Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: **Asia Harmonization Working Party Strategic Framework (2012~2014) - "The Foreseeable Harmonization Horizon"**

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"The Foreseeable Harmonization Horizon"

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Introduction:

The Asian Harmonization Working Party (AHWP) was established in 1999 as a voluntary group of regulators and industry members whose goal is to promote regulatory harmonization on medical device regulations in Asia and other regions in accordance with GHTF guidance. With the joint efforts of regulators and industry members over the past 12 years, AHWP has built important momentum:

- Membership: The membership of AHWP has been expanded to 23 economies, covering the Asia Pacific, Latin America and Middle East regions. The current members of AHWP includes: Abu Dhabi, Brunei Darussalam, Cambodia, Chile, China, Chinese Taipei, Hong Kong SAR, India, Indonesia, Jordan, the Kingdom of Saudi Arabia, Korea, Laos, Malaysia, Myanmar, Pakistan, the Philippines, Singapore, South Africa, Thailand, Vietnam, Yemen and Kuwait. In terms of membership, AHWP is now the largest medical device regulatory harmonization body in the world.

- Working model and structure: AHWP has an established technical and administrative work structure exemplified by a Technical Committee, seven working groups and a special task group (pre-market submission and CSDT, IVDD post-market surveillance and vigilance, quality management system, quality system audit, clinical safety/performance, capacity building and regulatory training as well as medical device nomenclature) to focus on the development of the technical contents on various aspects of medical device regulatory affairs, towards harmonization among AHWP member economies.

- 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

With all the previous achievements by AHWP, there are still many challenges and work to be done in future. Many AHWP members are developing economies with emerging medical device regulatory regimens. Regulators and industry members have limited experience and resources in implementing their medical device regulation. Meanwhile, medical technologies have been evolving rapidly, and playing a more and more important role in the healthcare service delivery. The locus of invention and production of medical devices has become more geographically dispersed. There is a growing demand for technologies to enable the diagnostic tests and therapies to be better appropriate, accessible and affordable in less developed economies. Since many of these regulatory systems are still in the formative stages, there is great opportunity for the prospective of harmonization on the regulatory requirements and practices within AHWP member economies.

In November 2011, Saudi FDA took over the chairmanship of AHWP from China SFDA (2009-2011). Under the new leadership, AHWP develops a Strategic Framework (2012-2014) with the theme on *"The Foreseeable Harmonization Horizon",* to enable 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.

Strategic Frame Work (2012-2014)

The Strategic Framework for 2012-2014: Foreseeable Harmonization Horizon serves as a guide for various AHWP activities, including: organizational presence and partnership, expansion, training and capacity building, and the regulatory convergence goal, which contributes to the achievement of AHWP's mission: to promote regulatory harmonization in order to enhance patient safety and increase access to safe, effective and clinically beneficial medical technologies across AHWP member economies.

Potential indicators of success:

- Increased inclusiveness of AHWP membership, therefore the further expansion of regulatory and industry members from more economies to join AHWP and participate in AHWP activities, for the benefit of both the AHWP members and non-members.
- Enhanced awareness on the robust and efficient medical device regulation, to ensure improved access, quality and use of medical devices to healthcare policy makers, regulators, industry and other stakeholders throughout the AHWP member economies.
- Adoption or adaptation of the GHTF global regulatory model and the model of the other international harmonization bodies for the construction of the regulatory system by AHWP members. and expedite the implementation of AHWP guidance which adopted or adapted from GHTF guidance in AHWP member economies, for example:
    - The definition of : "medical device", "manufacturer", "authorized representative", "distributor", "importer", and other terms as defined in GHTF guidance;
    - Registration of manufacturers, distributors, and importers and listing of medical devices;
    - Risk-based classification of medical devices;
    - Post market vigilance and surveillance framework;
    - Medical device nomenclature system, etc.
- Enhanced collaboration among AHWP member economies, to improve and promote greater efficiency on regulation and the use of resources. For example:
    - Single nomenclature system;
    - Convergence towards a single post-market surveillance framework; Mutual acceptance of quality management system and auditing report, etc.Synchronization in the adoption of international safety standards

- Enhanced global partnership between AHWP and the other international organizations. For example:
    - AHWP's participation and representation at regional/global forums;
    - Joint strategic planning, roadmap development, conference and activities with other regional and global organizations such as WHO, APEC, etc.

Framework Element One: AHWP Membership Expansion

Medical device manufacturing is booming in many economies worldwide, that are not member economies of AHWP. At the same time, member economies of AHWP are developing new medical device regulations or revising their existing systems. Given the rising wave of interest in the international and cross-regional collaboration and harmonization of medical device regulation, the AHWP should reach out to non-member economies and form the alliances with economies and associations across the globe.

AHWP would continue to welcome any members who show interest in participating, even though they may have no, or only rudimentary, medical device regulatory regimes. Their participations can benefit patients, regulatory authorities and medical device industry through improved access to high quality, safe and innovative medical devices by understanding and adoption of international best practices through AHWP training and capacity building, and by discussion on the development, adaptation, and adoption of the GHTF guidance documents.

Through the strategic set up of permanent secretariat office and legal entity in Hong Kong, AHWP is enabled to offer support to member economies with consistent and quality services through the secretariat office. AHWP has been offering necessary support to the member economies to regulatory authorities and industries in joining the AHWP meetings, workshops, conferences and events, which also strengthened our linkages and networks within member economies, creating good opportunities to narrow the gaps of medical device harmonization among member economies of AHWP.

While reaching out to non-member economies, it is equally important to invite economies with experience and knowledge on medical device regulation to take the leading roles at various levels (AHWP, AHWP TC, working groups) in AHWP, so that their extensive experience and knowledge on medical device regulatory affairs, including the adoption and adaption of GHTF guidance, can be shared further. Greater progress can be made through sharing of experience in improvement of practices and converging towards international best practices.

Framework Element Two: Training and capacity building

The support on strategic elements of membership expansion, training and capacity building are extremely important to AHWP. These are important elements of promoting better understanding of international best practices on medical device regulation and contributing to achieving the ultimate goal of AHWP, and to achieve regulatory convergence towards international best practices.

The objective of training and capacity building should be focused on helping regulators and the industry in understanding the medical device technology, the rationale behind medical device regulation and international best practices, thereby avoiding the mistakes that the other economies may have made, therefore to reduce the costs of re-inventing the wheel amongst AHWP member economies. For those AHWP member economies which have very limited resources and have no medical regulatory system in place, this training and capacity building should help healthcare policy makers, regulators, industry, healthcare professionals and other stakeholders to enhance their knowledge on medical devices, and to understand the most important and essential elements of medical device regulation.

AHWP has conducted training and capacity building activities over the years through its working groups, as well as the collaboration with other global organizations like APEC, GHTF, etc. Moving forward, AHWP shall look into a more systematic approach to the overall training plan.

As mentioned above, some current and prospective AHWP members have not yet established their medical device regimes. Most AHWP members have relatively very limited resources and experience on medical device regulation. AHWP would further offer support on training and capacity building to member economies through the resources of AHWP, in terms of financial and manpower in-kind support.

The training and capability building efforts should lead to the identification of priorities for regulatory system development, optimize the use of regulatory resources, and contribute to the ultimate goal of improved patient access to high quality, and safe medical devices.

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

developmentAll 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.

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

Some AHWP member economies have not yet established their medical device regimes or are in the process of establishing their medical device regimes. Some of them are re-visiting their existing systems.

AHWP should identify important areas with the most potential for success in harmonization based on the availability of GHTF global regulatory model and AHWP guidance within the AHWP region, and work out a clear timeline. Based on the progress achieved in AHWP, the areas below should be considered for regulatory convergence in a defined time frame.

- 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 similar 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 format);
- Recognition of ‘recognized regulatory agencies’ registration decisions to expedite evaluation process, etc.

Framework Element Four: Enhance AHWP's Global Partnership

AHWP should proactively approach international/regional organizations (e.g. IMDRF, APEC, ASEAN, WHO), global leaders and experts, to identify important topics and to establish mechanisms for effective interaction and networking. This could include, but not be limited to:

- a process of receiving from and providing feedback to these organizations;
- membership and representation at these organizations;
- joint strategic planning and roadmap development (especially in the areas of common interest and benefit)
- joint activities and events in promoting regulatory harmonization/convergence

All these partnerships would further enhance the extent of regulatory harmonization within the AHWP member economies.

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.