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Legal Updates

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1. Reform of Capital Contribution Rules in the 2023 Company Law – What Companies and Shareholders Need to Know

Authors: Aaron ZHOU | Han LIAO | Yumeng HE | Jiajie ZHANG

China's Company Law was enacted in 1993 and underwent certain amendments in 1999, 2004, 2005, 2013 and 2018. In response to the latest trends and demands in economic development, China adopted a comprehensive amendment to the Company Law on December 29, 2023 (the "**2023 Company Law**"), which will take effect on July 1, 2024.

The rules concerning capital contribution are of great importance to companies and their shareholders and creditors. This article will focus on the amendments related to the capital contribution rules with respect to limited liability companies in the 2023 Company Law, and will try to provide some insights and practical advice in relation to such amendments.

Capital contribution timeline

Paragraph 1 of Article 47 of the 2023 Company Law
The registered capital of a limited liability company is the total amount of capital contributions subscribed by all shareholders as registered with the company registration authority. The subscribed capital shall be fully paid by the shareholders within five years from the date of the company's establishment as stipulated in the company's articles of association.

I. Evolution of capital contribution timeline requirement for limited liability companies

The capital contribution timeline requirement for limited liability companies has undergone numerous discussions and amendments in light of the changing economic and social development since the first enactment of the Company Law in 1993 (as illustrated in the following table).

	Company Law of 1993	Amendment to Company Law in 2005	Amendment to Company Law in 2013	2023 Company Law
Capital contribution timeline for limited liability companies	One-time paid-in capital	The registered capital is required to be fully paid within 2 years (5 years for investment companies)	No specific requirement	The registered capital contributions are required to be fully paid within 5 years

The amendment to Company Law in 2013 removed the statutory time limit for making capital contributions and lifted the minimum registered capital requirements. This amendment raised considerable concerns, as shareholders can indefinitely postpone the capital contribution deadline, and the registered capital amount of a company may not accurately reflect such company's financial strength.

Article 47 of the 2023 Company Law provides that the capital contribution of a limited liability company shall be fully paid within five years of its incorporation, which will strengthen shareholders' commitments on capital contribution, better protect creditors' interests, and encourage a more rational approach in determining the registered capital amounts of limited liability companies.

II. Commentary on Article 47 of the 2023 Company Law

What impacts will Article 47 of the 2023 Company Law have on existing companies and their shareholders, and what are the key takeaways for companies to be incorporated and shareholders who may subscribe for increased registered capital in the future?

1. Impact on existing companies

■ Transition period

Existing companies and their shareholders may be concerned about the application of capital contribution timeline under the 2023 Company Law, including whether they are supposed to reduce the registered capital amounts or make capital contributions as soon as possible, and whether the company's article of association needs to be amended to adjust the timeline to make capital contributions. To clarify these points, paragraph 2 of Article 266 of the 2023 Company Law provides that "*For companies incorporated before this law comes into force, if their capital contribution timeline exceeds the timeline stipulated herein, they shall gradually adjust to meet the timeline provided herein, unless otherwise provided by any laws, administrative regulations, or the State Council; in the scenario where the capital contribution timeline or amounts are clearly abnormal, the company registration authority may require timely adjustments in accordance with the law. The specific implementation measures shall be prescribed by the State Council.*" The representative of the Legislative Affairs Commission of the Standing Committee of the National People's Congress also stated in the response to media inquiries on the 2023 Company Law that: "*The State Council is tasked to issue implementation measures for the 2023 Company Law, including setting a transition period for companies incorporated prior to the effectiveness of this law with capital contribution timeline exceeding the required timeline under this law, and such companies will be required to gradually adjust their capital contribution periods to be in line with this law.*"

The above regulations and statements have dispelled the previous speculation of "existing rules for existing companies, and new rules for new companies". In other words, there is no grandfathering for existing companies in this respect. The five-year capital contribution timeline will apply to all companies, including those incorporated before the promulgation and implementation of the 2023 Company Law. Therefore, it is suggested that the existing companies and their shareholders keep a close eye on the implementation measures to be promulgated by the State Council.

■ Registered capital reduction

Although the State Council has not promulgated implementation measures for the 2023 Company Law, it is anticipated that some companies may need to reduce their registered capital to lower capital contribution requirements to mitigate the potential impact on the cash flow of their shareholders.

Article 225 of the 2023 Company Law introduces a simplified capital reduction procedure, which applies to companies that have incurred losses and whose asset value is significantly lower than their registered capital. Under this simplified procedure, such companies may reduce their registered capital and announce capital reduction through the National Enterprise Credit Information Publicity System, without the need to notify creditors or publish an announcement in newspapers, which are typically required for normal capital reduction procedures. Such simplified capital reduction procedure aims to ensure such companies' registered capital aligns with their actual operational and financial strength, while keeping such companies' solvency and avoiding the companies' assets flowing back to their shareholders.

2. Key takeaways for companies to be incorporated

Article 50 of the 2023 Company Law generally follows the current Company Law on the capital contribution obligations of founding shareholders, and provides that: "*When a limited liability company is incorporated, if a shareholder fails to make an actual payment of capital contributions as stipulated in the company's articles of association, or if the actual value of non-monetary assets contributed falls significantly below the subscribed capital amount, the other shareholders at the time of establishment shall bear joint and several liability with that shareholder for such shortfall in capital contributions.*" However, compared with the current Company Law, the 2023 Company Law provides that founding shareholders shall bear joint and several liability only for the shortfall in capital contributions of the defaulting shareholder.

Therefore, for companies to be incorporated, it is suggested that founding shareholders set the amount of registered capital properly, monitor the progress of capital contributions made by other founding shareholders, conduct necessary due diligence and understand the financial strength of other founding shareholders.

3. Key takeaways for shareholders subscribing for increased share capital

Article 228 of the 2023 Company Law says that "*When a limited liability company increases its registered capital, the contribution of its shareholders to the new capital shall be made in accordance with the relevant provisions of this Law regarding the payment of capital contributions for the establishment of a limited liability company*", which means that the five-year capital contribution timeline also applies to capital increases. Consequently, shareholders subscribing for increased capital shall pay the increased registered capital within five years (or a shorter period provided for in the articles of association).

Written payment demand and forfeiture of shares

Article 51 of the 2023 Company Law
After the establishment of a limited liability company, the board of directors shall verify the shareholders' capital contributions. If it is found that a shareholder has not timely and fully made capital contributions as stipulated in the articles of association, the company shall serve a written notice to the shareholder to demand payment of capital contributions. Directors who fail to fulfill the obligations stipulated in the preceding paragraph in a timely manner,

resulting in losses to the company, shall be liable for compensation.
Article 52 of the 2023 Company Law
If a shareholder fails to make capital contributions by the date specified in the company's articles of association, and the company issues a written payment demand in accordance with the first paragraph of the preceding article, the company may specify a grace period for the capital contribution in the written payment demand, which grace period shall not be less than 60 days from the date the company issues the payment demand. If, upon the expiration of the grace period, the shareholder still fails to fulfill the capital contribution obligation, the company may, with a resolution of the board of directors, issue a notice of forfeiture to the shareholder, and such notice shall be in writing. From the date of the notice, the shareholder loses the rights to the unpaid share capital. The shares forfeited according to the preceding paragraph shall be transferred in accordance with the law or the registered capital shall be reduced accordingly with the cancellation of those shares; if the transfer or cancellation is not completed within six months, other shareholders of the company shall make corresponding capital contributions in full in proportion to their respective contributions. If the shareholder has objections to the forfeiture, it shall file a lawsuit with the people's court within 30 days of the receipt of the notice of forfeiture.

I. Comparison between Articles 51 and 52 of the 2023 Company Law and Article 17 of Judicial Interpretation III of the Company Law

Before the 2023 Company Law, Article 17 of the *Provisions of the Supreme People's Court on Several Issues Relating to Application of Company Law of the People's Republic of China (III)* ("**Judicial Interpretation III of the Company Law**") already provided mechanisms similar to the written payment demand and share forfeiture. The 2023 Company Law goes one step further and allows both the company and its shareholders to seek remedies against capital contribution defaults of other shareholders.

	Judicial interpretation III of the Company Law	2023 Company Law
Applicable scenarios	Failure to fulfil capital contribution obligations or withdrawal of all capital contributions, and such failure is not cured within a reasonable period after being demanded by the company.	Failure to pay capital contributions by the date specified in the company's articles of association, and still failure to fulfill the capital contribution obligations within the grace period.
	Comments: The share forfeiture mechanism stipulated in Judicial Interpretation III of the Company Law is not applicable if the shareholders have partially paid capital contributions or only partially withdrawn capital contributions, which makes it challenging to effectively achieve the intended purposes.	
Legal effect	The forfeited shareholder is disqualified from being a shareholder.	From the date of the demand, the defaulting shareholder loses the rights to the unpaid registered capital.
	Comments: The application of the Judicial Interpretation III of the Company Law will result in the defaulting shareholder losing the entire share capital and their shareholder status, although in practice judicial authorities have already started to support partial forfeiture of share capital in some cases. The 2023 Company Law has paved the	

	way to overcome such a predicament.	
Procedural requirements	■ Failure to make the payment or return the withdrawn capital contribution within a reasonable period after being demanded by the company. ■ The company passes a shareholders' resolution to disqualify the shareholder.	■ Failure to pay the capital contribution within the grace period after being demanded by the company. ■ Issuance of a notice of forfeiture to the shareholder pursuant to a resolution of the board of directors.
	Comments: According to the 2023 Company Law, the right to confirm the issuance of a notice of forfeiture shifts from shareholders to directors, which is in line with the board of directors' duties to supervise capital contributions.	
Subsequent process	Prompt completion of capital reduction procedures, or other shareholders or a third party paying such capital contribution.	Reduction or transfer of share capital within six months.
	Comments: The 2023 Company Law specifies the timeframe for the disposal of the forfeited share capital, which enhances the stability and clarity of the company's capital structure.	

II. Commentary on Articles 51 and 52 of the 2023 Company Law

1. Verification of capital contributions and issuance of written payment demand

Article 51 of the 2023 Company Law provides that the board of directors shall verify the capital contribution, and if a director fails to perform such obligations in a timely manner and causes losses to the company, such responsible director shall be liable for the compensation.

■ **Board of directors' right to verify capital contributions**

The 2023 Company Law tends to give the board of directors more supervisory rights, given that the supervisors/board of supervisors have not been proven to be very effective in supervising corporate governance in practice. For example, the 2023 Company Law introduces the concept of an audit committee (consisting of directors), which is expected to exercise the powers and functions of the supervisors/board of supervisors.

Although the 2023 Company Law provides that the board of directors shall verify and supervise the payment of capital contributions, it does not expressly grant the directors access to the company's accounting books or other materials. It is advisable for companies to specify in the articles of association or other corporate documents the rights and authorities of directors to review the register of shareholders, capital contribution certificates and necessary accounting records. This will help the board of directors exercise their rights to verify capital contributions, especially in light of the 2023 Company Law's emphasis on the supervisory functions of the board of directors. On the other hand, for confidentiality considerations, some companies may wish to limit directors' access to information that is necessary to perform their duties.

■ **Compensation liability of directors**

The 2023 Company Law imposes compensation obligations on directors who fail to fulfill the obligations to verify capital contributions and cause the company to demand payment. Therefore, it is advisable for directors to keep records of their efforts to verify shareholders' capital contributions and cause the company to demand payment of capital contributions from the defaulting shareholders, which could help directors defend against compensation claims.

Meanwhile, for investors in private equity and venture capital deals that are entitled to appoint directors, it is suggested that the transaction documents contain clauses granting the appointed directors the specific rights of verification and supervision. This will help the directors perform their statutory duties of verification and demanding payment of capital contributions. Director liability insurance is also a good option to protect the appointed directors.

2. Forfeiture of share capital

According to Article 52 of the 2023 Company Law, the company shall dispose of the forfeited share capital within 6 months by transferring such share capital or canceling such share capital through registered capital reduction. If the forfeited share capital is not transferred or canceled within such 6 months, the other shareholders shall pay such outstanding capital contributions in proportion to their respective shareholding ratio.

Given the time limit for the disposal of the forfeited share capital, the company may wish to start to find a transferee or start to prepare for capital reduction concurrently with or shortly after issuing the notice of forfeiture. Furthermore, to streamline the disposal process, it is advisable to specify in the articles of association and other corporate documents (such as the shareholders' agreement) that the shareholders whose share capital has been forfeited are obligated to cooperate with the disposal process, including the possible share transfer and registered capital reduction.

Additionally, since the 2023 Company Law imposes obligations on other shareholders to make capital contributions in proportion to their shareholding percentages for forfeited share capital not disposed of within the 6-month timeline, it is suggested that shareholders monitor the capital contribution progress of other shareholders and the register of members, and cause the directors and the company to promptly demand the relevant shareholders to rectify any default in capital contributions, thereby avoiding the risks of being asked to make capital contributions for forfeited share capital of other shareholders.

Meanwhile, companies may consider to address in the articles of association and other corporate documents (such as the shareholders' agreement) issues not specifically addressed in the 2023 Company Law, such as revoking the voting rights of directors appointed by the defaulting shareholders and/or allowing defaulting shareholders or their representatives to attend board meetings and present their cases.

Acceleration of capital contribution timeline

Article 54 of the 2023 Company Law
If a company is unable to pay off the due debts, the company or the creditors of the due debts shall have the right to demand early capital contributions from shareholders whose subscribed capital contributions are not yet due for payment.

The rationale behind the capital contribution acceleration rules is that, under certain circumstances, the interests of shareholders with respect to the capital contribution timeline shall give way to the interests of creditors, and the company's registered capital shall be used to facilitate the enforcement of creditors' rights.

Under the current rules, if a company is unable to pay its due debts, the creditors are generally unable to demand the shareholders of the company to pay capital contributions not due for payment, unless under limited circumstances such as the company already in the bankruptcy or dissolution process or intentional extension of capital contribution timeline to avoid debts.

Article 54 of the 2023 Company Law aims to expand the scenarios where acceleration of capital contribution timeline is applicable, pursuant to which, as long as a company is unable to pay off its due debts, the creditors may require early capital contributions from shareholders, even if such shareholders' subscribed capital contributions are not yet due for payment. This provision also shows that the 2023 Company Law puts more weight on creditor protection.

Meanwhile, further guidance is needed on how to determine whether a company "is unable to pay off its due debts" under Article 54 of the 2023 Company Law. For instance, it remains unclear whether creditors can demand to accelerate capital contributions when a company has sufficient assets or funds but refuses to pay off its due debts.

In addition, Article 54 of the Company Law does not elaborate on the nature and extent of shareholders' liability. Shareholders may want to specify in the articles of association and/or shareholders' agreement that the shareholders who are required to expedite their capital contributions only need to contribute an amount necessary to settle the company's outstanding due debts, and the timeline for the remaining capital contributions shall be unaffected, although such provisions (as an agreement between the shareholders and the company) may not be used as a defense against creditors. Some shareholders may want to go one step further to require to state in the articles of association and/or shareholders' agreement that the company shall, after paying off the creditors, reimburse the shareholders for any losses (such as the loss of benefits of the original capital contribution timeline) caused by such capital contribution acceleration.

Conclusion

Capital contribution rules form the bedrock of a company's financial strength and play a vital role in companies' operations. The 2023 Company Law introduces a series of reformative measures, including the capital contribution timeline, written payment demand and share capital forfeiture. It is advisable for shareholders, directors and management of limited liability companies to pay close attention to these new rules related to capital contribution, and implement appropriate measures to protect the companies' and their shareholders' interests.

2. Anatomy of Licensing Deals from China Regulatory Perspective[1]

Authors: Aaron GU | Pengfei YOU | Duzhiyun ZHENG | Yuzhen ZHANG | Fengqi YU[2]

Driven by the passion and belief, and fraught with various risks and challenges, the research and development of innovative drugs and medical devices is a journey that's never easy. Along the journey, an individual may stride resolutely, yet with companionship, two can traverse faster and farther. Therefore, pharmaceutical companies have been frequently collaborating in the research and development of drugs and medical devices to leverage each other's resources, share risks, explore regional markets, achieve profit maximization, or promote mutually beneficial effects in strategic partnerships. Meanwhile, licensing transactions are commonly used for the implementation of collaborative projects in the field of drugs and medical devices (including medical aesthetics).

Our team has been 100% dedicated to legal work in the field of life sciences, and we are honored to have the privilege of assisting numerous multinational pharmaceutical and medical device companies, as well as leading innovative biotech companies in China, in conducting licensing transactions and research collaboration projects. With the explosive growth of license-out transactions in recent years, in 2022 and 2023, we have handled over 50 pharmaceutical and medical device licensing (including collaborative development) projects, including but not limited to collaborative projects involving various small molecule drugs, ADC drugs, RDC drugs, mRNA drugs, AI pharmaceutical technologies and products, cell therapy products such as CAR-T/CAR-NK/TIL, medical aesthetics products, and various innovative medical devices for treatment or diagnosis (IVD/LDT). Recently, we have frequently observed a lack of consideration for regulatory issues related to drugs and medical devices in a considerable number of previous license agreements of our clients. As a result, many terms are ultimately unimplementable and require renegotiation between the parties. The business arrangements throughout the entire life cycle of the licensed products serve as the cornerstone for licensing projects. To smoothly carry out collaborative licensing projects, it is crucial to prudently allocate rights, obligations, and interests among the parties involved in the license agreement, and the parties shall take the entire life cycle of drugs and medical devices into consideration and pay particular attention to key aspects when drafting terms.

As mentioned above, as one of the few teams in China fully dedicated to the field of life sciences, we practice with a particular focus on regulatory issues throughout the entire life cycle of drugs and medical devices. We will share further insights on key terms of collaborative licensing projects, from the perspective of regulatory compliance and consideration of the entire life cycle of products, which mainly include research and development ("**R&D**"), registration, manufacturing, commercialization, and post-market regulations.

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[1] For the Chinese version, please click *汉坤 • 观点 | 从药械产品全生命周期视角解读License-in/out许可交易项目合作条款要点*.

[2] Leyi Wang and Shuwen Sun have contributions to this article.

Research and development

I. Project management and committees (JxC)

For the purpose of product R&D, the parties often establish a Joint Development Committee ("**JDC**") (or a committee with a different name but similar responsibilities) to discuss and determine on related matters. Despite the fact that both parties share a joint aspiration to promote product development, there typically remains tension between the Licensor and Licensee in terms of the control over R&D activities: The Licensee desires more autonomy to conduct R&D activities within the licensed territory and field, while the Licensor seeks supervision and control over the Licensee's R&D activities. Taking one of our medical device collaborative projects as an example, the Licensor sought comprehensive supervision of worldwide R&D activities of the licensed products and aimed to hold approval authority for clinical trial protocols and the selection of Contract Research Organizations (CROs) through the JDC. However, the Licensee believed that the Chinese market had its own unique characteristics and required ample autonomy to ensure timely and smooth progress in product R&D. Ultimately, we successfully negotiated on behalf of the Licensee to secure the exclusive decision-making power for the Licensee regarding the aforementioned matters within the licensed field and territory.

In fact, the establishment of project management committees depends on the specific circumstances and the practical needs of each project. For instance, in the case of comprehensive collaborative licensing projects, the parties typically set up various management committees, each designated for distinct phases of product development, including the R&D, registration, manufacturing, and commercialization. They might additionally opt to establish additional management committees, such as the Joint Bioanalytical Team ("**JBT**") and the Joint Finance Committee ("**JFC**"), to facilitate the project's progression. In contrast, for projects with a simpler transactional structure, parties might solely establish a Joint Steering Committee ("**JSC**") to supervise project management as a whole without the establishment of additional management committees. The structuring of project management mechanisms has no universal and optimal solution; instead, it involves seeking and discovering the most appropriate options for the particular project.

II. Diligence obligation

The development of innovative drugs and medical devices requires the collaborative parties to expend significant resources and exert diligent efforts. License agreements often include terms specifying diligence obligations of the parties during the R&D stage. On the one hand, the Licensor hopes to supervise the Licensee's active R&D activities to achieve early registration and commercialization of the licensed product. On the other hand, given the inherent uncertainties in R&D activities, the Licensee also needs to reasonably limit the R&D responsibilities it undertakes. Therefore, there is always considerable tension between the parties regarding how to stipulate, interpret, and enforce the diligence obligation terms. We've also seen cases where disputes arose over the fulfillment of diligence obligations during the R&D phase, eventually leading to arbitration.

Generally, in a licensing project, the Licensor typically establishes clear diligence obligations for the Licensee, to expedite the receipt of subsequent milestone payments and royalties. In addition, the Licensor may also specify particular diligence milestone events and require the Licensee to complete before specific deadlines. If the Licensee fails to complete such events, the Licensor may have the right to choose to terminate the agreement, seek for compensation, or take other remedial measures such as transitioning from an exclusive license to a non-exclusive license. For each specific project, the formulation of diligence obligation terms further depends on various factors such as the nature of the collaborative project, negotiation and demands from the parties, and advice from legal counsels. In general, diligence obligation terms stand out as distinctive and representative provisions in license agreements. Unlike traditional asset acquisition agreements, license agreements usually lack a typical closing stage; the signing of the agreement only marks the very beginning of the collaboration, while the post-execution cooperation is the focal point of the project. Hence, both companies and legal counsels need to consider the implementation of the license agreements with a forward-looking perspective over an extended period, to ensure that the agreements can be effectively implemented, reducing subsequent communication costs for both parties.

III. Data sharing

The sharing of research findings/data is crucial, especially in aspects such as product registration, further product development in other territories, and continued improvement in product technology. For instance, in multinational collaborative projects, parties may progress with the research and development of licensed products in various regions, and the sharing of research findings and data within different regions plays a crucial role in expediting product development in other jurisdictions. Therefore, the design of data sharing arrangement is crucial.

In China, a notable regulatory trend in recent years is the increased focus of regulatory authorities on data export and human genetic resources (HGR) information. (For our insights on the regulations of HGR in China, please refer to: *Highlights on HGR Regulation Implementation Rules*; *Key Takeaways of the New HGR Guidelines*; *Key Takeaways on the New HGR FAQs issued by the MOST of China*). Taking the regulation of HGR information as an example, if the collaborative party falls within the scope of “foreign entities” under the HGR regulation, HGR regulations may significantly impact such party’s access to HGR data (e.g. human genetic data). Therefore, it is crucial for the relevant parties to actively participate in proactive, thoughtful, and negotiable discussions and designs concerning the arrangements for sharing research data within the regulatory framework of data supervision in China. We will also consistently monitor updates and changes in regulatory requirements and provide professional advice to facilitate licensing projects.

Registration

I. MAH selection

The selection of the Market Authorization Holders (MAH) (or the registrants or record filing parties) of the products is crucial for both the products and the collaborating parties.

In licensing transactions, the Licensee typically takes the lead in product registration within the licensed territory and serves as the MAH, while in cross-licensing and collaborative projects, the selection of MAH may become more intricate. In practice, the selection of MAH involves considerations of the specific qualifications required for MAH in different jurisdictions, the rights and obligations associated with the MAH, and factors such as the resources and capabilities to take regulatory responsibilities possessed by specific collaborators in different territories. Moreover, the possibility of early termination of the collaborative project should also be taken into consideration and the transition of the status of MAH under post-termination circumstances should also be clarified accordingly. Due to the distinctions between China's regulations on the MAH frameworks for drugs and those for medical devices, such transition and obligations of the parties may be provided differently. In conclusion, companies and legal counsels shall carefully and strategically consider the selection of MAH.

Since the release of the famous *Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation of Drugs and Medical Devices* by the State Council of China in 2017, China has actively promoted the comprehensive implementation of the MAH system through amending the *Drug Administration Law* and the *Regulations on the Supervision and Administration of Medical Devices*, along with issuing supplementary regulatory provisions. Such laws and regulations have imposed regulatory requirements for the entire life cycle management responsibilities on MAHs of drugs as well as registrants and record filing parties of medical devices. Drug MAHs and registrants/record filing parties of medical devices are obligated to assume full responsibility throughout the entire life cycle of the products, encompassing product registration, manufacturing, distribution, and usage. They are also required to fulfill duties such as post-market research, monitoring adverse reactions, and conducting product recalls. Additionally, if the licensed product is to be registered as an imported product, the Licensee, typically as the domestic representative, will undertake the MAH responsibilities on behalf of the overseas MAH and bear the corresponding joint liabilities. Therefore, the selection of the MAH may also be influenced by appropriate business arrangements in light of regulatory requirements. It is also essential to consider various regulatory aspects such as the regulatory requirements for IND sponsors and NDA applicants, the non-transferability of medical device registrations, the regulatory requirements pertaining to "dual invoicing" policy, and the arrangements for product distribution.

Furthermore, the regulatory framework and requirements for drugs and medical devices in China are constantly being refined and updated. As an example, in our recent participation in the preliminary legislative research for the *Medical Device Administration Law*, numerous of studies and discussions have taken place concerning obligations and responsibilities of registrant and record filing parties of medical devices, along with their domestic representatives (if applicable). Industry practitioners need to keep track of regulatory requirements and make timely adjustments to strategies and arrangements within licensing transactions as needed.

II. Cooperations in registration process

The party not responsible for regulatory registration activities may also wish to supervise such activities to a certain extent. Therefore, in license agreements, it is necessary to pay attention to the requirements for the preparation and submission of regulatory filings, such as whether they need to be reviewed by the JDC, whether they must accept the comments from the JDC, and whether to agree on which party has the final decision-making power in certain matters. These arrangements may have a significant impact on the timeline for the market registration of licensed products.

Often, the parties other than the MAH also need to assume certain cooperation and assistance obligations, such as providing safety and efficacy data generated by the development activities outside the licensed territory or field. In addition, regulatory authorities such as NMPA and FDA typically require GMP inspections of the manufacturing site of the products when reviewing market applications. Therefore, the parties also need to clearly define their respective obligations in the license agreements in respect of regulatory inspections, and fully consider the practicality and operability of such arrangements. For example, in a medical aesthetic product license-in transaction, the products would be supplied by the Licensor's CMOs from overseas. During the negotiation, we, representing the Licensee, managed to request the Licensor to ensure that their CMOs will cooperate with China's regulatory authorities for extended GMP inspections.

Manufacturing

The arrangement of the manufacturing phase for licensed products in license agreements may be divided into two stages: the clinical study stage and the commercialization stage. The former is for the supply of products for development use, while the latter is for the supply of products for commercialization use.

In determining the party responsible for manufacturing, one of the key considerations is whether the licensed products will be registered as domestic products or imported products in the future. In other words, whether the MAH of the products is a domestic entity or an overseas entity. At present, except for the pilot projects for cross-border contract manufacturing of drugs and medical devices in the Greater Bay Area (For our insights on the pilot regulations of cross-border contract manufacturing, please refer to: *汉坤 • 观点 | 终于等到你 — 解读粤港澳大湾区药品医疗器械跨境委托生产新政*), products held by domestic MAHs shall be manufactured by domestic companies, while products held by overseas MAHs must be manufactured overseas. Therefore, the arrangement of MAHs will also affect the arrangement of manufacturing and supply of the licensed products. In addition, it is also necessary to consider whether outsourcing service providers such as CMOs need to be appointed. If so, the parties should also pay attention to the terms and conditions for subcontracting and sublicenses, including who to own the decision-making power for the selection of subcontractors and sublicensees, and who to bear responsibility for losses caused by subcontractors and sublicensees.

If the technology holder (Licensor) is not responsible for product manufacturing and supply, then it is common for the parties to specify the arrangement for manufacturing technology transfer in the license agreements. In such terms, the parties usually need to consider the scope, timing, methods and cost of the technology transfer, and the protection of relevant intellectual properties and confidential information. Taking the timing of technology transfer as an example, the parties usually need to pay attention to issues such as whether the manufacturing site for the pivotal clinical trial stage and the commercialization stage needs to be consistent, whether it involves the transfer of an imported product to a domestic product, and whether it is compliant and feasible from a regulatory perspective.

Finally, in cases where the Licensor is responsible for the manufacturing and supply of the products to the Licensee, it is necessary to specify in advance in the licensing agreement the requirements for signing subsequent supply agreements and quality agreements. For example, the parties may determine the time period for negotiating and executing the supply agreement and quality agreement. In addition, it is also common for the parties to agree on some major terms of the supply agreement and quality agreement in the license agreement to improve future negotiation efficiency.

Commercialization

I. Governance committee

Similar to the JDC arrangements mentioned above, during the commercialization stage of the licensed products, the parties may also choose to establish a joint commercialization committee (JCC) (or other committees with different names but similar responsibilities) as the governing body to discuss commercialization plans and other matters related to commercialization. Similarly, there is tension between the parties regarding such terms as the scope of JCC's responsibilities, the allocation of final decision-making power. For example, as the responsible party conducting commercialization activities within the territory, the Licensees typically hope to have more autonomy and decision-making power over commercialization matters. As a result, they would like fewer matters to fall within the scope of JCC responsibilities or have more final decision-making power in JCC. On the contrary, the Licensors often hope to retain a certain degree of supervision and decision-making power over the commercialization activities within the territory.

II. Commercialization plan and budget

Common areas of focus in the commercialization process include the formulation of commercialization plans and budgets, the agreement on diligence obligations, and the arrangement of product promotion. As for the formulation of commercialization plan and budgets, the parties need to pay attention to the frequency of updating and revising the commercialization plan, as well as the approval process. In licensing projects, the Licensees are typically responsible for the commercialization activities in the territory and bears the corresponding costs. While in co-development projects, the allocation of responsibilities and costs is often related to various factors such as each party's responsible territories, the capabilities of each party's sales force, and the way in which the revenue is shared. In particular, for the party who is not responsible the commercialization activities, how to reasonably control the scope of shared cost while not affecting the effective promotion of the product's commercialization, largely depends on the allocation of the formulation, approval and modification rights of the commercialization plans and budgets in the license agreement. In addition, it is noteworthy that there are many tax incentives at national and local levels in China that can be provided to Licensors/Licensees. Therefore, how to set up tax-related clauses in the license agreement to make good use of relevant policies may also bring real benefits to the companies.

III. Diligence obligation

The success of commercialization is closely related to how much royalties and milestone payment the Licensors can receive, so it is common that the license agreements may require the party leading the commercialization activities to fulfill certain diligence obligations. Depending on the bargaining power of the parties, different levels of strictness such as definitions of the terms "best effort", "reasonable effort" or "commercially reasonable effort" may be agreed upon. The parties may further agree on objective standards, such as requiring the Licensees to pay a minimum annual commercial payment.

In such way, if the actual amount of royalties owed by the Licensee is less than the applicable minimum annual commercial payment, the amount of royalties to be paid will automatically be deemed to be such minimum annual commercial payment.

Post-Market surveillance

As special products with significant impacts on the safety and health of patients, drugs and medical devices are subject to vigilance requirements such as adverse reactions reports and product recalls. In particular, for pharmaceutical products that are marketed both domestically and overseas, regulatory authorities in China have certain requirements for monitoring, collecting and reporting overseas adverse reaction information. There are also requirements to report and evaluate product recalls that occur outside of China. In practice, many biotechs may not have paid enough attention to pharmacovigilance (PV) matters because their products are still in the early development stages. Nevertheless, since we have previously been deeply involved in multiple NMPA regulatory actions on adverse events against pharmaceutical products or companies, we are well aware of the importance for the companies to comply with relevant regulatory requirements. Therefore, for the parties involved in cross-border licensing transactions, it is also important to focus on how to arrange the obligations and responsibilities related to product vigilance.

Usually, the cooperating parties will agree in the license agreement to sign a separate PV agreement before a certain point in time (e.g. before conducting the first clinical trial in the territory). In such PV agreements, the cooperating parties may allocate and clarify their respective responsibilities regarding matters including adverse event reporting, quality complaints, and safety data exchange.

Conclusion

On the journey of innovative pharmaceutical research and development, licensing transactions have built a bridge for communication and cooperation among companies, encouraging all parties to work together to achieve win-win outcomes. Improving the terms under licensing agreements from the perspective of the whole life-cycle of pharmaceutical products can better promote the implementation of the projects, fully leverage the advantages and resources of all parties, avoid legal risks that may be encountered in the development activities, and optimize the companies' business arrangements. We also look forward to providing professional advice for more licensing projects, reducing uncertainty and transaction barriers through reasonable arrangements, and ensuring smooth cooperation under the premise of protecting the clients' interests. We hope our humble efforts may assist industry practitioners in embarking on a broader path of future cooperation and bringing more breakthroughs and innovative pharmaceutical products for the benefit of patients around the world.

3. First Insights into China's New Corporate Landscape

Authors: Ray SHI | Claire XU

Introduction

Barely a week ago on December 29, 2023, China's legislative body passed and President Xi Jinping signed into law the newly revised Company Law, effective from July 1, 2024 (the "**New Law**"). It makes a big splash to the business community for both the law's as-pillar significance, and the striking degree of revisions (over a quarter of provisions are involved with major changes). The New Law will bring about a broad spectrum of changes comprising shareholder capital contribution, shareholders' rights protection, company capital system, corporate governance, company registration, company financing, etc., which may make even just a spreadsheet of bulletin points run dozens of pages long.

At Han Kun, we prioritize our clients' interests and aim to provide more than just prompt advice. Consequently, we wish to delve deeper into the New Law, decipher the legal changes most pertinent to you, and underscore the implications that demand your attention.

The U-turn in shareholders' capital contribution obligation

I. Shortened contribution deadline

The 2013 and 2014 revisions of the Company Law transitioned from the registered capital payment registration system to a subscribed capital registration system, eliminating statutory requirements for contribution deadlines, minimum registered capital, and initial contribution ratios. However, the New Law introduces provisions specifying deadlines for limited liability company shareholders to fully pay subscribed capital within five years from the company's establishment date. Founding shareholders of a joint-stock company must fully pay the capital upon its establishment. For existing companies predating the New Law's effective date, adjustments to deadlines are required, and the registration authority can demand timely adjustments if abnormal contribution deadlines or amounts are identified. Implementation rules for such existing companies will be formulated by the State Council.

II. Revocation of shareholder status

The New Law establishes a shareholder disqualification system for limited liability companies. If a shareholder fails to pay the contribution in full and on time, the company issues a written payment demand with a grace period of no less than sixty days. If, by the end of this period, the shareholder fails to fulfill the contribution obligation, the company, through a board resolution, can issue a disqualification notice. From the notice date, the shareholder loses rights to the unpaid contributions.

III. Added obligation of accelerated capital contribution

The New Law introduces a provision on the accelerated maturity of a limited liability company's shareholder contribution obligations. The triggering event, "the company cannot repay the due debts," is much less restrictive than the current legal conditions[3] for such obligation acceleration. In the future, a shareholder could face demands from the company or any creditor with unpaid debts, even if the payment schedule is not yet due.

IV. Expanded legal responsibilities

The New Law stipulates that when a limited liability company is established, if a shareholder fails to make full payment, other shareholders at the time will be jointly liable within the scope of the insufficient contribution. Additionally, supplementary liability is imposed on the former shareholder who has transferred shares to a buyer that later fails to make a full capital contribution to those shares. Joint liabilities are also applicable to the purchasing shareholder who bought shares from a former shareholder that failed to make a sufficient capital contribution on time.

The following diagram may illustrate the possible consequences of a shareholder's underpayment of capital contribution to a limited liability company:

	Consequences	Trigger	Exemplification	Index of the New Law
Shareholder fails to make capital contribution in full	Shareholder is disqualified	Demand must be served on time by the board, who otherwise will be subject to liability to compensate the company for the loss.	Nil	Article 51 and 52
	Shareholder to indemnify for company's loss	Company, company officers, eligible shareholders or creditors can make demand.	Nil	Article 49
	Other shareholders' joint liability for the underpaid amount	Company, company officers or creditors all have ground to demand.	Nil	Article 50 and 99
	Shareholder is obliged to accelerate capital payment	Any creditors can initiate it if the company cannot repay the due debts.	A former employee who disputes with the company for alleged unpaid benefit, may, other than sue the company itself, take the shareholder to court to require expedited capital	Article 54

[3] I.e., valid reasons exist for the company to go bankruptcy without it initiating the process, and shareholders extend their capital contribution schedule in response to the company incurring debt.

	Consequences	Trigger	Exemplification	Index of the New Law
			contribution. Action or threat.	
	Selling shareholder is subject to supplemental liability for buyer's later insufficient payment on time.	Company, company officers, eligible shareholders or creditors can make demand.	A transferred shares pertained with unpaid but on-schedule capital contribution to B. B later fails to make contribution on time. A creditor sues the company which in turn sues A to demand the unpaid amount by B even if by then A has long stopped being a shareholder.	Article 88
	Purchasing shareholder is subject to joint liability for seller's previous insufficient payment on time.	Company, company officers, eligible shareholders or creditors can make demand.	A bought shares with insufficiently paid capital from B. The company's board, to avoid liability on its own, resolves to sue A and B to bear joint liability for the unpaid capital amount.	Article 88

Despite the clarity provided by this diagram, uncertainties persist, particularly regarding how existing companies should transition for full compliance with the New Law. At this stage, we recommend existing foreign-invested enterprises with unpaid registered capital to assess the remaining contribution amount and adjust the timing accordingly. It is crucial to monitor subsequent legislative developments from regulatory authorities and formulate appropriate response plans. For newly established enterprises post the New Law's enactment, investors should carefully consider contribution deadline requirements aligned with initial business development plans, establishing a reasonable initial registered capital to mitigate risks of inability to fulfill contribution obligations. Ultimately, resolutions can be sought through subsequent capital increases.

More responsibilities falling on company officers

Under China's Company Law, the company officers consist of, mainly, director, senior executives and supervisors. Their personal liability have long been a focal point for foreign investors. Generally, the personal liability of such officers includes: (i) civil liability arising from breaches of fiduciary duties and unauthorized representation; (ii) administrative penalties and even criminal liability for directors and executives who hold relevant positions in the company or serve as key responsible persons in areas where the company violates significant compliance obligations (such as safety production, environmental protection); and (iii) directors participating in or driving decisions related to the company's criminal or irregular activities may be deemed to play a certain role in the "decision, approval, or instigation" of the company's actions and may be required to assume personal responsibility.

The New Law in this instance places a strong emphasis on the fiduciary and diligent duties of directors, supervisors, and senior management, adding administrative penalties beyond civil compensation. We summarize the main provisions, the implications and our recommendations as follows:

	Summary	Implication	Recommendation	Index of the New Law
General Provisions of Fiduciary Duties	Fiduciary duty requires directors, supervisors, and senior executives to take measures to avoid conflicts of interest with the company and not to use their powers to seek undue benefits. Diligent duty requires them to perform their duties for the maximum benefit of the company with the reasonable care that a manager should normally exercise.	The New Law facilitates claims against company officers for alleged breaches of fiduciary duties.	Nil	Article 80
Specific Responsibilities and Liabilities	Directors held indemnifiable for failing to verify shareholder capital contribution and make timely demands for payment.	Verification of shareholders' capital contribution and serve demand notice become essential.	Verification and demand notices become essential. Directors should regularly verify contributions and issue written payment demands when necessary.	Article 51 and 53
	Officers may be fined for shareholders' embezzlement of contributions after company establishment.	In cases of embezzlement, directly responsible executives (such as directors and senior management) may not only be subject to civil compensation liability but also face administrative penalty risks.	Officers should avoid involvement in embezzlement due to willful misconduct or gross negligence.	Article 53 and 252
	A series of procedural requirements for the	The New Law opens door to	Directors and supervisors should	Article 226

	Summary	Implication	Recommendation	Index of the New Law
	reduction of registered capital by companies is added. If a company reduced registered capital in violation, directors and supervisors with responsibilities should compensate the company's loss.	directors and supervisors' liabilities under this circumstance while also creating safe harbors for them to avoid liabilities by following all necessary procedures.	familiarize themselves with the latest requirements of the New Law regarding the procedures of company's capital reduction.	
	If the company or its subsidiaries provide financial assistance for others to acquire its shares, resulting in losses to the company, the responsible directors and senior executives should compensate the company for its loss.	The New Law, departing from the current law, allows financial assistance to other parties to purchase the company or its parent companies equity interests. Such assistance should be done	The revised law introduces significant changes, and officers should be vigilant in adhering to their expanded responsibilities to avoid potential liabilities.	Article 163
	The revised law introduces significant changes, and officers should be vigilant in adhering to their expanded responsibilities to avoid potential liabilities.	Directors and supervisors may be subject to liability if they are involved with or fail to evidently oppose to shareholders' abuse of power.	Directors should avoid knowingly participating in improper profit distributions and record opposition with proof.	Article 211
	Liquidators modified to be company directors with clarified compensation liability.	Directors' familiarity with day-to-day operations makes them suitable	Nil	Article 232

	Summary	Implication	Recommendation	Index of the New Law
		liquidators, but failure may lead to personal compensation liability.		
	New administrative penalties for the directly responsible executives if the company fails to publicize or falsely publicizes relevant information.	Nil	Nil	Article 251
	Individuals classified as dishonest debtors by the People's Court not eligible for company officers.	Nil	Nil	Article 178
	Shareholders gain the right to sue officers of wholly-owned subsidiaries.	Strengthens investor protection by holding officers of subsidiaries accountable.	Nil	Article 189
	Officers liable for harm caused during duty if found with willful misconduct or gross negligence.	Expands indemnification to include responsible company officers.	Nil	Article 191
	Reporting and approval requirements for officers involved in contracts or transactions with the company.	Nil	Nil	Article 139 and 182

Special attention should be given to the inclusion of "Actual Director" and "Shadow Director" in the law. Articles 180 and 192 of the New Law provide that the "Controlling Shareholder" or "Actual Controller", even if not the company's officers, shall be subject to the same fiduciary duties as company officers if they actually perform corporate duties. They shall also be jointly liable with the company's officers who are instructed by such "Controlling Shareholder" or "Actual Controller" and thus harm the company or shareholders' interests. These provisions have two key implications: (i) simply not being the documented officers, the direct or indirect controllers of a company may not be safer and free of legal responsibilities and the correlated liabilities if they are actually involved in the company's decision-making; and (ii) under the New Law, claims may be made against them by the company, other shareholders, company officers, and through surrogated litigation, any creditors of the company as well.

Significant changes in corporate governance

I. Greater flexibility in allocation of corporate powers

- The statutory powers of the shareholders' meeting have been reduced, and certain matters previously reserved for the shareholders' meeting can now be decided by the board of directors or management based on the actual situation of the company (Article 59);
- Beyond the enumerated powers of the board of directors, the shareholders' meeting can explicitly grant additional powers to the board of directors, including authorizing the board of directors to make decisions on "issuing corporate bonds" (Article 59);
- The exemplary list of the manager's powers has been removed, and thus the manager's authority is entirely subject to the company's articles of association and the agreements of the board of directors (Article 74).

After this revision, decisions on "company's operational policies and investment plans" and "review and approval of the company's annual financial budget and final accounts" are no longer mandatory for the shareholders' meeting. The New Law provides companies with more operational space, enabling them to allocate powers among the shareholders' meeting, board of directors, and managers based on their specific needs. This adjustment is particularly beneficial for foreign-invested enterprises, aligning with international corporate governance practices that focus on the board's role in significant operational and investment decisions.

II. Enhanced democratic management measures for employees

The New Law mandates companies to establish a democratic management system, primarily through the employee congress. Unlike the current Company Law, which defines appointment requirements based on the background of the investing state-owned assets, the New Law specifies that for a limited liability company with more than three hundred employees, except it has set up a supervisory board with at least one sitting employee supervisor, it must involve at least one employee director to its board.

Therefore, even for non-state-owned foreign wholly-owned enterprises or limited liability companies formed as joint ventures, if they meet the aforementioned employee threshold, they may need to appoint employee directors. At the same time, companies need to be aware that such requirements may have potential impacts on the structure of board seats, and reasonable arrangements should be made in advance.

III. Permitted absence of supervisory board or supervisors

The New Law clearly states that smaller-scale limited liability companies and joint-stock companies can choose not to have a supervisory board, appoint one supervisor, or not have supervisors at all. Under the New Law, a limited liability company can establish an audit committee composed of directors to exercise the powers of the supervisory board (Article 69), without having a supervisory board or supervisors. Smaller-scale or fewer-shareholder limited liability companies may not need to have a supervisory board and can appoint one supervisor to exercise the powers of the supervisory board; with unanimous agreement of all shareholders, they can also choose not to have supervisors (Article 83).

The New Law introduces flexibility in the presence of supervisory boards and supervisors, allowing companies to tailor their governance structures to their specific needs. This aligns with contemporary practices and provides companies with greater adaptability.

In summary, the latest amendment to China's corporate legislation introduces significant changes, shaping the legal framework for businesses. While providing opportunities for improved governance and transparency, these changes also warrant careful consideration and adaptation. As we navigate this evolving legal landscape, our legal team remains dedicated to guiding you through these modifications and addressing any concerns or questions you may have. We appreciate your ongoing partnership and are here to ensure your business is well-prepared for the implications of these revisions.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

If you have any questions regarding this publication, please contact:

Beijing	**Wenyu JIN**	**Attorney-at-law**
	Tel:	+86 10 8525 5557
	Email:	wenyu.jin@hankunlaw.com
Shanghai	**Kelvin GAO**	**Attorney-at-law**
	Tel:	+86 21 6080 0920
	Email:	kelvin.gao@hankunlaw.com
Shenzhen	**Jason WANG**	**Attorney-at-law**
	Tel:	+86 755 3680 6518
	Email:	jason.wang@hankunlaw.com
Hong Kong	**Dafei CHEN**	**Attorney-at-law**
	Tel:	+852 2820 5616
	Email:	dafei.chen@hankunlaw.com
Haikou	**Jun ZHU**	**Attorney-at-law**
	Tel:	+86 898 3665 5000
	Email:	jun.zhu@hankunlaw.com
Wuhan	**Jiao MA**	**Attorney-at-law**
	Tel:	+86 27 5937 6200
	Email:	jiao.ma@hankunlaw.com
Singapore	**Lan YU**	**Attorney-at-law**
	Tel:	+65 6013 2966
	Email:	lan.yu@hankunlaw.com
New York	**Mike CHIANG**	**Attorney-at-law**
	Tel:	+1 646 849 2888
	Email:	mike.chiang@us.hankunlaw.com