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

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Date: September 20th, 2012

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Asia Harmonization Working Party
Strategic Framework Towards 2020
“The Foreseeable Harmonization Horizon”

Introduction:

The Asian Harmonization Working Party (AHWP) was established in 1999 as a group of regulators and industry members whose goal is to promote voluntary regulatory harmonization of medical device regulations in Asia and other regions in accordance with Global Harmonization Task Force (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 are: 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. It is hoped more economies will join in future.

- **Working model and structure**: AHWP has an established technical and administrative work structure composed of a Technical Committee, seven working groups, and a special task group, to focus on the development of the technical contents of guidance on various aspects of medical device regulatory systems. They cover 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.

- **Link with the Global Harmonization Task Force (GHTF)**: As a liaison body of the GHTF, AHWP has worked in coordination with the GHTF by participating in the GHTF Steering Committee and study groups. AHWP has contributed to the development of GHTF guidance documents, promotion of understanding of GHTF guidance documents, and facilitation of the adoption and adaptation of these guidance documents in AHWP member economies.

- **International collaboration**: Besides GHTF, AHWP has also established a connection with other international organizations, such as IMDRF, WHO, ISO,
APEC, etc., to bring awareness of the needs and interests of AHWP to the global medical device arena. AHWP is also affiliated with the Management Committee of the newly formed IMDRF (International Medical Device Regulators Forum). AHWP will continue to work collaboratively with these international organizations to achieve regulatory harmonization.

With all the achievements by AHWP to date, there are still many challenges and much work to be done. Many AHWP members are developing economies with emerging medical device regulatory regimes. Regulators and industry members have limited experience and resources in implementing their medical device regulations. Meanwhile, medical technologies have been evolving rapidly and play a more and more important role in 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 diagnostic tests and therapies to be more 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 prospective harmonization of regulatory requirements and practices within AHWP member economies (rather than the more difficult task of retrospective convergence amongst established regulatory systems).

In November 2011, Saudi FDA took over the chairmanship of AHWP from China SFDA (2009-2011). Under the new leadership, AHWP develops the Strategic Framework Towards 2020 with the theme of “The Foreseeable Harmonization Horizon” It is intended to 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.

**Strategic Frame Work Towards 2020**

*The Strategic Framework Towards 2020: Foreseeable Harmonization Horizon* serves as a guide for AHWP activities, including: organizational presence and partnership, expansion, training and capacity building. The regulatory convergence goal 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 AHWP members and non-members.

- Enhanced awareness of robust and efficient medical device regulation, through the improved access, quality and use of medical devices amongst healthcare policy makers, regulators, industry and other stakeholders throughout the AHWP member economies.

- Adoption or adaptation of the GHTF regulatory model and the guidance of other international harmonization bodies for the construction of regulatory systems by AHWP members. Expedite the implementation of AHWP guidance 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 in 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 auditing reports, etc.

- Enhanced global partnership between AHWP and 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, ASEAN, etc.

Framework Element One: AHWP Membership Expansion

Medical device manufacturing is booming in many economies worldwide, including those 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 international and cross-regional collaboration and
harmonization of medical device regulation, AHWP should reach out to non-member economies and form alliances with economies and associations across the globe.

AHWP would continue to welcome as members any economies that support the objectives and show interest in participating, even though they may have no, or only rudimentary, medical device regulatory regimes. Their participation can benefit patients, regulatory authorities and the 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 GHTF guidance documents.

Through the strategic set up of a permanent secretariat office and legal entity in Hong Kong, AHWP is able to offer support to member economies with consistent and quality services. AHWP offers necessary support to member economy regulatory authorities and industries in joining AHWP meetings, workshops, conferences and events. This resource has also strengthened our linkages and networks within member economies, creating good opportunities to narrow the gaps in 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 leading roles at various levels in AHWP (AHWP, AHWP TC, working groups). Their extensive experience and knowledge on medical device regulatory affairs, including the adoption and adaptation 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 of strategic elements of membership expansion, training, and capacity building are extremely important to AHWP. These are essential elements of promoting better understanding of international best practices in medical device regulation and contributing to achieving the ultimate goal of AHWP: regulatory convergence towards international best practices.

The objective of training and capacity building should be focused on helping regulators and industry in understanding medical device technology and the rationale behind medical device regulation and international best practices. This will help avoid mistakes that other economies may have made and 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 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 very limited resources and experience in medical device regulation. AHWP would 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 (e.g. WHO, APEC, RAPS, MTI, ARPA, etc.), regional/global harmonization organizations, universities, etc., to leverage their expertise on the delivery of capacity training and to work with them in curriculum development on medical device regulations tailored for the needs of AHWP member economies. All training activities should be planned and reviewed periodically and serve the AHWP strategic goal of achieving regulatory convergence. Where feasible, 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, or are in the process of establishing, their medical device regimes. Some of them are revising their existing systems.
AHWP should identify important areas with the most potential for success in harmonization based on the GHTF regulatory model and AHWP guidance within the AHWP region, and work out a clear timeline. Based on 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 (important in establishing which medical devices are on the market or in use in a particular jurisdiction and under whose responsibility);
- 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 reports 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 and use of current international standards;
- Recognition of ‘recognized regulatory agencies’ registration decisions to expedite evaluation process, etc.

**Framework Element Four: Working Alongside APEC and ASEAN to Expand Beyond Regional Blocs**

The APEC strategic framework of Regulatory Convergence for Medical Products (including medical devices) was endorsed by 21 APEC economies in 2011. This framework outlines a strategic multi-year approach for achieving greater regulatory convergence toward international best practices in the APEC region by 2020. International best practices in the medical device area are described in GHTF guidance documents.

The ASEAN Medical Device Directive (AMDD) is under development and expected to be implemented by 2015, to support the general goal of a single ASEAN community by achieving regulatory harmonization in ASEAN. More specifically, the goal of the AMDD is to harmonize rules for medical devices, including definitions, essential principles of safety and performance, risk classification, registration for placement on the market, post-marketing alert system, etc.
Since many AHWP member economies are also members of APEC and/or ASEAN, AHWP can further leverage the efforts of APEC and ASEAN on the harmonization of medical device regulation in the future. For example, AHWP can jointly organize programs on training and capacity building with APEC and/or ASEAN to further increase the awareness and understanding of international best practices in medical device regulation.

**Framework Element Five: Enhance AHWP’s Global Partnership**

AHWP should proactively approach international organizations, 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) including joint conferences and activities, etc.

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, and to develop the strategic direction for the future development of AHWP. It includes working in alignment with the interests of APEC, ASEAN, GHTF and IMDRF to promote regulatory convergence to protect and promote public health, to bring about faster market access through engagement of all stakeholders, and to 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. Member economies of AHWP will be prepared to do by utilizing the platform of AHWP for training and capacity building. AHWP will contribute to confidence building through 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, quality and performance.

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