

AHWP TC Pre-Meeting

Friday AM, November 2, 2012

Venue: Great Room, Level 8, W Taipei

Time	Session	Speaker/Moderator
09:00 – 11:00	AHWP TC Working Group PRE-MEETING (Closed Meeting)	WG Chair / Co-chair
11:00 – 12:00	AHWP TC Leaders Meeting with AHWP Chair (Closed Meeting)	TC Leaders & AHWP Chair
12:00 – 13:00	Lunch	

AHWP TC Meeting

Friday PM, November 2, 2012

Venue: Mega Room, Level 8, W Taipei

Time	Session	Speaker/Moderator
13:00 – 13:10	Welcome Address	Dr. Shioh-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei
13:10 – 13:20	Opening Speech by AHWP Chair	Dr. Saleh S. Al-Tayyar, Chair, AHWP Director-General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
13:20 – 13:30	<ul style="list-style-type: none"> • Roll-call • Adoption of Agenda 	<p>AHWP Secretariat</p> <p>Mrs. Joanna Koh, Chair, AHWP TC Director, Medical Device Branch, Health Sciences Authority, Singapore</p> <p>Mr. Ali M. Al-Dalaan, Co-chair, AHWP TC Executive Director, Medical Device Sector, SFDA, Kingdom of Saudi Arabia</p> <p>Ms. Chadaporn Tanakasemsub, Co-chair, AHWP TC Vice President, Asia Pacific Quality Assurance/Regulatory Affairs Zimmer, Asia Pacific, Singapore</p>

13:30 – 13:45	Updates on AHWP TC Leaders Meeting in Chinese Taipei with AHWP Chair (Nov 2, 2012)	Mrs. Joanna Koh, Chair, AHWP TC Director, Medical Device Branch, Health Sciences Authority, Singapore
13:45 – 14:00	Report and Overview of TC Meeting in Manila (June 2012)	Mr. Ali M. Al-Dalaan, SFDA, Kingdom of Saudi Arabia Ms. Chadaporn Tanakasemsub, Zimmer, Asia Pacific, Singapore
14:00 – 14:15	Updates by WG1 (Pre-Market Submission)	Ms. Huifen Bai, HSA, Singapore Mr. Alfred Kwek, GE Healthcare, Singapore
14:15 – 14:30	Updates by WG1a (In-vitro Diagnostic Device)	Ms. Li-Ling Liu, TFDA, Chinese Taipei Mr. Jeffrey Chern, ITRI, Chinese Taipei
14:30 – 14:45	Updates by WG2 (Post-Market Surveillance and Vigilance)	Mr. Yorkie Chow, DOH, Hong Kong SAR Dr. Kulwant Saini, Johnson & Johnson, India
14:45 – 15:00	Tea Break	
15:00 – 15:15	Updates by WG3 (Quality Management System)	Mr. Ali M. Al-Dalaan, SFDA, Kingdom of Saudi Arabia Mr. Ee Bin Liew, Philips Healthcare, Singapore
15:15 – 15:30	Updates by WG4 (Quality System Audit)	Mr. Abdullah Al-Rasheed, SFDA, Kingdom of Saudi Arabia Ms. Eun Hee Cho, Abbott Vascular, Korea
15:30 – 15:45	Updates by WG5 (Clinical Evidence Requirements)	Ms. Sumati Randeo, Abbott Laboratories, India
15:45 – 16:00	Updates by WG6 (Capacity Building and Regulatory Training)	Dr. Rama Sethuraman, HSA, Singapore Mr. Jack Wong, Johnson & Johnson, Singapore
16:00 – 16:15	Updates by STG (N) (Medical Device Nomenclature)	Mr. Lian-Chun Yang, SFDA, China Ms. Carol Yan, Johnson & Johnson, China
16:15 – 16:30	- Update from Secretariat (Resolutions to be resolved in the Main Meeting)" - AHWP TC Meeting Closing Remark	Mr. Bryan So, HKPC, Hong Kong SAR Mrs. Joanna Koh, HSA, Singapore
End of AHWP TC Meeting		

AHWP TC Training Workshop

Saturday, November 3, 2012

Venue: Mega Room, Level 8, W Taipei

Time	Session	Speaker	Moderator/ Facilitator			
08:00 – 08:10	Opening Speech	Mrs. Joanna Koh, Chair, AHWP Technical Committee/ HSA, Singapore				
08:10 – 08:20	Welcome Address	Dr. Shiow-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei				
08:20 – 08:30	Souvenirs to Speakers & Photo Taking	Dr. Shiow-Ing Wu Deputy Director-General, TFDA, DOH, Chinese Taipei				
08:30 – 09:30	Affordable and Accessible IVD	Prof. Rosanna Peeling, LSHTM, UK	Dr. Chun-Nan Lee, Professor, Department of Clinical Laboratory Sciences and Medical Biotechnology, College of Medicine, NTU, Chinese Taipei			
09:30 – 10:00	Tea break					
10:00 – 12:00	Clinical rationale (basis) of Medical Devices and Medical Technology advances in Medical Device Panel Discussion and Q&A	Mr. Rainer Voelksen Edwards Lifesciences, France Dr. Peter Staehr Abbott Vascular, USA	Dr. Rong-Sen Yang, Dept. Orthopedics Surgery, NTUH, Chinese Taipei			
12:00 – 13:00	Lunch					
	Parallel Session 1 (Mega Room 1, Level 8, W Taipei)		Parallel Session 2 (Mega Rooms 2 + 3, Level 8, W Taipei)			
Time	Session	Speaker	Moderator/ Facilitator	Session	Speaker	Moderator/ Facilitator
13:00 – 14:30	Quality Management System (QMS)	Mr. Grant Ramaley, IAF, Australia	Dr. Han-Son Dawn, Taiwan Medical and Biotech	Introduction and International Comparative Overview	Ms. Nicole Denjoy, Vice-Chair, DITTA , EU	Dr. Yio-Wha Shau, General Director, BDL, ITRI, Chinese Taipei
	Overview of Global Issues and Activities Related to Counterfeit /Falsified Medicines	Mr. Albert Li, ITRI, Chinese Taipei Mr. Jeffrey Gren, Department of Commerce, USA	Industry Association, Chinese Taipei	European Union: How Medical Software are currently regulated? USA & Canada: Regulation and Guidelines on Medical Software Latest Developments on Medical Software in Japan	Mr. Laurent Selles, DG SANCO, EC Dr. John Abbott, MITA, Chair IEC TC87, USA Mr. Susumu Takahashi, JIRA, Japan	

	Panel Discussion and Q&A	All Speakers		Panel Discussion and Q&A	All Speakers	
14:30-15:00	Tea break					
15:00 – 16:30	<p>Enhancement of Post-market Surveillance Experiences in EU</p> <p>Elements of a successful registry in the post-market surveillance system</p> <p>- Experiences in Chinese Taipei</p> <p>- Experiences in Japan</p> <p>Panel discussion and Q&A</p>	<p>Mr. Laurent Selles, DG SANCO, European Commission, EU</p> <p>Ms. Tina Wu, TFDA, DOH, Chinese Taipei</p> <p>Dr. Atsushi Tamura, PMDA, Japan</p> <p>All Speakers</p>	<p>Dr. Jau-Min Wong, National Taiwan University, Chinese Taipei</p>	<p>Status on Standards Development for Medical Software</p> <p>Medical Software and IEC 62304 in Europe: Frequently Asked Questions on Interpretation and Application</p> <p>Practical Cases</p> <p>Panel discussion and Q&A</p> <p>Closing Remark</p>	<p>Dr. Peter Linders, Chair of CENELEC TC 62 Chair and Co-leader of IEC 82304-1, EU</p> <p>Mr. Michael Bothe, VDE Testing & Certification Institute, EU</p> <p>Mr. Maurizio Andreano, COCIR, EU</p> <p>All speakers</p> <p>Mrs. Joanna Koh, Chair, AHWP TC/HSA, Singapore</p>	<p>Ms. Nicole Denjoy, Vice-Chair, DITTA, EU</p>
16:30	End of AHWP TC Training Workshop					

2012 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products

Sunday, November 4, 2012

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

Time	Session	Speaker/Panelist/Moderator	
08:30 – 09:00	<p>Opening Remark : Objective and expected outcome of the workshop</p> <p>Opening Remark by AHC Director (video)</p> <p>Photo Session</p>	<p>Ms. Li-Ling Liu, AHWP Vice Chair, Director, Division of Medical Device and Cosmetics, TFDA, DOH, Chinese Taipei</p> <p>Dr. Kwang-Ho Lee Director, APEC Harmonization Center/KFDA, Korea</p>	
09:00 – 09:30	Keynote: Updates on APEC	Mr. Mike Ward, Chair of APEC RHSC/ Health Canada, Canada	
09:30 – 11:10	<p>Current Regulatory Perspectives and Challenges of APEC Economies on Regulating Medical Device Combination Products</p> <ul style="list-style-type: none"> • USA • Japan • Korea • China • Chinese Taipei : Survey Results of all APEC Economies 	<p>Speakers :</p> <p>Mr. John (Barr) Weiner, FDA, USA</p> <p>Dr. Yoichi Onodera, PMDA, Japan</p> <p>Mr. Young-Min Kim, KFDA, Korea</p> <p>Mr. Lian-Chun Yang, SFDA, China</p> <p>Dr. Hsien-Yi Lin, TFDA, Chinese Taipei</p>	<p>Moderator :</p> <p>Mrs. Elizabeth Baker, MHRA, UK</p> <p>Ms. Janet Trunzo, AdvaMed, USA</p>
11:10 – 11:40	Tea Break		

11:40 – 12:40	The European Approach	<p>Speakers :</p> <p>Mrs. Elizabeth Baker, MHRA, UK</p> <p>Dr. Gert Bos, BSI, UK</p>	<p>Moderator :</p> <p>Ms. Janet Trunzo, AdvaMed, USA</p> <p>Mrs. Elizabeth Baker, MHRA, UK</p>
12:40 – 13:40		Lunch	
13:40 – 14:30	<p>Panel Discussion : Current Regulatory Perspectives and Challenges of APEC Economies on Regulating Medical Device Combination Products</p>	All speakers and moderators from previous session	
14:30 – 15:00		Tea Break	
15:00 – 16:00	<p>Case Studies of Combination Products Regulated as Medical Devices</p> <ul style="list-style-type: none"> • Drug-eluting stent • Wound dressings with antibacterial properties • Antibacterial orthopedic and neurological devices <p>Panel Discussion and Q&A</p>	<p>Speakers :</p> <p>Ms. Geraldine Finn, Medtronic, USA</p> <p>Mr. Scott Sardeson, 3M, USA</p> <p>Ms. Karen Sylvia, Johnson & Johnson, USA</p>	<p>Moderator:</p> <p>Mr. Michael Gropp, Medtronic, USA</p>
16:00 – 17:30	<p>Future direction: Potential Path Toward Convergence</p> <ul style="list-style-type: none"> • Definition • Clinical Investigation (IDE) • Premarket Review (PMA) • GMP • Post Market Surveillance • International Cooperation • Industry Perspective <p>Panel Discussion and Q&A</p>	<p>Speakers :</p> <p>Dr. Sethuraman Rama HSA, Singapore</p> <p>Mr. John (Barr) Weiner , FDA, USA</p> <p>Ms. Janet Trunzo, AdvaMed, USA</p>	<p>Moderator :</p> <p>Ms. Lindsay Tao, Johnson & Johnson, China</p> <p>Mr. John (Barr) Weiner , FDA, USA</p>
17:30 – 17:50	Summary and Outcome of Workshop		Ms. Lindsay Tao, Johnson & Johnson , China



		Mr. John (Barr) Weiner, FDA, USA
17:50 – 18:00	Closing Remark	Ms. Li-Ling Liu, AHWP Vice Chair, Director, Division of Medical Device and Cosmetics, TFDA, DOH, Chinese Taipei
18:00	End of APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products	



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)	