

**REPORT OF THE 14TH MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)**

Hong Kong Convention and Exhibition Centre
Hong Kong SAR, People's Republic of China
6 – 7 November 2009

INTRODUCTION

(1) The 14th Meeting of the Asian Harmonization Working Party (AHWP) was held on 6 and 7 November 2009 at Hong Kong Convention and Exhibition Centre, Hong Kong SAR, People's Republic of China. The Meeting was chaired by the AHWP Chair, Mr Baoting WANG, Director-General of Medical Devices Supervision, State Food and Drug Administration, People's Republic of China and co-chaired by Mr Milind SHAH, Managing Director, India Medtronic Pvt Ltd.

WELCOME ADDRESS BY THE CHAIR

(2) The Chair welcomed and thanked all participants for attending the 14th AHWP Meeting. He then extended his thanks and gratitude to Department of Health of Hong Kong SAR for hosting this Meeting. He also thanked the Hong Kong Trade Development Council, Hong Kong Productivity Council, members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting. He then welcomed Chile and Jordan, the new AHWP member economies for attending this Meeting.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

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

AGENDA ITEM 2: ADMISSION OF NEW AHWP MEMBERS

(4) The Meeting confirmed the admission of Chile and Jordan as AHWP member economies.

AGENDA ITEM 3: ROLL CALL

(5) Near 400 participants attended the 14th AHWP Meeting. The list of participants and observers appears as **ANNEX 2**.

AGENDA ITEM 4: CONFIRMATION OF THE 13TH AHWP MEETING MINUTES

(6) The meeting confirmed the report of the 13th AHWP Meeting which was held in New Delhi, India on 5 and 6 November 2008 without any amendments.

AGENDA ITEM 5: 2008/09 – 2011/12 AHWP FUTURE PLAN

(7) Dr Xuejun ZHU, the AHWP Executive Deputy Secretary General, reported the AHWP future plan from Session 2008/09 to Session 2011/12 which appears as **ANNEX 3**, with the following highlights:

WORK REPORT

- (i) AHWP and AHWP Technical Committee (TC) Terms of Reference approval processes were kicked off
- (ii) New AHWP website (www.ahwp.info) was created and it was currently being managed by Hong Kong Productivity Council and Mr Jack WONG (AHWP Secretariat Team)
- (iii) Annual summary and comparison study on member economies' regulatory systems was conducted
- (iv) AHWP annual meeting and workshops were conducted
- (v) TC and Work Groups (WGs) regular communications by meetings and teleconferences were arranged
- (vi) Cooperation with Global Harmonization Task Force (GHTF), Asia-Pacific Economic Cooperation (APEC) and World Health Organization (WHO) was strengthened
- (vii) Permanent AHWP Secretariat and AHWP Legal Entity would be set up in Hong Kong SAR

WORK PLAN & TARGET

- (i) Experience of AHWP Common Submission Dossier Template (CSDT) pilot implementation would be accumulated
- (ii) Safety Alert Dissemination System (SADS) would be implemented
- (iii) A single nomenclature system and Unique Device Identifier (UDI) system would be managed to reach
- (iv) The principles of a rule-based classification system would be established
- (v) AHWP training capacity would be enlarged, including AHWP training program and AHWP workshop funded by APEC
- (vi) AHWP guidance documents for implementation of GHTF principles in quality management system (QMS) requirement would be drafted

AGENDA ITEM 6: AHWP TECHNICAL COMMITTEE (TC) & WORK GROUPS (WGs) REPORTS

(8) Ms Joanna KOH, the Chair of AHWP TC, thanked the support of members in TC, WGs and Special Task Groups (STGs). She then reported the updated on the AHWP TC activities, achievements and future plans for AHWP TC, with the following highlights:

- (i) TC structure

- (ii) TC's 3 Mission Statements, 3 Objectives, 3 guiding principles, 4 deliverables
- (iii) Work items for each WG and STG
- (iv) Commitment to implementation and project professionalism of TC

The presentation is as in **ANNEX 4**.

(9) Miss Daphne YEHL, the Co-chair of AHWP TC, reported the updated TC structure and linkage to GHTF Study Groups (SGs).

(10) Miss Daphne YEHL, the Co-chair of AHWP TC WG1 (Pre-market Submission and CSDT), reported that CSDT guidance document was posted for comment and 2 GHTF's guidance documents were also posted for comments.

ACTION

- (i) To conduct survey on definition of manufacturer, requirement of country of origin, information required for manufacturer registration, information on CFG/FSC, requirement of quality management on manufacturer/actual manufacturer/both among AHWP member economies
- (ii) To request for representation of AHWP WG1 to GHTF SG1 meeting before 20 December 2009

The report by WG1 is appended as **ANNEX 5**.

(11) Mr Jeffrey CHERN, Co-chair of WG1a (In-vitro Diagnostic Device), reported the structure and achievements of WG1a, as well as the release of definition, classification, conformity assessment guidance documents of GHTF. New GHTF's Summary of Technical Documentation (STED) documents consultation would be opened until January 2010.

ACTION

- (i) To collect comments on GHTF's guidance documents by 31 December 2009
- (ii) To conduct survey of IVD regulations from member economies by 31 January 2009
- (iii) To request more members to join WG1a and update list will be posted in AHWP website

The report including future work items by WG1a is appended as **ANNEX 6**.

(12) Mr Mark LAU, Chair of WG2 (Post-market Surveillance and Vigilance) and Ms Chadaporn TANAKASEMSUB (Miang), Co-chair of WG2, reported the completion of PMS survey and draft report, Joint WG2/GHTF SG2 Meeting on 5 November 2009 and 3 National Competent Authority Reporting (NCAR) trainings for AHWP member economies. Collaboration programs between WG2 and GHTF SG2 were briefed.

ACTION

- (i) To finalize PMS survey report
- (ii) To promote Safety Alert Dissemination System (SADS) and NCAR
- (iii) To propose harmonized requirements for adverse event reporting
- (iv) To study the definitions of field safety corrective actions in member economies
- (v) To study the feasibility of providing on-line training through AHWP website
- (vi) To collaborate further with GHTF SG2 to promote harmonization

The report by WG2 is appended as **ANNEX 7**.

(13) Dr Ali M AL-DALAN, Chair of WG3 (Quality Management System), presented the structure and strategic plan of WG3.

ACTION

- (i) To request more AHWP membership application
- (ii) To prepare comments on GHTF SG3's new proposal (N19 – QMS deficiencies)

The report by WG3 is appended as **ANNEX 8**.

(14) Mr Eun Hee CHO, Co-chair of WG4 (Quality System Audit), presented the confused area of ISO 13485.

ACTION

- (i) To issue ISO 13485 handbook in 2009/2010
- (ii) To study GHTF guidance for auditing in 2010
- (iii) To develop AHWP guidance in 2011
- (iv) To gather more inputs from notified bodies

The report by WG4 is appended as **ANNEX 9**.

(15) Ms Quan TRAN, Co-chair of WG5 (Clinical Evidence Requirements), presented the initiation of comparative studies with 10 member economies responded. The

representation of AHWP in GHTF meetings had been started. 3 subgroups were formed within WG5.

ACTION

- (i) To kick off training programs

The report by WG5 is appended as **ANNEX 10**.

(16) Mr Jack WONG, Co-chair of WG6 (Capacity Building and Regulatory Training) presented the background of training projects. Latest co-operation status with North Eastern University was reported. AHWP had agreed to conduct the training on her own, instead of partnering with other trainers.

ACTION

- (i) To roll out training program in 2010

The report by WG6 is appended as **ANNEX 11**.

(17) Mr Jack WONG, Co-chair of STG (AHWP Legal Entity), presented the background of establishment of AHWP Legal Entity and the work progress. Proposed Terms of Reference (TOR) was posed in AHWP for comment and discussed during TC Meeting on 4 November 2009. Approval was obtained from AHWP TC and AHWP to proceed legal entity registration in Hong Kong SAR.

The report by STG(LE) is appended as **ANNEX 12**.

(18) Mr Yan LIANG, Chair of STG (Medical Device Nomenclature), presented the objectives of AHWP and nomenclature developments.

The report by STG(N) is appended as **ANNEX 13**.

AGENDA ITEM 7: RESOLUTIONS

Resolution 1: Adopting the Proposed Requirements of Medical Device Nomenclature System for the AHWP in the Selection of Service Provider

(19) Miss Joanna KOH, the Chair of AHWP TC, presented the 6 requirements of Medical Device Nomenclature System for AHWP, which were endorsed during AHWP TC Meeting on 4 November 2009. The resolution was passed during the Meeting.

(20) AHWP Chair also supplemented:

- (i) AHWP supported GHTF's effort on establishment of single nomenclature

system

- (ii) AHWP would request service providers to consider AHWP's requirements
- (iii) AHWP's 6 requirements would be passed to service providers for feedback

Resolution 2: Adopting the Proposed AHWP and AHWPTC Terms of Reference

(21) Ms Jennifer MAK, Chair of STG(N), presented the key elements in Terms of Reference (TOR), including membership, representatives, leadership, decision and resolutions mechanism, languages used, AHWP TC roles, AHWP TC responsibilities, AHWP TC membership and AHWP TC leadership. It was proposed that the Term of Office for all AHWP and AHWP TC posts would be 3 years. "Regulator" and "Non-regulator" categorization would be used and considered to be reflected in TOR. AHWP endorsed and supported the proposed TOR during the Meeting. The resolution was passed.

Resolution 3: Setting Up a Legal Entity in Hong Kong for Administering AHWP Activities

(22) Mr Mark LAU from STG(LE) presented the setup of "AHWP Administration Services Limited". The Entity would be based in Hong Kong SAR, China and Hong Kong SAR, China would be used as the entity address. The reasons behind were given. Tax exemption would be obtained for the Entity later. Key points of the draft Memorandum and Articles of the new Entity were presented. AHWP endorsed and supported the proposed item and the resolution was passed.

(23) The AHWP Chair also requested that the Legal Entity should comply with all Hong Kong legal requirements, fulfill the tasks set by AHWP and handle financial affairs in a clear and open manner. The Legal Entity should report annually during AHWP meeting and financial report should be posted in AHWP website afterwards.

AGENDA ITEM 8: AHWP WEBSITE AND SPONSORSHIP

(24) Mr Bryan SO, the AHWP Secretariat, presented on the update of AHWP website status, design of website and website sponsorship received.

(25) Mr Jack WONG, the AHWP Secretariat, also requested all WGs and STGs to provide latest member list to AHWP Secretariat for website update.

AGENDA ITEM 9: 2009 Summary and Comparison of AHWP Regulatory Frameworks

(26) Dr Davey HAN, AHWP Secretariat, described the status of comparative study of registration requirement in different member economies. Study report was presented in detailed. Survey results would be provided to WGs and another survey would be conducted next year.

AGENDA ITEM 10: AHWP Member Economies Regulatory Updates

(27) Ms Maria Cecilia MATIENZO, AHWP representative from regulatory authority from Philippines, presented the new organization structure, history of medical device regulations since 1987, formation of “Centre Device Regulatory, Radiation Health, and Research” and implementation timeline in Philippines.

(28) Dr Saleh S AL-TAYYAR, AHWP representative from regulatory authority from Kingdom of Saudi Arabia, presented the history of Saudi FDA since its establishment in 2003, Saudi FDA structure, Medical Devices Interim Regulation introduction, use of conformity assessment bodies, labeling, importation and international achievements in Kingdom of Saudi Arabia.

(29) AHWP Chair requested member economies to provide electronic copies of medical device regulations / requirements to AHWP Secretariat.

AGENDA ITEM 10: CONFIRMATION OF 15th AHWP MEETING VENUE

(30) The next AHWP Meeting will be held in Kingdom of Saudi Arabia.

CLOSING REMARKS

(30) The AHWP Chair thanked and congratulated the Department of Health, Hong Kong Trade Development Council and Hong Kong Productivity Council of Hong Kong SAR who had been working very hard to make this Meeting a success. The Chair concluded the Meeting by thanking all participants for their contributions and wishing them a safe journey home. The meeting was adjourned at 12:30pm on 7 November 2009.

ACKNOWLEDGEMENT

(31) The participants from Abu Dhabi, Brunei Darussalam, Cambodia, Chile, China, Chinese Taipei, India, Indonesia, Jordan, Korea, Laos, Malaysia, Philippines, Saudi Arabia, Singapore and Thailand as well as the observers expressed their appreciation to the Department of Health, Hong Kong Trade Development Council and Hong Kong Productivity Council for the warm hospitality and the excellent arrangements made for this Meeting.

Report Prepared by:

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AHWP Secretariat