

Day 4 Agenda: 14 November 2019 (Thursday)

TIME	24 th AHWP Annual Meeting (Main Meeting) AGENDA	
08:30-09:10	<p>Under the auspices of His Excellency Dr. Ahmed Mohamed Obaid Al Saidi, the Minister of Health, Sultanate of Oman and His Excellency Dr. Mohamed Al Hosni, Undersecretary of Health Affairs, Ministry of Health, Sultanate of Oman</p> <p>Welcome Address Dr. Mohamed Al Rubayee, Director General of Pharmaceutical Affairs and Drug Control, Ministry of Health, Sultanate of Oman</p> <p>Opening Address Mr. Ali M. Al-Dalaan, AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p> <p>Group Photo</p>	
09:10-09:20	<p>Main Meeting</p> <ul style="list-style-type: none">- Roll Call- Adoption of Agenda- Adoption of 23rd AHWP Annual Meeting Minutes	<p>Mr. Ali M. AL-DALAAN AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p> <p>Supported by Ir. Bryan SO AHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, CUHK</p>

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09:20-10:00 (20mins each)	AHWP Status Reports - AHWP Overall Status Report - AHWPTC Status Report	Ms. TRAN Quan, AHWP Vice Chair (Industry), Vice President, RAGAQA, Asia Pacific, Align Technology Er. Alfred KWEK AHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd.
10:00-10:30	TEA BREAK	
10:30-10:45	IMDRF Status Update	Ms. Aysylu VALEEVA IMDRF Chairman of IMDRF Secretariat Federal Service on Surveillance In Healthcare (Roszdravnadzor) Russia
10:45-11:15 (15mins each)	IMDRF Member Country Harmonization Efforts - Medical Device Single Audit Program (MDSAP) - International Regulatory Cooperations	Mr. William M. SUTTON Assistant Country Director, USFDA China Office Mr. Fumihito TAKANASHI Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW) Japan

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<p>11:15-12:30 (15mins each)</p>	<p>International Organizations Updates</p> <ul style="list-style-type: none"> - APEC - ASEAN - African Medical Devices forum (former PAHWP) - WHO 	<p>Mr. Fikriansyah Bin IRMAN, Senior Medical Device Reviewer, Ministry of Health, Indonesia (APEC)</p> <p>Mrs. Korrapat Trisarnsri, Chair, Medical Device Committee, ASEAN</p> <p>Ms. Paulyne WAIRIMU, ViceChair, African Medical Devices forum (former PAHWP)</p> <p>Ms. Adriana Velazquez BERUMEN, Senior Advisor on Medical Devices, Essential In Vitro Diagnostics Secretariat, Medicines and Health Products Department, WHO</p> <p>Mr. Charles CHIKU, Technical Officer, Prequalification Team, Regulation of Medicines and other Health Technologies, WHO</p>
<p>12:30-13:45</p>	<p>LUNCH</p>	
<p>13:45- 14:15 (10mins each)</p>	<p>AHWP Liaison Member Updates</p> <ul style="list-style-type: none"> - APACMed Update - DITTA Update - GS1 Update 	<p>Ms. Harjit GILL, Chief Executive Officer, APACMed</p> <p>Ms. Kelly MALLINGER, Director, Product Controllershship, GE Healthcare, DITTA Representative</p> <p>Ms. Géraldine LISSALDE-BONNET, Director Public Policy, GS1 Global Office</p>

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14:15-15:15 (15mins each)	AHWP Member Country/Region Updates - China - Saudi Arabia - South Korea - Sultanate of Oman	Mr. Deyuan JIANG, Director General, Department of Medical Device Registration, NMPA, China Mr. Abdullah ALGHURAIBI, Director for Regulations and Registration Support, Medical Devices Sector, SFDA, Saudi Arabia Dr. Seil PARK, Assistant Director, High-Tech Devices Division, MFDS, South Korea Eng. Faiza ALZADJALI, Director, Medical Device Control Dept, DGPA&DC, Ministry of Health, Oman
15:15-15:35	TEA BREAK	
15:35-15:50 (15mins each)	AHWP Member Country/Region Updates (Con't) - Kyrgyz Republic (new member to be endorsed)	Ms. Ainura ABALIEVA, Head of Medical Devices Registration Department, Department of Drug Provision and Medical Equipment, Ministry of Health, Kyrgyz Republic
15:50-16:00	AHWP Secretariat Updates - Secretariat Report - Financial Report	AHWP Secretariat

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16:00-16:30	<p>Resolution and Endorsement</p> <p>1. Resolutions AHWP Secretariat: "Amendment 7 to Terms of Reference" AHWP Secretariat: "Amendment 6 to House Rules"</p> <p>2. Endorsement of White Paper AHWP, APACMed, Deloitte: "White paper on Competency Framework for Medical Technology Regulators"</p> <p>3. Endorsement of Guidance Documents from WG WG1,2,3:"Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)" WG2,1, 3:"Categorisation of Changes to a Registered Medical Device" WG9:"Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system"</p> <p>4. Endorsement of New Member Kyrgyz Republic</p> <p>5. Endorsement of New Liaison Member GMDN Agency</p>	<p>Mr. Ali M. AL-DALAAN AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia</p> <p>Supported by Ir. Bryan SO AHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, CUHK</p>

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16:30-16:35	Announcement of 25th AHWP Annual Meeting Host	Mr. Ali M. AL-DALAAN AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
16:35-16:45	Closing Remarks	Mr. Ali M. AL-DALAAN AHWP Chair Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia

END OF DAY 4

17:45-18:30	Adjourned 7th AHWP ASL Annual General Meeting For ASL Members only (Transfer to VIP room)	AHWP Secretariat
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