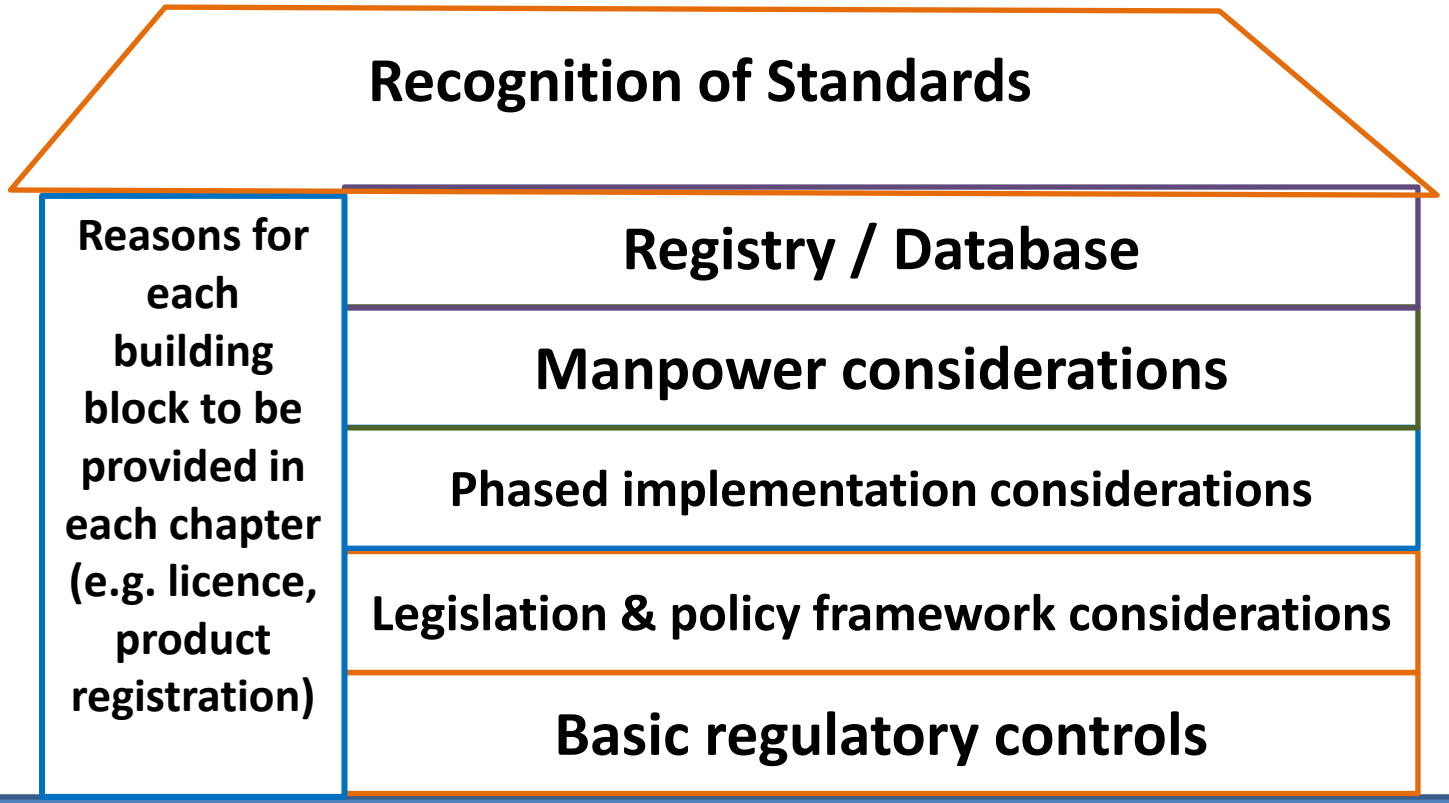
Playbook Elements Providing the Framework



Introduction & Rationale for Harmonization

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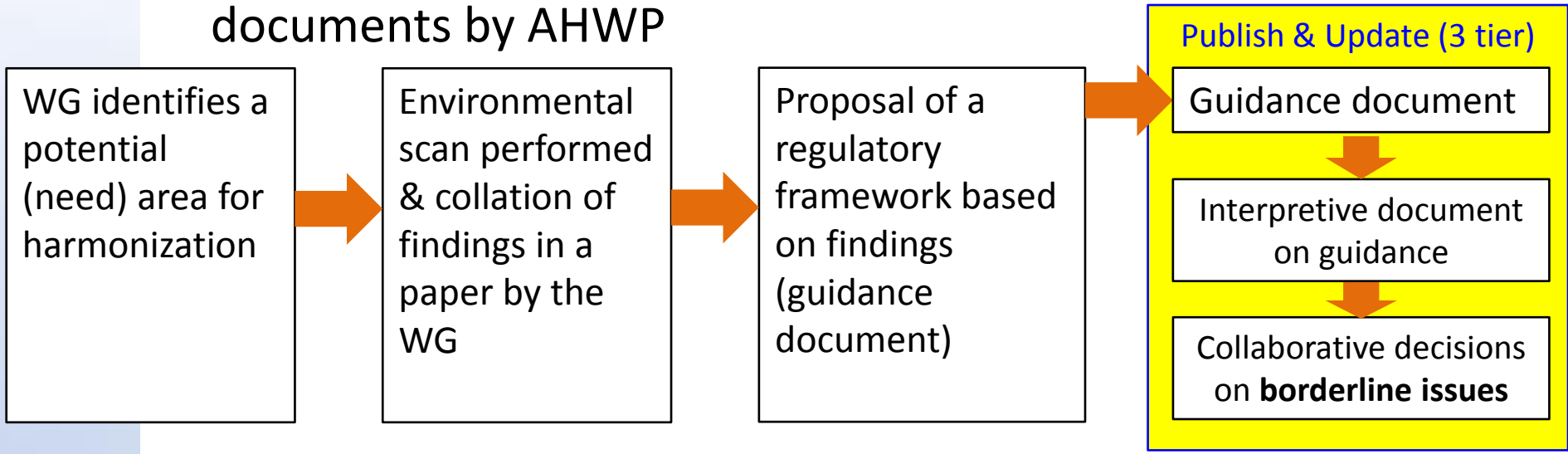
2. Gap Analysis Process

Proposed Gap Analysis Process

Identification (gap analysis) of building blocks for *Asia Regulatory Model*

Proposed process in place for adoption of guidance documents by AHWP



Proposed TC Advisory work item (future):
based on experience with publication of guidelines, standards (e.g. IMDRF/GHTF/ISO), AHWP TC may learn from thought process & procedure involved
Training session(s) on how to writing a guidance

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3. Workgroup on Standards

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New WG Proposal Standards Workgroup

- For endorsement at the TC meeting, the formation of WG7 for Standards

- Collaboration across industry & regulators - and setting of position on standards

<u>Objective of setting up WG on MD Standards</u>

Having recognised standards would

- *Serve as vital instrument to facilitate compliance and trade of medical devices across the Asia region*
- *Allow leveraging by industry and regulators on a recognised benchmark*
- *Assist organisations in improving the quality of medical devices & management systems*

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Thank You