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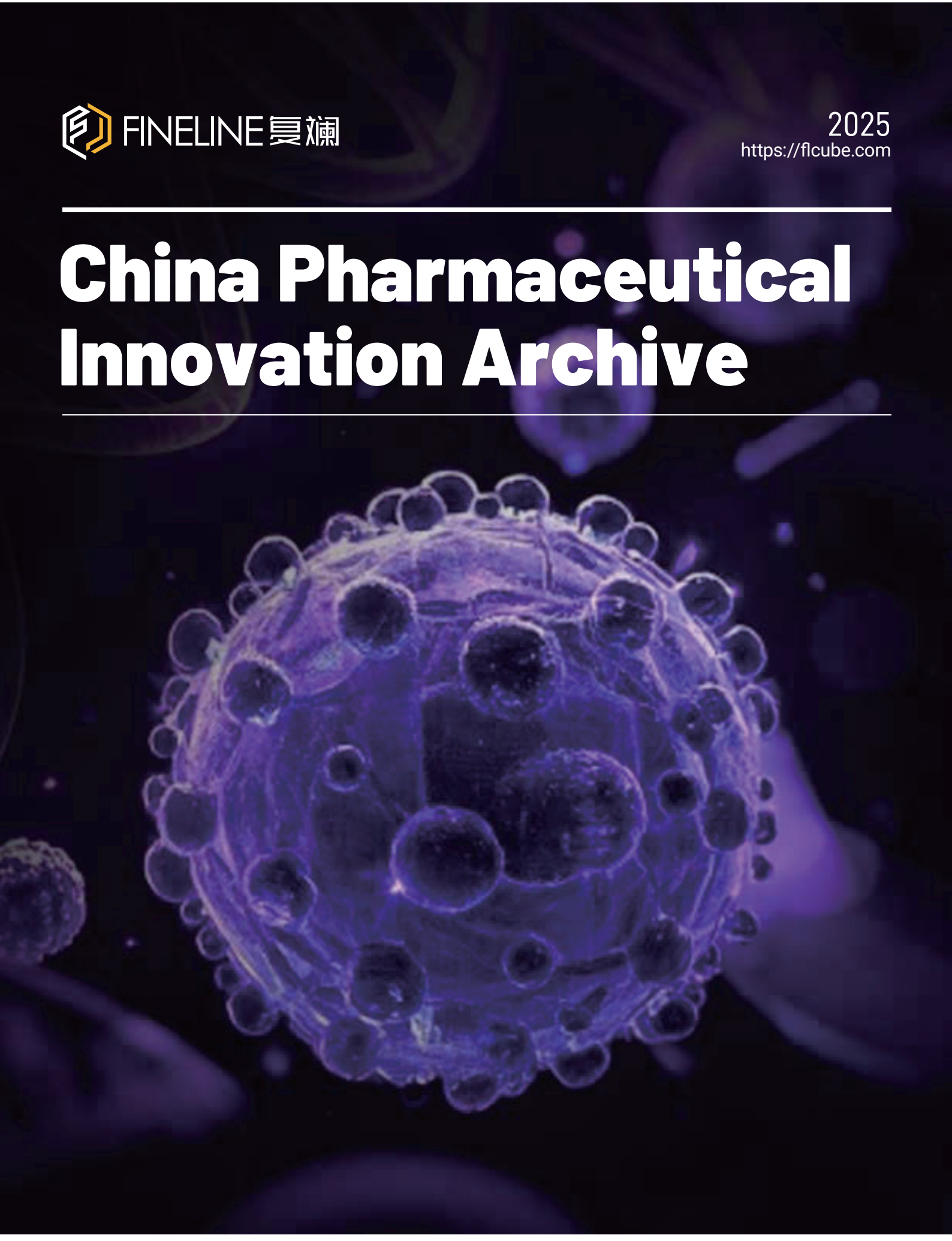
China Pharmaceutical Innovation Archive



Preface

In recent years, China has significantly elevated its position within the global pharmaceutical innovation supply chain. With the launch of regulatory reforms in the domestic pharmaceutical market in 2015, China's innovative drug industry has undergone a transformative journey: from its nascent stages to rapid growth, navigating the highs and lows of capital booms and busts, and enduring the trials of market evolution. Today, it occupies a pivotal role in the global supply chain of pharmaceutical companies.

According to authoritative statistics, by 2024, one-third of the products introduced by multinational corporations (MNCs) were originate from China, underscoring the nation's critical role in the global pharmaceutical innovation landscape.

In fact, China's pharmaceutical market has been experiencing a capital winter since the second half of 2021, and this challenging environment continues today. Furthermore, the international environment in 2024 was not optimistic, while the implementation of the "Biosecure Act" imposed numerous constraints on the global expansion efforts of Chinese biotechnology companies, the industry faced external pressures.

Meanwhile, positive policy signals have been consistently released. In March 2024, the term "innovative drugs" was mentioned for the first time in the China's Government Work Report, underscoring the nation's unwavering commitment to fostering the development of novel pharmaceuticals. This marks a pivotal shift in China's pharmaceutical industry, transitioning from a manufacturing-centric model to one driven by innovation. The "Implementation Plan for Full Industry Chain Support of Innovative Drug Development"*released earlier in 2024, has acted as a shot in the arm, injecting vigorous momentum into the sector. The plan provides robust support across the entire value chain—from research and development, regulatory approval, and production to market access—safeguarding the industry's growth trajectory.

Under the dual drivers of policy support and industry-driven innovation, China achieved remarkable milestones in pharmaceutical innovation in 2024. The number of novel approved drugs surpassed the symbolic threshold of 100 for the first time, while the volume and value of outbound licensing deals both reached new highs. Access to medical insurance was expanded to include more innovative drugs than ever before, and significant progress was made in protecting pharmaceutical intellectual property. Additionally, the synergy among healthcare, medical insurance, and pharmaceuticals became increasingly seamless, collectively propelling industry advancement. In stark contrast to tightening foreign policies, China continued to expand its openness by introducing new measures. Following earlier initiatives such as the Boao Lecheng Pilot Zone and the Greater Bay Area policies, in 2024, China further liberalized restrictions by allowing foreign investors to establish wholly-owned hospitals in nine major cities, including Beijing, Shanghai, Guangzhou, and Shenzhen. Furthermore, foreign investment was permitted in research and application of human stem cells, genetic diagnostics, and therapeutic technologies within the free trade zones of Beijing, Shanghai, Guangzhou, and Hainan. These measures opened new pathways for product commercialization and production, showcasing China's open and inclusive approach to its pharmaceutical market.

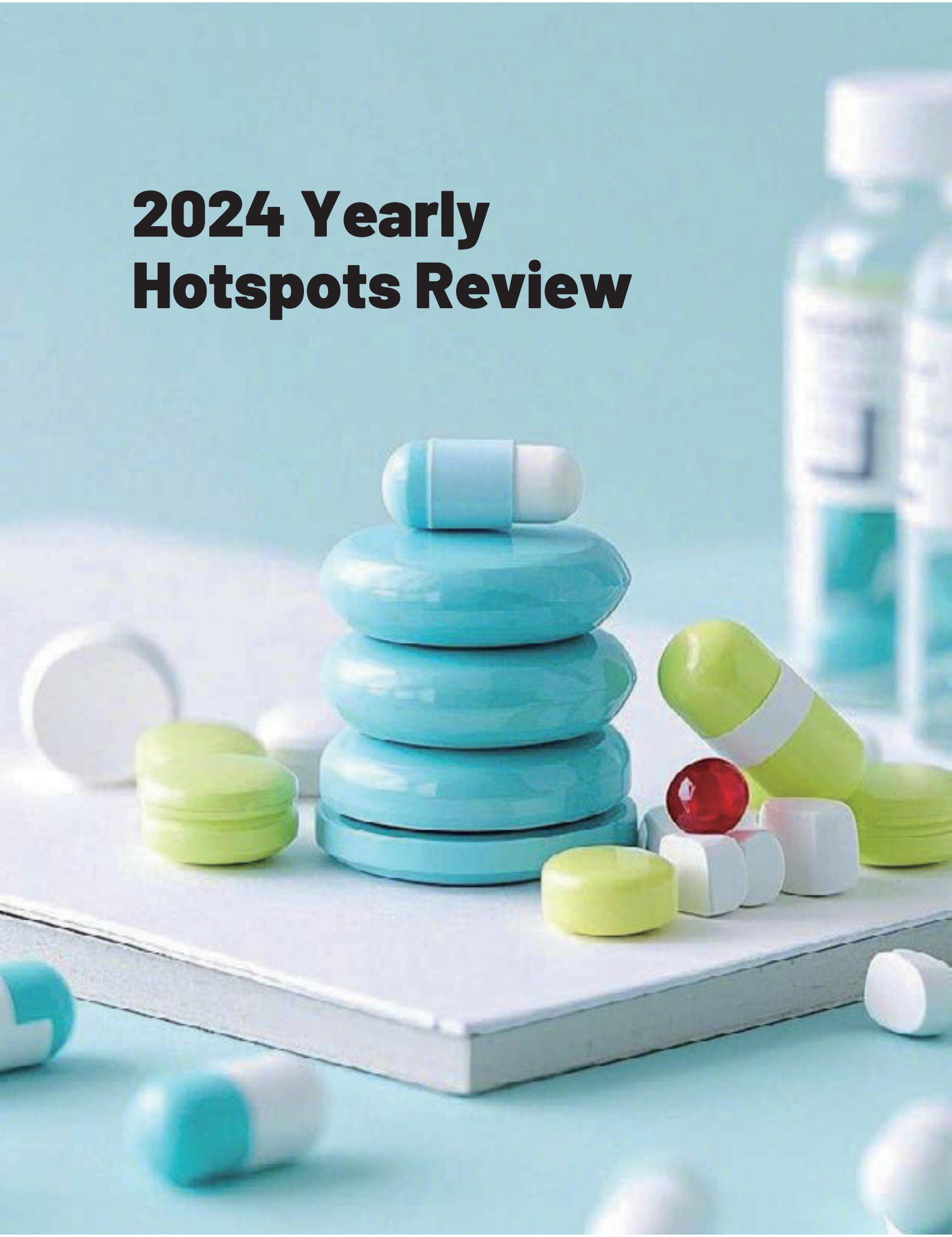
This Archive will conduct an in-depth analysis of China's abundant achievements in pharmaceutical innovation during 2024. It will also feature a special section revisiting the transformative journey of China's pharmaceutical reforms over the past few decades, providing a comprehensive overview of the industry's evolution. In addition, based on the dynamic changes in the domestic market environment, the archive will systematically analyze recent strategic adjustments made by both domestic and international enterprises in China's market, offering forward-looking insights to guide future industry development.

Content

2024 Yearly Hotspots Review

China's Pharmaceutical Development History

2024 Yearly Hotspots Review



1. Key Term of the Year – New Quality Productivity Forces

Under the impact of technological changes brought by the Fourth Industrial Revolution, at the 2024 Central Economic Work Conference, President Xi clearly emphasized that "innovation-driven development should lead to new quality productivity forces and the construction of a modern industrial system," providing clear guidance for future industrial development. As one of the vital elements of people's livelihood, pharmaceutical health has been one of the most dynamic and rapidly developing emerging industries in recent years' technological revolutions, and it is also a key area for fostering new quality productivity forces.

In 2024, China's pharmaceutical sector achieved remarkable progress in innovation. From the deep application of artificial intelligence (AI) in drug development, medical imaging diagnosis, and precision medicine, to the precise operations of surgical robots in clinical surgeries, and breakthroughs in biotechnologies such as antibody-drug conjugates (ADC), bispecific antibodies, mRNA drugs, CRISPR/Cas9 gene editing technology, as well as the emergence of brain-computer interface (BCI) technologies, these innovative achievements not only addressed unmet clinical needs in China's pharmaceutical market but also contributed numerous creative inspirations to the global stage.

Specifically, AI technology has been widely applied across various areas of the pharmaceutical industry, including algorithmic diagnosis, data-driven drug development, and intelligent surgery. These advancements have significantly improved medical efficiency while reducing costs. For instance, Sichuan University West China Hospital introduced an AI-assisted diagnostic system with an accuracy rate as high as 98%, surpassing the average level of human doctors. In drug discovery, AI technology has enhanced virtual prediction accuracy in target identification and molecular screening, drastically cutting preclinical validation costs. Surgical robot technology has also made significant progress, such as robotic arms achieving precise vascular suturing at a millimeter scale of 0.1 mm, thereby improving surgical precision and success rates. The emergence of brain-computer interface technology provides new tools for neuroscientific research and clinical applications, offering great potential in areas like neuromodulation, neural rehabilitation, and brain disease diagnostics.

2. A Strong tonic for the Industry – Full Industry Chain Policies

By 2024, the Chinese pharmaceutical market had experienced three years of a "capital winter." Compared to its previous reckless growth, the current market has returned to a more realistic valuation level. The shift from rapid growth to rational development has led investors to place greater emphasis on the actual value and long-term potential of companies.

As many industry insiders have noted, for China's innovative drugs to grow stronger and achieve greater success, they require stronger policy support. In March 2024, innovative drugs were first included in the *Government Work Report*, signaling the government's high priority on the development of innovative pharmaceuticals. Subsequently, a comprehensive implementation plan emerged within the industry, offering full-chain support for the development of innovative drugs. This plan provided holistic policy backing from multiple angles, including finance, research and development (R&D), regulatory review, and clinical application.

Following this, regions such as Beijing, Shanghai, Guangzhou, Zhuhai, and others rolled out their own region-specific, full-chain support policies. Specific measures included:

- **Establishing Long-Term Patient Capital:** A patient capital fund with a 15-year investment horizon was established, including a biopharmaceuticals mother fund exceeding RMB 21.5 billion to provide long-term and stable financial backing for innovative drug development.

- **Providing Financial Support for Innovation and R&D:** Special funds were allocated to support innovation and R&D efforts, reducing companies' R&D costs and improving their efficiency.

- **Streamlining Regulatory Approval Processes:** The regulatory review process was optimized to reduce approval timelines, accelerating the market entry of innovative drugs.

- **Removing Restrictions on New Drug In-Hospital Access:** Restrictions on new drug access in hospitals were lifted to promote the broader application of innovative drugs within healthcare institutions.

- **Promoting Market Expansion Abroad:** Support was provided for companies to expand into international markets, enhancing the global competitiveness of China's innovative drugs.

3. Record-High Approvals of New Drugs in 2024

The development of innovative drugs, as a key area in the new productive forces, has particularly significant social and economic benefits. It not only meets unmet clinical needs but also drives the upgrading of the pharmaceutical industry.

In addition to the gradual improvement in self-developed capabilities, by 2024, China had also made significant progress in introducing new drugs. Besides the regular approval of new drugs by the National Medical Products Administration (NMPA), policies previously implemented, such as the Lecheng Special Drug and Medical Device Policy and the Hong Kong Macau Drug and Device Access Policy, have played significant roles in continuously accelerating domestic access to new drugs.

- **Lecheng Special Drug and Medical Device Policy:** This policy allows the use of certain drugs and medical devices that have not yet been launched domestically within the Boao Lecheng International Medical Tourism Pilot Zone in Hainan Province, offering patients more treatment options.

- **Hong Kong Macao Drug and Medical Device Access Policy:** This policy permits the use of certain drugs and medical devices that have already been approved in Hong Kong and Macau but are not yet available on the mainland within the cities of the Guangdong-Hong Kong-Macau Greater Bay Area, further expanding channels for introducing new drugs.

The implementation of these policies has not only accelerated the introduction of overseas new drugs but also improved drug accessibility, enabling more patients to benefit promptly from the latest treatment methods.

3.1 NMPA approved 42 global new drugs

In 2024, China's National Medical Products Administration (NMPA) approved over 100 new molecular entities, with a significant increase in Category 1 New Drugs (drugs that had not been approved in any country or region at the time of submission for marketing authorization in China, excluding traditional Chinese medicine) compared to previous years. The number of Category 1 New Drugs reached 42 in 2024, representing a 44% year-over-year growth and a compound annual growth rate of 36% over the past decade. This data highlights China's notable progress in both the research and development of innovative drugs and their approval processes.

The acceleration of foreign imported drugs entering the Chinese market is also evident, with the time gap between their first approval abroad and in China narrowing significantly. For instance, Novo Nordisk's Insulin Icodec was approved in China just five days after its EU launch, showcasing the reduced lag period for imported medications.

In 2024, eight foreign-imported drugs were classified as Category 1 New Drugs, indicating that China is achieving near-synchronous launches with international markets. This reflects the recognition of China's supportive policies and efficient approval processes by international pharmaceutical companies, further advancing the globalization of China's pharmaceutical market.

Notably, on February 6, 2024, Roche's Crovalimab was approved in China, making it the second imported drug to have its first global approval there after FibroGen's Roxadustat in 2018 (FibroGen was acquired by AstraZeneca recently). This milestone underscores China's growing role as a key market for innovative drugs.

Table 1. 42 category 1 drugs were approved by NMPA in 2024

Product	Registrant	First approval date	Indications
Lecanemab (Leqembi)	Eisai	2024-01-05	Alzheimer 's Disease
Janagliflozin	Sihuan Pharma	2024-01-16	Diabetes mellitus
Tegileridine	Hengrui Pharma	2024-01-30	Postoperative analgesia
Crovalimab (Piasky)	Roche	2024-02-06	Paroxysmal nocturnal hemoglobinuria
Zevorcabtagene autoleucel	Carsgen Therapeutics	2024-02-23	Multiple myeloma
Tunlametinib	Colorado Drugs	2024-03-12	Melanoma
Iptacopan (Fabhalta)	Novartis	2024-04-24	Paroxysmal nocturnal hemoglobinuria
Unecritinib	Sino Biopharma	2024-04-24	Non-small cell lung cancer
Entinostat	EOC Pharma	2024-04-24	Breast cancer
Benmelstobart	Sino Biopharma	2024-04-30	Small cell lung cancer
Repotrectinib (Augtyro)	Bristol Myers Squibb	2024-05-08	Non-small cell lung cancer
Crisugabalin	Haisco	2024-05-15	Neuropathic pain
Rezivertinib	Beta Pharma	2024-05-15	Non-small cell lung cancer
Durlobactam, Sulbactam (Xacduro)	Zai Lab	2024-05-15	Bacterial infections
Ivonescimab	Akeso	2024-05-21	Non-small cell lung cancer
Zamerovimab，Mazorelvimab	Synermore	2024-06-04	Hydrophobia
Oritinib	Sanhome	2024-06-11	Non-small cell lung cancer
Envonalkib	Sino Biopharma	2024-06-11	Non-small cell lung cancer
Golidocitinib	Dizal	2024-06-18	T-cell lymphoma
Cofrogliptin	Haisco	2024-06-18	Diabetes mellitus
Insulin icodec (Awiqli)	Novo Nodisk	2024-06-18	Diabetes mellitus