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Life Sciences 2024

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China: Trends & Developments

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Trends and Developments

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Han Kun Law Offices

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 management, intellectual property and dispute resolution. Han Kun 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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Life Sciences in China: An Introduction

The market rebound that was anticipated in pharmaceutical investment and finance following the end of the pandemic did not materialise in 2023, due to factors such as stringent anti-corruption policies in the pharmaceutical industry and the changing dynamics of international politics. Nevertheless, amidst this shifting landscape, there were still notable deals and opportunities. Companies with robust innovation capabilities and promising product pipelines have continued to attract substantial investment.

Overall, the post-pandemic period has brought forth an era of both transformation and uncertainty. Navigating these changing dynamics requires a keen understanding of regulatory changes and geopolitical influences, and an unwavering commitment to innovation and quality within the industry.

Pharmaceutical Industry Transactions in the Post-Pandemic Period

IPOs

The pharmaceutical industry in China experienced a significant contraction in IPOs in 2023, with only 22 companies listing compared to 50 the previous year. Total IPO financing dropped sharply from RMB76.51 billion to RMB22.32 billion, representing a 70.8% decline. In addition, terminated IPO projects surged to 38, almost double the number recorded in 2022. Chemical pharmaceuticals accounted for the most IPOs, with nine listings, followed by biopharmaceuticals and medical devices, each with four listings.

The slowdown in IPOs was primarily due to stricter regulatory scrutiny focused on financial performance, promotional expenses and technological innovation criteria. These developments suggest a move towards more rigorous market entry standards, which may pose a challenging outlook for pharmaceutical IPOs in 2024, amidst continued stringent policies and increasing complexities in the industry.

VC/PE financing

Although it was anticipated that the relaxation of pandemic control measures would stimulate a resurgence in VC/PE investment activities, 2023 did not fully meet these expectations. In the Chinese market, the number of financing events in Q1-3 increased to 962, marking a 12.01% increase from the previous year, but

the total financing amount for Q1-Q3 2023 was only RMB85.02 billion, representing a significant decrease of 25.1% compared to the same period in 2022.

Despite the overall subdued market conditions, companies demonstrating strong innovation capabilities and high-quality product pipelines continued to attract substantial investment. This trend underscores that, in the pharmaceutical industry and particularly in innovative drugs and biotechnology, investors prioritise innovation and technological potential over general market sentiment.

License-in/out

In 2023, China's pharmaceutical industry achieved record numbers of license-out deals, with over 40 significant collaborations covering nearly 50 innovative drugs. Thirteen of these transactions exceeded USD1 billion, marking a new high in deal volume and financial vigour. While small molecule targeted drugs and antibody drugs were in high demand, the most notable transaction was an USD8.4 billion deal in the antibody-drug conjugate (ADC) sector involving BeiGene. This deal not only highlighted the rising global value of Chinese ADC products but also suggested the sector's potential for future breakthroughs. The pivot of biosimilars towards emerging markets such as Argentina, the Philippines and Thailand also indicated a strategic shift to uncharted territories, demonstrating the Chinese biopharmaceutical industry's adaptability and ambitious global outreach.

Alongside its remarkable license-out achievements, China's pharmaceutical industry actively engaged in license-in transactions. In 2023, there were more than 170 such deals, including partnerships with entities from the US, Japan, the UK and Switzerland. Although there was a slight drop in the number of transactions compared to the previous year, the overall financial commitment remained strong. Most of these license-in agreements focused on innovative drugs, particularly in the pre-clinical stage. This reflects China's strategic emphasis on early-stage pharmaceutical development and its continued integration into the global biotech innovation network.

Mergers and acquisitions

In 2023, China's pharmaceutical industry maintained a steady yet cautious pace in M&A, with most deals staying within the RMB1 billion range. Local pharma companies focused on sales collaborations and over-the-counter (OTC) channel integrations, showing less interest in acquiring innovative businesses compared to their global counterparts.

The medical device industry saw more diverse M&A activity, with a focus on market integration and technology enhancement. Small or medium-sized domestic companies led most of these deals, which often did not exceed RMB100 million, indicating a trend of smaller-scale, strategic acquisitions in China's evolving healthcare sector.

Regulatory Trends

In 2023, Chinese regulatory authorities updated a number of notable laws and regulations to keep up with the rapid development of the life sciences industry. Among the regulatory trends, significant updates included new rules on human genetic resources (HGR), ethics review, promotion and advertising, and imported drugs and medical devices for urgent clinical use.

Regulatory authorities made diligent efforts to protect national biosecurity and regulate HGR-related activities by adopting a set of new rules

and standards in 2023. To further refine the Regulations on Administration of Human Genetic Resources, promulgated in 2019, the Ministry of Science and Technology (MOST) issued the Implementation Rules for the Regulation of Human Genetic Resources Administration (Implementation Rules), which clarify the scope of HGR information, narrow down the scope of "foreign entities" and update requirements for collection and biobanking, international collaboration, etc. MOST also released new administrative guidelines and updated frequently asked questions, which serve to make further clarification in, for example, the determination of specific samples and regulatory procedures. China's new HGR regulations clarify many practical and key issues in industry practices for utilising HGR and still feature high standards and strict supervision.

Regulatory authorities have placed increasing focus on ethics review by releasing two new rules in 2023. The Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans have expanded the scope of application and clarified requirements in informed consent and exemptions, etc, while the Scientific and Technological Ethics Review Regulation has introduced new procedures for scientific and technological ethics review. Notably, the regulation stipulates that entities in the life sciences sector must establish an internal scientific ethics (review) committee if their research falls under sensitive fields in scientific ethics. Relevant industry players should monitor these trends closely in stricter ethics review supervision.

In 2023, the State Administration for Market Regulation (SAMR) released the Measures for Administration of the Review of Advertisements for Drugs, Medical Devices, Health Foods, and Food Formulas for Special Medical Purposes (Draft for Comment) (Draft), which would revise existing rules originally promulgated in 2019. To respond to practical needs, the Draft introduces several provisions in livestream advertisements and those with website links and QR codes. The Draft also proposes new requirements for labelling obligations and clarifies procedures for advertising approvals.

Chinese regulatory authorities have also explored the feasibility of the importation and use of drugs and medical devices for urgent clinical use. In early 2023, a pilot regulation was released and applied in the Hainan Free Trade Port, which introduced several requirements for the acceptance of real-world data as registration materials for regulatory approvals and also updated provisions on taking away for use and measures under occurrence of major safety events. Based on the pilot regulation, the National Medical Products Administration (NMPA) released a draft of administrative requirements for medical devices for urgent clinical use in late 2023, which could be applied nationwide in the future.

According to the NMPA at a national conference on drug supervision and administration in January 2024, the major regulatory focuses in 2024 will be on the management of safety risks of drugs, the continuing reform of the drug and medical device review system, and the enhancement of regulatory informatisation.

In addition to the general introductions to policy updates that are applicable to both drugs and medical devices, the following regulatory highlights apply to drugs or medical devices respectively.

Drug highlights

During 2023, several guidelines were released to enhance the regulation of clinical research into

drugs. On 18 August 2023, the China Medicinal Biotechnology Association was commissioned by the National Health Commission to issue the Guidelines on the Clinical Research of Somatic Cell (Trial), which have refined the regulatory requirements for clinical research programmes for somatic cell therapies such as CAR-T/NK. To establish a more complete and systematic regulatory system for the supervision of drug clinical trial institutions, the NMPA released the Measures for Supervision and Inspection of Drug Clinical Trial Institutions (Trial) and its supplemental technical guidelines on 3 November 2023, which officially came into effect on 1 March 2024.

Relevant authorities released several regulations and documents regulating drug distribution. On 27 September 2023, the SAMR released the Measures for Quality Supervision and Administration of Drug Distribution and Use. These measures became effective on 1 January 2024 and outline the obligations regarding drug distribution and the use of marketing authorisation holders (MAH), distributors and medical institutions.

Following the implementation of the Provisions for Supervision and Administration of Online Drug Sales, the NMPA has been enhancing the regulation on online drug sales. A notice on the NMPA's official website in June 2023 required companies and platforms to rectify information displays regarding prescription drugs. The release of the Guidelines for Inspection of Third-Party Platforms for Online Drug Sales (Trial) in December 2023 strengthened the supervision of online platforms in fulfilling their responsibilities.

Medical device highlights

China is currently working on a pre-legislative study of the Law on Medical Device Administration. On 7 September 2023, the 14th National People's Congress Standing Committee released the legislative agenda for 2023–2028, wherein the Law on Medical Device Administration was included for the first time. When this law is adopted in the future, it will provide an authoritative framework for medical device regulation.

The regulatory framework for China's laboratory developed tests (LDT) industry continues to mature. Shanghai launched its LDT pilot programme in March 2023, following a national pilot programme that began at the end of 2022. These two pilot regulations provide comprehensive and detailed guidelines on the use of LDT products, paving the way for future exploration in the development of a more mature regulatory regime.

As for the regulations over medical device distribution, the NMPA released the newly revised Good Supply Practice for Medical Devices (GSP) on 4 December 2023, which will come into force on 1 July 2024. The new GSP, which replaced the 2014 version, is more consistent with the 2021 Regulations for the Supervision and Administration of Medical Devices and will strengthen the requirements for quality management.

Compliance Practices

Commercial bribery in medical and healthcare industries

Rigorous monitoring and enforcement of commercial bribery is expected to continue, with a focus on the healthcare sector, including dawn raids, cross referrals of cases to other competent agencies, and collaboration among different government agencies to crack down on corruption and bribery. As law enforcement efforts against commercial bribery intensify, an increasing number of complex hidden bribery schemes are being identified and penalised by law enforcement agencies. Such schemes

include tailor-made bidding, bid rigging, exclusive profit sharing, and entertainment and kickbacks disguised as speaker fees for training or experience sharing at various conferences, as well as using ad hoc rebates and discounts to distributors for indirect payments to healthcare professionals, etc.

The National Health Commission has explicitly clarified that academic conferences and normal medical activities conducted in compliance with relevant national regulations should still be positively supported and encouraged. However, the regulatory authorities will actively rectify those bribery activities associated with academic conferences – eg, providing inappropriate benefits by fabricating academic meetings, or unlawful misappropriation of the sponsorship fees for academic conferences that do not take place as planned.

In sum, the payment of speaker fees in relation to academic conferences is not completely prohibited, but it remains one of the key compliance issues for healthcare companies to carefully review the process and collect the relevant event photos and materials for future internal audit or external inquiries by the enforcement agencies.

Strengthening regulation of national medical insurance fund usage

To increase scrutiny of medical insurance fund usage, new regulation methods will be piloted, including increasing unannounced inspections and fraud prevention mechanisms based on data collection from mobile applications and new payment methods for off-site supervision.

Continuous advancement of national centralised procurement of medical devices and pharmaceuticals

National centralised procurement became institutionalised in 2021, and remarkable achievements and valuable experience have been obtained in pharmaceutical chemicals and high-value consumables such as coronary stents and artificial joints. Deeper coverage of national centralised procurement over regular pharmaceutical chemicals is expected. Companies should enhance self-monitoring of compliance efforts to prevent procurement issues related to commercial bribery or taxation issues. Law enforcement agencies hope that the reduced profit margins due to centralised procurement will lead to less commercial bribery by life sciences companies involving healthcare professionals.

Trade secret protection

In 2022, relevant policies regarding trade secret protection were initiated at both national and local levels. Enterprises are encouraged to enhance internal control mechanisms, self-protection capabilities and management organisation, for the purpose of establishing systematic compliance. Meanwhile, local governments intend to strengthen the protection of key and specialised industries, especially new industries, new business models and trends. Priority will be given to the protection of knowledge- or technology-intensive, innovative and time-honoured businesses.

Changes in Chinese Intellectual Property Laws and Regulations

Revision of patent-related laws and regulations

On 21 December 2023, after five revisions, the State Council promulgated new rules for the implementation of the Patent Law of the People's Republic of China; on the same day, the

China National Intellectual Property Administration (CNIPA) published revised guidelines for patent examination. Both of these sets of changes came into effect on 20 January 2024.

The amendments to the rules relate mainly to optimising the patent application filing process, relaxing the provisions on the grace period for novelty, and improving the priority-related system. The changes also include aspects related to patent application filing, such as introducing the principle of good faith, adding a delayed examination system and improving the patent re-examination system. Other amendments include refining the patent term compensation system, improving the patent dispute handling and mediation system, and clarifying the criteria for defining patent infringement disputes with significant domestic impact. The revision of the CNIPA examination guide corresponds to these changes.

The biggest change related to life sciences is that specific content related to patent term extension and patent linkage are stipulated in Articles 77–84 of the new Rules for the Implementation of the Patent Law of the People's Republic of China, and a new chapter – "Several Provisions on the Examination of Patent Applications for Inventions in the Field of Traditional Chinese Medicines" – is added to Part II of the "Substantive Examination" of the Patent Examination Guidelines as Chapter 11. Regarding the examination of patent applications in the field of traditional Chinese medicines, the new Chapter 11 was added to make detailed and clear provisions on the examination standards for the subject of patent protection for traditional Chinese medicine inventions, as well as on the specification, claims, novelty, inventiveness and utility.

Changes in the number of patent applications and objects of patent protection

China's invention patent applications have continued to increase. According to nationally reported statistics, the number of valid domestic invention patents reached 4.015 million by the end of 2023, representing a year-on-year increase of 22.4% and making China the first country in the world where the number of valid domestic invention patents exceeded 4 million.

China's pharmaceutical-related patent applications have also continued to increase. In 2023 alone, the number of published drug-related patent applications in China, including chemical drugs, biopharmaceuticals and traditional Chinese medicines, reached 58,000, an increase of more than 3,000 compared with the 55,000 in 2022. Of this total amount, the number of published antibody-related patents alone reached about 13,000 in 2023.

In the field of life sciences, the objects of patent application protection have changed significantly. In addition to the traditional drugs themselves, strong innovation in the digital economy and the rapid development of artificial intelligence have played an important role. In recent years, the average annual growth rate of patent applications in the medical and healthcare industry using artificial intelligence technology has exceeded 32%, with the number of applications related to health monitoring and medical image processing technology increasing significantly.

The pharmaceutical and medical industries also represent a large part of the patent-intensive industry inside China. According to an explanation by CNIPA, patent-intensive industries rely on intellectual property rights to participate in market competition.

According to data released in January 2024, the added value of China's patent-intensive industries in 2022 was RMB15.3 trillion, an increase of 7.1% over the previous year. Of this amount, the contribution from the pharmaceutical and medical industry was RMB1.288 trillion. According to the growth trend of patent publications in 2023, the added value of the pharmaceutical and medical industry to China's GDP in 2023 continued to maintain its growth trend.

Tax Concerns

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

High and new technology enterprise (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 preference, although certain others may encounter difficulties, particularly PRC subsidiaries of multinationals, due to a lack of PRC-generated IP. Over the past 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.

R&D expense super-deduction

China's R&D expense super-deduction policy is similar to those of many other jurisdictions and allows an extra deduction for qualified expenditures. Life sciences companies are qualified to enjoy a 100% extra deduction by being recognised as either a "manufacturing enterprise" or a "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 transaction perspective, it is also important to have a proper understanding of the relevant tax implications. For example, for in-license 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 China for the licence project. The entire revenue package of the licensor may be subject to 25% PRC corporate income tax if the entity is deemed to have set up a permanent establishment in China.

Tax incentives extended

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

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