REPORT OF THE 11th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Seoul, Korea
15 September 2006

INTRODUCTION

(1) The 11th Meeting of the Asian Harmonization Working Party (AHWP) was held on 15 September 2006 at the Olympic Parktel, Seoul, Korea. 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 the 11th AHWP Meeting. He then informed that this Meeting has the biggest attendance so far and hoped the number of participants will increase in the future. The Pre-Meeting Workshop which was held on 13–14 September 2006 in conjunction with this Meeting was also a success and has benefited the participants. A total of 16 pertinent topics relating to medical devices and medical devices regulation have been delivered.

(3) The Chair then welcomed the representatives from the Saudi Food and Drug Authority (SFDA), the latest member in AHWP. He hoped that the participation of Saudi Arabia will encourage other Economies in Middle East to also join AHWP.

(4) The following developments was highlighted by the Chair in his welcoming address;

(i) *Active participation of all Asian Economies in AHWP* – Active participation of all Asian Economies in AHWP is crucial in working towards harmonization of medical devices regulations in the Asian region. All Asian Economies were urged to give their full support and continue their active participation in AHWP.

(ii) *AHWP Special Meeting in Lübeck, Germany* – The recent AHWP Special Meeting which was held in conjunction with the GHTF Conference in Lübeck, Germany was attended by 37 participants from 8 AHWP Member Economies and 13 observers. The Meeting mainly discussed the organization of the 11th AHWP Meeting in Korea.

(iii) *New AHWP website* – A new AHWP website was launched at the Special Meeting. The website provides a platform for effective communications network amongst Member Economies and all members were encouraged to maximize the use of this website.

(iv) *AHWP Participation in GHTF Steering Committee (SC) and Study Groups (SGs)* – AHWP representatives attended the SG1, SG2, SG3 and SG4 Meetings in conjunction with the 10th GHTF Conference in Lübeck, Germany. AHWP Chair presented the progress and latest development of AHWP at the Open Session of GHTF SC Meeting and the Conference. The terms of reference for future participation of Member Economies in GHTF SG & SC Meetings has been posted on the AHWP website.

(v) *Application to be GHTF Liaison Member* – The AHWP participation in GHTF is important to provide avenues for AHWP to present its views in matters relating to global harmonization effort. AHWP has officially applied to be a Liaison Member of GHTF. The application is currently being reviewed by GHTF.

(5) The Chair then thanked the host of the 11th AHWP Meeting, ie the Korean Food and Drug Administration (KFDA), the sponsors, namely the Korea Medical Devices Industry Association (KMDIA), Korea Health Industry Development Institute (KHIDI) and American Chamber of Commerce (AMCHAM) of Korea, members of the Organizing Committee and the AHWP Secretariat for making all the arrangements for this Meeting.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

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

AGENDA ITEM 2: ROLL-CALL

(7) 197 participants from 14 Member Economies as well as 24 observers attended the Meeting. 16 speakers during the Pre-Meeting Workshop also joined the Meeting as observers. The list of participants and observers appears as **ANNEX 2**.

AGENDA ITEM 3: CONFIRMATION OF THE REPORT OF 10TH AHWP MEETING

(8) The Meeting confirmed the report of the 10th AHWP Meeting which was held in Genting Highlands, Malaysia on 24–25 November 2006 without any amendments.

AGENDA ITEM 4: MATTERS ARISING FROM THE 10TH AHWP MEETING, GENTING HIGHLANDS, MALAYSIA

(9) The Chair went through briefly the following matters arising from the 10th AHWP Meeting in Genting Highlands, Malaysia in November 2005;

(i) *Active participation in AHWP* – Invitations have been extended to India, Sri Lanka, Pakistan and PR China to actively participate in AHWP and attend the 11th AHWP Meeting in Seoul, Korea. Visits to Saudi Food and Drug Authority (Saudi FDA) and State Food and Drug Administration (SFDA) of People's Republic of (PR) China were made to get the support and active participation of Asian Economies in AHWP. As a result of the two visits, Saudi Arabia has become the latest member of AHWP and PR China has committed its full support to AHWP. A similar visit to India is being planned. It was envisaged that the participation of Saudi Arabia will open the door for other Economies in Middle East to also join AHWP. South Africa which has shown interest in joining AHWP has been accepted as an Associate Member.

(ii) *Update on the AHWP Technical Committee (TC) activities* – Mr Albert Poon, the Chair of AHWP TC presented the report on the update of the AHWP TC activities. He reported the progress, proposed TC structure, implementation and milestones which include STED survey, CSDT, training proposal and future projects and plans. The report appears in **ANNEX 3**.

(iii) *Review of the AHWP policy directions* – The AHWP policy directions including objectives, aims and TOR which have been reviewed at the 10th AHWP have been posted on the AHWP website.

Action: For information

AGENDA ITEM 5: AHWP WORK PROGRAM 2005 – 2007

Comparative Study on Medical Devices Regulations in Asian Economies

(10) Malaysia reported the current status of the study. More information is required from some Member Economies to complete the study. The Secretariat was requested to write to Member Economies to obtain the required information. Member Economies were urged to provide the information within one month. Upon receiving the information, Malaysia will prepare draft report of the study. The draft report will then be circulated to Member Economies for comments before it is finalized.

Action: Malaysia, all Member Economies

Post-Market Alert System

(11) Singapore presented the proposal for post-market alert system framework which appears as **ANNEX 4**. The Meeting agreed that post-market system is

important to monitor medical devices on the market and should be put in place even in the absence of pre-market activities.

(12) The Meeting decided AHWP TC to finalize the proposal for adoption at the next AHWP Meeting. In finalizing the proposed post-market alert system framework, AHWP TC was suggested to consider the following;

(i) Make reference to GHTF recommendations and work closely with GHTF SG2 to try to eliminate the issue of having different sets of system;

(ii) The capacity and capability of Member Economies, especially those without regulation;

(iii) Mechanism for sharing information on adverse events.

(13) The Meeting also suggested AHWP TC to acquire the assistance of the appropriate experts in finalizing the proposed framework.

Action: Singapore, AHWP TC

Capacity Building through Training

(14) Mr Jack Wong, representative from the Hong Kong industry presented the proposal for capacity building through training (**ANNEX 5**). The proposed training will be in the form of a structured diploma program which will be conducted in collaboration with Hong Kong University. The Meeting requested Hong Kong industry to refine and include more details in the proposal including accreditation of the training program and incorporation of hands-on training.

(15) The Meeting agreed that the refined proposal should be sent to the AHWP Secretariat by 15 October 2006 after which it will be posted on the website for comments by AHWP Members. The AHWP Secretariat was requested to compile and forward all the comments to Hong Kong industry and AHWP TC for inclusion into the proposal by 15 November 2006.

Action: Hong Kong industry group, all Member Economies

Common Submission Dossier Template (CSDT)

(16) Mr Alfred Kwek, the Co-Chair of AHWP TC presented the progress in the development of CSDT. The CSDT is intended to be a descriptive document providing guidance for submission of device information to the regulators and to be a common submission template acceptable by all Asian regulators. His presentation appears in **ANNEX 6**.

(17) It was suggested that in preparing the CSDT, the AHWP TC should look into the work of GHTF SG1 on STED since there are many similarities in the elements of both CSDT and STED. The AHWP TC was also requested to look into the inclusion of *in-vitro* diagnostic device in the scope of CSDT.

(18) The Meeting then agreed that the draft CSDT should be put on the website for 4 months consultation before it is finalized.

Action: AHWP TC, all Member Economies

Funding

(19) The Meeting was informed that a number of companies have pledged to contribute to the AHWP Trust Fund. The Meeting then agreed that the Trust Fund Manager should come up with a document on the management of the Trust Fund.

Action: AHWP Trust Fund Manager

AGENDA ITEM 6: AHWP-WHO COPPERATION

(20) Mr Björn Fahlgren, WHO Technical Officer presented the possible areas for AHWP-WHO collaboration which include;

(i) Training on regulatory issues;

(ii) Improving access to information about regulatory action;

(iii) Mission to countries;

(iv) Self assessment of regulatory bodies;

(v) Improving knowledge about regulatory systems

(21) Member Economies were requested to provide specific feedback on the proposed areas for collaboration with WHO.

(22) Mr Björn then requested the information on medical devices regulatory systems within the Asian region. The Meeting agreed to extend a copy of the comparative study of medical devices regulations in AHWP Member Economies to WHO after the study is completed.

AHWP Secretariat, all Member Economies

AGENDA ITEM 7: OTHER MATTERS

Certificate of Export (COE)/Certificate of Free-Sale (CFS)

(23) The issue on COE/CFS was raised at the AHWP Special Meeting in Lübeck, Germany. The requirement of COE/CFS for manufacturers to put their products on some of Asian Economies has caused difficulties to the manufacturers. The Meeting decided that a working paper on this issue should be prepared by the AHWP Secretariat with the assistance of the affected industry. The following items should be included in the paper;

(i) Background of the issue;

(ii) Which Asian Economies require COE/CFS;

(iii) The nature of problems;

(iv) Comments and recommendations.

(24) The paper will be tabled and discussed further at the next AHWP Meeting.

Action: AHWP Secretariat, Industry

Acceptance of CE-Marked Medical Devices

(25) The issue of acceptance of CE-marked medical devices by Asian Economies was also brought up at the AHWP Special Meeting in Lübeck. The industry was of the opinion that a CE-marked product or any product that has been approved/ cleared to enter the market in certain Economy has undergone the scrutiny in terms its safety and performance. Such a product should not be subjected to another assessment to enter a different market as it is a waste of time and resources and may cause unnecessary delay for the product to enter the market.

(26) However, many of the delegates especially from the regulatory authorities were of the opinion that they still need to carry out their own assessment. The following are some of the rationales why they still need to conduct their own assessment;

(i) The issues of competencies of the European Notified Bodies and medical devices assessed by such Notified Bodies which are exported to markets outside Europe;

(ii) By conducting its own assessment, the authority of the importing Economy will be more comfortable and confidence on the safety and performance of the product;

(iii) A regulatory system is an issue relating to the sovereignty of a country. It is designed to protect the interest of the people taking into account the problems in that country. The regulatory system is of no use if a country is to accept a CE-marked product or other product that has obtained market approval/clearance in other countries;

(iv) It is up to the authority of that country to carry out its own assessment. In carrying out its own assessment, abridged process may be considered as one of the route for market clearance.

(27) The Meeting agreed that this subject is a complicated issue and it goes beyond safety and performance and timely market access. It should be further explored in a different forum.

AGENDA ITEM 10: DATE AND VENUE OF THE NEXT MEETING

(28) The next AHWP Meeting will be held tentatively in August or September 2007. PR China was requested to host the next Meeting. Among others, the next Meeting will further discuss the following items;

(i) CSDT;

(ii) Post-market alert system;

(iii) Harmonization of definition, classification and nomenclature;

(iv) Progress in AHWP work program.

CLOSING REMARKS

(29) On behalf of AHWP, the Chair thanked and congratulated KFDA for successfully organizing the 11th AHWP Meeting. He also thanked KMDIA, KHIDI and AMCHAM of Korea for sponsoring this Meeting. The Chair then thanked the Organizing Committee and the AHWP Secretariat for their efforts in making this Meeting a success.

(30) The Pre-Meeting Workshop which was organized in conjunction with this Meeting has benefited participants from AHWP Member Economies and this Meeting has attracted the largest attendance so far. The Chair hoped that the harmonization efforts undertaken by AHWP will contribute to the well-being of the Asian community.

(31) 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 Korean time.

ACKNOWLEDGEMENT

(32) The participants from PR China, Chinese Taipei, Hong Kong, India, Indonesia, Korea, Lao PDR, Malaysia, Philippines, Saudi Arabia, Singapore, Thailand and Vietnam as well as the observers expressed their appreciation to KFDA and the sponsors, KMDIA, KHIDI and AMCHAM of Korea for the warm hospitality and the excellent arrangements made for this Meeting.