Update on Asian Harmonization Working Party

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Overview of AHWP

- Established in 1997
- A group of experts from the medical device regulatory authorities and the medical device industry
- 23 economic member from Asia, middle East, Latin America: Abu Dhabi; Brunei Darussalam; Cambodia; Chile; Chinese Taipei; Hong Kong SAR, China; India; Indonesia; Jordan; Kingdom of Saudi Arabia; Republic of Korea; Laos; Malaysia; Myanmar; Pakistan; People's Republic of China; Philippines; Singapore; South Africa; State of Kuwait; Thailand; Vietnam; Yemen
- New Applicant: Tanzania (Food and Drugs Authority)
- Objective:
  - Established to forge a common direction for the harmonization of medical device regulation in Asia and other region
  - Encourage increased understanding on the benefits of harmonization
  - Provide a forum for discussion and training, facilitate information exchange and initiate projects relating to regulatory harmonization on medical devices
Achievements To Date

• **Membership:**
  — Has expanded to 23 economies from Asia pacific, Latin America and Middle East region

• **Working Model and structure**
  — The establishment of permanent secretariat office in HK

• **Linkage with International Organizations**
  — Official observer of GHTF and affiliate member of IMDRF
  — AHWP affiliates: GS1, DITTA

• **International cooperation**
  • A series of joint workshops with APEC (clinical evidence on premarket conformity assessment, implementation of GHTF guidance, Combination products, and etc.) since the establishment of APEC RHSC in 2009
  • 1st APEC – RAPS Conference at 18th AHWP annual meeting (2013)

• **Guidance development:**
  • Covers premarket submission, post market surveillance/vigilance, quality management system/audit, clinical safety/performance
Achievements to Date

• The development of Strategic Framework – The foreseeable Harmonization Horizon by 2020

Objective:

• Continue the momentum built in the past
• Provide a clear development plan and work targets towards the further enhancement of the capability of AHWP member economies in regulating medical devices, as well as the further strengthening of medical device regulatory harmonization and collaboration activities across the regions
• Serves as a guiding principles for various AHWP activities
Achievements to Date

Focus areas:

1. AHWP Membership Expansion
   - Welcome any non-AHWP economic members who shows interest on medical device regulatory convergence in participating

2. Training and Capacity building
   - Partner with regional/international organizations, focus on enhance knowledge on medical device, promote understanding of essential elements of medical device regulation, and promote international best practice
Focus areas:

3. **Harmonization in Key Areas based on GHTF Principles and AHWP guidance**
   - Harmonized definition, Adopt same risk-based classification of medical devices; Single adverse event reporting and post-marketing surveillance system; Single medical device nomenclature system; Single quality management system requirements, and broader acceptance of quality management system audit report by authorized competent authorities;

4. **Enhance AHWP’s Global Partnership**
   - Proactively approach and partner with international/regional organizations (e.g. IMDRF, APEC, ASEAN, WHO)
The development of AHWP Playbook for Implementation of a Medical Device Regulatory Framework

- Guided and supported by TC advisory panel
- Rationale behind Playbook: AHWP lays out basic requirements for a harmonized regulatory framework, **but** details of the implementation & framework are left to individual countries

**There is need for:**

- Guidance for member economies in developing their regulatory framework
- Encouragement of a harmonized regulatory environment across member economies
Playbook - Providing the Implementation Guidelines

Playbook provides the Implementation Guidelines

Implementation Guidelines

Full Framework

Basic Harmonisation Framework

Intermediate Framework
Structure of Playbook: Chapters

Introduction & Rationale for Harmonization

Reasons for each building block provided in each chapter

- Recognition of Standards
  - Registry / Database
  - Manpower considerations
  - Phased implementation considerations
  - Legislation & policy framework considerations
  - Basic regulatory controls

Currently: Published on AHWP website, open for public comments till 18 Sept 2014.

www.ahwp.info
On-going Work Items

• **WG1: Pre-market submission:**
  - Medical software premarket guidance
  - Combination products (medical device) guidance
  - Medical device grouping guidance

• **WG2: Post-market surveillance and vigilance**
  - Upgrade Safety Alert Dissemination System (SADS)
  - Revisit and revise SADS guidance

• **WG3: Quality management system**
  - Continuous working with ISO/TC210 on the revision of ISO13485 - 2003
  - Guidance document for the application of ISO 13485 for importers/distributors/small manufacturers

• **WG4: Quality management audit**
  - Auditing guidance for importer and distributors
On-going Work Items

• **WG 5: Clinical safety/performance:**
  • Survey on the regulation and implementation of clinical investigation including clinical trial requirements of member economies

• **WG 6: Regulatory Training/Capacity building**
  • Development of strategy and work plan

• **WG 7: Nomenclature (and UDI)**
  • GMDN board and Policy Advisory Group, promote GMDN implementation
  • Follow up member economy UDI implementation, ensure alignment with IMDRF global model, provide training needed
19th AHWP Annual Meeting in South Korea 2014, 18-21 November 2014, Sheraton Grand Walkerhill Hotel, Seoul, South Korea

- Nov 18 & 19, AHWP-AHC Joint Workshop
- Nov 20, 18th AHWP Technical Committee (TC) Meeting
- Nov 21, AHWP Main Meeting

For more information, please visit
www.ahwp.info
THANK YOU