

AHWP TC Leaders Bangkok Meeting 2013

Meeting Minutes

[DRAFT]

Date : 26 – 27 Feb 2013

Time : 9:30am (Bangkok Time)

Venue : Conference Room, 8/F, Zimmer Medical (Thailand), Bangkok, Thailand

Present:

- Ms. Joanna KOH, HSA, Singapore (TC Chair)
- Mr. Ali M. AL-DALAAN, SFDA, Saudi Arabia (TC Co-chair & WG3 Chair)
- Ms. Chadaporn TANAKASEMSUB (Miang), Zimmer Medical, Thailand (TC Co-chair)
- Ms. Quan TRAN, GE Healthcare, Singapore (Advisor to Chair)
- Mr. Bryan SO, Hong Kong Productivity Council, Hong Kong SAR (Executive Deputy Secretary General)
- Ms. Woei-Jiuang WONG, HSA, Singapore (Potential WG1 Chair)
- Mr. Alfred KWEK, GE Healthcare, Singapore (WG1 Co-chair)
- Ms. Pei-Weng TU, TFDA, Chinese Taipei (Deputy of Director LIU, WG1a Chair)
- Mr. Jeffrey CHERN, ITRI, Chinese Taipei (WG1a Co-chair)
- Mr. Wen-Wei TSAI, TFDA, Chinese Taipei (colleague from WG1a)
- Mr. Hsih-Te YANG, TFDA, Chinese Taipei (colleague from WG1a)
- Mr. Yorkie CHOW, MDCO, DOH, Hong Kong SAR (WG2 Chair)
- Mr. Saini Kulwant, Johnson & Johnson, India (WG2 Co-chair)
- Mr. Abdulah AL-Rasheed, SFDA, Saudi Arabia (WG4 Chair)
- Ms. E.H. CHO, Abbott Vascular, Korea (WG4 Co-chair)
- Ms. Yuwadee PATANAWONG, Thai-FDA, Thailand (WG5 Chair)
- Ms. Sumati Randeo, Abbott Lab, India (WG5 Co-chair)
- Ms. Ming Hao TAN, HSA, Singapore (Potential WG6 Chair)
- Mr. Philippe Auclair, Abbott Lab, Belgium (TC Advisor)
- Mr. Michael Gropp, Medtronic, Inc., USA (TC Advisor)
- Mr. Leighton Hansel, Abbott Lab, USA (TC Advisor)
- Dr. Petra Kaars-Wiele, Abbott Lab, Germany (TC Advisor)
- Mr. Mr Greg Leblanc, Cook Medical, Canada (TC Advisor)
- Dr. Peter Linders, Philips Healthcare, Netherlands (TC Advisor)
- Mr. Benny Ons, BD Europe, Belgian (TC Advisor)
- Mr. Grant Ramaley, Aseptico Inc., USA (TC Advisor)
- Mr. Scott Sardeson, 3M Health Care, USA (Advisor to TC)
- Ms. Shirley Sum, Johnson & Johnson, Singapore (Deputy of Dr Eamonn Hoxey)
- Ms. Carol LIU, Hong Kong Productivity Council, Hong Kong SAR (Secretariat)

Apology:

- Ms. Lindsay TAO, Johnson & Johnson, PRC (Vice-chair)
- Ms. Li-Ling LIU, TFDA, Chinese Taipei (Vice-chair)
- Mr. Ee Bin LIEW, Philips, Singapore (WG3 Co-chair)
- Dr. Rama SETHURAMAN, HSA, Singapore (WG6 Chair)
- Mr. Jack WONG, Terumo BCT (Asia Pacific) Ltd, Hong Kong SAR (WG6 Co-chair)
- Mr. YANG Lian-Chun, CFDA, PRC (STG(N) Chair)
- Ms. Carol YAN, Johnson & Johnson, PRC (STG(N) Co-chair)
- Dr. Eamonn Hoxey, Johnson & Johnson, USA (Advisor to TC)

Group Photo:



1 Opening Remarks

Joanna welcomed the delegates from Saudi Arabia, Singapore, Chinese Taipei, USA, Europe, Hong Kong and Thailand for attending this TC Leaders Meeting 2013 in Bangkok. She further introduced the Chair and Co-chairs of AHWP TC and the meeting agenda.

2 Adoption of the Agenda

After amendment the agenda as in **ANNEX (1)** was adopted.

3 Roll Call

- The meeting participants introduced their names and organizations during the roll call.
- Bryan introduced the Chairs and Co-chairs of each Working Groups & Special Task Group (WGs & STG), as well as the newly appointed TC Advisory Panel, as in **ANNEX (2)**.

4 AHWP Strategic Framework

- 4.1 Bryan introduced the goals of AHWP, and the AHWP Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon" as in **ANNEX (3)** to all the Advisors, including the background, strategic objectives, the five key framework elements and the indicator of success.
- 4.2 The following items were discussed, including:-
- The regulatory model adopted by AHWP TC;
 - The needs for continued education and capacity building, and
 - The identification and training of future leaders.

5 AHWP Member Economies (MEs) Current Regulatory Status

- 5.1 Bryan reported the brief summary of regulatory status of AHWP member economies by 22 Feb 2013, and updated it based on feedback received on-site on 27 Feb 2013, as in **ANNEX (4)**.
- 5.2 It was agreed that the regulatory status received could help understand the views from regulatory authorities of AHWP member economies.
- 5.3 It was suggested that the regulatory status chart could contain some concise descriptions in the future. Secretariat would collect the reference document from Mr Sardeson, revise the template and further circulate to MEs for reply.

6 Objective of AHWP TC Leaders Meeting in Bangkok

Joanna introduced the roles of AHWP TC to the TC Advisory Panel as well as the objective of this meeting, as in **ANNEX (5)**.

7 SWOT Analysis for AHWP TC

- 7.1 TC Co-chair Ali reported the strength, weakness, opportunity and treats (SWOT) of AHWP, which was summarized in 2012 Singapore TC Leaders Meeting, as in **ANNEX (6)**.
- 7.2 The following comments/suggestions were received from the TC Advisors, including:-
- It was mentioned that the proposed challenges were previously faced by GHTF and currently faced by other harmonization forums, including AHWP;
 - There was a potential issue of lacking of industrial commitment for harmonization. It was mentioned that the way to enhance the participation of local manufacturers would still rely on more close liaison with them by the regulatory authority;
 - The TC Advisors mentioned that it would be an opportunity for AHWP to develop the guideline/model which could be better adopted by member

economies, and it was important to have member economies to make active participation for developing the guidelines.

- It was suggested that AHWP could consider different phases of harmonization according to different classes of medical devices on a risk basis.

8 Discussion on the Role of Consultants in AHWP

8.1 Bryan reported the background and proposed the new type of membership for AHWP liaison member, as included in **ANNEX (7)**

8.2 The following items were discussed, including:-

- The objectives of including liaison participation or observers to AHWP, as well as their roles should be more clearly defined;
- The criteria for liaison members might be further clarified. AHWP should also consider including persons apart from regulator and industry background (e.g. academic associations, standardisation bodies and patient groups) as liaison members.

8.3 Secretariat would further consolidate the draft amendment to AHWP House Rule

9 Individual WGs Updates on Work Plans and Progresses

9.1 TC Co-chair Miang and Chairs/Co-chairs of individual WGs reported the WG implementation plans and the current status, as in **ANNEX (8)**;

9.2 A quick summary of WGs updates could also be found, as in **Meeting Summary ANNEX (9)**;

10 AHWP-RAPS Conference Updates

10.1 The status for organizing the 1st AHWP-RAPS Joint Conference was reported by Quan, as included in **ANNEX (10)**;

10.2 The conference would be held on 11-12 Nov 2013 in Malaysia, back-to-back with the 18th AHWP Annual Meeting on 13-14 Nov 2013.

[Post-meeting remark: The events dates were later revised to 2-3 Dec 2013 for the Conference, back-to-back with the Meeting on 4-5 Dec 2013.]

11 Closed Sessions for TC Leaders and Advisors in Own Groups

11.1 Voting among 4 options in regarding to “*whether WG membership could continued to be valid*” were conducted during the closed session for TC Leaders, as in **Meeting Summary ANNEX (9)**. The 4 options were:-

- i. WG member moving from member economy to non-member economy;
- ii. WG member moving from one company to another company within

member economies (Voted by WG1, WG1a, WG2, WG3, WG4, WG5 and WG6);

- iii. WG member moving from medical device industry to another industry;
- iv. Allow appointing a proxy/representative for whom NOT based in member economies;

Therefore, it was concluded that AHWP WG member must be working based in member economy, in medical device industry. This conclusion was proposed to Secretariat for the amendment in AHWP TOR and/or House Rules.

11.2 Scott presented the sharing summarized from the closed group discussion session for TC Advisors, on the development of AHWP Regulatory Model, e.g., gap analysis, focuses that could be considered, development processes, internal structure and international alignment, etc., as in **ANNEX (11)**;

12 Open Discussion for TC Leaders and Advisors

The discussions during this session, including the roles of TC, WGs and TC Advisors, etc., were summarized, as in **Meeting Summary ANNEX (9)**;

13 Upcoming AHWP Meetings

Bryan updated the schedule of upcoming AHWP major events as follows:-

- a. *AHWP Secretariat Meeting [6-7 May 2013 Malaysia]
 - b. 1st AHWP-RAPS Joint Conference [11-12 Nov 2013 Malaysia]
 - c. AHWP TC Meeting [13 Nov 2013 Malaysia]
 - d. AHWP Main Meeting [14 Nov 2013 Malaysia]
 - e. *Next AHWP TC Leaders Meeting [Feb/Mar 2014 India/Hong Kong]
- * Close Meeting

[Post-meeting remarks: The date for 1st AHWP-RAPS Joint Conference was later changed to 2-3 Dec 2013; AHWP TC Meeting date was later changed to 4 Dec 2013, and AHWP Main Meeting date was later changed to 5 Dec 2013.]

14 Closing Remarks

Joanna thanked all the meeting participants and the organizing team from Zimmer Medical (Thailand).

15 AOB

AHWP TC WG membership should be granted by member economy basis

16 Next Meeting Date, Time and Format

It was confirmed that the details of next AHWP TC Leaders Meeting will be further

circulated to TC Leaders and TC Advisors by email.

Meeting adjourned at 5:00pm (Bangkok) on day 2.

- End -