REPORT ON AHWP QUESTIONNAIRE SURVEY 2002

I Introduction

A survey was conducted by the AHWP Technical Committee during the period February and April 2002. The purpose of the survey was to obtain input from Asian regulators on their efforts to harmonize the regulation of medical devices with the Global Harmonization Task Force (GHTF) recommendations and guidance, and to obtain suggestions for possible regional collaboration and training.

II Survey returns

The survey questionnaires were sent to 10 Asian regulators (Brunei Darussalam, Peoples' Republic of China, Hong Kong SAR, Indonesia, Korea, Malaysia, Philippines, Thailand, Chinese Taipei and Singapore) with lead responsibilities for medical device regulations. 9 respondents from Asian regulators completed the questionnaires and submitted their returns.

III Status of medical device regulations

6 respondents (PRC, Indonesia, Korea, Philippines, Chinese Taipei and Thailand) indicated that they currently regulate medical devices and three (PRC, Indonesia and Thailand) indicated that their medical device regulations were developed independently from drug regulation and 2 respondents indicated impending plans to introduce new medical device Act (Korea, as soon as possible; Thailand, in 2007). Two respondents indicated that they are in the process of promulgating medical device regulation (Singapore, 2002/3; Malaysia, 2004) and one respondent (Hong Kong SAR) is studying various regulations and its applicability to local context.

IV What are primary concerns about medical devices offered in their economies?

The respondents indicated the following primary concerns about the medical devices offered in their economies:

(a) Member economies with regulatory systems in place:

- Safety and efficacy of a medical device
- Quality and safety, supported by substantiated documents
- Post-market surveillance
- Labelling not in accordance with requirements; nonsubmission of Certificates of Free Sale and cGMP from the country of origin issued by the regulatory authority
- Safety, Effficacy & Quality; Adverse events reporting; modern technology
- Quality, safety and effectiveness

(b) Member economies with developing regulatory systems:

- Quality, safety and effectiveness; low-risk alternative therapy medical devices with unsubstantiated treatment claims
- Ensure devices imported and manufactured locally meet international standards concerning quality, safety and effectiveness; to facilitate marketing authorization and export of locally manufactured devices
- Public safety, use of medical device by non-medical professionals

V Which existing regulatory systems in other economies have you evaluated as models for your own system?

(a) Member economies with regulatory systems in place:

- USA and Europe model;
- Code of Federal regulation for classification of medical devices, TGA regulation;
- US FDA and Japanese regulations;
- None in particular;
- US, EU;
- Modified from US FDA regulatory system.

(b) Member economies with developing regulatory systems

- EU, Canada, Australia, GHTF guidance documents;
- EU directives, Australia, GHTF guidance documents;
- GHTF founding members' models and economies of APEC.

VI GHTF Guidance Documents and Status of adoption and implementation in member economies

There is widespread consensus amongst Asian regulators in the adoption and implementation of various GHTF final guidance documents which illustrates the relevance of these guidance in working toward greater harmonization of medical device regulatory systems. 68% of the respondents indicated that they have considered or considered adopting and implementing various GHTF final guidance documents, while another 19% indicated they have implemented them into existing regulation. Only 4% of the respondents have no plan (relating to guidance on quality system and regulatory audit).

40% of the respondents indicated training is required on GHTF guidance documents, while 8% indicated there is no need for training.

About 67% of the respondents indicated interest and consideration in adopting and implementing the key guidance document "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" which is in working draft stage.

Table: Number of respondents indicating status of adoption and implementation of various GHTF guidance documents and training required:

Final Documents	No plan	Interested/ Considering adopting and implementing	Implemented into existing regulation	Training required on GHTF documents YES	NO
SG1: Essential Principles of Safety and Performance of Medical Devices		8	1	4	1
SG1: Labelling for Medical Devices		6	3	2	2
SG1: Role of Standards in the Assessment of Medical Devices		7	2	4	
SG2: Global Medical Device Competent Authority Report		6	2	3	1
SG2: Minimum Data Set for Manufacturer Reports to Competent Authority		5	3	2	2
SG2: Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices		7	1	4	
SG2: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative		8		5	
SG3: Guidance on Quality Systems for the Design & Manufacturing of Medical Devices	1	5	2	3	1
SG4: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies	1	6	1	5	
SG4: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements	1	5	2	5	
SG4: Audit Language Requirements	1	5	1	1	2
SG4: Training Requirements for Auditors		5	2	5	
subtotal	4	73	20	43	9
	4%	68%	19%	40%	8%
SG1: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) (DRAFT)	1	6			