



**REPORT OF THE 24th MEETING OF THE
ASIAN HARMONIZATION WORKING PARTY (AHWP)**

Grand Millennium Muscat, Muscat, Oman

14th November 2019

INTRODUCTION

(1) The 24th Meeting of the Asian Harmonization Working Party (AHWP) was held on 14th November 2019 at Muscat, Oman. The meeting was chaired by Mr. Ali M. Al-Dalaan, Chair of AHWP, co-chaired by Mr. Deyuan Jiang, who represented Mr. Gao Guobiao, Vice-Chair of AHWP (regulatory authority) and Ms. Tran Quan, Vice-Chair of AHWP (industry).

OPENING CEREMONY

(2) H.E. Dr. Mohamed Al Rubayee, Director General of Pharmaceutical Affairs and Drug Control, Ministry of Health, Sultanate of Oman, welcomed all the participants for joining the 24th AHWP Meeting in Muscat, Oman.

(3) Mr. Ali M. Al-Dalaan, Chair of AHWP, welcomed and thanked all participants for attending the 24th AHWP Meeting. He extended his gratitude to the Ministry of Health, Sultanate of Oman for hosting this Meeting in Oman 2019. He also thanked the members of the Organizing Committee, AHWP leadership, and particularly Dr. Mohamed Al Rubayee, the Directorate General of Pharmaceutical Affairs and Drug Control and the staff from Oman Ministry of Health for all the arrangements of this Meeting.

(4) Ms. Quan Tran, Vice Chair of AHWP (industry), thanked the Ministry of Health of Oman and congratulated the people of Sultanate of Oman for their 49th National Day of Oman. She then introduced the Asian Harmonization Working Party's journey to regulatory harmonization.

(5) H.E. Dr. Ahmed Mohamed Obaid Al Saidi, the Minister of Health, Sultanate of Oman expressed his gratitude and welcomed all participants for coming to Oman.



ROLL CALL

(6) The roll call was made by AHWP Chair and Vice-Chairs, AHWPTC Chair and Co-Chairs, Working Group (WG) Chairs and Co-chairs, AHWPTC Advisors as well as primary and secondary representatives from member regulatory authorities and industries of AHWP and AHWPTC. Over 200 participants attended the 24th AHWP Annual Meeting, with the list of participants as appended in **ANNEX (1)**.

ADOPTION OF AGENDA

(7) The revised agenda was tabled at the meeting, as appended in **ANNEX (2)**, which was adopted by members with applause.

ADOPTION OF MINUTES OF 23rd AHWP ANNUAL MEETING

(8) The 23rd AHWP Annual Meeting Minutes was adopted with applause as appended in **ANNEX (3)**.

UPDATES BY AHWP

(9) Ms. Tran Quan, Vice-Chair of AHWP, reported the highlights of progresses of AHWP over the past year, including the training and the capacity building activities, the enhancement of AHWP's global partnership with international organizations and AHWP membership expansion. The proposed AHWP white paper on "Competency Framework for Medical Technology Regulators" developed with APACMed and Deloitte had consolidated comments received from public with AHWP leadership advices, would seek for endorsement in this Meeting.

The presentation on AHWP Updates was appended as **ANNEX (4)**.

UPDATES BY AHWP TECHNICAL COMMITTEE (AHWPTC)

(10) Er. Alfred Kwek, Co-Chair of AHWP Technical Committee, reported the highlights of AHWPTC during the past year, including the AHWP TC strategic plan, summary of planned work items of Working Groups for 2019-2020, endorsed guidance documents of WG, the continuous efforts in achieving global harmonization and capacity building projects carried in the past year.

The presentation on AHWPTC Updates was appended as **ANNEX (5)**.



UPDATES ON IMDRF ACTIVITIES

(11) Ms. Aysylu Valeeva, Chairman of IMDRF secretariat (entrusted by Ms. Elena Astapenko, Chair of IMDRF), presented the latest updates on IMDRF activities, including the organization structure, co-operations with AHWP, updates on seven working groups and summary of on-going activities of the current work items.

The presentation on IMDRF Activities Updates was appended as **ANNEX (6)**.

UPDATES ON IMDRF MEMBER COUNTRIES

(12) Mr. William M. Sutton, International Program and Policy Analyst (Medical Devices) from U.S. FDA China Office, introduced the Medical Device Single Audit Program (MDSAP), including the assessment and audits, potential benefits, way to participate and updates in 2019.

The presentation on MDSAP was appended as **ANNEX (7)**.

(13) Mr. Fumihito Takanashi from Ministry of Health Labour and Welfare of Japan, presented the International regulatory cooperation updates, which has been recommended by WHO for Regulatory system strengthening through reliance. MDSAP Affiliate Membership has been introduced as one of the multiple channels of regulator cooperation.

The presentation on International regulatory cooperation was appended as **ANNEX (8)**.

UPDATES BY APEC:

(14) Mr. Fikriansyah Bin Irman, representative of APEC, presented the updates from APEC Life Science and Innovation Forum Regulatory Harmonization Steering Committee (LSIF-RHSC), including the health fora in APEC structure, vision to promote regulatory convergence, work of Centre of Excellence (CoE) in building a better harmonization model, report of trainings provided by APEC since 2009, and also RHSC's priority work areas.

The presentation on updates from APEC was appended as **ANNEX (9)**.



UPDATES BY ASEAN AMDC

(15) Mrs. Korrapat Trisarnsri, Chair of the 8th ASEAN Medical Device Committee (AMDC), presented the updates of AMDC. Updates included the implementation of AMDD in difference countries and technical assistance and co-operation with agencies.

The presentation of ASEAN AMDC Updates was appended as **ANNEX (10)**.

UPDATES BY AFRICAN MEDICAL DEVICES FORUM (FORMER PAHWP)

(16) Dr. Paulyne Wairimu, Vice Chair of the African Medical Devices Forum (AMDF), was not able to attend the meeting and provided the updates of the AMDF as appended as **ANNEX (11)**.

UPDATES BY WHO

(17) Ms. Adriana Velazquez, Senior Advisor on medical devices of WHO, presented the updates on WHO global program of work and guidance developed on medical devices. The way forward of standardizing the nomenclature of medical devices was explained with a proposed timeline on technical input to meet the goal of “Good Health and Well-Being” of the 17 WHO’s sustainable development goals to transform the world.

The presentations were appended as **ANNEX (12)**.

(18) Mr. Charles Chiku, Technical Officer of Diagnostics Assessment team of WHO, presented WHO’s work in IVD. Updates included explaining the work of prequalification of IVDs in WHO, expanding the Collaborative Registration Procedure (CRP) for IVDs, developing guidance and specifications for prequalification, international harmonization and convergence.

The presentation of WHO Updates was appended as **ANNEX (13)**.

UPDATES BY AHWP LIAISON MEMBER - APACMed

(19) Ms. Harjit Gill, Chief Executive Officer, presented the updates about APACMed current membership, collaboration with AHWP and Deloitte on Capacity Building,



2019 Asia Pacific MedTech Forum, 4th Asia Pacific MedTech Regulatory Summit and ASEAN regulators training.

The presentation of Updates on APACMed was appended as **ANNEX (14)**.

UPDATES BY AHWP LIAISON MEMBER - DITTA

(20) Ms. Kelly Mallinger, steering committee member of DITTA, presented the updates about DITTA global presence, structure and governance, achievements on standards, cybersecurity, UDI, nomenclature, standardization and good refurbishment practice, as well as additional information of MDSAP and artificial intelligence.

The presentation of Updates on DITTA was appended as **ANNEX (15)**.

UPDATES BY AHWP LIAISON MEMBER – GS1

(21) Ms. Géraldine Lissalde-Bonnet, Director Public Policy of GS1 Global Office, presented the updates about GS1 global system of standards in identification, capturing for Barcodes and EPC/RFID, and sharing for data exchange. Efforts made by GS1 in harmonizing the implementation of UDI and providing a platform for collaboration on UDI and distinguishing the need for alignment on UDI databases of USA and EU.

The presentation of Updates on GS1 was appended as **ANNEX (16)**.

REGULATORY UPDATES BY AHWP MEMBERS

The country/region regulatory updates were presented by:

- Mr. Deyuan Jiang, Director General, Department of Medical Device Registration, NMPA, China;
- Mr. Abdullah Alghuraibi, Director for Regulations and Registrations Support, Medical Devices Sector, SFDA, Saudi Arabia;
- Dr. Seil Park, Assistant Director, High-Tech Devices Division, MFDS, South Korea;
- Eng. Faiza Al Zadjali, Director, Medical Device Control Department, DGPA & DC, Ministry of Health, Sultanate of Oman;



- Ms. Ainura Abalieva, Head of Medical Devices Registration Department, Department of Drug Provision and Medical Equipment, Ministry of Health, Kyrgyz Republic

for the regulatory updates on medical device of their country/region, including the authorization organization structure, updates on regulations and guidance, requirements for approval, future trends and actions, etc.

The presentations of regulatory updates were appended as:

China	: ANNEX (17)
Saudi Arabia	: ANNEX (18)
South Korea	: ANNEX (19)
Sultanate of Oman	: ANNEX (20)
Kyrgyz Republic	: ANNEX (21)

REPORT BY SECRETARIAT

(22) Mr. Benjamin Chan, Deputy Chairman of Hong Kong Medical and Healthcare Device Industries Association, represented the AHWP Secretariat team to present the work summary and financial report for 2018-2019. He reported the summary of secretariat support work done, including:

- Support to AHWP strategic framework towards 2020 “The Foreseeable Harmonization Horizon”
- Support to AHWP Annual Meeting and capacity building project
- Support to the harmonization in key areas based on GHTF principles and AHWP guidance
- Support to the enhancement of AHWP’s global partnership
- Support to the organization of AHWP TC Leaders Meeting and channeling between WG leaders and TC leaders
- Support to the AGMs, management of AHWP reserve/fund in AHWP ASL
- Support to the organizations of secretariat meeting, OC and host of AHWP Annual Meeting
- Support to SADS On-line weekly updates
- Support to AHWP website revamp



The presentation on Secretariat work summary and Financial Report for 2018-2019 was appended as **ANNEX (22)**.

PROPOSED DOCUMENTS FOR RESOLUTION AND ENDORSEMENT

(23) Ir. Bryan SO, Executive Secretary General of AHWP presented the summary of items for resolution and endorsement in the meeting that included the amendments to AHWP Terms of Reference and House Rules, endorsement of White Paper, three WG Guidance Documents, one New Member and one New Liaison Member.

(24) Ir. Bryan So reported that the PROPOSED “Amendment 7 to Terms of Reference” as prepared by the Secretariat team was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of Amendment 7 to AHWP Terms of Reference as according to the simple majority rule.

(25) Ir. Bryan So reported that the PROPOSED “Amendment 6 to House Rules” as prepared by the Secretariat team was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of Amendment 6 to AHWP House Rules as according to the simple majority rule.

(26) Ir. Bryan So reported that the PROPOSED White paper on “Competency Framework for Medical Technology Regulators” as prepared by AHWP Capacity Building Program Leaders, APACMed and Deloitte was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of white paper on Competency Framework for Medical Technology Regulators as according to the simple majority rule.



- (27) Ir. Bryan So reported that the PROPOSED “Categorisation of Changes to a Registered Medical Device” as prepared by WG1, WG2 & WG3 was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of the guidance document on Categorisation of Changes to a Registered Medical Device as according to the simple majority rule.
- (28) Ir. Bryan So reported that the PROPOSED “Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)” as prepared by WG1, WG2 & WG3 was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of the guidance document on Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) as according to the simple majority rule.
- (29) Ir. Bryan So reported that the PROPOSED “Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system” as prepared by WG9 was available on AHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document with consolidated outcome of public consultations was also available on AHWP website. Supported by AHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP, declared the endorsement of the guidance document on Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system as according to the simple majority rule.
- (30) Mr. Ali M. Al-Dalaan, Chair of AHWP, announced that the AHWP new member application of Kyrgyz Republic was endorsed.
- (31) Mr. Ali M. Al-Dalaan, Chair of AHWP, announced that the AHWP new liaison member application of GMDN Agency was endorsed.

The presentation on resolution and endorsement was appended as **ANNEX (23)**.



ANNOUNCEMENT OF 25th AHWP ANNUAL MEETING HOST

(32) Mr. Ali M. Al-Dalaan, Chair of AHWP, informed members that the announcement of host for the next AHWP annual meeting will be announced through AHWP website.

CLOSING REMARKS

(33) Mr. Ali M. Al-Dalaan, Chair of AHWP, presented the closing remarks of the Meeting. Ali concluded the Meeting by summarizing all the presentations and thanking the host, all members of AHWP and all participants for their contributions. The meeting was adjourned at 17:00 on 14th November 2019.

ACKNOWLEDGEMENT

(34) The participants from over 30 countries/regions expressed their appreciations to the Directorate General of Pharmaceutical Affairs and Drug Control, Ministry of Health, Sultanate of Oman for their hospitality and excellent arrangements for this Meeting.

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