Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

17th AHWPTC Meeting Minutes

[DRAFT]

Date : 4 Dec 2013
Time : 10:30am (Malaysia local time)
Venue : Lagoon Room 3, 15/F, Sunway Resort Hotel & Spa, Kuala Lumpur, Malaysia

Present:

- Dr Saleh, SFDA, KSA (AHWP Chair)
- Ms Li-Ling LIU, TFDA, Chinese Taipei (AHWP Vice-chair & WG1a Chair)
- Ms Lindsay TAO, Johnson & Johnson, China (AHWP Vice-chair)
- Mrs Joanna Koh, HSA, Singapore (TC Chair)
- Mr Ali M. AL-DALAAN, SFDA, KSA (TC Co-chair & WG3 Chair)
- Ms Quan TRAN, GH Healthcare, Singapore (Advisor to Chair)
- Ms Tan Ming Hao, HSA, Singapore (WG1 Chair)
- Mr Alfred Kwek, GE Healthcare, Singapore (WG1a Co-chair)
- Mr Jeffrey Chern, ITRI, Chinese Taipei (WG1a Co-chair)
- Ms Jennifer Mak, DOH, HKSAR (WG2 Chair)
- Mr Ee Bin LIEW, Philips Healthcare, Singapore (WG3 Co-chair)
- Mr Abdulah AL-Rasheed, SFDA, Saudi (WG4 Chair)
- Ms Eun Hee CHO, Abbott Vascular, Republic of Korea (WG4 Co-chair)
- Ms Yuwadee PATANAWONG, Thai-FDA, Thailand (WG5 Chair)
- Ms SUMATI Randeo, Abbott Laboratories (WG5 Co-chair)
- Dr Rama SETHURAMAN, SHA, Singapore (WG6 Chair)
- Mr Jack WONG, Terumo BCT, HKSAR (WG6 Co-chair)
- Ms Victoria Qu, J&J, China (STG(N) Secretary)
- Dr Philippe Auclair, Abbott Laboratories (TC Advisor)
- Mr Michael Gropp, independent (TC Advisor)
- Mr Leighton Hansel, independent (TC Advisor)
- Dr Eamonn Hoxey, J&J (TC Advisor)
- Mr Greg Leblanc, Cook Medical (TC Advisor)
- Mr Benny Ons, BD Europe (TC Advisor)
- Mr Grant Ramaley, Aseptico Inc (TC Advisor)
- Mr Scott Sardeson, 3M Health Care (TC Advisor)
- Mr Bryan SO, Hong Kong Productivity Council, HKSAR (Exe-Deputy Secretary General)
- Ms Carol LIU, Hong Kong Productivity Council, HKSAR (Secretariat)

Apology:

- Ms Chadaporn TANAKASEMSUB (Miang), Zimmer (TC Co-chair)
- Mr YANG Lian-Chun, CFDA, China (STG(N) Chair)
- Ms Carol YAN, Johnson & Johnson, China (STG(N) Co-chair)
- Ms Petra Kaars-Wiele, Abbott (TC Advisor)
- Dr Peter Linders, Philips Healthcare (TC Advisor)

1. Opening

1.1 Mr Mohd Amin Yaakob, Senior Principal Assistant Director, Medical Device Authority, Malaysia welcomed and thanked all the participants for attending the 17th AHWPTC Meeting.

1.2 Dr Saleh, Chair of AHWP, thanked all the participants for their joining of the Meeting. He further extended his gratitude to the Medical Device Authority, Malaysia for their hosting of this Meeting. Dr Saleh also gave his appreciation to the organizing committee members, the members of Malaysian Medical Device Professional Association and the AHWP Secretariat for all the arrangements of this Meeting.

2. Adoption of the Agenda

The following amendments to the agenda were made:

2.1 The agenda items "Introduction of TC advisors" and "Short speech by TC Advisors Representatives" were changed right after the first Tea Break at 11am.

2.2 The agenda item "Updates from Secretariat" was changed to "Updates from Secretariat and Election of WG7 Co-Chair".

3. Roll Call

The roll call was made by AHWPTC leadership, Working Group (WG) and Special Task Group (STG) Chairs and Co-chairs, TC Advisors as well as representatives from AHWP member economies.

4. Introduction of TC Advisors

4.1 Joanna introduced the presenting TC Advisors to the Meeting participants.

4.2 Mr Scott Sardeson represented TC Advisors to share the recommendations made by TC Advisors in the TC Leaders Meeting in Bangkok, in regard to the prioritization of AHWP projects, the varying levels of experiences in AHWP member economies, and the future direction of AHWP.

5. TC Report

Joanna reported the feedback based on the recommendation by TC Advisors including 1) Playbook for regulatory control and implementation; 2) Gap analysis process in review GHTF guidance documents, and 3) Formation of Working Group 7 on standards.

6. Updates by WGs and STG(N)

6.1 WG1 Updates by Ms MingHao Tan (WG1 Chair)

a. MingHao reported the completed WG items, including the mapping of CSDT to STED, review of GHTF definition of medical device, the overview of software and the training on medical software completed in 2012. The number of active WG1 members was 35.

b. MingHao also updated the on-going WG1 items, including the gap analysis in pre-market aspects for ASEAN medical device control harmonization, medical software guidelines for pre-market registration, the preparation of combination products guidelines through research and white paper, and medical device grouping guidelines.

c. Mr Michael Gropp mentioned that the combination product guidelines done by GHTF and how the ministry had carried out the review at the drug side for combination products could be good reference for WG1. Joanna recommended the collaboration with WG1a-IVDD as well, to define combination product holistically.

6.2 WG1a Updates by Mr Jeffrey Chern (WG1a Co-chair)

a. Jeffrey reported the completed work items including the development of GHTF guidance on IVD, list of recognized standards for IVD, best practices for clinical evaluation and investigation on IVD. He also updated WG1a activities

including the first African Regulatory Forum for Medical Diagnosis held in Jul 2013, and the WG1a–PAHWP-LSHTM Joint Conference held in Sep 2013. The number of active WG1a members was 21.

b. Four proposed documents, including the IVD regulatory framework, IVD essential principle of safety and performance, IVD STED, comparison of IVD STED and IVD CSDT had gone through the call for comments process and would seek for endorsement at the 18th AHWP main meeting.

c. Jeffrey updated WG1a coming work focuses including the development of AHWP guidance documents on IVD medical devices, training, affordable and accessible IVD (AAIVD) medical devices. Other WG1a coming work targets were also reported, including the participation in ISO/TC212, gap analysis on registration, listing and product grouping and related guidance, guidance for implementation of GCP for IVD medical devices, etc.

d. Comments were received from the floor, which included that there was no binding of member economies on the proposed guidance documents but only recommendation (same for the GHTF documents in the past), and that the nomenclature for IVD should be in line with general medical devices to allow economies with emerging regulatory frameworks easier preparations of new legislations for both medical device and IVD for the playbook. The importance of training was confirmed and further stressed.

6.3 WG2 Updates by Ms Jennifer Mak (WG2 Chair)

a. Due to the change of post, Mr Yorkie Chow resigned and Ms Jennifer Mack took up the WG2 Chair. Jennifer thanked the leadership work done by the preceding WG2 Chair and Co-chair, and updated the vacant of WG2 Co-chair due to Dr Saini's retirement. The number of active WG1 members was 20.

b. The proposed document "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative" had gone through the call for comments process, and would seek for endorsement at the 18th AHWP main meeting.

c. Jennifer reported the endorsement of two AHWP guidance documents, i.e., Definition and Classification of Field Corrective Actions and Medical Device Adverse Event (AE) Report Form in AHWP 2012 main meeting. She also reported the completed work items including the harmonization of definitions of PMS terms, the electronic AE report form available on AHWP official website for member economies, and the training on WG2/GHTF SG2 guidance documents and implementations carried out together with WG6.

d. Coming work items were updated, including Safety Alert Dissemination System (SADS) upgrade and review of SADS guidance document, AE reporting requirements and timeline for medical device manufacturers and its authorized representatives.

e. Dr Philippe Auclair mentioned that IMDRF would modify NCAR system, and recommended WG2 future development of SADS in line with the modified NCAR system. Mr Scott Sardeson indicated the challenges on backward logistics and disposal of medical device. It was agreed the adopting of GHTF/ IMDRF FSCA guidance documents would be postponed until IMDRF document being ready.

6.4 WG3 Updates by Mr Ali M Al-Dalaan (WG3 Chair)

a. Ali reported the WG3 participation in GHTF SG3 for developing of the Quality Management System (QMS) guidance N17 on control of product and services obtained from suppliers, N18 on corrective actions, and N19 on criteria for characterizing deficiencies. The number of active WG3 members was 23.

b. The proposed document "Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange" had gone through the call for comments process, and would seek endorsement at the 18th AHWP main meeting.

c. Ali reported the adoption of GHTF guidance documents N17 and N18, the completed survey among AHWP member economies on QMS in Oct 2012 and the corresponding analysis finished to identify needs of member economies on QMS. He also updated that WG3 members represented AHWP to participate in ISO TC210 and supported the development of the new ISO13485. WG3 Chair also participated in the development of IMDRF MDSAP related documents N3 – N6.

d. Upcoming WG3 work focus would include the drafting of a guidance document on application of ISO13485 for importers/distributors, and expanding the format of guidance document for small manufacturers.

e. Michael Gropp reminded that AHWP should avoid distributors taking this guidance document as an easier QMS. He advised highlighting those clauses of ISO13485 applicable to good distribution practice. Guidance on how ISO9001 could be of useful would also be explored for the interest of the small and medium manufacturers.

6.5 WG4 Updates by Mr Abdualla Al-Rasheed (WG4 Chair) and Ms Eun Hae Cho (WG4 Co-chair)

a. Abdullah and EH reported the completion of WG4 survey on the development of an auditing guidance for importers and distributors among different AHWP member economies. The AHWP guidance documents "Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers (Part 1 - 5)" were endorsed in AHWP 2012 main meeting. Abdullah also reported the completed pilot training for WG 4 guidance document in Sep 2013. The number of active WG4 members was 19.

b. Abdullah updated that the upcoming WG4 focuses would include reviewing the identified references, developing auditing guidance for importers and distributors (I&D), and developing training module for beginners.

c. Comments were received from the floor, including exploring any harmonized approach for auditing in AHWP, for example GCP auditing. WG5 would also work with WG4 in the future on this GCP auditing work item.

6.6 WG5 Updates by Ms Yuwadee Patanawong (WG5 Chair) and Ms Sumati Randeo (WG5 Co-Chair)

a. Ms Yuwadee reported the WG5 comparative study on regulation and implementation of clinical investigation among AHWP member economies conducted in 2013, and shared the received feedback.

b. Sumati reported the completed work item on mapping of ICH GCP, SG5 GN and latest version of ISO14155, and the inputs to ISO/TC194 on preparing the clinical investigation of medical device in human. She also shared the updates of the past ISO 14155 Meeting. The number of active WG5 members was 14.

c. Upcoming WG5 focuses would include continuing participation in ISO 14155 meetings, further exploration the consensus on framing the guidance for clinical investigation, considering the concept of registry, sharing the mapping and comments on GHTF and ISO documents and survey highlights with the ISO committee, and additional ethics committee requirements. Training on clinical evaluation and investigation would be explored with the support from WG6.

d. It was updated that WG5 would like to initial the nomination of second advisor (non-industry) to WG5.

6.7 WG6 Updates by Dr Rama Sethuraman (WG6 Chair)

a. Dr Rama reported the completed work items, including the collection of training needs and coordination of training plan with WGs, as well as the identification of priority training areas for WGs. The number of active WG6 members was 19.

b. Future work items of WG6 would include assisting formulating different training modules based on needs and input from different work groups. The challenges for training were reported, such as identifying the venues, trainer, training materials, and the coordination with other WGs for guidance documents training. Dr Rama also mentioned that the future direction of WG6 would include identifying areas of focus in training for other organizations (WHO, APEC, RAPS, etc) and exploring the collaborating opportunities. Resources from ASL (AHWP legal entity) for budget on training would be explored.

6.8 STG(N) Updates by Ms Victoria Qu (STG-N Secretary)

a. Victoria reported the completed work items of STG on nomenclature, including GMDN agency outreach, continuous participations of nomenclature work at GMDN, IMDRF, WHO, and comments provided to AHWP through the meetings with EU DG SANCO and GMDN agency in Sep 2013. Five workshops were carried out in China for the feasibility analysis of GMDN application in China and a report was drafted, to be further shared with AHWP member economies. The number of active STG(N) members was 27.

b. Victoria also reported the meeting with GS1 and EU DG SANCO, with sharing of in-depth UDI information among member economies, STG(N) participations to IMDRF UDI working group on suggestions towards the UDI system for medical device (version 2) drafted by IMDRF. She also updated the organized workshop involving CMDSA and AdvaMed in China to enable alignment with IMDRF global model.

c. Upcoming work focus would include continuing the participation of nomenclature work in IMDRF, future research on use of UDI, and guiding AHWP member economies on the harmonized approach of the UDI system.

7 Updates from Secretariat and Election of WG7 Co-chair

7.1 Bryan updated the proposed amendment to AHWP House Rules related to WG memberships and number of WG advisors, which was initiated in TC Leaders Bangkok Meeting in Feb 2013.

7.2 Mr Lupi Trilaksono (MOH, Indonesia) was nominated and endorsed as WG7 Chair (regulator).

7.3 Mr Tony Low (Malaysia) was elected WG7 Co-chair with the highest votes.

7.4 Ms Yuwadee PATANAWONG, Acting Chair of WG5 was endorsed as WG5 Chair (regulator).

8 Closing Remarks

Joanna thanked Medical Device Authority, Malaysia, all the participants including TC Advisors, member economy representatives, WGs and STG Chairs and Co-Chairs for attending this TC Meeting.

8 **Any Other Business**

The TC Advisors meeting with AHWP representatives from member economies was announced, to be held at Business Center 4 at 6pm after this TC Meeting.

The TC Meeting was adjourned at 5:40pm (Malaysia local time).

- End -