

REPORT OF THE 25th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP) / GLOBAL HARMONIZATION WORKING PARTY (GHWP)

Online via Zoom

1st December 2021

13:00 (KSA)

INTRODUCTION

- (1) The 25th Meeting of Asian Harmonization Working Party (AHWP) / Global Harmonization Working Party (GHWP) was held on 1st December 2021 via Zoom online. The meeting was chaired by Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, co-chaired by Mr. Gao Guobiao, Vice-Chair of AHWP/GHWP (Regulatory Authority) and Ms. Tran Quan, Vice-Chair of AHWP/GHWP (Industry).

OPENING CEREMONY

- (2) Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, welcomed and thanked all participants for attending the 25th AHWP/GHWP Meeting online. He extended his gratitude to the members of the Organizing Committee, AHWP/GHWP leadership and the Secretariat for the arrangements of the Meeting.

KEYNOTE SPEECH - HIGHLIGHT OF GHWP STRATEGIC FRAMEWORK 2021-2026

- (3) Ms. Quan Tran, Vice Chair of AHWP/GHWP (Industry), thanked participants for attending the 25th AHWP/GHWP Meeting. She then shared highlight of GHWP Strategic Framework 2021-2026.

ADOPTION OF AGENDA

- (4) The agenda, as appended in **ANNEX (1)**, was adopted by members without objection.

ADOPTION OF MINUTES OF 24th AHWP ANNUAL MEETING

- (5) The 24th AHWP Annual Meeting Minutes was adopted as appended in **ANNEX (2)**.

AHWP/ GHWP OVERALL STATUS REPORT

- (6) Ms. Quan Tran, Vice-Chair of AHWP/GHWP, reported the highlights of progresses of AHWP/GHWP over the past year, including the training and the capacity building activities, the enhancement of AHWP/GHWP's global partnership with international organizations and AHWP/GHWP membership expansion.

The presentation on AHWP/GHWP overall status updates was appended as **ANNEX (3)**.

AHWP/ GHWP TC STATUS REPORT

- (7) Er. Alfred Kwek, Co-Chair of AHWP/GHWP Technical Committee, reported the highlights of AHWP/GHWPTC during the past year, including the AHWP/GHWP TC strategic plan, summary of planned work items of Working Groups for 2020-2021, endorsed guidance documents of WG, the continuous efforts in achieving global harmonization and capacity building projects carried in the past year.

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

IMDRF STATUS UPDATE

- (8) Dr. Jeong-Rim Lee, Director General, Medical Device Evaluation Department, National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS), South Korea, presented the latest updates on IMDRF activities, including the organization structure, co-operations with AHWP/GHWP, updates on working groups and summary of on-going activities of the current work items.

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

IMDRF MEMBER COUNTRY HARMONIZATION EFFORTS AND WGS UPDATES

- (9) Dr. Chung Keun Lee, IMDRF Secretariat | Assistant Director from High-Tech Medical Devices Division, NIFDS, MFDS, South Korea, introduced the IMDRF member country harmonization efforts and WGs updates.

The presentation on IMDRF WGs updates was appended as **ANNEX (6)**.

INTERNATIONAL ORGANIZATIONS UPDATES

(10) Ms. Cheng-Ning Emily Wu, Senior Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, Chinese Taipei presented the APEC LSIF-RHSC updates.

The presentation on APEC LSIF-RHSC updates was appended as **ANNEX (7)**.

(11) Mrs. Salbiah Yaakop, Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia presented the ASEAN updates.

The presentation on ASEAN updates was appended as **ANNEX (8)**.

(12) Ms Paulyne Wairimu, Interim Chair, African Medical Device Forum presented the African Medical Devices Forum (former PAHWP).

The presentation on African Medical Devices Forum was appended as **ANNEX (9)**.

(13) Ms. Adriana Velazquez Berumen, Team Lead, Medical Devices and In Vitro Diagnostics, Health Product Policy and Standards Department, Access to Medicines and Health Products Division, World Health Organization presented the WHO updates

The presentation on WHO updates was appended as **ANNEX (10)**.

(14) Mr. Jesús Rueda Rodríguez, Director General Strategies, Special Projects & International Affairs, MedTech Europe presented the Global Medical Technology Alliance (GMTA) updates.

The presentation on GMTA updates was appended as **ANNEX (11)**.

AHWP/GHWP JOINT EFFORTS WITH INTERNATIONAL ORGANIZATIONS

(15) Mr. Nicklas Christian Funk, Sustainability Engineer of AMBU provided the updates from Joint Advisory Group 5 (JAG5) of IEC TC 62 and ISO/TC 210.

(16) Mrs. Salbiah Yaakop, Director of Policy, Codes and Standards, Medical Device Authority, Ministry of Health, Malaysia highlighted on ISO16142 Recognized essential principles of

safety and performance of medical devices

The presentation on ISO16142 was appended as **ANNEX (12)**.

(17) Dr. Peter Linders, Chairman, ISO/TC210 Director of Global Regulations & Standards, Philips provided updates on ISO13485 and other updates by ISO/TC210.

AHWP/GHWP LIAISON MEMBER UPDATES

(18) Ms. Miang Tanakasemsub, Regulatory Affairs Committee Chair APACMed and Head of QA Commercial and Regulatory Affairs, APAC, Cardinal Health provided updates of APACMed.

(19) Dr. Peter Linders, Member of the DITTA Board of Directors and Director of Global Regulations & Standards, Philips, presented the updates about DITTA.

The presentation of updates on DITTA was appended as **ANNEX (13)**.

(20) Ms. Géraldine Lissalde-Bonnet, Director Public Policy of Global Healthcare presented the updates from GS1.

The presentation of updates on GS1 was appended as **ANNEX (14)**.

(21) Mr. Mark Wasmuth, CEO of GMDN AGENCY presented the updates about GMDN.

The presentation of updates on GMDN was appended as **ANNEX (15)**.

IAF UPDATES ON CERTSEARCH

(22) Mr. Matt Gantley, Chief Executive of UKAS presented the updates about IAF and CertSearch.

The presentation of updates on IAF and CertSearch was appended as **ANNEX (16)**.

PANEL DISCUSSION: GLOBAL CONVERGENCE ON MEDICAL DEVICE REGULATIONS

(23) Mr. Emmett Devereux, Chair, MedTech Europe and Director, Government and Regulatory Affairs, EMEA., Cook Medical EMEA Group Ltd moderated the panel discussion with Mr. Jesús Rueda Rodríguez, Director General Strategies, Special Projects & International Affairs, MedTech Europe as the panelist.

AHWP/GHWP MEMBER COUNTRY/REGION UPDATES

(24) The member country/region updates were presented by:

- Mr. ZHANG Hua, Deputy Director General, Department of Medical Device Registration, National Medical Products Administration, China;
- Eng. Abdullah Alghuraibi, Director of Regulations and Registration Support, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia;
- Dr. LEE Jeong-Rim, Director General, Medical Device Evaluation Department, National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety (MFDS), South Korea;
- Ms. Cheng-Ning Wu Emily, Senior Technical Specialist, Division of Medical Devices and Cosmetics, Food and Drug Administration, Ministry of Health and Welfare, Chinese Taipei

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 member country/region updates were appended as:

China	: ANNEX (17)
Saudi Arabia	: ANNEX (18)
South Korea	: ANNEX (19)
Chinese Taipei	: ANNEX (20)

DIGITAL TRANSFORMATION IN DEVICE REGULATORY: AI, SOFTWARE AND CYBERSECURITY

(25) The updates were presented by:

- Dr. Young-Woo Bae, Assistant Director, Digital Health Device TF, NIFDS, MFDS, South Korea
- Mr. PENG Liang, Deputy Director, Center for Medical Device Evaluation, National Medical Products Administration, China;

The presentations of digital transformation in device regulatory were appended as:

South Korea : ANNEX (21)

China : ANNEX (22)

**PANEL DISCUSSION: DIGITAL TRANSFORMATION IN DEVICE REGULATORY:
AI, SOFTWARE AND CYBERSECURITY**

(26) Dr. Peter Linders, Member of the DITTA Board of Directors| Director, Global Regulations & Standards, Philips moderated the panel discussion with panelists:

- Mr. PENG Liang, Deputy Director, Center for Medical Device Evaluation, National Medical Products Administration, China
- Dr. Young-Woo Bae, Assistant Director, Digital Health Device TF, NIFDS, MFDS, South Korea
- Mr. Abdullatif Alwatban, Saudi FDA
- Mr. Koen Cobbaert, DITTA | Senior Manager, Quality, Standard & Regulations, Philips
- Mr. Carlos Arglebe, DITTA | Vice President, Health Services QM, Siemens Healthcare

REPORT BY SECRETARIAT

(27) Ir Bryan So, AHWP/GHWP Executive Secretary General from CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong, represented the AHWP/GHWP Secretariat team to present the work summary and financial report for 2020-2021.

The presentation on Secretariat Work Summary and Financial Report for 2020-2021 was appended as ANNEX (23).

ENDORSEMENTS

- (28) Chaired by Mr. Ali M. Al-Dalaan, AHWP/GHWP Chair and supported by Ir Bryan SO, AHWP/GHWP Executive Secretary General, the summary of items for endorsement was presented in the meeting that included the Appointment of AHWP/GHWP TC Chair, AHWP/GHWP Guidance Documents, AHWP Re-branding to GHWP, Change of Terms of Reference (TOR), Change of House Rules (HR), Admission of New Member & Liaison Member.
- (29) Appointment of AHWP/GHWP TC Chair - Ir Bryan So reported the background for endorsement of TC Chair. Supported by AHWP/GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, declared the endorsement of Mrs Salbiah Yaakop of Medical Device Authority (MDA), Ministry of Health, Malaysia as AHWP/GHWP TC Chair for the remaining term until next election in physical annual meeting, as according to the simple majority rule.
- (30) AHWP/GHWP Guidance Documents - Ir Bryan So reported the PROPOSED “Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency” as prepared by WG1, WG2 & WG3 was available on AHWP/GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations was also available on AHWP/GHWP website. Supported by AHWP/GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, declared the endorsement of the guidance document on “Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency” as according to the simple majority rule.
- (31) AHWP/GHWP Guidance Documents - Ir Bryan So reported the PROPOSED “Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices” as prepared by WG2 & WG5 was available on AHWP/GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations was also available on AHWP/GHWP website. Supported by AHWP/GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, declared the endorsement of the guidance document on “Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for In Vitro Diagnostic Medical Devices” as according to the simple majority rule.

- (32) AHWP/GHWP Guidance Documents - Ir Bryan So reported the PROPOSED “Replacement Reagent and Instrument Family Policy” as prepared by WG2 was available on AHWP/GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations was also available on AHWP/GHWP website. Supported by AHWP/GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, declared the endorsement of the guidance document on “Replacement Reagent and Instrument Family Policy” as according to the simple majority rule.
- (33) AHWP re-branding to GHWP - Ir Bryan So reported the background of AHWP re-branding to GHWP, with the re-branding and draft new GHWP logo discussed in leadership meeting during 24th AHWP Meeting in Oman in 2019. Bryan further reported the design of the GHWP logo, the pre-announcement and the completed groundwork for the re-branding since the issuance of press-release in March 2020. Supported by AHWP/GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP, declared the endorsement on AHWP re-branding to GHWP as according to the simple majority rule.
- (34) Change of Terms of Reference (TOR) - Ir Bryan So reported that the PROPOSED “Amendment 8 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (TOR)” as prepared by the Secretariat team was available on AHWP/GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations was also available on GHWP website. Supported by GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of GHWP, declared the endorsement of “Amendment 8 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (TOR)” as according to the simple majority rule.
- (35) Change of House Rules (HR) - Ir Bryan So reported that the PROPOSED “Amendment 7 to the Asian Harmonization Working Party House Rules” as prepared by the Secretariat team was available on GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations was also available on GHWP website. Supported by GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of GHWP, declared the endorsement of “Amendment 7 to the Asian Harmonization Working Party House Rules” as according to the simple majority rule.

(36) Admission of New Member - Ir Bryan So reported that an application was received from the U.S. Food and Drug Administration (USFDA) in Oct 2021 for joining the Working Party as a member, which was supported by the Working Party leadership. Supported by the GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of GHWP, declared the endorsement of the new member application of USFDA, as according to the simple majority rule.

(37) Admission of New Liaison Member - Ir Bryan So reported that an application was received from Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (IACRC) in April 2021 for joining the Working Party as a Liaison Member, which was supported by the Working Party leadership. Supported by the GHWP members with applause, Mr. Ali M. Al-Dalaan, Chair of GHWP, declared the endorsement of the new liaison member application of IACRC, as according to the simple majority rule.

ANNOUNCEMENT ON AHWP/GHWP FACE-TO-FACE ANNUAL MEETING

(38) Mr. Ali M. Al-Dalaan, Chair of GHWP, announced that next physical annual meeting is targeted to be held by end of 2022 in China, subject to further review on the COVID-19 pandemic situation and the related measures on international travels.

REMARKS BY HOST OF NEXT ANNUAL MEETING

(39) Mr. Gao Guobiao, Vice-Chair of GHWP, Party Secretary of Center for Medical Device Evaluation, National Medical Products Administration, China thanked all participants for attending the 25th AHWP/GHWP Meeting. He extended his invitation to all GHWP members and stakeholders for participation in the next annual meeting in China, targeted to be held by end of 2022.

CLOSING REMARKS

(40) Mr. Ali M. Al-Dalaan, Chair of GHWP, presented the closing remarks of the Meeting. Ali concluded the Meeting by thanking all members of GHWP, speakers, participants, members of the organizing committee and secretariat teams for their contributions. The meeting was adjourned at 22:20 (KSA) on 1st December 2021.

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