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Life Sciences 2023

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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 more than 700 professionals located in offices in Beijing, Shanghai, Shenzhen, Haikou and Hong Kong. Han Kun has a dedicated life sciences and healthcare team consisting of senior partners and lawyers, and is widely recognised and well-known for its practice in life sciences and healthcare. The firm is committed to providing clients with comprehensive legal services, which include private equity and venture capital, MA&, capital markets, pharmaceutical licence in/out and asset sale/purchase transactions, intellectual property, data protection, compliance and regulatory, and dispute resolution.

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Min Zhu concentrates his practice on life sciences and healthcare, private equity investment, foreign direct investment, M&A, cybersecurity and data compliance, among other areas. He has provided legal services to dozens of multinationals, foreign companies and Chinese companies with respect to their establishment, domestic and overseas investments, and regulatory and compliance affairs. Min has been recognised as a highly recommended practitioner in the areas of life sciences, healthcare and corporate compliance.

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Chai Lu focuses on M&A transactions, private equity transactions, and securities offerings and listings. She has represented private equity funds and the principal investment departments of financial institutions in direct investment in China, represented US and European multinational companies in the acquisition or sale of Chinese businesses, and represented large Chinese state-owned enterprises and private companies in overseas acquisitions and asset disposals. Her clients are active in a broad range of industries, including financial services, insurance, telecommunications, TMT, consumer goods, mining, power and energy, manufacturing and healthcare.

Ying Li graduated from Peking Union medical university in 2005 with a PHD in pharmaceuticals and biotechnology, and started working as a patent attorney in the same year. For the past 18 years, her main work has covered patent prosecution, patent portfolio management, IP due diligence, and patent invalidation and litigation for both domestic and international clients. Ying has extensive experience in FTO searches related to small molecule drugs and biological macro-molecules. She has successfully represented many clients before CNIPA and the courts in various patent invalidation and administrative litigation cases.

Shiye Yuan concentrates his practice on tax planning. In the area of private equity and venture capital, he implements tax optimisations throughout the entire investment lifecycle, especially offering stable tax solutions in ever-evolving tax regimes. In the area of M&A and capital markets, Shiye provides feasible tax arrangements, properly balancing between tax savings and compliance, to design transaction structures that can withstand potential challenges from investors and listing authorities. In the area of wealth management and stock option incentives, he has expertise in designing focused tax arrangements for different participants, appropriately considering both tax savings considerations and asset security needs.

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Life Sciences in China after COVID-19

The COVID-19 pandemic has left an indelible mark across entire economies, and has provided an array of challenges and opportunities for every sector. The healthcare and life sciences sector in China has seen enormous interest. There were profound changes in the Chinese legal, regulatory and market landscapes during 2022, including market participants investing in life-saving treatments, the Chinese government providing ample support for facilitating transactions, innovations in high-quality technologies, protections for intellectual property and personal information, and a fairer and more open business environment. This article will examine these and other trends and developments in China's healthcare and life sciences sector.

Pharmaceutical Industry Transactions During the Pandemic Period

IPOs

The number of newly listed Chinese pharmaceutical companies in 2022 decreased significantly compared to 2021. A majority of these 2022 issuances fell below their initial offering prices, marking a return to more rational valuations in the pharmaceutical industry. In the future, investors are increasingly likely to favour pharmaceutical companies with solid track records of innovation and cutting-edge technologies that stand out in the market.

Venture capital/private equity financing

The pharmaceutical industry's downbeat performance in the capital markets may have dampened investors' enthusiasm and confidence in capital markets more broadly. The number and amount of Chinese pharmaceutical companies' primary market financings in 2022 dropped sharply, most notably in early-stage financings (series angel and series A). Given the shortage of financing and cash flow, biotech start-ups had to consider cutting pipelines (especially those lacking innovation or facing fierce competition, such as from "me-too" drugs). At this stage, the pharmaceutical industry had two principal concerns:

- how to reduce costs and increase efficiency to overcome the cold winter of financing; and
- how to enhance innovation capacity to become more competitive.

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License-in/out

Government policies and market incentives have driven Chinese pharmaceutical companies to place more efforts on the research and development (R&D) of innovative products, and 2022 witnessed remarkable achievements in pharmaceutical license-out transactions. Sources show that the total transaction value of license-out deals involving innovative drugs/new technologies in China reached a record high of USD27.55 billion in 2022, doubling the amount in 2021. The aggregate number of license-out transactions for China's innovative drugs/new technologies exceeded 220 by the end of 2022.

By contrast, the number of pharmaceutical license-in transactions in 2022 decreased significantly compared to the large increase in 2021, and no large-scale license-in transactions were concluded involving an amount of more than USD1 billion. The reasons for this decrease in pharmaceutical license-in transactions may include:

- cash flow shortages of potential licensees in China, particularly biotech companies;
- the lack of innovative target products;
- inflated transaction prices and tough competition for desirable target products; and
- the "fast follow" of Chinese pharmaceutical companies in developing their own innovative products.

Of note, ophthalmology has become an emerging area for license-in transactions, in addition to established fields such as oncology, infection, neuroscience and autoimmunity.

Mergers and acquisitions

Chinese pharmaceutical companies have been actively deploying high-quality technologies and pipelines. High-quality innovative biotech companies such as AI drug R&D and small-molecule targeted drug R&D companies continue to be popular M&A targets. Sources indicate that 21 major M&A transactions in China's pharmaceutical industry were concluded in 2022, with an aggregate deal value of more than RMB16 billion.

Regulatory Trends

In 2022, China continued to update regulatory policies frequently, with active contributions from the National Medical Products Administration (NMPA), the National Health Commission (NHC) and the Ministry of Science and Technology (MOST). Major regulatory issues among the various new policies include the regulation of human genetic resources (HGR), clinical trials and the expanding role of internet-based medical and pharmaceutical services.

In 2022, the regulatory authorities persisted in their efforts to safeguard biosecurity, particularly with respect to HGR regulation. As the authority responsible for formulating and implementing guidelines and policies for the development of national science and technology, MOST issued successive regulatory documents on HGR regulation, including two Q&A releases that clarify certain controversial questions in HGR administration and compliance practice, providing a more limited scope of HGR information subject to administrative filing and approval.

In addition, significant industry attention has been focused on two draft rules:

- the Rules for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comment); and
- the Measures for the Implementation of Administrative Penalty of the Ministry of Science and Technology (Draft for Comment).

These two draft rules reflect the regulatory authority's latest views, which could result in tightening regulation of certain matters while relaxing others, with a trend toward increased enforcement action in the future.

Regulations on clinical trials have been updated and specified to promote the orderly conduct of drug R&D. The NMPA has announced the Annex of Investigational Drugs to the Good Manufacturing Practices for Drugs, which responds to the implementation and enforcement of Good Manufacturing Practice (GMP) for investigational drugs, further strengthening the guidance on and regulation of the preparation of investigational drugs. The release of the Technical Guidelines for the Modification of Protocols during Clinical Trials for Drugs (for Trial Implementation) fills a previous policy gap, providing sponsors with guidelines to amend the protocols for ongoing clinical trials from both substantive and non-substantive perspectives.

Due to the pandemic, China accelerated the optimisation of its remote medical and pharmaceutical services policies in 2022. Internet hospitals and the online sale of prescription drugs are supported by new regulations, which inevitably bring challenges to traditional regulatory methods. The announcement of the Rules for the Regulation of Internet Diagnosis and Treatment (for Trial Implementation) set forth more transparent and effective requirements for the development of internet-based diagnosis and treatment. The Provisions for Supervision and Administration of Online Drug Sales were released, and the policy on the online sale of prescription drugs was gradually loosened. Notably, the online sale of prescription drugs was explicitly allowed.

In 2022, China started to pilot cross-border contract manufacturing arrangements by launching and implementing a new policy on cross-border contract manufacturing of drugs and medical devices in the Guangdong–Hong Kong–Macao Greater Bay Area. This policy is a significant step toward exploring new regulatory modes. Cross-border contract manufacturing will provide drug marketing authorisation holders (MAHs) and medical device MAHs with more flexibility in their arrangements for licence holding and manufacturing.

In respect of data security in healthcare industries, the Measures for Security Assessment of Cross-border Data Transfers, issued in 2022, specify the application of security assessments, the requirement of self-assessment before applications, and key requirements for security assessment of cross-border data transfers, which pose a challenge to international collaborative R&D and distribution in healthcare industries.

In addition to the aforementioned 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 2022, the NMPA released a series of regulations focused on clarifying the responsibilities and roles of MAHs. Since the implementation of the MAH system in 2019, the NMPA and other regulatory authorities have accumulated and updated a large number of supplementary rules, which are scattered across various regulations and guiding principles. On 9 May 2022, the NMPA released the Regulations for Implementation of the Drug Administration Law (Draft for Comment), which would integrate the aforementioned supplementary rules while refining and adding a number of provisions that were not

clarified in the Drug Administration Law. In addition, the latest amendment to the Measures for Administration of Drug Recalls has adjusted the regulatory requirements for drug recalls based on the MAH system.

The Center for Drug Evaluation (CDE) also released the Working Procedures on Speeding Up the Review of Innovative Drug Applications (for Trial Implementation), clarifying the requirements at various stages of the review process for marketing applications for innovative drugs that are included in breakthrough therapies. In this way, the CDE is making efforts to encourage the R&D of innovative drugs and thus meet certain clinical needs.

Medical device highlights

In 2022, the State Administration for Market Regulation (SAMR) released the Measures for the Supervision and Administration of Medical Device Distributions and the Measures for the Supervision and Administration of Medical Device Manufacturing, which serve as supporting documents for the Regulations on Supervision and Administration of Medical Devices (Revised in 2021). These documents effectively construct the distribution and manufacturing segment of the entire medical device life cycle regulatory system based on the needs of system reform and regulatory practice.

The Good Clinical Practice for Medical Device Trials (Revised GCP) has been updated in response to the requirements specified under heatedly revised regulatory provisions for medical devices. The Revised GCP emphasises ethical responsibility, explicitly includes in vitro diagnostic (IVD) reagents within the administrative scope, further clarifies the responsibilities of each party involved in clinical trials, and resolves certain issues and pain points in the industry.

In order to strengthen the on-site verification of quality management systems in the registration of medical devices, the NMPA amended the Guidelines for Medical Device Registration Quality Management System Verification in 2022. The latest guidelines clearly state that an applicant will fail to pass the verification if authenticity problems are found during on-site verifications.

Compliance Practices

Commercial bribery in the medical and healthcare industries

Rigorous monitoring and enforcement against commercial bribery focusing on the medical and healthcare industries are expected to continue, including dawn raids, cross-referrals of cases to other competent agencies, and collaboration among different government agencies. As law enforcement efforts against commercial bribery intensify, an increasing amount of complex hidden bribery schemes are being identified and penalised by law enforcement agencies. Such schemes include tailor-made bidding such as bid rigging, exclusive profit sharing, entertainment disguised as training or conferences, and using ad hoc rebates and discounts to distributors as indirect payments to healthcare professionals.

Strengthening regulation of national medical insurance fund usage

To increase scrutiny of medical insurance fund usage, new regulation methods will be trialled, including increasing unannounced inspections, and implementing 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 since 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

The China National Intellectual Property Administration (CNIPR) published the Revised Draft Patent Examination Guidelines (Draft for Comment) in August 2021. On 31 October 2022, it published the Draft Amendments to the Patent Examination Guidelines (Second Draft for Comment). As a chapter closely related to the fields of life sciences and chemistry, the Draft Amendment to the Patent Examination Guidelines (Draft for Comment) adds several provisions on the examination of patent applications for inventions in the field of traditional Chinese medicine to provide guidance for patent examination of traditional Chinese medicines. Once the guidelines are finally revised, they will also provide detailed guidance for the operation of the patent term adjustment (PTA) process, patent term extension (PTE) and the Early Resolution Mechanism for Pharmaceutical Patent Disputes (also called the drug-patent linkage system).

Developments in litigation and adjudication cases in life sciences and chemistry

The first drug-patent linkage ruling case in China

On 25 April 2022, the CNIPR announced that it had concluded the first batch of administrative ruling cases of the Early Resolution Mechanism for Pharmaceutical Patent Disputes. These were the first administrative cases of this type concluded nationwide since the implementation of the new Patent Law on 1 June 2021. The three cases concluded this time involved the patent for "oxycodone hydrochloride sustained-release tablets" belonging to Purdue Pharmaceutical, which requested confirmation that the generic drug-related technical solutions of Yichang Renfu Pharmaceutical Co., Ltd. fell within the scope of protection of the above-mentioned patent rights. After trial, the CNIPR held that the technical solutions related to generic drugs did not fall within the scope of protection of the above patent rights.

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The first drug-patent linkage litigation case in China

On 15 April 2022, the Beijing Intellectual Property Court made a first-instance judgment in the first Chinese patent linkage litigation case (between Chugai Pharmaceutical Co., Ltd. and Wenzhou Haihe Pharmaceutical). On 5 August 2022, the Supreme People's Court made a second-instance final judgment in the case, which lasted eight months from the date of filing on 8 November 2021; compared with the trial time of drug-related patent litigation before the implementation of the patent linkage system, the current trial time is greatly shortened. Predictability is enhanced for both the MAH and the generic pharmaceutical company, and the possible losses caused by later rights protection or infringement are reduced.

With the improvement of relevant laws and regulations, it is expected that there will be more and more drug-patent linkage cases.

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 tax preferential 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, apart from the potential input VAT refunds, one of the key tax considerations in in-license deals 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 it is deemed to have set up a permanent establishment in China.

Post COVID-19 tax incentives shrinking

While the COVID-19 pandemic is not yet over, some tax incentives for small enterprises in China are shrinking – eg, VAT tax exemption/super-deduction reduction. These preferential tax poli-

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