



The 17th AHWP Annual Meeting

Monday, November 5, 2012

Venue: Room 101, 1F, Taipei International Convention Center (TICC)

Time	Session	Speaker/Moderator
08:00 – 08:10	Welcome Speech	Dr. Jaw-Jou Kang, Director-General, TFDA, Department of Health, Chinese Taipei
08:10 – 08:15	Congratulation Speech	Mr. Abdulrahman Al Ghurairi Director, International Cooperation Department, SFDA, Kingdom of Saudi Arabia
08:15 – 08:25	Opening Speech	Dr. Saleh S. Al-Tayyar, Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
08:25 – 08:35	Speech by Honorable Guest	Dr. San-Cheng (Simon) Chang, Minister without Portfolio, Executive Yuan, Chinese Taipei
08:35 – 08:55	Souvenirs to Host, Honorable Guest and Sponsors	Dr. Saleh S. Al-Tayyar, Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
		Group Photo
08:55 – 09:25	Keynote Speech Medical Device Developments and Regulation Updates in Chinese Taipei	Dr. Huihua Chiang Executive Secretary, Board of Science and Technology, Executive Yuan, Chinese Taipei
09:25 – 09:45	Tea Break	
09:45 – 10:15	GHTF Status Report	Mr. Kentaro Azuma Deputy Director Office of Medical Device Evaluation, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, Japan
10:15 – 10:45	IMDRF Status Report	Dr. Atsushi Tamura International Coordination Officer for Medical Devices, Pharmaceuticals and Medical Devices Agency, Japan



10:45 – 12:00	<p>AHWP Status Report and Strategic Framework Including announcement of the AHWP Conference</p> <ul style="list-style-type: none"> - Adoption of Agenda - Roll Call (Only Official Members) - Confirmation on Minutes of 16th AHWP Meeting held in Indonesia, 8-12 Nov 2011 - Discussion on the proposed "AHWP Strategic Framework Towards 2020 - The Foreseeable Harmonization Horizon" - Introduction to the 1st AHWP-RAPS Joint Conference 	<p>Dr. Saleh S. Al-Tayyar, Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia</p> <p>Ms. Lindsay Tao Vice Chair, AHWP Corporate Director, Global health Policy, Johnson & Johnson, China</p> <p>Ms. Quan Tran Advisor to Chair, AHWP Vice President, Quality Assurance & Regulatory Affairs, Asia Pacific, GE Healthcare, Singapore</p>
12:00 – 13:00	Lunch	
13:00 – 14:20	<p>Country Update</p> <ul style="list-style-type: none"> i) China ii) Thailand iii) Indonesia iv) Brazil v) Chile 	Country representatives
14:20 – 14:40	Tea Break	
14:40 – 15:20	Report by AHWP TC	<p>Mrs. Joanna Koh Chair, AHWP TC Director, Medical Device Branch, Health Sciences Authority, Singapore</p>
15:20 – 15:50	<p>Report by Secretariat</p> <ul style="list-style-type: none"> - Report by AHWP Secretariat from 2011 to 2012 - Report on Financial Statement for 2011/2012 - Proposal for Budget 2012/2013 	<p>Mr. Ali M. Al-Dalaan Secretary General, AHWP Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia</p> <p>Mr. Bryan So Executive Deputy Secretary General, AHWP Senior Consultant, Hong Kong Productivity Council, Hong Kong SAR</p>
15:50 – 16:10	Tea Break	
16:10 – 16:40	<ul style="list-style-type: none"> - Resolution 1: Adoption of the Proposed "Amendment 2 to the AHWP & AHWPTC Terms of Reference" (by Mr. Bryan SO) - Resolution 2: Adoption of the Proposed 	<p>Dr. Saleh S. Al-Tayyar, Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia</p>

	<p><i>“Amendment 1 to the AHWP House Rules”</i> (by Mr. Bryan SO)</p> <ul style="list-style-type: none"> - Endorsement on the Proposed <i>“Medical Device Adverse Event (AE) Report Form”</i> (by Mr. Yorkie CHOW) - Endorsement on the Proposed <i>“Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions”</i> (by Mr. Yorkie Chow) -Endorsement on the Proposed <i>“Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers”</i> (by Mr. Abdullah A. Al-Rasheed) 	
16:40 – 16:50	Confirmation of Host of the 18 th AHWP Meeting	Dr. Saleh S. Al-Tayyar, Chair, AHWP Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
16:50 – 17:00	Closing Remarks	Ms. Li-Ling Liu, Vice Chair, AHWP Director, Division of Medical Device and Cosmetics, TFDA, Department of Health, Chinese Taipei
17:00 – 18:00	<p>1st AGM of AHWP ASL (Open to Industry and Regulatory Representatives of AHWP Member Economies)</p> <ul style="list-style-type: none"> - Adoption of Agenda - Introduction of ASL - Admission of New ASL Members - Election of Lindsay TAO, Li-Ling Liu, Quan Tran, and Chadaporn Tanakasemsub as the Directors of the Board 	Mr. Ali M. Al-Dalaan Secretary General, AHWP Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia
18:00	End of the 17th AHWP Annual Meeting	
18:30 – 21:00	Gala Dinner (3F Banquet Hall, TICC)	