

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Secretariat Meeting

JiuHua Resort & Convention Center Beijing, People's Republic of China 7 – 8 January 2010

Meeting Minutes (prepared by Mr Jack WONG)

1. AHWP Website

- 1.1 4 Sponsorship were obtained
- 1.2 This meeting summary will be posted in AHWP website after 2 weeks

2. Recruitment of New Members

2.1 Mark will send invitations to South and Latin American economies to join AHWP membership

3. AHWP newsletter

- 3.1 Still pending inputs from the following (deadline is end Jan)
 - (a) Working group 1, 2, 3, 4 chairs
 - please provide a picture of you
 - key achievement and next steps of your working group
 - (b) Dr Zhu and Dr Gao
 - please work with Mr Wang to provide the AHWP Chairman's welcome message on page 1
 - (c) Catagna (Chile), Ruwaida & Shereena (Abu-Dhabi), Anan Abu Hassan (Jordan)
 - For new member economies update, please provide a picture of you and introduction of your job

4. Updating of AHWP and AHWPTC Representatives

4.1 Bryan and Mark will request the Representatives to provide their updated emails in accordance with the new Terms of Reference

5. Nomenclature system

- 5.1 TC Chair presented 6 requirements of Medical Device Nomenclature system for AHWP and TC endorsed on 4 Nov. Chair and co-chair of AHWP endorsed the 6 requirements on 6 Nov
- 5.2 AHWP chair proposed 3 points
 - (a) AHWP supports GHTF's effort on establishment of single nomenclature

system

- (b) AHWP request Service providers to consider AHWP's requirements
- (c) AHWP's 6 requirements will be passed to Service providers to feedback
- 5.3 GMDN requesting 7 representatives from AHWP before the Mar GMDN meeting. The AHWP representatives will attend the meeting once to understand the role of PAG and to negotiate with GMDN Agency regarding the AHWP requirements
- 5.4 Mark suggested a survey on what nomenclature system that AHWP and GHTF members are using and their requirements for switching to a harmonized system. The survey will be conducted by the Secretariat

6. Legal entity

- 6.1 Mark and Jennifer will finalize the document with the legal advisors and propose a list of first Directors and founding Members
- 6.2 Aim to finalize entity by next Secretariat meeting (2-3 Jul)

7. AHWP fund

- 7.1 About 380 delegates (153 are regulators and VIP) attended AHWP meeting, HK\$350k surplus was achieved
- 7.2 4 website sponsorships was obtained (surplus HK\$140k)
- 7.3 Final financial statement will be posted on AHWP website (about HK\$490k)
- 7.4 Mark will propose a money spending mechanism and scope e.g. training will be the scope, AHWP member can write proposal for AHWP secretariat for approval
- 7.5 Dr Zhu suggest the income and expenditure of AHWP website managed separately
- 7.6 HKPC will manage all the AHWP funds until the AHWP Administration Services Ltd is in full operation
- 7.7 Jack will contact Joanna and Jacqueline about previous AHWP funds in HAS

8. Annual Summary and comparison study on member's regulatory systems

8.1 Plan to start collecting information on GHTF's members

9. Survey arrangement

- 9.1 HKPC will upkeep the latest email list of all AHWP representatives and delegates
- 9.2 All survey shall be coordinated by Secretariat with the results copied to the Secretariat for record purpose
- 9.3 Jack will inform TC

10. AHWP meeting in Saudi Arabia

- 10.1 Secretariat will propose 1-4 Dec for coming meeting
- 10.2 Mark will liaise with Saudi Arabia to provide assistance by setting up an advisory team around Mar 10
- 10.3 Suggest to setup organizing committee around Mar 10 and start regular teleconference around May 10

11. Next meeting

2-3 Jul

Appendix

Appendix I AHWP Secretariat Meeting Participant List

Appendix II AHWP Secretariat Meeting Agenda

Appendix III Presentation of Work Plan of AHWP Secretariat in 2010(Chinese version

only)

Appendix IV Presentation of Brief Report of the 14th AHWP Meeting

Remarks

Photo of the meeting

http://ecfoto.net/ahwpphoto/photo_sharing/LSFYDmJkN0rzDOtjJNd89w