



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

REPORT OF THE 16th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Grand Hyatt Hotel

Bali, Indonesia

8-12 November 2011

INTRODUCTION

- (1) The 16th Meeting of the Asian Harmonization Working Party (AHWP) was held on 8-12 Nov 2011 at Grand Hyatt Hotel, Bali, Indonesia. The Meeting was chaired by Mr WANG Baoting, Director-General of Medical Devices Supervision, State Food and Drug Administration, People's Republic of China (AHWP Chair), and co-chaired by Ms Joanna KOH (AHWPTC Chair), Ms Daphenne YEH (AHWPTC Co-Chair) and Eng. Ali AL DALAAN (AHWPTC Co-Chair).

WELCOME ADDRESS BY THE CHAIR

- (2) The Chair welcomed and thanked all participants for attending the 16th AHWP Meeting. He extended his thanks and gratitude to the Ministry of Health, Republic of Indonesia for hosting this Meeting. He also thanked the members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

- (3) The Agenda of the Meeting as in ANNEX (1) was adopted with applause.

AGENDA ITEM 2: ROLL CALL

- (4) Over 300 participants attended the 16th AHWP Meeting, with the list of participants as appended in ANNEX (2).

AGENDA ITEM 3: ADMISSION OF NEW AHWP MEMBER

- (5) The Meeting confirmed the admission of the State of Kuwait as an AHWP member economy.

AGENDA ITEM 4: CONFIRMATION OF THE 15th AHWP MEETING MINUTES

- (6) The meeting confirmed the report of the 15th AHWP Meeting, held in Riyadh, Kingdom of Saudi Arabia on 30 Nov – 1 Dec 2010, as in ANNEX (3) without any amendments.

AGENDA ITEM 5: REPORT OF AHWP SECRETARIAT (2009-2011)

- (7) Mr Bryan SO, Senior Consultant of Hong Kong Productivity Council (HKPC), represented the Secretariat Team to present the work summary for 2009-2011. Bryan highlighted the work



completed by the Secretariat Team during the term, which included the holding of six secretariat meetings, supports to the organization of three Main Meetings and six TC meetings, the migration and upgrade of AHWP Website, the recruitment of new member economies, the issue of AHWP e-Newsletter, the revision of TOR and setting up of House Rules, the supports to STG (LE) on setting up the legal entity, as well as the management of AHWP Reserve/Fund. A blue paper summarizing all the details work completed by the Secretariat Team during the 3-year term was also prepared and distributed by the China Secretariat Team at the 16th AHWP Bali Meeting on-site. The report was agreed and confirmed with applause.

The secretariat work summary for 2009-2011 was appended as **ANNEX (4)**.

The blue paper was appended as **ANNEX (5)**.

AGENDA ITEM 6: REPORT OF FINANCIAL STATEMENT 2010/2011 and BUDGET FOR 2011/2012

(8) Mr Bryan SO of the AHWP Secretariat presented the financial statement of 2010/2011, with a surplus of around USD142,000 as of 31/10/2011. The budget for 2011/2012 was presented with estimated income at around USD180,000 and expenditure of around USD92,000. The financial statement of 2010/11 and budget of 2011/2012 were agreed and confirmed with applause.

The financial statement and budget were appended as **ANNEX (6)**.

AGENDA ITEM 7: ANNOUNCEMENT OF AHWP ADMINISTRATION SERVICES LIMITED

(9) Ali reported the formation of the AHWP ASL and other details including its mission and goal, its current membership type, board of directors (BOD) and advisor, founding members, company secretary, etc. Ali reported that AHWP ASL has received the money transferred from the Hong Kong Productivity Council (HKPC) in Sep 2011 at the amount of USD84,624.76, from the AHWP Reserve/Fund. Ali also presented the existing mechanism of payment endorsement within the BOD of AHWP ASL. Work plan for 2012 would include the signing of service agreement with HKPC on the Secretariat Support Service, and to further evaluate the agreement with the potential partner on training.

The update on AHWP ASL was appended as **ANNEX (7)**.



AGENDA ITEM 8 : SUMMARY OF TC'S WORK 2009 - 2011 BY TC CHAIR

(10) Ms Joanne KOH, the Chair of AHWP Technical Committee (AHWP TC), presented the summary of work done by AHWP TC.

(11) Ms Daphenne YEH, Co-Chair of WG1, presented the work of WG1 – Member economies were recommended to adopt the CSDT based on the ASEAN guideline or STED based on the GHTF guideline. Guidance document for the matching of STED to CSDT was being prepared. The definition of manufacturer was under review. It was suggested that both legal manufacturer and actual manufacturing site could be listed on the product certificate. A common format of Free Sale Certificate in AHWP members was also recommended, and to be further studied. Review and comparison of e-labeling requirements of GHTF member economies would be carried out. The comparative study on combination products was in progress. Future work on developing common format of FSC, review e-label regulations and make recommendations, survey on classification and definition of medical device, combination product regulations, and to make recommendation to member economies of AHWP.

The report by WG1 was appended as **ANNEX (8)**.

(12) Eng. Essam AlMohandis, Chair of WG1a, presented the work of WG1a - Gap analysis of IVD medical devices regulations in member economies and the feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF was completed. Future work including the development of the related documents on clinical evidence for IVD medical devices, the Essential Principles and labeling of IVD medical devices, feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence, etc.

The report by WG1a was appended as **ANNEX (9)**.

(13) Ms Chadaporn TANAKASEMSUB (Miang), Co-Chair of WG2, presented the work of WG2 - Fifteen AHWP member economies joined SADS. Safety alerts information from Saudi FDA was disseminated to all SADS members in a weekly basis through the AHWP Secretariat. The AE and FSCA forms were harmonized across AHWP economy members. Future work included the adoption of the common AE and FSCA forms in AHWP, activities in training and further collaboration with GHTF SG2.

The report by WG2 was appended as **ANNEX (10)**.



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(14) Eng. Ali AL DALAAN, Chair of WG3, presented the work of WG3 - The tie between GHTF and AHWP was strengthened, with the WG3 chair and co-chair joined the GHTF SG3 as members. There was an increase of participation in the review and development of SG3 guidance documents. N17 and N18 guidance documents were adopted in AHWP. N19 was being reviewed, where comments would be prepared and feedback to GHTF. QMS survey was developed and disseminated to AHWP member economies. Future work included the continue participation in ISO TC210, completing of QMS survey by obtaining the responses from the remaining member economies, the completing of the ISO13485 Revision's User Requirements Survey in AHWP, and the completing of N19 development with GHTF SG3.

The report by WG3 was appended as **ANNEX (11)**.

(15) Ms Eun Hee CHO, Co-Chair of WG4, presented the work of WG4 - The survey on the demands of AHWP member economies for auditing was completed. The selection of the GHTF guidance based on the demands of the AHWP member economies on auditing was carried out. The highlights of GHTF guidance were introduced and the consensus on the adoption of GHTF guidance was made. Future work included the development of the official AHWP guidance for auditing, and the training of the AHWP member economies on the adoption of the guidance.

The report by WG4 was appended as **ANNEX (12)**.

(16) Ms TRAN Quan, Co-Chair of WG5, presented the work of WG5 - The study and review of five GHTF SG5 documents within WG5 was completed. Comparative study of Clinical Trials regulations in AHWP member economies was completed with two surveys conducted. Recommendations were made to the AHWP member economies on the feasibility of adopting the clinical trial regulation. Various trainings on clinical safety/performance were completed. Further study & evaluation of ISO14155:2011 for harmonization was recommended. Future work included the development/harmonization of clinical trial regulations for member economies, the collaboration with (GHTF SG5) Advisory Expert Panel /International Medical Device Regulators Forum (New) to provide guidance for clinical trials regulations development in emerging member economies.

The report by WG5 was appended as **ANNEX (13)**.

(17) Mr Jack WONG, Co-Chair of WG6, presented the work of WG6 – The updated status



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regarding collaboration with HKU on Capability Building and Regulatory Training was presented. Future work included the analysis of training needs by AHWP members, preparation of the training content, formulating formal agreement with HKU and put forward to TC for discussion, explore collaborations with other training organizers, including RAPS, WMDO, AHC, etc.

The report by WG6 was appended as **ANNEX (14)**.

- (18) Ms Althea LAU, Chair of STG (LE), presented the work of STG (LE) – All the work completed, which included the finalizing of the Memorandum & Articles of AHWP Administration Services Limited (AHWP ASL), appointment of company secretary for compliance with Hong Kong company law, setting up of the AHWP ASL legal entity in Hong Kong, opening of bank accounts for AHWP ASL, formation of Board of Directors and the recruitment of members of AHWP ASL. With all the tasks completed, the STG (LE) was dissolved in 16th AHWP Meeting.

The report by STG(LE) was appended as **ANNEX (15)**.

- (19) Mr YANG Lian-chun, Chair of STG(N), presented the work of STG (N) - The agreement from GMDN agency on providing free access and free training to AHWP regulators was received. AHWP has successfully lobbied GMDN for agreeing on AHWP's conditions for participation in GMDN BOT/PAG. AHWP has joined the ad hoc task force, and supported the GHTF on finalizing and publishing of the GHTF UDI guidance document in Sep 2011. Linkage and work with WHO on medical device nomenclature issue was established. Future Work included the continue participation of the nomenclature work at various organizations, the follow up of UDI development and the free access offered by GMDN.

The report by STG(N) was appended as **ANNEX (16)**.

AGENDA ITEM 9: SUMMARY OF AHWP'S WORK 2009 - 2011 BY AHWP CHAIR

- (20) Mr WANG Baoting, the Chair of AHWP, summarized the work done by AHWP as a whole in 2009-2011. In 2009 - 2011, AHWP enrolled 5 member economies including Jordan, Abu Dhabi Emirate of UAE, Chile, Pakistan and Yemen, with its number of members up to 22 and continuous expansion of influence.

- (21) The website obtained a new domain name and was managed by the branch Secretariat in Hong Kong. Presently, the website has its steady sponsors and sufficient operational funds. It



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is able to cover all the events of AHWP in time and has become an important medium to display the development of AHWP. We also published our first e-journal in March 2010, and circulated through the database of the Secretariat.

- (22) Subsequent to the 14th Annual Meeting in Hong Kong, AHWP reconstructed its Fund. With the authorization of AHWP Chairman, AHWP Fund was employed during 2010-2011 to support many representatives to participate in the annual meetings of AHWP and invite some industrial celebrities to deliver speeches.
- (23) AHWP had long been devoted to strengthening its cooperation with GHTF, WHO, APEC and other international organizations, further driving up its fame throughout the world. As a noticeable power, AHWP has played an important role in the global medical device regulation harmonization.
- (24) The work of establishing legal entity and permanent secretariat was completed. The legal entity of AHWP was established in Hong Kong, with the permanent Secretariat office in the Hong Kong Productivity Council.
- (25) The 14th Hong Kong Annual Meeting in 2009, the 15th Riyadh Annual Meeting in 2010 and the 16th Bali Annual Meeting in 2011 were held smoothly. Communication with TC and work groups has been strengthened, with more progress made towards the harmonization.
- (26) A comparative study of the medical device regulations was conducted in its member economies. The study results were compiled and distributed to the representatives of all member economies, thereby promoting the members to understand and exchange with each other.
- (27) Through persistent efforts, AHWP has come into cooperation with WHO, APEC, LSIF, GHTF and other international organizations. In 2009, we successfully organized some member economies of AHWP to take part in the GHTF annual meeting and the APEC-sponsored medical device regulation training program in Australia, as well as 2010 APEC medical device regulation training program in Chinese Taipei and 2011 LSIF medical device regulation training program in Seoul. AHWP has closely coordinated with GHTF, the Executive Committee of GMDN and other organizations on issues such as the nomenclature systems and UDI of medical devices, sparing no efforts to reach an agreement with them and promote the global harmonization of medical device regulations.



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AGENDA ITEM 10: RECOGNITION OF STAFF CONTRIBUTION TO AHWP'S WORK

- (28) Certificates of recognition were presented to AHWP and AHWPTC leaders, as well as the outstanding contributors of AHWP by Mr WANG Baoting, the Chair of AHWP.

AGENDA ITEM 11: BRIEFING ON ELECTION RULES AND LIST OF CANDIDATES

- (29) Mr Bryan SO of the AHWP Secretariat explained the election rules as according to the Terms of Reference (TOR) and House Rules of AHWP. Nomination requirement in TOR & House Rules, nomination administrative procedures, election requirement in TOR & House Rules and various nomination forms (A, B and C) and voting slips (A1 and A2) were presented and explained in details.

The arrangement for the election of AHWP office bearers was appended as **ANNEX (17)**.

- (30) The valid nominees for the election were reported. The election included the Office Bearers of AHWP, therefore AHWP Chair, AHWP Vice-Chair (Regulatory Authority), AHWP Vice-Chair (Industry), AHWPTC Chair, AHWPTC Co-Chair (Regulatory Authority), AWHPTC Co-Chair (Industry). The valid list of nominees for the Chair and Co-Chair of Work Groups and Special Task Groups were also reported.

The nominees for election were appended as **ANNEX (18)**.

AGENDA ITEM 12: ELECTION OF AHWP OFFICE BEARERS

- (31) The voting procedure and eligible voters were explained by Mr Bryan SO of the AHWP Secretariat. The voting process started with the verification of the eligibility of voters against the membership record of AHWP secretariat, followed by the distribution of voting slips, collection of voting slips, counting of votes and the announcement of the name of candidate with the highest number of votes. Dr Ir Gert BOS, Head of Regulatory and Clinical Affairs, BSI and Mr Peter PORZLER, Director of Medical and Health Services, TUV SUD Asia Pacific were invited to provide third party monitoring to the voting process.

The eligible voters and voting procedures were appended as **ANNEX (19)**.

- (32) Mr WANG Baoting, AHWP Chair, announced the results of the election at the 17th AHWP Meeting. The elected Office Bearers of AHWP were :-

1. AHWP Chair

Dr Saleh S Al Tayyar, Vice Executive President for Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia.



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2. AHWP Vice-Chair (Regulatory Authority)

Ms Li-Ling LIU, Director, Division of Medical Devices and Cosmetics, Food and Drug Administration, Department of Health, Chinese Taipei.

3. AHWP Vice-Chair (Industry)

Ms Lindsay Tao, Corporate Director, Regulatory Government Affairs, Asia Pacific and Latin America, Johnson and Johnson, People's Republic of China.

4. AHWPTC Chair

Ms Joanna KOH, Group Regulatory Consultant, Medical Devices Branch, Health Sciences Authority, Singapore.

5. AHWPTC Co-Chair (Regulatory Authority)

Eng. Ali M. Al-Dalaan, Executive Director, Radiation Protection & Safety, Saudi Food & Drug Authority, Kingdom of Saudi Arabia.

6. AHWPTC Co-Chair (Industry)

Ms Chadaporn TANAKASEMSUB, Vice President, Asia Pacific Quality Assurance/Regulatory Affairs, Zimmer, Asia Pacific.

(33) Mr WANG Baoting, AHWP Chair, also announced that all nominations of WG/STG Chairs and Co-Chairs were endorsed.

The endorsed list of WG/STG Chairs and Co-Chairs were appended as **ANNEX (20)**.

AGENDA ITEM 13: SPEECH BY NEWLY ELECTED CHAIR, AHWP

(34) Dr Saleh S Al Tayyar, Vice Executive President for Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia thanked the support of the AHWP members. Special thank was given to Mr WANG Baoting for his good leadership and achievement during his term of AHWP chairmanship.

AGENDA ITEM 14: CLOSING OF MEETING BY OUT GOING CHAIR, AHWP

(35) The AHWP Chair Mr WANG Baoting presented the meeting Closing Remarks. The Chair concluded the Meeting by thanking all participants for their contributions and wishing them a safe journey to home. The meeting was adjourned at 17:30 on 11 November 2011.



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AGENDA ITEM 15: ACKNOWLEDGEMENT

(36) The participants from Abu Dhabi, Australia, Brunei Darussalam, Cambodia, Chile, China, Chinese Taipei, Hong Kong, India, Indonesia, Japan, Jordan, Laos, Malaysia, Pakistan, Philippines, Saudi Arabia, Singapore, South Africa, South Korea, Thailand, UK, USA etc., expressed their appreciations to the Ministry of Health, Republic of Indonesia for their warm hospitality and their excellent arrangements made for this Meeting.

Report Prepared by:

Mr Bryan SO

AHWP Secretariat