



# Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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## REPORT OF THE 17<sup>th</sup> MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Taipei International Convention Center (TICC)

Chinese Taipei

2-6 November 2012

### INTRODUCTION

- (1) The 17<sup>th</sup> Meeting of the Asian Harmonization Working Party (AHWP) was held on 2-6 Nov 2012 at Taipei International Convention Center, Chinese Taipei. 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), and co-chaired by Ms Li-Ling LIU (AHWP Vice-Chair), Ms Lindsay TAO (AHWP Vice-Chair), Ms Joanna KOH (AHWPTC Chair), Eng. Ali AL DALAAN (AHWPTC Co-Chair) and Ms Chadaporn TANAKASEMSUB [Miang] (AHWPTC Co-Chair).

### WELCOME ADDRESS BY THE CHAIR

- (2) Dr Saleh, Chair of AHWP, welcomed and thanked all participants for attending the 17<sup>th</sup> AHWP Meeting. He extended his thanks and gratitude to the TFDA, Department of Health, Chinese Taipei 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 17<sup>th</sup> AHWP Meeting, with the list of participants as appended in ANNEX (2).

### AGENDA ITEM 3: CONFIRMATION OF THE 16<sup>th</sup> AHWP MEETING MINUTES

- (5) The meeting confirmed the report of the 16<sup>th</sup> AHWP Meeting, held in Bali, Indonesia on 8-12 Nov 2011, as in ANNEX (3) without any amendments.

### AGENDA ITEM 4: DISCUSSION ON THE PROPOSED “AHWP STRATEGIC FRAMEWORK TOWARDS 2020 – THE FORESEEABLE HARMONIZATION HORIZON”

- (6) Ms Lindsay TAO, Vice-Chair of AHWP, introduced the background and objective of the strategic framework. Ms TAO invited members to submit their comments via the AHWP



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Secretariat on or before 4 Feb 2013, where the proposed document of the strategic framework is available at AHWP website under CALL FOR COMMENT. The five key elements of the strategic framework were highlighted, which included Element ONE: AHWP Membership Expansion; Element TWO: Training and Capacity Building; Element THREE: Harmonization in Key Areas based on GHTF Principles and AHWP Guidance; Element FOUR: Working alongside with APEC and ASEAN to expand beyond regional blocks and Element FIVE: Enhance AHWP's Global Presence.

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

## **AGENDA ITEM 5: INTRODUCTION TO THE 1<sup>ST</sup> AHWP-RAPS JOINT CONFERENCE**

(7) Ms Quan TRAN, Advisor to AHWP Chair, introduced the first joint conference to be organized by AHWP and RAPS. Quan highlighted the background, purpose and format of the conference. Dr Saleh, Chair of AHWP, also added and explained the initiative of this joint conference with RAPS, the importance of this conference for the engagement of the healthcare professionals, to facilitate further support from the healthcare professionals to the harmonization of medical device regulations, etc., in order to enable a closer cooperation between healthcare professionals and regulators for the uphold of public health and safety.

The presentation on 1<sup>st</sup> conference was appended as **ANNEX (5)**.

## **AGENDA ITEM 6: COUNTRY UPDATE**

(8) Mr Gao Guobiao of China, Ms Yuwadee Patanawong of Thailand, Ms Ade Arinata of Indonesia and Ms Maria Cecilia Lopez of Chile presented their country updates on regulation of medical devices, with presentations on updates of their general administrative framework, current regulations, revision of medical device regulations, future priority plans, e-registration system, etc.

The presentations on country update were appended as~

China Update : **ANNEX (6a)**

Thailand Update : **ANNEX (6b)**

Indonesia Update: **ANNEX (6c)**

Chile Update : **ANNEX (6d)**

## **AGENDA ITEM 7: REPORT BY AHWP TC**

(9) Ms Joanna KOH, Chair of AHWP Technical Committee (AHWP TC), reported the summary



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of work done by TC, with the key achievements and next work items for each WG/STG being highlighted. Key achievements for WG1: a) Completed and published the mapping of CSDT to STED on AHWP website, b) Introduced the software overview in Manila TC meeting and catered for training on software; WG1a: a) Actively participated and offered inputs in the preparation of GHTF guidance documents on IVD clinical evidence, with the finalized and completed guidance documents to be further proposed to AHWP for endorsement, b) Organized conferences on regulatory convergence for IVDs; WG2: a) Developed the common AE and FSCA forms for use across AHWP member economies, b) Posted the proposed documents on AHWP website for comments; WG3: a) Completed QMS survey and analysis, b) Endorsed the adoption of GHTF N17 and N18 at AHWP for further consideration of implementation, c) Joined ISO TC210 as a liaison member and provided comments for the proposed new version of ISO13485; WG4: a) Completed the review of GHTF guidance documents on audit and proposed the guidelines for endorsement in AHWP, b) Developed new work item for the auditing of importers and distributors; WG5: a) Mapped the differences between old and new versions of ISO14155, b) Provided consolidated comments on new GHTF guidance documents on clinical evidence for IVDs; WG6: a) Collated and prioritized the training needs of TC workgroups, with some topics also covered in current AHWP meeting, b) Posted information and link of external training platforms on AHWP website; STG(N) : a) Recruited new members and updated membership, b) Collaborated and connected with GMDN on the conduction of UDI training, c) Carried out pilot study on UDI implementation in China. Next work items for each WG/STG were also highlighted at the meeting, with details at the appendix.

The presentation on AHWPTC report was appended as **ANNEX (7)**.

## **AGENDA ITEM 8: REPORT BY SECRETARIAT**

(10) Mr Bryan SO, Executive Deputy Secretary General of AHWP, represented the Secretariat Team to present the work summary for 2011-2012. Two secretariat meetings were held in Feb 2012 and Sep 2012 in Singapore and Riyadh respectively, both chaired by Dr Saleh, Chair of AHWP, and Mr Ali Al Dalaan, Secretary General of AHWP. Key issues discussed during secretariat meetings including the initiation of the strategic framework of AHWP, review of work completed, report on recent collaborations and meetings with other international organizations (IMDRE, GHTF, APEC, ISO, RAPS, DITTA, WHO, etc.), receipt of the progress report from TFDA on the 17th AHWP main meeting and the progress report from AHWPTC, receipt of updates on AHWP Fund from the Secretariat Hong Kong Office, recap on the administrative procedures of preparing official AHWP documents (4-step procedure), discussion on administrative procedures for TC Advisors, etc. Bryan reported the major



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updates on AHWP website, including the posting of AHWP Organization Chart, creation of a new tab for AHWP ASL with M&A and other updates uploaded, adding of external training links, posting of meeting reports and training materials, trial testing on SADS On-line system with logins and passwords, updating of new AHWP, AHWPTC and WG/STG membership, etc. The second e-newsletter of AHWP was being prepared by Prof Jack WONG, to cover the recent work done by AHWP and AHWPTC.

- (11) Bryan reported that the surplus from AHWP website, AHWPTC Meetings and AHWP Main Meetings were pooled into the AHWP Reserve/Fund under the AHWP ASL Account, which supported the round-trip air-tickets and hotel accommodations for the invited speakers and the sponsored regulatory representatives of member economies for their attendance to the AHWPTC and AHWP Main Meetings.

The presentation on secretariat work summary for 2011-2012 was appended as **ANNEX (8)**.

## **AGENDA ITEM 9: REPORT OF FINANCIAL STATEMENT 2011/2012 and BUDGET FOR 2012/2013**

- (12) Mr Bryan SO, Executive Deputy Secretary General of AHWP, presented the financial statement of 2011/2012, with a surplus of USD175,460.43 as of 30/09/2012. The budget for 2012/2013 was presented with estimated income at around USD403,000 and expenditure of around USD280,000. The financial statement of 2011/2012 and budget of 2012/2013 were agreed and confirmed with applause.

The financial statement and budget was appended as **ANNEX (9)**.

## **AGENDA ITEM 10: RESOLUTION AND ENDORSEMENT**

- (13) Mr Bryan SO, Executive Deputy Secretary General of AHWP, presented the “Amendment 2 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (TOR)”, where the PROPOSED document was available under CALL FOR COMMENT on the AHWP website, and the PROPOSED FINAL document was also available on AHWP website. Bryan highlighted the key amendments regarding membership, leadership, voting and representation in the absence of the representatives in the TOR. The amendments were to clarify the ambiguous areas in TOR and to eliminate conflicts within TOR. With no objection on the proposed amendment 2 to AHWP & AHWPTC TOR at the meeting, and according to the simple majority rule, Dr Saleh, Chair of AHWP, declared that the resolution was passed, and the proposed amendment 2 to AHWP & AHWPTC TOR was endorsed with applause.



The presentation on Amendment 2 to TOR was appended as **ANNEX (10a)**.

- (14) Mr Bryan SO, Executive Deputy Secretary General of AHWP, presented the “Amendment 1 to the Asian Harmonization Working Party House Rules”, where the PROPOSED document was available under CALL FOR COMMENT on the AHWP website, and the PROPOSED FINAL document was also available on AHWP website. Bryan presented the amendments on nominations and elections of the AHWP Chair/Vice-chairs, appointments of AHWP and AHWPTC representatives and addition of a new clause on the appointment of advisor to AHWPTC. The amendments were to remove the conflicts between TOR and House Rules and to add the new clause on AHWPTC Advisor. With no objection on the proposed amendment 1 to AHWP House Rules at the meeting, and according to the simple majority rule, Dr Saleh, Chair of AHWP, declared that the resolution was passed, and the proposed amendment 1 to AHWP House Rules was endorsed with applause.

The presentation on Amendment 1 to House Rules was appended as **ANNEX (10b)**.

- (15) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Medical Device Adverse Event (AE) Report Form” was available on AHWP website under CALL FOR COMMENT, and the PROPOSED FINAL document was also available on AHWP website. With no objection on the proposed AE form at the meeting, and according to the simple majority rule, Dr Saleh declared that the proposed AE Form was endorsed. The endorsement was also supported by AHWP members with applause.
- (16) Dr Saleh, Chair of AHWP, announced that the PROPOSED "Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions” was available on AHWP website under CALL FOR COMMENT, and the PROPOSED FINAL document 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 was endorsed. The endorsement was also supported by AHWP members with applause.
- (17) Dr Saleh, Chair of AHWP, announced that the PROPOSED “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers” was available on AHWP website under CALL FOR COMMENT, and the PROPOSED FINAL document was also available on AHWP website. With no objection on the proposed guideline at the meeting, and according to the simple majority rule, Dr Saleh declared that the proposed



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guideline was endorsed. The endorsement was also supported by AHWP members with applause.

## **AGENDA ITEM 11: CONFIRMATION OF HOST OF THE 18TH AHWP MEETING**

(18) Dr Saleh, Chair of AHWP, announced that Malaysia has volunteered and expressed their interests in hosting the next AHWP Main Meeting. As there was no other volunteer, Dr Saleh declared the confirmation of Malaysia as the host of the 18th AHWP meeting, which was supported by AHWP members with applause. Dr Saleh again expressed the appreciation, on behalf of all AHWP members, to the Malaysia MOH for their support on hosting the next meeting, with more details to be announced soon.

## **AGENDA ITEM 12: CLOSING REMARKS**

(19) Ms Li-Ling Liu, Vice-Chair of AHWP, presented the closing remarks of the Meeting. Ms Liu concluded the Meeting by thanking all participants for their contributions and wishing them a safe journey to home. The meeting was adjourned at 17:00 on 5 November 2012.

## **AGENDA ITEM 13: ACKNOWLEDGEMENT**

(20) The participants from Australia, Chile, China, Chinese Taipei, Hong Kong SAR, India, Indonesia, Japan, Kingdom of Saudi Arabia, Korea, Singapore, South Africa, Kuwait, Thailand, UK, USA, etc., expressed their appreciations to the TFDA, Department of Health, Chinese Taipei for their warm hospitality and their excellent arrangements made for this Meeting.

Report Prepared by:

Mr Bryan SO

Executive Deputy Secretary General

AHWP Secretariat