



AHWP Secretariat Singapore Meeting

Meeting Minutes

Date : 28 Feb 2012 (Tue)

Venue : Indiana Meeting Room, Fairmont Singapore & Swissotel the Stamford, Singapore

Time : 9:00am

Attendees

1. Dr. Saleh S. AL-TAYYAR, SFDA, Saudi Arabia (Chair)
2. Mr. Ali M. AL-DALAAN, SFDA, Saudi Arabia (Secretary General)
3. Mr. Essam Al Mohandis, SFDA, Saudi Arabia (Exe-Deputy Secretary General)
4. Prof. Jack WONG, Johnson and Johnson Medical, Singapore (Exe-Deputy Secretary General)
5. Mr. Bryan SO, Hong Kong Productivity Council, Hong Kong (Exe-Deputy Secretary General)
6. Mr. Abdullah ALRASHED, SFDA, Saudi Arabia (Deputy Secretary General)
7. Mr. Suhail AL QOMAIZY, Al-Jeel Medical & Trading, Saudi Arabia (Secretariat Team Member)
8. Ms. Carol LIU, Hong Kong Productivity Council, Hong Kong (Secretariat)

Attendees (by invitation)

9. Ms. Li-ling LIU, TFDA, Chinese Taipei (Vice-Chair) [Host of 17th AHWP Meeting]
10. Mr. Li-Fu LU, TFDA, Chinese Taipei [Host of 17th AHWP Meeting]
11. Mr. Shiu-huei YEH, TFDA, Chinese Taipei [Host of 17th AHWP Meeting]
12. Mr. Steven CHEN, TFDA, Chinese Taipei [Host of 17th AHWP Meeting]
13. Mr. Hui-Ye XU, TFDA, Chinese Taipei [Host of 17th AHWP Meeting]
14. Mr. Albert LI, ITRI, Chinese Taipei [Host of 17th AHWP Meeting]
15. Mr. Jeffrey CHERN, ITRI, Chinese Taipei [Host of 17th AHWP Meeting]
16. Ms. Lindsay TAO, Johnson and Johnson, China (Vice-Chair)
17. Ms. TRAN Quan, GE Healthcare, Singapore (Advisor to Chair)
18. Ms. Joanna KOH, Health Sciences Authority, Singapore (TC Chair)



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

19. Ms. Chadaporn TANAKASEMSUB [Miang], Zimmer (TC Co-Chair)

[Represented by Mr CAI Yiting and Ms Marianne YAP, Zimmer]

20. Ms Huifen BAI, Health Sciences Authority, Singapore

21. Ms. Patricia TEYSSEYRE, Johnson and Johnson Medical, Singapore

Group Photo



Opening Remarks

- Dr Saleh (Chair) welcomed the delegates from Saudi Arabia, Singapore, Chinese Taipei and Hong Kong for attending the AHWP Secretariat Meeting in Singapore.
- Dr Saleh stressed the importance of objective setting; priority setting for harmonizing within AHWP member economies; focusing on the interests of AHWP.

1. Adoption of the Agenda

The agenda as in **ANNEX (1)** was adopted without amendment.

2. Roll Call

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



3. AHWP Strategic Framework and Work Plan (2012-2014)

3.1 Strategic Framework

Lindsay reported the draft Strategic Framework of AHWP (2012-2014), as appended in **ANNEX (2)**, addressing the following five elements:

3.1.1 AHWP Membership Expansion

The following comments were received:-

- Means to better engage all member economies of AHWP would be needed.
- The acronym “AHWP” should remain unchanged even with further membership expansion and the global membership representation by AHWP.

3.1.2 Training & Capacity Building

The following comments were received:-

- To understand the needs of the 23 AHWP member economies would be the key.
- Trainings for both regulator authority and the industry were needed.
- Information technology should be applied to lower the financial barrier on receiving the training.
- AHWP would leverage the support from other international organizations on training (WHO, RAPS, WMDO, etc.),
- Q&A on the implementation of GHTF guidance could be prepared by TC and be accessible on AHWP web.
- Workshops should be organized on how to implement the adopted guidance of AHWP.

3.1.3 Harmonization in Key Areas Based on GHTF Principles

The following comments were received:-

- The criteria for “success” and “harmonization” should be further defined.
- AHWP’s self-initiated guidance documents should be developed in the future.
- Harmonized definitions, including definition of “Medical Device” should be further discussed and determined.
- Strategy towards counterfeit devices should also be developed.

3.1.4 Working Alongside with APEC towards Regional Regulatory Harmonization Goal by 2020

The following comments were received:-

- The APEC survey, as appended in **ANNEX (3)**, could serve as a reference for further understanding the needs of and gaps between AHWP member economies.



- Closer collaborations between AHWP and AHC should be made (e.g. the sharing of online training materials).

3.1.5 Increasing AHWP's Global Presence

The following comments were received:-

- Efforts should be made on understanding the needs and challenges of the developing countries within AHWP towards their setting up of regulatory framework.
- In view of the recent changes of GHTF and IMDRF, AHWP should strengthen our role to enable the active participation of the industry on harmonization of device regulatory.
- The involvement of the entire healthcare sector should be included in the AHWP strategic plan.
- AHWP should explore the stronger partnership with IMDRF, APEC, ASEAN, etc., and to further link up ISO, IEC, standard bodies, etc., for expert advisory. MOU could also be signed with the mentioned partners through AHWP ASL on need basis.
- AHWP would wait for the announcement of the TOR by IMDRF, before further discussion on any participation and involvement in IMDRF. Alternatively, AHWP could invite IMDRF to join AHWP work groups in the future.

3.2 Review on TOR and House Rules

3.2.1 Bryan reported the areas of ambiguity and the conflicting terms in the existing TOR and House Rules of AHWP.

3.2.2 A “DRAFT” documents on the revision of the TOR and House Rules would be prepared.

3.2.3 It was also recapped that, there were clearly defined procedures in AHWP House Rules (Clause 14), regarding the preparation of documents in AHWP.

3.2.4 Step-by-step preparation and endorsement of documents namely “DRAFT”, “PROPOSED”, “PROPOSED FINAL” and “FINAL” documents should be followed.

3.2.5 Awareness training on TOR and House Rules of AHWP would be organized.

3.3 Timeline of AHWP Meetings in 2012

- 27 Feb : 1st Secretariat Meeting, Singapore (completed)
- 1-2 Mar : 1st TC Leaders Meeting, Singapore (completed)
- 2 Mar : AHWP-WHO-APEC Meeting, Singapore (completed)



- 4 Mar : 3rd ASL BOD Meeting, Hong Kong
- 5-8 Jun : 15th TC Meeting, Philippines (to be confirmed)
- Sep (3rd week) : 2nd Secretariat Meeting, Saudi Arabia (to be confirmed)
- 2-6 Nov : 17th AHWP Main Meeting and 16th TC Meeting, Chinese Taipei
- Nov : 2nd ASL BOD Meeting, Chinese Taipei (during 17th Meeting)

3.4 AHWP ASL Updates

- 3.4.1 The next ASL Board of Directors (BOD) Meeting would be held on 4 Mar 2012 (Sun) at Hong Kong Productivity Council, Hong Kong.
- 3.4.2 The ASL BOD Meeting would review the financial status of AHWP, the services of the Company Secretary; discuss the mechanism for funding approval and disbursement, and the preparation of AGM, etc.
- 3.4.3 It was suggested that the sponsorship from the local companies, in addition to the meeting registration fees, could be directly received by the hosts of the TC and main meetings in the future.
- 3.4.4 ASL would directly receive the global sponsorship, mainly from the multi-national companies, to facilitate the invitation of delegates.

3.5 E-Newsletter

- 3.5.1 Jack would continue preparing the newsletter, where two newsletters would be produced each year to update the members as well as the external partners on the harmonization progress and activities of AHWP.

3.6 Nomenclature and UDI

- 3.6.1 Joanna highlighted the key items discussed in the IMDRF UDI meeting.
- 3.6.2 Discussions were focused on the 6 consultation areas, namely i) Combination Products, ii) IVD Kits, iii) Non IVD Kits, iv) Capital Equipment & other systems (Imaging, Refurbished/Remanufactured), v) DPM (Direct Part Marking of instruments and implants), vi) Software and "Stand Alone" Software.
- 3.6.3 UDI Ad-hoc work groups were formed, with leaders for different work groups also confirmed.
- 3.6.4 The support from the industry in different UDI Ad-hoc work groups was expected.
- 3.6.5 Other issues discussed during UDI meeting included GMDN/UMDN, coding system, UDI for reprocessed devices, where to place the UDI, level of packaging and exceptions on inclusion, etc.



3.7 TC Work Plan

- 3.7.1 The AHWP TC work plan would be discussed at the TC Leaders on 1-2 March 2012, after the Secretariat Meeting.

4. The 17th AHWP Annual Meeting Preparation

- 4.1 The day program for the 17th AHWP Meeting in Chinese Taipei was confirmed:-
2 Nov 2012 (Fri) : WG Meeting & TC Pre-Meeting [W Hotel Taipei]
3 Nov 2012 (Sat) : TC Meeting [W Hotel Taipei]
4 Nov 2012 (Sun): Workshops [Taipei International Convention Centre (TICC)]
5 Nov 2012 (Mon): Main Meeting [TICC]
6 Nov 2012 (Tue) : Main Meeting & Networking Forum [TICC]
- 4.2 TFDA would be supported by ITRI to host the 17th AHWP Meeting.
- 4.3 Organizing Committee (OC) for the 17th AHWP Meeting was formed and chaired by Ms LIU of TFDA, with OC members including Albert, Jeffrey, Ali, Joanna, Lindsay, Jack, Bryan, Miang and Quan.
- 4.4 ITRI would prepare the meeting budget and propose more details of the training workshops for discussion at the first OC tele-conference in late March 2012.
- 4.5 Promotion and registration would be started in April/May 2012.
- 4.6 HKPC of the AHWP Secretariat Hong Kong office would provide support on soliciting sponsorship from the multi-national companies, and to provide advice and support on meeting logistics.
- 4.7 Starting from the 17th AHWP meeting, each member economy which has received the financial subsidy from AHWP to attend AHWP meeting should provide a short report on the latest updates of their existing regulatory framework or challenges on setting up of regulatory framework in their corresponding economy.

5. AHWP TC Meeting

- 5.1 It was reported that Philippines has expressed their interests in hosting the next TC Meeting, tentatively on 5-8 June 2012.
- 5.2 Formal confirmation from Philippines MOH was pending.
- 5.3 Day program and finalized meeting schedule would be confirmed by Cecilia of the Philippines MOH, with details to be announced on AHWP website.

6. AHWP Secretariat Work Update

- 6.1 Bryan reported the recent updates on AHWP website, including the change of website sponsors, updating of office bearers for AHWP and AWHPTC, posting of new



membership list for WG and STG, etc.

- 6.2 SADS alert dissemination was performed weekly by HKPC of the AHWP Secretariat Office to the subscribed regulatory authorities of AHWP member economies.
- 6.3 Upcoming updates on AHWP website would include the putting up of the organization chart of AHWP, posting of new work plan of 2012-2014, etc.
- 6.4 Website enhancement including the setting of individualized front-page and further upgrading of SADS online system would be explored.
- 6.5 AHWP name cards would be produced for AHWP leaders and AHWP Secretariat team members. A name card request form would be prepared and circulated.
- 6.6 Having considered the expected utilization and cost-effectiveness, it was agreed that the support from the industry would continue to be sought on conference call line.
- 6.7 It was agreed that no paper-based AHWP official letters and envelopes would be prepared for the sake of environmental friendliness.
- 6.8 Standard AHWP letterhead in electronic format would be prepared by AHWP Secretariat.
- 6.9 It was agreed that the online payment gateway service would be procured, and to be reviewed after a one-year trial. Participants register to AHWP events via online payment would need to bear the extra administrative charges. Procurement of the online payment service would be made through AHWP ASL.

7. Group Discussion

7.1 AHWP Conference 2013

- 7.1.1 Dr Saleh proposed the organization of a 2-Day AHWP Conference in 2013. The Conference would compose of presentation sessions and a small-to-medium scale medical device exhibition.
- 7.1.2 Unlike the AHWP TC and Main Meeting which are more for internal discussion, the AHWP Conference would have a theme (e.g. the adverse incidents and emerging crisis in the medical device industry) and target more on the external parties.
- 7.1.3 The Conference, to be co-organized with other internal organizations in the harmonization of device regulatory, should target and address the concerns of the healthcare providers instead of the regulators and the medical device industries.
- 7.1.4 Quan would take the lead to further develop the details of the proposed Conference, with the support of a steering committee composing of Ali, Lindsay, Ms LIU, Joanna, Bryan and Jack. Progress would be reported in the next Secretariat Meeting.



7.2 To Promote the Active Participations of Members

It was proposed that new mechanisms to recognize the active member economies of AHWP should be developed, in order to encourage the active participations of all member economies. Ideas including the setting up of probation period for new members would be further discussed.

8. Conclusion

8.1 Dr Saleh delivered the closing remarks, and thanked all the members of the AHWP Secretariat Team, TC leaders and the Chinese Taipei team for their dedications and efforts in supporting the secretariat work of AHWP.

8.2 Participants were encouraged to continue sending their suggestions and comments to the Secretariat Team.

9. Date and Venue of the Next Meeting

Next AHWP Secretariat Meeting would be held in the 3rd week of September 2012. (Tentatively in Riyadh, Saudi Arabia)

The meeting was adjourned at 15:45.

Minutes Prepared by:

Mr Bryan SO

AHWP Secretariat