Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation

【Basic Information】

Moderator:

Qin Xiaoling	Director General of the Department of Science, Technology and International Cooperation, China National Medical Products Administration (NMPA)

Address:

Zhao Junning	Deputy Commissioner, NMPA
Wu Zhengping	Executive Director General of China International Import Expo (CIIE) Bureau
Zhuang Mudi	Deputy Secretary-General of the Shanghai Municipal Government

Keynote Speech:

Michael Levitt	2013 Nobel Laureate in Chemistry
Martin Taylor	WHO Representative to China
Paul Sinclair	President of the International Pharmaceutical Federation
Yang Zhimin	Deputy Director General of the Center for Drug Evaluation, NMPA
He Weigang	Deputy Director General of the Center for Medical Device Evaluation, NMPA
Qi Liubin	Deputy Director General of the Department of Cosmetics Regulation, NMPA
Qin Xiaoling	Director General of the Department of Science, Technology and International Cooperation, NMPA
Meng Dongping	Vice President of the China Chamber of Commerce of Medicines & Health Products Importers & Exporters (CCCMHPIE)
Chris Toth	Group President of Baxter Kidney Care
Vincent Warnery	Chief Executive Officer of Beiersdorf

【Brief Introduction】

On November 6, 2024, the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation of the 7th Hongqiao International Economic Forum (HQF) was hosted by China National Medical Products Administration (NMPA) and the Secretariat of the Hongqiao International Economic Forum (HQF) at National Exhibition and Convention Center (Shanghai). The session aims to introduce the latest policies on China's drug, medical devices, and cosmetics regulatory requirements, update regulatory science development and internationalization progress of drug regulation, carry out dialogues between regulatory authorities and the industry, and facilitate high-quality development of the industry.


一、药品监管科学化进展不断深入
国家药品监督管理局
推进创新药械审评审批
药品技术指导原则459个
医疗器械技术指导原则559个
创新药品130个
中药新药31个
创新医疗器械217个
第七届虹桥国际经济论坛
THE SEVENTH HONGQIAO INTERNATIONAL ECONOMIC FORUM (HQF)
全球药品安全治理和中国药品监管创新
GLOBAL DRUG SAFETY GOVERNANCE AND CHINESE DRUG REGULATION INNOVATION
主办单位：国家药品监督管理局 虹桥论坛秘书处
Hosted by: China National Medical Products Administration, Secretariat of the Hongqiao International Economic Forum
2024年11月6日
November 6th, 2024
中国 · 上海
Shanghai, China
I. Scientific advancement in medical products regulation has been constantly deepened
国家药品监督管理局
Promote the review and approval of innovative drugs and medical devices
459 technical guidelines for drugs
559 technical guidelines for medical devices
130 innovative drugs
31 innovative TCMs
217 innovative medical devices

【Address】

Zhao Junning, Deputy Commissioner, NMPA,
addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation

Zhao Junning, Deputy Commissioner of the NMPA, pointed out that the NMPA has always been committed to protecting and promoting public health. Upholding the principle of "Four Strictest Standards" in its work, the NMPA focuses on balancing development and safety, efficiency and fairness, as well as regulation and service, to ensure the overall stability of drug safety and promote high-quality development in the pharmaceutical industry. The NMPA maintains strict supervision to ensure the continuous compliance of drug production and operation while strengthening dynamic regulation throughout the entire drug life cycle. It deepens reforms to support the research, development, and market approval of innovative drugs and medical devices and advances the reform of examination and approval systems. It insists on regulating according to the law, improving the legal and regulatory framework for drug management, and promoting administration and regulation in accordance with the law. The NMPA focuses on capacity building, diligently advancing the modernization of drug regulation.

Wu Zhengping, Executive Director General of CIIE Bureau,
addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation

Wu Zhengping, Executive Director General of CIIE Bureau, stated that since 2018, CIIE has become a window for China to build a new development pattern, a platform to promote high-level opening-up, and a global public good to be shared internationally. At this year's CIIE, the top ten global medical device companies, 11 of the world's top 500 pharmaceutical enterprises, and eight major beauty and personal care companies showcased their latest achievements in innovative drug and medical device research and development, biopharmaceutical technology, and cross-industry digital diagnosis and treatment. As a platform for expanding openness and sharing opportunities, CIIE supports the pharmaceutical, medical devices, and cosmetics companies from various countries to further expand into the Chinese market, boost trade and investment, strengthen innovation and research and development, foster international cooperation, promoting the high-quality development of the pharmaceutical, medical device, and cosmetics industries.

Zhuang Mudi, Deputy Secretary-General of the Shanghai Municipal Government, addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation

Zhuang Mudi, Deputy Secretary-General of the Shanghai Municipal Government, stated that biomedicine is one of the three key leading industries for Shanghai's development and is an important area for cultivating new quality productive forces. In recent years, with the support of the NMPA, Shanghai has leveraged the Yangtze River Delta sub-center for pharmaceuticals and medical devices to take the lead in piloting major reform and innovation measures, including segmented production of biological products, self-developed in vitro diagnostic reagents used by medical institutions, and the labeling of imported medical devices. These efforts have continuously improved and expanded the biopharmaceutical industry, with its internationalization level rising and innovation outcomes becoming more evident. Looking to the future, Shanghai will implement a new round of the "Shanghai Plan" for biomedicine, focusing on building a world-class industrial cluster.

【Keynote Speech】

Michael Levitt, 2013 Nobel Laureate in Chemistry,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Michael Levitt, 2013 Nobel Laureate in Chemistry, introduced a multidisciplinary approach to the future of healthcare. He shared examples of his recent work using applied biotechnology and artificial intelligence in cancer research. By using AI technology to accelerate drug development, significant cost savings can be achieved, reducing the time from the typical 10 years to just a few years. In his concluding remarks, Michael Levitt emphasized his belief that the transformative power of artificial intelligence will ultimately improve human well-being in terms of health.

Martin Taylor, WHO Representative to China,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Martin Taylor, WHO Representative to China, emphasized that quality-assured, safe, and effective medicines, vaccines, and medical devices are the foundation of achieving universal health coverage. Strengthening the regulatory systems, particularly strengthening oversight during public health emergencies, is a key priority. WHO supports countries in enhancing their regulatory frameworks and contributes to the development of international norms and standards to ensure consistent oversight of products and technologies worldwide. Furthermore, the prequalification program evaluates medicines, vaccines, and medical devices for major diseases and facilitates information sharing within the global regulatory network. China is playing an increasingly vital role in the global supply chain for vaccines, medicines, and medical devices. Looking ahead, China is poised to make further progress, with its regulatory system and policy protections continuing to strengthen.

Paul Sinclair, President of the International Pharmaceutical Federation,
attended via video the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Paul Sinclair, President of the International Pharmaceutical Federation (FIP), shared his insights on "Prospects for Pharmaceutical Innovation." FIP is a global federation consisting of national organizations representing over 4 million pharmacists worldwide. Its vision is "a world where everyone benefits from access to safe, effective, quality and affordable medicines and health technologies." Its mission is "to support global health by enabling the advancement of pharmaceutical practice, sciences and education." The FIP helps its member organizations and pharmacists to improve their work, and one of its main goals is to deliver pharmaceutical care and services through digital media and to support the delivery of pharmacy services through digital health interventions.

Yang Zhimin, Deputy Director General of the Center for Drug Evaluation, NMPA,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Yang Zhimin, Deputy Director General of the Center for Drug Evaluation, NMPA, delivered a speech on "Deepening the Reform of Drug Evaluation and Approval Systems to Promote the High-Quality Development of the Biopharmaceutical Industry." In 2024, the NMPA introduced policies to further optimize the importation of urgently needed overseas products. Significant reforms in recent years have led to an increase in oncology drugs and the rapid development of global simultaneous R&D. China has joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and has actively participated in international standard-setting. Under the leadership of the NMPA, the Center for Drug Evaluation has established two regional branches in the Yangtze River Delta and the Guangdong-Hong Kong-Macao Greater Bay Area. Looking ahead, China aims to strengthen basic research, optimize drug R&D and approval processes, better implement data protection policies, attract more high-quality resources for R&D, promote the integration of cutting-edge technologies with international standards, increase the use of artificial intelligence, and fully utilize the country's resource advantages.

He Weigang, Deputy Director General of the Center for Medical Device Evaluation, NMPA, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation and delivered a keynote speech

He Weigang, Deputy Director General of the Center for Medical Device Evaluation, NMPA, introduced the progress and achievements in medical device technology review. The Center for Medical Device Evaluation has established 15 working groups to simultaneously advance 15 reform initiatives, benchmarking with the U.S. Food and Drug Administration (FDA). These efforts have significantly enhanced the informatization, modernization, and intelligence of the evaluation process, improved the quality of review, and established a comprehensive quality management system. The evaluation tools, methods, and standards have been continuously refined. Following the implementation of the reform, innovation in medical devices has been continuously enhanced, particularly with the approval rate of imported products surpassing that of domestic ones. Additionally, the Center has established an innovation cooperation platform, bringing together government, industry, academia, research, and medical sectors. It has also implemented initiatives related to artificial intelligence and biomaterials, issued industry white papers, and actively participated in international exchanges. The Center is driving the construction of sub-centers and closely monitoring cutting-edge technologies.

Qi Liubin, Deputy Director General of the Department of Cosmetics Regulation, NMPA, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation and delivered a keynote speech

Qi Liubin, Deputy Director General of the Department of Cosmetics Regulation, NMPA, outlined the regulatory framework for cosmetics supervision and management. In recent years, China has established a regulatory framework for cosmetics that includes one regulation, three administrative measures, more than 20 normative documents, and more than 40 technical guidelines. Looking ahead, the development of cosmetics regulations will enter a new phase. First, it is crucial to supplement and improve the existing regulations, fill any gaps and further strengthen the legal framework. Second, a pragmatic approach should be taken to adjust and optimize the regulations. Through research and analysis, efforts will be made to refine the current regulatory framework. Third, reform and innovation will be key priorities. As cosmetics is a fashion-driven industry with rapidly evolving technologies and trends, regulatory bodies should adopt an open and inclusive attitude toward new developments. This includes improving supervision and sampling methods, improving online regulation, strengthening uniform standards, promoting the use of innovative ingredients, offering personalized services, and exploring the use of electronic labels.

Qin Xiaoling, Director General of the Department of Science, Technology and International Cooperation, NMPA, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation and delivered a keynote speech

Qin Xiaoling, Director General of the Department of Science, Technology and International Cooperation, NMPA, presented the progress of China's scientific and international advancements in drug regulation. In April 2019, NMPA launched the China Action Plan on Scientific Drug Regulation. Over the past five years, the NMPA has focused on both strengthening basic scientific research capabilities and building a robust technical support system. It has initiated several key projects and continuously integrated into the national innovation system, making significant achievements. China has actively engaged in global pharmaceutical safety governance and the development of international regulations. It has deepened cooperation with the World Health Organization in the pharmaceutical sector and fostered greater understanding and trust with countries and institutions along the Belt and Road Initiative, as well as with other relevant countries and organizations. Particular attention has been paid to collaboration with African countries, supporting the development of pharmaceutical regulatory frameworks and cooperative plans. Efforts have been made to strengthen cooperation with the International Coalition of Medicines Regulatory Authorities and to deepen international collaboration on traditional medicines. In addition, the NMPA has actively promoted foreign trade and investment services, expanded pilot programs in related sectors, and attracted foreign capital to foster high-quality development in China's healthcare industry.

Meng Dongping, Vice President of the CCCMHPIE,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Meng Dongping, Vice President of the CCCMHPIE, delivered a keynote speech on the "Internationalization Development Trend and Direction of the Chinese Pharmaceutical Industry." She pointed out that the global healthcare market continues to expand, with the share of innovative drugs and biopharmaceuticals steadily increasing. They have become new drivers of industry growth, introducing new technologies, platforms, mechanisms, and models. The interdisciplinary high-tech and intelligent healthcare scenarios are witnessing broader application. At the same time, China's healthcare system and pharmaceutical industry environment are undergoing profound changes. The government continues to strengthen top-level policy design, and regulatory authorities are implementing continuous innovations and reforms throughout the entire lifecycle of pharmaceutical products. The pace of pharmaceutical innovation and the transformation of research results has accelerated significantly, with remarkable achievements in the development of the medical device trade. As a result, the internationalization of the pharmaceutical industry has become more multidimensional and diverse. However, several challenges remain in the pharmaceutical sector, including the industry's concentration on mid-to-low-end segments and the need to improve the conversion rate and pace of innovation in scientific research. Looking ahead, China's healthcare industry is poised to continue its global expansion.

Chris Toth, Group President of Baxter Kidney Care,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Chris Toth, Group President of Baxter Kidney Care, delivered a speech entitled "The Status Quo and Outlook of Multinational Medical Device Companies in China." Baxter has a 70-year history in renal care and 35 years of experience in China. The company's mission is to extend life and expand possibilities, with a vision of helping patients live longer and fuller lives. In China, Baxter serves hundreds of thousands of patients with end-stage renal disease and supports thousands of hospitals with emergency treatment. China offers significant investment opportunities, and Baxter has invested more than RMB 4 billion in the country over the past decade. The Chinese government attaches great importance to the innovative development of the medical device industry. The optimization of the approval process and registration system has significantly reduced the time it takes for products to enter the market. Baxter will actively participate in the regulatory framework and scientific supervision activities led by the NMPA.

Vincent Warnery, Chief Executive Officer of Beiersdorf,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulation Innovation
and delivered a keynote speech

Vincent Warnery, Chief Executive Officer of Beiersdorf, delivered a speech entitled "The Development Status and Outlook of Multinational Cosmetics Companies in China." Beiersdorf owns several well-known brands and premium skincare products, focusing on the skincare, suncare, and men's grooming markets. The company's breakthrough tyrosinase inhibitor has been certified by the NMPA, highlighting the Chinese government's strong support for innovation in cosmetic ingredients. As fundamental scientific research increasingly enters the field of cosmetics, advertising regulations should not only prevent misleading claims but also keep pace with scientific advancements. Products supported by evidence-based science should be allowed to responsibly communicate their effectiveness. Beiersdorf looks forward to collaborating with regulatory agencies to ensure that scientific innovations are accurately represented and appropriately regulated.