REPORT OF THE 12th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Pride International Convention Centre,
Century City, Chengdu West,
Chengdu, People's Republic of China
26 – 27 October 2007

INTRODUCTION

(1) The 12th Meeting of the Asian Harmonization Working Party (AHWP) was held on 26th and 27th October 2007 at the Pride International Convention Centre Century City, Chengdu West, People's Republic (PR) of China. The Meeting was chaired by the AHWP Chair, Datuk Dr M S Pillay, Deputy Director-General (Research and Technical Support), Ministry of Health Malaysia, and co-chaired by Dr Davey Han from Siemens Co Ltd China.

WELCOME ADDRESS BY THE CHAIR

(2) The Chair welcomed and thanked all participants for attending this Meeting. He then extended his thanks and gratitude to the State Food and Drug Administration (SFDA) of PR China for hosting this Meeting and Reed Sinopharm Exhibitions the main sponsor of this Meeting. He also congratulated the Organizing Committee, the China Association of Medical Devices Industry (CAMDI) as 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 with international organizations, especially with the Global Harmonization Task Force (GHTF) and the World Health Organization (WHO). AHWP has been formally accepted as a Liaison Body of GHTF and has been participating in many of the GHTF activities. As for WHO, AHWP would identify possible areas for collaboration. He hoped that the close cooperation with the two organizations will be further enhanced in the future. He thanked Dr Larry Kessler, the Chair of GHTF and Mr Björn Fahlgren, WHO Technical Officer who have made the efforts to attend and participate in this Meeting. He also thanked GHTF for providing trainers for the Pre-Meeting workshop which was held on 23–25 October 2007 in conjunction with this Meeting.

(ii) Participation of Asian Economies in AHWP –The success of AHWP as a regional grouping depends on active participation from Member Economies. With the active participation of PR China and India, AHWP has now grown bigger and stronger and it is envisaged that AHWP will take the lead and play

the important roles in global harmonization of medical devices regulation. The Chair then introduced and welcomed Mr Moloy Mitra, from Ministry of Health India who participated for the first time as the representative from the Ministry of Health of India. He then hoped that Saudi Arabia who participated in AHWP last year will bring other Economies in Middle East to join AHWP.

(iii) Capacity building – AHWP acknowledged the importance of training in building the capacity of Member Economies and all AHWP Meetings were designed as the avenues for learning, sharing knowledge and information as well as networking amongst those involved in medical devices industry. The Pre-Meeting Workshop which was held in conjunction with this Meeting was well attended with over 300 participants from various Economies not just within Asia from other regions as well. The Chair thanked all the speakers and trainers for their contributions in the Pre-Meeting Workshop.

(iv) The 58th Chinese Medical Device Exhibition Fair (CMEF) – The 58th CMEF which showcased the innovations of medical device manufacturers was also a venue to get an exposure on this industry. The participants were encouraged to take the opportunity to visit the exhibition.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

(3) The Agenda of the Meeting is as in **ANNEX 1**.

AGENDA ITEM 2: ROLL-CALL

(4) 305 participants, ie 253 from 14 AHWP Member Economies and 52 observers from 10 different Economies attended the Meeting. The list of participants and observers appears as **ANNEX 2**.

AGENDA ITEM 3: CONFIRMATION OF THE REPORT OF 11th AHWP MEETING

(5) The Meeting confirmed the report of the 11th AHWP Meeting which was held in Seoul, Korea on 13–15 September 2006 without any amendments.

AGENDA ITEM 4: MATTERS ARISING FROM THE 11th AHWP MEETING, SEOUL, KOREA

(6) The AHWP Secretariat briefly reported the status of the following matters arising from the 11th AHWP Meeting in Seoul, Korea;

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

(ii) Common Submission Dossier Template (CSDT);

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

(iv) Capacity building and training;

(v) AHWP-WHO Collaboration.

(7) Matters arising from the 11th AHWP Meeting are summarized in **ANNEX 3**. 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

(8) Mr Albert Poon, the Chair of AHWP Technical Committee (TC) reported the update on the AHWP TC activities, achievements and future plans for AHWP TC. His report is presented in **ANNEX 4**. The following are some of the highlights of his report;

(i) AHWP TC structure – AHWP TC proposed six workgroups in addition to the current office bearers, nominated representatives of Member Economies and resource persons. The proposed new structure of AHWP TC is as follows;

Office bearers

- Chair: Mr Albert Poon (Hong Kong)
- Co-Chairs: Mr Alfred Kwek (Singapore), Ms Daphne Yeh (Chinese Taipei)
- Acting Secretaries: Ms Jacqueline Monteiro (Singapore), Mr Jack Wong (Hong Kong)

Nominated representatives of Member Economies

- Resource persons: Ongoing, by invitation

Workgroups (WG)

WG01: Pre-market Submission and CSDT

- Chair: Mr Alfred Kwek (Singapore)
- Co-Chair: Ms Daphne Yeh (Chinese Taipei)
- IVDD Co-Chair: Ms Tran Quan (Singapore)

WG02: Post Market Surveillance and SADS

- Chair: Mr Mark Lau (Hong Kong)
- Co-Chair: Ms Chadaporn Tanakasemsub (Hong Kong)

WG03: Quality Management System - To be determined

WG04: Quality System Audits - To be determined

WG05: Clinical Evidence Requirements - To be determined

WG06: Capacity Building and Regulatory Training

- Chair: Mr Albert Poon (Hong Kong)
- Co-Chair: Mr Jack Wong (Hong Kong)

(ii) Nominated representatives and resource persons – Nomination of representatives from Member Economies and recruitment of resource persons are ongoing and AHWP TC anticipated to complete the update of its membership by the end of the year. Member Economies were requested to update the nomination of their representatives in AHWP TC. AHWP also appealed for volunteers to join AHWP TC and its WGs.

(iii) Activities of WGs – The following are the projects/activities currently undertaken by the various WGs;

- WG01: Review of Draft Guidance Common Submission Dossier Template (CSDT) for possible alignment with GHTF's STED
- WG02: Development of Safety Alert Dissemination System (SADS) and working mechanism for bridging SADS and GHTF's NCAR
- WG06: Development of Regulatory Training Program

(iv) Projects and future plans – AHWP TC identified new projects/activities in addition to the projects/activities currently undertaken by them. Amongst the identified projects/activities include in-vitro diagnostic device (IVDD), quality system requirements, clinical evidence requirements and framework for web-based regulatory training course.

(9) The Meeting agreed to the proposed new structure as well as the projects/activities to be undertaken by AHWP TC.

Action: AHWP TC, Member Economies

AGENDA ITEM 6: COMPARATIVE STUDY ON MEDICAL DEVCIES REGULATIONS IN ASIAN ECONOMIES

(10) Malaysia presented the findings and recommendations of the Study (**ANNEX 5**). From the Study, it was found that there were varying levels of capacity amongst Asian Economies in terms of knowledge and experience, policy clarity and maturity, financial and human resources as well as capability. Six recommendations were made for AHWP to move forward in its harmonization effort;

(i) Recommendation 1: There should be a clear and stated national policy on medical device regulation to provide the basis and framework for laws and guidelines.

(ii) Recommendation 2: The GHTF definition and risk-based classification of medical device should be adopted, and where adaptation is needed because of domestic concerns, these should be undertaken in a manner that is as consistent as possible with the GHTF definition and classification

(iii) Recommendation 3: ASEAN Member Economies are exploring the possibility of a region-wide nomenclature for medical devices and the AHWP could do the same

(iv) Recommendation 4: A comprehensive database and common reporting format to monitor and document adverse incidents and/or recalls at the Asian level would increase the quality of management at the national level and contribute to joint efforts that support harmonization. The ASEAN Post-market Alert System is an important feature of this database

(v) Recommendation 5: Bearing in mind the difficulties faced by GHTF founding members themselves to adopt the GHTF recommendations and guidelines, Asian Economies should assist each other in understanding, adapting and adopting GHTF recommendations. A common approach to any adaptation would contribute to AHWP harmonization

(vi) Recommendation 6: Capacity building – technical and financial assistance should be provided to Asian Economies, where necessary, to implement international standards and the experience of some Economies can be a valuable resource. Interactions with manufacturers, importers, distributors and users are also necessary, thus capacity building especially for domestic industry players should be considered.

(11) Member Countries were urged to seriously consider and subsequently incorporate these recommendations into their regulatory system. To assist Member Economies in establishing a sound national policy on medical devices regulation, AHWP was requested to come up with recommendations/guidelines on what should be incorporated in the policy.

(12) With regards to the AHWP decision to adopt the Global Medical Device Nomenclature (GMDN) system, some Member Economies raised the concern on the ability of GMDN Agency to continuously maintain GMDN database. The concern was also shared by GHTF. The Meeting decided that AHWP should work closely with GHTF to communicate and address the concern with GMDN Agency.

Action: AHWP Secretariat, Member Economies

AGENDA ITEM 7: COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

(13) Mr Alfred Kwek, the Chair of WG01 presented the work of the WG01 (**ANNEX 6**) which include the following;

(i) Review of the Common Submission Dossier Template (CSDT) for possible alignment with GHTF's STED;

(ii) Adopting the Principles and Elements of Conformity Assessment for Medical Devices; and

(iii) The proposed work item for WG01

(14) From the review of CSDT, it was found that there were no major differences between the two documents. He then outlined the following plausible strategies for the direction of CSDT and its eventual adoption;

(i) Revise the current CSDT and adapt for use in committed AHWP Member Economies;

(ii) Await publication of the revised STED document (in its draft form) before adopting a decision on the direction of CSDT; and

(iii) Take a collective decision to adopt STED.

(15) The Meeting decided that while the CSDT is being finalized, Asian Economies may proceed to adopt the CSDT in their regulatory system.

(16) Mr Alfred Kwek also presented the proposed work item "Adopting the Principles and Elements of Conformity Assessment for Medical Devices" for WG01. He highlighted the elements that may be included in a conformity assessment system and the benefits of having such a system. He then requested AHWP;

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

(ii) to adopt the proposed elements of conformity assessment for medical devices;

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

(iv) to approve the proposed work item for WG 01.

(17) The Meeting decided that the WG01's proposals to be put on the website for comments. Member Economies were requested to provide the comments in one-month time.

Action: AHWP TC WG01, Member Economies, AHWP Secretariat

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

(18) Mr Mark Lau, Chair of AHWP TC WG02 reported the update and progress made by WG02 on the framework for Safety Alert Dissemination System (SADS) (**ANNEX 7**). WG02 has drafted two documents, namely;

(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

(19) WG02 Three options were proposed for implementation;

(i) SADS + NCAR;

(ii) SADS only;

(iii) NCAR only.

(20) The Meeting decided that;

(i) AHWP Member Economies should proceed to implement SADS as there is an urgent need to share safety information within Asian Economies. Meanwhile all Member Economies were encouraged to join NCAR as Associate Participants and subsequently become Full Members. Eventually, only one system should be adopted globally;

(ii) WG02 should revise and finalize SADS and subsequently proceed for pilot implementation in January 2008.

(iii) Member Economies should take the necessary steps to join SADS, especially in dealing with confidential information

Action: AHWP TC WG02, all Member Economies

AGENDA ITEM 9: CAPACITY BUILDING

(21) Mr Jack Wong, Co-Chair of AHWP TC WG06 presented the proposal for capacity building through training and aimed to launch the training in the third quarter of 2008. The Chair reiterated the importance of this training program to build the capacity of those involve in this industry and to prepare them to build careers in medical device regulation.

(22) The Meeting agreed on the following;

(i) The proposed training will be in the form of a structured diploma program which will be conducted in collaboration with Northeastern University, Boston, USA;

(ii) A fee will be charged to enrol into this training;

(iii) An Advisory Board should be formed to oversee the execution of the training program such as training structure and design, timetable , fee structure and other related matters;

(23) The Meeting then requested the AHWP TC WG06 to formalize the Advisory Board and to draft the curriculum.

Action: AHWP TC WG06

AGENDA ITEM 10: AHWP-WHO COPPERATION

(24) Mr Björn Fahlgren, WHO Technical Officer reiterated that WHO always support health program by its Member Countries. He stressed the importance of training on regulatory system to build the capacity of Member Countries. He also emphasized the importance of sharing of regulatory information to ensure public health and safety related to the use of medical devices and this can be achieved by participating in NCAR program.

(25) The AHWP Secretariat then presented the suggested projects to be undertaken in collaboration with WHO (**ANNEX 8**);

(i) Training on regulatory issues – WHO sponsorship to carry out training program focusing on the following;

- Post-market surveillance;
- Quality Management System;
- Evaluation of implantable and other high risk medical devices.

(ii) Improving access to information about regulatory action

- Dissemination of information impacting public health through the existing WHO sentinel network;
- Access to information about regulatory action through establishment of good database linkage among WHO Member Countries.

(iii) Self assessment of regulatory bodies

- Development of a guidance document on the basic requirements to conduct self assessment needs;
- Provision of experts/consultants to gauge and to make recommendations on the development of the regulatory system.

(iv) Improving knowledge about regulatory system – To build a dense network of regulatory knowledge amongst regulators and industry with collaboration of GHTF and its liaison members.

(26) The Meeting decided that AHWP should communicate formally to WHO on the proposed areas of collaboration.

Action: AHWP Secretariat

AGENDA ITEM 11: FUNDING

(27) The Meeting was informed a number of companies as well as individuals have contributed to the AHWP Trust Fund. The Chair then encouraged Members, especially the industry to contribute generously the Trust Fund to enable AHWP to fund its planned projects/activities.

Action: All Member Economies

AGENDA ITEM 12: ELECTION OF A NEW CHAIR

(28) The term of office of the present AHWP office bearers will end in May 2008 and the next election will be done at the next Meeting.

For information

AGENDA ITEM 13: OTHER MATTERS

(29) **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 Meeting requested the industry group to write a paper identifying the issues and recommending what the regulators should do to help the industry. The paper is to be submitted to AHWP and GHTF Chairs by the end of the year.

Action: Industry group

(30) **Date and Venue of the Next Meeting** – The next AHWP Meeting was suggested to be held tentatively in August or September 2008 in India. The Meeting requested;

(i) AHWP Secretariat to officially write to India;

(ii) Mr Moloy Mitra to confirm the possibility of hosting the next Meeting in India.

Action: AHWP Secretariat, India

CLOSING REMARKS

(31) The AHWP Chair thanked and congratulated SFDA of PR China and CAMDI for supporting and hosting this Meeting. He also thanked Reed Sinopharm for sponsoring this Meeting. The Chair then thanked the Organizing Committee and the AHWP Secretariat for their efforts in making this Meeting a success.

(32) The Pre-Meeting Workshop which was organized in conjunction with this Meeting has benefited participants from AHWP Member Economies and this Meeting has attracted large attendance not only from Asian region but also from other regions as well. The Chair hoped that the harmonization efforts undertaken by AHWP will contribute to the well-being of the Asian community.

(33) 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 China time.

ACKNOWLEDGEMENT

(34) The participants from PR China, Chinese Taipei, Hong Kong SAR, India, Indonesia, Korea, Lao PDR, Malaysia, Philippines, Saudi Arabia, Singapore, Thailand and Vietnam as well as the observers expressed their appreciation to SFDA of PR China, CAMDI and Reed Sinopharm for the warm hospitality and the excellent arrangements made for this Meeting.