



AHWP Secretariat KL Meeting

Meeting Minutes

[DRAFT]

Date : 6 – 7 May 2013 (Kuala Lumpur Time Zone, GMT+8)
Time : Meeting started at 9:00am, daily
Venue : Room Bahamas Recess, Sunway Resort Hotel & Spa, Kuala Lumpur,
Malaysia

Attendees:

- Dr. Saleh S. Al-TAYYAR, SFDA, KSA (Chair)
- Mr. Ali M. Al-DALAN, SFDA, KSA (Secretary General)
- Ms. Quan TRAN, GE Healthcare, Singapore (Advisor to Chair)
- Mr. Essam Al-MOHANDIS, SFDA, KSA (Executive Deputy Secretary General)
- Mr. Bryan SO, Hong Kong Productivity Council, Hong Kong (Executive Deputy Secretary General)
- Mr. Jack WONG, Terumo BCT (Asia Pacific) Ltd, Hong Kong (Executive Deputy Secretary General)
- Ms. Carol LIU, Hong Kong Productivity Council, Hong Kong (Secretariat)

Attendees on Conference Line:

- Ms. Li-Ling LIU, TFDA, Chinese Taipei (Vice-chair)
- Ms. Joanna KOH, HSA, Singapore (TC Chair)
- Ms. Chadaporn (Miang) Tanakasemsub (TC Co-chair)
- Ms. Sherry KERAMIDAS, Regulatory Affairs Professionals Society (RAPS), USA
- Ms. Susan TAN, RAPS, Singapore

Attendees (by invitation)

- Mr. Zamane Abdul Rahman, MOH Malaysia, Malaysia
- Ms. Sasikala A/P Thangavelu, MOH Malaysia, Malaysia
- Ms. Aidahwaty M.Olaybal, MOH Malaysia, Malaysia
- Ms. Nashirah Naiimi, MOH Malaysia, Malaysia
- Mr. Ahmad Shariff Bin Hambali, MOH Malaysia, Malaysia
- Mr. Hwee Beng WANG, Malaysia Medical Device Professional Association, Malaysia



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

Official Website: www.ahwp.info

- Ms. Nellie Ong, QuinteSSENCE Consultancy, Malaysia
- Mr. Nyan Tun Oo, SIEMENS, Malaysia
- Mr. Mizril Rishah Bin Mustafar Kamal, Malaysia Medical Device Professional Association, Malaysia
- Ms. Suki Lim, Stryker, Malaysia

Apology:

- Ms. Lindsay TAO, Johnson & Johnson, China (Vice-chair)

Group Photo



Opening Remarks

- Dr Saleh welcomed the delegates from Saudi Arabia, Singapore, Hong Kong and Malaysia for attending the AHWP Secretariat Meeting in Kuala Lumpur.
- Dr Saleh stressed the importance of strategic planning, partnerships with other international organizations towards harmonization of medical device regulations.

1. Adoption of the Agenda

The agenda was further updated, to include the on-site review at Sunway Convention Centre at KL (appended as **ANNEX_1**).

2. Roll Call

The meeting participants introduced their names and organizations during roll call.

3. AHWP Strategic Framework Towards 2020

The AHWP Strategic Framework was further consolidated as **ANNEX_2a** and



presented as **ANNEX_2b**, with the received comments from COCIR, RTI and Cook Medical. The follow comments on the presented “AHWP Strategic Framework Towards 2020” were received:-

3.1 For Framework Element One - AHWP Membership Expansion:

- a. It was suggested addressing sentences to ensure no conflict of interest.
- b. AHWP should welcome the contributions from both regulatory authorities and industries, not necessarily only highlighting the welcome to industry contribution. Therefore it was suggested that the revision in Framework Element One (**ANNEX_2b**) be further consolidated.

3.2 For Framework Element Four - Working Alongside with APEC and ASEAN to expand beyond regional blocks

- a. It was not that appropriate to discuss APEC strategic framework with much details directly under AHWP strategic framework element (**ANNEX_2a** / **ANNEX_2b**). It was suggested that the details could be arranged in other alternative ways such as referring the original text or link of APEC strategic framework.

3.3 It was mentioned that Framework Element Four and Five have some overlapping areas, which should be better clarified and differentiated.

4 AHWP Liaison Membership with Other Organizations

4.1 The proposed AHWP liaison membership was agreed by AHWP leaders, and the corresponding revision to House Rules of the related procedures would be prepared by Secretariat for resolution during 18th Annual Meeting in KL, Malaysia. It was commented that the sentence “to *welcome* the participation of liaison member” should be revised as “to *recruit / accept* the participation of liaison member” for more precise presentation.

5 Review of DRAFT AHWP House Rules for Liaison Member

5.1 Bryan introduced the background of liaison membership and the draft clauses for liaison membership adding to AHWP House Rules were prepared, as in **ANNEX_3**. It was agreed that the amendment to AHWP House Rules would go through the 4-step procedures for preparing AHWP official documents.

6 E-Newsletter

6.1 Jack would continue preparing the draft 2nd AHWP E-Newsletter based on references including the latest working group progress till AHWPTC Leaders Meeting in Feb for comments by Sep 2013, and send it to Secretariat for publishing (softcopy) on AHWP website after the 18th AHWP Meeting.



7 Training & Capacity Building

- 7.1 WG6 would further communicate with other WGs for their training needs. Jack would prepare the training deliverables with WG3 for Ali's review.

8 Updates on AHWPTC Leaders Meeting in Feb 2013

- Ali updated the deliverables of the AHWPTC Leaders Meeting in Bangkok, including the discussions with AHWPTC Advisors, table of current regulatory status of AHWP member economies and progress summary from WGs (appended as **ANNEX_4**).
- Progress updates from WGs presented at AHWPTC Leaders Bangkok Meeting were appended as **ANNEX_5**.
- A PROPOSED DOCUMENT (Ref No.: AHWP/WG2/PF001:2013) from WG2 was proposed for resolution at the 18th AHWP Annual Meeting. It was confirmed that the further revised document according to the comments from AHWPTC leaders would go through the 4-step procedures for preparing AHWP official document.
- Bryan updated that the tentative next TC Leaders Meeting would be either in India or in Hong Kong.

9 Updates on AHWP ASL

- 9.1 Bryan updated the financial status of ASL, with net assets of HK\$1,840.7K (around US\$236K) as of Mar 2013, and the net profit of HK\$35K (around US\$4.5K) for the period of Jan 2013 to Mar 2013, as in **ANNEX_6a**. It was reported that the tax for 12/04/2011 to 31/03/2012 was zero. Financial arrangements for ASL, including the tentative arrangements for tax filing (2012 - 2013), were also reported as in **ANNEX_6b**.

- 9.2 Bryan updated the ASL membership up to date as in **ANNEX_7**.

- 9.3 Bryan presented the draft agenda for the 2nd AGM of AHWP ASL, which would be held on 14 Nov 2013, concurrent with AHWP Main Meeting, as in **ANNEX_8**.

- 9.4 It was also updated that there should be election of new ASL BOD during the 2nd AHWP ASL AGM, as in **ANNEX_9**.

- 9.5 It was updated that the time for next AHWP ASL BOD Meeting would be further circulated by email.

10 AHWP Secretariat Work Updates

10.1 Obligation of AHWP Annual Meeting Host

- Bryan introduced the background of summarizing the obligation of AHWP Annual Meeting host, and summarized the related clauses in AHWP House Rules and a guidance document posted on AHWP website



in 2006, namely “Guidance for Member Economy hosting the Meetings of AHWP or its Technical Committees”, as in **ANNEX_10**. Suggested amendments to this guidance document, per the discussions and decisions endorsed during AHWP leaders and Secretariat Meetings, were presented as in **ANNEX_10**.

10.2 Review and updates of AHWP TOR, House Rules, guidance document, and ASL M&A, summarized in **ANNEX_11**:

- House Rules Clause 8–Applications for Joining AHWP (slide 4-7):
 - Detailed procedures for submitting application form to join AHWP as member economy was proposed to be added in Clause 8, per the suggestions received from AHWP leaders during 17th AHWP Annual Meeting in Chinese Taipei.
 - Draft clauses for AHWP Liaison Membership was proposed, as mentioned in Section 5 of this minutes.
- Guidance Document–“GUIDANCE for Member Economy hosting the Meetings of AHWP or its Technical Committees”, posted on AHWP website in 2006 (slide 8-15):
 - It was suggested that the name of this guidance document be revised as “GUIDANCE for Member Economy hosting the *Annual* Meetings of AHWP or its Technical Committees”.
 - It was suggested that any seed money for AHWP annual meetings should be on a request basis, and should subject to the endorsement from ASL BOD based on the financial conditions of ASL.
 - Suggested arrangements for collecting registration fees & sponsorships, as well as the surplus of AHWP annual meetings were presented.
- ASL M&A Clause 37 - Board of Directors (slide 16-end):
 - Bryan reported the conflict of voting rights for ASL BOD and for ASL associate member. It was suggested that any Director of the Board, once elected, should have the right to vote at ASL general meetings even if he/she was elected from an associate member.

10.3 Bryan reported the Secretariat supports from HKPC team to AHWP, AHWPTC, WGs and AHWP ASL in terms of administration, marketing, communication and technical aspects, as in **ANNEX_12**.

10.4 Secretariat supports to AHWP annual meeting and Conference were presented as in slide 8 & 9 of **ANNEX_12**.

10.5 The status for AHWP official website sponsorship and the arrangement for



AHWP business card were reported.

11 18th AHWP Annual Meeting and AHWP-RAPS Conference Preparation

11.1 Two on-site visits were arranged for all meeting attendees to Mandarin Oriental Hotel and the Sunway Exhibition Centre in KL, and confirmed that the venue for the 18th AHWP Annual Meeting & the 1st AHWP-RAPS Joint Conference as at Sunway Exhibition Centre in KL.

11.2 It was agreed that the agenda and scientific programme for both Meeting and Conference should be later discussed in more details through email circulations and/or tele-conference of steering committees.

11.3 Speakers would be further invited by local host with the support of Secretariat after the tentative programme was discussed and developed.

11.4 It was agreed that registration forms & fees for both Meeting and Conference would be processed and received by the local host, with the supports from AHWP Secretariat and RAPS on channelling the registrations.

11.5 The registration fees for AHWP 18th Annual Meeting & Conference were tentatively suggested as following:-

➤ For overseas participants:

- a. US\$600 for each event (either pre- registration or on-site registration)
- b. US\$950 for both events (Pre-registration)
- c. US\$1,150 for both events (On-site registration)

➤ For local participants:

- a. US\$500 for the Meeting / Conference / Both events (either pre-registration or on-site registration)

➤ Delegates:

- a. No specific comment received on this category. The practice in 17th AHWP Annual Meeting, i.e. 2 quotas for regulators from authority of each member economy would be considered and confirmed by ASL on a request basis, could be used as a reference.

11.6 Secretariat would coordinate with TC WG Chairs to facilitate any documents which would like to take resolution during the 18th AHWP Main Meeting.

11.7 It was agreed that the Meeting and Conference should budget separately and make separate financial sheets for better monitoring and dealing with the cash flows.

11.8 The seed money request, if any, should be sent together with the budget plan for ASL BOD's review and endorsement.

11.9 Mr Nyan Tun Oo presented the draft Meeting & Conference budget, and



revised the budget based on the comments from AHWP leaders on-site the meeting.

11.10 It was discussed that the expenditure on local tours should be clarified whether as part of meeting programme or not. It was also suggested that local tours could be sponsored by the local host according to their own resources.

11.11 Bryan represented the supports from AHWP Secretariat (HKPC) for the Meeting and Conference to the local host team, to facilitate the communication between local host and Secretariat towards the preparation of Meeting and Conference.

11.12 Mr Zamane suggested the preparation timeline, where the 1st Meeting and Conference announcement should be ready by the end of June.

For AHWP-RAPS Joint Conference Only

11.13 Sheery and Susan from RAPS joined the tele-con and updated the discussion of last tele-con before the Secretariat Meeting (meeting agenda and minutes attached as **ANNEX 13**).

11.14 Mr Zamane suggested that scientific programme of Conference, in addition to the proposed ones including Good Regulatory Practice and the Global Regulatory Framework, Health Technology Assessment (HTA), MD Single Audit Program (MDSAP) and UDI, might consider topics which could attract the interests for local industries for better promoting the registration.

11.15 It was suggested the Conference budget presented by local host during the meeting should be forwarded to RAPS for their further double checking and feedback.

[Post-meeting Remarks:-

- a. Secretariat has contacted with IMDRF and received the reply that the IMDRF meeting date could not be changed.*
- b. The Meeting and Conference dates were later changed to 2-5 Dec2013, and the availability of venue would be further confirmed with the support from local host team.*
- c. The budget of Meeting would be further updated after the confirmation of finalized venue.]*

12 Group Discussion

12.1 Applications for WG Membership from Non-member Economies

- Bryan introduced the background that there have been applications for WG membership from non-member economies, while according to



current TOR & HR of AHWP, there was no such clause on excluding application from non-member economies.

- However, according to the discussions in AHWP TC Leaders Bangkok Meeting in Feb 2013, i.e., per the voting results by all presenting TC leaders, it was supported that the WG membership should be available to applicants from AHWP member economies, while each WG could accommodate 2 members from non-member economies as WG Advisors, by the confirmation of Chairs of that WG.
- It was agreed by the AHWP leaders to keep WG members from AHWP member economies. A change in TOR or House Rule to reflect this thinking was suggested. Secretariat would prepare the corresponding amendment to AHWP TOR or House Rule for resolution in 18th AHWP Annual Meeting.

13 AOB

13.1 It was mentioned that the Meeting & Conference dates (11-14 Nov 2013), which would overlap with IMDRF annual meeting (12-14 Nov 2013) and might affect the invitation of speakers as well as the updates of IMDRF at AHWP Annual Meeting. It was suggested that Secretariat further communicate with IMDRF Secretariat to see if any possibilities for IMDRF to change the meeting dates.

13.2 It was suggested to open an account for AHWP in LinkedIn (Account name: “*AHWP Secretariat*”) for publicity. The AHWP LinkedIn account should be only for connection and membership promoting purpose, while all the official information and announcements should be posted on AHWP website.

14 Closing Remarks

14.1 Dr Saleh thanked all the participants from local industry and overseas, and the organizing team from MOH Malaysia.

15 Next meeting date, time and format

It was confirmed that the details of next AHWP Secretariat Meeting would be circulated by email.

Meeting adjourned at 15:30 on 7 May 2013.

- End -

Minutes Prepared by:

Mr Bryan SO & Ms Carol LIU

AHWP Secretariat