

REPORT OF THE 29<sup>th</sup> MEETING OF  
THE GLOBAL HARMONIZATION WORKING PARTY (GHWP)  
Millennium Hilton Bangkok, 123 Charoen Nakhon Rd,  
Khlong Ton Sai, Khlong San, Bangkok, Thailand  
4<sup>th</sup> December 2025

INTRODUCTION

- (1) The 29<sup>th</sup> Meeting of Global Harmonization Working Party (GHWP) was held on 4<sup>th</sup> December 2025 at Millennium Hilton Bangkok, 123 Charoen Nakhon Rd, Khlong Ton Sai, Khlong San, Bangkok, Thailand. The meeting was chaired by Dr. Jinghe Xu, 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. Jinghe Xu, Chair of GHWP, welcomed all the participants for joining the 29<sup>th</sup> GHWP Meeting in Bangkok, Thailand.
- (3) Mr. Morakot Jaroonwattana, Senior Advisor in Safety, Effectiveness and Use of Health Product, on behalf of Thai FDA, welcomed and thanked all participants for attending the 29<sup>th</sup> 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. Nearly 300 participants attended the 29<sup>th</sup> GHWP Annual Meeting.

ADOPTION OF AGENDA

- (5) The agenda was tabled at the meeting, as appended in ANNEX (1), which were adopted by members with applause.

ADOPTION OF MINUTES OF 28<sup>th</sup> GHWP ANNUAL MEETING

- (6) The 28<sup>th</sup> GHWP Annual Meeting Minutes was adopted with applause as appended in ANNEX (2).

### GHWP STATUS REPORTS

- (7) GHWP Chair Dr. Jinghe Xu, delivered the GHWP Status Report of progresses of GHWP over the past year. A video of retrospective video was displayed with highlights of the past 3 years achievement under his chairmanship.
- (8) Dr. Mohammed Majrashi, 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 (3).

- (9) Ms. Quan Tran, SAB Member, and Prof. Fei Hang, Executive Vice President of GHWP (China) Academy South China University of Technology reported respectively the GHWP Capacity Building Status and Academy Status, with highlights of current progress of capacity building platform, trainings and development plan.

The presentation was appended as ANNEX (4).

- (10) Ms. EunHee Cho, GHWP Vice Chair and Prof. Fei Hang, Executive Vice President of GHWP (China) Academy South China University of Technology reported respectively on the GHWP White Paper Initiative and GHWP White Paper Progress Report, with highlights on the Strategic Framework, White Paper Working Mechanisms and Future Work.

The presentation was appended as ANNEX (5).

### INTERNATIONAL ORGANIZATIONS & HARMONIZATION EFFORTS

- (11) Ms. Agnes Kijoa, Technical Officer of WHO, shared the latest updates and work by the WHO on Medical Device.

The presentation on WHO was appended as ANNEX (6).

- (12) Ms. Lerato Moeti, Programme Officer-African Medicines Regulatory Harmonisation Programme (AMRH), presented the AMRH plans and updates.

The presentation on AMRH was appended as ANNEX (7).

GHWP LIAISON MEMBER UPDATES

- (13) Ms. Cindy Pelou, Lead for Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) provided brief introduction of APACMed.

The presentation on APACMed was appended as ANNEX (8).

- (14) Ms. Sunny Woo, Team Leader of Korea Medical Devices Industry Association, International Affairs Team, presented the work of DITTA and collaboration with GHWP.

The presentation on DITTA was appended as ANNEX (9).

- (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 (10).

- (16) Ms. Deniz Bruce, CEO of GMDN Agency, presented the GMDN Agency history, vision, mission and its work.

The presentation on GMDN Agency was appended as ANNEX (11).

- (17) Ms. Diana Kanecka, Director of the International Affairs department at MedTech Europe and co-chair of Global Medical Technology Alliance (GMTA introduced GMTA, regulatory convergence and reliance.

The presentation of updates on GMTA was appended as ANNEX (12).

- (18) Representative of Inter-American Coalition for Regulatory Convergence (IACRC) could not participate physically in this meeting. The presentation of updates on IACRC was appended as ANNEX (13).

- (19) Representative Mecomed could not participate physically in this meeting. The presentation of updates on Mecomed was appended as ANNEX (14).

#### UPDATES BY REEDS

(20) Mr. Michael Ding, Vice General Manager of Reed Sinopharm Exhibitions, shared the latest updates of Reed Exhibitions and the collaboration of CMEF with GHWP.

The presentation on REEDS was appended as ANNEX (15).

#### COUNTRY/REGION UPDATES

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

- Ms. Chayanee Pinkaew Pharmacist, Professional Level, Food and Drug Administration, Thailand
- Dr. Muralitharan Paramasua, Chief Executive of MDA, Malaysia
- Dr. Rania Soliman, General manager of general administration of medical devices, Marketing authorization, Egyptian Drug Authority
- Dr. Miho Sato, Principal Coordinator, pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Eng. Faiza Al Zadjali, MD Director, Ministry of Health, Sultanate of Oman
- Ms. Dong Jiangping, Director General, Department of Medical Device Regulation NMPA, People's Republic of China
- Ms. Hyekyung Son, Deputy Director of Cardiovascular and Imaging Device Division, 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:

Thailand	: ANNEX (16)
Malaysia	: ANNEX (17)
Egypt	: ANNEX (18)
Japan	: ANNEX (19)
Oman	: ANNEX (20)
People's Republic of China	: ANNEX (21)
Republic of Korea	: ANNEX (22)

#### RESOLUTION AND ENDORSEMENT

- (22) GHWP “Amendment 10 (R2) to GHWP TOR and House Rules” was announced endorsed by E-voting on 19<sup>th</sup> October 2025.
- (23) “GHWP Strategic Framework towards 2030” prepared by Leadership, TC advisors, SAB was reviewed and commented by GHWP, GHWPTC, WGs Leaders and TC Advisors. Then posted on GHWP website, email circulated and completed call for comments. Then posted on GHWP website towards endorsement. It is endorsed by GHWP members with applause.
- (24) “Renaming of GHWP (Guangzhou) Academy to GHWP (China) Academy” prepared by Leadership, TC advisors, SAB was reviewed and commented by GHWP, GHWPTC, WGs Leaders and TC Advisors. Then posted on GHWP website, email circulated and completed call for comments. Then posted on GHWP website towards endorsement. It is endorsed by GHWP members with applause.
- (25) “Decision on Holding Events to Celebrate the 30th Anniversary of GHWP in next GHWP annual meeting and TC meeting” prepared by Leadership was reviewed and commented by GHWP, GHWPTC, WGs Leaders and TC Advisors. Then posted on GHWP website, email circulated and completed call for comments. Then posted on GHWP website towards endorsement. It is endorsed by GHWP members with applause.
- (26) Dr. Tingting Xie 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) WG1-WG2-WG3 “Guidance on Determining of Lead Authority and Communication Process for Combination Products”
  - b) WG3 “Guidance on Pre-market submission requirement for artificial intelligence/machine learning based computer-assisted detection (CADE) and computer-assisted diagnosis (CADx) software as a medical device”
  - c) WG4 “Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non-Safety related Field Corrective Actions”

- d) WG4 “Playbook for Design and Implementation of Active Post-Market Surveillance System”
- e) WG7 “White Paper on Overview of Quality Management System Requirements and Implementation in GHWP member country or region”
- f) WG7 “Guidance for Control of Sterilized and Implantable Medical Device”
- g) WG7 “Guidance for Remote Inspections of Medical Device Manufacturers”
- h) WG9 “UDI Application Guidance Considerations for Manufacture to facilitate an effective UDI Implementation”

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

#### ENDORSEMENT OF NEW MEMBER

- (27) Mr. Keneni Benti Tuji, Medical device dossier assessor, Ethiopian Food and Drug Authority delivered a speech in recorded video to introduce the medical device regulatory system in Ethiopia and the expectation for joining GHWP as a member.

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

#### ELECTION AND ENDORSEMENT OF GHWP OFFICE BEARERS

- (28) Dr. Tingting Xie provided a briefing on election and endorsement procedures, including election of GHWP Chair and Vice Chairs, election of GHWPTC Chair and Co-Chairs, and election of Working Groups Chairs and Co-Chairs.

- (29) Chaired by Dr. Jinghe Xu, GHWP Chair, and supported by Dr. Tingting Xie, GHWP Executive Secretary General, the election and endorsement of GHWP Office Bearers, TC Office Bearers and WGs Chairs and Co-Chairs, Years 2025-2028, was carried out.

The result was appended as ANNEX (23).

SPEECH BY GHWP CHAIR-ELECT

(30) Dr. Muralitharan Paramasua, Chief Executive of MDA, Malaysia, delivered a speech as the GHWP Chair-Elect.

PRESENTATION OF CERTIFICATES AND RECOGNITION AWARD

(31) Dr. Jinghe Xu, Chair of GHWP, presented certificates and recognition awards on stage.

ANNOUNCEMENT OF NEXT GHWP ANNUAL MEETING HOST

(32) Dr. Jinghe Xu, Chair of GHWP, announced Hong Kong SAR the host for the next GHWP Annual Meeting. A short video was displayed introducing Hong Kong SAR followed by a speech from Dr. Liza To, Assistant Director of Health (Health Sciences and Technology), Department of Health, Hong Kong SAR.

CLOSING REMARKS

(33) Dr. Jinghe Xu, 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 17:20 (GMT+7) on 4<sup>th</sup> December 2025.

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