Asia Harmonization Working Party Strategic Framework (2012~2014)

The Foreseeable Harmonization Horizon

Introduction:

The Asian Harmonization Working Party (AHWP) was established in 199 as a voluntary group of regulators and industry whose goal is to study and recommend ways to harmonize medical device regulations in the Asian and other regions.

註解 [MBG1]: I believe it was later than 1992 – 1994 or 5? Also – the reference to "15 years" in the next paragraph isn't consistent with 1992.

In the joint efforts of regulators and industry over the last 16 years, AHWP has achieved a lot:

- Membership: AHWP membership has expanded to include 23 economies from the Asia Pacific, Latin America and Middle East regions. The full member list today is: Abu Dhabi, Brunei Darussalam, Cambodia, Chile, China, Chinese Taipei, Hong Kong, 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 members, AHWP is now the largest medical device regulatory harmonization body

- Working model and structure: AHWP has an established technical and administrative work structure, a Technical Committee and seven working groups (premarket evaluation, post market vigilance, quality system; auditing, clinical evidence, training, nomenclature/ UDI) to focus on development of technical work and guidance, and an outside service provider to provide administrative services.

- Link with the Global Harmonization Task Force (GHTF): As a liaison body of GHTF, AHWP works in coordination with GHTF by participating in the GHTF Steering Committee and study groups as observers, contributing to the development of GHTF guidance, promoting understanding, and facilitating the adoption and adaptation of GHTF guidance in AHWP member economies. [What about IMDRF? It is probably too early to say, but you should probably recognize the formation of the new forum and indicate an interest in working with it.]

- International collaboration: Besides GHTF, AHWP has also established a connection with other international organizations, like WHO, ISO, APEC, etc, to bring awareness of AHWP's needs and interests to global medical device society.

Although much has been achieved, there are still many challenges and much work to be done ahead. Among AHWP members, most of them are developing countries with emerging medical device regulatory regimens. Regulators and industry have limited experience and resources for medical device regulation; while at the same time, medical technology is evolving rapidly and playing a more important role in health care. The locus of invention and production of medical devices is also becoming more geographically dispersed. There is also growing demand for technologies for diagnostic tests and therapies appropriate, accessible, and affordable in less developed societies. Because so many of these regulatory systems are in formative stages, there is the opportunity for prospective harmonization of regulatory requirements and practices.

註解 **[MBG2]:** "economies"? Inconsistent use throughout paper.

In November 2011, Saudi Arabia FDA took over chairmanship of AHWP from China SFDA (2009-2011). Under the new leadership, AHWP plans to launch a Strategic Framework aimed to further enhance the capacity of AHWP member economies in regulating medical devices and to strengthen regulatory harmonization and collaboration activities across and among 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.

[As a general opening for the elements that follow, should the paper propose a "vision" of regulatory harmonization?

- What is meant by "harmonization"?
- How is "success" defined?
- What does harmonization "look and feel like" to regulators? To industry?
- What are the claimed advantages of harmonization?
- Who would benefit and how?

Should the paper make the point that, in general, AHWP regulatory harmonization would generally be based upon convergence upon, and adoption and implementation of, GHTF guidance documents, adapted as necessary to suit AHWP member economy needs?

Should the paper briefly address the obstacles to harmonization and how to overcome them?

I suggest regional regulatory harmonization can help promote a high level of safety, quality, and performance of medical devices; encourage innovation in technology and regulatory practices, and facilitate international trade.

Does AHWP see itself as a developer of harmonized guidance on good regulatory practices, as a body seeking to promote the adoption and implementation of harmonized guidance developed by others (e.g., as APEC seeks), or both? I suggest greater clarity.]

Framework Element One: AHWP Membership Expansion

Medical device manufacturing is booming in a number of countries that are not participants in the AHWP. Other countries are developing new medical device regulations or revising existing systems. Given the rising wave of interest in international and cross-regional collaboration and harmonization of certain aspects of regulatory processes among nations with advanced regulatory programs and those with programs in early stages of development, the AHWP should reach out to non-member countries and form alliances with countries and associations across the globe.

註解 [MBG3]: "economies"?

註解 [MBG4]: "economies"?

The AHWP will commit itself to increasingly welcome nations and regions wishing to be more active participants in the ongoing work of the organization.

註解 [MBG5]: What will this mean for resources, management, procedures, structures, and administration? Should the paper not address these challenges, or, at least, identify them as challenges? Can today's structure effectively manage such expansion?

Different from GHTF and IMDRF, AHWP should welcome any members who show interest in participating, even though they may have no, or only rudimentary, medical device regulatory regimens. Their participation can benefit medical device industry through innovation and trade, by understanding and adoption of best international best practice through AHWP training and capacity building, and by discussion on the development, adaptation, and adoption of GHTF guidance document.

註解 [MBG6]: Be careful – benefits should be seen first to come to patients, then (balanced) to regulators and industry.

While reaching out to non-member countries, it is equally important to invite countries with experience and knowledge on medical device regulation to take leadership roles at various levels (AHWP, AHWP TC, working groups) in AHWP, so that their experience and knowledge can be shared. Greater progress can be made through sharing their experience in improvement of practices and converging toward international best practices.

註解 [MBG7]: "economies"?

註解 [MBG8]: "economies"?

Framework Element Two: Training and capacity building

In supporting the strategic element of membership expansion, training and capacity building is extremely important to AHWP. Training and capacity building are important means of promoting better understanding of international best practices on medical device regulation and contributing to the ultimate AHWP goal to achieve regulatory convergence toward international best practice.

AHWP conducted series of training and capacity building activities over the years through its working groups, collaboration with other global organizations like APEC, GHTF, and etc., most of them are very successful, but it should be noted that most of them are of ad hoc nature.

註解 [MBG9]: I agree with the observation. Does it suggest AHWP should take a more strategic approach to training (much as APEC is doing)?

As mentioned above, some current and prospective AHWP members have not yet established their medical device regimen. Most AHWP members have only limited resources and experience on medical device regulation as compared to GHTF members. There is a ever-growing interest and need for training, so training and capacity building should be highlighted in the Strategic Framework.

註解 [MBG10]: Even US FDA has "limited" resources.

註解 [MBG11]: How does training address the question of limited resources for regulation?

The objective of training and capacity building should be focused on helping regulators and industry understand medical device technology, the rationale behind medical device regulation and international best practices, thereby avoiding the mistakes other countries have made and reducing the costs of re-inventing the wheel in AHWP members.

With this objective, AHWP should speed up the process of building relationships with potential training partners from non-profit organizations, regional/global harmonization organizations, universities, etc. who have appropriate capability and qualifications and who share the objectives of AHWP. This will allow AHWP and member economies to leverage the resources and expertise of those bodies, and to work with them on building strong curriculum on medical device regulation tailored for AHWP needs. 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 web case, web seminar, on-line training, etc. besides traditional workshops and conferences.

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

Unlike GHTF members, most AHWP members have not yet established their medical device regimens, are in the process of establishing their medical device regimens, are revising existing systems, or have incomplete medical device regulations. This gives a significant advantage to AHWP in achieving regulatory harmonization by adopting

international best practice without the need for all member economies to change existing laws, regulation, and policies.

AHWP should identify priority areas with the most potential for success in harmonization within the AHWP region, and work out a clear timeline. Based on the progress achieved, the areas below, derived from the GHTF regulatory model, should be considered for regulatory convergence in a short time frame (e.g., by 2014):

- 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
- 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 mutual recognition of quality management system audit report by authorized competent authorities
- Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members

註解 [MBG12]: "mutual recognition" may be too ambitious. Among other things, it requires a political willingness and rough equivalence of requirements. Consider "mutual acceptance" or (perhaps better) "broader acceptance".

Other areas for regulatory convergence eventually (by 2020)

- Recognition and use of international standards
- Clinical evaluation and evidence
- Single submission format for premarket evaluation and mutual recognition on premarket review

註解 [MBG13]: "mutual recognition" may be too ambitious. Among other things, it requires a political willingness and rough equivalence of requirements.

Framework Element Four: Working Alongside with APEC towards Regional Regulatory Harmonization Goal by 2020

The strategic framework of Regulatory Convergence for Medical Products (including medical devices) by 2020 was adopted in 2010 by APEC's Regulatory Harmonization Steering Committee (RHSC) and the Life Sciences Innovation. It provides the basic framework and rationale for achieving regional regulatory convergence for medical products by 2020.

Recognizing that not all members of AHWP are members of APEC, AHWP will work in concert with governments, industry, academia and others to develop specific working plans to promote regulatory convergence within AHWP member economies based on APEC's strategic framework of Regulatory Convergence. To achieve this goal, it is critical to launch an ongoing strategic approach, to increase awareness of regulators and industry of regulatory best practices, and to promote implementation of the underlying harmonized regulatory guidance.

註解 [MBG14]: Is there a need to explain the rationale for this linkage? Especially for AHWP members who are not members of APEC?

註解 [MBG15]: Is that not the purpose of this document?

The APEC proposed strategic approach for Regulatory Convergence in the Medical Products Sector is a multi-phase program. Each phase is a series of steps on the continuum of activities leading to 2020

- Phase One - Setting the Foundation – Building Capacity in Procedures for Developing and Implementing Regulations (2011-12)
- Phase Two - Advancing the Process (2013-15)
- Phase Three – Assessing Convergence (2015-20)

Framework Elements V: Increase AHWP's Global Presence

AHWP covers half of the world population, the majority of world small and medium size medical device manufacturers. Its enhanced global presence can benefit global medical device regulators, industry and patients.

註解 [MBG16]: How?

Despite the linkage established with formal international organizations like ISO, GHTF, WHO, and APEC, it is recognized that AHWP has not fully utilized and leveraged these international organizations to achieve regulatory harmonization in AHWP region.

註解 [MBG17]: And therefore? What is proposed here?

AHWP should proactively approach international organizations and global leaders and experts, identify priority topics, establish mechanisms for effective interactions and networking, improve the process of getting input and providing feedback, and ultimately promote the outcome of greater regulatory harmonization in AHWP region.

註解 [MBG18]: To what extent is this goal dependent upon political will of member economies? How will that political will be gained?

Summary

This Strategic Framework is intended as a path forward for the AHWP, building on its success of the past, with the goal for the AHWP to take leadership role and provide a strategic direction which aligns with APEC, GHTF, and IMDRF interests and promote regulatory convergence focusing on speed market access; to engage all stakeholders; to promote wider understanding of the benefits of international harmonization, so that they can implement best practice in national regulatory systems and speed market access based on the confidence built upon harmonized standards ; to use AHWP as a platform for training and capacity building for regulators and industry; to ensure alignment of directions and leverage of resources of AHWP with other regional/global regulatory harmonization organizations to maximize the timely access of patients to the benefits of safe high quality medical device technologies .

註解 [MBG19]: What do you see as those "successes"? Should they be outlined earlier in this paper?

註解 [MBG20]: Chair and TC?

註解 [MBG21]: In what?