
CHAMBERS GLOBAL PRACTICE GUIDES

Healthcare M&A 2024

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**China: Law & Practice and
Trends and Developments**

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CHINA

Law and Practice

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1. Market Trends

1.1 Healthcare M&A Market Insight

The current healthcare M&A market in China is generally less active than it was 12 months ago and is not as robust as the global market.

On the one hand, except for a few notable mega-deals (eg, the acquisition of Shanghai RAAS by Haier and the acquisition of Gracell by AstraZeneca), the average deal value of healthcare M&A transactions in China has been trending downwards. The continuing growth of inflation, the downturn in the capital market, and geopolitical tensions, combined with the long-term legacy of COVID-19, have caused deal makers to adopt a more cautious approach in their target selections, and led to a decline in the valuation of healthcare players over time.

On the other hand, deal volume has seen a rebound to some extent. Despite the comprehensive implementation of a registration-based stock issuance system, the China Securities Regulatory Commission and stock exchanges have in 2023 promulgated a series of rules and policies to tighten their scrutiny of IPOs, as well as regulation on post-IPO financing and share reduction. Consequently, it has become quite challenging for healthcare companies to consummate IPOs. M&A is expected to be a more important and feasible exit strategy for investors. The healthcare market actually witnessed an increase in M&A deals at the end of year 2023.

Among different subsectors of the healthcare market, M&A deals involving medical service providers are more flourishing than those involving biotech and medical device companies. Hospitals, clinics and retail chain pharmacies have increasingly captured the spotlight of healthcare

M&A buyers. The underlying reasons might be that players in the medical service sector usually have sufficient cash on hand and deem M&A as the most efficient way to expand their business operations. Moreover, many small medical service providers are under pressure to maintain sustainable businesses, making M&A transactions potentially beneficial for both buyers and sellers.

1.2 Key Trends

Overview of the Past Two Years

Government-sponsored funds and state-owned enterprises (SOE) had been active participants in the healthcare M&A market. In recent years, SOEs, especially central SOEs, have been encouraged to enhance their core competitiveness and improve their key functions by way of M&A and restructuring. The healthcare industry, as a national strategic sector, has increasingly drawn the attention of government-sponsored funds and SOEs. At the central level, SOEs, such as Sinopharm, have completed a series of M&A deals over the past several years. At the local level, local governments and government-guided funds are also paving the way for integration in the healthcare industry.

While the M&A and equity financing market has undergone a period of slump, the market has witnessed a boom in both the value and volume of license-out deals. For licensors, licensing deals have emerged as a new sources of cash flow from overseas licensees to support their development and operations. For licensees, licensing deals have become an increasingly important way to supplement their product pipeline and product candidates.

2. Establishing a New Company

2.1 Establishing a New Company Procedures and Requirements

Since China has launched a series of policies to optimise business environment and boost foreign investment, new start-up companies are generally encouraged to incorporate and operate in China so long as they comply with foreign investment rules.

The registration of a new company usually involves the following steps:

- determining a company name and submitting the name to the local Administration of Market Regulation (AMR) for approval;
- leasing a physical office or virtual premises as the registered address;
- preparing and submitting the registration documents to the AMR for approval; and
- making company seals after the grant of business licence.

Certain post-registration matters, such as reporting foreign-invested enterprise information to the Ministry of Commerce, opening bank accounts, completing foreign exchange registration with the relevant bank, and establishing a social insurance account and a housing provident fund account might also be required for the operations of a company. The whole process for the above procedures can typically take around three to five months.

Under the amended Company Law of China, effective from 1 July 2024, the shareholder of a company is required to contribute the subscribed capital within five years from the establishment of such company. The permitted forms of capital contribution include cash, intellectual

property rights, land use rights, equity interest and other forms of assignable non-cash assets.

2.2 Type of Entity Major Forms of Legal Entity for Doing Business in China

Forms of business entity in China mainly include limited liability company (LLC), company limited by shares, partnership, and representative office of foreign enterprises.

An LLC is established by up to 50 shareholders, each of whom has limited liability for the company up to the amount of their capital contributions. An LLC has independent legal status and is generally subject to fewer restrictions compared to other business entities. This allows the LLC to draft its articles of association with a high degree of flexibility. Therefore, LLC is considered the most commonly used form of business entity for new establishments. The majority of start-ups opt to launch their operations in the form of LLC.

A company limited by shares is formed by up to 200 promoters, whose entire capital is divided into shares of equal value. This type of company has independent legal status and is typically operated under more complex and stringent regulations regarding its formation, corporate governance, share issuance, and transfer. Companies seeking to list on the Chinese stock exchanges or to be quoted through the National Equities Exchange and Quotations are required to adopt the form of a company limited by shares.

A partnership is usually formed by two or more natural persons or entities and has no independent legal status. The partnership structure is primarily established as an investing or share-

holding vehicle, rather than for the purpose of business operations.

A representative office is regarded as an extension of its headquarters and has no independent legal status. A representative office is only permitted to conduct non-revenue-generating activities such as market research, exhibition or promotional activities relating to the products or services and certain liaison activities in China.

2.3 Early-Stage Financing

Start-up enterprises usually seek early-stage financing from the entrepreneur's family members and friends, and individual angel investors. Venture capital funds are also an essential financing option for start-ups and small and medium-sized enterprises (SMEs).

Typical equity financing documents mainly include share purchase/subscription agreement, shareholders' agreement, and articles of association:

- share purchase/subscription agreement outlines the terms and conditions of the transaction, such as share subscription/transfer arrangement, representations and warranties, closing conditions, post-closing covenants;
- shareholders' agreement usually sets forth investors' rights such as redemption right, anti-dilution right, drag-along right, tag-along right, right of first refusal, pre-emptive right, liquidation preference, and protective provision; and
- articles of association is the constitutional document of a company, which mainly provides for the organisational structure and governance mechanism of the company.

2.4 Venture Capital Funding and Investment

The primary sources of venture capital in China include government-sponsored funds, government-guided funds, and major enterprises, particularly large state-owned enterprises.

Fostering financing and sustainable development for start-ups has consistently been a priority for the Chinese government. In recent years, both the central and local Chinese governments have promulgated a series of policies and incentives (such as awards on incorporation and operation, preferential tax treatment, contribution by government-guided funds) to stimulate the growth of venture capital. The Chinese government has also initiated numerous efforts to encourage domestic venture capital to provide funding to start-ups and SMEs. Therefore, start-ups that meet certain criteria (such as operating the high-tech sectors) may have access to both domestic venture capital and government-sponsored funds.

Over the past two decades, offshore venture capital firms have been active players in the Chinese market, providing financing to start-ups (particularly those with offshore corporate structure) in a robust momentum. Many well-known enterprises such as Baidu, Tencent and Alibaba received early-stage funding from offshore venture capital. It has been indicated that offshore venture capital is generally beneficial to enterprises' long-term growth, offering not only financial resources but also value-added services such as networking opportunities, management expertise and market insights. However, due to the intensifying competition between China and the US and regional conflicts, the volume of foreign venture capital deals in the Chinese market has decreased substantially. Some offshore venture capital firms have chosen to exit

from China, while others have taken measures to raise domestic capital for their transformation.

2.5 Venture Capital Documentation

In China, there is no uniformly standardised set of venture capital documentation. However, there are indeed some common market practices recognised by investors and enterprises. As mentioned in 2.3 Early-Stage Financing, typical venture capital investment documents include share purchase/subscription agreement, shareholders' agreement and articles of association, which provide for the terms and conditions of the financing. In addition, the following documents are typically required:

- a shareholder resolution and board consent of the company to approve the deal;
- a closing certificate to confirm that the company has satisfied all closing conditions; and
- a register of members and share certificates to prove the equity interest in the company.

2.6 Change of Corporate Form or Migration

As discussed under 2.2 Type of Equity, at the early stage of a company, LLC is usually the most common form of business entity. However, after several years' development and growth, if the company plans to seek listing on the Chinese capital market or the Hong Kong Stock Exchange directly, it must undertake a joint-stock system reform which involves converting the company from an LLC to a company limited by shares.

For companies that plan to conduct business in sectors where foreign investment is prohibited or restricted, or that intend to seek financing from overseas venture capital or private equity funds, with further plans to list on overseas capital markets such as the New York Stock Exchange,

NASDAQ or the London Stock Exchange, they may consider restructuring by implementing a variable interest entity (VIE) structure. Under a typical VIE structure, the existing Chinese entity will function as a VIE entity owned by certain nominee shareholders. New holding companies will be established offshore to hold the shares of a newly established wholly foreign-owned enterprise in China (WFOE). The WFOE will then enter into a series of control documents with the VIE as well as its shareholders, which allow the WFOE to exercise control and receive substantially all of the economic benefits from the VIE. As a result, the offshore holding company is considered the primary beneficiary of the VIE for accounting purposes and is able to consolidate the financial results of the VIE in its consolidated financial statements, thereby facilitating the application for listing on offshore stock exchanges.

3. Initial Public Offering (IPO) as a Liquidity Event

3.1 IPO v Sale

Going Public is the Natural Preference

In China, investors often prioritise taking a company public over pursuing a sale process when considering liquidity events. This preference stems from various factors: not just economic ones as in other jurisdictions, but also systemic and even cultural considerations. For instance, in terms of the legal system, Chinese law disallows leveraging against the company, essentially cutting off a major funding source in a Western-style sale process. Meanwhile, culturally, the obsession of East Asian entrepreneurs with controlling stakes in a business largely directs investors to seek the success, prestige and legitimacy of going public rather than selling to another controller, which may be seen as surrendering.

Even if, due to the gloomy performance of the capital market for Chinese companies, more investors are considering the selling option, it cannot be said there has been any trend to have a dual-track process (IPO and sale) from the outset. The preference of IPO is deep-rooted. In addition, the preparations for both largely overlap in China while those for IPO are certainly more demanding. Therefore, most companies that are actually sold were prepared for an IPO by investors in the first place.

3.2 Choice of Listing Open-Minded but Narrow-Pathed

Chinese companies are generally open to both domestic and foreign listing venues. Although, for various reasons, the domestic A-share market has long promised significantly higher valuation multiples, extraordinarily cut-throat requirements and a hyper-burdensome process have taught companies generally to prepare on both fronts. For healthcare companies specifically, however, listing on foreign exchanges is more likely the choice, mainly due to regulatory considerations. For example, medical service providers, which are presumed to shoulder more social responsibilities, are basically unwelcomed by the regulators of the A-share market, and pre-revenue biotech companies would face inquiries nearly equivalent to “soul-searching” if they applied for listings on the domestic stock markets.

3.3 Impact of the Choice of Listing on Future M&A Transactions Easier to Sell on a Foreign Exchange

Takeovers of A-share listed companies are disproportionately less common than those of foreign-listed Chinese companies for a reason. The substantive and procedural requirements for buyers, sellers and the target A-share company are extremely cumbersome, and almost every-

thing considered vital in the sale process is subject to substantive review, not formal review, by regulators. Therefore, choosing a foreign listing over a domestic one would actually increase the feasibility of a future sale.

4. Sale as a Liquidity Event

4.1 Liquidity Event: Sale Process

If the sale of the company is chosen as a liquidity event, the sale process will be typically conducted in a bilateral negotiation with a chosen buyer. An auction is relatively rare to see but may appear in a private sale where the target company develops a broad and diversified pipeline.

4.2 Liquidity Event: Transaction Structure

The most common transaction structure for a sale of a privately held venture-backed healthcare company is to either sell 100% of the company's shares or sell the controlling stake of the company with the founder(s) and management team staying in the surviving entity. VC funds typically seek full exit in the context of a liquidity sale. Nevertheless, in certain share swap transactions VC funds stay as shareholders in the buyer or the surviving entity, usually a late-stage biotech with a promising potential of an IPO.

4.3 Liquidity Event: Form of Consideration

Most transactions in China are done as a sale of the entire company for cash but increasing numbers of stock-for-stock or a combination of stock and cash transactions are being observed.

4.4 Liquidity Event: Certain Transaction Terms

Representations and Warranties and Certain Other Transaction Terms

Founders are typically expected to stand behind representations and warranties after closing. In fact, it is not uncommon that founders are expected to make representations and warranties and indemnify the buyer against its losses together with the target company on a joint and several basis.

VC investors are only generally expected to give some fundamental representations and warranties, and those related to the day-to-day operation of the company, such as employee benefits, tax and environmental matters, are usually covered by the representations and warranties made by the company. Also, VC investors' liabilities will typically be subject to a cap (for example, 10% of the company's liabilities) for the avoidance of uncertainty towards their future liabilities.

Similarly, escrow/holdback is customary for the avoidance of uncertainty. A certain percentage of the consideration may be held back and will be available to founders after the occurrence of some events such as obtaining market authorisations for the drug products of the company.

Representations and warranties insurance is not customary in China in healthcare M&A transactions.

5. Spin-Offs

5.1 Trends: Spin-Offs

Rise of Spin-Offs in China's Healthcare Industry

In China, spin-offs are becoming increasingly common in the healthcare industry. A growing

number of multinational companies are opting for spin-offs to divest non-core businesses or low-profit-margin products in China. Similarly, domestic Chinese listed companies are pursuing spin-offs to broaden financing channels, seek higher valuations or enhance operational efficiency. However, unlike multinational pharmaceutical firms, there is not a widespread trend of actively spinning off or divesting over-the-counter (OTC) businesses in China. Since 2023, Chinese pharmaceutical companies disclosing plans for spin-offs have focused on areas such as anti-tumour drugs, ophthalmic preparations, and innovative medical devices.

5.2 Tax Consequences

Tax Considerations for Intra-Group Spin-Offs in Structuring

Intra-group spin-offs can be structured as a tax-free transaction if certain requirements are satisfied. Such requirements include the following:

- the restructuring must have a business purpose and not be for tax avoidance;
- there is no change to the original operating activities of the target within a prescribed period;
- at least 85% of the consideration paid by the acquiring entity must be equity (not cash); and
- the acquiring entity may not transfer the newly acquired equity in the target during a 12-month period after the restructuring.

5.3 Spin-Off Followed by a Business Combination

Tax Implications

If a tax-free spin-off is immediately followed by a business combination, the spin-off may be treated as a taxable event because one of the main requirements for a tax-free spin-off is that the acquiring entity may not transfer the newly

acquired equity in the target during a 12-month period after the restructuring.

In addition, with respect to any indirect transfer of equity in a Chinese target company (ie, an indirect sale of a Chinese company), the seller may be required to report and pay a 10% tax on its gain under Announcement 7 issued by the PRC State Tax Bureau.

5.4 Timing and Tax Authority Ruling

The timing varies according to the different types of spin-off. It usually takes several months to complete a spin-off. The parties do not need to obtain a ruling from the tax authority prior to completing a spin-off.

6. Acquisitions of Public (Exchange-Listed) Healthcare Companies

6.1 Stakebuilding

The To-Do List

It is common to acquire an insignificant stake (less than 5% to avoid disclosure) before offering to buy an A-share company. When the interest purchased by a new entrant reaches 5%, the buyer (including any parties acting in concert) is required to report to the regulators and disclose to the public through the listed company within three days. Afterwards, any increase or decrease of more than 1% of interest should be disclosed to the public through the listed company the next day, while any subsequent change of 5% should also be reported to the regulators. When the stake reaches anywhere below 20%, or more than 20% but below 30%, the buyer is required to submit short-form and long-form equity change reports respectively to the regulators for review and disclosure. The equity change reports should include more

information on the buyer if it is short-form, and more substantial information on the relationship between the buyer and the target company if it is long-form. Most importantly, the buyer needs to include the purpose of stake acquisition and the subsequent acquisition plan for the next 12 months in any equity change report, whether proposing further acquisition, maintaining the stake or decreasing stakes.

6.2 Mandatory Offer

Tender-Offer Threshold

The buyer needs to make a blanket or partial tender offer to take over stocks of the A-share company when the equity it owns reaches 30%, unless waived under very limited circumstances.

6.3 Transaction Structures

Cash-Only Buyout is the Norm

Acquisitions of A-share companies commonly occur through cash transactions, whether to controlling shareholders, major investors or public shareholders. Mergers of A-share companies (only allowed among listed companies, as provided in **10.2 Prospectus Requirements**) are uncommon and largely limited to state-owned or state-controlled enterprises, typically involving strategic restructuring of state assets. Legal infrastructure and policy orientation contribute to the rarity of mergers. For instance, laws, in addition to the already stringent requirements for typical takeovers, impose further conditions for stock-to-stock transactions and effectively prohibit stock swaps with foreign investors. Regulators often insist on maintaining a company's listing status "to protect small and medium investors".

6.4 Consideration; Minimum Price Pricing Mechanism of the Acquisition

Cash payment is the industry standard in all types of acquisitions of A-share companies, regardless

of whether they involve a tender offer. The tender offer price must never be lower than the highest purchase price paid by the buyer for the target company's stocks within the six months before the tender offer's disclosure. Contingent value rights or other variable pricing mechanisms are generally not allowed in such transactions.

6.5 Common Conditions for a Takeover Offer/Tender Offer

Very Limited Conditions to Closing of Tender Offer

In tender offers, regulators typically only accept closing conditions related to necessary regulatory approvals and the minimum number of stocks to be tendered.

6.6 Deal Documentation

Agreements Are Not Common in Tender Offers

While tender offers are made available to all shareholders, except for rare cases involving a merger of a listed company, agreements may only exist between the buyer and certain selling shareholders. Such agreements usually occur when the buyer purchases stocks from specific selling shareholders via over-the-counter share transfer, resulting in the buyer's stake exceeding 30%, thus legitimising a public tender offer. Target companies' obligations are mostly passive and limited to necessary disclosures to the public. Representations and warranties of the public company are generally non-existent in such tender offers.

In the event of a merger, agreements are entered into by the bidder and the target company, primarily outlining the following:

- stock-to-stock ratio;
- profit distribution arrangements;
- surviving company's rights and obligations;

- taxes and expenses; and
- protections for shareholders, etc.

Representations and warranties of the target company, if any, should be limited to those available to public shareholders.

6.7 Minimum Acceptance Conditions

Acceptance conditions, as mentioned above, are usually limited to regulatory approvals (antitrust clearance, foreign investment approval, state asset approval, etc) and the minimum percentage of stocks to be tendered. The legal requirement for the minimum tender stocks is 5%.

6.8 Squeeze-Out Mechanisms No Squeeze-Out, Yet

Although once considered by the regulators through a consultation paper on the relevant legislation in 2015, the squeeze-out mechanism in relation to public companies has not been adopted by the Chinese law. However, the recent adopted Company Law, effective from 1 July 2024, opens the door to a mechanism named short-form merger, where a company owning more than 90% of another company's stocks may merge with the subsidiary without the approval of the subsidiary's shareholders. If Chinese securities law follows suit in the future, it may create a Chinese-style squeeze-out system whereby the acquiring company could first obtain 90% or more of a public company's stocks and then merge with the target company without the remaining shareholders' approval, essentially squeezing them out.

6.9 Requirement to Have Certain Funds/ Financing to Launch a Takeover Offer Proof of Funds Is a Hard Must

The commitment of the bidder to have sufficient funds and the proof of funds are not just subject to due diligence by the professional parties

required to be involved by law in a tender offer, but also substantially reviewed by the regulators as a precondition to launching the offer. Therefore, the bidder can never condition its offer on obtaining financing. In the event of financing, it is still the bidder, not the financing provider, that makes the offer, while the financing provider may be considered as a party acting in concert with the bidder.

6.10 Types of Deal Protection Measures Deal Protection Allowed but Uncommon

In a cash-only acquisition of an A-share company, the transaction is almost certainly only between the buyer and the selling shareholders, which leaves no space for the target company to grant deal protection measures. If the acquisition is done by merger (see **6.3 Transaction Structures**), it is most likely between state-owned or state-controlled companies under political agenda, and thus typical deal protection measures are much less common than in the West.

6.11 Additional Governance Rights

According to Chinese law, even if a shareholder owns 100% of the company, not to mention less than 100%, the company's independence as required by law mandates that the controlling shareholder should only enjoy the corporate governance rights provided by law to any other shareholder. The exercise of power beyond that permitted by law may be considered an abuse of control and subject to legal consequences.

6.12 Irrevocable Commitments Major Shareholder's Commitment

Except for the relatively rare hostile takeovers of listed companies in China's environment, to facilitate a successful tender offer for an A-share company in which major shareholders still exist by then, the bidder usually obtains the major shareholders' commitment or support for

the transaction. If such an undertaking exists, it is a contractual obligation of the maker that is supposed to be honoured but could also be breached, subjecting the maker to contractual liabilities. Due to the high bar of tendering a public company in China, competing offers are very uncommon, making "out" provisions for the principal shareholder very uncommon as well.

6.13 Securities Regulator's or Stock Exchange Process

Regulatory Review of the Tender Offer

The tender offer, before being made to the public, must undergo substantial review by the stock exchange. The timeframe for such review falls within the 60-day window for the bidder to disclose the tender offer. The key commercial terms of the offer, including price, payment terms and conditions, will be subject to the stock exchange's substantive review, not just formal review. The tender period is at least 30 days and at most 60 days. It is also permitted by law to extend this period, case by case, if a competing offer arises.

6.14 Timing of the Takeover Offer No Other Extension Allowed

The only permitted extension of a tender offer is in the event of a competing offer. Therefore, failure to obtain regulatory approvals within the requisite tender timeline would cause the tender to fail as well. Accordingly, if regulatory approvals are necessary for the transaction, bidders would initiate the process as early as possible, even before launching the tender offer.

7. Overview of Regulatory Requirements

7.1 Regulations Applicable to a Healthcare Company Establishing a Company in the Healthcare Industry

General provisions of the Company Law are applicable to establishing a new company in the healthcare industry. This includes requirements such as having the following:

- an independent legal status;
- designated director(s) and manager;
- legal representative;
- Articles of Association;
- subscribed capital by all shareholders;
- company name; and
- registered address.

The State Administration for Market Regulation oversees the company registration process in China. The duration of the registration process varies depending on local requirements, but it typically takes at least a few weeks to obtain a business licence once all the application documents are complete.

In addition, conducting specific operations within the healthcare industry may entail specialised requirements or approval. For instance, enterprises engaged in pharmaceutical production and operation must obtain pharmaceutical production licences and pharmaceutical operation licences in accordance with the Drug Administration Law. Enterprises involved in the production and operation of medical devices need to undergo government filing procedures as stipulated by the Regulation on the Supervision and Administration of Medical Devices. The licensing and filing processes are primarily supervised by the National Medical Products Administration,

and the timeline for obtaining different licences varies.

7.2 Primary Securities Market Regulators

In China, the primary securities market regulator is the China Securities Regulatory Commission (CSRC). It supervises and administers activities related to the takeover and changes of the relevant share equities of listed companies by force of law.

7.3 Restrictions on Foreign Investments

China implements a Pre-establishment National Treatment plus a Negative List system for foreign investment. The National Development and Reform Commission and the Ministry of Commerce issued the Special Administrative Measures for Access of Foreign Investment (the “Negative List”) outlining prohibited or restricted industries for foreign investors. Industries not on the list are presumed open to foreign investment.

According to the latest Negative List, investments in the development and application of human stem cells and gene diagnosis and treatment technologies are prohibited. Medical institutions can only be established as equity joint ventures (except in pilot zones like the Shanghai Free Trade Zone, which allows wholly foreign-owned medical institutions).

For restricted investment industries, certain approval or filing requirements may apply. The Measures for the Administration of the Approval and Record-filing of Foreign Investment Projects delineate the specific approval or filing requirements pertaining to respective industries. Compliance with this mandatory approval and filing requirements is generally a prerequisite for successfully completing investment transactions.

7.4 National Security Review/Export Control

China first introduced its national security review framework in 2011 when the State Council released the Circular on the Establishment of a System for Security Review of Acquisition of Domestic Enterprises by Foreign Investors. In December 2020, the National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) jointly issued the Measures on Foreign Investment Security Review, which came into effect on 18 January 2021. These measures prohibit or restrict foreign investments that may be deemed to have a significant impact on China's national security. The national security review process applies to a wide range of sectors, including military, military support, national defence, and security-related sectors, as well as important agricultural products, energy and resources, major equipment manufacturing, infrastructure, transportation services, cultural products and services, information technology (IT), internet/online products and services, financial services, critical technologies, and other significant sectors/areas.

China does not impose additional restrictions on foreign investors based on their nationality or location.

In 2020, China promulgated the Export Control Law of the People's Republic of China to regulate export control. Corresponding export control lists were established for sensitive items such as nuclear, biological, chemical and missile-related materials and military products. For export control in the healthcare sector, according to the Catalogue of Prohibited and Restricted Export Technologies of China (2023), certain traditional Chinese medicinal resources and production technologies, as well as certain traditional Chinese medical treatment technologies,

were listed as prohibited for export. Additionally, some biotechnology drug production technologies, certain medical device processing technologies and certain traditional Chinese medical treatment technologies were categorised as restricted for export.

7.5 Antitrust Regulations

In China, the laws and regulations governing business combinations include the Anti-Monopoly Law (as amended in 2022), the State Council's Provisions on Notification Thresholds for Concentrations Between Undertakings (as amended in early 2024), and the Provisions on Centralised Examination of Operators (as promulgated in 2023).

The State Administration for Market Regulation oversees the filing of concentrations between undertakings. The current filing threshold is determined based on the revenues of all parties involved in the business concentration, which can be summarised as follows:

- the combined global turnover for all operators participating in the concentration exceeded CNY12 billion in the previous fiscal year, and at least two participating operators each had a turnover within China exceeding CNY800 million in the previous fiscal year; or
- all operators participating in the concentration in China exceeded CNY4 billion in the previous fiscal year, and at least two participating operators each had a turnover within China exceeding CNY800 million in the previous fiscal year.

7.6 Labour Law Regulations

Acquirers should pay attention to the following labour laws and regulations:

- the PRC Labour Law (as amended in 2018);

- the PRC Labour Contract Law (as amended in 2012) and its Implementing Regulations (2008);
- the PRC Social Security Law (as amended in 2018); and
- the Provisions on the Democratic Management of Enterprises.

In China, the assembly of employee representatives (the “Employee Assembly”) serves as a platform for employees to exercise their democratic governance rights within the enterprise. Although the PRC Company Law does not explicitly mandate the consultation of the Employee Assembly for M&A activities, certain significant operational matters (such as restructuring, dissolution and bankruptcy applications) do require the consideration of employee opinions and suggestions through the Employee Assembly. Moreover, under the Provisions on Democratic Management of Enterprises, state-owned enterprises must consult their labour unions, and employee opinions and suggestions should be solicited through the Employee Assembly before certain significant events.

The authority of the Employee Assembly’s decisions varies among different enterprise types. For collectively owned enterprises (a special form of public-owned enterprise in China), mergers, divisions, equity and asset acquisitions must undergo review and approval by the enterprise Employee Assembly. Failure to obtain such approval may render the transaction invalid. In the case of state-owned enterprises and state-controlled enterprises, if an M&A entails staff reduction, relocation or resettlement plans, these arrangements must be submitted for approval by the Employee Assembly. However, for foreign-invested enterprises and other private enterprises, proposals from the Employee

Assembly regarding M&A transactions are not binding on the board.

7.7 Currency Control/Central Bank Approval

Cross-Border Transactions in China

China imposes restrictions on cross-border currency transfers and the conversion between RMB and foreign currencies. According to the Provisions of the Ministry of Commerce on M&A of a Domestic Enterprise by Foreign Investors, parties involved in the acquisition of domestic enterprises by foreign investors should promptly handle various currency approval, registration, filing and change procedures with local or State Administration of Foreign Exchange authorities. China’s currency control covers various aspects related to the following:

- foreign exchange registration;
- opening of foreign exchange accounts;
- forward settlement and sale of foreign exchange; and
- proof of fund usage in cross-border mergers and acquisitions.

Currently, with China’s gradual opening of its capital markets, the process for currency inflows and outflows under foreign investment has become increasingly convenient. Currency matters are primarily handled and reviewed by local banks within the jurisdiction of the target company’s local foreign exchange bureau.

8. Recent Legal Developments

8.1 Significant Court Decisions or Legal Developments

On 10 May 2023, the PRC National Health Commission and 13 other government departments issued the Key Points to Correct Unhealthy

Tendency in the Field of Medical Purchase and Sale and Medical Services, marking a seemingly unprecedented crackdown on corruption in the healthcare sector. This campaign is mainly targeted against government officials in the healthcare authorities, hospital directors and practitioners on the one hand; on the other hand, pharmaceuticals and medical device companies are asked to assist in the investigations into business bribery and unfair competition.

The impact of the said campaign is manifold, but the response from the capital market is mostly negative. As of 15 August 2023, 14 healthcare companies have terminated their IPO process. The Shanghai Stock Exchange puts heavy emphasis on the legality of the promotional services of pharmaceutical companies, including the authenticity and reasonableness of CSO costs and internal controls. Similarly, in the context of healthcare M&A, compliance issues are put under the spotlight. Buyers tend to interrogate the target company during due diligence process, specifically:

- how the target company conducts its promotional services;
- whether all the promotional services actually happened and can be supported by evidence like sign-in sheets, pictures and PowerPoint slides;
- whether the target company or the CSOs provided illegal or unethical gifts to medical practitioners in the course of academic meetings;
- the percentage of promotion fees among total revenue, etc.

Plus, sellers will be expected to make representations and warranties regarding their compliance with anti-corruption and anti-bribery regulations.

The 2023 anti-corruption campaign still awaits its finale. As of March 2024, medical practitioners are still being put under investigation for corruption. It is anticipated that compliance management and monitoring will remain a major concern for healthcare providers and pharmaceuticals companies in 2024.

9. Due Diligence/Data Privacy

9.1 Healthcare Company Due Diligence Disclosure by Public Companies

Currently, there are no mandatory rules in China prohibiting or restricting a public company from providing due diligence information or materials to potential acquirers. The request of due diligence information and materials will normally be set out in the due diligence request list and the public company may, at its discretion, provide due diligence information, including its inside information.

Inside information refers to non-public information that concerns a public company's business or financial affairs or may have an important effect on the market price of a public company. Hence, the potential acquirer will be deemed as an "insider" and shall (i) not disclose such inside information, purchase or sell securities of the public company, or procure others to purchase or sell such securities, before the inside information is made public; and (ii) truly, accurately and completely record the persons that have access to inside information and deliver the record files to the public company. In addition to the restriction on the handling of inside information, if some information requested by the acquirer is confidential information of third parties and the public company bears non-use or non-disclosure obligations under a confidentiality clause in a business contract or a separate

confidentiality agreement, the public company's disclosure of such confidential information to the potential acquirers shall be subject to such non-use or non-disclosure obligations (as applicable). Additionally, the disclosure of information must also comply with applicable laws regarding state secrets and cross-border data transfers, such as the Law on the Protection of State Secrets and the Data Security Law (which will be addressed in detail below).

Under the Chinese law, directors and senior management of a public company bear the duty of loyalty and the duty of diligence to the company. They are obligated to treat all prospective acquirers in a fair manner. Therefore, if there are multiple potential acquirers, the public company is, in principle, required to provide the same level of information to all potential acquirers to serve the best interests of the company. Having said that, directors and senior management are also granted the discretion to exercise judgment regarding the disclosure of information to potential acquirers that are competitors of the company.

As a principle, the decision made, and measures adopted, by the board of directors in respect of an acquisition shall be in the best interest of the public company and its shareholders. According to relevant laws, the board of directors:

- shall not abuse its powers to create inappropriate obstacles for an acquisition;
- shall not use company resources to provide any form of financial assistance to any acquirer; and
- shall not harm the legitimate interests of the company and its shareholders.

Given that public companies typically disclose information and matters concerning their busi-

ness, financial and legal affairs to the public, the board of directors might consider allowing due diligence based on public information first, then provide additional information and materials that are necessary and appropriate.

9.2 Data Privacy Impact of Data Privacy Rules on Healthcare Due Diligence

Data privacy has been a topical issue in China in recent years, particularly in the healthcare sector – an area that is stringently regulated and encompasses extensive data-processing activities. The Chinese regulatory authorities are actively refining their oversight and regulatory framework for healthcare data.

Medical data, genetic data and biometric data, which are generally considered sensitive personal information, are subject to an elevated level of legal safeguarding. Under the Personal Information Protection Law, Data Security Law, Cybersecurity Law, as well as other applicable rules and standards in China, the processor of sensitive personal information is required to:

- obtain explicit and separate consent from individuals (for minors below the age of 14, the consent of their parents or guardians is required);
- notify individuals of the specific purposes, the necessity of processing, the methods, scope, duration of storage, and the impact on their rights and interests;
- take protective technical measures such as encryption, de-identification, and access control;
- conduct a privacy impact assessment prior to processing; and
- complete security assessment or obtain personal information protection certification, or conclude a standard contract for the cross-

border transfer of personal information, prior to the export or transmission of such personal information.

10. Disclosure

10.1 Making a Bid Public

A bid for a private company is generally not required to be made public. However, for a public company, the bid should be conducted through a tender offer by the bidder to the shareholders. This offer must be announced within a 60-day window by the bidder after it decides (by informing the target company and disclosing a reminder announcement) to further purchase 30% or more of the target company's stocks.

10.2 Prospectus Requirements

A stock-for-stock tender offer is only allowed by Chinese law if made by another publicly traded company, essentially limited to domestic public companies only. In such a case, the bidder will be another Chinese listed company issuing additional shares solely to acquire the stocks owned by the target company's shareholders. A prospectus is not required in this scenario. Consequently, the shares of the bidder would naturally be listed on its already-listed venue.

10.3 Producing Financial Statements Financial Statement Not Required

A cash-only transaction does not require a financial statement from the bidder. A stock-to-stock transaction is only permitted by another public company, which has routine disclosure of financial reports to its shareholders, and therefore an ad hoc financial statement is not required for the transaction as well.

10.4 Disclosure of Transaction Documents

Filing

If there are transaction documents (see 6.6 Deal Documentation), the documents need to be submitted for the stock exchange's review. The key terms will be disclosed to the public, though the full texts are usually just archived without being made public per se.

11. Duties of Directors

11.1 Principal Directors' Duties

The principal directors' duties in a business combination include preparation and supervision of the proposed combination. As the main body responsible for the daily supervision of the company, the board of directors must weigh all acquisition or sale decisions and regularly review the entire merger process, from strategy to integration, risk and execution, to ensure a smooth implementation of the acquisition process. Additionally, board directors are obligated to conduct investigations, analyse offer terms, enlist financial advisers for transaction guidance, and present recommendations to shareholders.

Board directors of a target company owe a duty of loyalty and duty of care only to the company and its shareholders, and do not owe such duties to any other stakeholders.

11.2 Special or Ad Hoc Committees

It is unusual for a target company's board of directors to have or create specific or ad hoc groups to discuss and assess potential business mergers. However, in cases where a significant number of directors have conflicts of interest and abstain from participation, a special committee comprising independent and impartial directors may be established to examine the transaction.

11.3 Board's Role

The board of directors is responsible for formulating plans for company merger, division, dissolution or change of company form. Therefore, the board's role tends to lean towards recommending or advising on the proposed transaction. It is relatively uncommon to see shareholder litigation challenging the board's decision to recommend an M&A transaction in China.

In a public takeover not involving a tender offer, selling shareholders commonly consult third-party advisers for guidance, including financial, legal and tax advice regarding the transaction.

Fairness opinions are commonly provided in the sale of public companies or the sale of state-owned entities or assets but are less common in sales of private-owned companies or assets.

11.4 Independent Outside Advice Advice and Fairness Opinions

In a tender offer, the target company's board of directors must enlist an independent financial adviser to generate a report. This report evaluates various aspects, including:

- the bidder's qualifications to make the offer;
- its business viability;
- the potential ramifications of the takeover on the target's operations and growth prospects; and
- the fairness and appropriateness of the offer.

Trends and Developments

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Han Kun Law Offices is a leading full-service law firm in China, with over 800 professionals located in Beijing, Shanghai, Shenzhen, Hong Kong, Haikou, 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, compliance, banking and finance, foreign direct investment, antitrust/competition, data protection, private

client/wealth management, intellectual property, bankruptcy and restructuring, and dispute resolution. Han Kun is widely recognised and well-known for its practice in life sciences and healthcare, with a dedicated life sciences and healthcare team led by multiple partners and comprised of tens of specialist attorneys. Over the years, it has been widely recognised as a leader in complex cross-border and domestic transactions and compliance matters.

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CHINA TRENDS AND DEVELOPMENTS

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The Increasing Importance of M&A as an Exit Route for Investors

IPO has always topped the list of choices for investors of Chinese companies in a liquidity event. However, listings on domestic and foreign venues by healthcare companies have faced unprecedented challenges in recent years. On the domestic front, although China has fully implemented the registration-based stock issuance system across the Chinese stock market since February 2023, it does not imply that regulators have relaxed their oversight. With the aim of maintaining quality control over IPO applications and ensuring the stable operation and healthy development of the stock market, the China Securities Regulatory Commission (CSRC) promulgated a series of rules and policies in August 2023 to enhance scrutiny of IPOs, as well as regulations on refinancing and shareholding reduction by controlling shareholders and actual controllers of listed companies. According to CSRC data, of the over 1,000 enterprises that have submitted IPO applications since the pilot implementation of the registration-based system, nearly 40% have withdrawn their applications or been rejected by regulators. Meanwhile, on the foreign front, the largely dismal performance of previously listed healthcare companies and the lukewarm attitude of foreign investors towards Chinese companies have increasingly made a successful IPO seem like a luxury.

In light of the current challenges in consummating IPOs, M&A is emerging as a vital exit strategy for investors seeking investment returns. The healthcare sector experienced a surge in M&A activities towards the end of 2023 and is expected to see an increase in the number of M&A transactions in 2024.

The Active Participation of SOEs and Government-Sponsored Funds

Among the various players in the healthcare M&A market, state-owned enterprises (SOE) and government-sponsored funds are becoming increasingly active. On the one hand, SOEs serve as a critical source of capital for venture capital funds and private equity funds, including buyout funds. On the other hand, the State-Owned Assets Supervision and Administration Commission of the State Council (SASAC) has initiated numerous efforts to encourage SOEs, particularly central SOEs, to bolster their core competitiveness and improve their key functions by way of M&A and restructuring. As a national strategic sector, the healthcare industry has increasingly drawn the attention of government-sponsored funds and SOEs, especially listed SOEs, which have sufficient cash flow on hand.

The market has recently seen a thriving momentum in M&A deals led by SOEs. For instance, in the first quarter of 2024, Sinopharm has revived a take-private bid for China Traditional Chinese Medicine Holdings Co, Ltd (a leading company in the traditional Chinese medicine industry) at a price of over HKD15.4 billion. CR Double-crane has also announced its intention to acquire CR Zizhu Pharmaceutical Co, Ltd (a company focusing on reproductive health products) for over CNY3.1 billion, and Genertec is contemplating a strategic acquisition of and restructuring with Chongqing Pharmaceutical Health Industry Co, Ltd (a financing, investment and industrial integration platform for the healthcare industry in Chongqing). Through M&A and restructuring, these state-owned pharmaceutical giants can expand their market share and integrate their supply chains. Drawing insights from the available data and observations, it is anticipated that these state-owned pharmaceutical giants will

continue to play a pivotal role in the healthcare M&A market.

Apart from SOEs, local government agencies, government sponsored funds and government-guided funds are also paving the way for healthcare industrial integration.

The Rising Popularity of Licensing Deals in the Pharmaceutical and Biotech Industry

While the M&A and equity financing market is undergoing a period of slump, the market is witnessing a boom in both the value and volume of licensing deals. Given the challenging equity investment environment, licensing deals are gaining popularity among biotech companies and pharmaceutical enterprises. For licensors, licensing deals represent a growing source of cash flow, which helps to support their development and operational activities. For licensees, licensing deals are becoming an increasingly important approach for supplementing their pipeline and product candidates.

According to data from PharmCube, approximately 240 licensing deals were completed in China in 2023. This included around 70 license-out deals, with a disclosed total deal value exceeding USD35 billion, and roughly 170 license-in deals. Notably, the number of license-out deals saw a 45.8% increase from 2022. The drivers likely include the increasing research and development (R&D) expenses of Chinese pharmaceutical and biotech firms, which are bringing forward promising preclinical and clinical drug candidates. This, in turn, has garnered increased interest and growing confidence from multinational companies in dealing with the Chinese counterparts. It is expected that license-out deals will remain active and robust in 2024.

Pharmaceutical Industry M&A Integration and Transition to High-Quality Development Driven by Policies and Capital Environment *General policy supports M&A integration in the pharmaceutical industry*

From a policy perspective, China's support for high-quality development through mergers and acquisitions by listed companies is becoming increasingly evident, especially at the state-owned enterprise level. Restructuring and M&A are seen as key measures to drive reform and improve efficiency.

In 2023, the State-Owned Assets Supervision and Administration Commission of the State Council, the National Health Commission, and 13 other government ministries jointly issued a notice on the "Work Plan to Support High-Quality Development of State-Owned Medical Institutions". This notice explicitly supports restructuring and M&A of state-owned enterprises with a healthcare focus. The introduction of this policy not only establishes a policy framework but also sends a clear message to the market that high-quality development in the pharmaceutical industry may be achieved through M&A integration.

As various new policies are enacted, traditional pharmaceutical companies, under the pressure of market changes, are also accelerating mergers and acquisitions of innovative products to explore new avenues for growth.

Capital market policies supporting pharmaceutical M&A integration

New policies in the capital market are providing robust support for high-quality M&A integration in the pharmaceutical industry as well. In the latter half of 2023, the China Securities Regulatory Commission released several significant policies. These policies included:

- lowering the financing margin ratio to facilitate financing and securities lending, invigorating existing funds;
- further standardising share reduction practices; and
- periodically tightening IPOs.

Additionally, the implementation of a pre-communication mechanism for refinancing activities of certain companies, along with appropriate restrictions on their financing frequency and scale, will significantly impact the pharmaceutical industry.

Moreover, the stringent requirements set by the STAR Market IPO for the commercial realisation and profitability of innovative pharmaceutical companies have placed immense financing pressure on many such entities in both primary and secondary markets. Faced with such pressures and the risks associated with share buybacks, numerous companies are opting to transfer equity or product rights instead to alleviate cash flow crises. This trend further accelerates the M&A integration process in the pharmaceutical industry.

Transaction Volume and Active Trading Boosted by Mega Mergers in Biotech

Despite the dual challenges of a capital and economic downturn, statistical data indicates that the domestic pharmaceutical industry still demonstrates strong M&A vitality. Throughout 2023, there was a notable increase in the number of M&A cases in the pharmaceutical sector, particularly driven by significant deals such as AstraZeneca's acquisition of Gracell Biotechnologies, and Haier Group's acquisition of Shanghai RAAS. These transactions significantly augmented the total transaction volume.

The Biotech sector is witnessing a new phase of heightened activity characterised by diverse types of deals, with AstraZeneca's acquisition of Gracell Biotechnologies setting new industry records. However, despite this surge, the concentration of China's pharmaceutical industry remains low, structural changes have yet to materialise, and mergers and integrations continue to be a long-term trend for the industry's future development.

In 2023, Biotech M&A entered an accelerated phase due to the combined effect of multiple factors. Firstly, after two years of a downturn, market sentiment gradually adjusted, leading to more reasonable and aligned expectations regarding valuation between buyers and sellers, facilitating smoother transaction completions. Secondly, with the tightening of pharmaceutical IPO policies and the continued underperformance of the secondary market, Biotech investors faced challenges in exiting the market, making M&A exits a more viable option. Thirdly, intense market competition has driven buyers to continuously seek innovative pipelines to complement their product portfolios and bolster their competitiveness.

M&A Activity Heating Up in the Medical Services Field

The medical services sector is experiencing a surge in M&A activity, with approximately 40% of transactions stemming from financial difficulties faced by companies. From the end of August to early December 2023, statistics on M&A activities in the medical industry revealed a total of 45 M&A cases, with the medical services sector leading with nine cases, representing the highest proportion. This trend is primarily driven by leading companies in the medical services sector having substantial funds, with M&A viewed as the optimal strategy for the expansion of

medical service groups. At the same time, many individual medical service hospitals and small medical service enterprises, facing operational pressures, opt for acquisition as a mutually beneficial solution.

Furthermore, data indicates that, in the past few years, the focus of M&A activities in various key sectors of China's medical and health services has been notably distinct, particularly in digital medicine. The acceleration of medical informatisation infrastructure driven by data and the upgrade of medical digital technology centred around artificial intelligence have resulted in a significant increase in both the quantity and value of transactions. With ongoing innovation in medical technology and the continuous improvement of regulatory standards, technologies such as artificial intelligence, big data, and 5G are increasingly being integrated into medical service scenarios. As the medical service industry continues to enhance quality and efficiency while reducing costs, its financing and M&A landscape offer ample room for expansion and will remain dynamic.

Decoupling in Global Biotechnology Supply Chain

The biotechnology sector has long been considered as a “safe harbour” in the context of US–China rivalry. However, the reality may have been changed since biotechnology is selected as a new target by US regulators, allegedly for “national security” concerns, which reminds people of the recent TikTok ban. Here is a summary of regulatory events based on chronological order.

- On 12 September 2022, the Biden administration issued the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and

Secure American Bioeconomy. This executive order undertakes to take a whole-of-government approach to advance biotechnology and biomanufacturing, and to address policy concerns including supply chain resilience. Of particular attention for the healthcare industry, this executive order touches on the following.

- (a) Global Screening – US government, together with foreign partners, will conduct horizon scanning to anticipate threats, particularly national security threats from foreign adversaries acquiring sensitive technologies or data, or disrupting essential bio-related supply chains.
 - (b) Supply Chain Derisking – Federal government agencies were asked to advise on actions to “mitigate risks posed by foreign adversary involvement in the biomanufacturing supply chain and to enhance biosafety, bio security, and cybersecurity in new and existing infrastructure”. This executive order launched a National Biotechnology and Biomanufacturing Initiative to ensure biotechnology invented in the US is also made in the US. Essentially, the US aims to strengthen its domestic biomanufacturing ecosystem and reduce its reliance on, or replace the supply chain from, China.
- On 22 March 2023, the White House Office of Science and Technology Policy issued a report titled Bold Goals for US Biotechnology and Biomanufacturing. One of the goals is to improve the US domestic supply chain for critical drugs. It points out that most active pharmaceutical ingredients (APIs) of small molecule drugs are synthesised in China and India, which poses supply chain risks. Biomanufacturing innovations, such as advances in synthetic biology, would make cost-effective domestic API production possible.

- On 28 February 2024, the Biden administration issued an executive order to limit the distribution of certain government-related data and bulk sensitive data, including personal health data and human genomic data, to countries of national security concern (including China). Restrictions on accessing sensitive data may affect cross-border collaborations and partnerships in the biotechnology industry, potentially leading to disruptions in the supply chain.
- Following introduction of the Biosecure Act in the House of Representatives on 25 January, a Senate's draft of this bill was approved to be sent to the Senate floor on 6 March 2024. Of particular notice to the biotechnology sector is that this bill prohibits federal agencies from entering into contracts with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern", which includes: (i) specifically named entities, such as WuXi AppTec; and (ii) entities subject to the jurisdiction of a foreign adversary's government and posing a threat to US national security, to be further identified by the Office of Management and Budget. Despite being in its early stage of legislation, the bipartisan support from both the House and the Senate means it is more than likely to be enacted. This would significantly disrupt drug development projects conducted by US drugmakers and their Chinese contract development and manufacturing organisations (CDMOs).
- On 15 March 2024, WuXi AppTec, a renowned global biotechnology R&D and manufacturing service provider, voluntarily ended its membership in the Biotechnology Industry Organization (BIO), after BIO changed stance and announced its support for the Biosecure Act. Previously, BIO strived to remove WuXi AppTec from the named entity list of the said

act, citing reasons that it might undermine R&D and supply chain for US drugmakers. This showcases how political pressure may affect industry practice.

Due to increasing competition in the domestic market and the centralised procurement of drugs, the profit margin of Chinese healthcare companies keeps getting squeezed. Therefore, globalisation is widely deemed as a solution leading to new profits for Chinese companies. How to navigate in a growingly hostile regulatory landscape is the key to a successful globalisation process.

- For foreign companies – The shifting regulatory landscape will make foreign customers more precautionous before entering into contracts with Chinese CXOs. The Biosecure Act, if passed into legislation, is anticipated to impact the eligibility to contract with certain Chinese companies. Therefore, it is recommended that foreign companies conduct due diligence on their Chinese service providers and include in the contract certain compliance representations.
- For Chinese companies – The complexity of regulations does not render globalisation impossible. Chinese biotechnology companies, especially CXOs, are recommended to consider reorganisation of their companies, such as moving the company headquarters to a third country (Singapore, for example) and splitting off subsidiaries based on their place of business in order to minimise risk exposure. For Chinese biotech founders, they may consider incorporating in the United States, then setting up a Chinese subsidiary in China through foreign direct investment. By doing this, it gives the company a neutral look and makes it less likely to be deemed as subject to the jurisdiction of an alleged "foreign adversary".

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