

**Report of the 8th Asia Harmonization Working Party Meeting
20 September, 2000, Ottawa, Canada**

The 8th Meeting of the Asia Harmonization Working Party (AHWP) was held in Ottawa, Canada, on 20 September 2000 in conjunction with the 8th Global Harmonization Task Force (GHTF) Conference of 18-22 September 2000.

Call To Order

The meeting of the AHWP was called to order at 1:30 pm by the Acting Chair of the Working Party, Dr Clarence Tan, Singapore Ministry of Health. Dr Tan welcomed participants and thanked GHTF for their help in facilitating the AHWP meeting. He outlined the afternoon's agenda and proposed a discussion of the draft procedural documents of GHTF Ad-Hoc Procedures Group if time permitted.

Members from 7 participating Asian economies at the meeting confirmed the agenda items and the report of 7th AHWP meeting (3 March 2000, held in Singapore) without any amendment. The agenda and the report had been circulated to Asian medical device regulatory authorities and industry in the call invitations of 27 July 2000 and 18 Aug 2000 to the regional meeting in Canada.

The sixty-four government and industry participants from 8 participating Asian economies and other observer economies including GHTF member countries then introduced themselves to the Working Party (see Annex - List of attendees present at the 8th AHWP meeting).

Agenda Items

- I. Confirmation of Member Economy's representatives
- II. Election of Chair and Vice-Chair of AHWP
- III. Formation of Technical Committee(s)
- IV. Discussion of GHTF Study Group Documents and Identification of Work Projects
- V. Brief Presentation on a proposed system to list medical devices by Singapore Ministry of Health
- VI. Next Meeting of AHWP
- VII. Closing Remarks

Confirmation of Member Economy's representatives

Changes were made to representatives from regulatory authorities in Indonesia (Mrs Lucky S. Slamet) and South Korea (Mr Hee-Kyo Jeong).

Election of Chair and Vice-Chair of AHWP

Only one nomination for the AHWP Chair in the earlier call invitation to regulatory authorities was received. Indonesia's nomination of Singapore's Dr Clarence Tan for the AHWP Chair was tabled. As there were no further nominations at the meeting and no objections raised, Dr Clarence Tan from Singapore Ministry of Health was elected unanimously as Chair, AHWP, for a 3-year term of office at the meeting. For the election of Vice-Chair, the meeting unanimously elected Mr Edward Woo, the industry representative from Hong Kong, also for a 3-year term.

In the addresses that followed, both Dr Tan and Mr Woo emphasised AHWP's commitment to harmonize medical device regulations in Asia with global trends by working closely with GHTF and Asian member economies.

Matters arising from Last Meeting

There were no amendments to the Report of the 7th AHWP regional meeting held in Singapore on 3 March 2000. Dr Tan highlighted that pre-market review and standards were broad areas of interest in harmonization as ranked by respondents in the survey among six medical device regulators present at the last meeting.

Formation of Technical Committee

The meeting discussed the agenda for the Technical Committee and decided that priority would be given to the documents from Study Group 1 (Regulatory Requirements/Premarket Review) of GHTF. To facilitate the study and implementation of these documents, the meeting decided to look into the possibility of conducting a seminar with the assistance of SG1, if possible.

The meeting also decided that it would be beneficial for the Technical Committee to participate in the GHTF Study Group discussions as observers. For a start, the Chairs of SG1 and SG4 (Quality System Auditing) have been approached and both have very kindly and willingly extended an invitation to AHWP to attend their next meetings. It is the intention of AHWP to seek observer participation in all the GHTF Study Groups but this will depend on our resource availability.

The following persons were duly elected by consensus to the Technical Committee:

- Chair: Mr Albert Li (Industrial Technology Research Institute, Chinese Taipei)
- Co-Chairs: Mr Mohd Zin Che Awang or representative (Pharmaceutical Control Bureau, Malaysia); and
Mr Jack Moore (Boston Scientific, Singapore).

Dr Tan asked representatives from participating economies in Asia to nominate appropriate persons to sit in the Technical Committee. A wider representation will help to facilitate harmonization efforts within each economy as well as acting as a technical interface regionally and with GHTF.

The meeting re-affirmed that the consensus, recommendations and guidance documents of GHTF would serve as the basis for AHWP in working towards the development and harmonization of medical device regulation in Asia.

The discussion on the activities and operations of Technical Committee had the invaluable inputs and comments from members of GHTF and its SGs who were present at the meeting. The followings were highlighted for further consideration by the Working Party:

- Reciprocity and close collaboration of TC with GHTF SGs; especially with SG1 and SG4 where expressed support from its members was most encouraging;
- TC should review SG documents for its inter-relatedness and completeness rather than focussing on a single document;
- Coordinators in TC to participate in and report on the work of all SGs, if resources permit;
- TC to target recommendations leading to building and implementation of measures and regulatory framework that are aligned to GHTF, global harmonization and MRA efforts and removing technical regulatory barriers while recognising the jurisdiction of each member economy;
- Set objectives and frequency of meetings for TC;
- Opportunity for AHWP and TC to facilitate the introduction of harmonised regulations in member economies because of the absence of a regulatory framework in place currently or in its early stages of development.

Other New Matters

GHTF Ad-Hoc Procedures Group

Dr Tan referred to the three draft procedural documents posted on the GHTF website for comment. One of the documents, "Roles and Responsibilities" elaborated on membership of founding and other participating members and the Steering Committee management group in the GHTF organisation with implied provision for expansion of this management group in the future and consideration of new members such as

regional grouping like AHWP. Over the last two and the half years, Dr Tan noted that AHWP has evolved from an informal forum into an organised and structured regional group of Asian medical device regulators and industry representatives with clear objectives and a common direction to achieve harmonization of medical device regulation in support of GHTF. AHWP is strongly committed to communicating and cascading the GHTF process to Asia.

The meeting agreed that AHWP will be able to add value to GHTF in furthering the cause of global harmonization in Asia and that it will prove to be effective as the preferred regional partner in Asia for GHTF. When AHWP showed success in its endeavours as a regional grouping, the possibility of seeking more formal representation on the GHTF Steering Committee could be explored with GHTF. In the meantime, AHWP was grateful for the recognition given to it as an affiliated regional grouping of the GHTF. AHWP will continue to work closely with GHTF to achieve the GHTF objectives.

GHTF Plenary Session

As Chair, AHWP, Dr Tan informed the meeting that he has been invited to present an update report of today's AHWP meeting and the last meeting held in Singapore at the GHTF Plenary Session on 21 September 2000.

Special Presentation

Mr Wong Yew Sin, Director, Product Regulation Department, Singapore Ministry of Health, gave a brief presentation on the proposed notification system to list medical devices on a register in Singapore which was targeted for introduction in 2001. A desktop PC-based notification system to support submission of information on devices and distributors was demonstrated. The system will be available in a CD-ROM format and distributed free.

Next Steps for AHWP

Dr Tan noted, with the consensus of participants at the meeting, that these follow-up steps will be taken by AHWP:

- Organise awareness education, training and seminars for medical device regulators and industry in the area of regulatory requirements (such as Essential Principles of Safety and Performance of Medical Devices; Classification Rules and risk-based management approach) and premarket review processes. One possibility is to tap the availability of GHTF SG resource persons on business trips or visits to Asia;
- Define the scope and deliverables and tasks of Technical Committee, including the conduct and frequency and venue of meetings;

REPORT OF 8TH AHWP MEETING

- Seek budgetary and strategic support for AHWP activities and programmes;
- Establish an effective communication network and presence amongst participating Asian economies through scheduled AHWP meeting, e-mails, correspondence and Internet-based access site;
- Plan for the next AHWP Meeting;
- Work towards enlarging the base of participating economies so as to maximise the benefit of the GHTF harmonization process to Asia.
- Explore participation as observers at the next GHTF Study Group meetings: SG1, 4 & 6 December 2000, Lausanne, Switzerland; SG4, 28 Feb - 2 March 2001, London, UK).

Closing Remarks

Dr Tan noted and thanked the contributions of the many persons and organisations who had helped to plan and organise the 8th Meeting of AHWP. The meeting agreed that the next AHWP meeting will be held again in conjunction with the 9th GHTF Conference in Barcelona, Spain, in October 2001 and that there should be at least one meeting of the Technical Committee before that.

Date: 6 November 2000

Vetted and approved by:

Dr Clarence Tan
Chair, AHWP

Edward Woo
Vice-Chair, AHWP

Recorded by: *Wong Yew Sin (Singapore).*

Annex

**Participants from Asian Member Economies
at 8th AHWP Regional Meeting, 20 Sep 2000, Ottawa, Canada**

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Other Attendees: GHTF member countries and others

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29	Paul Barry	Advanced Medical Technology Association (AdvaMed), USA
30	Robert D Wurzel	AdvaMed, USA
31	Daniel McLain	Becton Dickinson, USA
32	Rita Maclachlan	Therapeutic Goods Administration, Australia
33	Joe Dhillon	National Institute for Standards and Technology, USA
34	Masato Yoshida	Japanese Federation of Medical Device Associations (JFMDA)
35	Daisaku Sato	Ministry of Health and Welfare, Japan
36	Kenji Aoyama	JFMDA, Japan
37	Michael Gropp	Guidant Corp; AdvaMed, USA
38	Brian Vale	MIAA, Australia
39	Maurice F Freeman	Chair, Study Group 1 of GHTF
40	Alan Kent	Secretary, SG1 of GHTF
41	Fred Halverson	Medtronic Europe SA
42	Michael C Baker	EUCOMED, Brussels
43	Zeger Vercooteren	EUCOMED, Brussels
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DISTRIBUTION LIST

Asian Harmonization Working Party List of Representatives from Participating Member Economies

(Updated at 8th AHWP Meeting, 20 September 2000, Ottawa, Canada)

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