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Life Sciences 2022

China: Trends & Developments

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Trends and Developments

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Introduction

The COVID-19 pandemic has left an indelible mark across entire economies and has provided an array of challenges and opportunities to every sector. Among these, the healthcare and life sciences sector in China has seen enormous interest. There have been profound changes in the Chinese legal, regulatory, and market landscapes during 2021, be it market participants investing in life-saving treatments to the Chinese government providing ample support for facilitating transactions, 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.

Transactions during the Pandemic

VC/PE financing deals

The pharmaceutical industry continues to be a top destination for VC/PE investment and an active area for M&A deals, notably due to the ongoing effects of the COVID-19 pandemic. In particular, we have seen significant interest in vaccine technologies (including the research and development of siRNA, mRNA, and DNA drugs), which has given rise to large financing deals and high-valuation biotechnology companies. Non-VIE structured deals grew significantly more popular among offshore transactions involving entities whose principal business remains in China. This is directly attributable to China's gradual liberalisation of foreign investment controls and exceptional progress in developing new technologies in this area.

Licence-in/out transactions

Driven by government policies and market incentives promoting drug and medical device innovations, Chinese pharmaceutical companies, including biotech start-ups and local big pharmas, have focused more on the research and development of innovative drug products and have gradually begun to accelerate their pharmaceutical innovations, eg, demonstrating a clear transition from "me-too" or "me-better" to first/best-in-class candidates in their product pipelines. Over the past few years, these companies showed more interest in enriching their pipelines through licence deals, either from local partners or abroad. Sources show that the licence deals in 2021 continued to boom, with total licence-in deals reaching over 40, and the aggregate transaction value exceeding USD15.43 billion, and those for licence-out deals over 130 and USD13.90 billion respectively, all reaching record highs.

Licence-in transactions are also experiencing a significant transformation. Compared with traditional product-based licence-in arrangements that introduce innovative drugs or generic drugs, the market has shown a preference for technology-based licence-in arrangements, such as introducing technology platforms for front-end drug development or for drug research and development on the licensee's own platform. This trend is expected to continue for the next few years, with the market remaining focused on the innovation capabilities of Chinese pharmaceutical companies and promoting their further innovations.

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Regulatory Trends

China continues with its reform efforts to reach a more advanced level of innovation capability, greater pharmaceutical scale, and international competitiveness for drugs and devices, which was initiated by the Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (No 42 of 2017).

The National Medical Products Administration (NMPA), the chief drug and device regulator, and the Centre for Drug Evaluation under the NMPA, issued various implementation measures and administrative and technical guidance over the last year in support of the latest revision of the Measures for Administration of Drug Registration in 2020. Meanwhile, China also released its third significant revision of the framework regulation for medical devices, followed by several updates to the corresponding implementing regulations, including registration measures for in vitro diagnostics.

As further discussed in sections below, China has placed increased emphasis on a policy area called "biosecurity." The chief issue in this area affecting life sciences industries is the regulation of human genetic resources (HGR). China considers HGR to be a national resource that has implications for national security, public health, and the public interest. This position has led to the promulgation of HGR regulations and the Biosecurity Law. China has vigorously enforced these rules, subjecting several foreign companies to penalties and bans from conducting further clinical studies in China for a certain period of time, and recently even added specific HGR-related criminal violations to its Criminal Law.

Drug highlights

Over 2021, the NMPA have focused on further clarifying the responsibilities and roles of marketing authorisation holders (MAH) across the entire life cycle of drug products, but particularly post-market with new rules on drug registration amendments, pharmacovigilance, inspections, and recall proposals.

Notably, the NMPA might be accepting data from investigator-initiated trials because it has released a trial version of rules in 2021 for certain pilot areas to formalise and standardise investigator-initiated trial requirements and restrictions and has also accepted real-world data for drug registrations by issuing guidance for how to obtain and manage real-world data in practice. This guidance specifically states that the NMPA has accepted real-world data as a supplementary material for the application of drug marketing approvals.

Medical device highlights

For medical devices, in 2021, China's State Council made significant revisions to the framework administrative regulations for medical devices, the Regulations on Supervision and Administration of Medical Devices (RSAMD). The newly revised RSAMD, after a trial for several years (established in a limited scale and expanded to 21 provinces and municipalities in 2019), officially adopts a nationwide MAH system for medical devices and makes clear that the medical device MAH is responsible for the safety and efficacy of the device throughout its entire life cycle, which are similar to those for drugs.

For example, the newly revised RSAMD adopts similar priority programs to encourage innovation, such as priority review and conditional approval for innovative medical devices. The RSAMD also addresses other issues, such as new clinical evaluation requirements. Specifically, the clinical evaluation requirements under the newly revised RSAMD are different from the previous mechanism. The previous version of the RSAMD required all medical devices to submit

clinical evaluation reports (which may or may not include clinical trial reports) and exempted from clinical trials all Class I devices and certain types of devices on a list for which NMPA considered clinical trials were no longer needed.

Under the newly revised RSAMD, clinical evaluation requirements and exemptions are no longer based on the class of the device, and it changes the catalogue management approach in the previous regulations. Medical devices that meet certain criteria, which were used to exempt only clinical trials under the previous RSAMD, can be exempted from clinical evaluation entirely, regardless of class.

Compliance Practices

Due to the outbreak of the COVID-19 pandemic, the public in China ha become more cautious and expressed more concern about their health conditions, which in turn has pushed China's governmental authorities to impose stricter supervision and regulation of healthcare and life sciences industries for the purpose of ensuring sustainable industry development. Along with the development of market demand and governmental regulation, compliance practices in the healthcare and life sciences industries have witnessed gradual changes, the most notable of which are as follows.

Stricter regulation on commercial bribery

Commercial bribery remains the hotspot of compliance supervision in the life sciences field. China's government has no plans to stop or ease their anti-bribery efforts, despite that pharmaceutical companies, both multinational and State- or privately-owned local enterprises, have been well-educated and willing to invest in internal compliance systems after years of intensively combating commercial bribery. In September 2021, a new policy jointly released by several party and judicial organs vowed to punish both offering and accepting bribes, after long criticism that merely offering bribes escaped penalty.

ESG compliance on high alert

In transactions in the life science field, market players in recent years have paid more attention to the partners or targets' environmental, social, and governance (ESG) obligations and ESG due diligence has gradually become a must, echoing the Chinese government's increasing emphasis and attention upon issues of environmental protection, and corporate social responsibility and governance. Similarly, ESG information disclosure has also been well-acknowledged by listed companies. In January 2022, the Shanghai Stock Exchange issued a notice on disclosure requirements for annual reports, requiring mandatory disclosure of their ESG information.

Health data compliance affecting cross-border transactions

Recent legislative developments regarding personal information protection have had an impact on cross-border transactions in the healthcare sector. For example, the Regulations on Administration of Human Genetic Resources, effective as of 1 July 2019, subjects HGR information to certain requirements with respect to its collection, preservation, utilisation, and disclosure. These requirements include ethical reviews, prohibition on purchase and sale, prohibition on collection or preservation by foreign or foreign-controlled organisations, individuals or institutions, and prohibition of cross-border transfers. All these mandatory rules are echoed in the Biosecurity Law, a higher-level piece of legislation which took effect on 15 April 2021.

These latest legislative developments have had a noticeable impact upon pharmaceutical, medical device, and medical services companies, particularly foreign-invested entities in these industries. Competent authority filings are now required for the utilisation of HGR, which is an

inevitable part of nearly all clinical trials conducted by pharmaceutical and medical device companies. These filing formalities, however, have proven to be lengthy and thus cumbersome for the entire clinical trial process. Mandatory localisation and prohibition on cross-border transfers of healthcare data represent another point of consternation for multinationals because global sharing and management of clinical, commercial and patient treatment data have long been a common practice.

Changes in Chinese Intellectual Property Laws and Regulations

PTA and PTE requests allowed since 1 June 2021

The patent term adjustment (PTA) mechanism allows for compensation of the loss of rights and term of patent life due to unreasonable and undue delays in prosecution by the China National Intellectual Property Administration (CNIPA). Similarly, the patent term extension (PTE) mechanism enables compensation for losses in patent life term arising from unreasonable delays by the NMPA during the marketing approval process of patent-protected drugs.

Both the PTA and PTE can be used to extend the protection period of pharmaceutical patents, with the PTE allowing a maximum extension of five years, while for a PTA the extension term will be assessed based on the actual delay in prosecutorial procedures. In both cases, the request should be filed with the CNIPA. A patentee is allowed to request a PTA for an invention patent within three months after receiving the granting notification; while for a PTE concerning a patent-protected drug, the request must be submitted within three months after receiving the marketing authorisation approval for the drug product. The CNIPA also launched a campaign in 2021 to "improve the quality of and hasten examinations", which will hopefully result in a decrease in PTA requests over the next few years.

New drug-patent linkage policy in China

Another important development in 2021 was the much-anticipated launch of China's own drug-patent linkage system. This system was heralded by three separate proclamations in support of this system: On 4 July 2021, the NMPA and the CNIPA jointly issued the Implementing Measures for Early Resolution Mechanism for Drug Patent Disputes (for Trial Implementation); on 5 July 2021, the Supreme People's Court and the CNIPA jointly issued the Provisions of the Supreme People's Court on Several Issues Concerning Application of Law in the Trial of Civil Cases Involving Patent Disputes Related to Drugs Under Approval for Marketing Authorization; and the Measures for Administrative Ruling on Early Resolution Mechanism for Drug Patent Disputes.

China's own drug-patent linkage system has gradually been established as a result of these three proclamations. The new system provides a regulatory path for resolving patent disputes during the drug evaluation and approval process and is expected to, in addition to stimulating further innovation, facilitate fair competition and healthy development of the pharmaceutical industry. A particularly noteworthy aspect is the "Category IV" declaration, which is used in the new system to trigger patent challenge disputes. On 10 November 2021, the Beijing IP Court accepted the first drug-patent linkage lawsuit, between Japan Chugai Pharmaceutical Co, Ltd and China Wenzhou Haihe Pharmaceutical Co, Ltd. Given the fierce competition between branded and generic drugs in China's market, similar patent link lawsuits will undoubtedly increase in the future.

Tax Concerns

As one of the most encouraged industries currently in China, healthcare and life science companies may enjoy a wide range of tax incentives,

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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 science 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, which allows an extra deduction for qualified expenditures. Life science companies are qualified to enjoy a 100% extra deduction by being recognised either as 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 science companies can have their qualified accumulated input VAT refunded. This is particularly beneficial for life science 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 right understanding of the relevant tax implications. For example, in-licence 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 it is deemed to have set up a permanent establishment in China.

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Han Kun Law Offices is a leading full-service law firm in China with over 700 professionals located in five 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, mergers and acquisitions, capital markets, pharmaceutical licence in/out and asset sale/purchase transactions, intellectual property, data protection, compliance and regulatory, and dispute resolution. The firm has been continuously ranked as a top-tier law firm by authoritative legal directories in the life sciences and healthcare sector.

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

Yaling (Michelle) Gon focuses her practice on representing clients in complicated and challenging compliance and regulatory matters, including anti-corruption, unfair competition, anti-monopoly, anti-fraud, export control, and trade sanction areas. Ms Gon is well respected for being personally devoted to her clients and offering practical advice on resolving complex legal issues. Most of Ms Gon's clients are leading multinationals doing business in China or large, China-based multinationals doing business globally across a wide range of industries, including pharmaceuticals, medical devices, life sciences and healthcare.

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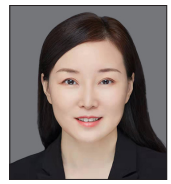

Dr Ying Li graduated from Peking Union medical university in 2005 with a PhD in pharmaceuticals and biotechnology. In the same year, she started working as a patent attorney. For the past 17 years, her main work has covered patent prosecution, patent portfolio management, IP due diligence as well as patent invalidation and litigation for both domestic and international clients. Dr Li has extensive experience in FTO searches related to small molecule drugs and biological macro-molecules. Dr Li has successfully represented many clients before CNIPA and the courts in various patent invalidation and administrative litigation cases.

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. Ms Chai has represented clients in a broad range of industries, including financial services, insurance, telecommunications, TMT, consumer goods, mining, power and energy, manufacturing and healthcare.

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