



## **AHWP Secretariat Riyadh Meeting**

### **Meeting Minutes**

**[DRAFT]**

Date : 18 – 19 Sep 2012 (Saudi Arabia Time Zone, GMT+3)  
Time : 9:00am (18 Sep), 8:30am (19 Sep)  
Venue : Al Majlis 3, AlFaisaliah Hotel, Riyadh, Kingdom of Saudi Arabia (KSA)

#### Attendees:

- Dr. Saleh S. Al-TAYYAR, SFDA, KSA (Chair)
- Mr. Ali M. Al-DALAN, SFDA, KSA (Secretary General)
- Mr. Bryan SO, Hong Kong Productivity Council, Hong Kong (Executive Deputy Secretary General)
- Mr. Essam Al-MOHANDIS, SFDA, KSA (Executive Deputy Secretary General)
- Mr. Abdullah Al-RASHEED, SFDA, KSA (Deputy Secretary General)
- Mr. Fahad ALMOAMMER, Saudi Medical Devices Industry, KSA (Deputy Secretary General)
- Mr. Faisal MATBULI, GE El Seif Medical Services Co. (Secretariat Team Member)
- Mr. Hattan GABBANI, Covidien AG, KSA (Secretariat Team Member)
- Ms. Carol LIU, Hong Kong Productivity Council, Hong Kong (Secretariat)

#### Attendees on Conference Line:

- Mr. Jack WONG, Johnson & Johnson, Singapore (Executive Deputy Secretary General)

#### Attendees (by invitation)

- Ms. Li-Ling LIU, TFDA, Chinese Taipei (Vice-chair)
- Ms. Quan TRAN, GE Healthcare, Singapore (Advisor to Chair)
- Ms. Reem El SAYED, GE Healthcare, United Arab Emirates (Observer)

#### Attendees on Conference Line (by invitation):

- Ms. Lindsay TAO, Johnson & Johnson, China (Vice-chair)
- Ms. Joanna KOH, SHA, Singapore, (TC Chair)
- Ms. Chadaporn TANAKASEMSUB [Miang], Zimmer (TC Co-chair)
- Ms. Sherry KERAMIDAS, Regulatory Affairs Professionals Society (RAPS), USA

## Group Photo



## Opening Remarks

- Dr Saleh welcomed the delegates from Saudi Arabia, Chinese Taipei, Singapore and Hong Kong for attending the AHWP Secretariat Meeting in Riyadh.
- 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 adopted without amendment (appended as **ANNEX\_1**).

### 2. Roll Call

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

### 3. AHWP Strategic Framework (2012-2014)

3.1 Lindsay reported the revised draft of Strategic Framework of AHWP (2012-2014), after the internal proof reading by Secretariat as appended in **ANNEX\_2**. The follow comments and updates were received:-

- The year of AHWP establishment should be further confirmed as in

- 1999 or 2000.
- In “*Working model and structure*”, it should be eight working groups and special task groups instead of seven.
  - It is very important to expand AHWP memberships by recruiting new member economies, and also to have more GHTF guidance documents adopted and implemented to further demonstrate the harmonization.
  - The description about potential training partners for cooperation with AHWP should be general, while the examples such organizations could also include ARPA, therefore revised as “*e.g. WHO, APEC, RAPS, MTLI, ARPA, etc*”.
  - Country updates from AHWP member economies including the latest regulatory news and directions should be included as regular reports.
- 3.2 Bryan will obtain any other comments from the leaders, consolidate it and seek for more comments from AHWP members via posting on the official website and via email circulation. The deadline for comments will be 24 Oct 2012. The document with consolidated comments from AHWP members will be made as PROPOSED FINAL for resolution at the 17th AHWP Meeting at Chinese Taipei.
- 4 Cooperation with Other Organizations
- 4.1 Dr Saleh reinforced the importance of strengthening AHWP partnerships with other international and regional organizations.
- 4.2 It was updated that AHWP has accepted the invitation by IMDRF, and confirmed our joining as an IMDRF Affiliated Organization in Apr 2012. Dr Saleh, AHWP Chair, will represent AHWP at the future IMDRF Management Committee Meetings as an Official Observer.
- 4.3 It was updated that ISO/TC 210 has accepted AHWP as a Liaison Member, and invited AHWP to nominate representatives of AHWP to join ISO/TC210 as formal members on behalf of their economies in Apr 2012. It was greatly encouraged for AHWPTC leaders to attend the coming ISO meeting to demonstrate our partnership.
- 5 Review of DRAFT AHWP TOR and House Rules
- 5.1 Bryan introduced the background of this amendment as to eliminate the ambiguous areas in AHWP TOR and the confliction between TOR and House Rules. It should be the principle to make the minimum amendments to the original TOR and HR possible.

5.2 The PPT for potential amendments to TOR and House Rules was appended as **ANNEX\_3**. The following comments were received:-

5.3 TOR Clause 1.2–Membership (slide 6):

- It was agreed that the Secondary AHWP Regulatory Representative should also be nominated by the medical device regulatory authority of the corresponding government.
- Organizations from the Industry should nominate the Primary and Secondary Representatives for each member of economy. The nominated industry representatives should be endorsed by the regulatory representatives of the same member economy, and be notified to the Secretariat.
- Any changes of industry representatives should be notified to regulatory representatives of the same member economy, and then be updated to the Secretariat.
- It was agreed that the nomination of AHWP both Primary and Secondary Industry Representatives should be left to each member economy themselves as there would be various situations for different economies.

5.4 TOR Clause 1.3–Leadership (Slide 7):

- It was agreed AHWP Chair and Vice-chair shall be elected from Primary regulatory representatives. Therefore House Rules Clause 3 should be corrected.
- Only primary representatives presented at the meeting could vote. Therefore it should be revised as “*through voting by all presenting Primary AHWP Representatives for a term of office until the next election*”.
- The whole sentence “*In the absence of the AHWP Chair and/or AHWP Vice-chairs at a given AHWP Meeting, they or the organizations that they are representing may nominate suitable persons as acting AHWP Chair and/or AHWP Vice-chairs for the purpose of the said meeting.*” shall be deleted as the Chair and Co-chairs have the responsibility to be present at such meetings.

5.5 House Rules Clause 3–Nominations and Elections of the AHWP Chair/Vice-chairs (Slide 8)

- Clause 3.A should be revised as “*AHWP Primary Representatives from Regulatory Authorities could be nominated by Primary AHWP Representatives as the candidates in the AHWP Chair election and AHWP Vice-chair (Regulatory Authority) election*”, to be consistent with

- TOR Clause 1.3–Leadership and with House Rules Clause 1.3.1.
- 5.6 TOR Clause 1.5–Relationship with Other Parties (slide 9)
- It was agreed to delete all the examples in Clause 1.5.1 as there may be new organizations established, making the updates of TOR unnecessarily frequent.
  - It was agreed that to revise Clause 1.5.1 as “*The Working Party shall work closely with other international and regional organizations to...*”.
- 5.7 TOR Clause 1.5–Relationship with Other Parties (slide 10)
- The proposed Clause 1.5.2 for liaison member was decided NOT to be included in the TOR at this moment.
- 5.8 TOR Clause 2.2–AHWPTC Membership (slide 11)
- It was agreed that this clause should be revised as “*The Primary AHWP Representative from the Regulatory Authority shall (changed from could) nominate both the Primary and Secondary AHWPTC Representatives for the Regulatory Authority of his/her economy. The Primary and Secondary AHWPTC Representatives from the Industry should be nominated (changed from elected) by the industry representatives of their own economy*”.
- 5.9 TOR Clause 2.3–AHWPTC Leadership (slide 12)
- It was agreed to leave the election of TC leaders by AHWP Primary Representatives unchanged, and the same as those clearly explained in the Bali meeting.
  - It was agreed AHWPTC Chair and Co-chairs shall be elected “*at the AHWPTC Meeting in line with AHWP Annual Meeting*”.
- 5.10 TOR Clause 4–Voting, Nomination, Election, Terms of Service, Change of Office Bearers/Representatives and Representation in the Absence of Representatives (slide 13)
- It was agreed to revise Clause 4.1–Voting as “*Each Primary AHWP Representative shall have one vote at the AHWP Meeting. Each Primary AHWPTC Representative shall have one vote at AHWPTC Meeting*”.
  - It was agreed to add clause 4.6 –4.6 Representation in the absence of the Representatives, that there should be NO cross-side representation, i.e. the industry side cannot represent the regulatory side, and vice versa.
- 5.11 TOR Clause 2.4–Working Groups (WGs) and Special Task Groups (STGs) (slide 14)
- The mechanism for WG Chairs election is not detail discussed in the TOR and House Rules. However it was agreed to leave the current mechanism

unchanged at this moment.

## 6 E-Newsletter

- 6.1 Jack would continue preparing the draft 2<sup>nd</sup> AHWP E-Newsletter based on references including the latest working group progress for comments by Sep 2012, and send it to Secretariat for publishing (softcopy) on AHWP website after the 17<sup>th</sup> AHWP Meeting.
- 6.2 It was suggested to leave some detailed contents only available at AHWP website to attract more visitors to the official website.

## 7 Training & Capacity Building

- 7.1 Jack updated that all links to relevant online training course providers and privileged pricing for AHWP members could be posted on AHWP website.
- 7.2 Jack updated that the training programme discussed with WHO only included tentative topic, financial arrangement, venue and date, and could not be conducted during the 17<sup>th</sup> AHWP Meeting at Chinese Taipei.
- 7.3 Dr Saleh suggested AHWP should sign MOU with WHO to identify the principles of cooperation, in order to facilitate the further arrangement and implementation under the umbrella of the signed MOU.
- 7.4 Jack would work with Bryan to prepare the draft MOU with WHO and seek the support for legal review from the Board of AHWP ASL.
- 7.5 Jack would prepare the training deliverables with WG3 for Ali's review, and work with Secretariat to obtain Ali's advice on the timeslot for this training during the 17<sup>th</sup> AHWP Meeting at Chinese Taipei.

## 8 17<sup>th</sup> AHWP Meeting Preparation

- 8.1 Director Liu reported the current preparation status of 17<sup>th</sup> AHWP Meeting, including the overall programme, the agenda individual events, budget overview, and the most updated registration status. (appended as **ANNEX\_4**)
- 8.2 It was noticed that if according to the reported budget, there would be a big gap of around US\$95K between estimated expenditure and income. It was suggested that the local host would approach more industry sponsorships while at the same time reduce some expenses. Director Liu mentioned that she would try her best to cover the deficits if any with the support from TFDA.
- 8.3 The current speaker invitation status was also updated (appended as **ANNEX\_5**). It was agreed to confirm the availability of speakers as soon as possible for the further arrangement of the meeting agenda.

## 9 AHWP Secretariat Work Updates

- 9.1 Bryan reported the Secretariat supports from HKPC team in terms of administration, marketing, communication and technical aspects (appended as

## ANNEX\_6).

- 9.2 The 4-step procedure for preparing AHWP official documents and the procedure for preparing AHWP reference documents (ANNEX\_7) were reinforced for their applications to AHWP strategic framework, resolutions, as well as the reference documents if applicable.
- 9.3 The status for AHWP official website sponsorship and the on-line SADS system with login password (currently for internal test only) were reported.
- 9.4 It was updated that the on-line payment gateway service from PayPal had already been communicated, where ASL has been paying the first year of services, and to be reviewed after one year. Local host of any AHWP activities could utilize it if it is preferred.

## 10 1st AHWP-RAPS Joint Conference

10.1 Quan recapped the background of the conference, i.e. as an echo to the Strategic Framework on partnership with other international organizations, AHWP has confirmed to take this best time cooperating with RAPS to upgrade the profile of AHWP in training capacity. The tentative conference proposal was appended as ANNEX\_8.

### 10.2 Principles

- It was agreed that the most important issue needs to be concerned for the success of the conference with exhibition is the audience. Mr Fahad suggested that the conference programme to be fine tuned to attract the participation of physicians and nurses.
- It was agreed that the conference theme & programme should be very carefully designed to make it unique & value-added in order to attract more audience and consequently the exhibitors.
- It was agreed that conference date should be further confirmed to avoid conflicting with other meetings in regulatory affairs and regular exhibitions. Two scenario for the conference date were suggested as follow:-
  - In May 2013, taking the time for enhancing AHWP partnership with RAPS a.s.a.p. However the conference in between two AHWP annual meetings might affect the number of attendees.
  - In Nov 2013, making the conference with exhibition in line with the 18<sup>th</sup> AHWP annual meeting as a grouped mega event.
- It was reinforced that the partnership shall be reflected, in terms of the arrangement, preparation, logistic and etc., as well as the steering and supports from RAPS for conference scientific part.

- Dr Saleh mentioned that he would meet Sherry in Seattle and have further discussion on issues including conference date and suggested topics.

### 10.3 Financial Issues

- Dr Saleh pointed out that the budgeted income was to some extent too optimized, and highly depends on regional participants, especially for the exhibition. Sherry also agreed on this and mentioned will try best to liaise the RAPS team and AHWP team for exhibition promotions.
- Dr Saleh raised the question about risk sharing mechanism. Sherry mentioned that RAPS is not taking benefit from the conference. It was confirmed by Sherry that RAPS would absorb the deficits resulted by RAPS manpower.

### 10.4 MOU:

- Sherry mentioned that the MOU draft would be sent out by end of Sep. Dr Saleh would discuss it with Sherry during his trip to Seattle in late Oct, targeting signing the MOU during the 17<sup>th</sup> AHWP Meeting at Chinese Taipei.

### 10.5 Other Issues:

- It was agreed that for exhibition the host will only need to provide the area and tables.
- Several conference logos were proposed was appended as **ANNEX\_9**. There was an unanimous vote on the 1st one and it was agreed that the wording including the conference theme needs to be further consolidated to better describe the conference. SFDA KSA shall be included as the supporter.
- Secretariat team would send the further information of conference date to Mr Fahad for further preparations.

## 11 Updates on 15th AHWP TC Meeting

- Ali updated the deliverables of the 15<sup>th</sup> AHWPTC Meeting at Manila, including the mechanism for Advisors, progress summary from WGs and STG(N) (appended as **ANNEX\_10**).

## 12 Updates on AHWP ASL

12.1 Bryan reported the updates on AHWP ASL (appended as **ANNEX\_11**). The financial status of ASL by 10 Sep 2012, with current assets of HK\$1,437K (around US\$185K) and total net assets of HK\$321K (around US\$41K) was reported.

12.2 The time, venue, and agenda of AHWP ASL 1<sup>st</sup> AGM were reported.

12.3 The action items to be conducted in the next step were reported.

13 Group Discussion

13.1 Advisor to AHWP

- Joanna proposed draft appointment of the Expert Panel of Advisors for the AHWPTC.
- Dr Saleh indicated that there should be some criteria for AHWPTC advisor. It was decided that the detailed mechanism of appointing Expert shall be further elaborated and circulated for comments.
- Once revised according to the comments from AHWP leaders, Secretariat will circulate appointment proposal for resolution at the 17<sup>th</sup> AHWP Meeting.

13.2 It was agreed that for the current vacancy of WG5 Chair, Joanna would contact SFDA China to confirm their availability. If not then new nomination could be further processed.

13.3 Host of 18<sup>th</sup> AHWP Meeting was preliminarily discussed. Joanna mentioned more reference information would be required for further consideration.

14 AOB

14.1 Quan mentioned the maintenance of GHTF FINAL documents given the scenario GHTF will dismiss at the end of 2012. Bryan reported that Secretariat has made some preparations to back up the GHTF website and documents.

15 Closing Remarks

15.1 Dr Saleh thanked all the participants from local industry and overseas, and the organizing team from SFDA.

16 Next meeting date, time and format

It was confirmed that the details of next AHWP Secretariat Meeting will be circulated to ASL BOD by email.

Meeting adjourned at 11:25am (SAT) on 19 Sep 2012.

- End -

Minutes Prepared by:

Mr Bryan SO & Ms Carol LIU

AHWP Secretariat