

3rd AHWP Secretariat Meeting

Meeting Minutes

Date : 22 July 2010
Venue : Shanghai Rainbow Hotel, 2000 Yan'an West Road, Shanghai, China
Time Started : 9.05am

Attendants

- Mr WANG Baoting, State Food and Drug Administration, China (Chair)
- Mr GAO Guobiao, State Food and Drug Administration, China (Secretary-General)
- Dr ZHU Xuejun, China Association for Medical Device Industry, China (Executive Deputy Secretary-General)
- Ms DU Huiqin, State Food and Drug Administration, China (Deputy Secretary-General)
- Mr WANG Xiangyu, State Food and Drug Administration, China (Deputy Secretary-General)
- Mr Mark LAU, Department of Health, Hong Kong (Deputy Secretary-General)
- Mr Bryan SO, Hong Kong Productivity Council, Hong Kong (Secretariat)
- Mr PENG Da, State Food and Drug Administration, China (Secretary of Secretariat)
- Mr ZHOU Siyuan, State Food and Drug Administration, China
- Ms Althea LAU, Department of Health, Hong Kong
- Ms BAI Jing, Abbott China, China
- Ms Rena HAN, Boston Scientific, China
- Ms Linda LIN, Boston Scientific, China
- Mr Davey HAN, BrightStars Hi-tech Development Co Ltd, China
- Ms Lindsay TAO, Johnson & Johnson, China
- Ms Amber WANG, Medtronic, China
- Mr Oscar YOUNG, Mindray Bio-medical Electronics Co Ltd, China
- Mr TIAN Yuehui, Neusoft Medical Systems Co Ltd, China
- Ms ZHAO Yixin, Shandong Xinhua Medical Instrument Co Ltd, China
- Mrs Chadaporn TANAKASEMSUB (Miang), Zimmer Medical Co Ltd, Hong Kong

Guests

- Dr Saleh AL-TAYYAR, Saudi Food and Drug Authority, Kingdom of Saudi Arabia (Host of the 15th AHWP Meeting)
- Ms Joanna KOH, Health Sciences Authority, Singapore (AHWPTC Chair)
- Mr CAI Yiting, Health Sciences Authority, Singapore

Opening Remarks

- Mr WANG Baoting, on behalf of the AHWP and Chinese SFDA, delivered the opening speech. Mr WANG expressed his warm welcome to all the participants of the 3rd AHWP Secretariat Shanghai Meeting.
- Mr WANG summarized the good progress made in 14th AHWP Hong Kong Meeting in Nov 2009 and the successful completion of the 10th AHWP TC Singapore Meeting in May 2010. Separate meetings were held with GHTF during the TC Meeting in Singapore, with good exchange of ideas with GHTF including the medical device nomenclature.
- Mr WANG expressed special thanks to Saudi FDA for the hosting of the 15th AHWP Riyadh Meeting to be held on 27 Nov – 1 Dec 2010 and all the planning and organizing activities that had been done.
- Mr GAO Guobiao, Secretary-General of AHWP, expressed his sincere thanks to all the colleagues in the Secretariat for their great efforts contributed to the smooth operations and many accomplishments of the Secretariat.

1. Adoption of Agenda

- 1.1. Mr WANG proposed and was unanimously agreed to add to the agenda a visit to the Shanghai Expo on 23 July 2010 after the completion of the discussion items.

2. Roll Call

- 2.1. Mr GAO announced the start of the meeting, followed by a roll-call.

3. Preparation Work for the 15th AHWP Meeting

- 3.1. Dr Saleh briefed on the progress of the preparation work for the 15th AHWP Riyadh Meeting to be held on Nov 27 to Dec 1, 2010 at the Al Faisaliah Hotel, Riyadh, Saudi Arabia.
- 3.2. Dr Saleh reported the formation of the Saudi Meeting Organizing Committee, confirmation of meeting venue, assignment of the event manager and drafting of the programme.
- 3.3. Registration through the event manager was commenced and the registration form was posted on the AHWP website. There were nine registrations received separately from China, Pakistan, Jordan, Singapore and Saudi Arabia. More registrations were expected when getting closer to the event.
- 3.4. Hotel information was uploaded to the AHWP website. The most economic hotel recommended by Saudi FDA would cost around USD95-110 per person per night. Transportation between the airport, hotels and the meeting venue would be arranged and provided by Saudi FDA. Saudi FDA would assign one resident staff to every recommended hotel for providing support to the meeting participants.

- 3.5. The draft meeting programme was posted on the AHWP website, where:~ 27 Nov- AHWPTC Meeting, 28 Nov- Workshop Training and Visit, 29 Nov- Updates by Member Economies, 30 Nov- 15th AHWP Main Meeting, 1 Dec- Workshops and GHTF Update.
- 3.6. Saudi FDA would take care of the invitations to new members and neighboring countries (e.g. Egypt), and the invitation to the senior executives from international authorities (e.g. USFDA, WHO, Health Canada, etc).
- 3.7. Mr Mark LAU supplemented that all the invitations to guest speakers had been sent out and some had already accepted. He would pursue the invitations and provide the update in the monthly teleconferences.
- 3.8. Mr Bryan SO reported the updates on sponsorship for the 15th AHWP Riyadh Meeting The detailed arrangement on cocktail, lunch and dinner sponsors would be further discussed with the Event Manager.
- 3.9. Mr Bryan SO also reported the overall budget for the sponsorship to guests, speakers and regulators was at around USD50-80K. The budget would cover the hotel accommodation and air ticket costs. The detailed arrangements would be discussed in the monthly teleconferences.
- 3.10. Dr Saleh reported that the 15th AHWP Riyadh Meeting was endorsed by the King of Saudi Arabia, and all government departments would provide full support to the event.
- 3.11. Special arrangement would be made with the Ministry of Foreign Affairs and Immigration Authority in Saudi Arabia to provide support on entry visa and related matters at the Saudi Airport. A help counter would be set up in the airport to assist delegates upon their arrival.
- 3.12. Dr Saleh informed that normal dress code would be fine for all male and female participants. Covering jackets would be distributed to female participants at the help counter. AHWP Secretariat would send reminders to all participants regarding this arrangement in due course.

4. TC Work Progress

- 4.1. Ms Joanna KOH reported the successful completion of the 10th AHWP TC Singapore Meeting in May 2010 and highlighted the work progress of each TC Working Group.
- 4.2. The revenue generated from 10th AHWP TC Singapore Meeting was being transferred to the AHWP Secretariat.
- 4.3. Under the current practice, new member applications received through AHWP Secretariat would be passed to WG Chairs for endorsement. It was proposed and agreed that approval criteria should be setup for working group members such that they could make contributions. The criteria should include the requirement to attend the AHWP/AHWPTC Meetings and the maximum number of WGs that each person could join. It would be further discussed by the TC and Secretariat.

- 4.4. Mr CAI Yiting reported a request made by a consultant to join AHWP. After discussions, it was agreed that consultants would be allowed to join as “Observers” if not objected by the regulatory authorities of their corresponding member economies.
- 4.5. In order to keep the most updated list of active members, the Secretariat would prepare and send the membership form to all AHWP members, to request for updating of contacts and designations.
- 4.6. Ms Joanna KOH also reported the areas of collaboration with GHTF, including the certificate training, advisory and expert panel.
- 4.7. The 11th AHWP TC Chinese Taipei Meeting would be held on 6-7 Sep 2010 at the Far Eastern Plaza Hotel, Chinese Taipei. More promotion would be made in due course.
- 4.8. Ms Joanna KOH reported the updates from the GMDN Board of Trustees Meeting held in Oxford, UK. The updated fees for entry, membership annual renewal, access codes (category code) and fee structure for different types of subscribers were reported. Two representatives from AHWP were invited to join the board of trustees of GMDN agency. It was discussed and agreed that one from Singapore HSA and one from China SFDA would be nominated to represent AHWP to negotiate with GMDN Agency and their travelling expenses would be covered by AHWP funds if needed. Five representatives tentatively proposed from China, Malaysia, Saudi Arabia, Singapore and South Korea would be nominated to join the PAG of GMDN.
- 4.9. Mr WANG Baoting commented that the organizational structure, fee charging mechanism, etc., of the GMDN agency was still not satisfactory despite the great effort made to increase the number AHWP representatives in the GMDN Board of Trustees and the number of AHWP members in PAG. Should it be unable to meet the requirements resolved in the 14th AHWP Meeting, AHWP might consider other alternatives in the 15th AHWP Riyadh Meeting.

5. Summary of Secretariat Work in 2010

- 5.1. AHWP website was kept updated under the management of the Hong Kong Productivity Council as the AHWP Secretariat Hong Kong Branch. Website sponsors were recruited or renewed.
- 5.2. Mr Bryan SO reported the AHWP financial status with funds at around USD80K, contributed from the surplus of 14th AHWP Hong Kong Meeting, AHWP website sponsorship and the 10th AHWP TC Singapore Meeting. A budget plan for the year 2011 and the annual financial statement would be prepared and presented during the 15th AHWP Riyadh Meeting.
- 5.3. Ms Althea LAU reported the progress on the setting up of legal entity. The revised draft M&A had been posted on AHWP website until end May 2010 and no further comment was received. The invitation to Mr Ali Al Dalaan of Saudi FDA to be the First President

and invitations to join the first Board of Directors would be sent out shortly so that the AHWP Administration Services Ltd could be set up as soon as possible. It was anticipated that the setting up of the legal entity could be completed before the 15th AHWP Riyadh Meeting so that it could commence operations as scheduled..

- 5.4. The next e-Newsletter was being prepared. The Secretariat would seek updates from Mr Jack WONG who had been collecting information from member economies.
- 5.5. Some economies expressed interests in joining AHWP and the Secretariat would arrange the invitations.
- 5.6. Update on the cooperation with GHTF was reported. GHTF invited AHWP to join the GHTF as a member. This matter would be further discussed in details.
- 5.7. Training plans and activities were discussed. Proposed ideas included the organization of free training sponsored by companies would be explored in details.
- 5.8. AHWP Training platform would be set up in Hong Kong upon the setting up of the AHWP legal entity in Hong Kong.
- 5.9. The nomenclature issue would be further discussed in the coming 11th AHWP TC Chinese Taipei Meeting and AHWP Secretariat Meetings.
- 5.10. Mr WANG expressed his appreciation to the AHWP Secretariat Hong Kong Branch for their dedications in AHWP activities and taking care of the AHWP financial arrangement. Thanks also given to all the company sponsors of AHWP for their generous supports. He also suggested that principles and criteria for using the funds should be developed for ensuring their best use in the future.
- 5.11. Mr WANG thanked the great passion and dedication of Ms Joanna KOH, Chair of TC, for her excellent accomplishments and contributions to the TC.
- 5.12. Mr Wang also thanked Dr Saleh for the well planning and organizing of the 15th AHWP Meeting and the hospitality to the participants.

6. Work Plan of AHWP Secretariat in next half-year

- 6.1. Summary and comparison on regulatory framework of AHWP in 2010 was discussed. Mr Davey HAN presented the plan on the comparison study. By September 2010, the comparison template would be sent to all member economies with the support of the Secretariat. Findings would be summarized and presented during the 15th AHWP Riyadh Meeting for the member economies to make reference. Other WGs who also conducted their separate surveys (e.g. definition of manufacturers, clinical trials and studies, etc) would be consolidated for processing and reporting.
- 6.2. Nomenclature and UDI would be further discussed. Ms Joanna KOH and Mr CAI Yiting would follow up and report progress in the next meeting.
- 6.3. The setting up of AHWP Administration Services Ltd. in Hong Kong would proceed as planned. Ms Althea LAU and Mr Mark LAU would follow up and report progress in the

next meeting.

6.4. The e-Newsletter would be prepared by Mr Jack WONG.

6.5. Financial budget for the year 2011 would be prepared by Mr Bryan SO and submitted for approval in the 15th AHWP Riyadh Meeting.

7. **Summary of Meeting by AHWP Chair or Secretary General**

7.1. Mr GAO Guobiao summarized the agenda items discussed during the 3rd AHWP Secretariat Shanghai Meeting and thanked all participants for their contributions, efforts and dedications to achieve a fruitful meeting with all the agenda items duly completed.

7.2. The meeting was adjourned at 5:30pm.