国家药品监督管理局代表参加全球医疗器械法规协调会议并顺利当选副主席

2023年2月3日至16日，全球医疗器械法规协调会议（GHWP）第26届技术委员会会议在里亚德召开。国家药品监督管理局高级别代表参加技术委员会会议并顺利当选副主席。

GHWP技术委员会会议讨论了全球医疗器械法规协调会议的进展及工作重点，特别讨论了《医疗器械法规协调会议》的实施工作。会议期间，国家药品监督管理局副局长黄果（中国）作为高级别主席代表中国参加技术委员会副主席会议。黄果副主席在会议中表示，中国将积极参与GHWP工作，为全球医疗器械法规协调会议的发展作出贡献。

NMPA delegate elected co-chair of GHWP's Technical Committee

The 26th Annual Meeting and Technical Committee Meeting of the Global Harmonization Working Party (GHWP) were held from Feb 3 to 16, 2023, in Riyadh, capital of Saudi Arabia. Xu Jinghe, deputy commissioner of China's National Medical Products Administration (NMPA), led a delegation to the meeting.

The meetings of the GHWP Technical Committee included closed-door meetings and open meetings. The nine working groups of the GHWP respectively introduced the latest progress of their work and discussed the focus and development directions in the next steps. The meeting elected the technical committee office and the chairs and co-chairs of all working groups for the new term. Delegates of the NMPA participated in the election of the co-chair of the Technical Committee and chairs of Working Group 7 and Working Group 9.

NMPA delegate elected co-chair of GHWP’s Technical Committee

In accordance with the Terms of Reference and House Rules of the GHWP, Li Jun, deputy director-general of the NMPA’s Department of Medical Device Regulation, was voted as the new co-chair of the GHWP Technical Committee; Chen Yan, director of the Inspection Division V of the Center for Food and Drug Inspection of the NMPA, was voted as the chair of Working Group 7; and Zhou Weixun, second-level consultant of the Registration Research Department of the NMPA’s Department of Medical Device Registration, was voted as the chair of Working Group 9. Assuming leading positions of the Technical Committee will further deepen the technological exchanges between China’s medical device regulators and their international counterparts, and will promote the coordination and reliance in global medical device regulation.

(Feb 17, 2023)
the regulatory capacity and standards of member countries and regions. Fourth, he will push forward regulatory reform and accelerate the realization of regulatory mutual recognition among member countries and regions. Fifth, he will advance the application of technological guidance and the sustainability of regulatory capacity. Sixth, he will bolster industrial cooperation and facilitate trade among member countries and regions.

(Oct 27, 2023)

### Provisions for Supervision and Administration of Online Drug Sales

The Provisions for Supervision and Administration of Online Drug Sales is promulgated by Decree No. 58 of the State Administration for Market Regulation on August 3, 2022 and shall be effective as of December 1, 2022.

(Dec 29, 2022)

### Importation of MSD’s Molnupiravir Capsules approved with condition

The importation registration of Molnupiravir Capsules (trade name: LAGEVIR®) for the treatment of COVID-19 of MSD Inc. is approved with condition for marketing by China NMPA on December 29, through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law.

This oral small-molecule drug for the treatment of COVID-19 is indicated for treating adult patients with mild to moderate SARS-CoV-2 (COVID-19) infection with high risk factors of progressing to severe disease, such as advanced age, obesity or overweight, chronic kidney disease, diabetes, severe cardiovascular disease, chronic obstructive pulmonary disease, active cancer and so on. The patients should use the drug strictly following the package insert under doctors’ guidance.

The MAH is asked by NMPA to complete relevant research works of the conditions requirements within a time limit, and submit the follow-up research results in time.

(Dec 30, 2022)

### NMPA issues the Food Safety Commodity Administration Guidelines

The NMPA issued an Article about Network Sales Supervision Management Methods on Aug 20, 2022. The Food Safety Commodity Administration Guidelines are effective on Dec 1, 2022.

(Dec 22-29)

### National Medical Products Newsletter Issue 745

The National Medical Products Newsletter Issue 745 includes the following articles:

1. **Provisions for Supervision and Administration of Online Drug Sales**
2. **Importation of MSD’s Molnupiravir Capsules approved with condition**
3. **NMPA issues the Food Safety Commodity Administration Guidelines**
4. **Biosimilar Tocilizumab Injection approved for marketing**
5. **NMPA issues the Food Safety Commodity Administration Guidelines**

(Dec 29, 2022)

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### Inhaler Guidelines

The Inhaler Guidelines are issued by the NMPA, effective on Mar 20, 2022. The guidelines include the following:

1. **Provisions for Supervision and Administration of Online Drug Sales**
2. **Importation of MSD’s Molnupiravir Capsules approved with condition**
3. **NMPA issues the Food Safety Commodity Administration Guidelines**
4. **Biosimilar Tocilizumab Injection approved for marketing**
5. **NMPA issues the Food Safety Commodity Administration Guidelines**

(Mar 29, 2022)

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### Biosimilar Tocilizumab Injection approved for marketing

Recently, the Tocilizumab Injection (Chinese trade name: Xiemu®) of Bio-Techne Solutions, Ltd. is approved for marketing by China NMPA. This drug is the first Biosimilar Tocilizumab Injection approved by China, which is indicated for rheumatoid arthritis, systemic juvenile idiopathic arthritis, and cytokine release syndrome.

(Dec 30, 2022)

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### NMPA issues the Food Safety Commodity Administration Guidelines

The NMPA issues the Food Safety Commodity Administration Guidelines, effective on Dec 30, 2022. The guidelines include the following:

1. **Provisions for Supervision and Administration of Online Drug Sales**
2. **Importation of MSD’s Molnupiravir Capsules approved with condition**
3. **NMPA issues the Food Safety Commodity Administration Guidelines**
4. **Biosimilar Tocilizumab Injection approved for marketing**
5. **NMPA issues the Food Safety Commodity Administration Guidelines**

(Dec 29, 2022)
the regulatory capacity and standards of member countries and regions. Fourth, he will push forward regulatory reform and accelerate the realization of regulatory mutual recognition among member countries and regions. Fifth, he will advance the application of technical guidance and the sustainability of regulatory capacity. Sixth, he will bolster industrial cooperation and facilitate trade among member countries and regions.

(Feb 7, 2023)

Aimovirine, Lamivudine and Tenofovir Disoproxil Fumarate Tablets approved for marketing.

Recently, the innovative drug Aminorine, Lamivudine and Tenofovir Disoproxil Fumarate Tablets (trade name: HFA-100) of Jiangsu Aidea Pharmaceutical Co., Ltd. is approved by China NMPA. This product is a compound medicine composed of Aminorine, Lamivudine and Tenofovir Disoproxil Fumarate, which is indicated for the treatment of adult HIV-1 infected patients.

(May 15, 2023)

Moclobemid succinate capsules approved for marketing with conditions.

Recently, the Class I innovative drug moclobemid succinate capsules (trade name: MOCK) of Takeda Pharmaceutical, Inc. is approved for marketing with conditions through the priority review and approval procedure by China NMPA. This drug is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. Moclobemid is an irreversible tyrosine kinase inhibitor targeting the EGFR exon 20 insertion mutations. The marketing of this drug provides a new treatment option for patients with advanced NSCLC with EGFR exon 20 insertion mutations.

(May 13, 2023)

Biosimilar Tolculizumab Injection approved for marketing.

Recently, the Tolculizumab Injection (Chinese trade name: Zhuhui) of Bio-Techne Solutions, Ltd. is approved for marketing by China NMPA. This drug is the first biosimilar Tolculizumab Injection approved in China, which is indicated for rheumatoid arthritis, systemic juvenile idiopathic arthritis, and cytokine release syndrome. Tolculizumab is a recombinant humanized monoclonal antibody against the human interleukin-6 (IL-6) receptor that specifically binds to soluble and membrane-bound IL-6 receptors and inhibits signal transduction mediated by IL-6 receptors. At present, the Tolculizumab Injection has been included in the Diagnosis and Treatment Protocol for COVID-19 Infection (Tenventh Edition), Diagnosis and Treatment Protocol for Severe Case of Covid-19 Infection (Tenventh Edition), which can be used for severe cases with significantly elevated IL-6 levels detected by laboratory.

(May 16, 2023)

The approval of Tolcizumab Injection is expected to provide a new treatment option for patients with COVID-19 infection, and has the potential to improve the treatment outcomes and reduce the mortality rate and recurrence rate of COVID-19. It is a major breakthrough in the treatment of rheumatoid arthritis and systemic juvenile idiopathic arthritis.

(May 16, 2023)

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National Medical Products Newsletter
**Simnotreliv Tablets/Ritonavir Tablets (co-packaged) and Deuemidievir Hydrobromide Tablets for treating COVID-19 infection approved with conditions for marketing**

Recently, the class I innovative drug Simnotreliv Tablets/Ritonavir Tablets (co-packaged) (Chinese trade name: 诺华混) of Simcere Pharmaceutical Group Limited and Deuemidievir Hydrobromide Tablets (Chinese trade name: 维德碧) of Shanghai Wangshi Biotechnology Medicine Inc. are approved for marketing by China NMPA through emergency review and approval procedures in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. The above-mentioned two drugs are both small molecular drugs for COVID-19 infection treatment, indicated for adult patients with mild to moderate SARS-CoV-2 (COVID-19) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors. The MAAs are asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results as soon as possible.

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**Medical Devices Intravascular Ultrasound Diagnostic Equipment and Disposable Intravascular Ultrasound Diagnostic Catheter approved for marketing**

Recently, the innovative products “Intravascular Ultrasound Diagnostic Equipment” of SonoScape Medical Corp. and “Disposable Intravascular Ultrasound Diagnostic Catheter” of Shanghai Acoustic Life Science Co., Ltd are approved for marketing by China NMPA. The two products are used together for ultrasound imaging examination of coronary vascular diseases. This combination product uses pulse echo technique to perform ultrasonic scanning and imaging of blood vessels. It helps doctors to determine the severity and nature of the disease, further improve the understanding of coronary artery disease and guide interventional treatment. The launch of this combination product is conducive to reducing the cost of clinical treatment, facilitating the clinical application and promotion of this technology, providing better diagnostic evidence for PCI precision diagnosis, and formulating better treatment strategies to benefit patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

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**Medical Angiography X-Ray Machine approved for marketing**

Recently, the innovative product “Medical Angiography X-Ray Machine” of Shanghai United Imaging Healthcare Co., Ltd is approved for marketing by China NMPA. The product consists of high-voltage generator, X-ray tube assembly, beam limiter, filter grid, flat panel detector, rack, patient table, display, display cabinet, nappe, sub-unit component, touch panel, control module, control box, foot switch, hand switch, image acquisition workstation, video management workstation, image advanced processing workstation, 3D imaging workstation, and accessories. It is applicable to X-ray fluoroscopy, photography, vascular subtraction image and tomography image for angiography and interventional surgery. This product adopts a 192-column tube, which can realize cone beam imaging of the whole abdomen and chest, and solves the problem of small field of view upon the cone beam CT reconstruction of traditional cone beam CT. In addition, the product uses computer vision technology to realize one-click automatic cone beam CT scanning and one-click positioning, which can simplify the workflow of positioning and cone beam CT, reduce radiation exposure and intraoperative steps. Compared with the traditional medical angiography X-ray machine, this product can significantly expand field of view upon the cone beam CT reconstruction of traditional cone beam CT, reduce the operation steps, operation time and radiation dose of cone beam CT scanning, shorten the preparation time before imaging, and improve the surgical efficiency.

The NMPA will strengthen the post-marketing surveillance of the product to ensure the safety of medical devices used by patients.
**Second Biosimilar Tocilizumab Injection approved for marketing**

Recently, the Tocilizumab Injection (Chinese trade name: 依妥单抗) of Liven Pharmaceutical Group Inc. is approved for marketing by China NMPA. This drug is the second Tocilizumab Injection biosimilar approved in China, which is indicated for rheumatoid arthritis. Tocilizumab is a recombinant humanized monoclonal antibody against the human interleukin-6 (IL-6) receptor that specifically binds to soluble and membrane-bound IL-6 receptors and inhibits signal transduction mediated by IL-6 receptors. At present, the Tocilizumab Injection has been included in the Diagnosis and Treatment Protocol for Severe Cases of COVID-19 Infection (Tentative 4th Edition), which can be used for severe cases with significantly elevated IL-6 levels detected by laboratory.

(Dec 15, 2022)

**Simotrelvir Tablets/Ritonavir Tablets (co-packaged) and Deuremidievir Hydrobromide Tablets for treating COVID-19 infection approved with marketing conditions**

Recently, the class I innovative drug Simotrelvir Tablets/Ritonavir Tablets (co-packaged) (Chinese trade name: 诺引®) of Simercere Pharmaceutical Group Limited and Deuremidievir Hydrobromide Tablets (Chinese trade name: 瑞拉®) of Shanghai Wangshi Biomedicine Technology Inc. are approved for marketing with conditions by China NMPA through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. The above-mentioned two drugs are both oral small molecular drugs for COVID-19 infection treatment, intended for adult patients with mild to moderate SARS-CoV-2 (COVID-19) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors. The MAAs are asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results as soon as possible.

(Jan 29, 2023)

**“血管内超声诊断设备”和“一次性使用血管内超声诊断导管”获批上市**

Recently, the innovative products "Intravascular Ultrasound Diagnostic Equipment" and "Disposable Intravascular Ultrasound Diagnostic Catheter" of SonoScope Medical Corp. are approved for marketing by China NMPA. The two products are used together for ultrasonic imaging examination of coronary vascular diseases. This combination product uses pulse echo technique to perform ultrasonic scanning and imaging of blood vessels. The diagnosis host and catheter controller send drive pulses to the ultrasonic transducer at the distal end of the catheter, and drive the transducer to rotate at a high speed through the driving shaft inside the sheath catheter. The transducer sends ultrasonic pulses and receives the ultrasonic echo signals reflected by the vascular tissue, which are amplified, collected and preprocessed by the catheter controller and transmitted to the device host to realize the display and processing of vascular images. The disposable intravascular ultrasonic diagnostic catheter is on the PMN-PT high frequency single crystal composite transducer, using the design method of preparing glue free layer by evaporation with thickness of 0.05mm. It realizes the localized manufacturing of high performance high frequency transducer, improves the image resolution and optimizes the image quality. This combination product uses ultrasonic imaging with high frequency, wide bandwidth and high sensitivity, which can realize scanning, imaging and vessel diameter and measurement of coronary vessels. It helps doctors to determine the severity and nature of the disease, further improve the understanding of coronary artery disease and guide interventional treatment.

(Dec 30, 2022)

**Medical Angiography X-ray Machine approved for marketing**

Recently, the innovative product "Medical Angiography X-ray Machine" of Shanghai United Imaging Healthcare Co., Ltd. is approved for marketing in China NMPA. The product consists of high-voltage generator, X-ray tube assembly, beam limiter, filter grid, flat panel detector, rack, patient table, display, Display cabinet module, switch box, control panel, control module, control box, foot switch, hand switch, image acquisition workstation, video management workstation, image advanced processing workstation, 3D image processing software, and accessories. It is applicable to X-ray fluoroscopy, photography, vascular subtraction image and tomography image for angiography and interventional surgery.

This product adopts a 3-axis robot DSA, which can realize cone beam imaging of the whole abdomen and chest, and solves the problem of small field of view upon the cone beam CT reconstruction of traditional cone beam CT. In addition, the product uses computer vision technology to realize one-click automatic cone beam CT scanning and one-click positioning, which can simplify the work process of positioning and cone beam CT, reduce radiation exposure and improve the image quality. Compared with the traditional medical angiography X-ray machine, this product can significantly expand the field of view upon the cone beam CT reconstruction of traditional cone beam CT, reduce the operation steps, operating time and radiation dose of cone beam CT scanning, shorten the preparation time before imaging, and improve the surgical efficiency.

The NMPA will strengthen the post-marketing surveillance of the product to ensure the safety of medical devices used by patients.

(Dec 30, 2022)
Patient monitor approved for marketing

Recently, the innovative product “patient monitor” of Shanghai Chemen Medical Instruments Co., Ltd is approved for marketing by China NMPA. The product consists of the main unit, plug-in module and accessories. Indicators such as ECG (including ST segment measurement and arrhythmia analysis), impedance respiration, body temperature, pulse oxygen saturation, pulse rate, non-invasive blood pressure, invasive blood pressure, respiratory and end-tidal carbon dioxide, anesthetic gas, non-invasive cardiac output (only applicable to adult patients), invasive cardiac output (only applicable to adult patients) can be monitored, and functions such as ECG, PICC, respiratory oxygenation diagram, renal function calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation, drug calculation and recorder are also available. The product is expected to be used by trained and qualified professional clinicians and nurses in medical institutions, and its application fields include operating rooms, ICUS and general departments.

On January 17, 2023, the Extracorporeal Membrane Oxygenation auxiliary device of RocketMedical Co., Ltd (Rocket Medical) is approved with conditions through emergency review by China NMPA. This product is the second ECMO product granted approval. The product provides power and safety monitoring during extracorporeal circulation, and is used in combination with compatible disposable consumables for pulmonary support. The product is intended for adult patients with acute respiratory failure that is difficult to control by other treatments and where there is a foreseeable risk of continued deterioration or death. The product is composed of Revive ECMO, flow/bubble sensor, emergency drive, emergency drive holder, pressure connection cable, oxygenator holder, medical gas holder and cart. The marketing of the product will further improve China’s ECMO product supply capacity, meet clinical needs, improve treatment of severe cases of COVID-19, and better implement the goal of “protecting health and preventing serious diseases of COVID-19 prevention and control.” During the registration and application process of this product, the NMPA establishes an emergency review task force, in accordance with the principle of “unified command, early intervention, fast and efficient, and scientific and systematic review and approval,” with specific person in charge, giving guidance during the whole process, releases technical review guidelines, increases the guidance of product registration and application, accelerates the review and approval process, and promotes the product to be marketed as soon as possible on the premise of ensuring safety and effectiveness, to meet the urgent needs of epidemic prevention and control. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.
China Domestic ECMO products approved for marketing

On January 4, 2023, the Extracorporeal Membrane Oxygenation System Console and its matching disposable kit of Chinesch (Shenzhen) Medical Technology Co., Ltd. are approved through emergency review by China NMPA, to ensure the treatment needs of patients with severe cases of COVID-19 infection according to the demands of epidemic prevention and control. The system and disposable kit are used together for acute respiratory failure, acute cardiopulmonary failure or other effective treatment methods for adults patients who have a foreseeable risk of continuous deterioration or death. As the first domestic ECMO system and disposable kit, the above products have independent intellectual property rights, and the devices' performance is on par with international level of similar products. The Extracorporeal Membrane Oxygenation System is composed of a console, pump, emergency pump, battery, flow and bubble sensor, etc. The disposable kit consists of a centrifugal pumphead, a membrane oxygenator and 3x integrated pressure sensors all pre-connected with medical grade tubing along with a priming kit, oxygen tubing and other accessories. As a rescue treatment device for patients with severe SARS-CoV-2 infection who failed to respond to conventional treatment, ECMO is the treatment measure specified in the diagnosis and treatment plan for the novel coronavirus disease (COVID-19). The launch of domestic products will play an important role in meeting clinical needs, ensuring the treatment of patients with cases of COVID-19, and ensuring the implementation of the goal of "to protect public health and prevent severe cases" for epidemic prevention and control. During the registration and application process of this product, the NMPA establishes an emergency review task force, in accordance with the principle of "unified command, early intervention, fast and efficient, and scientific review and approval", with special person in charge, giving guidance during the whole process of guidance, releases technical review guidelines, increases the guidance of product registration and application, accelerates the review and approval process, and promotes the product to be marketed as soon as possible on the premise of ensuring safety and effectiveness, to meet the urgent needs of epidemic prevention and control. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

Second China domestic ECMO products approved for marketing

On January 17, 2023, the Extracorporeal Membrane Oxygenation System auxiliary device of RocketMedicalCo., Ltd. (Rocket Medical) is approved with conditions through emergency review by China NMPA. This product is the second domestic ECMO product granted approval. The product provides power and safety monitoring during extracorporeal circulation and is used in combination with compatible disposable consumables for pulmonary support. The product is intended for adult patients with acute respiratory failure that is difficult to control by other treatments and where there is a foreseeable risk of continuous deterioration or death. The product is composed of Revivco ECMO, flow/bubble sensor, emergency drive, emergency drive holder, pressure connection cable, oxygenator holder, medical gas holder and cart. The marketing of the product will further improve China’s ECMO product supply capacity, meet clinical needs, improve professional clinicians and nurses in medical institutions, and its applications fields include operating rooms, ICUs and general departments. The product adopts ECG signal adaptive filtering technology and four-electrode ECG system technology, which can realize real-time positioning of catheter end during establishment by observing the changes of P wave of intracardiac ECG in real-time. Compared with the traditional central venous catheterization method, this product has the function of positioning the catheter end during central venous catheterization, which is helpful to improve the accuracy of PCEC catheterization. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

Patient monitor approved for marketing

Recently, the innovative product “patient monitor” of Shenzhen Cheng Medical Instruments Co., Ltd. is approved for marketing by China NMPA. The product consists of the main unit, plug-in module and accessories. Indicators such as ECG (including ST segment measurement and arrhythmia analysis), impedance respiration, body temperature, pulse saturation, pulse rate, non-invasive blood pressure, invasive blood pressure, respiratory and end tidal carbon dioxide, anesthetic gas, non-invasive cardiac output (only applicable to adult patients), invasive cardiac output (only applicable to adult patients) can be monitored, and functions such as ECG, PICC, respiratory oxygenation diagram, renal function calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation, drug calculation and recorder are also available. The product is expected to be used by trained and qualified professional clinicians and nurses in medical institutions, and its applications fields include operating rooms, ICUs and general departments. The product adopts ECG signal adaptive filtering technology and four-electrode ECG system technology, which can realize real-time positioning of catheter end during establishment by observing the changes of P wave of intracardiac ECG in real-time. Compared with the traditional central venous catheterization method, this product has the function of positioning the catheter end during central venous catheterization, which is helpful to improve the accuracy of PCEC catheterization. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

Second款国产ECMO产品获批上市

2023年1月17日，国家药监局发布通告，同意

第二款国产ECMO产品注册上市。该产品与国外

ECMO产品相比，并未在技术上占据明显优势，但

在价格方面，由于国内企业的生产成本较低，

本地化生产，因此价格比国外进口产品便宜

很多，性价比更高。该产品的上市将进一步提

升我国重症ECMO产品供应能力，满足患者需

求，提升我国重症救治水平，进一步推动我国

医疗器械领域“国产替代进口”进程。

该产品的上市将进一步提升我国ECMO产品

供应能力，满足患者需求，提升我国重症

救治水平，进一步推动我国“国产替代进口”

进程。
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NMPA delegate elected co-chair of GHWP’s Technical Committee

The 26th Annual Meeting and Technical Committee Meeting of the Global Harmonization Working Party (GHWP) were held from Feb 13 to 16, 2023, in Riyadh, capital of Saudi Arabia. Xu Jinghe, deputy commissioner of China’s National Medical Products Administration (NMPA), led a delegation to the meeting. The meetings of the GHWP Technical Committee included closed-doors meetings and open meetings. The nine working groups of the GHWP respectively introduced the latest progress of their work and discussed the focus and development directions of the next steps. The meeting elected the technical committee office and the chairs and co-chairs of all working groups for the new term. Delegates of the NMPA participated in the election of the co-chairs of the Technical Committee and chairs of Working Group 7 and Working Group 9.

In accordance with the Terms of Reference and House Rules of the GHWP, Li Jun, deputy director-general of the NMPA’s Department of Medical Device Regulation, was voted as the new co-chair of the GHWP Technical Committee; Chen Yan, director of the Inspection Division V of the Center for Food and Drug Inspection of the NMPA, was voted as the chair of Working Group 7; and Zhou Wenwen, second-level consultant of the Registration Research Division of the NMPA’s Department of Medical Device Registration, was voted as the chair of Working Group 9. Assuming leading positions of the Technical Committee will further deepen the technological exchanges between China’s medical device regulators and their international counterparts, and will promote the coordination and reliance in global medical device regulation.

(February 27, 2023)

2023 February-03-17

On Feb. 13, Xu Jinghe, deputy commissioner of China’s National Medical Products Administration (NMPA), was elected chairman of the 27th Global Harmonization Working Party (GHWP) in Riyadh, capital of Saudi Arabia. This is the first time China has chaired the GHWP.

The GHWP is an international medical device regulatory and technological exchange platform involving the participation of regulatory authorities and industry representatives. Its predecessor was the Asian Harmonization Working Party (AHWP) and was officially renamed the GHWP in 2022. With its growing number of members and increasing international influence, the membership of the GHWP has expanded from Asia to the Middle East, North and South America as well as Africa, covering 33 countries and regions. The population of the countries and regions involved accounts for more than half of the global total, with nearly 80 percent of the members being located along the Belt and Road.

The 26th GHWP Annual Meeting and Technical Committee Meeting was held from Feb 13 to 16 in Riyadh. The event included open forums on regulatory reliance, digital therapy, innovative medical devices, regulatory capacity building, the GHWP Technical Committee Meeting, and the GHWP Annual Meeting. Experts from GHWP member countries and regions, the GHWP Technical Committee and related working groups, capacity building program and representatives from the International Medical Device Regulators Forum (IMDRF), member states of the Association of Southeast Asian Nations, Asia-Pacific Economic Cooperation member economies, and other international coordinating organizations shared the latest progress in global medical device regulation.

One of the main tasks of the GHWP annual meeting is to elect a new term of the GHWP leadership. According to the Terms of Reference and House Rules of the GHWP, Xu Jinghe, deputy commissioner of the NMPA, was elected the new chairman of the GHWP by the vote of the representatives.

Xu’s election as the new chairman of the GHWP demonstrates that China’s well-organized medical device regulatory system and effective regulatory work are widely and highly recognized by the international community. In his acceptance speech, Xu said that over the years, every step of the GHWP’s actions has written its own history of rapid growth, and its work has been fruitful and influential. This annual meeting adopted the 2025 strategic framework and set out the development goals of the GHWP from 2023 to 2026. Working together with other members of the GHWP, he will devote himself to the coordination of global medical device regulatory rules and the common improvement of regulatory capacity among members.

Xu also said that during his term as chairman, he will prioritize the following six aspects of work. First, he will focus on the cutting-edge technology and promote the harmonization and unification of regulatory rules. Second, he will promote the research on regulation sciences and bring innovative products to the market at an early date. Third, he will strengthen laws and regulations training and improve

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