# Parallel Session On Global Drug Safety Governance and Chinese Drug Regulation Innovation

## 【Basic Information】

### Host:

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| Dr. He Li | Director General of Department of science, Technology and International cooperation, NMPA |

### Opening ceremony:

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| Dr. Yang Sheng | Deputy commissioner, NMPA |
| Dr. Xia Kejia | Deputy Secretary General of Shanghai Municipal People's Government |
| Mr. Wu Zhengping | Party committee secretary & Deputy Director General, china International Import Expo Bureau |

### Session 1: Global Drug Regulation:

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| Dr. Micheal Levitt | Lifetime Professor of Structural Biology at Stanford University, USA |
| Dr. Rogerio Gaspar | Director, Department of Regulation and Prequalification, WHO |
| Ms. Amakobe sande | Representative to China, UNICEF |

### Session 2: Chinese Drug Regulation Innovation

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| Dr. Yu Jiangyong | Deputy Director General of Department of Drug Registration, NMPA |
| Ms. Du Huiqin | Deputy Director General of Department of Medical Device Registration, NMPA |
| Dr. Li Yunfeng | Deputy Director General of Department of Cosmetics Regulation, NMPA |
| Dr. He Li | Director General of Department of Science, Technology and International Cooperation, NMPA |

## Session 3: Voice of the Industry

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| Ms. Meng Dongping | Party Committee Secretary & Vice President, CCCMHPIE |
| Mr. Giuseppe Accogli | CEO of Chiesi Group |
| Dr. Laurent Leksell | Chairman of Elekta |
| Dr. Liu yi | CEO of Fosun Pharma Group |

## 【Brief Introduction】

The parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation" was held on the morning of November 6, 2025, at the Silk Road Hall, Pavilion 4.2 of the National Exhibition and Convention Center (Shanghai). Hosted by the China National Medical Products Administration (NMPA) and the Secretariat of the Hongqiao International Economic Forum, this session consisted of four segments, including the opening ceremony and three thematic sessions: Global Drug Regulation, Chinese Drug Regulation Innovation, and Voice of the Industry.

## 【Opening Ceremony】

At the opening ceremony, Dr. Yang Sheng, Deputy Commissioner of the China National Medical Products Administration (NMPA), Mr. Xia Kejia, Deputy Secretary-General of the Shanghai Municipal People's Government, and Mr. Wu Zhengping, Party Committee Secretary & Deputy Director General of the China International Import Expo Bureau, were invited to deliver introductions focusing on the platform value of the China International Import Expo (CIIE), China's drug regulatory practices, and local industrial development. The CIIE serves as an important platform for expanding high-level opening-up and an opportunity to showcase global pharmaceutical innovation achievements and deepen international regulatory cooperation; the NMPA has stimulated innovation vitality through deepening reforms, approving 63 innovative drugs and 63 innovative medical devices respectively from January to October 2025, while enforcing strict regulation to consolidate the safety bottom line, improving the regulatory and standard system, and actively integrating into the global drug regulatory system. As a key development area for the biopharmaceutical industry, Shanghai has ranked among the top in China in terms of the number of approved innovative drugs and medical devices in recent years, with many world-class pharmaceutical companies establishing layouts in the city; in the future, it will implement a new round of development plans to build a world-class industrial cluster. The CIIE has achieved remarkable results in promoting the rapid access of innovative drugs to patients, enhancing the confidence of international enterprises in the Chinese market, and gathering global "health dividends"-a number of innovative drugs have accelerated their market launch in China through the CIIE, and the Medical and Health Exhibition Area has attracted exhibitors from numerous countries, regions and enterprises, demonstrating the attractiveness and openness of the Chinese market.


Dr. Yang Sheng | Deputy commissioner, NMP
Attended the parallel session themed "Global Drug Safety Governance
and Chinese Drug Regulation Innovation" and delivered a speech


Mr. Xia Kejia | Deputy Secretary General of Shanghai Municipal People's Government
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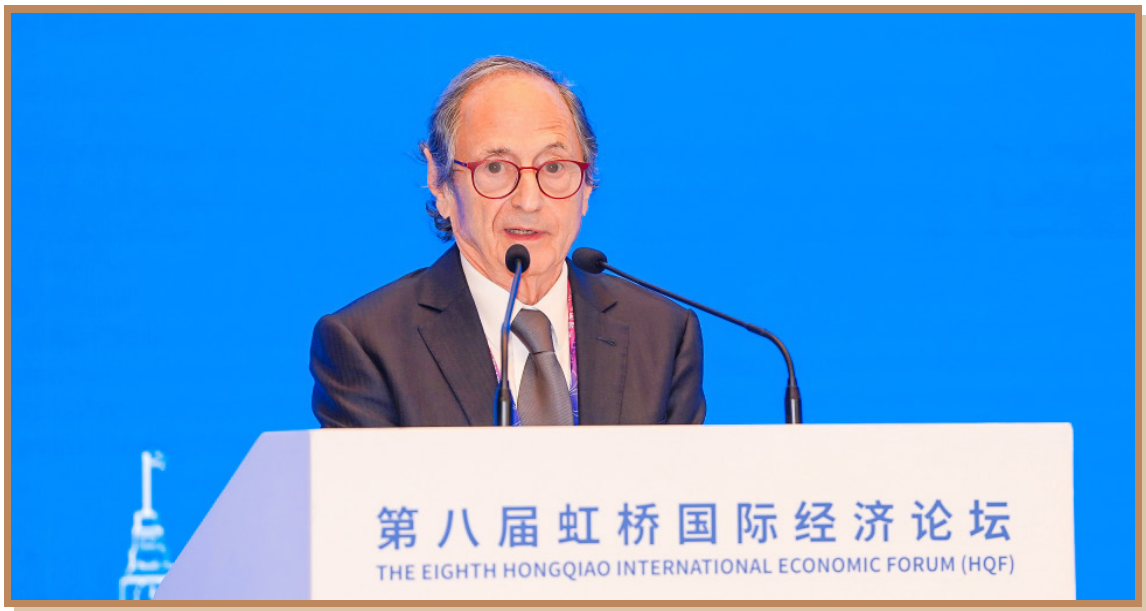
and Chinese Drug Regulation Innovation" and delivered a speech

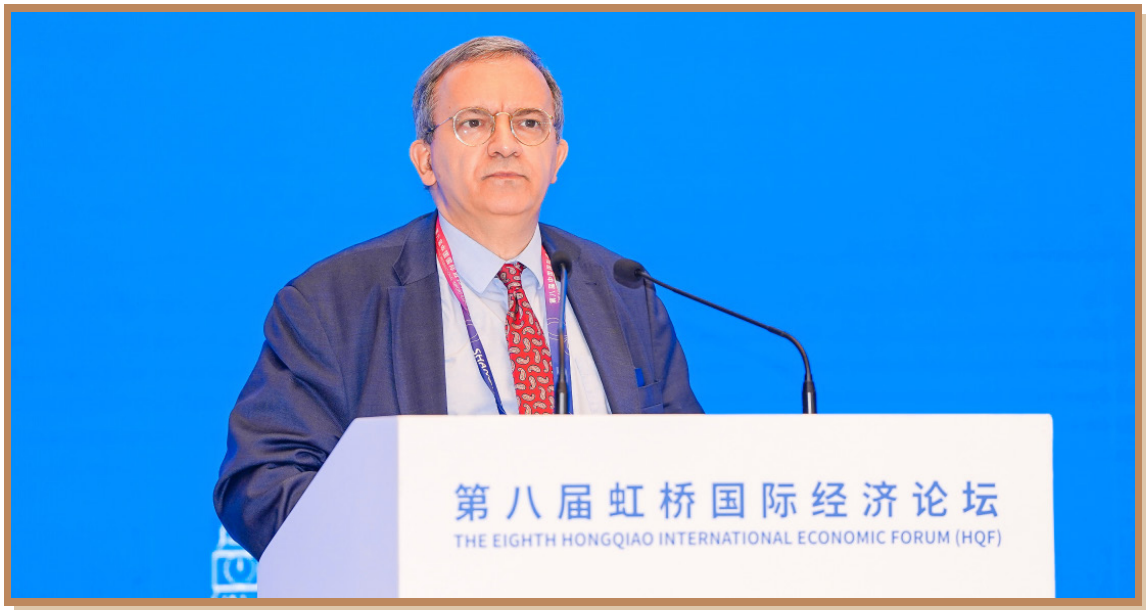

Mr. Wu zhengping | Party committee secretary & Deputy Director General, china International Import Expo Bureau
Attended the parallel session themed "Global Drug Safety Governance
and Chinese Drug Regulation Innovation" and delivered a speech

## 【Session 1】

In Session 1 (Global Drug Regulation), Dr. Micheal Levitt, Tenured Professor of the Department of Structural Biology at Stanford University in the United States, Dr. Rogerio Gaspar, Director of the Department of Regulation and Prequalification at the World Health Organization (WHO), and Ms. Amakobe Sande, Representative to China of the United Nations Children's Fund (UNICEF), were invited to discuss topics including the application of multidisciplinary medical technologies, global drug regulatory challenges and opportunities, and the current status of international procurement of children's medicines. From the perspective of computational biology, the guests elaborated on the importance of DNA and protein structure analysis for drug research and development, shared practices of artificial intelligence (AI) and generative AI in shortening drug R&D cycles and reducing costs, introduced how quantum science supports the upgrading of magnetic resonance imaging (MRI) technology to achieve precise observation of tumor metabolites, and mentioned the broad application prospects of AI in fields such as translation, transcription, and medical consultation. Relevant reports from the WHO pointed out that it is necessary to adhere to the original aspiration of safeguarding the health of all humanity, strengthen global regulatory cooperation to address challenges such as the COVID-19 pandemic and substandard medical products, share achievements such as vaccine prequalification and emergency use listing, promote the application of global benchmarking tools, increase investment and training in regulatory capacity building for developing countries, and introduce the transition plan of the WLA platform and cooperation progress with regulatory authorities of various countries. UNICEF introduced the scale and coverage of international drug procurement, emphasized the strict control of drug quality, ensured that materials are safely and effectively delivered to children worldwide through improving the system, mentioned the cooperation achievements with Chinese manufacturers, and called for strengthening public-private partnerships to enhance global access to children's medicines.




Dr. Micheal Levitt | Tenured Professor of the Department of Structural Biology at Stanford University in the United States
Attended the parallel session themed "Global Drug Safety Governance
and Chinese Drug Regulation Innovation" and delivered a thematic speech



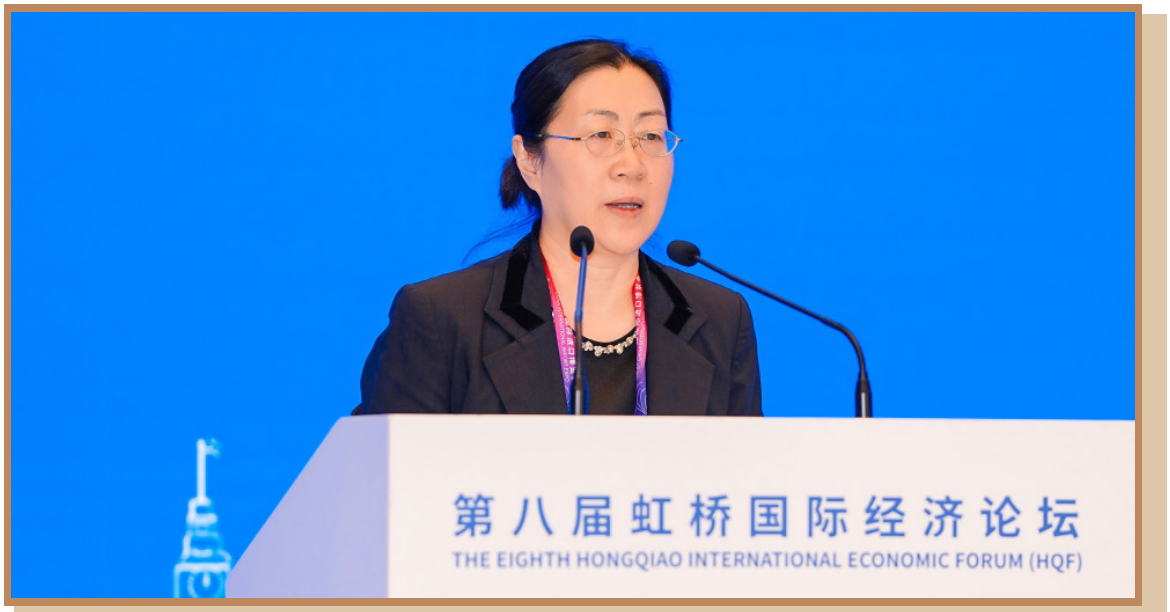

Dr. Rogerio Gaspar| Director, Department of Regulation and Prequalification, WHO
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation"
and delivered a thematic speech


Ms. Amakobe sande | Representative to China, UNICEF
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation"
and delivered a thematic speech

## 【Session 2】

In Session 2 (Chinese Drug Regulation Innovation), Dr. Yu Jiangyong, Deputy Director General of the Department of Drug Registration of the China National Medical Products Administration (NMPA), Ms. Du Huiqin, Deputy Director General of the Department of Medical Device Registration of the NMPA, Dr. Li Yunfeng, Deputy Director General of the Department of Cosmetics Regulation of the NMPA, and Dr. He Li, Director General of the Department of Science, Technology and International Cooperation of the NMPA, were invited to exchange views on the regulatory innovation and internationalization progress of China's drugs, medical devices, and cosmetics. In terms of drug regulation, efforts have been made to deepen the reform of the review and approval system, optimize accelerated pathways such as conditional approval, shorten the time for clinical trial approval of innovative drugs, revise relevant norms to align with international standards, launch pilot projects for supplementary applications to improve efficiency, introduce special plans for pediatric drugs and orphan drugs, optimize the registration inspection and verification processes, and promote the inheritance and innovation of traditional Chinese medicine as well as the transformation of international rules. For medical device regulation, a four-level regulatory system has been established, and the legislative process of the "Medical Device Administration Law" has been advanced; the industry's operating income reached 1.35 trillion yuan in 2024. Measures such as encouraging innovation, optimizing review methods, and advancing smart regulation have accelerated product market launch, while deepening cooperation with international organizations has enhanced the internationalization level of regulation. Regarding cosmetics regulation, the regulatory system has been improved, with the total market transaction volume reaching 1.07 trillion yuan in 2024. In response to industrial challenges, reform measures such as raw material innovation, registration of new efficacy, and global launch of new products have been introduced, along with quality improvement initiatives and the construction of a standardization system. In addition, China's drug regulation has actively integrated into the global system, establishing cooperation with multiple international organizations, countries, and regions, promoting products to pass WHO prequalification, participating in the formulation of international rules, and strengthening regulatory assistance and cooperation with countries along the Belt and Road Initiative.


Dr. Yu Jiangyong| Deputy Director General of Department of Drug Registration, NMPA
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation"
and delivered a thematic speech




Ms. Du Huiqin| Deputy Director General of Department of Medical Device Registration, NMPA
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation"
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Dr. Li yunfeng | Deputy Director General of Department of Cosmetics Regulation, NMPA
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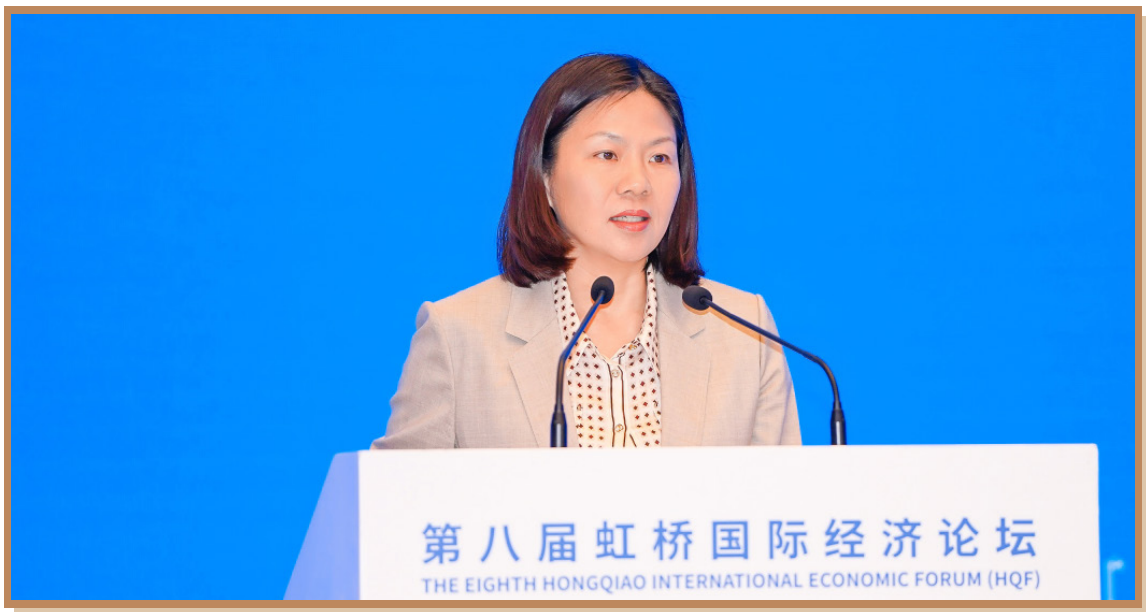
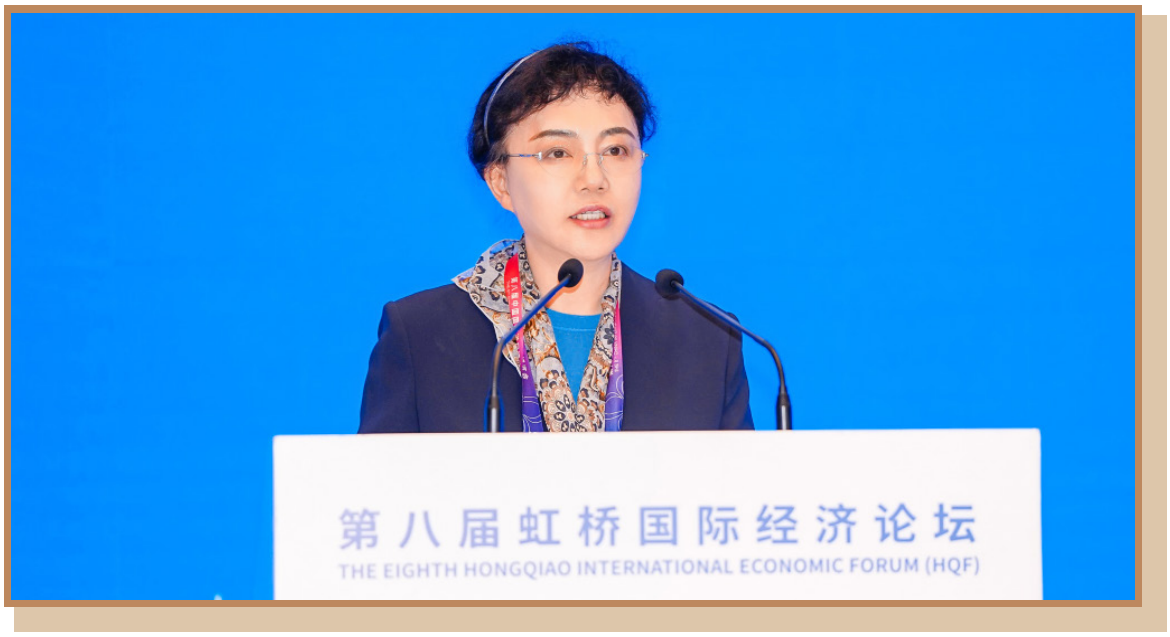



Dr. He Li | Director General of Department of Science, Technology and International Cooperation, NMPA
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation" and delivered a thematic speech

## 【session 3】

In Session 3 (Voice of the Industry), Ms. Meng Dongping, Party Committee Secretary & Vice President of the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), Mr. Giuseppe Accogli, CEO of Chiesi Group, Dr. Laurent Leksell, Chairman of Elekta, and Dr. Liu Yi, President & CEO of Fosun Pharma Group, were invited to discuss topics including international cooperation in China's medical and health industry, the development of multinational enterprises in China, and the global exploration of innovative drugs and medical devices. Supported by policies, China's medical and health industry has continuously enhanced its innovation capacity, with a significant increase in the number of approved innovative drugs and medical devices as well as the scale of clinical pipelines; overseas licensing and import transactions have been active, the medical device industry has shifted from product export to industrial chain rooting, and countries along the Belt and Road Initiative have become new growth poles for pharmaceutical trade. However, it is still necessary to strengthen basic research and original innovation and improve enterprises' internationalization capabilities. Multinational enterprises stated that China's reform of the drug review and approval system has achieved remarkable results, with accelerated review speed and optimized clinical R&D environment; a number of policies have provided development opportunities for enterprises, which have continued to increase investment in China and carried out multi-model cooperation with local institutions to promote innovative therapies to benefit Chinese patients. They suggested further aligning the registration system with international standards and realizing scientific and flexible quality supervision. Innovative drug and medical device enterprises shared their global development experiences, illustrated the collaborative cooperation with regulatory authorities through specific cases, and called on enterprises and regulatory authorities to conduct in-depth R&D-oriented cooperation, promote the integration of Chinese innovation with global innovation, and help innovative drugs and medical devices benefit patients and doctors around the world.

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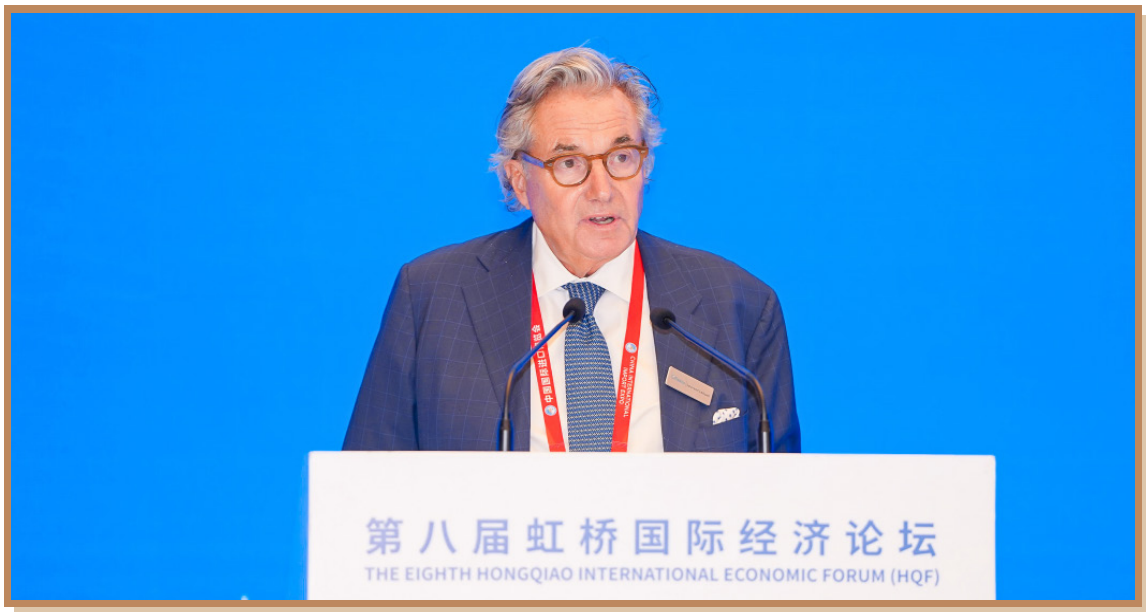


Dr. Laurent Leksell | Chairman of Elekta
Attended the parallel session themed "Global Drug Safety Governance and Chinese Drug Regulation Innovation" and delivered a thematic speech


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