ASIAN HARMONIZATION WORKING

Working towards medical device harmonization in Asia

ANNEX 3

AHWP SPECIAL MEETING

Musik und Kongresshalle Lübeck, Germany 28 June 2006 in conjunction with the 10th GHTF Conference, 26 – 30 June 2006

AHWP WORK PROGRAM FOR 2005 – 2007

Strategy	Expected output	Timeframe	Responsible Member Economy/TC/WG	Status
 Comparative study on the existing medical device regulations in AHWP Member Economies 	Printed report ready to be sold in GHTF Conference, Lubeck, Germany	By May 2006 New target for completion: Sept 06	Malaysia, Member Economies	Draft report is being finalized.
2) Harmonization of definition, classification, nomenclature of medical devices	To be defined after comparative study			
3) Formalization of a post marketing alert system	Proposal paper to be presented in the next AHWP Meeting, Korea	By Sept 06	Singapore	Draft report is being finalized
 Capacity building through training 	Proposal paper on training strategy to be presented at the next AHWP Meeting, Korea.	By Sept 06	Hong Kong industry	Draft proposal is being finalized
	Draft standard procedures for organizing meetings/ conference/training to be presented at the next AHWP Meeting, Korea.	By Sept 06	Korea, Singapore	Draft standard procedure is ready for discussion
 Work towards a common submission dossier in alignment with ASEAN project 	Decision on the strategy and work plan to firm up the work towards the development of common submission dossier	Sept 06	TC/WG01	Draft is ready for discussion
6) Funding	Letter to request for funding to companies, international organizations	Dec 05	Chair/Co-Chair	Requests for contribution have been circulated to regulators, industry organizations, companies
	Proposal for AHWP funding mechanism to be presented at the next AHWP Meeting, Korea	Sept 06	Chair/Co-Chair	Funding mechanism is being drafted