REPORT OF THE 28th MEETING OF THE GLOBAL HARMONIZATION WORKING PARTY (GHWP)

Hall 1, Kuala Lumpur Convention Centre, Kuala Lumpur, Malaysia

12th December 2024

INTRODUCTION

(1) The 28th Meeting of Global Harmonization Working Party (GHWP) was held on 12th December 2024 at Kuala Lumpur, Malaysia. The meeting was chaired by Dr. Xu Jinghe, Chair of GHWP, co-chaired by Ms. Eka Purnamasari, Vice-Chair of GHWP (Regulatory Authority) and Ms. EunHee Cho, Vice-Chair of GHWP (Industry).

OPENING CEREMONY

(2) Dr. Muralitharan Paramasua, Chief Executive, Medical Device Authority (MDA), Ministry of Health, Malaysia, welcomed all the participants for joining the 28th GHWP Meeting in Kuala Lumpur, Malaysia.

(3) Dr. Xu Jinghe, Chair of GHWP, welcomed and thanked all participants for attending the 28th GHWP Meeting. He extended his gratitude to the members of the GHWP Leadership and Organizing Committee 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, Strategic Advisory Board (SAB) Members, 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 350 participants attended the 28th 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 were adopted by members with applause.

ADOPTION OF MINUTES OF 27th GHWP ANNUAL MEETING

(6) The 27th GHWP Annual Meeting Minutes was adopted with applause as appended in **ANNEX (3)**.

GHWP STATUS REPORTS

(7) On behalf of GHWP Chair Dr. Xu Jinghe, Ir. Bryan So, GHWP Executive Secretary General, reported the GHWP Overall Status Report with highlights of progresses of GHWP over the past year, including the GHWP Strategic Objectives, highlights on the enhancement in GHWP website, lobal partnership with international organizations and the GHWP TC Leaders Meeting to be held in June 2025 and to be hosted by Egypt EDA, which will be the first GHWP meeting in Africa.

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

(8) Dr. Mohammed Majrashi, Acting 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)**.

(9) Prof. Fei Hang, Executive Vice President of GHWP (Guangzhou) Academy South China University of Technology reported the GHWP Academy Status, with highlights of current progress on website, fund raising channel, capacity building platform, trainings and development plan.

The presentation was appended as **ANNEX (6)**.

INTERNATIONAL ORGANIZATIONS & HARMONIZATION EFFORTS

(10) Mr. Hiiti Baran Sillo, Unit Head of Regulation and Safety, Department of Regulation and Prequalification, WHO , shared the latest updates and work by the WHO on Medical Device.

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

(11) Dr. Miho Sato, Principal Coordinator of Pharmaceuticals and Medical Devices Agency PMDA, Japan, presented the IMDRF plans and updates.

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

(12) Ms. Paulyne Wairimu, Chair of the African Medical Devices Forum (AMDF) presented the AMDF plans and updates.

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

GHWP LIAISON MEMBER UPDATES

(13) Ms. Cindy Pelou, Leader for Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) introduced APACMed and its collaboration with GHWP.

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

(14) Ms. Sunny Woo, Team Leader of Korea Medical Devices Industry Association, International Affairs Team, presented the prioritization work of DITTA.

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

(15) Ms. Chiara Bernini, Senior Manager of Healthcare Public Policy, GS1 introduced GS1 role in UDI across the world.

The presentation on GS1 was appended as **ANNEX (12)**.

(16) Ms. Chinaniso Majoni, Senior Nomenclature Developer and Quality Lead of Global Medical Devices Nomenclature Agency (GMDN Agency) presented the GMDN Agency vision, mission and its focus in 2025-2026.

The presentation on GMDN Agency was appended as **ANNEX (13)**.

(17) 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 (14)**.

(18) Ms. Sandra Ligia Gonzalez, Executive Secretary of Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) shared IACRC's

updates by video presentation.

COUNTRY/REGION UPDATES

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

- Ms. Aidahwaty M. Olaybal, Director of Pre-market Control Division, MDA, Malaysia
- Dr. Rania Soliman, General manager of general administration of medical devices, Marketing authorization, Egyptian Drug Authority
- Ms. Helsy Pahlemy, Senior Health Administrator, Ministry of Health, Indonesia
- Ms. Yukina Ueno, Deputy Director, Medical Devices Evaluation Division, Ministry of Health, Labour and Welfare (MHLW), Japan
- Eng. Abdullah Mohammed Alghuraibi, Executive Director, Medical Devices Evaluation, Medical devices Sector, SFDA, Kingdom of Saudi Arabia
- Ms. Dong Jiangping, Director General, Department of Medical Device Regulation NMPA, People's Republic of China
- Dr. Seil Park, Assistant Director, Division of High-Tech Medical Devices, Ministry of Food and Drug Safety, Republic of Korea

For the regulatory updates on medical devices 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:

Malaysia	: ANNEX (15)
Egypt	: ANNEX (16)
Indonesia	: ANNEX (17)
Japan	: ANNEX (18)
Kingdom of Saudi Arabia	: ANNEX (19)
People's Republic of China	: ANNEX (20)
Republic of Korea	: ANNEX (21)

RESOLUTION AND ENDORSEMENT

(20) Endorsements of TC Chair, WG5 Chair, WG8 Chair, STG (CERP) Chair and STG (CERP) Co-Chair positions were chaired by Dr. Xu Jinghe, GHWP Chair and supported by Ir. Bryan So, supported by GHWP members with applause. Dr. Xu Jinghe, Chair of GHWP, declared the endorsement of the resolution with details as follows:

a) Dr. Mohammed Majrashi, "Acting TC Chair' to be "TC Chair"
b) Ms. Aidahwaty M. Olaybal, "WG5 Chair"
c) Ms. Idamazura Idris @ Harun, "WG8 Chair"
d) Mr. ZHANG Shiqing, "Acting STG (CERP) Chair" to be "STG (CERP) Chair"
e) Ms. Asmma Awad, "Acting STG (CERP) Co-Chair" to be "STG (CERP) Co-Chair"

(21) Endorsement of Amendments to TOR and House Rules, and New WG Guidance Documents- Ir. Bryan So reported the following documents were available on GHWP website under CALL FOR COMMENTS, and the PROPOSED FINAL document after public consultations were also available on GHWP website:

a) GHWP Secretariat "Amendment 9 to the GHWP TOR and House Rules (on e-Voting)"

b) GHWP Secretariat "Amendment 11 to GHWP House Rules on Descriptions of Secretariat Team"

c) WG1-WG2-WG3 "Change Management to Registered Medical Devices"

d) WG3 "Software as a Medical Device (SaMD) Pre-Market Submission Requirement – Comparison of requirement from Key jurisdictions"

e) WG4 "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative"

f) WG4 "Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative"

g) WG7 "*White Paper on Overview of Quality Management System Requirements in GHWP member county or region against ISO 13485:2016*"

h) WG7 "Guidance Document for Medical Device Organizations-Product Localisation for Manufacturing and Importation"

i) WG8 "Guidelines on Development of GHWP Documents-Part 1: Procedure for Development"

j) WG8 “Guidelines on Development of GHWP Documents-Part 2: Structure and Drafting”

k) WG9 “Creation and Placement of Unique Device Identifier”

l) WG9 “UDI Data Elements”

Supported by GHWP members with applause, it was declared the endorsements of the guidance documents as according to the simple majority rule.

Besides, it was endorsed the following principles, instead of Amendment 10 to GHWP TOR and House Rules on Establishment of Management Committee in GHWP:

1. To carry out reform on the organizational structure of GHWP
2. To enlarge the leadership size via establishment of Management Committee (MC) in GHWP
3. To allow more members to participate in the planning and decision-making process in GHWP
4. To continue the discussion and preparation on the detail arrangement on the establishment of MC in Q1 of 2025

(22) Endorsement of New Members

a) Endorsement of New Member, Botswana

Mr. Batlegang Dallas Mosweu, Manager, Medical Devices, Botswana Medicines Regulatory Authority (BOMRA), Botswana , delivered a speech to introduce the medical device regulatory system in Botswana and the expectation for joining GHWP as a member.

Supported by GHWP members with applause, Dr. XU Jinghe, Chair of GHWP, announced that the GHWP new member application of Botswana was endorsed.

b) Endorsement of New Member, Ghana

Mr. Emmanuel Nkrumah, Director of Medical Devices, Cosmetics and Household Chemicals Directorate, Food and Drugs Authority (FDA), Ghana delivered a speech to introduce the medical device regulatory system in Ghana and the expectation for joining GHWP as a member.

Supported by GHWP members with applause, Dr. XU Jinghe, Chair of GHWP, announced that the GHWP new member application of Ghana was endorsed.

c) Endorsement of New Member, Macao SAR, China

Mr. CHAN Tak In, Chief, Division of Chemical Medicines and Devices, Pharmaceutical Administration Bureau, Macao SAR, China, delivered a speech to introduce the medical device regulatory system in Macao SAR, China and the expectation for joining GHWP as a member.

Supported by GHWP members with applause, Dr. XU Jinghe, Chair of GHWP, announced that the GHWP new member application of Macao SAR, China was endorsed.

d) Endorsement of New Member, Uzbekistan

Mr. Alisher Temirov, Director, The Center for Pharmaceutical Products Safety, Uzbekistan delivered a speech to introduce the medical device regulatory system in Uzbekistan and the expectation for joining GHWP as a member.

Supported by GHWP members with applause, Dr. XU Jinghe, Chair of GHWP, announced that the GHWP new member application of Uzbekistan was endorsed.

(23) Endorsement of New Liaison Member

Ms. Rana Chalhoub, Regulatory Affairs Director of MECOMED, delivered a speech to introduce MECOMED and the expectation for joining GHWP as a liaison member.

Supported by GHWP members with applause, Dr. XU Jinghe, Chair of GHWP, announced that the GHWP new liaison member application of MECOMED was endorsed.

ANNOUNCEMENT OF NEXT GHWP ANNUAL MEETING HOST & SHORT SPEECH

(24) Based on earlier web announcement and email circulation with open invitation to all members of GHWP for the expression of interests to host the 29th GHWP and TC Annual Meeting in 2025, there were express of interests received from member countries/regions. However, as it is still undergoing internal processing and approval, we shall announce the host of the next annual meeting later on via web posting and email circulation.

CLOSING REMARKS

(25) Dr. Xu Jinghe, Chair of GHWP, presented the closing remarks of the Meeting. He concluded the Meeting by thanking the meeting host Malaysia MDA, all members of GHWP, speakers, participants, members of the organizing committee and secretariat teams for their contributions. The meeting was adjourned at 17:05 (GMT+8) on 12th December 2024.

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