

**Report of the
7th Asia Harmonization Working Party Meeting
March 3, 2000, Singapore**

The 7th meeting of the Asia Harmonization Working Party (AHWP) was held in Singapore on March 3, 2000 in conjunction with the March 1-2 Seminar for Government Regulators / Harmonization of Medical Equipment Regulations, a seminar approved and partially funded under the auspices of the Asia-Pacific Economic Cooperation (APEC) initiative on medical devices.

Call To Order

The meeting of the AHWP was called to order at 9:00 am by the acting chair of the working party, Dr. Clarence Tan, Singapore Ministry of Health. Dr. Tan provided welcoming remarks and outlined the day's agenda items. The fifty four government and industry participants representing 12 countries then introduced themselves to the group (see Annex A - List of Participants, which was circulated).

Dr. Tan then identified three "end points" for the day's meeting:

- I. Affirm commitment to global harmonization and the work of the Global Harmonization Task Force.
- II. Affirm the value of regional harmonization and regional grouping within Asian region, and to gain recognition and representation to the GHTF.
- III. Determine the structure and operating procedures of the AHWP as outlined in the draft Terms of Reference.

Agenda Items

- I. Next steps for the Global Harmonization Task Force (GHTF) to be presented by the GHTF study group representatives invited to attend the meeting.
- II. Call for amendments and adoption of the Terms of Reference.
- III. Nomination of representatives to the AHWP.
- IV. Organizational issues.
- V. Presentations: "The role of medical device type testing in harmonization" and "Harmonized standards for device biocompatibility evaluations – a toxicologist's perspective".
- VI. Next steps for the AHWP.
- VII. Closing Remarks.

Next Steps for GHTF

Mr Bob Britain from GHTF briefed participants at the meeting on recent proposed changes that are of relevance to member economies and regional groupings. Apart from its founding members, GHTF would extend its memberships to (i) other participating member country and (ii) liaison membership such as standards organizations. The executive Steering Committee of GHTF would have representation from the three regions, North America, Europe and Asia Pacific, by its founding members at the first instance.

Terms of Reference

A draft Terms of Reference was first circulated to participants during the 6th AHWP meeting held in conjunction with the GHTF conference in Bethesda, Maryland, USA, in June 1999. Dr. Tan circulated a second draft with comments for participants' consideration (see Annex B). The Terms of Reference outlines the AHWP's purpose as well as its framework and procedures (including membership, leadership, support, meetings, decisions, and relationship to trade groups).

Minor modifications were discussed and agreed upon during the meeting, and a vote to adopt the revised Terms of Reference was held. The motion passed unanimously and the Terms of Reference were formally adopted by the AHWP participants. A final copy of the amended Terms was circulated by the Chairman (see Annex C). It was noted and fully agreed upon that the Terms of Reference will remain subject to modifications (updates, additions, etc.) upon the request and consent of members of the AHWP at the time of future meetings, or on occasions as agreed to by the Chairman of the working party.

Membership

The representatives to the AHWP discussed and agreed to a plan to limit "official" participation in the AHWP to economies in the Asia region. It was agreed that experts from any economy in the areas of harmonization and other pertinent disciplines would be invited to participate in the capacity of observers, resource persons or other roles on an as needed/requested basis.

Participating economies discussed and agreed to a plan to identify two "official" representatives to the working party, one each from government and industry. The economies present provided the following designated contacts, or reserved the right to identify the appropriate person and their affiliation at a later date. Annex D is the list of representatives nominated to the working party by those present at the meeting.

Those economies not present at the 7th AHWP meeting will be invited by the Chair to nominate their official representatives to the AHWP at a later date. It was discussed and agreed that each economy will be allowed to appoint an alternate to the officially designated representative in his/her absence.

Organizational Issues

The issues of AHWP chairmanship was discussed, and it was agreed upon by the participants that a formal nomination and voting process should take place at the time of the next AHWP meeting, proposed to coincide with the GHTF meeting in Ottawa, Canada, which is tentatively scheduled for September 17-22, 2000.

A motion was made by the Hong Kong industry representative to nominate Dr. Clarence Tan of Singapore to continue on as acting Chairman of the AHWP. The motion passed unanimously and was accepted by Dr. Tan.

Special Presentations

Michael Gropp, Chief Compliance Officer for Guidant Corporation, was invited to speak to the AHWP participants on the topic of type testing of medical devices. Mr. Gropp's presentation: "The role of medical device type testing in harmonization," noted the futility of conducting type testing, and instead promoted Quality Systems as a more productive means to ensure product safety. Mr. Gropp emphasized the need to focus on "good processes" by manufacturers as a more practical, cost-effective, and realistic alternative. Mr. Gropp also noted that the cost-saving benefits of many medical devices are being jeopardized by redundant testing, and that in some cases, additional testing poses potential barriers to trade.

Dr. Daniel McLain, Director of Worldwide Medical Toxicology for Becton Dickinson Corp., spoke to the participants on the issue of harmonized standards for device biocompatibility evaluations. Dr. McLain presented through a case-study approach, methods for manufactures to ensure product safety through appropriate testing to accepted standards.

Survey

Dr. Tan circulated a survey of government regulators participating in the AHWP meeting to gauge support for harmonization of medical device regulations. Based on 6 returns (see Annex E), the surveys indicated that there was general commitment to the concept of harmonization, and a willingness to participate in future harmonization activities. There was significant consideration of means to implement harmonized regulation in the future. Respondents ranked pre-market review and standards as their top areas of interest in harmonization.

Next Steps for AHWP

Dr. Tan noted, with agreement among the participants, the follow-up steps to be taken by the AHWP, including:

- Finalizing membership of AHWP (one government and one industry representative per economy). Singapore will inform other Asian economies not present at the proceedings of this arrangement, and request their nomination of participants in the AHWP.
- Inform the GHTF of the status of the working party and its adoption of a Terms of Reference.
- Establish a technical committee to examine issues or particular concern to the region, and to examine how to develop a technical interface with the GHTF study groups in the future.
- Call for nominations of the Chair and Vice-Chair of the working party at its next formal meeting. Chair will assume position for three years.
- Decide on next meeting of the working party. Possible location and dates include the next GHTF meeting, September 17-22, 2000 in Ottawa, Canada. Participants provide suggested topics for discussion directly to the Chair.
- Explore participation as observers in the next GHTF Study Group 2 meeting in Japan, June 14-16.

Closing Remarks

Dr. Tan noted the contributions of the many persons and organizations who helped plan, organize and execute the 7th meeting of the AHWP, including Lauren Saadat of the U.S. Dept. of Commerce, Jessica Lim of American Chamber of Commerce in Singapore, HIMA staff and member companies, and the various participants in the meeting.