REPORT OF THE SPECIAL MEETING OF THE ASIAN HARMONIZATION WORKING PARTY

28 June 2006, Lübeck, Germany

(held in conjunction with the 10th GHTF Conference, 26 – 30 June 2006)

INTRODUCTION

1) The Special Meeting of the Asian Harmonization Working Party (AHWP) was held on 28 June 2005 at the Musik und Kongresshalle (MUK), Lübeck, Germany, from 1300 – 1600 hrs (Lubeck time). The Meeting was held in conjunction with the 10th Global Harmonization Task Force (GHTF) Conference and was chaired by the AHWP Chair, Datuk Dr M S Pillay, Deputy Director-General (Research and Technical Support), Ministry of Health Malaysia.

2) This Special Meeting mainly discussed the updates on;

i) the work program that has been agreed at the 10th AHWP Meeting in Malaysia in November 2005; and

ii) the preparation for the 11th AHWP Meeting in Seoul, Korea.

WELCOME ADDRESS

3) The Chair welcomed and thanked all representatives from Member Economies as well as the observers from GHTF Founding Members for attending this Meeting. He was very pleased to note the good support as demonstrated by the large turnout in this Meeting. He then thanked Mr Jeffrey Gren (US Department of Commerce) and the organizer of the GHTF Conference for making the arrangement for this Meeting.

4) The Chair then stressed the importance of the participation and commitment of Member Economies in the harmonization effort. He believed with the active participation and strong commitment of Member Economies, AHWP can harmonize faster. He then reiterated that in the harmonization effort, AHWP should not "re-invent the wheel" and should adopt and adapt the works of GHTF.

AGENDA ITEM 1: ADOPTION OF AGENDA

5) The Meeting adopted the Agenda which appears as **ANNEX 1**.

AGENDA ITEM 2: ROLL CALL

6) The Meeting ensued with the introduction of the representatives from People's Republic of China (PR China), Chinese Taipei, Hong Kong, Indonesia, Korea, Malaysia, Singapore, Saudi Arabia and Thailand. In addition to representatives from AHWP Economies, representatives from GHTF Steering Committee (SC) and Study

Groups (SGs) as well as industry representatives from GHTF Member Economies also attended this Meeting as observers. The list of attendees is shown in **ANNEX 2**.

7) The Chair then introduced and welcomed Dr Saleh Al-Tayyar from Saudi Arabia, the latest member of AHWP. In his returning note, Dr Saleh expressed his gratitude to AHWP for extending the membership to the Middle East, especially to Saudi Arabia. He envisaged that this would open the door to other Economies in the Middle East to also join AHWP.

AGENDA ITEM 3: UPDATE ON THE AHWP WORK PROGRAM

8) Prior to discussing the update on the AHWP work program, the Chair highlighted some initiatives that have been undertaken by AHWP recently;

i) *Development of a new AHWP website* – A new website has been developed and will be launched very soon. It is envisaged that the website will be fully used as a platform for effective communications as well as exchange of ideas and views;

ii) *Visit to Saudi Food and Drug Authority (Saudi FDA)* – During his recent visit to Saudi FDA, the Chair discussed the participation of Saudi Arabia in AHWP. As a result of the visit, Saudi Arabia has now become the latest member of AHWP. It is envisaged that the participation of Saudi Arabia will open the door for wider participation of other Economies in Middle East in AHWP;

iii) *Visit to State Food and Drug Administration (SFDA) PR China* – A delegation from AHWP visited SFDA PR China recently following the decision of the 10th AHWP Meeting last year. The main aim of the visit was to discuss active participation of PR of China in AHWP. PR China has shown the positive response and pledged its full support to AHWP;

iv) *Attendance in GHTF SG and SC Meetings* – Representatives from AHWP participated in SG1, SG2, SG3 and SG4 Meetings as observers. Three documents have been approved at the GHTF SC Meeting. The approved documents are Principles of Medical Devices Classification (SG1-N15), Role of Standards in the Assessment of Medical Devices (SG1-N009) and Conformity Assessment. These documents which have undergone the scrutiny by the GHTF experts will be discussed at the next AHWP Meeting in Seoul, Korea. The Chair has also attended and presented the updates on the AHWP work program at the GHTF SC Meeting.

9) The Meeting was informed that at its 10th Meeting, AHWP has outlined a work program incorporating various strategies in its effort towards harmonization. The following are the strategies that have been identified in the work program;

i) Comparative study on medical devices regulations in AHWP Member Economies;

ii) Harmonization of definition, classification and nomenclature of medical devices;

iii) Formalization of a post marketing alert system;

iv) Capacity building through training;

v) Work towards a common submission dossier template (CSDT); and

vi) Funding.

10) The summary of the update on the AHWP Work Program is as in **ANNEX 3.**

AGENDA ITEM 4: UPDATE ON THE PREPARATION FOR THE 11TH AHWP MEETING, SEOUL, KOREA

11) Mr Kyung-Mun Lee, the representative from local host, Korea, presented the update on the preparation for the 11th AHWP Meeting. The Meeting will be held on 15 September 2006 at the Seoul Olympic Parktel (Songpa-Gu, Seoul). A two-day Pre-Meeting Workshop will be held on 13 and 14 September 2006. In addition, an exhibition of the Korean domestic medical devices will also be held in conjunction with the Meeting. His presentation appears as **ANNEX 4**.

12) The Pre-Meeting Workshop is aimed at enhancing the knowledge on various topics in medical devices regulation. The topics that will be covered at the Pre-Meeting Workshop include;

i) Conformity assessments procedure;

ii) Adoption of the Summary Technical Documentation (STED);

iii) Evidence gathering in clinical trials;

iv) Practical issues in combination products;

v) Global Medical Device Nomenclature (GMDN);

vi) Risk management;

vii) Quality Management System (QMS); and

viii) Post-market vigilance system

13) The tentative program of the Meeting is as appears in **ANNEX 5** and the synopsis of the topics to be covered at the Pre-Meeting Workshop is as appears in **ANNEX 6**.

14) The Chair commended the preparation made by the local host. He then requested the local host and the Secretariat to work together to make all the necessary preparation to make the 11th AHWP Meeting a success. The final announcement and registration details should be made available on the AHWP website http://www.asiahwp.org .

AGENDA ITEM 5: UPDATE ON THE AHWP TECHNICAL COMMITTEE (TC) ACTIVITIES – THE DEVELOPMENT OF PRE-MARKET COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

15) Mr Alfred Kwek (Health Science Authority of Singapore) the Co-Chair of AHWP TC reported the update on the development of CSDT. His presentation is as appears in **ANNEX 7**.

16) 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. It is envisaged that CSDT will harmonize differences in documentation formats that presently exist within the Asian Economies.

The adoption of CSDT in Asia will eliminate the preparation of multiple dossiers for regulatory submission to different regulatory authorities in Asia.

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.

18) Mr Alfred then informed that the AHWP TC intends to have more memberships and resource persons and the TC welcomes nominations from Member Economies. The Chair requested the TC to take the necessary steps in this matter.

AGENDA ITEM 6: OTHER MATTERS

19) The Chair invited comments and feedback from the floor. Amongst the comments and feedback received include;

i) The AHWP was requested to look into the issue of certificate for export which has become a requirement for manufacturers who intend to put their products into several Asian Economies.

ii) CE-marked medical devices – whether products that have been CE-marked will be accepted by the Asian Economies.

iii) The process of adopting GHTF documents should be done carefully. Documents should be reviewed thoroughly before they are adopted.

iv) Some Asian Economies require type testing to be done on every device to be put on their markets.

20) In response to the comments and feedback, the Chair reiterated that the AHWP should eventually subscribe to the principle of "not to re-invent the wheel". Repeating what others have done is a waste of resources and should be avoided. The Chair added that the ultimate aim of harmonization is the implementation of a single system everywhere in the world. This system should be based on international standards and all medical devices that have obtained market clearance/approval in one Economy should be acceptable anywhere else in the world.

CLOSING

21) In his closing remarks, the Chair thanked every one for attending and participating in this Meeting. The Chair informed that issues raised at this Meeting will be further discussed at the next Meeting in Korea. The Chair then invited every one to attend and participate in the 11th AHWP Meeting in Seoul, Korea.

ACKNOWLEDGEMENT

22) The AHWP expressed its appreciation to the GHTF and the organizer of the GHTF Conference for the excellent arrangements made for this Meeting.