



REPORT OF THE SPECIAL MEETING OF THE ASIAN HARMONIZATION WORKING PARTY

14 June 2005, Bangkok, Thailand

(held in conjunction with 3rd APEC-funded Seminar on Harmonization of Medical Device Regulation, 13-17 June 2005)

INTRODUCTION

The Special Meeting of the Asian Harmonization Working Party (AHWP) was held on 14 June 2005 in Bangkok, Thailand, from 0830 - 0950hrs.

2. The Meeting was chaired by Mr Wong Yew Sin from Singapore, on behalf of AHWP Secretariat.

3. The Meeting was attended by regional representatives/proxies from Brunei Darussalam (Mr Rosli Hj Abang Morsidi), China (Mr Hao Heping, Dr Davey Han), Hong Kong (Dr Monica Wong, Mr Jack Wong), Indonesia (Mr Bahdar Hamid), Korea (Mr Gun-Ho Lee, Mr Doki Park), Malaysia (Dr M.S. Pillay, Ms Teh Har Yin), Philippines (Ms Virginia Laboy, Ms Charmaine Roson), Singapore (Mr Wong Yew Sin, Ms Jacqueline Monteiro), Chinese Taipei (Dr Huang Hsiau-Wen, Ms Daphne Yeh), Thailand (Ms Yuwadee Patanawong, Ms Mallika Lektrakul) and Viet Nam (Mr Nguyen Minh Tuan, Mr Ngo Hung Cuong).

OPENING OF MEETING

4. Mr Wong Yew Sin called the Meeting to order at 0830hrs (Bangkok time). In his welcome remarks, Mr Wong highlighted that he was presiding over and facilitating this Special Meeting on behalf of AHWP Secretariat. He also introduced the office bearers from the incumbent committee, namely, Mr Edward Woo (Co-Chair, AHWP), Mr Albert Li (Chair, AHWP Technical Committee), Mr Wang Hwee Beng (Co-Chair, AHWP Technical Committee) and Ms Ginnie Chao (Co-Chair, AHWP Technical Committee). Through Mr Wong, Dr Clarence Tan (Chair, AHWP) conveyed his apologies to the Meeting for not being able to attend.

5. Mr Wong Yew Sin further highlighted that this Special Meeting was convened with the objective of electing new office bearers to lead AHWP for the next 3 years. Election would be held for the following office for a term of 3 years:

- AHWP Chair & Co-Chair
- AHWP Technical Committee Chair & 2 Co-Chairs

6. On behalf of AHWP, Mr Wong Yew Sin extended his gratitude to Mr Jeffrey Gren of US Department of Commerce, the convenor of the 3rd APEC Seminar, for kindly allocating this time slot within the Seminar to AHWP for this Special Meeting.

AGENDA ITEM 1: ADOPTION OF AGENDA

7. Mr Wong reported that the regional representatives of AHWP member economies had been duly notified of this Meeting and its agenda in early April 2005. The AHWP community at large had also been informed through the dissemination list. The Meeting adopted the Agenda without any change which appears as ANNEX 1.

AGENDA ITEM 2: ROLL CALL

8. Delegates from eleven member economies attended the meeting. The list of participating member economies appears as ANNEX 2.

AGENDA ITEM 3: CONFIRMATION & UPDATE OF MEMBER ECONOMY'S REGULATORY AND INDUSTRY REPRESENTATIVES IN AHWP

9. The updated list of regulatory and industry representatives appears as ANNEX 3.

AGENDA ITEM 4: BUSINESS ARRANGEMENT

10. The Meeting was held in plenary.

AGENDA ITEM 5: ELECTION OF AHWP OFFICE BEARERS (BY VOTING) FOR THE NEXT 3-YEAR TERM

11. Dr M.S. Pillay, a regulator from Malaysia and Dr Davey Han, an industry representative from China, were elected to the office of Chair and Co-Chair, AHWP respectively, uncontested.

AGENDA ITEM 6: NOMINATION OF AHWP TECHNICAL COMMITTEE FOR THE NEXT 3-YEAR TERM

12. Mr Albert Poon, Hong Kong SAR, was nominated to the office of Chair, AHWP Technical Committee, uncontested.

13. Five nominations were received for the two posts of Co-Chairs for AHWP Technical Committee. The Meeting agreed to have the 2 posts up for resolution by majority votes.

14. The following candidates vied for the 2 posts of Co-Chairs of AHWP Technical Committee. The results of the votes cast by the regional representatives, in decreasing counts, are as follows:

| <u>Name of Candidate</u> | <u>Results</u> |
|----------------------------|----------------|
| Alfred Kwek, Singapore | Elected |
| Daphne Yeh, Chinese Taipei | Elected |
| Tran Quan, Singapore | - |
| Jack Wong, Hong Kong | - |
| Jimmy Ip, China | - |

15. Alfred Kwek from Singapore and Daphne Yeh from Chinese Taipei were confirmed as Co-Chairs of AHWP Technical Committee. All votes cast were counted by Mr Albert Li, Chinese Taipei.

AGENDA ITEM 7: OTHER MATTERS

BRIEF ADDRESS BY INCOMING CHAIR OF AHWP

16. Mr Wong invited the incoming Chair, AHWP, Dr M.S. Pillay, to briefly address the Special Meeting. In his address, Dr Pillay started by expressing his gratitude to all for their support. He went on to address the need to move towards a greater degree of harmonization in Asia, and increase dialogue between AHWP and GHTF. He hoped to see more vigilance information sharing to enhance safety of devices in the Asian region. He pledged to garner greater support from the industry to work in cooperation with the regulators in moving towards harmonization.

VENUE AND DATE OF THE NEXT MEETING

17. Two member economies were suggested. Hong Kong SAR declined the offer to host the next AHWP Meeting. Korea indicated an interest in holding the meeting, but highlighted that they will not be able to accommodate dates before June 2006.

18. As there was no confirmation of offers from member economies, the Meeting agreed that the venue and date of the next AHWP Meeting be discussed at a later date.

[**Footnote:** Korea Food & Drug Administration offered to host the next AHWP Meeting in Korea. This offer was subsequently announced at the Closing of 3rd APEC Seminar.]

UPDATE OF LATEST DEVELOPMENT IN JAPANESE REGULATIONS

19. On behalf of Japan's Ministry of Health, Labour and Welfare, Mr Masaaki Naito from Nihon Kodon Corp, Japan, and Mr Morichika Tanemura from Sakura Fine Chemicals, Japan, jointly presented to the Meeting updates on the Japanese medical device regulations.

ACKNOWLEDGEMENT

The representatives from Brunei Darussalam, Brunei Darussalam, China, Hong Kong SAR, Indonesia, Korea, Malaysia, Philippines, Singapore, Chinese Taipei, Thailand and Vietnam expressed their appreciation to Thai FDA, ThaiMed and the organizers of the 3rd APEC-funded Seminar for Harmonization of Medical Device Regulation for the warm hospitality extended and the excellent arrangements made for the Meeting.

AGENDA

1. Adoption of Agenda
2. Roll Call of member economies present
3. Confirmation and update of member economy's Regulatory and Industry Representatives in AHWP
4. Business Arrangement
5. Election of AHWP Office Bearers (by voting) for the next 3-year term for:
 - Chair of AHWP (regulatory rep)
 - Co-Chair of AHWP (industry rep)
6. Nomination of AHWP Technical Committee for the next 3-year term for:
 - Chair of AHWP TC
 - Two Co-Chairs of AHWP TC
7. Any Matters

LIST OF PARTICIPATING MEMBER ECONOMIES

1. Brunei Darussalam
2. China
3. Hong Kong
4. Indonesia
5. Korea
6. Malaysia
7. Philippines
8. Singapore
9. Chinese Taipei
10. Thailand
11. Viet Nam

**UPDATED LIST OF REGIONAL REPRESENTATIVES
FROM MEMBER ECONOMIES**

| S/N | Member Economy | Regulator | Industry |
|------------|-----------------------|-----------------------|------------------------|
| 1 | Brunei Darussalam | Dr Sablee Aspar | - |
| 2 | China | Mr Hao Heping | Dr Davey Han |
| 3 | Hong Kong | Dr Monica Wong | Mr Jack Wong |
| 4 | Indonesia | Drs H. Tato Suprpto | - |
| 5 | Korea | Mr Gun-Ho Lee | Mr Doki Park |
| 6 | Malaysia | Dr M.S. Pillay | Ms Teh Har Yin |
| 7 | Philippines | Ms Cecilia Matienzo | To be confirmed |
| 8 | Singapore | Mr Wong Yew Sin | Ms Jacqueline Monteiro |
| 9 | Chinese Taipei | Dr Huang Hsiau-Wen | Ms Daphne Yeh |
| 10 | Thailand | Ms Yuwadee Patanawong | Ms Mallika Lektrakul |
| 11 | Viet Nam | Mr Nguyen Minh Tuan | Mr Ngo Hung Cuong |