

**REPORT OF THE 26th MEETING OF
THE GLOBAL HARMONIZATION WORKING PARTY (GHWP)**

Crowne Plaza Riyadh RDC Hotel & Convention,
Riyadh, The Kingdom of Saudi Arabia
16th February 2023

INTRODUCTION

(1) The 26th Meeting of Global Harmonization Working Party (GHWP) was held on 16th February 2023 at Riyadh, The Kingdom of Saudi Arabia. The meeting was chaired by Mr. Ali M. Al-Dalaan, Chair of GHWP, co-chaired by Mr. Gao Guobiao, Vice-Chair of GHWP (Regulatory Authority) and Ms. Tran Quan, Vice-Chair of GHWP (Industry).

OPENING CEREMONY

(2) Dr. Hisham bin Saad Aljadhey, Chief Executive Officer, Saudi Food and Drug Authority, Kingdom of Saudi Arabia, welcomed all the participants for joining the 26th GHWP Meeting in Riyadh, The Kingdom of Saudi Arabia.

(3) Mr. Ali M. Al-Dalaan, Chair of GHWP, welcomed and thanked all participants for attending the 26th GHWP Meeting. He extended his gratitude to the members of the Organizing Committee, GHWP leadership for all the arrangements of this Meeting.

ROLL CALL

(4) The roll call was made by GHWP Chair and Vice-Chairs, GHWPTC Chair and Co-Chairs, Working Group (WG) Chairs and Co-chairs, GHWPTC Advisors as well as primary and secondary representatives from member regulatory authorities and industries of GHWP and GHWPTC. Over 300 participants attended the 26th GHWP Annual Meeting, with the list of participants as appended in **ANNEX (1)**.

ADOPTION OF AGENDA

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

ADOPTION OF MINUTES OF 25th AHWP /GHWP ANNUAL MEETING

(6) The 25th AHWP/GHWP Annual Meeting Minutes was adopted with applause as appended in **ANNEX (3)**.

GHWP STATUS REPORT

- (7) Mr. Ali M. Al-Dalaan, Chair of GHWP, reported the GHWP Overall Status Report with highlights of progresses of GHWP over the past year, including the enhancement of GHWP's global partnership with international organizations and GHWP membership expansion to 33 member countries or regions covered more than 57% population in the world.

The presentation on GHWP Overall Status Report was appended as **ANNEX (4)**.

- (8) Mrs. Salbiah Yaakop, Chair of GHWP Technical Committee, reported the GHWPTC Status Report with highlights of GHWPTC during the past year, including the GHWP TC strategic plan, report summary of planned work items of Working Groups, endorsed guidance documents of WG, the continuous efforts in achieving global harmonization and capacity building projects carried in the past year.

The presentation on GHWPTC Status Report was appended as **ANNEX (5)**.

IMDRF STATUS UPDATES

- (9) Dr. Andrzej Rys, IMDRF Chair 2023, Principal Scientific Adviser, Directorate-General for Health and Food Safety (DG SANTE), European Commission, introduced the Working Groups and latest updates on IMDRF Strategic plan 2021-2025.

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

INTERNATIONAL ORGANIZATIONS & HARMONIZATION EFFORTS

- (10) Dr. Jeewon Joung Ph.D., Director, Pre-submission Consultation Team, Ministry of Food & Drug Safety (MFDS), Republic of Korea, APEC Harmonization Center (AHC), provided introduction to the AHC and its effort for Medical Device.

The presentation on APEC Harmonization Center (AHC) was appended as **ANNEX (7)**.

- (11) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, MDA, Ministry of Health, Malaysia, ASEAN presented the ASEAN Medical Device Committee Action Plans and updates.

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

GHWP LIAISON MEMBER UPDATES

(12) Mr. Anirudh Sen, Director, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) introduced APACMed and its collaboration with GHWP.

The presentation on APACMed was appended as **ANNEX (9)**.

(13) Mr. Yuji Yanagida, GRP WG Vice chair of DITTA presented the Working Groups and DITTA Priorities.

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

(14) Ms. Géraldine Lissalde-Bonnet, Vice-President Healthcare, GS1 Global Office introduced GS1 role in UDI across the world.

The presentation of updates on GS1 was appended as **ANNEX (11)**.

(15) Mrs. Deniz Bruce, Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency) presented the GMDN Agency vision, mission and its focus in 2023-2024.

The presentation of updates on GMDN Agency was appended as **ANNEX (12)**.

(16) Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) introduced GMTA, regulatory convergence and reliance.

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

(17) Ms. Sandra Ligia Gonzalez, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) shared IACRC's updates, Capacity Building and a success story of Colombia.

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

COUNTRY/REGION UPDATES

(18) The country/region updates were presented by:

- Ms. Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality, Therapeutic Goods Administration (TGA), Australia
- Ms. Nada Alkhatat, Policy Officer, Directorate-General for Health and Food Safety (DG SANTE) European Commission
- Ms. TOGASHI Mika, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Eng. Abdullah AlGuraibi, Saudi Food and Drug Authority (SFDA), Kingdom of Saudi Arabia
- Dr. Xu Jinghe, Deputy Commissioner, National Medical Products Administration (NMPA), People's Republic of China
- Dr. Jeong-Rim LEE, (GHWPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety (MFDS), Republic of Korea
- Ms. Melissa Torres, Associate Director for International Affairs, The United States Food and Drug Administration (US FDA), United States of America

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 country/region updates were appended as:

Australia	: ANNEX (15)
European Commission	: ANNEX (16)
Japan	: ANNEX (17)
Kingdom of Saudi Arabia	: ANNEX (18)
People's Republic of China	: ANNEX (19)
Republic of Korea	: ANNEX (20)
United States of America	: ANNEX (21)

RESOLUTION AND ENDORSEMENT

(19) Resolution - Chaired by Mr. Ali M. Al-Dalaan, GHWP Chair and supported by Ir Bryan SO, GHWP Executive Secretary General, the Resolution Amendment 8 to the Global

Harmonization Working Party House Rules on GHWP Strategic Advisory Board (SAB) was supported by GHWP members with applause. Mr. Ali M. Al-Dalaan, Chair of GHWP, declared the endorsement of the resolution.

- (20) Endorsement of Strategic Framework - Ir Bryan So reported the PROPOSED “Global Harmonization Working Party Strategic Framework towards 2026” 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 the Strategic Framework.
- (21) Endorsement of White Paper - Ir Bryan So reported the PROPOSED “Medical Device Regulatory Authorities Training Curriculum White Paper” 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 the White Paper.
- (22) GHWP Guidance Documents - Ir Bryan So reported the PROPOSED “Categorisation of Changes to a Registered Medical Device” as prepared by WG1, WG2 & WG3 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 the guidance document on “Categorisation of Changes to a Registered Medical Device” as according to the simple majority rule.
- (23) GHWP Guidance Documents - Ir Bryan So reported the PROPOSED “Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance” as prepared by WG8 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 the guidance document on “Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance”.

(24) Endorsement of New Member- Mr. Ali M. Al-Dalaan, Chair of GHWP, announced that the GHWP new member application of Japan was endorsed.

(25) Short Speech by New Member

Mr. Masahiro Takahata, Director, Office of Regenerative Medicines Products Evaluation, Ministry of Health, Labour and Welfare (MHLW), Japan, delivered a speech as the new member of GHWP.

ELECTION AND ENDORSEMENT OF GHWP OFFICE BEARERS

(26) Chaired by Mr. Ali M. Al-Dalaan, GHWP Chair, and supported by Ir Bryan SO, GHWP Executive Secretary General, the election and endorsement of GHWP Office Bearers, TC Office Bearers and WGs Chairs and Co-Chairs, Years 2023-2025, was carried out.

The result was appended as ANNEX (22).

(27) Speech by GHWP Chair-Elect

Dr. Xu Jinghe, Deputy Commissioner, National Medical Products Administration (NMPA), People's Republic of China delivered a speech as the GHWP Chair-Elect.

(28) Presentation of Certificates and Recognition Award

Mr. Ali M. Al-Dalaan, Chair of GHWP, presented certificates and recognition awards on stage.

ANNOUNCEMENT OF NEXT GHWP ANNUAL MEETING HOST & SHORT SPEECH

(29) Mr. Ali M. Al-Dalaan, Chair of GHWP, asked if any member would host the next GHWP Annual Meeting. Representative of the People's Republic of China has shown of hands and volunteered to host the meeting in Shanghai, China. Chair announced the host for the next GHWP Annual Meeting is the People's Republic of China.

CLOSING REMARKS

(30) Mr. Ali M. Al-Dalaan, Chair of GHWP, presented the closing remarks of the Meeting. He 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 17:55 (KSA) on 16th February 2023.

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