

Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice

【Basic Information】

Moderator:

Xia Cheng

News Anchor of CGTN

Addresses:

Zhao Junning

Deputy Commissioner of the National Medical Products Administration of China (NMPA)

Chen Jie

Vice Mayor of Shanghai

Sun Chenghai

Deputy Director General of the China International Import Expo (CIIE) Bureau

Thematic Speeches:

1: Global Drug Regulation

Barry Marshall

2005 Nobel Laureate in Physiology or Medicine

Michel Sidibé

Special Envoy for the African Medicines Agency (AMA) of the African Union (AU),
Former UN Under-Secretary-General

John Chave

Director-General of Cosmetics Europe

2: Chinese Drug Regulatory Practice

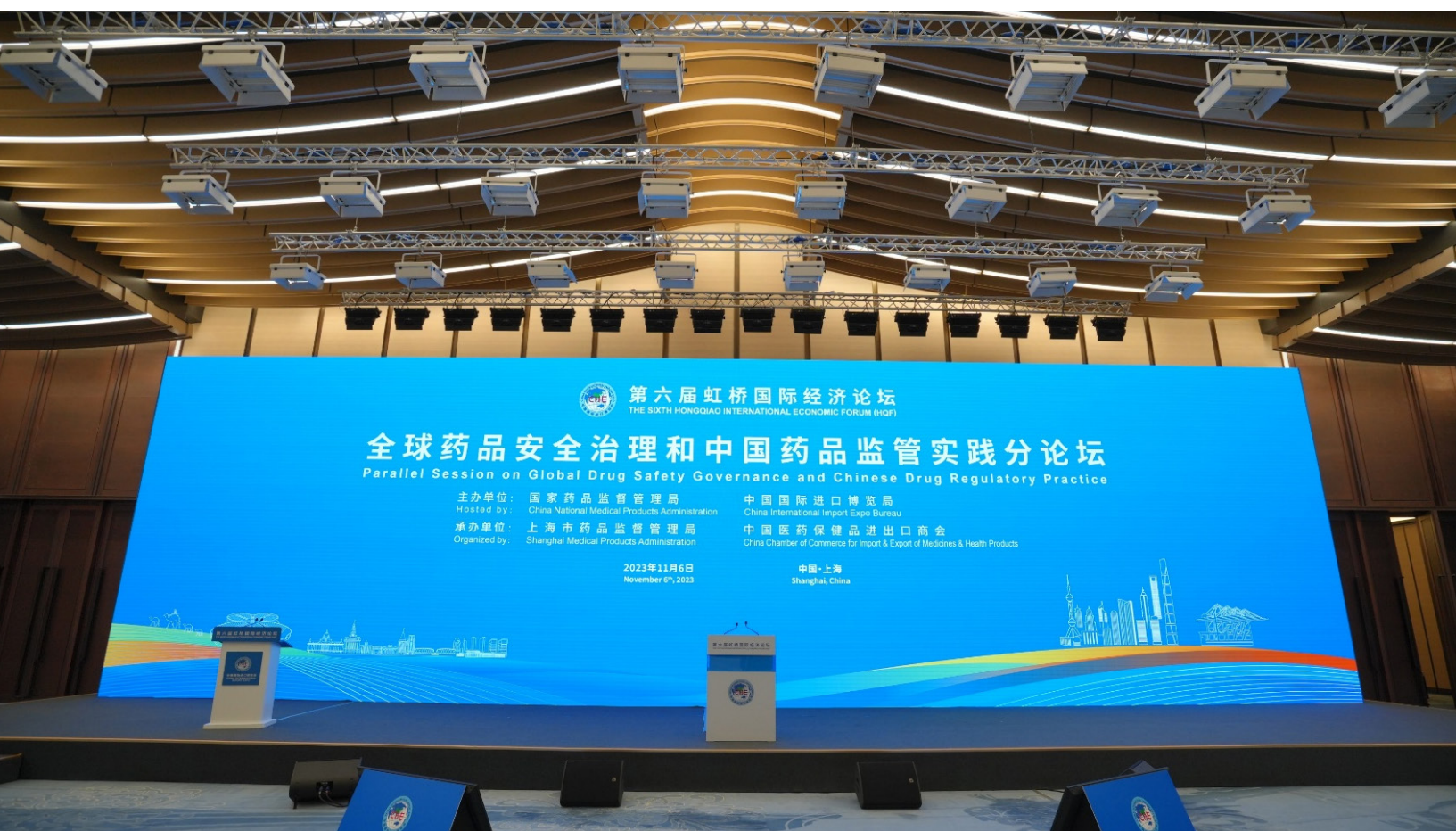
Wang Hainan	Deputy Director General of the Department of Drug Registration, NMPA
Lü Ling	Director General of the Department of Medical Device Registration, NMPA
Li Jinju	Director General of the Department of Cosmetics Regulation, NMPA
Qin Xiaoling	Director General of the Department of Science, Technology and International Cooperation, NMPA

3: Voice of the Industry

Meng Dongping	Vice President of China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE)
Pascal Soriot	Executive Director and CEO of AstraZeneca
Paul Hudson	CEO of Sanofi
Gustaf Salford	President and CEO of Elekta

【Brief Introduction】

On the afternoon of November 6, 2023, the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice of the Sixth Hongqiao International Economic Forum (HQF), hosted by NMPA and the CIIE Bureau and organized by Shanghai Municipal Medical Products Administration and the CCCMHPIE, was held at the National Exhibition and Convention Center (Shanghai). The parallel session aims to jointly explore drug regulation and governance from a global perspective, comprehensively strengthen international communication in drug regulation, and further boost the high-quality development and international cooperation of the pharmaceutical industry. Distinguished guests, including government officials, academicians, experts, and business representatives both at home and abroad, delivered speeches on three themes: Global Drug Regulation, Chinese Drug Regulatory Practice, and Voice of the Industry.



【Addresses】



Zhao Junning, Deputy Commissioner of NMPA,
addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai

Zhao Junning, Deputy Commissioner of NMPA, pointed out that health is the aspiration and pursuit of the people. NMPA has always adhered to the mission of protecting and promoting public health, actively carried out actions to consolidate and enhance drug safety, focused on key links such as clinical trials, entrusted production, and online sales, concentrated on key categories such as vaccines, blood products, and selected drugs in collective procurement, strengthened the investigation of risks and hidden dangers, intensified law enforcement and case handling efforts, and ensured that the situation of drug safety would remain stable and make progress. With the ongoing improvement of regulatory laws and regulations, the continuous optimization of the regulatory system and mechanism, and the continuous innovation of regulatory methods, the market access and regulatory policy environment for drugs, medical devices, and cosmetics in China will become more scientific, open, fair, and transparent.



Chen Jie, Vice Mayor of Shanghai,
addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai

Chen Jie, Vice Mayor of Shanghai, stated that the biopharmaceutical industry is one of the three key pioneer industries in Shanghai. In recent years, Shanghai has taken the lead in piloting a series of major reform measures, including the drug marketing authorization holder (MAH) system, the medical device registrant system, and the transition from review and approval to notification of imported general cosmetics. With the accelerated evolution of the global new sci-tech revolution and industrial transformation, biopharmaceuticals have become one of the most active and fruitful high-tech industries. Shanghai aims to align with the highest international standards and levels, adapt to the transformation of R&D and innovation models in the biopharmaceutical industry, and construct a regulatory system compatible with high-level opening-up.



Sun Chenghai, Deputy Director General of the CIIE Bureau, addressed the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai

Sun Chenghai, Deputy Director General of the CIIE Bureau, emphasized that drug safety is crucial for the physical and mental health and life safety of the people. In the process of promoting the Chinese path to modernization, China has raised higher requirements for drug safety. The CIIE, as a platform to expand opening-up and share opportunities, supports pharmaceutical, medical device, and cosmetics companies from all countries in expanding their presence in the Chinese market. The Sixth Hongqiao International Economic Forum (HQF) focused on drug safety governance for the first time, and guests from international and domestic government, industry, academic and research communities were invited to conduct in-depth research, contributing to better consensus-building and synergy-forming. Mr. Sun hoped that all parties would strengthen communication, exchange ideas, and achieve positive results.

【Thematic Speeches】 1: Global Drug Regulation

Barry Marshall, 2005 Nobel Laureate in Physiology or Medicine, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Barry Marshall, 2005 Nobel Laureate in Physiology or Medicine, spoke on the topic “Innovative Directions in Gastric Disease Diagnosis: A Nobel Laureate’s Insights into Discovery, Innovation, and Translation”. He introduced the process of the discovery of *Helicobacter pylori* and main treatment methods. Due to the misuse of antibiotics, *Helicobacter pylori* has developed resistance, making personalized precise medication the main approach to current treatment. Some new gastric drugs are now entering the approval process, and they are capable of more effectively addressing drug-resistant bacteria. Marshall emphasized the necessity of drug regulation, and highlighted that even seemingly simple sampling line for detecting *Helicobacter pylori* requires rigorous drug regulation to ensure the accuracy of test results and benchmark against international clinical trial results.



Michel Sidibé, Special Envoy for the African Medicines Agency of the AU and Former UN Under-Secretary-General, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Michel Sidibé, Special Envoy for the African Medicines Agency of the AU and Former UN Under-Secretary-General, delivered a speech on “Challenges and Opportunities in Drug Regulation of Developing Countries”. In Africa, 99% of drugs and vaccines rely on imports, posing the urgent challenge of reducing dependence on imported drugs and vaccines. The African Medicines Agency is committed to promoting local production, strengthening regional cooperation, enhancing and coordinating regulatory systems, introducing new vaccines and drugs, and assisting African companies in exporting products. Through the China-Africa drug regulatory partnership, both pledge to enhance drug quality and regulation efforts, promote cooperation in economic, political, social, and other fields. This multi-sector cooperation and capacity-building will strengthen political and social ties between the two sides.



John Chave, Director-General of Cosmetics Europe, attended via video the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice and delivered a speech

John Chave, Director-General of Cosmetics Europe, noted that regulation plays a crucial role in promoting cosmetics trade. EU countries implement the same cosmetics safety rules and standards, but coordination in regulation is needed in trade with other countries. The main goals of cosmetics legislation are safety, quality, and efficacy, which are also key points for coordination and compatibility among economies. Currently, China, the EU, and the United States are revising their cosmetics legislation, which presents an opportunity for coordinated regulation among all parties. To boost global integration and connectivity, forums, summits, and conferences at different levels should be held, and countries must learn from each other's best practices and implement them.

2: Chinese Drug Regulatory Practice



Wang Hainan, Deputy Director General of the Department of Drug Registration, NMPA, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Wang Hainan, Deputy Director General of the Department of Drug Registration, NMPA, made a speech on the theme of “Deepening the Reform of Drug Review and Approval System to Encourage Drug Innovation and High-quality Development”. NMPA actively constructs a scientific and rigorous drug registration and regulation framework. In 2023, it issued the *Measures for the Administration of Standards for Medicinal Products* and is currently accelerating the revision of the *Regulations for Implementation of the Drug Administration Law*. Meanwhile, NMPA is further building a complete, transparent and efficient review and approval mechanism, striving to expedite the drug registration process, improving conditional approval procedures and the process for the accelerated marketing of innovative drugs, and ensuring early intervention, coordinated research and review, and whole-process guidance.



Lü Ling, Director General of the Department of Medical Device Registration, NMPA attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Lü Ling, Director General of the Department of Medical Device Registration, NMPA, delivered a speech on “Progress and Achievements of China’s Medical Devices Review and Approval System Reform”. The regulatory system for medical devices in China has basically taken shape. Currently, NMPA is actively piloting the self-production of reagents by medical institutions, and promoting the roll-out of regulations for emergency use of medical devices and the design of special systems for urgent clinical import needs. The legislative work for the law regarding the administration of medical devices has also been initiated. NMPA adheres to planning in advance, strengthens top-level design, sticks to innovation, and accelerates product entry into the market through conditional approval, emergency use, small-volume import for urgent clinical needs, or a combination of prioritized approval and conditional approval.



Li Jinju, Director General of the Department of Cosmetics Regulation, NMPA, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Li Jinju, Director General of the Department of Cosmetics Regulation, NMPA, delivered a speech on “Improving Regulatory Approaches and Measures to Promote the High-quality Development of the Cosmetics Industry”. She pointed out that the construction of the regulatory framework has laid the foundation for cosmetics regulation. The regulatory framework for cosmetics has a four-tier structure, with the Regulations on Supervision and Administration of Cosmetics serving as the basic law for cosmetics governance in China, three departmental regulations thereunder, and a series of normative documents, technical guidance norms and technical guidelines further down. During the regulation development process, China has continuously optimized regulatory procedures, such as piloting the transition from registration to notification of imported general cosmetics, which greatly facilitates international trade in cosmetics.



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 Regulatory Practice in Shanghai and delivered a speech

Qin Xiaoling, Director General of the Department of Science, Technology and International Cooperation, NMPA, spoke on “Progress in China’s Drug Regulation Science and Internationalization Process”. NMPA continues to deepen the scientific and international drug regulation. First, NMPA is constructing a scientific system for drug regulation, and developing a series of evaluation principles, inspection guidelines, testing methods and standards. Second, efforts are made to enhance the international influence and level of drug regulation. Third, NMPA aligns with international standards and strengthens capacity building. Fourth, bilateral exchanges and cooperation have been carried out in a comprehensive manner; NMPA has established working contacts with the drug regulation agencies of more than 60 countries and regions, and has actively carried out exchanges and cooperation on relevant international occasions.

3: Voice of the Industry



Meng Dongping, Vice President of CCCMHPIE, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Meng Dongping, Vice President of CCCMHPIE, delivered a speech on the “Status quo and Development Path of the Internationalization of Chinese Medical Products Industry”. The development of the medical and health sector has shown new characteristics in recent years. The size of the global healthcare market is growing, the percentage of innovative drugs in use is increasing, and biopharmaceuticals are becoming a development direction. Traditional pharmaceuticals are entering a new stage of development, with information technology and artificial intelligence being widely applied in the healthcare industry and bringing revolutionary changes. For the Chinese pharmaceutical industry to engage in economic and trade cooperation globally, corresponding standards and regulations should be established, and convergence and integration with the interests of all countries should be expanded.



Pascal Soriot, Executive Director and CEO of AstraZeneca, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Pascal Soriot, Executive Director and CEO of AstraZeneca, spoke on the topic of “With Roots in China, Pioneering Innovation for Global Benefits”. In the early stages of AstraZeneca’s development in China, the focus was primarily on the development and production of drugs needed by Chinese patients, with the goal of being “in China and for China”. AstraZeneca is now continuously learning how to develop drugs for the global market. Collaborations have been established with local governments and peers to realize the goal of “Foothold in China and Vision of the World” and take more innovative initiatives with all parties. AstraZeneca has set a carbon reduction target for 2025 and an overall supply chain carbon reduction goal, so as to collaborate with industry partners across the entire chain in cutting carbon emissions.



Paul Hudson, CEO of Sanofi,
attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and
delivered a speech

Paul Hudson, CEO of Sanofi, gave a speech on the “Status-quo and Prospects of Transnational Pharmaceutical Enterprises in China”. Breakthrough innovations are crucial for the modernization of Chinese drugs and the development of the biopharmaceutical industry. In recent years, NMPA has taken significant measures to promote innovative development in international drug approval and review. Over the past 4 to 5 years, the approval of Sanofi’s drugs has been about 3-4 times faster, with around 80% of the drugs being new ones. Looking ahead, there are broader opportunities in the continuous modernization of regulation, which will accelerate the breakthrough innovative drug R&D of Sanofi. China has pioneered the framework for reforming the entire public health system, laying a solid foundation for future social and economic development.



Gustaf Salford, President and CEO of Elekta, attended the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice in Shanghai and delivered a speech

Gustaf Salford, President and CEO of Elekta, spoke on the topic of “Elekta in China”. Elekta is dedicated to radiation therapy for cancer and entered the Chinese market 40 years ago. The company has participated in the CIIE for six consecutive years, and introduced advanced tumor diagnosis and treatment systems to China through the CIIE. It places importance on talent development, and has established the Elekta Radiotherapy (RT) Academy, and talent cooperation mechanisms with many domestic and foreign universities, including Tsinghua University, Tianjin University, and Wuhan University. Elekta will enhance the cancer treatment capabilities for residents, support the implementation of the Healthy China 2030 action plan, and provide advanced tumor treatment solutions for third and fourth-tier cities in China.



Xia Cheng, News Anchor of CGTN,
moderated the Parallel Session on Global Drug Safety Governance and Chinese Drug Regulatory Practice