



**REPORT OF THE 19th MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)**

Vista Hall, Sheraton Grande Walkerhill

Seoul, Republic of Korea

21 November 2014

DRAFT

INTRODUCTION

- (1) The 19th Annual Meeting of the Asian Harmonization Working Party (AHWP) was held on 21 Nov 2014 at Sheraton Grande Walkerhill in Seoul, Republic of Korea. The Meeting was chaired by Dr. Saleh S. Al-Tayyar, Chair of AHWP, co-chaired by Ms. Pei-Weng TU, Vice-chair of AHWP (regulatory authority) and Dr. Lindsay TAO, Vice-chair of AHWP (industry).

- (2) In conjunction with the 19th AHWP Annual Meeting, the AHC-AHWP Joint Workshop was held on 18-19 Nov 2014, co-organized by APEC Harmonization Center (AHC) and AHWP, and the 18th AHWP Technical Committee (TC) Meeting was held on 20 Nov 2014, chaired by Mrs. Joanna Koh, Chair of AHWPTC, co-chaired by Mr. Ali M. AL-DALAN, Co-chair of AHWPTC (regulatory authority) and Ms. Chadaporn Tanakasemsub, Co-chair of AHWPTC (industry).

OPENING CEREMONY

- (3) Dr. Chung Seung, Minister, Ministry Of Food And Drug Safety (MFDS) of Korea welcomed all the participants for joining the 19th AHWP Meeting in Seoul.

- (4) Dr. Saleh, Chair of AHWP, welcomed and thanked all participants for attending the 19th AHWP Meeting. He extended his thanks and gratitude to the Ministry Of Food And Drug Safety, Korea for hosting this Meeting. He also thanked the members of the Organizing Committee, Korea Medical Devices Industry Association and the AHWP Secretariat for all the arrangements of this Meeting. Dr. Saleh further highlighted the activities and progresses by AHWP during the past three years – “AHWP JOURNEY / THE ROAD TO HARMONIZATION / JANUARY 2012 – NOVEMBER 2014” – as the summary of the achievements of its term.



GROUP PHOTO



IMDRF STATUS UPDATES

(5) Mr. Hideyuki Kondo, Management Committee member representative of IMDRF, presented the brief background and updates of International Medical Devices Regulators Forum (IMDRF) activities. Mr. Kondo highlighted the IMDRF work items progress, including the recently completed work items, the technical and information documents issued in 2014, as well as IMDRF on-going activities with planned timeline.

The presentation on IMDRF Status Updates was appended as **ANNEX (1)**.

UPDATE OF APEC REGULATORY HARMONIZATION

(6) Dr. Lindsay Tao, representative of Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee (RHSC) Medical Device Industry Coalition, presented the introduction and updates of APEC regulatory harmonization for medical device, the strategic framework, the priority work items, deliverables in 2014, highlights to date for on-going work items, as well as the model for driving and sustaining change.



The presentation on Updates of APEC Regulatory Harmonization was appended as **ANNEX (2)**.

Present of Certificate of Appreciation to Guest Speakers

(7) Dr. Saleh presented the certificate of appreciation to the guest speakers for acknowledging their presentations on IMDRF and APEC status updates.

ADOPTION OF AGENDA

(8) The programme was slightly updated and the finalized agenda as in **ANNEX (3)** was adopted with applause.

ROLL CALL

(9) The roll call was made by AHWP Chair and Vice-chairs, AHWPTC Chair and Co-chairs, Working Group (WG) and Special Task Group (STG) Chairs and Co-chairs, TC Advisors as well as representatives from AHWP member economies. Over 300 participants attended the 19th AHWP Meeting, with the list of participants as appended in **ANNEX (4)**.

CONFIRMATION OF MINUTES OF THE 18th AHWP MEETING MINUTES

(10) The meeting confirmed the report of the 18th AHWP Meeting, held in Malaysia on 1-5 December 2013, as in **ANNEX (5)** without any amendments.

AHWP STATUS UPDATES:

(11) Dr. Lindsay Tao, Vice-chair of AHWP, reported the status updates on implementation of AHWP Strategic Framework towards 2020 – “The Foreseeable Harmonization Horizon”, including the objective and milestones, the four strategic elements and the indicator of success. She concluded with the highlighting of important projects and the way forward under the new leadership of the next term.

The presentation on AHWP status updates was appended as **ANNEX (6)**.



ANNOUNCEMENT OF ELECTION ARRANGEMENT FOR OFFICE

BEARERS OF AHWP

(12) Mr. Bryan So, Executive Deputy Secretary General of AHWP, made the announcement of election arrangement and voting procedures for the AHWP office bearers' election, to be held in the afternoon of the 19th annual meeting on 21 Nov 2014.

The presentation on election announcement was appended as **ANNEX (7)**.

MEMBER ECONOMY UPDATES

(13) The regulatory updates were presented by Mr. GAO Guo-Biao, Deputy Director General, Medical Device Registration, China Food and Drug Administration, Dr. Jeong-Rim LEE, Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety, Republic of Korea, Ms. Joanna Koh, Director, Vigilance & Compliance Branch, Health Sciences Authority, Singapore, and Mr. Ali Al Dalaan, Executive Director, Radiological Health, Saudi Food & Drug Authority, Kingdom of Saudi Arabia presented the regulatory updates of their member economies on medical devices, including the current status of their general administrative frameworks, latest updates on medical device regulations and approval requirements.

The presentations on economy updates were appended as:

China	: (not for uploading on AHWP website)
Republic of Korea	: ANNEX (8)
ASEAN	: ANNEX (9)
Kingdom of Saudi Arabia	: ANNEX (10)

ENDORSEMENT & PRESENTATION OF AHWP PUBLICATION – TC

PLAYBOOK

(14) The AHWP publication – TC PLAYBOOK officially introduced and reported at the AHWP TC Meeting on 20 Nov 2014 was endorsed without objection. Dr. Saleh, Chair of AHWP, presented the printed TC PLAYBOOK to representatives including regulator primary representatives of AHWP member economies, leadership of AHWP, AHWPTC and TC Advisors, 19th annual meeting local host,



AHWP liaison members GS1 and DITTA, and international organizations on including IMDRF, APEC, RAPS and WHO.

REPORT BY AHWPTC

(15) Ms. Joanna Koh, Chair of AHWP Technical Committee (AHWPTC), reported the highlight of updates by AHWPTC, including the newly streamlined TC WG structure, the introduction, launching and next steps on application of AHWP publication TC PLAYBOOK, discussion on roles of TC Advisors and recommendations from TC Advisors, as well as the accomplished TC Working Group (WG) work items and proposed work items for the future.

The presentation on AHWPTC highlight of updates was appended as **ANNEX (11)**.

OUTLINES OF AHWPTC WG DOCUMENTS TOWARDS ENDORSEMENT

(16) Mr. Ali M. Al-Dalaan, Co-chair of AHWPTC, briefly introduced the background of AHWPTC WG Proposed Final documents towards endorsement at this annual meeting, including the scope, objective and summary of these documents.

The presentation on outlines of WG documents towards endorsement was appended as **ANNEX (12)**.

The WG documents towards endorsement were:

- ◆ “White Paper on Medical Device Software Regulation - Software Qualification and Classification” by *WG1 – Pre-market: General MD* as **ANNEX (13)**
- ◆ “Comparison between Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices” by *WG2 – Pre-market: IVDD* as **ANNEX (14)**
- ◆ “Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorised Representative” by *WG4 – Post-market* as **ANNEX (15)**
- ◆ “Guidance on Medical Device Quality Management System – Requirements for Distributors” by *WG 7 – Quality Management System: Operation & Implementation* as **ANNEX (16)**



- ♦ “Role of Standards in the Assessment of Medical Devices” by WG 2 –
Pre-market: IVDD & WG 8 – Standards as ANNEX (17)

REPORT BY SECRETARIAT

(17) Mr. Bryan So, Executive Deputy Secretary General of AHWP, represented the AHWP Secretariat Team to present the work summary for 2013-2014. A Secretariat meeting was held in May 2014 in Singapore, chaired by Dr. Saleh, Chair of AHWP and Mr. Ali Al-Dalaan, Secretary General of AHWP. Key issues discussed during the secretariat meeting included updates on recent collaborations and meetings with other international organizations (IMDRF, APEC, ISO, RAPS, WHO, etc.), reports on the recently launched SADS On-Line system at AHWP official website, updates from AHWPTC, review and discussion on proposed amendments to AHWP House Rules (e.g., roles of TC Advisors) and WG guidance documents, receipt of the financial report from RAPS and Medical Device Authority Malaysia on the 18th AHWP meeting and the 1st AHWP-RAPS joint conference, financial updates from AHWP Administration Services Limited (ASL), progress updates from Korea local host on 19th annual meeting preparations, and the strategic planning on the election in Nov 2014. Bryan reported the summary of secretariat support work done, including supports to leadership of AHWP, TC and WG for the progresses and deliverables embodying the key strategic elements in the endorsed AHWP Strategic Framework towards 2020, e.g., the supports to the new application for AHWP member economy from Tanzania, the supports to the development of WG guidance and reference documents, the supports to the streamline of new WG structure and the publishing of TC Playbook, the supports to preparation for nomination and election of the new leadership for 2015-2017 term, the supports to AHWP ASL on organizing board of directors (BOD) meetings, the maintenance and updates of AHWP memberships, and the major updates on AHWP website.

(18) Bryan also reported that surplus from company sponsorship to AHWP meetings and website were pooled into the AHWP reserve/fund under the AHWP ASL account, to be further managed to support the travel and/or accommodation for invited speakers and the sponsored regulator representatives of member economies for their participation to AHWPTC and main meetings. Bryan further reported the progress of application for tax-exemption under Section 88 of Inland



Revenue Ordinance in Hong Kong for AHWP ASL, based on the latest updates from the honorary legal advisor to ASL. He further acknowledged the whole Secretariat Team 2012-2014 for their contributions.

The presentation on Secretariat work summary for 2013-2014 was appended as **ANNEX (18)**.

REPORT OF FINANCIAL STATEMENT 2013/2014 AND BUDGET FOR 2014/2015

(19) Mr. Bryan So, Executive Deputy Secretary General of AHWP, presented the financial statement of 2013/2014, with a surplus of US\$171,837.73- as of 30 Sep 2014. The budget for 2014/2015 was presented with estimated income at around US\$262,983.97- and expenditure of around US\$117,275.13-. The financial statement of 2013/2014, and the budget of 2014/2015 were agreed and confirmed with applause.

The financial statement and budget was appended as **ANNEX (19)**.

PROPOSED DOCUMENTS FOR RESOLUTION AND ENDORSEMENT

(20) Dr. Saleh, Chair of AHWP, announced that the official letter of application for AHWP member economy from Tanzania FDA (Tan-FDA), and the application form with nominated representatives was received from Dr. Hiiti B. Sillo, the nominated primary representative from Tan-FDA. With no objection on the proposed new application at the meeting, and according to the simple majority rule, Dr. Saleh declared that Tanzania was endorsed as the 24th member of AHWP, supported by AHWP members with applause.

Dr. Hiiti B. Sillo, Director General of Tan-FDA, also the primary representative (regulatory authority) of Tanzania thanked AHWP & AHWPTC leadership, the local host and Secretariat for guidance and facilitating the application process. He expressed the gratitude to AHWP for welcoming Tanzania as a new member, and presented a short speech on brief introduction of the current medical device regulatory status in the United Republic of Tanzania and the expected Tan-FDA future participations to AHWP activities towards the medical device regulatory harmonization.



(21) Dr. Saleh, Chair of AHWP, announced that the PROPOSED “White Paper on Medical Device Software Regulation - Software Qualification and Classification” was available on AHWP website under CALL FOR COMMENTS, the PROPOSED FINAL document which consolidated the received public comments was also available on AHWP website, and the outline was presented by Mr. Ali M. Al-Dalaan at the morning session of this meeting. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Saleh declared that the proposed white paper on medical device software was endorsed, supported by AHWP members with applause.

(22) Dr. Saleh, Chair of AHWP, announced that the PROPOSED “Comparison between the Common Submission Dossier Template (CSDT) format for In Vitro Diagnostic Medical Devices and the GHTF Summary Technical Documentation (STED) formats for In Vitro Diagnostic Medical Devices” was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated the received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Saleh declared that the proposed comparison document between CSDT and STED for IVDD was endorsed, supported by AHWP members with applause.

(23) Dr. Saleh, Chair of AHWP, announced that the PROPOSED “Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorized Representative” was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated the received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Saleh declared that the proposed adverse event reporting timeline document was endorsed, supported by AHWP members with applause.

(24) Dr. Saleh, Chair of AHWP, announced that the PROPOSED “Guidance on Medical Device Quality Management System – Requirements for Distributors” was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated the received public comments was also available on AHWP website. With no objection on the proposed



document at the meeting, and according to the simple majority rule, Dr. Saleh declared that the proposed document on medical device quality management system for distributors was endorsed, supported by AHWP members with applause.

(25) Dr. Saleh, Chair of AHWP, announced that the PROPOSED “Roles of Standards in the Assessment of Medical Device” was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website. With no objection on the proposed document at the meeting, and according to the simple majority rule, Dr. Saleh declared that the proposed document on roles of standards was endorsed, supported by AHWP members with applause.

(26) Mr. Bryan So, Executive Deputy Secretary General of AHWP, presented the “Amendment 3 to the Asian Harmonization Working Party House Rules”, where the PROPOSED document was available under CALL FOR COMMENTS on AHWP website, and the PROPOSED FINAL document was also available on AHWP website. Bryan presented the new clause added for clarifying the roles of AHWPTC advisors, for the purpose of distinguishing the responsibilities of AHWPTC and TC advisors. With no objection on the proposed amendment 3 to the House Rules on roles of TC advisors at the meeting, and according to the simple majority rule, Dr. Saleh, Chair of AHWP, declared that the resolution was passed, supported by AHWP members with applause.

All the documents for resolution were appended as **ANNEX (20)**.

ELECTION OF AHWP LEADERSHIP 2015-2017

(27) Mr. Bryan So, Executive Deputy Secretary General of AHWP, reported the nomination results and the election arrangements for AHWP office bearers, AHWPTC office bearers as well as AHWPTC WG office bearers for the term 2015-2017. Mr. Bryan So and Ms. Carol Liu, AHWP Secretariat, confirmed and invited all the presenting eligible voters to sign against his/her names on the latest list of eligible voters prepared by Secretariat, and distributed voting slips to each individual eligible voters. The collected voting slips were counted by Bryan, with the observation by two scrutineers, i.e., Dr. Ir. Gert Bos of BSI and Mr. Vincent Lam of TUV SUD.



(28) The election results summarized as follows could be found at **ANNEX (21)**:

Elected Office Bearers of AHWP:

- Chair (regulatory authority) : Dr. Hee-Kyo Jeong, MFDS, Korea
- Vice-chair (regulatory authority) : Mr. Zamane Abd Rahman, Medical Device Authority, MOH, Malaysia
- Vice-chair (industry) : Ms. Tran Quan, GE Healthcare, Singapore

Elected Office Bearers of AHWPTC

- Chair (regulatory authority) : Mr. Ali M. Al-Dalaan, Saudi-FDA, KSA
- Co-chair (regulatory authority) : Dr. Jeong-Rim Lee, MFDS, Korea
- Co-chair (industry) : Mr. Alfred Kwek, Samsung Electronics, Singapore

Elected Office Bearers of AHWPTC WGs/STGs:

- WG1 – Pre-market: General MD
 - Chair : Mr. Essam Mohammed Al Mohandis, Saudi-FDA, KSA
 - Co-chair : Ms. Tan Minghao, Regulatory Associates LLP, Singapore
- WG2 – Pre-market: IVDD
 - Chair : Mr. Wen-Wei TSAI, TFDA, Chinese Taipei
 - Co-chair : Mr. Albert POON, Consultant, Hong Kong SAR
- WG3 – Pre-market: Software as a Medical Device
 - Chair : Dr. Rama SETHURAMAN, HSA, Singapore
 - Co-chair : Mr. Tony Yip, Elekta Limited, Hong Kong SAR
- WG4 – Post-Market
 - Chair : Ms. Jennifer MAK, MDCO, DOH, Hong Kong SAR
 - Co-chair : Ms. Kitty MAO, GE Healthcare, Singapore
- WG5 – Clinical Performance & Safety
 - Chair : Ms. Yuwadee PATANAWONG, Thai-FDA, Thailand
 - Co-chair : Ms. Sumati Randeo, Abbott Laboratories, India
- WG6 – Quality Management System: Audit & Assessment
 - Chair : Mr. Abdullah AL RASHEED, Saudi FDA, KSA
 - Co-chair : Ms. Shirley SUM, J&J, Singapore
- WG7 – Quality Management System: Operation & Implementation



- Chair : Ms. Aidahwaty M.Olaybal, Medical Device Authority, MOH, Malaysia
- Co-chair : Mr. Ee Bin Liew, Access-2-Healthcare, Singapore
- WG8 – Standards
 - Chair : Ms. Maria Cecilia MATIENZO, Bureau of Health Devices & Technology, Philippines
 - Co-chair : Mr. Tony Low, TÜ V Rheinland, Malaysia
- STG (U&N) –Special Task Group on UDI & Nomenclature
 - Chair : Mr. Yang Lian-Chun, CFDA, China
 - Co-chair : Ms. Carol Yan, Johnson & Johnson, China

SPEECH BY NEWLY ELECTED CHAIR OF AHWP

(29) Dr. Hee-Kyo Jeong, MFDS, also the AHWP primary representative (regulatory authority) from Korea, gave a short speech and thanked AHWP members for supporting him as the new leadership for the next three years. Dr. Jeong acknowledged the impressive work progress done by AHWP towards regulatory convergence in the past term, and thanked Dr Saleh, all the other AHWP and AHWPTC leadership of the immediately past term as well as secretariat for the hard work and the supporting of successful organization of the AHWP Annual Meeting 2015 in Seoul.

CONFIRMATION OF HOST OF THE 19TH AHWP MEETING

(30) Dr. Hee-Kyo Jeong, the newly elected Chair of AHWP, announced that Thailand had volunteered and expressed the interests in hosting the next AHWP Annual Meeting. As there was only a single candidate, Dr. Jeong declared the confirmation of Thailand as the host of the 20th AHWP Annual Meeting, which was supported by AHWP members with applause. Dr. Jeong again expressed the appreciation on behalf of all AHWP members, to the Food and Drug Administration of Thailand (Thai-FDA) for their support on hosting the next meeting, with more details to be announced soon.

CLOSING REMARKS BY OUTGOING CHAIR OF AHWP

(31) Dr. Saleh, the outgoing Chair of AHWP presented the closing remarks of the



Meeting. Dr. Saleh expressed his deepest thanks to the outgoing AHWP, TC, WG leadership and Secretariat for their supports during his term as AHWP Chair. Dr. Saleh concluded the Meeting by thanking AHWP and all participants for their contributions and wished them a safe journey home. The meeting was adjourned at 17:30 on 21 November 2014.

- END -