COUNTRY COMPARATIVE GUIDES 2024

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Summary Of Legal Hot Topics For Foreign Investment In PRC Healthcare And Pharmaceutical Industry In 2023-2024

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SUMMARY OF LEGAL HOT TOPICS FOR FOREIGN INVESTMENT IN PRC HEALTHCARE AND PHARMACEUTICAL INDUSTRY IN 2023-2024

The People's Republic of China ("**PRC**") is the world's second largest healthcare and pharmaceutical market. According to Frost & Sullivan's forecast, the PRC healthcare and pharmaceutical market will increase to US$320 billion by 2025. There has been an upturn in M&A activity in the PRC healthcare and pharmaceutical market since 2023[1]. At the end of 2023, AstraZeneca announced its acquisition of Gracell Biotechnologies Inc., a leader in cell therapy in the PRC, for US$1.2 billion, which is the first M&A deal in which a multinational pharmaceutical company fully acquired a PRC biotechnology company. Based on the project experience and observations of King & Wood Mallesons' Life Sciences & Healthcare Group, over the past year, foreign-invested pharmaceutical enterprises in the PRC have remained active in conducting M&A, technology licensing, and other related deal-making activities. We anticipate this trend will persist into 2024, despite the uncertainty of the international and domestic macro environment and other factors.

Looking back at the overall legal environment for foreign investment in the PRC healthcare and pharmaceutical industry in 2023:

Firstly, the PRC government continues to introduce various favorable policies to: (i) encourage foreign investment in the PRC healthcare and pharmaceutical industry. This is especially so in the fields related to the research, development and production of cell therapy drugs, development and production of drugs for rare diseases and pediatrics, development and production of pharmaceutical manufacturing-related consumables, research, development and manufacturing of smart healthcare products for the elderly, etc.[2]; (ii) support foreign investors to invest in R&D centers in the PRC, and to conduct technology R&D and industrialized application jointly with domestic enterprises; (iii) speed up the launching of foreign investment projects in biopharmaceutical field; (iv) encourage foreign-invested enterprises to carry out clinical trials of cell and gene therapy drugs that have been marketed overseas in the PRC in accordance with the laws; and (v) optimize the marketing authorization application procedures for drugs that are marketed in the PRC and manufactured overseas to be manufactured in the PRC. Furthermore, local governments are continuously strengthening the protection of foreign investment and improving the facilitation of investment and operations[3]. According to the statistics released by the State Administration for Market Regulation ("**SAMR**"), by the end of September 2023, 684,000 foreign-invested enterprises had registered in the PRC, an increase of 1.5% from the end of last year, indicating a steady rise in the number of newly established foreign-invested enterprises.

Secondly, with respect to legislation and law enforcement in 2023, a series of significant laws and regulations closely associated with the healthcare and pharmaceutical industry were either revised or

enacted. Concurrently, a series of law enforcement activities in key fields were frequently carried out. These developments could potentially exert a significant influence on the investment, M&A, licensing-in/out, and daily business operations of foreign-invested pharmaceutical enterprises in the PRC.

This article reviews and outlines the substantial changes in the legal environment of the PRC healthcare and pharmaceutical industries in 2023-2024, aiming to provide guidance and reference for foreign-invested pharmaceutical enterprises conducting business in the PRC.

I. Revisions to PRC Company Law

The newly revised *PRC Company Law* (the "**New *Company Law***") was formally promulgated on December 29, 2023, and will come into force on July 1, 2024. Compared to the version currently in force, the New *Company Law* adopts comprehensive amendments related to capital contribution rules, corporate governance structure, shareholders' rights, responsibilities of directors, supervisors and senior management, etc. Among these amendments, foreign-invested pharmaceutical companies should pay particular attention to the following:

Firstly, the New *Company Law* requires the shareholders of a limited liability company to make full capital contribution within five years after the establishment of the company. This provision replaces the long-standing subscribed capital system under the current law. Therefore, if a foreign investor intends to set up a new company in the PRC after the New *Company Law* comes into force, it shall comply with the capital contribution period required under the New *Company Law*. Furthermore, the New *Company Law* provides that existing companies (including foreign-invested companies) whose capital contribution period exceeds the required period under the New *Company Law*, shall gradually adjust their capital contribution period to meet the statutory requirement[4].

Secondly, the New *Company Law* introduces alternative corporate governance structures, allowing the establishment of an audit committee comprised of directors in lieu of a board of supervisors or supervisors, to perform the functions and duties of a board of supervisors. In addition, limited liability companies of a small size or having a small number of shareholders may choose not to have any supervisor. We understand that foreign investors usually set up a company in the form of a limited liability company in the PRC, which is usually a wholly foreign owned enterprise (WFOE) or a joint venture (JV) having a small number of shareholders. Therefore, foreign-invested companies may consider optimizing their corporate governance structure based on their own situation to reduce costs and increase efficiency.

It is worth noting that the *PRC Foreign Investment Law* promulgated in 2019 requires foreign-invested enterprises previously established under the *Sino-Foreign Equity Joint Venture Law*, the *Sino-Foreign Cooperative Joint Venture Law* and the *Wholly Foreign Owned Enterprise Law* to adjust their organizational form and structure as well as operating rules according to the PRC Company Law within a five-year transitional period (this period will end on December 31, 2024). The promulgation and implementation of the New *Company Law* is at a juncture when the transitional period is about to expire. **Therefore, regardless of whether a foreign-invested pharmaceutical enterprise has completed the adjustment following the Company Law or not, it needs to review and update its current articles of association, shareholders' agreement/joint venture agreement and other legal documents according to the provisions of the New *Company Law*.**

II. Promulgation of HGR Regulation Implementation Rules

Out of consideration of biosafety, national security, and social and public interest, the PRC government supervises and regulates the collection, preservation, and utilization of human genetic resources ("**HGR**")[5] as well as provision of HGR to foreign[6] parties and other HGR-related activities. Since 1998, the PRC government and other competent authorities have promulgated the *Interim Measures on the Administration of Human Genetic Resources*, the *Regulations on the Administration of Human Genetic Resources*, the *Biosafety Law*, and other relevant laws and regulations, gradually establishing the HGR regulatory framework and setting up approval or record-filing procedures for HGR-related activities including the collection, preservation and utilization of HGR and provision of HGR to foreign parties.

On July 1, 2023, the newly released *Implementation Rules for the Regulations on the Administration of Human Genetic Resources* ("***Implementation Rules***") came into effect. The *Implementation Rules* further clarify the definition of HGR[7] and the scope of "foreign parties"[8]. The *Implementation Rules* also further simplify the international cooperation administrative approval and record-filing procedures that foreign-invested pharmaceutical enterprises may be involved in. For example, the *Implementation Rules* provide certain exemptions for foreign parties from ethics review, and simplify the record-filing procedure for the provision of the HGR information to, or open utilization of HGR information by, foreign parties to "prior reporting" procedure, etc.

In practice, when a foreign-invested pharmaceutical enterprise carries out clinical trials in the PRC to obtain marketing authorization for the relevant products or engages in technology licensing, cooperative development, commissioned development and other relevant activities with PRC institutions, HGR compliance issues may arise and special attention should be paid to these issues.

III. Further Clarification of MAH's Quality Management Responsibilities

The *PRC Drug Administration Law* revised and implemented in 2019 formally established the drug marketing authorization holder ("**MAH**") system. According to relevant laws and regulations, MAHs shall be responsible for the quality and safety of drugs during their full lifecycle.

On 1 March 2023, the *Provisions on the Supervision and Administration of Drug Marketing Authorization Holders Implementation of the Main Responsibilities of Drug Quality and Safety* issued by the PRC National Medical Products Administration ("**NMPA**") came into force, requiring MAHs to set up quality management departments staffed with quality management personnel, and further clarifying the specific requirements for MAHs in carrying out quality management work. Drug administration authorities will supervise and inspect the quality management work performed by the MAHs. In October 2023, with regard to contract manufacturing of drugs by MAHs, NMPA issued the *Announcement on Strengthening the Supervision and Administration of Contract Manufacturing by Drug Marketing Authorization Holders*, putting forward a series of specific requirements on quality management by MAHs in relation to contract manufacturing.

A foreign-invested pharmaceutical enterprise who is the MAH of a certain drug needs to take full responsibility for the quality and safety of its drug (if a foreign entity is the MAH, such foreign MAH shall designate a PRC entity as its local agent to perform the obligations of the foreign MAH and bear joint and several liability with the foreign MAH). If the MAH holding a

class B drug production license entrusts a third party to manufacture the drugs, it should pay particular attention to the quality management issues during the entrusted manufacturing.

IV. Promulgation of New Regulations on Drug Distribution

Following the revision of the *PRC Drug Administration Law* in 2019, the *Provisions for Drug Registration* and the *Provisions for the Supervision and Administration of Drug Manufacturing*, have been successively revised and promulgated as the implementing regulations. However, the regulations in the field of drug distribution (*Provisions for Drug Distribution License* and *Provisions for Supervision of Drug Distribution*), which were promulgated earlier, are no longer in line with current regulatory thinking and requirements. In September 2023, the SAMR issued the *Provisions for Supervision and Administration of the Drug Quality in Distribution and Usage* ("***Provisions***"), updating the regulatory rules in the field of drug distribution. The *Provisions* were implemented on 1 January 2024.

The newly issued *Provisions* replace the *Provisions for Drug License* and *Provisions for Supervision of Drug Distribution*, becoming the core regulatory document in the field of drug distribution. The *Provisions* simplify the administration of drug distribution approval, clarify the cross-regional supervision responsibilities, and provide clear provisions on the requirements for self-owned warehouses of drug wholesalers, commissioned storage and transportation, and self-sales as well as commissioned sales by MAHs.

Foreign-invested pharmaceutical enterprises conducting business in the PRC should comply with the relevant requirements of the *Provisions*. Specifically, for online drug sales, online trading platforms and other emerging online business modes, the SAMR issued the *Provisions for Supervision and Administration of Online Drug Sales*, effective as of December 1, 2022. Foreign-invested pharmaceutical enterprises involved in related businesses should take note of these provisions.

V. Compliance Requirements for Advertising Continue to be Detailed

Due to the unique characteristics of pharmaceutical products and medical services which differ from other general goods or services, advertising and promotional activities in the healthcare and pharmaceutical industry shall strictly comply with the requirements of the law. In recent years, accompanied by the emergence of a wide variety of new advertising campaigns resulting from the development of e-commerce and digital marketing activities, the PRC government has continued to refine the regulatory system in the field of advertising through the introduction of relevant laws and regulations.

In March 2023, the SAMR issued the *Measures on the Administration of Internet Advertising*, which comprehensively optimize and supplement the *Interim Measures on the Administration of Internet Advertising* promulgated in 2016, expressly prohibiting any publication of advertisements for medical treatments, drugs, medical devices, health food and formula foods for special medical purposes in disguised forms such as introducing health and wellness knowledge. Furthermore, newly emerged popular marketing methods, such as live streaming, are also subject to advertising regulation and must comply with relevant requirements.

In May 2023, the SAMR issued the *Measures for Examination and Administration of Advertisements of Drugs, Medical Devices, Health Food and Formula Foods for Special Medical Purposes (Draft for Comments)*, which further supplement the compliance requirements for the advertisements of drugs, medical devices, health food and formula foods for special medical purposes. For instance, it is forbidden to conceal the promotion of the aforementioned products as imparting health and wellness information during live streaming; it is also prohibited for spokespersons in advertisements to endorse or certify the aforementioned advertised products during live streaming. Additionally, it optimizes the existing rules of advertising review and approval for the aforementioned products by advertising censorship authorities. For example, it clarifies that advertising review is not required for introduction and display of product information, specified the exceptions for a new advertising review and adjusted the validity period of advertising approval numbers, etc.

When conducting promotional marketing activities in the PRC, foreign-invested pharmaceutical enterprises should pay great attention to whether certain promotional behaviors are considered advertisements which therefore must comply with relevant laws and regulations.

VI. Intensifying Enforcement in Anti-Bribery

In recent years, with the aim of improving the industry environment and maintaining fair competition, the PRC government has continued to focus on cracking down on various types of bribery and corruption activities. The "anti-corruption storm" in 2023 has had a major and far-reaching impact on the whole healthcare and pharmaceutical industry. On May 8 last year, the National Health Commission of PRC (**"NHC"**) and the NMPA, together with other 12 ministries, jointly issued the *Key Points for Rectifying Misconducts in Field of the Medicinal Purchase and Distribution and Medical Services in 2023*; later on July 21, the NHC, in conjunction with the NMPA and other 8 ministries, convened a video conference to deploy a one-year nationwide concentrated rectification against corruption in the healthcare and pharmaceutical industry; on July 28, the Central Commission for Discipline Inspection and the National Supervisory Commission convened a kickoff meeting with prefectural-level authorities of discipline inspection and supervision, reiterating the requirements of focusing on the cadres and key personnel, insisting on the supervision of both committing and accepting bribes, as well as concentrating on dealing with a number of corruption cases in the healthcare and pharmaceutical industry. So far, this special anti-bribery action has made certain achievements.

This anti-bribery enforcement action is sweeping, covering the whole process of pharmaceutical manufacture, supply, distribution, use and reimbursement, with the joint action of multiple ministries such as NMPA and NHC, forming a coordinated regulatory and enforcement mechanism. Since then, hundreds of leaders and cadres of medical institutions have been investigated or have voluntarily surrendered, and various academic conferences have been suspended or postponed. Once again, the issue of commercial bribery in the pharmaceutical marketing sector has become a hot topic in the industry.

This anti-corruption action is an alarm bell as well as a good opportunity for pharmaceutical enterprises to carry out compliance management. **On the one hand, foreign-invested pharmaceutical enterprises should be more cautious in convening academic conferences, providing commercial sponsorships and other marketing activities to meet the compliance requirements. At the same time, in investment and M&A activities or business cooperation,**

they should also pay attention to the compliance status of target companies or suppliers, and strengthen external compliance management to avoid attracting joint liability and compliance risks. On the other hand, enterprises could also make use of this opportunity to conduct self-evaluation of their compliance management system, further enhancing their compliance management.

VII. Improving Legislation and Tightening of Enforcement in the Anti-monopoly Field

2023 is the year when the whole anti-monopoly law system in PRC was comprehensively perfected. Till the beginning of 2024, the SAMR has successively revised a series of anti-monopoly regulations, which include six implementing rules and regulations relevant to the *Anti-monopoly Law (2022 revision)* , i.e. *Provisions on Prohibition of Monopoly Agreements*, *Provisions on Prohibition of the Abuse of Market Dominance*, *Provisions on the Review of Concentration of Undertakings*, *Provisions on the Abuse of Administrative Power on the elimination and restriction of competitions*, *Provisions on the Abuse of Intellectual Property Rights on the elimination and restriction of competitions*, and *Regulations on the Merger Control Filing Thresholds*.

The healthcare and pharmaceutical industry has always been a key focus of anti-monopoly enforcement. The anti-monopoly enforcement in PRC is developing towards a more transparent and high-level trend, which also increases the risks to enterprises, especially in the healthcare and pharmaceutical industry, which is closely related to people's livelihood. According to relevant research reports[9], since the implementation of the *Anti-monopoly Law,* cases in the pharmaceutical and healthcare industry account for 10% of all administrative enforcement cases, making it one of the industries with the highest amount of anti-monopoly enforcement activities. In recent years, anti-monopoly law enforcement activities in the PRC pharmaceutical industry have mainly focused on the APIs field, while other fields such as drugs and medical devices have also received increasing attention, particularly in the marketing sector. The anti-monopoly enforcement activities mainly target at monopolistic behaviors which directly affect prices, such as unfairly high prices and fixed prices, and manipulating price by refusing deals or attaching unreasonable conditions. Since February 2023, the SAMR and other provincial and municipal market regulatory authorities have launched several special anti-monopoly enforcement activities, focusing on monopolistic behavior in healthcare and pharmaceutical industry and other key industries. In 2023, SAMR disclosed three batches of typical anti-monopoly enforcement cases in the field of people's livelihood, of which 8 were related to the healthcare and pharmaceutical industry and involved 13 pharmaceutical enterprises.

In the future, anti-monopoly enforcement activities in the PRC healthcare and pharmaceutical industry would continue to be strict and rigorous. **Because of the heavy penalties in a single anti-monopoly case and the high cost of violating laws, foreign-invested pharmaceutical enterprises need to pay extra attention to the monopolistic behaviors such as concentration of undertakings, abuse of market dominance, or maintenance of resale price in their investment and M&A activities as well as daily operations in PRC, and carry out necessary anti-monopoly reviews to certain business practices.**

Based on the experience and observations of King & Wood Mallesons Life Sciences & Healthcare Group, it is anticipated that the PRC government will continue to focus on the development of the healthcare and pharmaceutical industry and encourage foreign investment in the PRC. In the future, PRC's

healthcare and pharmaceutical industry will develop towards a more law-based and standardized trend. When investing in the PRC, on the one hand, foreign-invested enterprises should pay close attention to legal and regulatory developments, which would help ensure successful implementation of investments, M&A, and licensing transactions, as well as maintain smooth operations. On the other hand, experienced PRC lawyers in the healthcare and pharmaceutical industry could also assist foreign-invested enterprises in managing legal risks related to investment, M&A, operation, and exit. Due to space constraints, this article only provides a general overview of the PRC's healthcare and pharmaceutical industry's legal environment from last year to the present. Please feel free to contact us if you have any queries.

Footnotes:

[1] Referring to *China M&A 2023 Mid-Year Review and Outlook* published by PWC.

[2] Referring to the *Catalogue of Encouraged Foreign Investment Industries (2022)* issued by the PRC National Development and Reform Commission and the PRC Ministry of Commerce which came into force on January 1, 2023.

[3] Referring to the *Guidelines regarding Further Optimizing the Foreign Investment Environment and Intensifying Efforts to Attract Foreign Investments* issued by the State Council and came into force on July 25, 2023.

[4] According to the *Provisions of the State Council on the Implementation of the Registration and Administration System of Registered Capital under the PRC Company Law (Draft for Comments)* released by the SAMR on February 6, 2024, existing company shall, during a three-year transition period (from July 1, 2024 to June 30, 2027), adjust the remaining capital contribution period to within 5 years, and the remaining capital contribution period following the adjustment shall not exceed five years from 1 July 2027. If the remaining capital contribution period is less than five years by July 1, 2027, there is no need to adjust the contribution period further.

[5] According to the *Regulations on the Administration of Human Genetic Resources*, human genetic resources include human genetic resources materials and human genetic resources information. Human genetic resources materials refer to organs, tissues, cells and other genetic materials that contain the human genome, genes; human genetic resources information refers to data and other information materials generated from the use of human genetic resources materials.

[6] Only due to the different applicable legal systems, any reference herein to "PRC" or "domestic" is to mainland PRC; and any reference herein to "foreign" is to regions outside mainland PRC, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan.

[7] According to Article 2 of the *Implementation Rules for the Regulations on the Administration of Human Genetic Resources*, clinical data, imaging data, protein data, and metabolic data are excluded from the human genetic resources information.

[8] According to Article 12 of the *Implementation Rules for the Regulations on the Administration of Human Genetic Resources*, foreign parties (i.e., foreign entity that are established or actually controlled by foreign organizations or individuals) include the following circumstances: (1) a foreign organization or an individual holds or indirectly holds 50% or more of the shares, equity, voting rights, property shares or other similar rights and interests of the entity; (2) although the shares, equity, voting rights, property shares or other similar rights and interests of the entity held or indirectly held by a foreign organization or an individual do not reach 50%, the voting rights or other rights and interests it owns are sufficient to control or have significant influence on the resolutions, decision-making and internal management of the entity; (3) investment, agreements, or other arrangements by a foreign organization and an individual are sufficient to control or have significant influence on the decision-making, internal management and other major matters of an entity; (4) other circumstances provided by the laws, administrative regulations, rules.

[9] Referring to the *Case Study on Anti-monopoly in Fourteen Years in the Pharmaceutical and Healthcare Industry in PRC*

(2008-2022).

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