Promote Global Medical Device Regulations towards Convergence, Harmonization and Reliance by Seeking for Openness, Cooperation, Robustness and Win-Win

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Building a human community with a shared future is the permanent pursuit of people all over the world. We should expand our global vision with joint efforts to promote and protect public health, thus to build a better world. Medical device is a booming industry full of vigor and prospect with great influences on the wellbeing of mankind. GHWP is one of the long-standing international organizations on medical device regulations harmonization, with members covering the continents of Africa, America, Asia as well as the Middle East. GHWP is the international platform representing regulatory authorities and industry from 33 countries and regions, through which active exchange and communication, including regulatory and technological insights and ideas regarding medical device have been conducting by all stakeholders worldwide. Keeping pace with economic globalization and regulations integration, the international community should strive to bring together global wisdom and power, and promote global medical device regulations towards convergence, harmonization and reliance with a broader vision, more concerted efforts, stronger belief and steadier pace, to jointly make great contribution to the public health.

I. The growth of GHWP shows a bright future for global medical device regulation

GHWP was established in 1997 as a non-profit organization that comprises medical device regulatory authorities and industry representatives across the globe. In GHWP, regulatory authorities and the industry work together to promote convergence, harmonization and reliance of the global medical device regulations, boost the regulatory capability, and bring in more wisdom to improve the quality of medical device and safeguard the public health.

GHWP was formerly known as the Asian Harmonization Working Party (AHWP).With the rapid growth of GHWP, more members have been attracting.

The members of GHWP have expanded from Asia to America and Africa as well as Middle East, covering 33 countries and regions and accounting for nearly 60% of the global population.Under the circumstances, AHWP was rebranded to GHWP in December 2021.

GHWP's vision is to achieve international harmonization of medical device regulatory framework among regulatory authorities, convergence of regulatory requirements, open and trust-based efforts between regulatory authorities and the industry across the globe.

GHWP's mission is to strategically accelerate medical device regulatory convergence by promoting an agile and fit-for-purpose regulatory model for medical devices based on latest development in regulatory science, and to lead and promote systematic capacity building for future-ready regulatory professionals in light of emerging technologies, while enabling patient safety and timely access to safe and effective medical devices.

GHWP's goals are to develop and recommend approaches for the global convergence and harmonization of medical device regulations; to facilitate the exchange of knowledge and expertise amongst regulatory authorities and the industry for the establishment of harmonized requirements; to promote capacity building in members and to foster strategic membership expansion; to work in collaboration with related international organizations such as IMDRF, WHO, ISO, and IEC.

GHWP is co-led by a Chair from regulatory authorities and two Vice-Chairs respectively from regulatory authorities and the industry. Its organization structure encompasses a technical committee (TC), strategic advisory board (SAB), capability building task force, secretariat and GHWP Administration Services Limited (ASL). The TC is co-led by a Chair from regulatory authorities and two Vice-Chairs respectively from regulatory authorities and the industry. Under TC, there are eight working groups and a TC advisory panel.

By now, GHWP has issued more than 50 technical guidance documents, vigorously propelling the global harmonization of medical device regulations. GHWP promotes the capacity building of medical device regulatory authorities and industry stakeholders, and has staged more than 40 online and offline regulatory capability trainings tailored to different needs of medical device

regulatory authorities and the industry which are at different maturity levels. Members have benefited from the harmonization of regulation, and are steadily promoting their regulatory capability.

II. Global medical device regulation is confronting with huge challenges and great opportunities

(I) Challenges

Currently, the regulation of medical device is at the critical transition era from industrial period to information age, while the global medical device industry is at the crucial stage of transition from high-speed to high quality. Global medical device industry and the regulations on medical devices are facing enormous challenges: growing new demand, evolving new technology, and ground-breaking new concept.

1. Coping with new demands needs regulatory upgrade

The public all over the world always expect medical device with good quality. With the increasing demand on personalized and intelligent medical devices, the requirements on safety and efficacy grow higher, where regulatory convergence is the key to enable better accessibility and affordability of medical devices with new technologies. Quick and effective responses to the new challenges are required for regulatory authorities and medical device industries. Regulatory authorities should make governance more prospective, agile, flexible and adaptive, and to accelerate the pace of formulating of regulatory policies; the industry needs to cultivate medical device talents, and to develop medical devices adaptable to clinical needs with innovative technologies.

2. Evaluating new technology needs regulatory innovation

It is becoming more difficult to regulate medical devices with the advancement of new materials, new technologies, new processes, new products and new models. The innovation of medical devices is unprecedented with emerging technologies such as robotics, artificial intelligence and digital therapies, and the traditional regulatory framework is required to adapt to cutting-edge technologies. The regulatory authorities in all countries and regions are seeking highly for new approaches, new tools and new standards, propelling the research and application

of regulatory science, safeguarding the safety and efficacy of medical devices, and striving to be a promotor and leader in industry innovation, other than an obstacle.

3. Disseminating new concept needs regulatory reliance

All countries and regions are vigorously bringing domestic medical devices to the world while importing the international leading medical devices. With limited regulatory resources, all the regulatory authorities in the world are considering how to avoid overlaps, maximizing the use of existing regulatory resources, exploring new regulatory concepts and expanding the new regulatory models. Regulatory authorities are attempting to develop modern regulatory systems and tools like virtual audit, rolling submission and electronic filing, establish the mechanism of resource sharing, regional reliance and mutual recognition, and to create a platform for the sharing of regulatory information. The global regulatory reliance, convergence and harmonization will bring a series of new challenges to the international medical device regulatory systems, mechanisms, approaches, strategy and culture.

(II) Great opportunities

The medical device is the crucial elements of healthcare system, together with drug and medical technology. The medical device involves many fields such as acoustics, optics, electricity, magnetism, material science and clinical science and etc., with remarkable attributes of interdisciplinary, intensive technology, robust innovation. It is the important tool to evaluate the comprehensive strengths of cutting-edge technological development.

Nowadays, the global innovation of medical device is booming, and market is consistently expanded. It is anticipated that in the next few years, global medical device industry will continue to maintain vigorous growth driven by multiple health needs, cutting-edge technological innovation, and regulatory science research. According to Fortune Business Insights, the medical device market is projected to grow at a CAGR of 5.5% during 2022-2029, with the global market reaching USD 719 billion. Frost & Sullivan forecasts that the global medical device market will grow at a CAGR of 4.4% over the next five years, with revenues reaching USD 471.5 billion in 2023 and USD 512.4 billion by 2025.

1. Health needs drive high-speed development of medical devices

People's health is an important underpinning of national prosperity. The *World Social Report 2023* released by the United Nations suggests that population ageing is a defining global trend of our time. The number of aged people above 65 will rise from 761 million in 2021 to 1.6 billion in 2050, more than doubled. With population ageing intensifying and life expectancy increasing, noncommunicable diseases (NCDs) are becoming a growing burden. Also, critical diseases have become an inevitable issue amid social and economic development, and new and old infectious diseases remain an immense threat throughout the world. Undoubtedly, NCDs and critical diseases have become the largest disease burden in the world, and there is a rising demand for medical device to combat these diseases, spurring the rapid development of the medical device industry. In the future, healthcare will be transforming from hospitals to homes, with medical devices turned into "3P" medical models, namely "preventive", "predictive" and "personalized".

2. Technological innovation enables the high-speed development of medical devices

Innovation is the primary driving force for development. The high-end technology advances the fast development of medical device industry. Moreover, the advent of such new technologies as artificial intelligence, biological materials and 3D printing provides more accurate and efficient techniques for the diagnosis, treatment and monitoring of diseases. With increasing availability of early diagnosis and urgently needed medical devices in clinical practices, the concept of preventative treatment is permeating, and the medical devices featuring multi-disciplinary integration like "active health", "remote diagnosis and treatment" and "combination product" are gaining widespread attention throughout the world. Real-world data, computer modelling, organ chip, organoid and other new techniques are gradually replacing the traditional ways in which clinical effects are confirmed, lowering R&D costs of medical devices, accelerating the marketing pace of innovative products.

3. Regulation harmonization and reliance accelerates the rapid development of medical devices

Establishing a community with a shared future for mankind is the aspiration of people all over the world. The quality of medical devices directly connects to the

health and safety of people in all countries. To protect and promote the public health, authorities have been increasingly issuing regulations for medical device based on the scale of medical device development, the history of medical device regulation, and the coordination of medical policies. From a global perspective, there are both opportunities and challenges for convergence, harmonization and reliance in medical device regulations. Regulatory authorities and industry in more and more countries and regions have recognized the necessity and urgency of promoting convergence, harmonization and reliance in regulatory rules. However, effectively advancing the convergence, harmonization and reliance of regulatory regulations requires joint efforts from the international community. Nowadays, there is a greater need for the spirit of unity and the power of solidarity. We must accelerate the pace of scientific research and application in the field of medical device regulation, expedite the promotion in coordination and harmonization of regulation, and enhance the effectiveness and standards of regulatory practices. Through these efforts, we strive to facilitate the smooth development of international trade and better ensure the safety and efficacy of medical devices for the global public.

In conclusion, the global medical device industry is experiencing favorable development trends driven by scientific and technological advancements as well as increasing health demands. However, these advancements and growing health needs also pose a series of new challenges. Regulatory authorities of different countries and regions are in urgent need of strengthening communication and collaboration, sharing governance experiences, and enhancing regulatory capabilities. Efforts should be made to promote convergence, harmonization and reliance in global medical device regulations, continuously advancing the scientific, law-based, international, and modern governance levels of medical device regulation.

III. Persistently strive for the prosperous development of the GHWP.

In the era of globalization, GHWP, as one of the international organizations with increasing global influence in the field of medical device regulations, strives to promote the convergence, harmonization and reliance in global medical device regulations. Based on the principles of openness, cooperation, robustness, and win-win, GHWP endeavors to achieve this goal through communication and collaboration among regulatory authorities and industry representatives.

Convergence is the aspiration of endeavor, Harmonization is the power of creation, and Reliance is the fruit of advancement. GHWP is determined to promote high-quality development in global medical device regulation and industry.

In July, 2023, GHWP TC open meeting was successfully held in Shenzhen, China. More than 350 representatives from 33 countries and regions attended the meeting. Now, GHWP is in the process of preparation of the 27th Annual Meeting and GHWP TC Meeting in Shanghai. More representatives are heartly welcomed.

As the Chair of GHWP for the term 2023-2025, I, in collaboration with the GHWP leadership team, have collectively formulated ten key projects for the year 2023. These projects provide clear objectives, responsibilities, establish timelines, and outline a roadmap. Our diligent efforts aim to advance the implementation of the *Global Harmonization Working Party Strategic Framework towards 2026.*

(I) Attracting more members

Many hands make light work. As an international organization dedicated to global harmonization of medical device regulations, GHWP is committed to its noble mission of protecting and promoting worldwide public health. Building upon our existing membership of 33 countries and regions, GHWP will fervently endeavor to appeal to more members. We wholeheartedly welcome countries and regions, particularly developing countries, and regions that are dedicated to advancing global convergence, harmonization and reliance of medical device regulations, to actively join GHWP and contribute to the sublime cause of advancing public health.

(II) Formulating the development strategies

It takes strategy and practical work to make accomplishment. To fully utilize the intellectual support of renowned international experts for the future development of GHWP, it was decided at the 26th Annual Meeting in February 2023 to establish the GHWP Strategic Advisory Board (SAB). The SAB experts will leverage their expertise and extensive experience to support GHWP's strategic planning and future development, thereby promoting the realization of GHWP's mission, vision, and goals. In accordance with the approved amendments to the GHWP House Rules, the "SAB Establishment and Operation Procedures" has been published on the GHWP website, demonstrating the orientation, responsibilities, criteria, establishment procedure, and operational rules of the SAB members. Following

thorough discussions during the leadership meeting, I, on behalf of the GHWP Chair, have extended invitations to the prospective experts and intend to form the first SAB in the near future.

(III) Improving the procedures for guideline management

The devil is in the details. Facing the ever-evolving advancements in science and technology, over the next 2-3 years, GHWP will increasingly concentrate on the forefront of high-tech. It is essential to expedite the application of scientific research in regulatory practices, accelerate the innovation of regulatory methods, speed up the development of new technical guidance documents, and hasten the progress of regulatory convergence, harmonization and reliance. After reviewing thoroughly the existing guidance documents, GHWP has optimized the mechanisms for drafting, solicitation of opinions, revision, and approval for new guidelines. The Technical Committee (TC) of GHWP is devoted to the reviewing, organizing and publicizing the released guidance documents. Additionally, annual plans for drafting, revising, and withdrawing guidance documents have been established, with a strict scrutiny. Each Working Group (WG) submits the annual plan for guidance documents, new work item proposal (NWIP) and corresponding timelines.

(IV) Advancing the transformation and implementation of guidance

Law holds no power without effective implementation. GHWP gives priority to accelerate the transformation of laws on paper into laws in action. GHWP is currently engaged in establishing an evaluation mechanism for the implementation of technical guidance documents, aiming to motivate members to fulfill their responsibilities with self-awareness. Each year, GHWP member countries and regions are encouraged to report on their progress in adopting GHWP guidance documents. GHWP will invite third-party evaluation institutions to assess the progress of all member countries and regions in adopting GHWP guidance documents as needed and provide feedback on the evaluation results, so as to serve as key performance indicator for regulatory convergence. Currently, GHWP is formulating requirements related to evaluation entities, evaluation methods, evaluation criteria, and the application of results, while exploring the establishment of whole-process, meticulous, and standardized mechanism for evaluating the adoption of guidance documents, encouraging the members to

strengthen the reference, transformation, and adoption of GHWP guidance documents when formulating medical device regulatory policies, thereby incorporating them into national regulatory frameworks.

(V) Strengthening regulatory capacity building

Authority originates from professionalism. Practice enhances ability. GHWP has been further promoting GHWP's vision, mission and goals by means of website, seminars, workshops, trainings and implementation of guidance documents and etc. Moving forward, GHWP will continue to leverage its advantage in regulatory capacity building by utilizing comprehensive systems, extensive platforms, and big data. By hybrid training methods, GHWP aims to enhance the regulatory capabilities across member countries and regions. While sustaining high-quality online training and exploring the development of a training technology service platform, GHWP will expedite the building of GHWP Academy, establish the Capacity Building (CB) Committee, and conduct the training for regulators and management personnel of the industry with support from reputable universities in GHWP member countries and regions. The contents of training offering by GHWP Academy including GHWP’s mission, vision, goals, as well as its organization structure, development strategy, operation mechanism, technical guidance, also covering the status quo, trend, priority, mapping, and strategy of innovative development of global medical device industry, the innovation of philosophy, legal system, mechanism, method, strategy and culture, the development of medical device regulatory science and convergence, harmonization and reliance of medical device regulation, etc.

(VI) Establishing an international platform for dialogue

Broad platform brings great cause. The enduring vitality and wide-reaching impact of GHWP lie in direct dialogues and collaborative participation between regulatory authorities and industry stakeholders. It also stems from the unity, cooperation, and practical advancements fostered by GHWP in collaboration with regulatory personnel from member countries and regions. Furthermore, GHWP actively engages in regular exchanges and knowledge sharing with international organizations such as WHO, IMDRF, ISO, and IEC. Through this significant platform, member countries and regions have established tighter bilateral exchanges and cooperation. During the GHWP Annual Meeting, many regulators

from member countries and regions express their intention to sign cooperative agreements. The leadership of GHWP, along with like-minded leaders of other international organizations, have actively sought common grounds of collaboration through high-level dialogues. Looking ahead, GHWP will actively fulfill its role as a platform to facilitate multi-tier and multi-sector exchanges and cooperation among member countries and regions.

(VII) Deepening bilateral communication and cooperation

Extensive cooperation usher in broad way. The principle of equality is one of the fundamental principles in international relations. Cooperative approaches based on this principle contribute to enhancing mutual reliance and communication among international organizations. GHWP will continue to foster its longstanding partnership with IMDRF and other international organizations. During the 26th GHWP Annual Meeting, the closed-door meeting between GHWP and IMDRF was successfully held for the first time, marking an exploratory initiative of the GHWP Annual Meeting. Constructive discussions took place between the leadership of GHWP and the IMDRF Management Committee, both organizations expressing the need for further exploration of a closer partnership. In order to achieve a deeper and more comprehensive cooperation, GHWP is actively working towards the signing of a Memorandum of Understanding between GHWP and IMDRF.

(VIII) Expanding exchanges and cooperation

Cooperation is like blossom and facilitates win-win scenario. Through a series of constructive discussions during leadership meetings, GHWP has deliberated upon the key priorities for its future development, conducting feasible analyses and task deployments for priority projects. In March 2023, GHWP explored collaboration with the China International Medical Device Regulatory Forum (CIMDR), focusing on the dynamic changes in medical device regulatory frameworks. With an international perspective and professional expertise, GHWP organized extensive exchanges and in-depth discussions among member countries and regions during the CIMDR, showcasing a high-standard, high-level, and high-quality international platform for communication. GHWP plans to regularly host international forums for industrial innovation and development, as well as industry exhibitions, facilitating mutual learning and exchange among member

countries and regions and providing a platform for displaying innovative medical devices. GHWP has determined to collaborate with the globally influential China International Medical Equipment Fair (CMEF), actively encouraging enterprises from GHWP member countries and regions to participate in CMEF.

(IX) Promoting global regulatory reliance

Higher-level reliance fosters stronger solidarity. Regardless of the market size, maturity level and existing resources in member countries and regions, GHWP consistently encourages applying reliance throughout different stages of the whole life cycle of the product, including product nomenclature and classification, quality management system audits, safety and efficacy evaluations, pre-market approvals, post-market surveillance, and post-approval changes. GHWP suggests member countries and regions to utilize existing platforms, resources, and expertise, and to concentrate regulatory efforts and resources where they are most needed within the regions. GHWP is considering to collaborate with related international organizations and cross-regional alliances to promote the development of global post-market surveillance information exchange programs. The aim is to promote the global Unique Device Identification (UDI) database at the GHWP or regional level, standardize the adoption of established definitions and requirements, and specify procedures for labeling or modification instructions.

A just cause finds great support, and a journey with many companions gets far. Along with the deepening of concepts on proactive health and early diagnosis, in response to the development of integrated products like biomaterials, and digital therapies, based on the principles of openness, cooperation, robustness and win-win, GHWP is determined and capable to deepen international exchanges and cooperation, strengthen coordination between regulators and industry, promote a scientifically efficient mode of medical device regulation, and strategically accelerate global convergence, harmonization and reliance of medical device regulations. Efforts will be dedicated to fulfilling the noble mission of ensuring patient safety and timely access to safe and effective medical devices, thereby making a greater contribution to protecting and promoting global public health.

Dr. Xu Jinghe holds a postgraduate degree from Peking University and a doctorate degree in law, and is now the Deputy Commissioner of China National Medical Products

Administration (NMPA). On February 16, 2023, Dr. Xu Jinghe was elected as the Chairman of the Global Harmonization Working Party (GHWP).