Asian Harmonization Working Party
Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"

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AHWP Strategic Framework

Background and Objective

- **Strategic Objectives:**
  - 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

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Background and Objective (Cont.)

- **Background:**
  - Agreed and decision made by leaders at 16th Annual conference in Bali, Indonesia
  - Draft developed and discussed at February AHWP leaders' meeting
  - Revision based on comments received and circulation for leaders' comments between March to June
  - Draft endorsement by AHWP leaders at AHWP TC meeting in June, 2012
  - Further revision between June to Oct, 2012
  - Final draft posted at AHWP website in Oct 2012 for soliciting AHWP members comments
  - Presented in 17th AHWP meeting in Chinese Taipei
  - Call for comment by all AHWP members by Feb 4, 2013

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Framework Elements

- **Element One: AHWP Membership Expansion**
  - Welcome any non-AHWP economic members who shows interest in participating
  - Invite current AHWP economic member who has experience and knowledge on medical device regulation to take leadership role at various levels (AHWP, AHWP TC, working groups) at AHWP
  - Secretariat office offer consistent support to member economies

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- **Element Two: Training and Capacity building**

  - Focus on enhance knowledge on medical device, promote understanding of essential elements of medical device regulation, and promote international best practice

  - AHWP offer support to training and capacity building of members economies, in terms of financial and manpower

  - Identify priorities, partners of NGO, regional/international harmonization organizations (e.g. WHO, APEC, RAPS, MTLI, ARPA, and etc.)

  - Develop curriculum and review periodically

  - Promote utilization of advanced technology on training

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- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**

  Harmonization in important areas based on availability of GHTF global regulatory model and AHWP guidance:

  - Harmonized definition of the term "medical device" (important in determining what and who are subject to regulation);
  - Registration of manufacturers, distributors, and importers and listing of medical devices marketed;
  - 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 ;
  - Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members ;
  - Acceptance of the same dossier (technical file) template for registration submission (e.g. the CSDT/STED format);
  - Recognition of 'recognized regulatory agencies' registration decisions to expedite evaluation process, etc.

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- **Element Four: Working Alongside with APEC and ASEAN to expand beyond regional blocks**
  - APEC strategic framework on regulatory convergence by 2020 was endorsed by 21 economic members in 2011
  - ASEAN will implement AMDD in 2015 to harmonize medical device regulation
  - With common member economies, such efforts will be further leveraged, for example, joint programs on training and capacity building

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- **Element Five: Enhance AHWP's Global Presence**

  - Proactive reach out to international originations, global leaders and experts

  - Establish mechanism for effective interaction and networking:
    - Process of receiving from and providing feedbacks
    - Membership and representation
    - Joint strategic and roadmap development

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Indicator of Success

- Increased inclusiveness of AHWP membership
- Enhanced awareness on the robust and effective medical device regulation in improving access, quality and use of medical device
- Adoption or adaption of the GHTF global regulatory model, AHWP and other harmonized international guidance and standards
- Enhanced collaboration among AHWP members, to improve and promote greater efficiency on regulation and use of resource: nomenclature, single post-market surveillance; multi-acceptance of QMS auditing report
- Enhanced global partnership, AHWP's participation at regional/global forums, and joint activities.

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Comments received during public consultation from Oct 2012 to Feb 2013

- **COCIR / DITTA,** by Nicole Denjoy
- **RTI Biologics, Inc.**, by Kristina Hall
- **Cook Medical**, by Greg LeBlanc
- **Taiwan FDA**

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- **Proposed change:**
- Introduction:
  - Link with the Global Harmonization Task Force (GHTF) and International Medical Device Regulator Forum (IMDRF) : As a liaison body of the GHTF, AHWP works in coordination with the GHTF by participating in the GHTF Steering Committee and study groups contributing to the development of the GHTF guidance documents, promotion of understanding to the GHTF guidance documents and the facilitation on the adoption and adaptation of these guidance documents in the AHWP member economies. AHWP aims to work with IMDRF, successor to GHTF and custodian of the GHTF legacy, to keep guidance documents actualized.
  - International collaboration: Besides GHTF, AHWP has also established a connection with other international organizations, such as IMDRF WHO, ISO, IEC, APEC, etc., to bring awareness of the needs and interests of AHWP to the global medical device arena. AHWP is also affiliated with the Committee of the newly formed IMDRF (International Medical Device Regulators Forum). AHWP will continue to work collaboratively with the related international organizations to achieve regulatory harmonization. AHWP recommend its members to have an active role in international standardization as one of the most powerful tools to achieve harmonization

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- **Proposed change:**
- Framework Element One: AHWP Membership Expansion
  - AHWP continues to welcome contributions from medical device industry, both in the working groups as at the level of the plenary meetings, where it is supportive of the interests of AHWP and of regulatory harmonization in particular.
- Framework Element Two: Training and capacity building
  - AHWP will facilitate the process of building consensus among potential training partners from non-profit organizations, regional/global harmonization organizations (e.g. WHO, APEC, RAPS, MTLI, ARPA, etc.), universities, etc., to leverage on their expertise on the delivery of capacity training, to work with them in curriculum development on medical device regulations tailored for the needs of AHWP member economies. Informative materials as in international standards will also be considered in the curriculum development. All training activities should be planned and reviewed periodically and serve the AHWP strategic goal of achieving regulatory convergence.
  - AHWP should actively promote the full utilization of advanced technologies in training, such as webcast, web seminar, on-line training, etc., in supplement of traditional workshops and conferences.

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- **Proposed change:**
- Framework Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance
  - Acceptance of the same dossier (technical file) template for registration submission (e.g. the CSDT/STED format);
- Summary
  - This Strategic Framework is intended as a path forward for the AHWP, to build on its momentum from the past, to develop the strategic direction for the future development of AHWP, which includes working in alignment with the interests of APEC, ASEAN, GHTF and IMDRF to promote regulatory convergence to bring about faster market access through engagement of all stakeholders, and achieve a wider understanding of the benefits of international harmonization so that member economies of AHWP can implement best practices in their national regulatory systems. AHWP intends to share its consideration with IMDRF in order to keep the legacy of GHTF guidance documents actualized Member economies of AHWP will be adequately prepared to achieve their goal this based upon the application of AHWP as a platform for training and capacity building, the confidence building with the use of harmonized standards and best practices, and the assurance of alignment of the direction of AHWP with other regional/global regulatory harmonization organizations. This will ensure timely access of patients to the medical device and related new medical technologies based on the fundamental principles of safety and efficacy.

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- **Proposed Next Step:**
  - **Finalization of AHWP Strategic Framework by May 6 & 7, Secretariat Meeting**
  - **Distribution to all AHWP members**
  - **Endorsement at Annual Conference**

THANK YOU