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To Promote and Protect Public Health through Global Collaboration

Dear GHWP members and GHWP partners,

With your vigorous support and concerted efforts, the 27th GHWP Annual Meeting and TC Meeting was successfully held in Shanghai, China from November 27 to 30, 2023. More than 600 representatives from 25 countries and regions attended the meeting, jointly writing a new chapter of the GHWP endeavor. On behalf of GHWP leadership, I would like to express my heartfelt gratitude to all representatives, experts, and friends.

This is the first annual meeting after the election of the new GHWP leadership. Plentiful achievements have been made.

Firstly, we summarized the work achievements of GHWP in the past 9 months. The work achievements mainly included (1) improving the drafting procedures of GHWP guidance documents for medical devices to advance the quality and efficiency, (2) setting up the Strategic Advisory Board (SAB) to strengthen the research of forward-looking regulatory strategy, (3) establishing the first GHWP Academy to enhance the regulatory capacity building of GHWP member countries and regions, (4) building the first GHWP global industry exchange platform to promote the achievement through exhibition and exchange of innovative medical devices, and (5) intensifying communication with relevant international organizations to foster global medical device regulatory convergence, harmonization, and reliance.

Secondly, we delivered extensive and in-depth exchanges and discussions around cutting-edge technologies for medical device innovation. Focused on the opportunities and challenges brought by new technologies, innovative products and new regulatory approaches, multiple topics were designed for this annual meeting, at which academic discussions were profoundly delivered on cutting-edge technologies, regulatory pathways for innovation, regulatory tools fostering innovation, risk management of innovative medical devices, and application practice of unique device identifier (UDI). Owing to novel topics and advanced views, this annual meeting was highly praised by both regulatory authorities and industry representatives.

Thirdly, relevant international organizations, partners, and representatives from some countries and regions reported the latest progress in medical device regulation. Specifically, the International Medical Device Regulators Forum (IMDRF), World Health Organization (WHO), Africa Medical Devices Forum (AMDF), Asia Pacific Medical Technology Association (APACMed), Global Medical Technology Alliance (GMTA), Global Medical Device Nomenclature (GMDN), Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA), Globe Standard 1 (GS1), and Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) reported the latest work progress. Representatives from 11 countries and regions reported the latest progress of regulatory work, including Chile, the European

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Commission, Indonesia, Japan, Kingdom of Saudi Arabia, Laos PDR, Malaysia, People's Republic of China, Republic of Korea, Thailand, and Vietnam.

Fourthly, a series of important arrangements were made at this Annual Meeting. Such arrangements included (1) approving 8 GHWP guidance documents, (2) agreeing to set up a special task group to conduct research on common evaluation reliance practice, (3) agreeing to accept Egypt and Cuba as new GHWP members, (4) approving the membership withdrawal request from the U.S. FDA, and (5) approving Medical Device Authority (MDA), Malaysia to host the 28th GHWP Annual Meeting.

Besides busy work, all representatives attended the city tour, visited the beautiful night scene of the Huangpu River, enjoyed the elegance and charm of Shanghai, and experienced the wonderful integration of traditional art and modern music at the Gala Dinner.

Looking back on the extraordinary course that GHWP has gone through in the past 27 years, all representatives resonate with common viewpoints and feelings that GHWP has our distinct features. With the joint participation of medical device regulatory authorities and industry representatives, GHWP has always directly confronted major issues in the medical device regulatory field, adhered to the coordinated development and growth for both regulators and the industry and actively cope with big challenges in medical device industry.

GHWP is open and inclusive. At present, GHWP has 34 member countries and regions. With SAB, Capacity Building Committee (CBC), and Technical Committee, GHWP can deliver extensive and in-depth discussions on major issues. In this big family, all GHWP member countries and regions consult on an equal footing and pool their wisdom, striving to seek common development and create a bright future together.

GHWP is enterprising and pioneering. Over the years, GHWP has always focused on the major topics of medical device regulation and industry development, endeavoring to actively serve GHWP member countries and regions and contribute to global public health by constantly innovating platforms and carriers.

GHWP upholds laws and regulations. Major decisions of GHWP are made according to its Terms of Reference and House Rules. GHWP member countries and regions, regardless of large or small, communicate on an equal footing, and are strongly encouraged to contribute more wisdom and strength to global medical device regulatory convergence, harmonization, and reliance by making full use of their resources.

During the annual meeting, representatives from regulatory authorities and industry repeatedly talked about regulatory convergence, harmonization and reliance. Convergence is the trend of development, harmonization is the consistency of action, and reliance is the goal of endeavor.

We must be aware that achieving global medical device regulatory convergence, harmonization, and reliance is a common expectation, and at the meanwhile, it is a gradual process of growth that takes time. The world is diverse. GHWP member countries and

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regions are at different stages of development, embrace different resources and with different regulatory capacities. In this context, it is impossible to accomplish regulatory convergence, harmonization, and reliance overnight. Instead, we must go forward step by step.

We must be aware that we should not be only aiming high and looking far, but also be down-to-earth to achieve global medical device regulatory convergence, harmonization, and reliance. In the face of a new round of scientific and technological revolution and industrial transformation, we must focus on the present and plan for the future in the long term. We should proceed from consensus, grasp critical links, go ahead steadily and firmly, and consolidate at every step. Practical results will further foster the in-depth participation of all GHWP member countries and regions and build a stronger sense of accomplishment and fulfillment.

We must be aware that we should not only adhere to our own good traditions but also actively draw on others' successful experiences to achieve global medical device regulatory convergence, harmonization, and reliance. In addition to mission and vision, every organization has its strengths and weaknesses. An organization can only achieve better development through open communication. GHWP has established its strategic focus and work priorities. We will be problem-oriented and goal-driven to concentrate on doing our work. Insisting on the principles of equality, openness, robustness, and win-win, GHWP will continue to cordially cooperate with international organizations, relevant countries and regions, and partners that are committed to fostering regulatory convergence, harmonization, and reliance.

Profound insight brings new height, sound mindset brings best condition and broad layout brings wonderful outcome. Looking into the future, GHWP will continue to expedite the achievement of medical device regulatory convergence, harmonization, and reliance with more united strength, more open mind, more enterprising attitude, and more pragmatic style, striving to make new and greater contributions to the protection and promotion of global public health.

Best regards,

Xu Jinghe

GHWP Chair