Matters Arising from 12th AHWP Meeting, Chengdu, PR China

Item	Action Required	Responsible Parties	Status
Update on AHWP Technical Committee (TC)	(i) AHWP TC to update its membership. (ii) New projects/activities to be undertaken by AHWP TC include IVDD, quality system requirements, clinical evidence requirements and framework for web-based regulatory training course.	AHWP TC	AHWP TC will present report on the update in Agenda Item 5.
(i) **Comparative study on medical devices regulations in Asian economies** (ii) **Adoption of Global Medical Device Nomenclature (GMDN) system**	(i) Some member economies requested AHWP to come up with recommendations/ guidelines on what should be incorporated in a national policy on medical device regulation. (ii) Due to concern of some member economies on the ability of GMDN Agency to maintain GMDN database, the Meeting decided that AHWP should work closely with GHTF to communicate and address the concern with GMDN Agency.	Secretariat	(i) WHO has published "Aide-Memoire for National Medical Device Administrations" and "Aide-Memoire: Strengthening National Regulatory Authorities" (Appendix 1) which can be used as guidelines for establishing a national policy on medical device regulation. WHO has also published a book entitled "Medical Device Regulations: Global overview and guiding principles". These documents can be accessed from www.who.int/medical_devices/policies/en. (ii) Special Task Group (STG) on GMDN has been formed and worked together with GHTF to bring up this issue to GMDN Agency. This item will be further discussed in Agenda Item 13.

Item	Action Required	Responsible Parties	Status
Common Submission Dossier Template (CSDT)	AHWP TC/WG01 proposed the following; (i) Adoption the principles of conformity assessment as a fundamental. (ii) Adoption of the proposed elements of conformity assessment for medical devices. (iii) Sharing of the experience regulating medical devices. (iv) Approval of the proposed work item for WG01. (v) The proposals to be posted on the website for comments. Member Economies to provide comments on the proposal by WG01.	AHWP TC/ WG01 Member Economies	AHWP TC/WG01 will report the current status and this item will be further discussed in Agenda Item 7.
Post-market surveillance system – a framework for safety alert dissemination system (SADS)	The Meeting decided the following; (i) Implementation of SADS by member Economies (ii) All Member Economies are encouraged to join NCAR as Associate Participants and subsequently become Full Members (iii) WG02 should revise and finalize SADS and subsequently proceed for pilot implementation in January 2008 (iv) Member Economies should join SADS, especially in dealing with confidential information	AHWP TC/ WG02	AHWP TC/WG02 will report the current status and this item will be further discussed in Agenda Item 8.

Item	Action Required	Responsible Parties	Status
Capacity building	The proposed diploma program will be conducted in collaboration with Northeastern University, Boston, USA. AHWP TC WG/06 to formalize the Advisory Board and to draft the curriculum.	AHWP TC/ WG06	AHWP TC/ WG06 will report the current status and this item will be further discussed in Agenda Item 9.
AHWP-WHO Cooperation	AHWP to formally communicate to WHO on the proposed areas of collaboration.	AHWP Chair, AHWP Secretariat	WHO has proposed the mechanism of cooperation as in Appendix 2. This item will be further discussed in Agenda Item 10.
Funding	Members, especially the industry, to contribute generously the Trust Fund to enable AHWP to fund its planned projects/activities.	All Member Economies	
Election of New Chair			To be done in Agenda Item 14.
Other matters – Certificate of Export (COE)/ Certificate of Free-Sale (CFS)	The industry group to write a paper identifying the issues and recommending what the regulators should do to help the industry. The paper is to be submitted to AHWP and GHTF Chairs by the end of the year.	Industry group	Industry group has submitted the paper as in Appendix 3. To be further discussed in Agenda Item 13.