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# Life Sciences 2025

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## **China: Trends & Developments**

Min Zhu, Ya-ling Gon, Yang Gu,  
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Han Kun Law Offices



# CHINA

## Trends and Developments

### Contributed by:

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Han Kun Law Offices is a leading full-service law firm in China, with over 800 professionals located in eight offices in Beijing, Shanghai, Shenzhen, Haikou, Hong Kong, Wuhan, Singapore and New York City. The firm's main practice areas include: private equity; mergers and acquisitions; international and domestic capital markets; investment funds; asset management; antitrust/competition; banking and finance; aviation finance; foreign direct investment; compliance; private client/wealth man-

agement; intellectual property; and dispute resolution. It provides a full range of legal services and business advice to Chinese companies and multinationals doing business in China. Over the years, it has been widely recognised as a leader in complex cross-border and domestic transactions that cover foreign investment access, industry compliance, labour and national security review, taxation, foreign exchange and intellectual property.

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**Min Zhu** has extensive legal practice experience in the life sciences and healthcare industries. He has served life sciences and healthcare companies in different stages of

development, including financing and licensing deals for start-ups, mergers and acquisitions, and various regulatory and compliance matters, such as anti-corruption and anti-bribery, clinical trials, drug and medical device registration, distribution, advertising and promotion, as well as medical and healthcare data compliance. Before joining Han Kun Law Offices, he practised law for many years at another leading Chinese firm and also in the Shanghai office of an international law firm.



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# CHINA TRENDS AND DEVELOPMENTS

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**Ying Li** specialises in patent prosecution, invalidation, litigation and IP counselling, with a notable record in aiding clients to secure patents in China.

Before joining Han Kun Law Offices, she amassed 16 years' experience at CCPIT Patent and Trademark Law Office. Her expertise extends to patent mining, drafting, office action responses and conducting prior art and freedom-to-operate searches, particularly using the STN database for small molecule drugs and biological macromolecules. She is recognised for her outstanding case management and communication skills and has successfully represented clients before the China National IP Administration and in court, earning widespread trust and commendation for achieving excellent outcomes.



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career in 2004 and specialises in PE/VC tax optimisation, offering stable solutions amidst changing tax laws. In M&A and capital markets, he devises tax-efficient, compliant structures for transactions, balancing savings with regulatory acceptance. For wealth management and stock option incentives, he crafts personalised tax plans that consider tax efficiency and asset protection, catering to the individual needs of various stakeholders.

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### Introduction

In 2024, China's pharmaceutical industry entered a recovery phase, marking a rebound from a period of stagnation. Despite the continued cautious attitude of investors and the tightened regulations surrounding initial public offerings (IPOs), the industry began to show promising signs of revival. Notably, the development of antibody-drug conjugates (ADCs) and bi-specific/multi-specific antibodies emerged as focal points of pharmaceutical innovation where China's pharmaceutical industry has demonstrated remarkable capabilities in engineering innovation and operational efficiency.

### Pharmaceutical Industry Transactions in 2024 IPOs

In 2024, the pharmaceutical industry continued to experience a decline in IPOs. Only five pharmaceutical companies were listed on the Chinese A-shares market, compared to 22 in the previous year, the lowest number since 2008. Additionally, at least 24 pharmaceutical companies announced the withdrawal of their IPOs or the suspension of the IPO review process. The slowdown was primarily due to stricter regulatory scrutiny, with a focus on financial perfor-

mance, promotional expenses and technological innovation. These developments indicate a shift toward increasing regulatory complexity within the industry due to more rigorous market entry standards.

### VC/PE financing

In 2024, securing VC/PE financing in China's primary market became even more challenging, with companies likely to attract funding limited to those in high-growth fields or holding leading market positions. Throughout the year, a total of 652 companies completed financing rounds in the primary market, of which 550 disclosed their financing amounts. The cumulative financing reached RMB51.315 billion, representing a 35% decline from RMB79.203 billion in 2023.

The average financing amount per deal stood at RMB93 million, a 15% decrease from the RMB109 million in 2023. Most financings in 2024 were concentrated in early funding rounds, particularly around Series A. The combined proportion of seed, Series A and Series B financing events accounted for 82.4% of all deals. Investors showed a greater preference for early-stage

investments, aiming to reap higher returns when the market recovers.

## *License-in/out*

In 2024, innovative Chinese drug companies continued to achieve remarkable milestones in license-out transactions, setting new records in both the number of deals and the total transaction value. A total of 76 license-out deals were concluded, which is three times the number of concurrent license-in deals (26 deals). In terms of transaction amounts, from January to October 2024, the upfront payments for license-out deals amounted to approximately USD3.16 billion, with the total transaction value reaching USD51.1 billion. This figure surpassed the total amount of license-out deals for the whole of 2023.

Half of the license-out transactions (38 deals) were related to antibodies and conjugated drugs, with a particular focus on bi-specific antibodies and ADC drugs. Meanwhile, the cell and gene therapy drug area witnessed a total of five license-out transactions, which is expected to emerge as another promising subsector for innovative Chinese drug development, with the potential to gain global market recognition in the future.

Multinational corporations (MNCs) have become the primary purchasers in license-out transactions. The 24 deals involving MNCs accounted for 55.4% of the total license-out transaction value and 71.5% of the total upfront payments. This trend underscores the recognition by MNCs of the robust R&D capabilities of innovative Chinese drug companies. As a result, innovative Chinese drug assets have become a crucial source for MNCs to sustain and enhance their own innovative capabilities.

## *Newco model*

The newco model, which gained significant industry attention in 2024, has emerged as a novel pathway for innovative Chinese drug companies to expand globally. The newco model involves granting the overseas rights of a Chinese company's core products to a newly established overseas entity (ie, a newco), while simultaneously introducing overseas funds and assembling an international management team, with the ultimate goal of exiting through the newco's overseas listing, merger or acquisition.

In May 2024, Hengrui Pharmaceuticals launched the first notable newco transaction in the Chinese market, by licensing the global rights of its GLP-1 product portfolio outside the Greater China Region to Hercules CM, a company jointly funded by Bain Capital and other investors. Beyond the approximately USD6 billion in upfront payments, milestone payments and sales milestone payments, Hengrui Pharmaceuticals also acquired a 19.9% stake in Hercules CM.

From May to November 2024, six newco transactions took place, with a total transaction value of USD8.23 billion and a combined upfront payment of about USD200 million. With market participants actively exploring the potential of the newco model, it is anticipated that this will become one of the predominant models for cross-border co-operation and transactions in the coming years.

## *Mergers and acquisitions*

With the tightening of domestic IPOs and policy support from Chinese authorities, mergers and acquisitions are gradually emerging as the preferred exit strategy in the Chinese market. In 2024, 35 domestic merger and acquisition (M&A) events occurred in the pharmaceutical

industry, involving a total transaction amount of RMB112.58 billion. M&A activity in 2024 was predominantly characterised by reorganisations within industry chains, with a notable trend being the acquisition of innovative drug assets by major pharmaceutical companies. Out of the 35 M&A events in 2024, ten involved the acquisition of innovative biotechnology start-ups, and the transaction amounts of these ten events accounted for 61.1% of the total disclosed M&A transactions.

## Regulatory Trends

In 2024, the Chinese regulatory authorities introduced a series of pivotal updates to laws and regulations in the life sciences sector. Key changes included easing some of the key restrictions on foreign investment, the nationwide implementation of regulations on investigator-initiated trials (IIT), updated human genetic resource (HGR) regulations, and enhanced oversight of drugs and medical devices.

China initiated pilot programmes to gradually ease foreign investment restrictions in the life sciences sector in 2024. On 8 September 2024, three governmental bodies in China jointly issued the Notice on Carrying Out Pilot Programmes to Expand Opening-Up in the Healthcare Sector. The Notice permits foreign-invested enterprises to participate in the development and application of stem cell, gene diagnosis and therapeutic technologies in four free trade zones (FTZs) or ports in Beijing, Shanghai, Guangdong and Hainan. This initiative is expected to stimulate growth and international collaboration in numerous industries including iPSCs, CAR-T, TCR-T, CAR-NK, TILs, mRNA, gene sequencing and IVD/LDT. More detailed measures in the FTZs are expected to be introduced soon.

Regarding IITs, the release of the Measures for the Administration of IITs (the “*IIT Measures*”) in 2024 marked a new phase in China’s IIT regulations. Under the IIT Measures, all IITs are required to only use marketed drugs approved by the National Medical Products Administration (the “*NMPA*”), except for IITs of stem cells and somatic cells. The IIT Measures apply nationally, in contrast to pilot regulations implemented in 2021 in selected regions (the “*Pilot Regulations*”). The IIT Measures further simplify the process for initiating observational studies and strengthen the role of clinical research management committees while retaining many key provisions from the Pilot Regulations, including IIT protocol signing requirements and research filing.

In terms of the updates to the HGR Regulations in 2024, the State Council issued an order to amend the Administrative Regulations of HGRs to designate the National Health Commission (the “*NHC*”) as the regulatory authority for HGR, replacing the Ministry of Science and Technology. These amendments highlight that HGR remains China’s key regulatory focus. In January 2025, the administrative guidelines for HGR approval and filing requirements were further amended, reflecting ongoing refinements in regulatory implementation.

In 2024, the State Council issued its Opinion on Deepening Drug and Medical Device Regulation Reform to Promote High-Quality Development of the Pharmaceutical Industry, focusing on improving regulatory efficiency, supporting innovation and strengthening compliance. It also advocates for extending the data protection period, enhancing the market exclusivity system, shortening clinical trial approval timelines and optimising the import approval process for drugs and medical devices.

In addition to these key regulatory updates, there have been other regulatory highlights for drugs and medical devices, respectively as follows.

## *Drug highlights*

In 2024, several regulations were introduced to strengthen the marketing authorisation holder (MAH) system. For example, to strengthen compliance enforcement for MAHs of imported drugs, the NMPA issued the Interim Provisions on the Administration of Domestic Responsible Entities Designated by Overseas MAHs, providing specific obligations and procedural requirements for MAH domestic responsible entities.

Several regulations were also released to regulate the manufacture and promotion of drugs. In April 2024, the NMPA issued the Announcement on the Optimisation of Registration Application Procedures for the Transfer from Overseas Manufacture to Domestic Manufacture for Marketed Drugs in China. The Announcement provides a feasible pathway to localise the production of imported drugs and clarifies the requirements for these transfers.

For the manufacture of biological products, the NMPA released the Pilot Work Plan for Segmented Production of Biological Products in October 2024, suggesting the feasibility of cross-provincial and cross-border production of some specific biological products. With respect to promotions, the NMPA released the Draft Measures for the Administration of Pharmaceutical Representatives in November 2024, which would regulate the conduct of pharmaceutical representatives and ensure compliance for promotional activities in pharmaceutical academic settings.

China also released multiple guidelines to address anti-monopoly issues in the pharmaceutical industry. In August 2024, the State Admin-

istration for Market Regulation (the “SAMR”) issued the Draft Anti-Monopoly Guidelines for the Pharmaceutical Industry, which aim to prohibit monopolistic practices and promote fair competition specifically within the pharmaceutical market.

## *Medical device highlights*

China made significant breakthroughs and landmark developments in the medical device regulatory framework in 2024. In August, the NMPA released the draft Medical Device Administration Law (the “draft MDAL”) for public consultation. This is a remarkable milestone, which has been achieved within one year of its inclusion in China’s legislative agenda. The draft MDAL introduces several significant reforms, including establishing clear pathways for medical device marketing approval transfers, strengthening oversight of domestic responsible entities, streamlining clinical trial approval processes and proposing the establishment and enhancement of a vigilance system.

China has also updated its regulations for innovative medical device importation. In July 2024, the NMPA and the NHC issued the Announcement on the Temporary Import and Use of Clinically Urgent Medical Devices for Medical Institutions. This Announcement establishes and refines a nationwide framework for the importation of clinically urgent medical devices, while also integrating insights from local pilot programmes. It has paved the way for the temporary importation of medical devices that lack equivalent products marketed in China, facilitating the entry of innovative solutions into China.

As for the regulations covering medical device clinical trials, in March 2024, the NMPA released the Regulations on the Supervision and Inspection of Medical Device Clinical Trial Institutions

(For Trial) (Draft for Comment) and the Key Points and Determination Principles for the Supervision and Inspection of Medical Device Clinical Trial Institutions (Draft for Comment). The two drafts provide comprehensive guidance on the stringent inspection criteria and procedures for clinical trial institutions. Once finalised, they are expected to significantly strengthen regulatory oversight and improve the integrity of medical device clinical trials.

## Compliance Practices

Following the stringent anti-corruption measures in 2023, rectification actions in the pharmaceutical industry continued to intensify in 2024. From legislation to enforcement, these efforts underscore China's determination to combat corruption in the life sciences and healthcare industries.

### *Commercial bribery in life sciences and healthcare*

In 2024, Chinese regulators remained keenly focused on anti-bribery and anti-corruption, publishing a number of documents to maintain strong oversight of commercial bribery in the life sciences and healthcare sectors and to provide further compliance guidelines.

Effective 1 March 2024, the Amendment (XII) to the Criminal Law of the People's Republic of China adopted a more severe stance toward bribery in the healthcare sector. It explicitly outlined standards for "*aggravated penalties*" under various circumstances, with the maximum penalty against the offenders being life imprisonment.

On 11 October 2024, the SAMR issued the Guidance on Preventing Commercial Bribery Risks for Pharmaceutical Enterprises (Draft for Comment). On 10 January 2025, the Guidance on Preventing Commercial Bribery Risks for Pharmaceutical Enterprises (the "*Guidance*") was officially

released by the SAMR and took effect immediately. The Guidance aims to assist pharmaceutical and medical device enterprises in effectively preventing and addressing commercial bribery risks during their daily operations, ensuring compliance with relevant laws and regulations.

On 25 December 2024, the Standing Committee of the National People's Congress released the draft Anti-Unfair Competition Law of the PRC (the "*2024 Draft*") for public comment. The 2024 Draft would make significant revisions regarding commercial bribery, emphasising prohibitions against accepting bribes. Additionally, it would increase the maximum fine for commercial bribery from RMB3 million to RMB5 million and introduce personal penalties for legal representatives, primary executives and directly responsible personnel of entities engaging in commercial bribery. The 2024 Draft would also add provisions for administrative penalties for those who offer bribes.

Meanwhile, anti-corruption enforcement and judicial actions in the pharmaceutical industry were strengthened nationwide in 2024. This again emphasises that both recipients and offerors of the bribe may be subject to punishment.

On 27 May 2024, the NHC, the SAMR, the Ministry of Public Security, the National Audit Office and ten other departments jointly issued the Key Work Points for Rectifying Malpractices in the Procurement and Sales of Pharmaceuticals and Medical Services in 2024. This document specifically targets illegal activities such as bundled sales and "*kickback sales*" disguised as conferences, donations, research collaborations and trial promotions.

## *Strengthened regulation of medical insurance fund usage*

On 28 February 2024, the Supreme People's Court, the Supreme People's Procuratorate and the Ministry of Public Security jointly issued the Guidance on Several Issues Concerning the Handling of Criminal Cases Involving Medical Insurance Fraud. Effective from the date of issuance, this document aims to legally punish medical insurance fraud crimes, safeguard the security of medical insurance funds and protect the legitimate rights and interests of the public with respect to medical insurance.

On 2 April 2024, the National Healthcare Security Administration (the "NHS"), together with multiple national departments, issued the Notice on Conducting Special Rectification Work on Illegal and Non-Compliant Issues of Medical Insurance Funds, initiating a nationwide special rectification campaign targeting illegal and non-compliant issues in medical insurance funds.

In April 2024, the NHS, along with four other national agencies, issued the Notice on Conducting Unannounced Inspections of the Medical Insurance Fund in 2024, officially launching unannounced inspections of the use of the National Medical Insurance Fund for 2024.

## **Intellectual Property**

### *Continued growth in patent applications related to life sciences and healthcare*

The number of invention patent applications in China continued to grow. According to national statistical reporting, by the end of 2024, the total number of patents granted in 2024 reached 1.045 million, representing a year-on-year increase of 13.5%. In 2024 a total of 67,000 patent re-examination and invalidation cases were concluded, and the number of high-value invention patents per 10,000 people in China reached 14.

Consistent with this trend, patent applications related to life sciences and healthcare in China also continued to increase. In 2024 alone, the number of published patent applications related to life sciences and healthcare (including chemical drugs, biopharmaceuticals, traditional Chinese medicines and medical devices) exceeded 252,000, including 176,000 medical device-related patent applications and 76,000 drug-related patent applications. This represents a year-on-year increase of more than 30% compared to the 58,000 drug-related patent applications in 2023.

### *Changes in patent examination and patent industrialisation*

Guided by the principle of "quality over quantity", the government strengthened control over patent examination and prosecution procedures in 2024. For example, when examining healthcare-related patent applications, the number of citations of integrity clauses and notices identifying abnormal application behaviour significantly increased compared to previous years. This has had a significant impact on improving patent quality.

According to data disclosed by the China National Intellectual Property Administration, the patent industrialisation rate of valid invention patents held by Chinese enterprises reached 53.3%. The number of recorded patent transfer and licensing transactions throughout the year exceeded 613,000, representing a year-on-year increase of 29.9%. Among these, the number of recorded transfer and licensing transactions by universities and research institutions reached 76,000, representing a year-on-year increase of 39.1%. From January to November 2024, the total import and export value of intellectual property royalties nationwide reached RMB356.41 billion, representing a year-on-year increase of 6.6%.

Corresponding to the trend of increased patent industrialisation, the pharmaceutical industry in China completed 102 transfer and licensing deals in 2024, with a total upfront payment of USD3.16 billion and a total transaction value exceeding USD51.1 billion.

### *Judgments in pharmaceutical patent infringement litigation with significant impact*

In 2024, China's Supreme People's Court delivered a landmark judgment in a patent infringement case involving sitagliptin metformin tablets. The Court clarified that if a generic drug manufacturer submits an application to the NHTA to include its generic drug in the national medical insurance catalogue during the patent protection period of the original drug, such an act is not considered an offer to sell. Therefore, this behaviour does not infringe upon the patent rights of the original drug manufacturer.

In contrast, in 2023, the Supreme People's Court rendered a judgment in a patent infringement case involving the online listing for sale of vildagliptin tablets. The Court held that the act of a generic drug company participating in the centralised drug procurement bidding process and listing its products online during the valid patent term of the original drug constituted an offer to sell, which infringed upon the original drug manufacturer's patent rights. The ruling explicitly stated that during the patent protection period, generic drug companies may not engage in certain sale preparation activities, such as bidding, without the permission of the patent holder.

The judgments in these 2023 and 2024 Supreme Court rulings together serve as typical cases to help clarify legal boundaries and reduce infringement disputes arising from legal ambiguity. They also demonstrate a legislative goal of balancing intellectual property protection for innovative

pharmaceutical companies and market access opportunities for generic drug companies.

### **Tax Concerns**

As one of the most encouraged sectors in China currently, healthcare and life sciences companies may enjoy a wide range of tax incentives, mainly including the following preferential tax treatments.

#### *High and new technology enterprises (HNTE)*

The HNTE policy offers a reduced 15% corporate income tax rate (as opposed to 25% for normal enterprises). Many life sciences companies find it relatively easy to qualify for this tax incentive, although certain others may encounter difficulties, particularly Chinese subsidiaries of MNCs, due to a lack of People's Republic of China or PRC-generated IP. Over the last few years, more pharmaceutical companies, particularly biotechnology start-ups, have devoted themselves to developing first-in-class or best-in-class drug products, which places them in a better position to enjoy HNTE tax incentives.

However, in 2024, there were some notable instances where life sciences companies (including listed companies) had their HNTE status withdrawn due to compliance issues and other factors. This serves to underline the importance of legal compliance for companies that obtain this tax incentive.

#### *R&D expense super deduction*

The PRC's R&D expense super deduction policy is similar to those of many other jurisdictions, which allows an extra deduction for qualified expenditures. Life sciences companies are qualified to enjoy a 100% extra deduction by being recognised either as "*manufacturing enterprise*" or "*small and medium technology enterprise*".

## *Input VAT refunds*

In terms of VAT treatment, a major incentive is the input VAT refund mechanism, under which small-scale or manufacturing life sciences companies can have their qualified accumulated input VAT refunded. This is particularly beneficial for life sciences companies that incur significant input VAT out of payments due to R&D or licence activities during their early stages when they have no chance to book revenue.

From a transactional perspective, it is also important to have a proper understanding of the relevant tax implications. For example, for license-in deals, apart from the potential input VAT refunds, one of the key tax considerations is the identification of a permanent establishment for overseas licensors that plan to assign personnel to work in the PRC for the licence project. The entire revenue package of the licensor may be subject to a corporate income tax rate of 25% if it is deemed to have set up a permanent establishment in the PRC.

## *Tax incentives extended*

Since 2023, the economic environment in the PRC has proven to be mixed. In order to promote business development, the government and tax authorities have extended many tax incentives including those designed for small and medium-sized companies. These incentives are not only applicable to life sciences companies but reduce the tax burden for start-up companies significantly as well.

## *License-out tax matters*

In 2024, we observed more PRC-based life sciences companies license-out IP to overseas companies. Proper design of transaction structures is needed to avoid triggering a significant tax burden for these PRC-based licensors, especially with respect to foreign withholding taxes.

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