



**REPORT OF THE 18th MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)**
Grand Lagoon Ballroom, Sunway Lagoon Hotel Resort & Spa
Kuala Lumpur, Malaysia
5 December 2013

INTRODUCTION

(1) The 18th Meeting of the Asian Harmonization Working Party (AHWP) was held on 5 Dec 2013 at Sunway Lagoon Hotel in Kuala Lumpur, Malaysia. The Meeting was chaired by Dr Saleh S. Al-Tayyar, Director General, Medical Devices Sector, Saudi Food and Drug Administration, Kingdom of Saudi Arabia (AHWP Chair), co-chaired by Ms Li-Ling LIU (AHWP Vice-Chair), Mrs Joanna KOH (AHWPTC Chair), and Eng. Ali AL DALAAN (AHWPTC Co-Chair).

OPENING CEREMONY

(2) Mr. Zamane Abdul Rahman, Chief Executive, Medical Device Authority, Ministry of Health Malaysia welcomed all the participants for joining the 18th AHWP Meeting in Kuala Lumpur.

(3) Dr Saleh, Chair of AHWP, welcomed and thanked all participants for attending the 18th AHWP Meeting. He extended his thanks and gratitude to the Medical Device Authority, Malaysia for hosting this Meeting. He also thanked the members of the Organizing Committee, Malaysian Medical Device Professional Association and the AHWP Secretariat for all the arrangements of this Meeting.

(4) Dr Sherry Keramidas, Executive Director, Regulatory Affairs Professional Society (RAPS) gave the keynote Speech.

(5) Y.B Datuk Seri Dr. Hilmi Bin Haji Yahya, Deputy Minister of Health, Malaysia expressed the appreciation to AHWP for considering Kuala Lumpur as the venue of 18th AHWP Meeting, with his wishes on the success of the Meeting, and the future convergence of medical device regulations in AHWP member economies.



GROUP PHOTO

(High resolution group photo to be further added)

ADOPTION OF AGENDA

(6) The finalized agenda as in **ANNEX (1)** was adopted with applause.

ROLL CALL

(7) The roll call was made by AHWP Chair and Vice-chair, AHWPTC Chair and Co-chair, 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 18th AHWP Meeting, with the list of participants as appended in **ANNEX (2)**.

CONFIRMATION OF MINUTES OF THE 17th AHWP MEETING MINUTES

(8) The meeting confirmed the report of the 17th AHWP Meeting, held in Chinese Taipei on 2-6 November 2012, as in **ANNEX (3)** without any amendments.

FINAL PROPOSED DOCUMENT “AHWP STRATEGIC FRAMEWORK TOWARDS 2020 – THE FORESEEABLE HARMONIZATION HORIZON”

(9) Ms Li-Ling Liu, Vice-chair of AHWP, presented the background and objective of AHWP strategic framework. Director Liu highlighted the important momentum AHWP had built, the indicator of success, and the four key elements, meaning Element ONE: AHWP Membership Expansion, Element TWO: Training and Capacity building, Element THREE: Harmonization in Key Areas based on GHTF Principles and AHWP guidance and Element FOUR: Enhance AHWP’s Global Partnership. The proposed AHWP strategic framework had consolidated comments received from public as well as further advice from AHWP leadership, and would seek for endorsement in this Meeting.

The presentation on AHWP strategic framework was appended as **ANNEX (4)**.



SUMMARY ON 1st AHWP-RAPS JOINT CONFERENCE

(10) Ms Tran Quan, Advisor to AHWP Chair, also the Project Manager of the 1st AHWP-RAPS Joint Conference reported the summary of the Conference which was successfully completed on 2-3 Dec 2013 in Kuala Lumpur. The 1.5-day event with exhibition was well received by 327 delegates and 32 countries from Asia, Middle East, Africa, USA and Europe regions, with program topics on 5 key themes by 12 expert speakers. Quan thanked the Medical Device Authority, Malaysian, Regulatory Affairs Professionals Society (RAPS), AHWP Administration Services Limited (legal entity of AHWP), AHWP leadership, Organizing Committee and the AHWP Secretariat on making this first conference very successful. Quan highlighted the topic on costs of regulatory divergence and innovation.

The presentation on summary of 1st AHWP-RAPS Joint Conference was appended as **ANNEX (5)**.

REPORT BY AHWPTC

(11) Mrs Joanna Koh, Chair of AHWP Technical Committee (AHWPTC), reported the summary of updates by AHWPTC, with highlights on of key achievements and work items in progress of AHWPTC Working Groups (WG) and Special Task Group (STG): WG1 – Pre-Market Submission and CSDT: Completed the mapping of CSDT to STEP, review of amended GHTF definition of medical device, and the introduction and training on medical software in 2012. WG1a – IVDD: Completed the list of standards for IVD devices, development of guidance documents on IVDs, training on IVD documents, and the collaboration with PAHWP and LSHTM. WG2 – Post-market Surveillance and Vigilance: Completed the harmonization of definitions of PMS terms, development of AE reporting form available at AHWP website, trial test of the upgraded Safety Alert Dissemination System (SADS), as well as training on WG2 guidance documents and implementation. WG3 – Quality Management System: Completed work items included: 1) Participated QMS work in GHTF SG3 for the development of GHTF guidance documents N17, N18 and N19, b) Completed the adoption of N17 and N18 by AHWP, 3) Participated in ISO/TC210 activities. WG4 – Quality System Audit: Completed work items: 1) Survey on reference documents on audit,



2) Survey on demands for importer and distributor (I&D) guidance documents, 3) Pilot program for of different training modules. WG5 – Clinical Safety/Performance: Completed the mapping with ICH GCP, SG5 GN and the latest version ISO14155 and provided inputs to ISO/TC 194 “Clinical Investigations of medical devices in humans. Completed the comparative study on regulations and related guidelines including clinical trial requirements. WG6 – Capacity Building/Regulatory Training: Completed the collection of training needs from WGs and prioritization of training areas for WGs. Links for relevant online course providers were provided on AHWP website for members’ ease of access. STG – Medical Device Nomenclature: Completed work items: 1) Participation of nomenclature work in GMDN, IMDRF and WHO, 2) Provided AHWP comments, 3) Completed meeting with EU DG SANCO and GMDN Agency, 4) Conducted 5 workshops & discussions in China for the feasibility analysis of GMDN application in China and drafted a report.

The presentation on AHWPTC report was appended as **ANNEX (6)**.

ECONOMY UPDATES

(12) Mr Zamane Abdul Rahman, Chief Executive, Medical Device Authority, Ministry of Health Malaysia, Dr Hye-Won Roh, Deputy Scientific Director, Ministry of Food and Drug Safety (formally KFDA), Republic of Korea, Mr Essam Al Mohandis, Executive Director, Surveillance and Biometric, Kingdom of Saudi Arabia, and Ms Li-Ling Liu, Director, Division of Medical Devices and Cosmetics, TFDA, Chinese Taipei 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, electronic systems, and future priority plans.

The presentations on economy updates were appended as:

Malaysia	: ANNEX (7a)
Republic of Korea	: ANNEX (7b)
Kingdom of Saudi Arabia	: ANNEX (7c)
Chinese Taipei	: ANNEX (7d)



REPORT BY SECRETARIAT

(13) Mr Bryan So, Executive Deputy Secretary General of AHWP, represented the AHWP Secretariat Team to present the work summary for 2012-2013. The Secretariat meeting was held in May 2013 in Kuala Lumpur, Malaysia, chaired by Dr Saleh, Chair of AHWP and Mr Ali Al-Dalaan, Secretary General of AHWP. Key issues discussed during the secretariat meeting included the further comments on the AHWP strategic framework consolidated received public comments, updates on recent collaborations and meetings with other international organizations (IMDRF, APEC, ISO, RAPS, WHO, etc.), updates from AHWPTC, review and discussion on proposed amendments to AHWP House Rules (e.g., liaison membership) and guidance document, receipt of the progress updates from RAPS and Medical Device Authority Malaysia on the 18th AHWP meeting and the joint conference preparations. Bryan reported the summary of secretariat support work done, including supports to AHWP leadership on promoting global appearance of AHWP, supports to the organizing committees for the joint conference and the 18th AHWP meeting, supports to AHWPTC and the nomination as well as formation of TC advisory panel, supports to TC working group projects (e.g., SADS upgraded system), 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.

(14) Bryan also reported that surplus from company sponsorship to AHWP website and meetings were pooled into the AHWP reserve/fund under the AHWP ASL account, to be further managed to support the travel and 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, which was initialed and confirmed at AHWP ASL BOD meetings in 2013.

The presentation on Secretariat work summary for 2012-2013 was appended as **ANNEX (11)**.



REPORT OF FINANCIAL STATEMENT 2012/2013 AND BUDGET FOR 2013/2014

(15) Mr Bryan So, Executive Deputy Secretary General of AHWP, presented the financial statement of 2012/2013, with a surplus of US\$192,066.04 as of 30 Sep 2013. The budget for 2013/2014 was presented with estimated income at around US\$227,450 and expenditure of around US\$100,887. The financial statement of 2012/2013, and the budget of 2013/2014 were agreed and confirmed with applause.

The financial statement and budget was appended as **ANNEX (12)**.

PROPOSED DOCUMENTS FOR RESOLUTION AND ENDORSEMENT

(16) Dr Saleh, Chair of AHWP, announced that the PROPOSED “AHWP Strategic Framework Towards 2020 - The Foreseeable Harmonization Horizon” was available on AHWP website under CALL FOR COMMENTS, the PROPOSED FINAL document which consolidated received public comments was also available on AHWP website, and the highlighted contents was presented by Ms Li-Ling Liu at the morning session of this meeting. With no objection on the proposed strategic framework at the meeting, and according to the simple majority rule, Dr Saleh declared that the proposed AHWP strategic framework was endorsed, supported by AHWP members with applause.

(17) Dr Saleh, Chair of AHWP, announced that the PROPOSED “AHWP Regulatory Framework for IVD Medical Devices” 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 IVD regulatory framework document was endorsed, supported by AHWP members with applause.

(18) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Essential Principles of Safety and Performance of IVD Medical Devices” 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 IVD essential principles related document was endorsed, supported by AHWP members with applause.

(19) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices” 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. However, concerns were received during the meeting from the floor, and Dr Saleh thus recommended the proposed document to be further reviewed.

(20) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format” 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 comparison of STED and CSDT for IVD medical device was endorsed, supported by AHWP members with applause.

(21) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative” 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 AE reporting was endorsed, supported by AHWP members with applause.



(22) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange” 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 QMS was endorsed, supported by AHWP members with applause.

(23) Mr Bryan So, Executive Deputy Secretary General of AHWP, presented the “Amendment 1 to the GUIDANCE for Member Economy Hosting the Meetings of AHWP or its Technical Committees”, 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 amendments on administration and financial arrangements related clauses, for the purpose of providing more detailed operation procedures for member economy hosting AHWP meetings, and eliminating the ambiguous areas between AHWP House Rules and the clauses in this document. With no objection on the proposed amendment 1 to the guidance 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.

(24) Mr Bryan So, Executive Deputy Secretary General of AHWP, presented the “Amendment 2 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 AHWP liaison membership and the related operation procedures, for the purpose of supporting the AHWP strategic framework element “Enhance AHWP’s Global Partnership”. With no objection on the proposed amendment 2 to the House Rules on liaison membership 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.

(25) Dr Saleh, Chair of AHWP, announced that two applications for AHWP liaison membership had been received from a) DITTA and b) GS1, and declared the confirmation of liaison membership for DITTA and GS1. Mr Susumu Takahashi, representative of DITTA, and Ms Géraldine Lissalde-Bonnet, representative of GS1 briefly introduced their associations and thanked AHWP for accepting their joining of liaison members.

(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 applications from non-member economies for joining AHWPTC working groups/special task group, for the purpose of supporting the AHWP strategic framework element “AHWP membership expansion”. However, there were further discussions and concerns were received during the meeting from the floor, and Dr Saleh thus recommended the proposed document to be further reviewed.

All the documents for resolution were appended as **ANNEX (13)**.

CONFIRMATION OF HOST OF THE 19TH AHWP MEETING

(27) Dr Saleh, Chair of AHWP, announced that Republic of Korea had volunteered and expressed the interests in hosting the next AHWP Main Meeting. As there was only a single candidate, Dr Saleh declared the confirmation of Republic of Korea as the host of the 19th AHWP Annual Meeting, which was supported by AHWP members with applause. Dr Saleh again expressed the appreciation on behalf of all AHWP members, to the Ministry of Food and Drug Safety (MFDS, former KFDA), Republic of Korea, for their support on hosting the next meeting, with more details to be announced soon.



CLOSING REMARKS

(28) Mr Zamane Abdul Rahman, Chief Executive, Medical Device Authority, Ministry of Health Malaysia, also the AHWP primary representative (regulatory authority) from Malaysia, presented the closing remarks of the Meeting. Mr Zamane concluded the Meeting by thanking AHWP and all participants for their contributions and wished them a safe journey home. The meeting was adjourned at 17:00 on 5 December 2013.

ACKNOWLEDGEMENT

(29) The participants from over 30 economies expressed their appreciations to the Medical Device Authority, Malaysia for their hospitality and excellent arrangements for this Meeting.

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