

**REPORT OF THE 27<sup>th</sup> MEETING OF  
THE GLOBAL HARMONIZATION WORKING PARTY (GHWP)**  
Grand Ballroom I, 7/F, Shanghai International Convention Center  
Shanghai, The People's Republic of China  
30<sup>th</sup> November 2023

**INTRODUCTION**

(1) The 27<sup>th</sup> Meeting of Global Harmonization Working Party (GHWP) was held on 30<sup>th</sup> November 2023 at Shanghai, The People's Republic of China. 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) Mr. Li Li, Commissioner of NMPA and Mr. Zhuang Mudi, Deputy Secretary General of the Shanghai Municipal People's Government welcomed all the participants for joining the 27<sup>th</sup> GHWP Meeting in Shanghai, The People's Republic of China.

(3) Dr. Xu Jinghe, Chair of GHWP, welcomed and thanked all participants for attending the 27<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 & industries of GHWP and GHWPTC. Over 600 participants attended the 27<sup>th</sup> 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 26<sup>th</sup> GHWP ANNUAL MEETING**

(6) The 26<sup>th</sup> GHWP Annual Meeting Minutes was adopted with applause as appended in **ANNEX (3)**.

### **GHWP STATUS REPORTS**

- (7) Dr. Xu Jinghe, 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 Strategic Framework towards 2026.

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

- (8) Dr. Abdullatif S. AlWatban, 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) Ms. Chloe Spathari and Ms. Nada Alkhayat, Policy Officers, Medical Devices, European Commission, introduced the Working Groups and latest updates on IMDRF Strategic plan.

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

### **INTERNATIONAL ORGANIZATIONS & HARMONIZATION EFFORTS**

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

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

- (11) 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 (8)**.

### **GHWP LIAISON MEMBER UPDATES**

- (12) 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 (9)**.

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

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.

(15) Mrs. Deniz Bruce, Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency) presented the GMDN Agency vision, mission and its focus in 2024-2025.

(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 (11)**.

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

### **COUNTRY/REGION UPDATES**

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

- Ms. Maria Cecilia Lopez, Head of the Authorization and Registration of Medical Devices Subdepartment - ANDID/ISP Department, Chile
- Mr. Graeme Tunbridge, Senior Vice President, Global Regulatory and Quality, Medical Devices at BSI
- Ms. Ismiyati Surata, Senior Health Administrator, Ministry of Health, Indonesia
- Mr. Miho Sato, Coordinator, Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA), Japan
- Mr. Abdullah Alghuraibi, Director of Regulation and Standard, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
- Mr. Bounxou Keohavong, Director General, Food and Drug Department, Ministry of Health, Laos PDR

- Dr. Muralitharan Paramasua, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
- Mr. Lyu Ling, Director General, Department of Medical Devices Registration, NMPA, People's Republic of China
- Mr. Ahn Young Wook, Deputy Director, In-vitro Diagnostic Devices Division at NIFDS of MFDS, Republic of Korea
- Mr. Lertchai Lertvut, Deputy Secretary-General, Food & Drug Administration, Thailand
- Mr. Nguyen Tu Hieu, Deputy Director, Infrastructure and Medical Device Administration, Ministry of Health, Vietnam

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:

Chile	: ANNEX (12)
European Commission	: ANNEX (13)
Indonesia	: ANNEX (14)
Japan	: ANNEX (15)
Kingdom of Saudi Arabia	: ANNEX (16)
Laos PDR	: ANNEX (17)
Malaysia	: ANNEX (18)
People's Republic of China	: ANNEX (19)
Republic of Korea	: ANNEX (20)
Thailand	: ANNEX (21)
Vietnam	: ANNEX (22)

## **RESOLUTION AND ENDORSEMENT**

(19) Endorsement of Vice-Chair (Regulatory Authority) and WG5 Chair positions were chaired by Dr. Xu Jinghe, GHWP Chair and supported by Ir Bryan SO, GHWP Executive Secretary General, with the earlier endorsement of Mrs. Eka Purnamasari, Director for Medical Devices Control, Ministry of Health, Indonesia as GHWP Vice-Chair (Regulatory Authority) and Dr. Mohammed Majrashi, Executive director of surveillance and biometric, Saudi FDA, Kingdom of Saudi Arabia as WG5 Chair supported by GHWP members with applause. Dr. Xu Jinghe, Chair of GHWP, declared the endorsement of the resolution.

(20) GHWP 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) WG1-WG2-WG3 "Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)"

b) WG2 "Guidance for Additional Considerations to Support Conformity Assessment of In vitro Companion Diagnostic Medical Devices"

c) WG4 "Post Market Resource Center"

d) WG7 "Guidance document on the risk based approach to quality management system aspects: ISO13485:2016"

e) WG7 "Guidance for Auditing Supplier to Medical Device Manufacturers"

f) WG7 "A Guide to Understanding Presently Available Audit Duration Determination Systems"

g) WG7 "A Guide to Understanding Best Practices in Audit Life Cycle Management"

h) WG9 "GHWP UDI Rule"

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

(21) Endorsement of New Member, Egypt-

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

(22) Short Speech by New Member

Dr. Rania Soliman, General Manager of General Administration of Medical Devices

Marketing authorization, Egyptian Drug Authority, Egypt, delivered a speech as the new member of GHWP.

(23) Endorsement of New Member, Cuba-

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

(24) Short Speech by New Member

Ms. Yadira Alvarez Rodriguez, Specialist of Medical Devices Department, CECMED, Cuba, delivered a speech as the new member of GHWP.

(25) Endorsement of Membership Withdrawal, USA

It was reported that on 27<sup>th</sup> November 2023, Dr XU Jinghe, Chair of GHWP, received a letter from Dr. Jeffrey Shuren of US FDA, requested for the withdrawal of their membership from GHWP. The GHWP Leadership and SAB have made evaluation, and unanimously approved the membership withdrawal application from USA. Supported by GHWP members with applause, it was declared the endorsement of the membership withdrawal of USA.

**PRESENTATION OF CERTIFICATES OF APPOINTMENT TO THE MEMBERS OF GHWP STRATEGIC ADVISORY BOARD**

(26) Background of the GHWP Strategic Advisory Board (SAB) was presented.

(27) Dr. XU Jinghe, Chair of GHWP, presented certificates of appointment to the following Members of GHWP Strategic Advisory Board:

- a) Dr. Jeong-Rim Lee
- b) Mr. Gao Guobiao
- c) Ms. Tran Quan
- \* Mr. Alfred Kwek (by pre-recorded video)

(28) SAB Members delivered short speeches after their receipt of the certificates.

**PRESENTATION OF BRONZE PLAQUE TO GHWP (GUANGZHOU) ACADEMY AND SHORT PRESENTATION**

(29) Background, selection procedures and approval on the establishment of the GHWP Academy was presented.

(30) Dr. XU Jinghe, Chair of GHWP, presented the Bronze Plaque of GHWP (Guangzhou) Academy to Prof. Yong XU, Vice President of South China University of Technology, People's Republic of China.

(31) Prof. Yong XU presented a short speech after the receipt of the Bronze Plaque.

**CEREMONY ON STRATEGIC COOPERATION BETWEEN GHWP AND REED SINOPHARM EXHIBITIONS ON CMEF**

(32) Background on the strategic cooperation with Reed Sinopharm Exhibitions (RSE) was presented.

(33) GHWP and Reed Sinopharm Exhibitions on CMEF were exchanged between Ms. EunHee Cho, GHWP Vice-Chair (Industry) and Mr. Li Chao, Managing Director of Reed Sinopharm Exhibitions exchanged the signed agreements during the Ceremony.

**PRESENTATION OF SOUVENIRS TO COMPANY SPONSORS**

(34) Dr. Xu Jinghe, Chair of GHWP, and Ms. Eka Purnamasari, GHWP Vice-Chair (Regulatory Authority), presented the souvenirs to company sponsors of the 27<sup>th</sup> GHWP Annual Meeting and 27<sup>th</sup> TC Meeting.

**ANNOUNCEMENT OF NEXT GHWP ANNUAL MEETING HOST & SHORT SPEECH**

(35) With single application received by the deadline on the show of interests to host the next GHWP Annual Meeting, Dr. Xu Jinghe, Chair of GHWP, announced Malaysia as the host for the next GHWP Annual Meeting in 2024.

(36) Dr. Muralitharan Paramasua, Chief Executive, Medical Device Authority, Ministry of Health, Malaysia presented a short speech as host of next GHWP Annual Meeting.

**CLOSING REMARKS**

(37) Dr. Xu Jinghe, Chair of GHWP, presented the closing remarks of the Meeting. Dr. Xu 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+8) on 30<sup>th</sup> November 2023.

- END-