REPORT OF THE 13th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Intercontinental The Grand, Connaught Place
New Delhi, India
5-6 November 2008

INTRODUCTION

(1) The 13th Meeting of the Asian Harmonization Working Party (AHWP) was held on 5th and 6th November 2008 at the Intercontinental The Grand, Connaught Place, New Delhi, India.

(2) A Pre-Meeting Session was held in the morning of 5th November 2008 prior to the proper Meeting. This session was arranged to discuss strategies to further strengthen AHWP. During this session, the Chair delivered a presentation entitled "Strengthening AHWP: Organizational Perspectives". The presentation touched on some general information on the organization of AHWP, what are the goals of AHWP, what have been achieved, what are currently being done and what are the future plans. His presentation appears in **ANNEX I**.

(3) The following are some suggestions given by the participants to strengthen AHWP;

(i) AHWP should have a formal constitution which will address various aspects of the organization in a more structured and formal way;

(ii) Capacity building program should be properly planned and implemented to bring Member Economies to higher level of competency;

(iii) Every effort should be done to attract participation of other Asian Economies;

(iv) Transparency;

(v) AHWP should work out ways and means to raise and manage funds to be used to carry out its activities;

(vi) AHWP should ultimately establish a single system similar to CE Marking for placement of medical devices into the Asian market.

WELCOME ADDRESS BY THE CHAIR

(4) The 13th AHWP Meeting started at about 2.00 pm on 5th October 2008. It was chaired by the AHWP Chair, Datuk Dr M S Pillay, from Malaysia, and co-chaired by Dr Davey Han from Siemens Co Ltd China. The Chair welcomed and thanked all participants for attending this Meeting. He then extended his thanks and gratitude to the Ministry of Health and Welfare of the Government of India and the Federation of Indian Chambers of Commerce and Industry (FICCI) for hosting and making local arrangement for this Meeting. He also thanked all the sponsors and congratulated the main organizing committee, the local organizing committee as well as the AHWP Secretariat who have made the effort to make this Meeting a success. In his welcome address, the AHWP Chair highlighted the following;

(i) Cooperation with international organizations – AHWP has been working very closely and participating in many of the activities organized by the Global Harmonization Task Force (GHTF). AHWP had also identified possible areas for collaboration the World Health Organization (WHO) and had written formally to WHO.

(ii) Participation of Asian Economies in AHWP – The works of AHWP had attracted participation of Economies from other region. The Chair then announced the attendance of industry representatives from South Africa and Zambia and welcomed them to be the new members of the AHWP family. He also informed that the representative of the South African regulatory authority was very keen to attend this Meeting; however it was cancelled due to unforeseen circumstances. AHWP had now grown bigger and stronger and it was envisaged that AHWP will take the lead and play an important role in global harmonization of medical devices regulation.

(iii) Capacity building – AHWP had always acknowledged the importance of training in building the capacity of Member Economies. In this respect, AHWP is currently at the final stage of finalizing the training program on regulatory affairs in collaboration with the Northeastern University, Boston, USA. It is envisaged that this will provide another avenue for those involved in this industry to be professionally trained in medical device regulatory affairs.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

(5) The Agenda of the Meeting is as in **ANNEX 2**.

AGENDA ITEM 2: ROLL-CALL

(6) A total of 223 participants, including organizers and speakers attended the Meeting. The list of participants appears as **ANNEX 3**.

AGENDA ITEM 3: CONFIRMATION OF THE REPORT OF 12th AHWP MEETING

(7) The Meeting confirmed the report of the 12th AHWP Meeting which was held in Chengdu, China on 25-26 October 2007 without any amendments.

AGENDA ITEM 4: MATTERS ARISING FROM THE 12th AHWP MEETING, SEOUL, KOREA

(8) The AHWP Secretariat briefly reported the status of the following matters arising from the 12th AHWP Meeting in Chengdu, China;

(i) Update of the AHWP Technical Committee (TC);

(ii) Comparative Study on Medical Devices Regulations in Asian Economies;

(iii) Common Submission Dossier Template (CSDT);

(iv) Post-Market Alert System (PMAS);

(v) Capacity building and training;

(vi) AHWP-WHO Collaboration.

(9) Matters arising from the 12th AHWP Meeting are summarized in **ANNEX 4**. They were presented and further discussed in Agenda Items 6, 7, 8, 9 and 10 of this Meeting.

AGENDA ITEM 5: UPDATE ON THE AHWP TECHNICAL COMMITTEE (TC) ACTIVITIES

(10) AHWP TC presented the report for 2005-2008 session in terms of its;

(i) organizational development;

(ii) achievements;

(iii) networking opportunities.

The AHWP TC report appears in **ANNEX 5**.

AGENDA ITEM 6: COMPARATIVE STUDY ON MEDICAL DEVICE REGULATION IN ASIAN ECONOMIES

(11) The Meeting was informed that this Study was done and funded by the Malaysian Government. The Study had been completed and the report had been circulated to all Asian regulators. Member Economies were advised to consider and subsequently incorporate the recommendations of the Study into their regulatory system. The Chair then recorded his thanks and appreciation to the Malaysian Government for funding the Study.

(12) With regards to the request by some Member Economies to AHWP to develop guidelines to assist them in establishing a national policy on medical devices regulation, the Meeting was informed that WHO has published several documents that can be referred to for that purpose. These documents are available on the WHO website at www.who.int/medical_devices/policies/en. Member Economies were encouraged to refer to these documents in drafting the national policy for their respective Economies.

Action: AHWP Member Economies

AGENDA ITEM 7: COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

(13) WG01 reported the following;

(i) Status of CSDT implementation in four Member Economies, namely Malaysia, Philippines, Singapore and Thailand;

(ii) Latest development in GHTF IVD related documents and progress report of WG01a IVDD Subgroup;

(iii) Update on GHTF SG1 development (Meeting in Buenos Aries and Ottawa);

(iv) Discussion on future work items.

The reports by WG01 are appended as **ANNEX 6** and **ANNEX 6a**.

(14) The Meeting then discussed and agreed to the following work items proposed by WG01;

(i) To keep close link with the development of GHTF SG1;

(ii) To compare CSDT and STED;

(iii) To prepare guidance for submitting CSDT.

(15) With regards to the work item entitled "Adopting the Principles and Elements of Conformity Assessment for Medical Devices" and implementation phases and timelines for WG01's work items which were initiated at the last Meeting in China, the Meeting requested Member Economies to;

(i) reach consensus on adopting the principles of conformity as a fundamental;

(ii) adopt the proposed elements of conformity assessment for medical device; and

(iii) have the commitment to share experience regulating medical devices.

(16) WG01 also proposed a workflow to finalize guidance documents for WG01.

(17) The Meeting then requested Member Economies to review and to give feedback to the proposal made by WG01. For that purpose, AHWP Secretariat was requested to put the proposed WG01 work items on the website.

Action: AHWP TC WG01, AHWP Secretariat, AHWP Member Economies

AGENDA ITEM 8: POST-MARKET SURVEILLANCE SYSTEM – A FRAMEWORK FOR SAFETY ALERT DISSEMINATION SYSTEM (SADS)

(18) WG02 reported the update and progress made by WG02 on the framework for Safety Alert Dissemination System (SADS) (**ANNEX 7**). SADS was implemented to enable Asian regulators to work together with manufacturers for a better public protection in the use of medical devices by sharing important safety information. SADS was targeted to provide a platform for sharing of non-confidential safety information and ultimately to merge with GHTF National Competent Authority Report (NCAR) Exchange Program for a common platform for the global sharing of medical device safety information.

(19) The following documents had been prepared by WG02 as guidelines for the implementation of SADS;

(i) AHWP/WG2/SADS/001 – Framework for AHWP Safety Alert Dissemination System (SADS)

(ii) AHWP/WG2/SADS/002 – Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form

The documents elucidate the structure for disseminating safety alerts among AHWP Member Economies; the roles and responsibilities of various affected parties in the implementation of SADS; and dissemination criteria and procedures as well as the forms to be used. WG02 will continue to work to refine SADS and it will collaborate with GHTF NCAR Exchange Program to work towards one harmonized system.

(20) WG02 then presented the following update on its activities relating to post-market surveillance and vigilance system (**ANNEX 7a**);

(i) Key achievements;

(ii) Survey on Post-Market Surveillance System in Member Economies;

(iii) Training for NCAR Exchange Program and GHTF SG2 documents in Asia;

(iv) AHWP NCAR membership update;

(v) GHTF SG2 update; and

(vi) Projects and planning.

(21) AHWP Member Economies were encouraged to participate in the implementation of SADS as there will always be safety concerns in the use of medical devices. These safety concerns can be addressed via the implementation of SADS without waiting for full enforcement of a regulatory system. The Meeting was then informed that representatives of the regulatory authorities from most Member Economies had been trained in NCAR and they are competent enough to manage medical devices safety information in SADS.

(22) For future activities, WG02 planned to undertake the following;

(i) To complete the survey on post-market surveillance systems in AHWP Member Economies;

(ii) To facilitate participation of Member Economies in SADS and NCAR program; and

(iii) To propose medical device post-market surveillance and vigilance definitions and requirements.

(23) Member Economies were requested to review and to give feedback on the future activities proposed by WG02. For that purpose, AHWP Secretariat was requested to post the WG02's proposal on the website.

Action: AHWP TC WG02, AHWP Secretariat, AHWP Member Economies

AGENDA ITEM 9: CAPACITY BUILDING

(24) WG06 reported the latest development in the proposed AHWP Professional Certificate in Regulatory Affairs training to be conducted in collaboration with the Northeastern University, Boston, USA. The report is appended as **ANNEX 8**. The Meeting was informed that the Advisory Board had approved the scope, curriculum, tuition fee and budget of the training program. The Meeting was also informed that the website for the on-line training program had been completed and except for some minor issues that need to be resolved, the training program is ready to be launched.

(25) As part of the participation and contribution in the development of the training program, Member Economies were requested to develop the curriculum and prepare the training materials on the regulatory systems in their respective Economies. Thus far, China, Hong Kong, Chinese Taipei, Thailand and Philippines have committed to participate and other Member Economies were also requested to do so.

Action: AHWP TC WG06

AGENDA ITEM 10: GHTF UPDATE AND COLLABORATION ACTIVITIES

(26) Dr Rohan Hammett of GHTF Steering Committee updated the Meeting on the

latest development in GHTF. He informed that the current GHTF Chair is Dr Roland Rotter from Health Canada who took over the Chairmanship from Dr Larry Kessler of the US FDA. On behalf of the GHTF Chair, he thanked Dr Pillay who had been very instrumental in bringing AHWP to work very closely with GHTF under his leadership and hoped that the close relationship will continue under the new leadership.

(27) Dr Rohan also informed that during its recent meeting in Ottawa, GHTF Steering Committee had finalized several guidance documents and several new documents were proposed. These documents will be made available on the GHTF website soon.

(28) The Meeting was also informed on the following;

(i) GHTF has formed an Ad-Hoc Working Group on Nomenclature which is working together with AHWP Special Task Group on Nomenclature to resolve the issue on global nomenclature system;

(ii) GHTF is making every effort to work more effectively and efficiently especially in finalizing guidance documents;

(iii) AHWP had been actively participating in GHTF's SG1 and SG2 and GHTF reemphasized its invitation to AHWP to participate in GHTF's study groups;

(iv) GHTF hoped that it will continue to work together with AHWP in the harmonization effort;

(v) AHWP members are invited to attend the upcoming GHTF Conference which will be held in May 2009 in Toronto, Canada.

(vi) APEC had approved the proposed visit from Economies with developing regulation to regulatory authorities of GHTF Founding Members. The details will be worked out later.

(29) In response to the briefing by Dr Rohan, the AHWP Chair hoped that AHWP will continue the good working relationship with GHTF. He also urged all regulators and industry representatives to take initiatives to participate in activities and training programs organized by GHTF.

Action: AHWP Member Economies

AGENDA ITEM 11: AHWP-WHO COOPERATION

(30) Mr Björn Fahlgren, WHO Technical Officer briefed the Meeting that the World Health Assembly (WHA) had made a resolution (Resolution 60.29 Health Technologies May 2007) urging Member States to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices, and where appropriate to participate in international harmonization. Member Economies were encouraged to request assistance (including financial) to the respective WHO regional offices on any projects related to the resolutions made by WHA.

(31) With regards to AHWP-WHO Cooperation, the Meeting was informed that WHO is currently in the process of preparing a draft memorandum of understanding on the collaborative projects proposed by AHWP at the last Meeting in China. In addition, Mr Björn suggested the following projects that may be taken up with WHO;

(i) Support to Member States if necessary

(ii) Nomenclature/Glossary

(iii) Counterfeit medical devices

The report by Mr Björn is appended in **ANNEX 9**.

Action: AHWP Member Economies

AGENDA ITEM 12: AHWP TRUST FUND

(32) The Meeting was informed that AHWP only has a very limited financial resource in the form of a Trust Fund. The financial resource was mainly contributed by the industry. The Chair encouraged Members, especially the industry to contribute to the Trust Fund to ensure that all the projects/activities can be carried out as planned.

Action: AHWP Member Economies, industry

AGENDA ITEM 13: ISSUES RELATED TO GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)

(33) The issue on GMDN arose following the experience of several Member Economies and their concerns on the ability of GMDN Agency to continuously maintain GMDN database. The concern was also shared by GHTF. GHTF had formed an Ad-Hoc Working Group whilst AHWP had formed a Special Task Group (STG) on Nomenclature to resolve this issue. Both groups had been working together and they had negotiated with GMDN Agency recommending the way forward to resolve this issue. However, no decisions had been made on this issue.

(34) Dr Rohan Hammett presented GHTF's views on this issue; GMDN was developed for regulatory purpose and it provides a good platform for that purpose. However, for the system to work well, it should be sustainable, affordable and transparent. The concern raised was mainly related to good governance which may affect the ability of GMDN Agency to sustain the maintenance of GMDN. GHTF was of the opinion that GHTF and AHWP should continue to negotiate with GMDN Agency to resolve this issue. GHTF also suggested both GHTF and AHWP should get the support from European Commission (EC) to apply pressure to GMDN Agency to address the concern raised by the users of GMDN.

(35) STG (Nomenclature) presented the report on the initiatives that have been taken by AHWP to resolve this issue. Among others, the report touched on the progress made by STG (Nomenclature), comparison between GMDN and Universal Medical Device Nomenclature System (UMDNS) and the way forward to resolve this issue. Besides the concern related to good governance which may lead to the ability of GMDN Agency to sustain the maintenance of GMDN, AHWP also raised the concerns on user fee and management of GMDN Agency. The STG (Nomenclature) report is appended as **ANNEX 10**.

(36) The Meeting was also informed that all Member Economies were given temporary access to both GMDN and UMDNS to assist them in making decision which system should be adopted. The Meeting decided that;

(i) Member Economies should continue to use and compare the two nomenclature systems (UMDNS and GMDN) with the view to reach consensus on which system should be adopted;

(ii) STG (Nomenclature) should continue to participate in the discussions with GHTF and WHO to resolve this issue;

(iii) STG (Nomenclature) should continue to represent AHWP in all the discussion on this issue particularly on three areas of AHWP's concern, namely user fee, management mechanism and sustainability.

(37) The Meeting then requested GHTF and WHO to make a clear decision on a single nomenclature system to be used globally.

Action: AHWP Member Economies, AHWP STG (Nomenclature), GHTF, WHO

AGENDA ITEM 14: OTHER MATTERS

(38) **Certificate of Export (COE)/Certificate of Free-Sale (CFS) –** The issue of CFS was highlighted by the industry where in many cases have caused difficulties to the manufacturers. The industry group had written a White Paper identifying the issues and recommending what the regulators should do to help the industry. The paper (as in **ANNEX 11**) will be put on the AHWP website for comments by the AHWP regulators.

Action: AHWP Member Economies, AHWP Secretariat

(39) **Date and Venue of the Next Meeting** – Hong Kong volunteered to host the next AHWP Meeting in 2009. Hong Kong was requested to work with the Secretariat to make all the necessary arrangements.

Action: AHWP Secretariat, Hong Kong

AGENDA ITEM 15: ELECTION OF NEW CHAIR, CO-CHAIR AND OFFICE BEARERS

(40) The new AHWP Chair, Co-Chair and office bearers were elected at this Meeting. The Chair congratulated the new elected Chair, Co-Chair and office bearers and hoped they will continue to work harder and lead AHWP to greater success. In response, Mr Wang Baoting, the new elected Chair, thanked Datuk Dr M S Pillay, the outgoing Chair, for his strong leadership that has brought AHWP to what it is today. Mr Wang also wished Datuk Dr Pillay well and every success in his future endeavor. The representatives from all Member Economies echoed Mr Wang in wishing Dr Pillay.

(41) The new elected AHWP Chair, Co-Chair and office bearers are as follows;

AHWP

Chair: Mr Wang Baoting, State Food and Drug Administration (SFDA), China

Co-Chair: Mr Milind Shah, Medtronic Pvt Ltd, India

Secretariat: China

AHWP Member Economies' Representatives

Member Economy	Representatives	
	Regulator	Industry
Brunei Darussalam	Dr Sablee Aspar	to be determined
Cambodia	Ms Sar Kuy Heang	to be determined

China	to be determined	Dr Davey Han
Chinese Taipei	Dr Huang Hsiau Wen	Ms Daphne Yeh
Hong Kong SAR	Dr Monica Wong	Mr Jack Wong
India	Mr Moloy Mitra	to be determined
Indonesia	Dr T Bahdar J Hamid,	Ms Fiametta Sacra
Korea	Mr Rho Yang Rae	Ms Cho Eun-Hee
Malaysia	Mr Zamane Abdul Rahman	Mr Tony Low
Philippines	Ms Maria Cecilia Matienzo	to be determined
Saudi Arabia	Dr Saleh al-Tayyar	to be determined
Singapore	Mr Alfred Kwek	to be determined
South Africa	Dr Leon L du Toit	Ms Ruwaida Shaikh
Thailand	Ms Yuwadee Patanawong	Ms Mallika Ayudhaya

AHWP Technical Committee (TC)

Chair: Mr Alfred Kwek, Health Sciences Authority (HSA), Singapore

Co-Chair (Regulator): Mr Ali M Al-Dalaan, Saudi Food and Drug Authority (SFDA), Saudi Arabia

Co-Chair (Industry): Ms Daphne Yeh, Philips Medical Systems, Chinese Taipei

Secretariat: Mr Jack Wong, BSI, Hong Kong

AHWP TC/WG01

Chair: Ms Elaine Tan, HSA, Singapore

Co-Chair: Ms Daphne Yeh, Philips Medical Systems, Chinese Taipei

AHWP TC/WG01a

Chair: Mr Esam Al Mohandis, SFDA Saudi Arabia

Co-Chair: Mr Jeffrey Chern Jiin Feng, Industrial Technology Research Institute, Chinese Taipei

AHWP TC/WG02

Chair: Mr Mark Lau, Medical Device Control Office (MDCO), Hong Kong

Co-Chair: Ms Chadaporn Tanakasemsub, Bausch & Lomb, Hong Kong

AHWP TC/WG03

Chair: Mr Ali M Al-Dalaan, SFDA Saudi Arabia

Co-Chair: Mr Ronald Goon, Singapore

Senior Advisor: Prof Tony C Chan, Virginia Polytechnic Institute

AHWP TC/WG04

Chair: Mr Moloy Mitra, Ministry of Health and Family Welfare, India

Co-Chair: Ms Cho Eun Hee, Korea industry

AHWP TC/WG05

Chair: Ms Gao Jie, SFDA China

Co-Chair: Ms Tran Quan, GE Healthcare, Singapore

AHWP TC/WG06

Chair: Ms Marianne Yap, HSA Singapore

Co-Chair: Mr Jack Wong, BSI, Hong Kong

AHWP TC/STG (Nomenclature)

Chair: Mr Yan Liang, Shanghai Food and Drug Administration

Co-Chair: Ms Lindsay Tao, Johnson & Johnson Medical, Greater China

AHWP TC/STG (Legal Entity)

Chair: Ms Jennifer Mak, MDCO, Hong Kong

Co-Chair: Mr Jack Wong, BSI, Hong Kong

CLOSING REMARKS

(42) The AHWP Chair thanked and congratulated the Ministry of Health and Welfare of the Government of India especially Mr Moloy Mitra who was very instrumental in bringing AHWP meeting to India. The Chair also thanked Ms Bishakha Bhattacharya and Ms Sumitha Rondeo from FICCI and their team who had been working very hard to make this Meeting a success. The Chair then thanked the Organizing Committee and the AHWP Secretariat for their efforts in making this Meeting a success. The Pre-Meeting Workshop which was organized in conjunction with this Meeting has attracted large attendance not only from Asian region but also from other regions as well. The Chair concluded the Meeting by thanking all participants for their contributions and wishing them a safe journey home. The Meeting adjourned at about 1.00 pm of 6 November 2008 India time.

ACKNOWLEDGEMENT

(43) The participants from China, Chinese Taipei, Hong Kong SAR, Indonesia, Korea, Lao PDR, Malaysia, Philippines, Saudi Arabia, Singapore, Thailand, South Africa, Zambia and the AHWP Secretariat as well as the observers from other economies expressed their appreciation to the Ministry of Health and Family Welfare of the Government of India and FICCI for the warm hospitality and the excellent arrangements made for this Meeting.