Report of the 9th Asian Harmonization Working Party Meeting 14 May 2002, Singapore

The 9th Meeting of the Asian Harmonization Working Party (AHWP) was held in Singapore, on 14 May 2002, in conjunction with the 9th Global Harmonization Task Force (GHTF) Conference of 12-16 May 2002 and the 2nd APEC Seminar of 17-18 May 2002.

1 Welcome

Chair AHWP, Dr Clarence Tan, opened the Meeting and welcomed all members to Singapore for the 9th Meeting of the Asian Harmonization Working Party. Dr Tan thanked GHTF for facilitating the AHWP meeting.

2 Introduction of Member Economy's AHWP Representatives and Personal Introduction of Participants

Representatives from the 9 Asian member economies then introduced themselves to the Working Party. Altogether, an estimate total of about 130 persons attended the Meeting, comprising members who were regulatory and industry representatives from the 9 participating Asian member economies and other attendees who attended as observers from other member economies present at the GHTF Conference and the APEC Seminar. (See Annex - List of attendees present at the 9th AHWP meeting who signed their attendance).

3 Adoption of Agenda

Members accepted and adopted the items presented in the Agenda for this Meeting that has been circulated to members on 1 April 2002.

4 Minutes of the 8th AHWP Meeting (20 September, Ottawa, Canada)

The minutes of the 8th Meeting were included in the Meeting folder that was circulated to members on 1 April 2002. Members confirmed the minutes of the last Meeting without any amendment.

5 Discussion on Matters Arising

Dr Tan reaffirmed that the Technical Committee had amended AHWP Term of Reference to reflect its new functional role and other administrative details. These would

be discussed at the Meeting under proposed changes to AHWP Terms of Reference that were included as the agenda item.

6 Update and confirmation of Member Economy's Technical Committee Representatives

Nomination or change of the member economy's representatives to the Technical Committee has been circulated to member economies on 1 April 2002. In particular, members welcomed and reaffirmed the appointment of a new member, Ms Ginnie Chao (Singapore), who replaced Mr Jack Moore (Singapore), a Vice-Chair of AHWP Technical Committee, following his posting to USA. The Chair requested members to inform him if there is any nomination or change of the representatives to keep members list as current as possible.

7 Acceptance of Proposed Changes to AHWP Terms of Reference

The Chair ran through proposed changes to the AHWP Terms of References. The followings were discussed and members accepted and adopted all the proposed changes to the Terms of Reference:

Membership

- Each member economy has two representatives to the Working Party – one from the Medical Device Regulatory Authority and the other from the industry. It is expected that industry representatives will consult with other industry representatives in their member economy in developing industry views.
- Members of the AHWP, both the regulators and industry, are expected to participate as representatives of their respective economies to develop understanding of the GHTF approaches to harmonization and guidance documents. With this understanding members are to review recommendations of the AHWP Technical Committee for adoption of GHTF harmonized guidance documents and review proposed feedback to the GHTF on draft guidance documents ensuring that the results of these activities can be utilized to initiate harmonization efforts in their respective regulatory systems.

Leadership

- The Chair and co-chair persons will be elected by way of voting by the members for a period of 3 years. These office bearers in the Working Party will normally rotate among member economies once every three years. The Chair and Co-Chairs of the Technical Committee, being duly elected, will similarly rotate among member economies once every three years.

The Role of Technical Committee

- The functional role of the Technical Committee is defined and expanded.

Change of Office Bearers

- Change to replace the incumbency by a person nominated from the incumbent member economy to be affirm soonest at next AHWP Meeting.

Observers of AHWP and AHWP Technical Committee Meetings

- All meetings are open to interested observers from regulatory authorities, industry or conformity assessment bodies as the thrust of harmonization will be facilitated and implemented with other observers' participation.

The Chair requested members to propose or recommend any appropriate change to the Terms of References as AHWP develops and consolidates its harmonization activities.

8 Report of 1st AHWP Technical Committee Meeting & Workshop 2001

Mr Albert Li (Chinese Taipei), Chair AHWP Technical Committee, reported on the 1st AHWP Technical Committee Meeting and Workshop 2001. It was held on 6 to 7 September 2001, in Kuala Lumpur, Malaysia. Attendees (about 60) included delegates from Australia, Taiwan, Hong Kong, Japan, Korea, Malaysia, Philippines, People's Republic of China, Singapore, Thailand and USA, representing their respective medical device industries and regulatory authorities. The invited speakers were from FDA (Christine Nelson and Judy Strojny) and SG1 (Michael Gropp). The 1st AHWP TC Meeting received the honoured presence and support from Rita Maclachlan (GHTF Chair and Director of TGA's Conformity Assessment Branch).

Selected GHTF SG final documents (Essential Principles, Regulatory Auditing, Auditor Training and Process Validation) were introduced as training element to bring participants to an understanding of GHTF principles. Discussions during the meeting were also focused on working draft GHTF SG documents (Summary Technical Documentation and Device Classification).

The meeting proposed changes and amendments to the AHWP Terms of Reference to incorporate new functional roles of the Technical Committee. The major roles for the TC were emphasised to help AHWP to facilitate the process of acceptance of the "Final" GHTF SG guidance documents for adoption and implementation to the regulatory framework of member economies. Significant changes were also made to the four compulsory criteria for TC members, ratifying his representation, commitment, level of authority, level of medical device regulatory knowledge and English language skills. Lastly, at the meeting, it was agreed that the GHTF concepts, principles and guidance documents should be adopted and implemented, where appropriate, by the AHWP member economies.

The Chair thanked GHTF resource persons: Mr. Michael Gropp from Guidant and Ms Christine Nelson and Judy Strojny from US FDA; Vice-Chairs, Jack Moore (Singapore) and especially Ms Eishah Rahman (Malaysia), for being actively involved.

9 Discussion on the Outcomes of Technical Committee Meeting

A key focus of the AHWP Technical Committee was to facilitate wider acceptance of SG documents and their application to local systems. It conducted a survey, in March 2002, amongst medical device regulators in the Asian member economies about 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 collaboration and training. The survey sought to obtain information about the status of adoption and implementation of guidance documents in a specific member economy in harmonizing their medical device regulation to GHTF.

Ms Ginnie Chao (Singapore) reported on behalf of the Technical Committee the findings of the survey, with 9 of the 10 member economies responding to the survey. The followings are the findings:

Status of Medical Device Regulations

- 6 economies currently regulate the use of medical devices. They are China, Indonesia, Korea, Philippines, Taiwan and Thailand. 3 countries have developed the regulations from existing drug regulations and 2 are intending to introduce new and independent regulations. 2 economies are in the process of promulgating regulations (Singapore and Malaysia). Hong Kong is studying various regulatory systems.

Primary Concerns about Medical Devices

- Both of the member economies with regulatory systems in place and those with developing regulatory systems have expressed concern on the safety, quality and performance of certain devices even with supporting and substantiated documents. Examples are biologic products which they feel they do not have the capability to evaluate with confidence.

Models Used for The Existing Regulatory Systems

- The GHTF founder members and the economies of APEC are the models used in the existing and developing AHWP members economies' regulatory systems.

Status of Adoption and Implementation of GHTF Guidance Documents

- The Guidance documents from GHTF Study Group 1, 2, 3 and 4 have been adopted by the member economies included post market and labeling requirements for medical devices. Statistically, 68% are interested and are considering adopting and implementing the GHTF guidance documents. 19% has implemented this into the existing regulations, 4% has no plan in adopting and 9% have not responded. In response to training requirements, 40% have responded positively to the need for training, 2% with negative response and 52% with no response.

10 Regulatory Updates

Singapore: The Centre for Medical Device Regulation, Health Sciences Authority (Mr Wong Yew Sin), provided a brief presentation on the Voluntary Product Registration scheme in Singapore. The Voluntary product registration was introduced in April 2002 for the manufacturers and suppliers of medical devices to lodge their higher risk devices with the Authority. The medical device regulation proper will be implemented in early 2003.

Hong Kong: Hong Kong (Mr Albert Poon) presented their concerns on the safety of beauty saloon equipment. The Department of Health is studying the importance of medical device control with the technical support from the electrical and mechanical services department. At present, Hong Kong is looking into other economies' experience in the control of medical devices and will propose the control of medical device including *in vitro* diagnostic devices and post-marketing and vigilance system controls in near future.

Korea: Korea (Dr Lee Jeong Rim) also presented their new medical device regulations, namely, the establishment of the guidance for clinical trial procedure; the establishment of the review guidance for safety and effectiveness to be harmonized with international standards; and the implementation of technical file review for designated Class II devices by the third party.

11 Next Step In AHWP Harmonization Project

Members agreed to look at common approaches in the following areas: (i) Quality Systems and Audit, and (ii) Premarket requirements and STED requirements, as the next step in its harmonization projects. The Chair commented that such activities will bring member economies closer from coordinating and operationalising identified processes and moving ahead at practical yet pragmatic steps towards harmonization objectives.

12 Other New Matters

- Chair appealed to member economies to nominate both regulatory and industry representatives to sit in the Technical Committee which is the workhorse for AHWP. Members of the Technical Committee who have inputs or comments for SGs and would be interested in attending their meetings would keep AHWP informed.

- Members took note of a suggestion to report on member economies' consensus and adoption of SG documents and follow-up for possible inclusion into in the AHWP meeting in order to elicit discussion and to exchange ideas and implementation experience.

- Mr Maurice Freeman (SG1) informed that GHTF is crafting new requirements for the classification rules and GHTF SG1 would like to seek feedback from the member economies. IVD requirements are still being deliberated by SG1.

- New emerging technology and innovative bioengineered products are being introduced into the market from accelerated research and development. Members agreed that this would be a concern in Asia as well as the well developed member economies where traditional boundaries of device classification may become less meaningful. TC will be tasked to look into this issue with GHTF.

- AHWP Home Page at http://www.asiahwp.org/ was launched on 4 Dec 2001 with a link to GHTF website. This website will serve to provide members and others with the latest updates and information about AHWP activities, and as the best way to keep all available reports and information and record the progress of this regional grouping. A contact address for e-mails (Info@asiahwp.org) was also established.
  [All the training materials and the reports of meetings, surveys and regulatory updates are available at AHWP website]

13 Next Meeting

Members agreed that the next AHWP meeting will be held again in conjunction with the 10th GHTF Conference in Tokyo, Japan, in May 2003 and that there should be at least one meeting of the Technical Committee before that.

14 Closing Remarks

The Chair noted and thanked the contributions of the many persons and organizations that had helped to plan and organise the 9th Meeting of AHWP.

Date: 12 *October 2002*

Vetted and approved by:

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Dr Clarence Tan	*Edward Woo*
Chair, AHWP	*Vice-Chair, AHWP*

Recorded by: *Wong Yew Sin (Singapore)*

Annex

Participants from Asian Member Economies at 9th AHWP Regional Meeting, 14 May 2002, Singapore

S/N	Particular of participant		
1	Clarence Tan	Health Sciences Authority	Singapore
2	Edward Woo	Medtronic International Ltd	Hong Kong
3	Albert Li	Industrial Technology Research Institute	Chinese Taipei
4	Wong Yew Sin	Health Sciences Authority	Singapore
5	Anggraini Armyn	National Agency of Drug and Food Control	Indonesia
6	Erwi Adini Soewarno	National Agency of Drug and Food Control	Indonesia
7	Ma Cecilia Matienzo	Bureau of Health Devices & Technology	Philippines
8	Lennie Caldreron	Johnson & Johnson Medical	Philippines
9	Hsiau-wen Huang	Department of Health	Chinese Taipei
10	Chanchai Uerchaikul	Thai Food & Drug Administration	Thailand
11	Boonchai Somboonsook	Thai Food & Drug Administration	Thailand
12	Hao Heping	State Drug Administration	China
13	Linda Lin	Boston Scientific	China
14	T C Khoo	Johnson & Johnson Medical Asia Pacific	Singapore
15	Ginnie Chao	Guidant Corporation	Singapore
16	Jacqueline Monteiro	Becton Dickinson & Co	Singapore
17	Yoo Hee-Sang	Korea Food & Drug Administration	Korea
18	Lee Jeong Rim	Korea Food & Drug Administration	Korea
19	Lee Sang Yeul	Korea Food & Drug Administration	Korea
20	Young Cheol Chun	Johnson & Johnson Medical	Korea
21	Constance Chan	Department of Health	Hong Kong
22	Albert Poon Ka-Fat	Electrical & Mechanical Services Dept	Hong Kong
23	Teh Har Yin	Ansell Ltd	Malaysia
24	Rezza Huzzieni	B Braun	Malaysia
25	Jeong Jin Baek	Korea Food & Drug Administration	Korea
26	Kyung-Ho Yu	Korea Testing Laboratory	Korea
27	Prompong Ukkakimapan	Guidant Thailand	Thailand
28	Terrenz Leung	Guidant HK Ltd	Hong Kong
29	Rosely Liu	Guidant Beijing	China
30	Wong Tze-Kin	Electrical & Mechanical Services Dept	Hong Kong
31	Yan Liang	Shanghai Drug Administration	China
32	Ba Xin Guo	Shenyang Centre of Control for Medical Device	China
33	Jih-Horn Chen	State Drug Administration	China
34	Chadaporn Tanakasemsub	Johnson & Johnson Medical	Thailand
35	Yvonne Yeo	Johnson & Johnson Medical	Singapore
36	Nealda Leila M Yusof	Health Sciences Authority	Singapore
37	Ng Yin Mei May	Health Sciences Authority	Singapore
38	Clement Ng	Health Sciences Authority	Singapore
39	Chen Yong	State Drug Administration	China
40	Upsorn Kriaksorn	Boston Scientific	Thailand
41	Suhoung Thitisatthayakorn	Thai Food & Drug Administration	Thailand
42	Ting Teck Yeo	SeerPharma Consulting	Singapore
43	Victoria Shih	Johnson & Johnson Medical	Chinese Taipei
44	Tran Quan	Johnson & Johnson Medical Asia Pacific	Singapore

S/N	Particular of participant		
45	Xiaobin Qu	Medtronic Beijing	China
46	Jean Chen	Medtronic Taiwan	Chinese Taipei
47	Yung-chuan Lee	Department of Health	Chinese Taipei
48	Soo Jung Yoo	Medtronic Korea	Korea
49	Yujin Han	Medtronic Korea	Korea
50	Hong-Kyung Uhm	Becton Dickinson Korea	Korea
51	Wendy Tan	Tyco Healthcare	Singapore
52	George CH Tan	Igel CM Laboratory Pte Ltd	Singapore
53	Lee Siew Hoon	Igel CM Laboratory Pte Ltd	Singapore
54	Jolynn Lim	Boston Scientific	Singapore
55	Yuan Yang Wei	MIRDC	Chinese Taipei
56	Xi Zi Li	Tyco Healthcare Beijing	China
57	Chen Zhigang	CMDC Beijing	China
58	Deng Gang	State Drug Administration	China
59	Nellie Ong	Johnson & Johnson Medical	Malaysia
60	JeongJa Oh	Smith & Nephew	Korea
61	Sally Ji Hyun Kim	Tyco Healthcare	Korea
62	Jean Chan	Tyco Healthcare	Singapore
63	Melinda Serrano	Becton Dickenson	Philippines
64	Yvonne Ma	Tyco Healthcare	Chinese Taipei

Other Attendees: GHTF member economies and others at 9th AHWP Regional Meeting, 14 May 2002, Singapore

S/N	Particular of participant		
1	Karen Riley	Clinica	USA
2	Johan Brinch	Medical Industry Association Australia	Australia
3	Soichiro Isobe	Ministry of Health, Labour & Welfare	Japan
4	Kiyohito Nakai	Ministry of Health, Labour & Welfare	Japan
5	Alan Kent	SGI	UK
6	Mark Brager	FDC Reports	USA
7	Michael McKay	Ortho-Clinical Diagnostics, Asia Pacific	Australia
8	Joseph Putzeys	European Commission	EU
9	Brian Vale	Medical Industry Association Australia	Australia
10	Werner Schoenbuehler	Siemens AG/COCIR	Germany
11	Carl Wallroth	EUROM VI/Drager Medical	Germany
12	Saburo Kimura	Johnson & Johnson Medical	Japan
13	Robert Turocy	Philips Medical Systems	USA
14	Larry Kroger	NEMA/GE Medical Systems	USA
15	Naoki Morooka	JIRA/Shimadzu Corp	Japan
16	Ishikawa Hiroshi	JFMDA/Toshiba	Japan
17	Barry Simpson	EDMA/Abbot Laboratories	Germany
18	Christine Cuthbertson	Smith & Nephew Pty Ltd	Australia
19	Peter Pratt	Medsafe, Ministry of Health	New Zealand
20	Jorge Garcia	Therapeutic Goods Administration	Australia
21	Elke Lehmann	Federal Institute for Drugs & Medical Devices	Germany
22	Jeffrey Gren	US Departmetn of Commerce	USA
23	Helen Hall	Gradipore Ltd	Australia
24	Gosia Pendel	BOC Gases Australia Ltd	Australia
25	Morichika Tanemura	JFMDA/Sakura Seiki Co Ltd	Japan
26	Preeti Jain	Medtronic Perfusion Systems	USA
27	Michael Gropp	Guidant Corp	Belgium
28	Yoshikazu Ando	Boston Scientific	Japan
29	Johann Rader	TUV Product Service	Germany
30	Kenji Aoyama	TUV Reinland Japan	Japan
31	Masaaki Naito	Nihon Kohden Corp	Japan
32	Wayne Brod Beskow	National Agency for Health Surveillance of Brazil	Brazil
33	Juan Villacorta	General Direction of Medicines, Ministry of Health	Peru
34	Eric Ulloa	Ministry of Health	Panama
35	Dulce Maria Martinez	Ministry of Health	Cuba
36	Kristeen Campbell	Guidant Australia	Australia
37	Makiko Isozaki	Ministry of Health, Labour & Welfare	Japan
38	Fred Halverson	Medtronic Inc	USA
39	Ed Bozynski	AdvaMed/BSCI	USA
40	Paul Barry	BSC	USA
41	Tim Ulatowski	US FDA	USA
42	Jack Moore	Boston Scientific	USA
43	Yoshiko Yamamoto	Quintiles	Japan
44	Trevor Nisbet	Medsafe, Ministry of Health	New Zealand
45	Yoshihiro Noda	Terumo Japan	Japan
46	Michael Cheng	WHO	
47	Raelyn Campbell	AdvaMed	USA
48	Michiko Masaka	Medtronic Japan	Japan